

**The Quality Journey
CPHQ Exam Blueprint Matrix**

1. Quality Leadership and Structure (20 Items)

A. Leadership

1. Support organizational commitment to quality
2. Align quality and safety activities with strategic goals
3. Engage stakeholders
4. Provide consultative support to the governing body and medical staff regarding their roles and responsibilities (e.g., credentialing, privileging, quality oversight)
5. Participate in the integration of environmental safety programs within the organization (e.g., air quality, infection control practices, building, hazardous waste)
6. Assist with survey or accreditation readiness
7. Evaluate and integrate external quality innovations (e.g., resources from IHI, WHO, AHRQ, NQF)
8. Promote population health and continuum of care (e.g., handoffs, transitions of care, episode of care, utilization)

B. Structure

1. Assist in developing organizational measures (e.g., balanced scorecards, dashboards)
2. Assist the organization in maintaining awareness of statutory and regulatory requirements (e.g., OSHA, HIPAA, PPACA)
3. Assist in selecting and using performance improvement approaches (e.g., PDCA, Six Sigma, Lean Thinking)
4. Facilitate development of the quality structure (e.g., councils and committees)
5. Communicate the impact of health information management on quality (e.g., ICD10, coding, electronic health record, meaningful use)
6. Assure effective grievance and complaint management
7. Facilitate selection of and preparation for quality recognition programs and accreditation and certification options (e.g., Magnet, Baldrige, TJC, DNV, ARF, ISO, NCQA)
8. Communicate the financial benefits of a quality program
9. Recognize quality initiatives impacting reimbursement (e.g., capitation, pay for performance)

2. Information Management (25 items)

A. Design and Data Collection

1. Maintain confidentiality of performance/quality improvement records and reports
2. Apply sampling methodology for data collection
3. Coordinate data collection
4. Assess customer needs/expectations (e.g., surveys, focus groups, teams)
5. Participate in development of data definitions, goals, triggers, thresholds
6. Identify or select measures (e.g., structure, process, outcome)
7. Assist in evaluating quality management information systems
8. Identify external data sources for comparison (e.g., benchmarking)
9. Validate data integrity

B. Measurement and Analysis

1. Use tools to display data or evaluate a process (e.g., fishbone, Pareto chart, run chart, scattergram, control chart)
2. Use statistics to describe data (e.g., mean, standard deviation)
3. Use statistical process controls (e.g., common and special cause variation, random variation, trend analysis)

4. Interpret data to support decision making
5. Compare data sources to establish benchmarks
6. Participate in external reporting (e.g., core measures, patient safety indicators)

3. Performance Measurement and Process Improvement (52 items)

A. Planning

1. Assist with establishing priorities
2. Facilitate development of action plans or projects
3. Participate in selection of evidence-based practice guidelines
4. Identify opportunities for participating in collaboratives
5. Identify process champions

B. Implementation and Evaluation

1. Establish teams and roles
2. Participate in monitoring of project timelines and deliverables
3. Evaluate team effectiveness (e.g., dynamics, outcomes)
4. Participate in the process for evaluating compliance with internal and external

requirements for:

- a. clinical practice (e.g., medication use, infection prevention)
- b. service quality
- c. documentation
- d. practitioner performance evaluation (e.g., peer review)

5. Perform or coordinate risk management activities (e.g., identification, analysis, prevention)

C. Education and Training

1. Design organizational performance/quality improvement training (quality, patient safety)
2. Provide training on performance/quality improvement, program development, and evaluation concepts
3. Evaluate effectiveness of performance/quality improvement training
4. Develop/provide survey preparation training (e.g., accreditation, licensure, or equivalent)

D. Communication

1. Facilitate conversations with staff regarding quality issues
2. Compile and write performance/quality improvement reports
3. Disseminate performance/quality improvement information within the organization
4. Facilitate communication with accrediting and regulatory bodies
5. Lead and facilitate change (e.g., change theories, diffusion, spread)
6. Organize meeting materials (e.g., agendas, reports, minutes)

4. Patient Safety (28 items)

A. Assessment and Planning

1. Assess the organization's safety culture
2. Determine how technology can enhance the patient safety program (e.g., computerized physician order entering (CPOE), barcode medication administration (BCMA), electronic medical record (EMR), abduction/elopement security systems, human factors engineering)

B. Implementation and Evaluation

1. Assist with implementation of safety activities
2. Facilitate the ongoing evaluation of patient safety activities
3. Participate in these patient safety activities

- a. incident report review
 - b. sentinel/unexpected event review
 - c. root cause analysis
 - d. failure mode and effects analysis (proactive risk assessment)
 - e. patient safety goals review
 - f. identification of reportable events for accreditation and regulatory bodies
4. Integrate patient safety concepts throughout the organization
 5. Educate staff regarding patient safety issues

Recall 26%
 Application 57%
 Analysis 17%

Each test form will include 15 unscored items in addition to the 125 scored items.

Crosswalk

Quality Leadership and Structure	
Leadership	
Support organizational commitment to quality	55, 216, 220, 468
Align quality and safety activities with strategic goals	31, 26-43, 49-50, 68, 156, 460
Engage stakeholders	81, 155, 181, 220-221, 239-241, 274, 344
Provide consultative support to the governing body and medical staff regarding their roles and responsibilities (e.g., credentialing, privileging, quality oversight)	95, 231, 262, 265, 291, 302, 317, 413-414, 412-448
Participate in the integration of environmental safety programs within the organization (e.g., air quality, infection control practices, building, hazardous waste)	225-228, 346
Assist with survey or accreditation readiness	276, 305, 335, 344, 368, 469-477
Evaluate and integrate external quality innovations (e.g., resources from IHI, WHO, AHRQ, NQF)	66-67, 176-178, 217, 225, 348, 353, 390
Promote population health and continuum of care (e.g., handoffs, transitions of care, episode of care, utilization)	40, 66, 192, 330-350
Structure	
Assist in developing organizational measures (e.g., balanced scorecards, dashboards)	45-49, 50, 53, 85, 185, 422
Assist the organization in maintaining awareness of statutory and regulatory requirements (e.g., OSHA, HIPAA, PPACA)	11- 12, 97, 227, 386-388
Assist in selecting and using performance improvement approaches (e.g., PDCA, Six Sigma, Lean Thinking)	53-67
Facilitate development of the quality structure (e.g., councils and committees)	68-69
Communicate the impact of health information management on quality (e.g., ICD10, coding, electronic health record, meaningful use)	113, 384-390
Assure effective grievance and complaint	91-97, 136-137, 157, 189-192

management	
Facilitate selection of and preparation for quality recognition programs and accreditation and certification options (e.g., Magnet, Baldrige, TJC, DNV, ARF, ISO, NCQA)	176-178, 276, 305, 335, 344, 268, 469-477
Communicate the financial benefits of a quality program	31-36, 260-263
Recognize quality initiatives impacting reimbursement (e.g., capitation, pay for performance)	7, 11, 17-21, 48
Information Management	
Design and Data Collection	
Maintain confidentiality of performance/quality improvement records and reports	78, 117-118, 189, 386-412
Apply sampling methodology for data collection	122-124, 138-139, 369, 496
Coordinate data collection	10, 54, 104-111
Assess customer needs/expectations (e.g., surveys, focus groups, teams)	63-71, 86-90, 113, 136-139, 153-159, 174-175, 465-466
Participate in development of data definitions, goals, triggers, thresholds	25, 385-388
Identify or select measures (e.g., structure, process, outcome)	22, 109-132, 137, 149, 209
Assist in evaluating quality management information systems	249-261, 347, 363-366, 386-388, 500
Identify external data sources for comparison (e.g., benchmarking)	41, 70, 98, 118, 136, 157, 169-179
Validate data integrity	118, 125-127, 244, 352-353, 366-367, 388, 422
Measurement and Analysis	
Use tools to display data or evaluate a process (e.g., fishbone, Pareto chart, run chart, scattergram, control chart)	25, 101, 106, 112, 139, 140-141, 143-145, 146-150, 156, 158, 159, 160, 270, 465
Use statistics to describe data (e.g., mean, standard deviation)	121, 128-133
Use statistical process controls (e.g., common and special cause variation, random variation, trend analysis)	22, 139, 148-150, 228, 268, 270, 271
Interpret data to support decision making	153, 179-180, 185-186, 215, 273, 345, 351, 364, 389
Compare data sources to establish benchmarks	170, 172, 187-188, 222
Participate in external reporting (e.g., core measures, patient safety indicators)	178-189, 229-230, 483, 498-499
Performance Measurement and Process Improvement	
Planning	
Assist with establishing priorities	38, 43, 46, 60, 78, 83, 90, 98, 102, 138, 155-157, 173-174, 355, 471, 480, 495
Facilitate development of action plans or projects	29, 37, 41, 43, 73, 170-171, 176, 261, 269-270, 423, 470-471
Participate in selection of evidence-based practice guidelines	217, 248, 351-355, 361-362, 364, 418, 422-423, 494

Identify opportunities for participating in collaboratives	66-67
Identify process champions	50, 58-59, 70-81, 347
Implementation and Evaluation	
Establish teams and roles	70-81, 466
Participate in monitoring of project timelines and deliverables	8, 42, 46, 268, 355, 356, 500, 501
Evaluate team effectiveness (e.g., dynamics, outcomes)	74, 79-81
Participate in the process for evaluating compliance with internal and external requirements for clinical practice (e.g., medication use, infection prevention)	446, 480, 485-488, 495, 497, 499
Participate in the process for evaluating compliance with internal and external requirements for service quality	64, 460, 469
Participate in the process for evaluating compliance with internal and external requirements for documentation	56-58, 75-78, 82, 94, 97, 99, 101, 110, 114, 116, 118, 137, 165, 180-186, 191-194, 211, 219, 243, 246, 262-265, 278, 311-314, 317-321, 393=403, 405-412, 415
Participate in the process for evaluating compliance with internal and external requirements for practitioner performance evaluation (e.g., peer review)	91, 106, 118, 220, 264, 291, 254- 256, 319, 390-391, 418, 420-455
Perform or coordinate risk management activities (e.g., identification, analysis, prevention)	118, 179, 182, 255, 260-274, 291- 315
Education and Training	
Design organizational performance/quality improvement training (quality, patient safety)	460-468
Provide training on performance/quality improvement, program development, and evaluation concepts	460-468
Evaluate effectiveness of performance/quality improvement training	468-469
Develop/provide survey preparation training (e.g., accreditation, licensure, or equivalent)	470-499
Communication	
Facilitate conversations with staff regarding quality issues	455-460
Compile and write performance/quality improvement reports	455-460
Disseminate performance/quality improvement information within the organization	455-460
Facilitate communication with accrediting and regulatory bodies	455-460, 470-499
Lead and facilitate change (e.g., change theories, diffusion, spread)	161-169
Organize meeting materials (e.g., agendas, reports,	82-86

minutes)	
Patient Safety	
Assessment and Planning	
Assess the organization's safety culture	215-228, 269
Determine how technology can enhance the patient safety program (e.g., computerized physician order entering (CPOE), barcode medication administration (BCMA), electronic medical record (EMR), abduction/elopement security systems, human factors engineering)	116, 268, 271-274, 301, 384
Implementation and Evaluation	
Assist with implementation of safety activities	215-228
Facilitate the ongoing evaluation of patient safety activities	215-228
Participate in these patient safety activities: incident report review	231, 263, 292, 295-297, 305-308, 390
Participate in these patient safety activities: sentinel/unexpected event review	179-180, 231, 247-256, 266-267
Participate in these patient safety activities: root cause analysis	252-254, 267-274
Participate in these patient safety activities: failure mode and effects analysis (proactive risk assessment)	274-290
Participate in these patient safety activities: patient safety goals review	231-252
Participate in these patient safety activities: identification of reportable events for accreditation and regulatory bodies	179-180, 215-228, 231, 247-256, 266-267
Integrate patient safety concepts throughout the organization	215-228, 269
Educate staff regarding patient safety issues	215-228, 269, 294

Introduction

The healthcare system has weathered significant changes. Since the modern healthcare system began in the United States during the early 1800's, the trends in treatment models had been those of systematically moving care out of the home and into institutions. Over time, complex healthcare institutions were created to treat infectious diseases, house technology, and conduct professional education and research in central locations. Beginning with community based hospitals, these institutions eventually grew into large medical center complexes. The economic system for healthcare was unique. Public and private financing of healthcare in the United States ensured its continuous survival by supplying additional capital based on an escalating cost-based reimbursement policy. A period of

sustained growth launched new technology, supported treatment programs, funded enormous research programs, and employed the staff necessary for successful implementation. Healthcare in the United States was kept apart from the influencing of the free market system through a not-for-profit system of revenue generation and accounting. The medical-industrial complex grew virtually unchecked and essentially unaccountable, according to the same market forces and standards utilized in the for-profit business sector where revenue, expenses, and profits were carefully balanced and controlled.

Although times have changed dramatically, the healthcare system of the last two decades remained largely a cottage-based industry that took pride in establishing healthy relationships between patient and provider, and obtaining defined responses to treatment. As competitive pressures on hospitals in the United States have mounted during the last twenty years, healthcare has sought economies through organized models of care. Preferred Provider Organizations (PPOs) and Health Maintenance Organizations (HMOs), which incorporate cost and quality strategies, such as utilization management, preferred provider contracting, physician credentialing, continuous quality improvement (CQI) programs, and reengineering were developed in order to cut costs. These developments and the accompanying changes in reimbursement structures together form the basis of managed care. Managed care has a clinical goal of providing healthcare with best possible outcomes, while promoting tighter administrative controls over patient care.

Since the mid-1980's, the managed care industry has elevated the role of economics in determining how the healthcare industry does business. The health care industry's journey through managed care has followed the path of healthcare financing. External forces have transformed the structure of healthcare from that of a guild with fee-for-service transactions, cost-based reimbursement, and a monopoly on information, to that of a market-based industry. Without cost-based reimbursement, the healthcare industry has been forced into economic competition, where in the constant pressure of the free market, forces began shaping its business practices. Since then, the business of healthcare has not been the same. Now that healthcare is financed and organized within a market economy, its consumers, employers, employees, and patients wield much greater influence over its evolution. In a free market, consumers exercise choices, which encourages competition among the suppliers selling services.

In the competitive managed care arena, providers first competed on cost. Once cost became equalized across the industry, the focus turned to service. Since at the beginning of managed care, competition centered on price, prices were driven down as a result. In response, the consumer turned toward service as the key differentiator among health plans. As competition has increased, service naturally has improved, diminishing in importance as a factor in distinguishing the value of one plan from another. The decline of service as the primary factor in determining sales has brought the final differentiator, quality, to the forefront. Hospitals today are under enormous pressure to decrease expenses in order to make changes rapidly. The pressure is caused by recent Medicare payment reductions, capitation, and per diem payments for managed care, as well as a decrease in traditional fee-for-service reimbursements. Aggressive efforts to streamline the production of services have flourished in an attempt to determine the actual cost of care, and control those costs once determined.

Providing clinically effective and cost efficient care is necessary for healthcare organizational survival. In today's market, acute healthcare is shrinking and hospitals are closing. Additionally, competition in this environment is not just among hospitals. Hyperspecialization in healthcare has resulted in the development of stand-alone facilities for programs such as imaging, surgery, oncology, and women's services that also compete for patients and profits. Hyperspecialization has also promoted the shift in healthcare from inpatient to outpatient. During the last twenty years, the use of ambulatory services in the United States has increased. From 1993 to 1997, the number of total outpatient visits per 1000 population increased 18%. Ambulatory care services continue to be extremely important to survival of hospitals because outpatient care is contributing to a greater percentage of total hospital revenues. Increased technicalization, patient preferences, and insurance company payer demands are

continuing to push services from the inpatient to the outpatient setting. As this occurs, outpatient services revenues are approaching inpatient service revenues. With this increase, ambulatory services are becoming key figures in hospital profitability. People gain exposure to a healthcare facility from outpatient contacts. The outpatient/inpatient ratio is 10:1 in many hospitals. The importance of outpatient services to most hospitals continues to escalate. The number of ambulatory outpatients is much larger than the number of inpatients, and revenues from outpatient services are predicted to equal or exceed inpatient revenues in the near future. The ability to provide outpatient services to patients, with exceptional quality, is paramount to long-term survival of hospitals.

The basic concept of managed care is to create a system of accountable care where the buyer understands the service delivered based on the actual cost involved in determining a market value price paid for the product. What has happened in the last twenty years is the production of quality of care at a cheaper price, which provided both a risk and an opportunity. At its best, managed care eliminates waste and duplication, but the rapid turn-around to tightly control costs may be unnecessarily aggressive and potentially dangerous. Critics of managed care have worried that administrative controls may result in less personal and satisfying care from the patient perspective. Somehow, a balance has to be struck between quality and cost.

During the last decade, the new era of healthcare reforms has resulted in efforts to decrease growth in the progressive escalation in the percentage of the gross domestic product (GDP) dedicated to healthcare. There are changes in financing, expectations among consumers, and practice patterns of providers. There is also a national trend toward system re-engineering. Today's environment is chaotic and unresponsive in the face of great uncertainty and fear about the future. The definition of demand for healthcare services is changing. From the consumer's point of view, demand is the gradual but consistently emerging trend to have a more independent role in determining service, providers, and costs associated with purchases in an expanding marketplace. This is a changing healthcare marketplace where realistic timelines and a known, consistent and reasonably priced product began to influence the system to change by adopting free market values in order to meet new and quickly emerging demands.

Managed care dictates where most patients go for healthcare. Meanwhile, employees increasingly demanded the right to choose their physicians which resulted in employers offering multiple health plans. This development completed the transition of the healthcare industry from a wholesale business in which one plan would be sold to an employer, to a retail business. This shift further pinched the industry, on cost by eliminating the basis for volume discounts, and on price by increasing the competition. Marketing to individual employees became more important than selling to corporate managers. Human resource directors might base choice of a health plan on its quality outcomes and other metrics but most picked on basis of reputation.

At first, healthcare professionals, patients, and the public simply assumed that the industry delivered quality healthcare. Quality is extremely difficult to define and measure. In addition, the key players all met an expected level of service or didn't survive. Therefore, employees focused on cost to differentiate among health plans. Driven by this new emphasis, healthcare went from cost-based pricing to price-based costing. As the industry began competing on cost, its participants evaluated its components to determine how to gain an advantage. As a result, healthcare inflation was decreased from 12% annually in 1993 to 2.9% annually in 1996. In addition, pricing in many markets no longer distinguished one plan from another. Consumers measure value by weighing the factors of quality and service in the overall context of a health plan's impact on the pocket book. They then choose the health plan with the greatest perceived value. The healthcare industry has come a long way from the old guild days when hospitals, physicians, nurses, pharmacists, and other providers could ignore concerns about costs, investments, and the deployment of resources. Managed care and its emphasis on fiscal responsibility have improved healthcare.

In today's market, consumers want to know what quality of care will be provided and have information on how that will be measured, in advance. They want few or no surprises with health care,

and because they can make choices, demand to have needs rapidly accommodated. They consider access, cost, quality, and the perception of satisfaction. These emerging consumer demands and the realization that they cannot be dismissed, nor are they going to disappear, has put healthcare on notice. Today, marketplace demands require a new emphasis that includes both quality and a tighter control on the cost implications of care. Competing demands are requiring the healthcare system to reverse many of its priorities and traditions, thereby destabilizing a system that had become comfortable and affluent in some sectors, with limitless growth and expansion in the marketplace, encouraged by the willingness of the public to pay more and more for services annually.

Perceptions and behaviors of payers, providers, government, and consumers are also changing as the healthcare system attempts to reorganize and take on a new image, that of a gatekeeper. The pressure to do more with less is dramatically affecting healthcare. This pressure is forcing the healthcare industry to restructure in order to be more efficient and cost-effective in delivering care. Achieving quality outcomes in patient health improves the bottom line. By transforming healthcare into a competitive industry governed by free market principles, managed care has set it along the road to establishing quality as a critical factor in healthcare management as well as in the consumer's perception of value. The competitive battle over quality is beginning, with consumers deciding who delivers the most quality healthcare.

Managed care is not the problem, but quality is. There is a tremendous opportunity to improve quality of care and lower cost. There is a growing realization among consumers that providers who are paid for results should be held accountable. High quality care actually costs less, but the greatest challenge is for healthcare to prove it. Delivering the right care at the right time, in the right place, with the fewest complications for the right indicators will produce the best quality care at the lowest cost, and achieve the greatest level of patient satisfaction. Today's healthcare environment is experiencing changes that require creative solutions to problems; there is no one model for all healthcare organizations. Managed care, as the initial change agent, has affected each section of the country to various degrees with a variety of outcomes, and there will continue to be changes in the future. How positive or negative these changes will be depends on the strength of the organization, and its commitment to sound financial management and to the improvement of customer service and quality of patient care.

Consumers know that healthcare has room to improve. Service has hardly been the hallmark of HMO business practices, in the public's mind. People have viewed healthcare systems as impersonal and incomplete. Improving service is a manageable task, though it necessitates redefining organizational culture, which is extremely difficult. As healthcare competitors have reached the same level of care provided, quality has become a key factor in delivering healthcare services having the greatest likelihood of achieving the desired outcomes. Trends toward hyperspecialization and technicalization in the healthcare industry have produced increasingly sophisticated individual consumers, who have instant access to determining information and analysis on the Internet. These new consumers are driving the new market-driven economics of the industry to focus on outcomes to meet the goal of health for patients as well as assist healthcare to position itself as a business. Patient satisfaction and functional health status have emerged as critical outcomes of medical care because of the increasing emphasis on patients as consumers in the medical market place. According to some authorities, the way patients increasingly judge providers and their opinions are critically important, because they pay providers, receive provider services, and have faith in provider skills.

Technicalization in healthcare has provided a wealth of information available on keyboard and the Internet. This is the information age, with access to information systems readily available in the home, workplace, and library. Most businesses, hospitals, managed care companies, and insurers use computers. Healthcare workers who work in progressive organizations are using computers with word processing and database or spreadsheet programs. It is estimated that nearly 130 million consumers access the Internet. Consumers can find out what's happening in the larger healthcare community, and tap into resources and sites. There is no longer a need to go to a library to research materials on new topics. E-

mail connects people with others who are looking for same type of information. Consumers use the Internet to study illness in order to make health care decisions with providers. Yet the healthcare industry is in its infancy in terms of information technology and information management. Supporting the trend toward increased technology are pressures for the industry to take full advantage of computer technology and tap into the Internet. This technicalization is leading the industry into the future of data and information management, which are the instruments of the trade and the means for survival in today's healthcare climate. Continually escalating healthcare costs are generating more interest in the area of cost containment methodologies focusing on quality cost-effective outcomes.

When Wennberg publicized that variations in processes and protocols in medical practices were unaccounted for by patient mix in 1984, payers immediately recognized the connection to reimbursement, although not to quality. Even though several hundred articles were published which confirmed these results, providers did not fully realize the connection to practice parameters, critical paths, and clinical outcomes. In 1988, Ellwood proposed that a new technology, outcomes management, be used to evaluate, monitor, and ensure the provision of quality healthcare. One of the challenges for healthcare today is how to connect outcomes, practices, quality, and cost. Advances in technology have brought practice guidelines, benchmark data, articles, and sources of data to the consumer's fingertips. Consumers are aware of disease management programs and computer information systems that can provide information on positive treatment and disease outcomes. The key to connecting outcomes, practices, quality, and cost is measurement. Healthcare organizations need to know what measures of systems, processes, and outcomes will yield information on how to use resources to add value, for patients, payers, and providers.

Encouraged by the increasingly informed consumer, healthcare organizations are beginning to use outcome information to measure and demonstrate the effectiveness of healthcare practices. Across the country, managed care organizations, large employer groups, and other healthcare networks are using outcomes measurement tools to identify, measure, and evaluate the results of care. These organizations measure and evaluate their return on investment to make effective business decisions for the future. Purchasers and providers of healthcare are required to provide evidence of value in treatment and service. By performing outcome studies, healthcare organizations are better able to determine which treatment or therapy offers the best clinical, humanistic, and cost effective outcomes for their members and also to validate the outcome of care. Managed care organizations, healthcare networks, large self-insured employer groups, and even government agencies are examining their return on investment and measuring outcomes and the quality of care in a variety of ways to establish direction for the future. Because third party payers are demanding information on results of treatment and services, partly as a result of escalating costs, outcomes research and management are flourishing.

Programs focused on outcomes research, measurement, and management have emerged over the past decade as a result of rapidly rising healthcare costs, questions about the effectiveness of medical interventions, and the need for the efficient delivery of care. Clinicians, epidemiologists, clinical researchers, statisticians, and economists are among those who are becoming actively involved in the field of outcomes research and measurement to address these critical concerns. Many of these groups are designing outcomes tools that will measure the consequences of various therapeutic interventions. Multiple professional organizations, academic centers, and independent research labs, as well as government agencies, are now involved in the research & description of outcomes measurement tools.

An example of how technicalization has affected healthcare can be seen in the combination of two major technologies, which have made it easier and less expensive to monitor healthcare from the consumer's perspective and determine outcomes. The first major technology involves modern psychometric methods. There are improved methods for measuring what consumers think of healthcare as well as their health status. The second major technology involves computers and the Internet, which have provided a whole new way to communicate with consumers. These two technologies allow patient assessments to be conducted at any time; a convenient and inexpensive method, while ensuring accuracy

of data to be used in clinical decision-making. Computerized testing has not previously been used in healthcare, although it has been used for decades in psychology and education. Dynamic assessments, use of the Internet, interactive television, and advances in telephone technology, such as interactive voice response, all make it possible to use technology to improve services. This results in a lower cost, and makes it easier for patients.

The use of the Internet and outcomes databases will allow clinicians to be compared with each other on clinical effectiveness, not just utilization. Data can be real-time, clinically relevant patient data. The result will be that patients can potentially receive better, safer care. Using Internet-based data collection techniques might also encourage the movement toward standardized care, which should provide better care over time. An Internet-based outcomes system can demonstrate quality, along with a competitive advantage, by the lowering cost of care and increasing returns on investment. Ideally, providers can set high standards to improve care.

Indicators of outcomes can be derived from massive databases, with millions of cases to determine which therapies work best for the greatest number. Outcome measures as a management tool can make professional practice more databased, driving cost down and quality up at the same time. Rapid advances in computer and information-sharing technologies have fueled the expansion of outcomes management. Widespread use of expert computer programs change the role of healthcare providers away from providing mere facts toward helping patients change beliefs and make difficult judgments.

As a result, healthcare is looking at system performance in terms of overall health. The future will demonstrate the effectiveness of use of prospective measurement databases. Clinical trials can be conducted in the real world under more realistic conditions, and providers will be able to demonstrate whether they really can manage care and improve outcomes. This data will give providers the decision-making ability to improve outcomes data and care. Eventually measures of each individual patient's need for care and response to treatment will be available to be given to clinicians to improve decisions and treatment. Databases with thousands of cases will provide data for improved decision-making among providers. Given today's climate of cost containment and increased concern about the quality of medical care, the consumer's voice will continue to grow in importance in the medical marketplace.

The Affordable Care Act (ACA), also known as the health care law, was created to expand access to affordable health care coverage to all Americans, control/lower health care costs and improve health care quality and care coordination. Under the health care law, people will:

- Have health coverage that meets a minimum standard (called minimum essential coverage)
- Qualify for an exemption, or
- Pay a fee when filing their taxes if they have affordable options but remain uninsured.

Intended to reduce the fragmentation of care delivery (thereby improving quality and reducing cost), the ACA has triggered market forces that are working to essentially flip the provider-side business model from fee for service (FFS) to value/risk-based reimbursement models (e.g., accountable care/shared savings, bundled payments, partial or full capitation arrangements). This shift

One of the most significant unintended consequences of the passage of the ACA in March 2010 has been the ignition of another wave of consolidation activity among U. S. healthcare providers. Similar to the industry's response to the threat of managed care in the 1990's, merger and acquisition activity between multihospital systems, stand-alone hospitals, large multispecialty medial groups, small independent physician group practices, and other provider organizations has accelerated dramatically in response to the ACA. Well-conceived and properly executed health system transactions have the ability to deliver greater value than ever before and to strengthen an organization's positioning for value-based competition.

Migrating from the current transactional FFS system to a value-based model will require transformational change for all but a handful of health systems across the country. The best positioned organizations have spent decades refining their integrated care delivery models. The operational challenges confronting administrative and clinical hospital leaders cannot be overstated as the

fundamental economic model shifts from volume driven FFS visits and days to value driven episodes of care and chronic disease management. The challenge is further compounded by the fact that the shift is occurring piecemeal, one payer and one contract at a time, thus forcing hospitals to operate in both the volume and value driven models simultaneously.

This is the era of accountability in healthcare. Hyperspecialization and technicalization in healthcare, along with rapidly rising healthcare costs, questions about effective medical intervention, and the need for efficient delivery of healthcare services have compelled organizations to focus on outcomes research, measurement, and management. This should produce significant benefits, including increased physician and patient information, increased understanding of the effectiveness of different treatments, interventions, and established guidelines for medical management.

Because healthcare is a complex, highly technical industry, and a complex adaptive system, it is more prone to accidents. Healthcare consumers expect events to take place in a predictable pattern and tightly controlled sequence. By definition, a complex system has interacting components that work in both expected and unexpected ways. If one component fails, all downstream components may fail. In an adaptive system, it's impossible to predict how each component will respond to a particular stimulus. In the healthcare system, the human factor contributes the element of unpredictability, which can lead to errors.

Creating high reliability means simplifying and standardizing processes as well as building levels of redundancy in personnel and safety measures. Understanding the human-system interface can help to improve the designs of systems and processes. Systems thinking and continuous quality improvement focus on understanding how people do their work and how people are connected to each other when providing a service. In the complex healthcare system, nonlinear thinking is used to understand how things work, trying to understand the human and operational relationships within a system. Systems thinking can be used to see how the parts of an organization interact and how effectively people are working together. Expanded thinking allows recognition and imagining ways of solving problems by grasping entire processes and systems. Systems thinking also reinforces the idea that the whole system is greater than the sum of its parts.

Systems thinking is fundamental to quality improvement, which requires unity and constancy of purpose. Having a unified or shared vision allows individuals and departments to come together, so all energy is directed toward achieving a single goal. Systems thinking creates a drive for never-ending improvement. It instills a sense of doing good work and learning to do better while working.

W. Edwards Deming believed in driving out fear, and changing from what did the individual do wrong to what is wrong with the system that created the opportunity for improvement? Eliminating fear and blame encourages reporting and allows the development of creative solutions. Continuous improvement produces better and safer patient care.

Health Care Financing

Health care financing has evolved from a system supported primarily by consumers to a system financed by third party payers. The United States government became involved in health care financing for population groups early in its history. In 1798, the federal government created the Marine Hospital Service to provide medical care for sick and disabled sailors, and to protect the nation's borders against the importing of disease through seaports. Medicare and Medicaid, two federal programs administered by the Centers for Medicare and Medicaid Services (CMS), account for the majority of public health care spending. The CMS is the federal regulatory agency within the U. S. Department of Health and Human Services (USDHHS) that is responsible for overseeing and monitoring Medicare and Medicaid spending. This agency routinely collects and reports actual health care use and spending and projects future spending trends. Through these services, the federal government purchases health care services for population groups through independent health care systems, such as managed care organizations, private practice physicians, and hospitals.

Medicare

The Medicare program, established in Title XVIII of the Social Security Act of 1965, provides hospital insurance to persons aged 65 and over, to permanently disabled persons, and to persons with end-stage renal disease, altogether approximately 46 million people. Medicare has two parts: Part A (hospital insurance) covers hospital care, home care, hospice care, and skilled nursing care (limited); Part B (non-institutional care insurance) covers medically necessary services like health care provider services, outpatient care, home health, and other medical services such as diagnostic services, and physiotherapy. In 1999 a program called Medicare Advantage was added to the program (Part C). This is an option that can be chosen for additional coverage. This option includes both Part A and B services. The Part C plans are coordinated care plans that include health maintenance organizations (HMOs), private fee-for-service plans, and medical savings accounts (MSAs). Part C provides for all health care coverage costs after a high deductible.

Medicare Part A is primarily financed by a federal payroll tax that is paid by employers and employees. The proceeds from this tax go to the Hospital Insurance Trust Fund, which is managed by the CMS. If a person did not have federal payroll deductions, Part A can be obtained by paying a monthly premium. Part A coverage is available to all persons who are eligible to receive Medicare, with older adults comprising the majority of these individuals. Part A requires a deductible from recipients for the first 60 days of services with a reduced deductible for 61 to 90 days of service. The deductible has increased as daily hospital costs have increased. For skilled nursing facility (SNF) care, persons pay nothing for the first 20 days and a cost per day for days 21 through 100. After 100 days, persons must pay the total cost for care. The person pays zero for hospice care and home health.

The medical insurance package, Part B, is a supplemental (voluntary) program that is available to all Medicare-eligible persons for a monthly premium. The vast majority of Medicare-covered persons elect this coverage. Part B provides coverage for services other than hospital (physician care, outpatient hospital care, outpatient physical therapy, mental health, and home health care) that are not covered by Part A, such as laboratory services, ambulance transportation, prostheses, equipment, and some supplies. After a deductible, up to 80% of reasonable charges are paid for medical and other services. For mental health services, 55% of the costs are paid. Part B resembles the major medical insurance coverage of private insurance carriers.

As a result of rising health care costs, Congress passed a law in 1983 that radically changed Medicare's method of payment for hospital services. In 1983 federal legislation (Public Law 98-21) mandated an end to cost-plus reimbursement by Medicare and instituted a 3 year transition to a prospective payment system (PPS) for inpatient hospital services. The purpose of the new hospital payment scheme was to shift the cost incentives away from the providing of more care and toward more efficient diagnosis-related groups (DRGs). Also, the Balanced Budget Act of 1997 determined that payments to Medicare SNFs would be made on the basis of the PPS, effective July 1, 1998. The PPS payment rates cover SNF services, including routine, ancillary, and capital-related costs. In 2001 CMS developed a PPS for home health with the Health Insurance Prospective Payment System (HIPPS) codes.

Medicaid

The Medicaid Program, Title XIX of the Social Security Act of 1965, provides financial assistance to states and counties to pay for medical services for poor older adults, the blind, the disabled, and families with dependent children. The Medicaid program is jointly sponsored and financed with matching funds from the federal and state governments. Since the beginning of Medicaid, full payment has been provided for the five types of services:

- Inpatient and outpatient hospital care
- Laboratory and radiology services
- Physician services

Skilled nursing care at home or in a nursing home for people more than 21 years of age
Early periodic screening, diagnosis, and treatment (EPSDT) for those less than 21 years of age
The 1972 Social Security amendments added family planning to the list of full-pay services. States can choose to add prescriptions, dental services, eyeglasses, intermediate care facilities, and coverage for the medically indigent as program options. By law, the medically indigent are required to pay a monthly premium.

Any state participating in the Medicaid program is required to provide the six basic services to persons who are below state poverty income levels. Optional programs are provided at the discretion of each state. In 1989, changes in Medicaid required states to provide care for children less than 6 years of age and to pregnant women under 133% of the poverty level. In the 1990's states were allowed to petition for a waiver and could use their Medicaid monies for programs other than the six basic services. The major expense categories for the Medicaid program have historically been skilled and intermediate nursing home care and inpatient hospital care.

Methods of Health Care Financing

Most public government agencies operate on an annual budget and plan for costs by estimating salaries, expenses, and costs of services for a year. Public health agencies, such as public health departments, and WIC programs (for women, infants, and children) receive primary funding from taxes, with additional money for select goods and services through private third-party payers. Selected public health programs receive reimbursement for services as follows: through grants given by the federal government to states for prenatal and child health; through Medicare and Medicaid for home health, nursing homes, WIC programs, and EPSDT; and through collecting of fees on a sliding scale for select client services, such as immunizations.

The federal government finances health services for retired military persons and dependents, veterans, and Native Americans through TriCARE, the VA, and Indian Health Services.

Private health care payer sources include insurance, employers, managed care, and individuals. Although insurance and consumers have been prominent health care payment sources for some time, the role of employers, managed care, and consumers became increasingly prominent and powerful during the first decade of the 21st century.

Insurance for health care was first offered for the private sector in 1847 by a commercial insurance company. The purpose of the insurance was to provide security and protection when health care services were needed by individuals. The idea behind was insurance was that it provided security, guaranteeing (within certain limits) monies to pay for health care services to offset potential financial losses from unexpected illness or injury related to accidents, catastrophic communicable diseases (such as smallpox and scarlet fever), and recurring (but unexpected) chronic illnesses.

A comprehensive study in the 1920's by the Committee on the Costs of Medical Care showed that a small portion of the population was paying most of the costs of medical care for the majority of people. The depression of the 1930's, rising medical costs, and the need to spread financial risk across communities spurred the development of the third-party payment system. The system began as a major industry in the 1930's with the Blue Cross system, which initially provided prepayment for hospital care. In 1939 Blue Shield created plans to provide physician payment. The Blue Cross plans began as tax-free, non-profit organizations established under special enabling legislation in various states.

In the 1940's and 1950's, hospital and medical-surgical coverage increased. Employee group coverage appeared, and profit-making commercial insurance underwriters began offering health insurance packages with competitive premiums. The commercial insurance companies could offer lower premium rates because of the methods used to set rates. Insurance and premium setting, in general, are based on the notion of risk pooling (i.e., insurance companies were willing to risk the unlikely event that all or even a large portion of individuals covered under a plan would need payment for health services at any given time). Blue Cross used a community rate, establishing a similar premium rate for all subscribers

regardless of illness potential. In contrast, the commercial companies used an experience rate, in which the premium was based on an estimate of the illness risk of the number of claims to be made by the subscriber.

Premium competition, the offering of health insurance as a fringe benefit, and the use of health insurance as a negotiable collective bargaining item led to an increase in covered benefits, first-dollar coverage for medical care expenses, and increased employer-paid premiums. In turn, these factors pushed up insurance premium costs and health care costs and enabled insurance plans to cover high cost segments of the population (the aged, poor, or disabled) because of the number of low risk enrollees.

The health needs of the high risk populations led to the passage of Medicare and Medicaid legislation. Because these programs directed additional money into the health care system to subsidize care, there were financial incentives to encourage the providing of services (i.e., the more services that were ordered, the greater the amount of money that would be received). Other incentives were related to the use of services by clients (i.e., the more available the payment was for services that might otherwise have gone unused, the more services were requested). Greater increases in private insurance premiums have occurred as a result of pressure from employers, consumers, and policy makers. Driving forces behind this pressure are quality of care, client dissatisfaction, clients' rights, and the concern that these areas are being compromised in the managed care system. The initial cost savings from managed care may have occurred already, and costs will have to be increased to simply maintain coverage, not to mention providing new services and technologies. Although managed care changed the structure of financing and delivery of care, it was soon recognized that it was not the solution to the health care system's problems.

Since the beginning of Blue Cross and Blue Shield, health insurance has been tied to employment and the business sector. This tie was strengthened during World War II to compensate, attract, and retain employees. Since that time, employers have played the major role in determining health insurance benefits. Since the economic downturn in 2008, employers began to reduce their health insurance benefits or return the cost of insurance premiums to the employee.

The substantial contribution to health care by employers paying a large part of insurance premiums gave the employer a lot of health care buying power in making policy about what services insurance would cover. All but 600,000 older Americans were covered by Medicare; low-income children can be covered by the Children's Health Insurance Program (CHIP) if enrolled by parents or guardians, and some low income adults were covered by Medicaid. ACA projects that an additional 32 million will be covered by 2016.

Before the growth of insurance, the health care consumer had more influence over health care costs because payment was out of pocket. Consumers made decisions about how they would spend their money, making certain tradeoffs, for example about the type of health care they were willing to buy and how much they would pay. Entering the system was restricted in large part to those who could afford to pay for care, or to those few who could find care financed through charitable and philanthropic organizations. With the beginning of the insurance (or third party) payer system, health care costs were set by payers, and they determined the type of care or service that would be offered and its price. This began to change somewhat in the 1980's with the increased use of managed care.

As the cost of health insurance has increased, some employers, in an effort to bypass the costs established by insurers, have found it less costly to self-insure. The employer does this by contacting directly with providers to obtain health care services for employees rather than going through health insurance companies. Some large businesses directly employ onsite providers for care delivery or offer wellness programs. This move to self-insure resulted in savings to companies and reduced overall sick care costs.

The average monthly cost for private health insurance has increased greatly through the years. Premiums reflect a shift of the health care cost burden from employers to employees as the percentage of employer contributions to health care declines. The decrease in employer contributions to health

insurance premiums parallels the economic downturn of 2008, the move away from traditional insurance plans, and the move toward managed care plans or self-insurance plans by both small and large employers or toward dropping health insurance as a benefit. Public Law 111-148 includes a mandate for all citizens and legal residents to have qualifying health coverage. Employers are required to offer coverage also, except for employers with less than 50 employees.

Because access to health insurance is tied to employment, there was growing concern in the late 1980's and early 1990's about the employment layoffs and downsizing occurring in private business. Those who lost their jobs lost their ability to pay for health insurance and to qualify for purchase insurance privately. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted to protect health insurance coverage for workers and families after a job change of loss.

Managed Care

Managed care is the term used for a variety of health care arrangements that integrate the financing and delivery of health care. Managed care offers an array of services to purchasers, such as employers, Medicaid, or Medicare, for a set fee. These are called risk-based plans. This fee, in turn, is used to pay providers through preset arrangements for services delivered to individuals who are covered. This concept of managed care is based on the notion that the use of costly care could be reduced if consumers had access to care and services that would prevent illness through consumer education and health maintenance. Managed care uses disease prevention, health promotion, wellness, and consumer education. In addition to the risk-based plan whereby the managed care organization accepts the set fee to cover all costs of care for the enrollee, there are also cost-based plans. The primary care case management (PCCM) organization is often used by Medicaid programs. The PCCMs are comprised of a variety of health care providers contracted with states to locate, coordinate, and monitor covered primary care and other services on a per client case management fee payment. Whereas HMOs assume risks for the costs of care, the PCCMs do not.

Two common types of managed care are health maintenance organizations (HMOs) and preferred provider organizations (PPOs). HMO's have actually been around since the 1940's. The Health Maintenance Organization Act was enacted in 1972. Managed care is based in part on the principles of managed competition. Managed competition was introduced in health care in the late 1980's and early 1990's to address the increasing costs of health care and to introduce quality into the forefront of the discussion. Managed competition simply means that all clients make decisions and choose the health care services they want on the basis of the quality or reputation of the service. To make decisions, they use knowledge and information about health care problems, care, and providers, and they look at the costs of care.

Medical Savings Accounts

Another insurance reform discussion at the political level concerns medical savings accounts (MSAs). MSAs are touted as a way of turning health care decision making control over to the individuals receiving care. MSAs are tax-exempt accounts available to some employees of small companies. Money is contributed to the MSA by the employer, and the initial money put into an MSA does not come out of taxable income. MSAs in theory would allow individuals to make cost/quality tradeoffs and would require that individuals become knowledgeable about health care, become involved in health care decision making, and take responsibility for the decisions made.

Health Care Payment Systems

Retrospective reimbursement is the traditional reimbursement method, whereby fees for the delivery of health care services in an organization are set after services are delivered. Reimbursement is based on either organization costs or charges. The cost method reimburses organizations on the basis of cost per unit of service (e.g., home health visit, patient-day) for treatment and care. Costs include all or a

percentage of added, allowable costs. Allowable costs are negotiated between the payer and provider and include items such as depreciation of building, equipment, and administrative costs (e.g., administrative salaries, utilities, and office supplies).

The charge method reimburses organizations on the basis of the price set by the organization for delivering a service. In this case, the organization determines a charge for providing a particular service, provides the services to a client, and submits a bill to the payer; the payer in turn provides payment for the bill.

Prospective reimbursement or payment is a more recent method of paying an organization, whereby the third party payer establishes the amount of money that will be paid for the delivery of a particular service before offering the services to the client. Since the establishment of prospective payment in Medicare in 1983, private insurance has followed by requiring pre-approvals before clients can receive certain services, such as hospital admission or mammograms more than once a year. Under this payment scheme, the third party payer reimburses an organization on the basis of the payer's prediction of the cost to deliver a particular service; these predictions vary by case mix (e.g., different types of clients, with different types, levels, and intensities of health problems), the client's diagnosis, and geographic location. This process is used in the DRG system of the hospital.

Similarly, ambulatory care services received by Medicare recipients are classified into ambulatory payment classes (APCs), which reflect the type of ambulatory clinical services received and resources required. Prospective payment to skilled nursing facilities is also adjusted for case mix and geographic variations.

Positive and negative incentives are built into these reimbursement schemes. The retrospective method of payment encourages organizations to inflate prices in one area to offset agency losses in another. These losses can result from providing service to non-paying clients or from providing care to clients covered under plans that do not cover the total costs of delivering a service. The major disadvantage of this system is that little regard is given to the costs involved. This practice of charging a payer at a higher rate to cover losses in providing care is referred to as cost-shifting.

Prospective cost reimbursement encourages agencies to stay within budget limits and adds an incentive for providing less service to contain or reduce costs. If an organization provides care to a particular patient or group of patients and keeps the costs of delivering the service lower than the amount of reimbursement, the provider keeps the difference. However, if the provider's costs exceed the reimbursement, the provider must assume the risk and pay the difference. The major disadvantage of this method is that organizations tend to overemphasize controlling costs and sometimes compromise quality of care.

The traditional method of paying health care practitioners is known as fee for service and is like the retrospective method. The practitioner determines the costs of providing a service, delivers the service to a client, and submits a bill for the delivered service to a third party payer. The payer then pays the bill. This method is based on usual, customary, and reasonable (UCR) charges for specific services in a given geographic region, determined by periodic regional evaluations of physician charges across specialties.

A major effort to regulate and control the costs of physician fees was introduced in 1990 in the Omnibus Reconciliation Act. After a study by the Physician Payment Review Commission established by Congress, the resource-based relative value scale (RBRVS) was established. The RBRVS method reimburses physicians for specific services provided and the amount of resources required to deliver the service. Resources are defined broadly and include not only the costs of providing the service, but also the time that is required to provide a particular service and the time required to perform certain procedures, including client diagnosis and treatment. The RBRVS method of reimbursement, adopted by Medicare in 1991, acknowledges the breadth and depth of knowledge required by primary care physicians to provide services aimed at prevention, health promotion, teaching and counseling.

Capitation is similar to prospective reimbursement for health care organizations. Third-party payers determine the amount that practitioners will be paid for a unit of care, such as a client visit, before the delivery of the service, thereby placing a limit on the amount of reimbursement received per patient. In contrast to a fee for service arrangement, where the practitioner determines both the services that will be provided to clients and the charges for those services, practitioners being paid through capitation are given the rate they will be paid for a client's care, regardless of specific services provided. Providers are aware in advance of the payment they will receive to provide specific services.

In capitated arrangements, providers are paid a set amount to provide care to a given client or group of clients for a set period of time and amount of money. This arrangement, typically used by managed care organizations, is one whereby the practitioner contracts with the managed care organization to provide health care services to plan members for a preset and negotiated fee. The agreed upon fee is negotiated between the practitioner and the managed care organization before the delivery of services and is set at a discounted rate, and the practitioner and managed care organization come to a legal agreement, or contract, for the delivery and payment of services. The managed care organization pays the predetermined fee to the practitioner, often before delivery of services, to provide care to plan members for a set period.

Pay for Performance

Pay for performance is an umbrella term for initiatives aimed at improving the quality, efficiency, and overall value of health care. These arrangements provide financial incentives to hospitals, physicians, and other health care providers to carry out such improvements and achieve optimal outcomes for patients. Pay for performance has become popular among policy makers and private and public payers, including Medicare and Medicaid. The Affordable Care Act expands the use of pay for performance approaches in Medicare in particular and encourages experimentation to identify designs and programs that are most effective. Policy makers have been concerned with the incentive structure built into the U. S. health care system. The predominant fee for service system under which providers are paid leads to increased costs by rewarding providers for the volume and complexity of services they provide. Higher intensity of care does not necessarily result in higher quality care, and can even be harmful.

The typical pay for performance program provides a bonus to health care providers if they meet or exceed agreed upon quality or performance measures, such as reductions in hemoglobin A1c levels in diabetic patients. The programs may also reward improvement in performance over time, such as year to year decreases in the rate of avoidable hospital readmissions.

Pay for performance programs can impose financial penalties on providers that fail to achieve specified goals or cost savings. For example, the Medicare program no longer pays hospitals to treat patients who acquire certain preventable conditions during their hospital stay, such as pressure sores or urinary tract infections associated with use of catheters.

The quality measures used in pay for performance generally fall into three categories:

1. Structure measures relate to the facilities, personnel, and equipment used in treatment. For example, many pay for performance programs offer incentives to providers to adopt health information technology.
2. Process measures assess the performance of activities that have been demonstrated to contribute to positive health outcomes for patients. Examples include whether or not aspirin was given to heart attack patients or whether patients were counseled to quit smoking.
3. Outcome measures refer to the effects that care had on patients, for example, whether or not a patient's diabetes is under control based on laboratory tests. Use of outcome measures is particularly controversial in pay for performance because outcomes are often affected by social and clinical factors unrelated to the treatment provided and beyond the provider's control. For example, providers may follow practice guidelines regarding monitoring blood sugar levels and counseling diabetic patients

regarding their diet, but ultimately, the patient's eating and exercise behaviors will determine control of his/her diabetes. Patient experience measures are a type of outcome measure that assesses patients' perceptions of the quality of care they have received and their satisfaction with the care experience. In the inpatient setting, examples include how patients perceived the quality of communication with their doctors and nurses, and whether their rooms were clean and quiet. Increasingly outcome measures also include cost savings.

Private sector initiatives

More than 40 private sector pay for performance programs currently exist. One of the largest and longest-running private sector pay for performance program is the California Pay for Performance Program, which is managed by the Integrated Health Association, a nonprofit, multistakeholder group that promotes quality improvement, accountability, and affordability in health care. Founded in 2001, the California Pay for Performance Program is the largest physician incentive program in the U. S. It has focused on measures related to improving quality performance by physician groups and transitioned to include value-based cost measures in 2014. A more recent initiative is the Alternative Quality Contract, which was implemented in 2009 between Blue Cross Blue Shield of Massachusetts and seven provider groups, which has now increased to 11. Under the program, the providers receive a budget to take care of their patients rather than payments for separate services. The budget includes pay for performance bonuses if certain quality targets are met. In the first year of the program, a study by Harvard Medical School researchers found reduced medical spending and improved quality of patient care relative to a comparable group of providers paid through the traditional fee for service approach.

Public Sector Initiatives

In the public sector, the Centers for Medicare and Medicaid Services (CMS) has established a Value-Based Purchasing Program to provide incentives for physicians and providers to improve the quality and efficiency of care. CMS has also been involved in a number of pay for performance demonstration projects testing a variety of approaches among different categories of providers.

EXHIBIT 1

Overall Goals of Value-Based Purchasing in Medicare

Financial viability	The financial viability of the traditional Medicare fee-for-service program is protected for beneficiaries and taxpayers
Payment incentives	Medicare payments are linked to the value (quality and efficiency) of care
Joint accountability	Providers have joint clinical and financial accountability for health care in their communities
Effectiveness	Care is evidence based and outcomes driven to better manage diseases
Ensuring access	Restructured fee-for-service system provides ensured access to high-quality, affordable care
Safety, transparency	Beneficiaries receive information on the quality, cost, and safety of their care
Smooth transitions	Payment systems support well-coordinated care across providers and settings
Improved technology	Electronic health records help providers deliver high-quality, efficient, and coordinated care

SOURCE Centers for Medicare and Medicaid Services.

The largest and most notable of these has been the Premier Hospital Quality Incentive Demonstration project. From 2003 to 2009, CMS and Premier, a nationwide hospital system, tested the extent to which financial bonuses would improve the quality of care provided to Medicare patients with certain conditions, including acute myocardial infarction, heart failure, and pneumonia. Another major CMS demonstration was the Physician Group Practice Demonstration, a program in which group practices could share cost savings with Medicare as long as they met targets for quality of care. Many states have also experimented with pay for performance in their Medicaid and Children's Health Insurance Program initiatives. One of the largest of these has been the Massachusetts Medicaid's hospital-based pay for performance program, which was initiated in 2008. Under this program, hospitals received incentive payments based on their scores for a set of quality indicators related to care for pneumonia (for example, providing antibiotics within six hours of arrival) and surgical infection prevention (for example giving prophylactic antibiotics within one hour of surgical incision.) Most early pay for performance experiments narrowly focused on quality with very little, if any, consideration of cost. However, the field has been evolving and many programs now address overall value by incorporating both quality and cost as major design elements. The Affordable Care Act explicitly pushes CMS in this direction.

The Affordable Care Act includes a number of provisions designed to encourage improvements in the quality of care. Some are not strictly pay for performance programs. For example, Medicare's Hospital Readmissions Reduction Program, which took effect October 1, 2012, can reduce payments by 1% to hospitals that have excessively high rates of avoidable readmissions for patients experiencing heart attacks, heart failure, or pneumonia. The best known of the programs that will pay for performance are accountable care organizations (ACOs), which are groups of providers that agree to coordinate care and to be held accountable for the quality and costs of the services they provide.

The Affordable Care Act also expands pay for performance efforts in hospitals by establishing a Hospital Value Based Purchasing Program. Starting October 1, 2012, hospitals are rewarded for how well they perform on a set of quality measures as well as on how much they improve in performance relative to a baseline. The better a hospital does on its quality measures, the greater the reward it will receive. The law also requires CMS to develop value based purchasing programs for home health agencies, skilled nursing facilities, ambulatory surgical centers, specialty hospitals such as long term care facilities, and hospice programs.

ACA also extends the Medicare Physician Quality Reporting System that provides financial incentives to physicians for reporting quality data to CMS. Beginning in 2015, the incentive payments will be eliminated, and physicians who do not satisfactorily report quality data will see their payments from Medicare reduced.

ACA also provides for bonus payments to Medicare Advantage plans that achieve at least a four-star rating on a five-star quality rating scale, which began in 2012. CMS announced that it would replace this provision with a demonstration project in which bonus payments would be awarded to Medicare Advantage plans that have at least an average of three stars and would increase the size of bonuses for plans with four or more stars.

Despite limited evidence of effectiveness, pay for performance remains popular among policy makers and public and private insurers as a tool for improving quality of care and containing health care costs. Serious concerns have been raised about the impact of pay for performance approaches on poorer and disadvantaged populations. In particular, there are fears that these programs may exacerbate racial and ethnic disparities in health if providers avoid patients that are likely to lower their performance scores. However, pay for performance programs are likely to expand across U. S. health care in the near future, especially with implementation of the Affordable Care Act.

Quality Pioneers

- Statistical Process Control (SPC)
 - Walter Shewhart
 - Statistician Bell Laboratories 1920's statistical process control in manufacturing
 - PDCA-Plan Do Check Act
 - Shewhart Cycle continuously improve quality
- World War II
 - Producing enormous quantities
 - Top priority meeting delivery dates
 - Quality suffered
- War Production Board
 - Improve quality of military goods
- W. Edwards Deming
 - Statistician
 - PDSA – Plan Do Study Act
 - Deming Wheel
 - Quality Circles
 - Teaching quality to middle management
 - Statistically controlled management process to determine when and when not to intervene in a process
 - Common cause
 - Special cause
- Joseph Juran
 - Engineer
 - Quality is product performance that results in customer satisfaction
 - Freedom from deficiencies avoid customer dissatisfaction
- Phil Crosby
 - Cost of poor quality
 - High quality less costly than waste
- Japanese Quality Revolution
 - Sending teams abroad to learn & invited lecturers to Japan
 - Juran & Deming went to Japan
 - Upper managers responsible for leading the quality revolution
 - All levels and functions received training in managing for quality
 - Quality improvement at a continuing, rapid pace
 - Quality circles employee empowerment
- Dr. Ernest Codman
 - American College of Surgeons
 - Identified variability in patient outcomes
 - Systematic evaluation process
 - Establishing quality standards
- Dr. Avedis Donabedian
 - University of Michigan
 - Structure, Process, Outcome
- Joint Commission
 - First standards mainly structure, some process; didn't address outcomes directly
- Don Berwick
 - Bad apple theory of quality
 - Institute for Healthcare Improvement

Total Quality Management (TQM)

Total quality is an approach to quality improvement that encompasses all systems and processes, clinical and non-clinical, with actions directed towards processes to improve the quality of all services and products for patients and all other customers.

- TQM is a process for meeting and exceeding customer requirements.
- It extends the concept of customers to include employees within an organization as a critical customer group.
- It is both a philosophy and a new way of doing business.
- TQM is a participative team-oriented process.
- On a step by step basis, through the application of a scientific problem solving methodology, the organization learns to manage with fact rather than with intuition.
- A TQM approach allows an organization to enhance all critical systems and processes.
- It helps managers focus on long term strategies rather than a quick fix approach.
- Each employee is taught how to listen to the voice of the customer, continually improve those essential services, reduce cost, and ultimately help the organization to compete more effectively.

Experience shows that high quality and return on investment usually go together. In the long run, the most important single factor affecting a business unit's performance is the quality of its products and services, relative to those of the competitors. Quality leads to both market expansion and gains in market share. Excellent service translates to satisfied customers who will use the organization again and recommend it to their friends.

In 1950, W. Edwards Deming told the Japanese that if quality improves, productivity automatically improves. This is done by lowering waste, lowering restarts, and lowering rework. When this happens, organizations can capture the market with higher quality and lower costs of goods and services, allowing them to stay in business and provide jobs. Deming viewed quality, productivity, and cost as a chain reaction. For healthcare, this means that all critical business functions, clinical as well as administrative, must be involved.

- Total quality management (TQM) is a very comprehensive process with many component parts. TQM means the vast collection of philosophies, concepts, methods, and tools being used throughout the world to manage quality.
- TQM is most widely used in the United States, and Total Quality Control (TQC) has been widely used in Japan. Another term used is continuous quality improvement. Many of its concepts, tools, and techniques are familiar and have been around for many years.
- TQM should be viewed as a combination of philosophy, knowledge, and skills that is uniquely effective in accomplishing major organizational change through improvement in quality, cost effectiveness, and human relations.

There are three fundamental concepts:

- Customer focus,
 - Continuous improvement, and
 - Value of every associate
- TQM is an integrated effort focused on customers. The purpose and success of an organization is based on its internal and external customers. TQM is the integration of a customer-focused, continuous-improvement philosophy, analytical skills, people skills, and a structure and organization, within an internal and external culture affected by leadership. The power of TQM comes from the integration and balance of these components. An overemphasis on any one of them will fail to achieve the potential benefits of TQM.

TQM is also a management approach that strives for the following:

1. Under strong top management leadership, establish clear mid and long term vision and strategies.
2. Properly utilize the concepts, values, and scientific methods of TQM.
3. Regard human resources and information as vital organizational infrastructures.
4. Under an appropriate management system, effectively operate a quality assurance system and other cross-functional management systems such as cost, delivery, environment, and safety.
5. Supported by fundamental organizational powers, such as core technology, speed, and vitality, ensure sound relationships with customers, employees, society, suppliers, and stockholders.
6. Continuously realize corporate objectives in the form of achieving an organization's mission, building an organization with a respectable presence, and continuously securing profits.

TQM Philosophy

With the emphasis on customer-focused, continuous improvement philosophy, TQM is grounded in a philosophy of meeting and exceeding customer-defined requirements and working for continuous improvement. **W. Edwards Deming's 14 points** are examples of elements of this philosophy.

1. Create constancy of purpose for improvement of product and service
2. Adopt the new philosophy
3. Cease dependence on inspection to achieve quality
4. End the practice of awarding business on the basis of the price tag alone. Instead, minimize total cost by working with a single supplier. Move toward a long-term relationship of loyalty and trust.
5. Improve constantly and forever the system of production and service to improve quality and productivity, and thus constantly decrease costs.
6. Institute training on the job.
7. Adopt and institute leadership. The aim of supervision should be to help people and machines do a better job.
8. Drive out fear, so that everyone may work effectively for the company.
9. Break down barriers between departments.
10. Eliminate slogans, exhortations, and targets for the workforce asking for zero defects and new levels of productivity.
11. Eliminate numerical quotas for the workforce and numerical goals for management. Eliminate management by objective.
12. Remove barriers that rob the hourly worker of his right to pride of workmanship. Eliminate the annual rating or merit system.
13. Institute a vigorous program of education and self-improvement. Encourage education and self-improvement for everyone.
14. Put everybody in the company to work to accomplish the transformation.
 - Improve quality
 - Improve productivity
 - Decrease cost
 - Decrease price
 - Increase market share
 - Stay in business
 - Provide jobs
 - Return on investment

Outcomes of TQM

The U. S. General Accounting Office (GAO) produced a report detailing the effect of quality improvement activities on corporate performance. The report, *Management Practices, U.S. Companies Improve Performance Through Quality Efforts*, is based on the responses of 20 of the 22 companies that were finalists for the Malcolm Baldrige Quality Award. The report concentrated on five categories of success: improved market share, improved profitability, greater customer satisfaction, quality and lower cost, and better employee relations. The results were consistently positive. Market share was boosted an annual average of 13.7%, customer complaints dropped by 11.6%, employee turnover was reduced by 6%, and defects declined by 10.3%.

Companies that adopted TQM practices experienced an overall improvement in corporate performance. In nearly all cases, companies that used total quality practices achieved better employee relations, higher productivity, greater customer satisfaction, increased market share, and improved profitability.

Each of the companies studied developed its practices in a unique environment with its own opportunities and problems. However, there were common features in their quality management systems that were major contributing factors to improved performance.

Many different kinds of companies benefited from putting specific TQM practices into place. However, none of these companies reaped the benefits immediately. Allowing sufficient time for results to be achieved was as important as initiating a quality management program.

Focus of TQM

- The focus on TQM is on continuous improvement rather than achieving fixed goals.
- There must be improvement every year. This is contrary to traditional quality assurance efforts, which used the same thresholds for years. Thresholds are difficult to establish, may be inaccurate, and once reached may receive little additional attention.
- Since TQM focuses on continuous quality improvement, the organization is beginning a never-ending journey. Total quality will never be completed. The organization will seek to improve continually, with quantitative measurements to demonstrate that improvement. Customers and other providers will keep raising the quality bar. Changes in knowledge, technology, and expectations will cause ever-increasing expectations.
- TQM is a means, not an end. The objective is to improve performance continually, as judged by internal and external customers. TQM provides an approach and methods to help organizations accomplish goals. The aim of TQM is to accomplish the mission, vision, and goals of the organization through meeting and exceeding the requirements of the customers.

Deming's Basic Ideas

Employees want to do their best.

They know the most about their own jobs, and they should be involved in planning improvements. For many managers, who have accomplished their responsibilities by making most decisions and controlling everything, this represents a major shift in thinking. Clearly there is a minority of employees, suppliers, and others who do not want to do their best, but it is counter productive to develop a whole management philosophy and system to address the non-performers. This is an example of focusing on the "bad apple" theory, described by Donald M. Berwick. Often staff members who have wanted to do their best have been beaten down by barriers in the system, and have lost initiative. In adopting the new philosophy, management concentrates on removing barriers that prevent employees from doing their best.

Analytical knowledge and skills

The concept of making business decisions based on the use of data and analytical tools and techniques is very important in a TQM process. Engineers, business managers, quality control staff, and others have used measurement, graphs of data, control charts, statistics, and other quantitative measures for years. However, these skills were not been widely used by healthcare managers and staff to improve organizational performance. Another issue is that certain people who advanced due to strong analytical skills may lack effective interpersonal skills. They tend to be very task oriented.

Interpersonal or people skills

Work is accomplished by people, and involvement of everyone in the organization is critical to success in a highly competitive environment. Better ideas are generated and changes implemented faster if staff closest to the process are involved in the analysis and decision making process. Human resources staff and others have encouraged the participative management style, continuing education and training for all staff, and other people oriented skills for years. However, they often failed to demonstrate quantitatively to results oriented top leadership the effectiveness of these approaches in day to day management.

Structure and organization

A supportive structure and organization should be established to ensure the success of a wide range of quality improvement efforts ranging from formal quality improvement teams through daily quality improvement efforts of every employee. If quality improvement is to become an organizational focus, it must be actively led by the organization's leaders.

Culture and environment

It is important to understand that, though the principles remain the same, TQM must be tailored to the unique internal and external culture and environment of every organization. TQM should be integrated into all of the organization's quality efforts. The culture of the organization needs to be assessed for the environment for change and readiness for change.

Becoming Superior in Quality

For an organization to become superior in quality, it needs:

1. Technologies to create products and processes that meet customer needs. Part of this is the design of the individual jobs.
2. A culture throughout the organization that continually views quality as a primary goal. Quality culture is the pattern, the emotional scenery, of human habits, beliefs, and behavior concerning quality. Designing and maintaining jobs to meet the criteria of self-control are essential prerequisites to achieving a quality culture.

To build a strong quality culture, organizations must collect information to determine the present quality culture, and take the steps necessary to change the culture. The road to developing a positive quality culture is lengthy and difficult, though essential for an organization's survival.

Dimensions of Performance (Joint Commission)

Performance is what is done and how well it is done to provide health care. The level of performance in health care is

- the degree to which what is done is efficacious and appropriate for the individual patient; and
- the degree to which it is available in a timely manner to patients who need it, effective, continuous with other care and care providers, safe, efficient, and caring and respectful of the patient.

Characteristics of what is done and how well it is done are called dimensions of performance:

- The degree to which an organization does the right things and does them well is influenced strongly by its design and operation of a number of important functions--many of which are described in this manual.
- The effect of an organization's performance of these functions is reflected in patient outcomes and in the cost of its services.
- Patients and others judge the quality of the health care based on patient health outcomes (and sometimes on their perceptions of what was done and how it was done).
- Patients and others may also judge the value of the health care by comparing their judgments about quality with the cost of the health care.

I. Doing the Right Thing

The **efficacy** of the procedure or treatment in relation to the patient's condition

The degree to which the patient's care and services have been shown to accomplish the desired or projected outcome(s)

The **appropriateness** of a specific test, procedure, or service to meet the patient's needs

The degree to which the care and services provided are relevant to the patient's clinical needs, given the current state of knowledge

II. Doing the Right Thing Well

The **availability** of a needed test, procedure, treatment, or service to the patient who needs it

The degree to which appropriate care and services are available to meet the patient's needs

The **timeliness** with which a needed test, procedure, treatment, or service is provided to the patient

The degree to which the care and services are provided to the patient at the most beneficial or necessary time

The **effectiveness** with which tests, procedures, treatments, and services are provided

The degree to which the care and services are provided in the correct manner, given the current state of knowledge, to achieve the desired or projected outcome for the patient

The **continuity** of the services provided to the patient with respect to other services, practitioners, and providers and over time

The degree to which the patient's care is coordinated among disciplines, among organizations, and over time

The **safety** of the patient and others to whom the services are provided

The degree to which the risk of an intervention and risk in the care environment are reduced for the patient and others, including the health care provider

The **efficiency** with which care and services are provided

The relationship between the outcomes (results of care) and the resources used to deliver patient care and services

The **respect and caring** with which care and services are provided

The degree to which those providing care and services do so with sensitivity and respect for the patient's needs, expectations, and individual differences; degree to which the patient or a designee is involved in his or her own care and service decisions

Organizational Culture

Organizational cultures consist of commonly held beliefs and values about work life. A strong culture, with well-socialized members, improves organizational effectiveness because it facilitates the exchange of information and coordination of behavior. The actions and decisions of organization leaders create and reinforce key values and shape the culture.

- Do the management practices in an organization cause anxiety, lack of trust, and self-protective behaviors?
- Or are there strong feelings of trust, collaboration, and practices that contribute to the development of each person's competence and self-esteem?
- Employee involvement and empowerment can thrive only where the culture is positive and the value of the individual is upheld.
- Actually changing strongly held beliefs is a very difficult and time-consuming task.

Corporate culture

This is the basic assumptions driving life in a given organization. A working description of the word culture is the way things get done in an organization. Every organization has a culture created by the shared beliefs, values, norms, and expectations of the workforce. Corporate culture has a measurable impact on the bottom line performance of an organization. Involvement, consistency, adaptability, and mission are significant elements of culture that help determine future organizational effectiveness.

Positive Culture

A positive culture is one in which employees experience pride in their work, where everyone is involved and committed to continuous improvement, where people freely help each other to achieve goals and have fun during the process. In positive cultures, people feel appreciated, their opinions are solicited, and action follows suggestions. In a total quality culture, there is an attitude based on trust, teamwork, objective problem solving, and shared accountability. In a positive culture, people are able to see new possibilities and are open to change. They develop confidence in their own problem solving, and need little or no supervision. They also take calculated risks and stretch their learning potential. Peak performance becomes possible.

Negative Culture

If the environment is negative, there are also many visible signs. Negativity is an energy depleter. In negative organizations, people spend a lot of time guarding their turf and protecting themselves. Energy is spent in attacking others, getting angry, and getting even. There is little risk taking because if a mistake is made, the boss searches for the guilty party and punishment occurs. Punishment, even if subtle, creates the wrong tone. Change is resisted and maintaining the status quo becomes the goal. Rather than being pulled by a positive vision, the organization is driven by fear and the desire to protect oneself.

Organizational Cultural Assessment

Organizations can assess organizational culture; one common way is through questionnaires. Employees are asked to describe the current environment, and describe the way they would like the culture to be, giving the organization a look at the current perceived culture and they desired culture. Questionnaires commonly ask people to think about what it takes to fit into the culture and meet expectations. They are asked to respond on a five-point scale from strongly agree to strongly disagree to phrases describing the organization, such as go along with others, win against others, take moderate risks, never make a mistake. Most employees within organizations describe the same desired culture. Other ways to complete organizational cultural assessments are to look at existing patterns of behavior, and review the current assumptions, shared beliefs, values, norms, and expectations. Organizational assessments generally reveal subcultures within the organization. Leadership drives the process and creates the pressure for cultural change within the organization, which can significantly influence the external culture.

Changing the Quality Culture

1. Create and maintain an awareness of quality. This means create and disseminate information on the current status of quality. Go to upper management, middle and lower management, and all other personnel, using language that fits each territory.
2. Provide evidence of management leadership on quality. This is not only cheerleading but also serving on a quality council, doing strategic planning for quality, providing resources for quality, and doing a host of other tasks to plan and deploy quality councils.
3. Provide for self-development and empowerment. This includes designing jobs for self control, selection and training for jobs, organizing work using approaches for self development such as self managing teams, and encouraging personal commitment for quality.
4. Provide participation as a means of inspiring action. The forms of participation are almost endless; serve on a quality council or an improvement team, be a process owner, take part in a product or process design review, or make presentations on quality.
5. Provide recognition and rewards. These expressions of esteem play an essential role in inspiring people on quality. Recognition takes the form of public acknowledgement for great performance on quality. Rewards are tangible benefits (salary increases, bonuses, promotions, etc.) for quality. Quality of working life concerns must also be addressed.

Effective Leadership for Quality

Effective leadership for quality is essential. Characteristics for leading a quality/performance improvement effort include:

1. Being a visionary: Developing the skill to look ahead and describe a better organization in which each individual's work is optimized and quality is the number one goal of each employee.
2. Being socially responsible: Developing a concern about the cost effectiveness of healthcare as well as the means to provide access. Social responsibility is also about meeting the healthcare needs of communities, truly being customer-focused rather than provider-focused.
3. Managing uncertainty: Becoming more flexible, capable of leading successfully in the face of increasing external challenges and ambiguity.
4. Being a change agent: Exhibiting a bias for action. Personally acting as a change agent and supporting other risk takers in the environment.
5. Being people oriented: Believing in the collective intellectual power of people in the organization.
6. Fostering teamwork and collaboration and empowering people so they can contribute to organizational successes.
7. Sharing information: Sharing all types of information broadly. Recognizing that information is a way to empower others and give them a big-picture perspective of the organization.
8. Being driven by customers' values: Learning to listen to the customer's requirements effectively.
9. Developing action plans to exceed requirements and delight the customer. Encouraging and reinforcing the customer focus at all levels in the organization.
10. Being committed to innovation: Promoting innovation and creativity throughout the organization. Teaching and modeling creative problem-solving skills for managers and employees.
11. Being visible: Management by walking around builds employee commitment and loyalty to the organization. Providing instant recognition to those who are modeling quality behaviors reinforces commitment. Speaking directly to customers indicates the level of personal involvement in achieving customer satisfaction goals.

12. Being committed to education and training: Setting the tone for the learning organization by attending educational sessions and demonstrating the importance of knowledge.
13. Being willing to decentralize and delegate: Recognizing the importance of delegation. Constantly assess how to push power, information, and knowledge down in the organization to the people who interface with the customer.
14. Fostering supplier relationships: Promoting strategic partnerships with suppliers to improve products and services jointly.
15. Knowing yourself: Constantly assessing personal strengths and weaknesses and developing action plans for improvement. Utilizing performance evaluations as a two way street where the boss and the subordinate each discuss what went well, what went poorly, and what needs to be improved. The goal is for each party to understand how to make the other successful.

The uniqueness and power of TQM is in the integration and balance of components, not in the use of individual parts. The key to organizational goal achievement is people, especially in a labor-intensive industry like healthcare. Inattention to people and cultural change are the most common reasons for the failure of change strategies and excessively long periods for implementing changes.

Definitions of Quality

The definitions of quality change based on who is defining the terms, including as customers, healthcare providers, patients and their families, the payers, and society at large. Customers don't judge quality as the technical and scientific aspects of care. Technical measures of quality have not been defined. Most quality measures are indicative of quality failure, such as mortality, morbidity, hospital-acquired infection rates, and unplanned readmissions, all indicators of process failure.

Providers: The traditional way of viewing quality within healthcare is that quality means doing more, using greater technology, doing more tests, giving more intensive care, making every effort to save lives. There is no relationship between cost and quality indicators such as medical/surgical death rates and post operative surgical infection rates. Findings suggest that there is no tradeoff between efficiency and high-quality care. In fact, performing unnecessary tests and procedures exposes patients to avoidable medical risks along with unnecessary costs.

Consumers: They are willing to pay more for quality products, however quality does not always cost more. Confusion arises when the word quality is used without making it clear whether it's referring to quality of design or quality of conformance. Generally speaking, quality of design can be attained only at an increase in costs, whereas higher quality of conformance can often be attained with an accompanying reduction in costs. Achieving quality through defects reduces the cost of the product or service, but achieving quality through added features often increases costs.

Organizations: They may define quality as meeting professionally established specifications, or quality in fact.

Customers: They may define quality as based on their perception of whether a product or service is as good or better than it was expected to be, or quality of perception. A successful quality organization needs to consider both aspects of quality.

Barriers to Quality

1. **Lack of common direction:** Few organizations have a well-communicated common direction that is understood by all employees. This common direction is described by statements of values, vision, mission, guiding principles, goals, and expectations, and must be demonstrated through the actions of ongoing organizational leaders.

2. **Loss of key leaders:** If the organization loses one or more key leaders of TQM implementation, it can cause the implementation to slow down or stop. Since the average tenure of CEOs in hospitals averages about three years, this raises the question of who is going to carry on. The organization must recruit new leaders who share the commitment to TQM and the organization's common direction. Another behavior that produces similar stalls is leadership that vacillates its active support and promotion of TQM.
3. **Poor communication:** Probably the single biggest barrier to continuous improvement is poor communication. It may begin with the supplier's not fully understanding customer requirements. Most processes in healthcare organizations have many steps. The case of healthcare processes is analogous to a relay race; the dropped baton is some form of miscommunication.
4. **Too many steps in a process:** When a process becomes very complex, it typically has a high failure rate.
5. **Dysfunctional culture:** One of the key barriers to change is the conscious or unconscious retention of old beliefs and actions that discourage innovations, creativity, empowerment, diversity or other components of TQM. The first step is to identify and raise these to the attention of the people involved.
6. **Lack of integration and balance:** There are many components of implementing TQM in a healthcare organization which must be integrated and balanced to be successful. The processes that must be integrated and balanced include:
 - a. Customer oriented, continuous improvement philosophy, analytical skills, people skills, and structure.
 - b. Quality assurance, quality control and quality improvement
 - c. Suppliers, the healthcare organization, and customers
 - d. Healthcare organization, the medical staff, and other key groups

W. Edwards Deming Seven Deadly Diseases

1. **Lack of constancy of purpose:** An organization that is without constancy of purpose has no long-range plan for staying in business. Management is insecure and so are employees.
2. **Emphasis on short-term process:** Looking to increase quarterly dividends undermines quality and productivity.
3. **Personal review system:** The effects of these are devastating, teamwork is destroyed, rivalry is nurtured. Performance ratings build fear and leave people bitter, despondent, and beaten. They also encourage defection in the ranks of management.
4. **Mobility of management:** Job-hopping managers never understand the companies they work for and are never there long enough to follow through on long-term changes that are necessary for quality and productivity.
5. **Running a company on visible figures alone:** The most important figures and unknown and unknowable, the multiplier effect of a happy customer, for example.
6. **Excessive medical costs for employee health care,** which increase the final cost of goods and services: High medical costs contribute to the high prices of good and services, which decreases profit margins.
7. **Excessive cost of warranty,** fueled by lawyers who work on contingency fees: High legal fees, like high healthcare costs, decrease competitiveness.

Rising Healthcare Costs

New technology—Many new healthcare technologies are less invasive, reduce length of hospital stay, reduce complications, and return the patient to work more quickly, such as laparoscopic surgery, lithotripsy, laser surgery, balloon angioplasty, and drugs such as Streptokinase, TPA, and retavase. However, much new technology supplements rather than replaces old methods and makes it difficult to

determine the effectiveness and benefits of the new procedures. Radiology has MRIs, CT scans, PETS, and standard tests. Few guidelines are available to serve as gatekeepers to approve the use of tests.

Aging populations—The most rapidly growing age groups are over 65. While life expectancy has been extended, more than 80% of people over 65 have at least one chronic illness.

Medical malpractice—There is built in bias to order more procedures for the protection of both the patient and the physician.

Overspecialization—Given the expanded level of expertise and new professions accompanying the expansion of technology, there has been a tendency for overspecialization among physicians and other providers. There are too few family practitioners and primary care providers, and too many specialists and subspecialists. Another example of overspecialization is in the allied health professions. There are many new specialties each with a narrowly defined scope of responsibility, adding to complexity of care.

Managing for Quality

To attain quality, the first step is establishing the vision for the organization, along with strategic goals and objectives. Conversion of goals into results is what makes quality happen. This is accomplished through managerial processes, sequences of activities that produce the intended results. According to Joseph Juran, managing for quality makes use of the following:

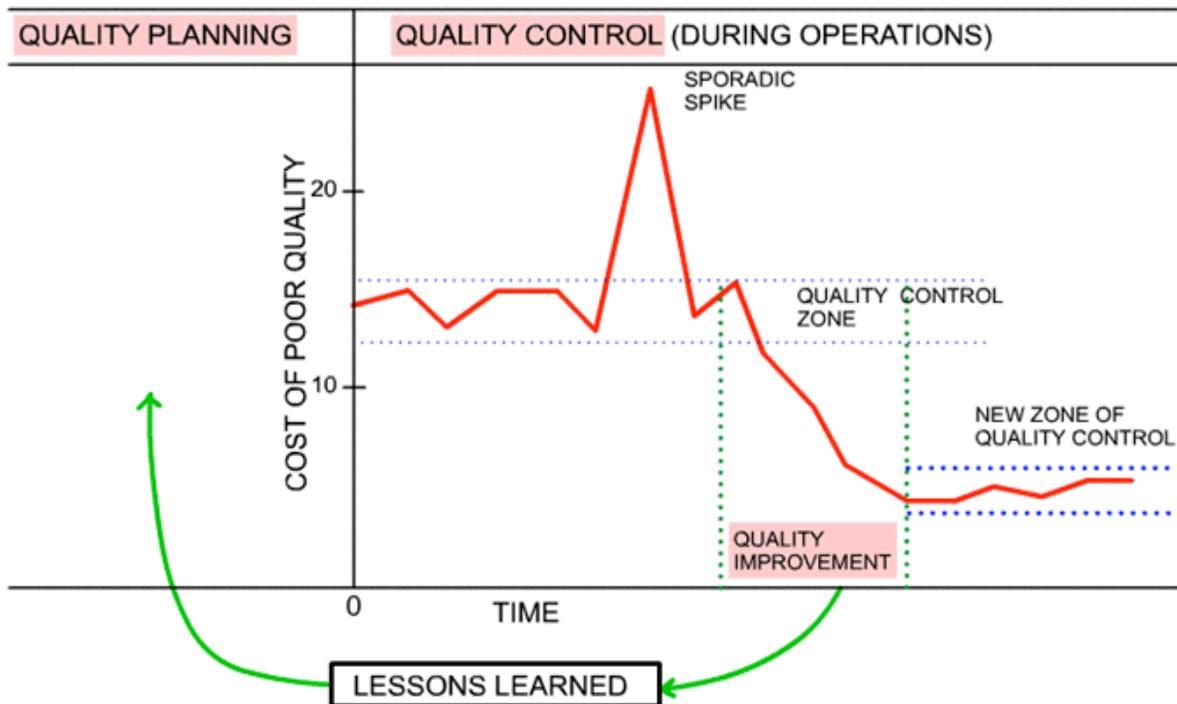
Quality planning

Quality control

Quality improvement

These processes are known as the **Juran trilogy** and parallel processes used in financial management.

The Juran Trilogy Diagram



Financial planning: This process prepares the annual financial budget. This consists of defining the needs to be done in the year ahead, translating those needs into money, determining the financial consequences of doing all those things, and finally establishing the financial goals for the organization and its departments.

Financial control: This process consists of evaluating actual financial performance, comparing this with the financial goals, and taking action on the difference, the variance. There are sub-processes for financial control including cost control, expense control, inventory control and others.

Financial improvement: This process aims to improve financial results. This includes things like cost reduction projects, new facilities to improve productivity, new product development to increase sales, acquisitions, and joint ventures.

These universal processes provide the basis for financial management, no matter what type of organization. The financial analogy reminds managers that they can manage for quality by using the same process of planning, control, and improvement. The approach is essentially the same.

Cost of Poor Quality

The cost of poor quality is the cost incurred when things are not done correctly the first time. It can also be caused by not doing the right things or doing the wrong things, errors of omission or commission. There are many examples of this in healthcare, such as x-ray retakes, illegible prescriptions, procedures cancelled due to poor preparation, lost records. In most organizations, the cost of poor quality runs about 25% of revenues. Phillips Crosby says you can spend 15-20% on the cost of poor quality without even trying hard. Many managers are unaware of the magnitude of poor quality on the bottom line. The cost of poor quality is never addressed on the balance sheet because in most organizations, it remains hidden and unknown. Rework, complexity and waste must be eliminated by applying the tools and techniques of performance improvement in every area and in every job in the organization. The concept of continual improvement means a commitment to identifying critical processes and improving them across the organization. It is a long-term strategic commitment.

Cost/Benefit Analysis

A cost benefit analysis is done to determine how well, or how poorly, a planned action will turn out. Although a cost benefit analysis can be used for almost anything, it is most commonly done on financial questions. Since the cost benefit analysis relies on the addition of positive factors and the subtraction of negative ones to determine a net result, it is also known as running the numbers.

- A cost benefit analysis finds, quantifies, and adds all the positive factors. These are the **benefits**.
- Then it identifies, quantifies, and subtracts all the negatives, the **costs**. The difference between the two indicates whether the planned action is advisable.
- The most important element in doing a cost benefit analysis well is making sure you include all the costs and all the benefits and properly quantify them.

Should an organization hire an additional staff person in admitting or assign overtime? Is it a good idea to purchase the new CT scanner? Will we be better off putting our free cash flow into securities rather than investing in additional capital equipment? Each of these questions can be answered by doing a proper cost benefit analysis.

Example Cost Benefit Analysis

You are proposing the purchase of a \$1 Million drug packaging machine to increase output. Before you can present the proposal to the Vice President, you know you need some facts to support your suggestion, so you decide to run the numbers and do a cost benefit analysis. You itemize the benefits. With the new machine, you can produce 100 more units per hour. The three workers currently doing the drug packaging by hand can be replaced. The units will be higher quality because they will be

more uniform. You are convinced these outweigh the costs. There is a cost to purchase the machine and it will consume some electricity. Any other costs would be insignificant. You calculate the selling price of the 100 additional units per hour multiplied by the number of production hours per month. Add to that two percent for the units that aren't rejected because of the quality of the machine output. You also add the monthly salaries of the three workers. That's a pretty good total benefit. Then you calculate the monthly cost of the machine, by dividing the purchase price by 12 months per year and divide that by the 10 years the machine should last. The manufacturer's specs tell you what the power consumption of the machine is and you can get power cost numbers from accounting so you figure the cost of electricity to run the machine and add the purchase cost to get a total cost figure. You subtract your total cost figure from your total benefit value and your analysis shows a healthy profit. With this scenario, you have left out a lot of detail.

Running the numbers means including all the numbers. Look at the benefits first. Don't use the selling price of the units to calculate the value. Sales price includes many additional factors that will unnecessarily complicate your analysis if you include them, not the least of which is profit margin. Instead, get the activity based value of the units from accounting and use that. You remembered to add the value of the increased quality by factoring in the average reject rate, but you may want to reduce that a little because even the machine won't always be perfect. Finally, when calculating the value of replacing three employees, in addition to their salaries, be sure to add their overhead costs, the costs of their benefits, etc., which can run 75-100% of their salary. Accounting can give you the exact number for the workers' "fully burdened" labor rates.

In addition to properly quantifying the benefits, make sure you included all of them. For instance, you may be able to buy feed stock for the machine in large rolls instead of the individual sheets needed when the work is done by hand. This should lower the cost of material, another benefit. As for the cost of the machine, in addition to its purchase price and any taxes you will have to pay on it, you must add the cost of interest on the money spent to purchase it. The organization may purchase it on credit and incur interest charges, or it may buy it outright. However, even if it buys the machine outright, you will have to include interest charges equivalent to what the organization could have collected in interest if it had not spent the money. Check with finance on the amortization period. Just because the machine may last 10 years, doesn't mean the organization will keep it on the books that long. It may amortize the purchase over as little as 4 years if it is considered capital equipment. If the cost of the machine is not enough to qualify as capital, the full cost will be expensed in one year. Adjust your monthly purchase cost of the machine to reflect these issues. You have the electricity cost figured out but there are some costs missed.

The typical failure of a cost benefit analysis is not including all the costs. In the case of the drug packaging machine, here are some of the overlooked costs:

Floor Space

Will the machine fit in the same space currently occupied by the three workers?

Installation

What will it cost to remove the manual drug packaging equipment and install the new machine? Will you have to cut a hole in a wall to get it in or will it fit through the door? Will you need special rollers or machinists with special skills to install it?

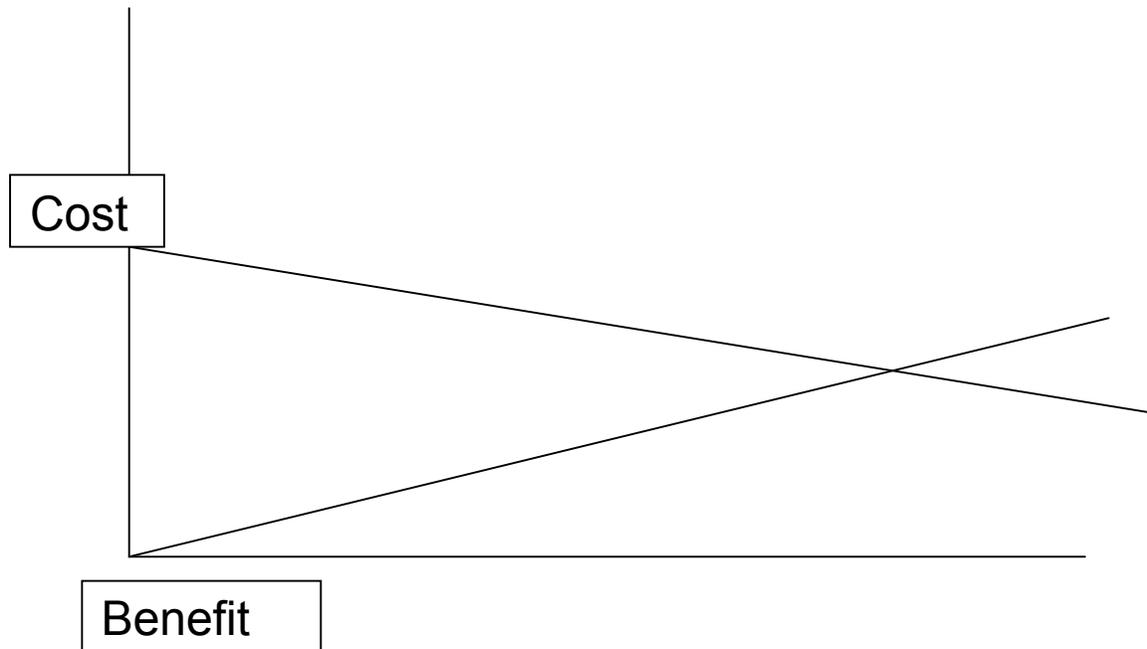
Operator

Somebody has to operate the machine.

Does this person need special training? What will the operator's salary, including overhead, cost?

Environment

Will the new machine be so noisy that you have to build soundproofing around it? Will the new machine increase the insurance premiums for the company due to possibility of accident or other environmental factors?



Accurate Cost Benefit Analysis

Once you have collected all the positive and negative factors and have quantified them, you can put them together into an accurate cost benefit analysis. Some people like to total up all the positive factors (benefits), total up all the negative factors (costs), and find the difference between the two. Others prefer to group the factors together. It makes it easier for you, and for anyone reviewing your work, to see that you have include all the factors on both sides of the issues that make up the cost benefit analysis. For the example above, cost benefit analysis might look something like this: Cost Benefit Analysis - Purchase of New Drug Packaging Machine

(Costs shown are per month and amortized over four years)

1. Purchase of Machine (includes interest and taxes) -	\$20,000
2. Installation of Machine (including screens & removal of existing packaging machine)	-\$3,125
3. Increased Revenue (net value of additional 100 units per hour, 1 shift/day, 5 days/week)	\$27,520
4. Quality Increase Revenue (calculated at 75% of current reject rate)	\$358
5. Reduced material costs (purchase of bulk supply reduces cost by \$0.82 per hundred)	\$1,128
6. Reduced Labor Costs (3 operators salary plus labor overtime/hour)	\$18,585
7. New Operator (salary plus overhead, includes training)	-\$8,321
8. Utilities (power consumption increase for new machine)	-\$250
9. Insurance (premiums increase)	-\$180
10. Square footage (no additional floor space required)	0
Net Savings per Month	\$15,715

Your cost benefit analysis clearly shows the purchase of the drug packaging machine is justified. The machine will save your company over \$15,000 per month, almost \$190,000 a year.

Before proceeding with an implementation plan, organizations and/or teams should conduct cost/benefit analyses. The purpose of a cost/benefit analysis is to consider the full financial impact of a project or recommended actions. In a cost benefit analysis, the organization or team identifies various costs and benefits associated with the proposed project.

Summary: Cost benefit analysis is a powerful, widely used and relatively easy tool for deciding whether to make a change. First, work out how much the change will cost to make. Then, calculate the benefit you will receive from it. Where costs or benefits are paid or received over time, work out the time it will take for the benefits to repay the costs. Cost benefit analysis can be worked out using only the financial costs and financial benefits, but you may decide to use intangible elements within the analysis. As you must estimate a value for this, this brings an element of subjectivity into the process.

Performance Improvement Costs

Costs have successfully provided the common denominator in business terms both for managing quality as well as for communication among all who are involved.

During the planning phase of performance improvement, a determination should be made regarding how the effort will be funded initially and long term. Start-up costs include staff time for development, training costs for employees, materials for training and to support projects, facilities, and consultants, if part of your plan. Maintenance costs include continuation of training and internal program support.

Cost calculations should include all associated costs even if they are only estimates. The price of nonconformance (PONC) takes into account everything that would not have to be done if everything was done right the first time. This includes the expenses associated with correcting the faulty product or service. The price of conformance (POC) includes quality education, professional quality functions and prevention efforts. Return on investment in quality improvement is among the highest available to managers. The rate of waste in United States businesses is high.

Poor-quality costs can be defined as:

- Controllable poor quality costs:
- Prevention costs—costs involved in helping the employee do the right job every time.
- Appraised costs—all costs associated with determining whether the activity was done right every time.
- Resultant poor quality costs:
- Internal error costs—cost of errors detected before output is accepted by the customer.
- External error costs—costs incurred by the company because the appraisal process did not detect all errors.
- Indirect poor quality costs:
- Are associated with customer dissatisfaction and loss of reputation costs which are difficult to measure and predict.

There is general agreement that cost/benefit determinations are difficult but accounting for quality costs needs to be started. As companies gain experience, the system and methodologies can be improved.

Strategic Planning

Strategic planning is a systematic approach to defining long term business goals and identifying the means to achieve them. Once an organization has established long term goals, effective strategic planning enables it to create the annual business plan which includes the necessary annual goals, resources, and actions needed to move toward the future envisioned in the strategic plan. To institute organization wide change efforts of any kind, an organization must incorporate the effort into the strategic planning process and into the annual business plan. This includes a program of annual performance/quality improvement. This will ensure that the effort will become part of the plan and not compete with the well established priorities for resources. It is used to help an organization do a better job - to focus its energy, to ensure that members of the organization are working toward the same goals, to assess and adjust the organization's direction in response to a changing environment. Strategic

planning is a disciplined effort to produce fundamental decisions and actions that shape and guide what an organization is, what it does, and why it does it, with a focus on the future

Total quality management has become a pervasive change process that can be included in the strategic plan. The integration of TQM and strategic planning has been referred to by various names, including strategic quality planning, Hoshin planning, or policy deployment. Strategic planning is often misunderstood to be the creation of the strategic plan and not the careful deployment of strategic goals, sub-goals, and annual goals, and the assignment of resources and actions to achieve them.

Strategic planning is only useful if it supports strategic thinking and leads to strategic management - the basis for an effective organization. Strategic thinking means asking, "Are we doing the right thing?" It means making that assessment using three key requirements about strategic thinking: a definite purpose be in mind; an understanding of the environment, particularly of the forces that affect or impede the fulfillment of that purpose; and creativity in developing effective responses to those forces.

Strategic management is the application of strategic thinking to the job of leading an organization. The following is a framework for understanding strategic management: continually asking the question, "Are we doing the right thing?" It entails attention to the "big picture" and the willingness to adapt to changing circumstances, and consists of the following three elements:

- 1) Formulation of the organization's future mission in light of changing external factors such as regulation, competition, technology, and customers
- 2) Development of a competitive strategy to achieve the mission
- 3) Creation of an organizational structure which will deploy resources to successfully carry out its competitive strategy.

Strategic planning involves anticipating the future environment, but the decisions are made in the present. This means that over time, the organization must stay abreast of changes in order to make the best decisions it can at any given point - it must manage, as well as plan, strategically.

Strategic planning has also been described as a tool - but it is not a substitute for the exercise of judgment by leadership. Ultimately, the leaders of any enterprise need to sit back and ask, and answer, "What are the most important issues to respond to?" and "How shall we respond?" Just as the hammer does not create the bookshelf, so the data analysis and decision-making tools of strategic planning do not make the organization work - they can only support the intuition, reasoning skills, and judgment that people bring to their organization.

Finally, strategic planning, though described as disciplined, does not typically flow smoothly from one step to the next. It is a creative process, and the fresh insight arrived at today might very well alter the decision made yesterday. Inevitably the process moves forward and back several times before arriving at the final set of decisions.

Strategic Quality Planning

If there is not a clear, strategic plan for quality with a step-wise approach, there will be false starts and many disappointments in the quality process. Most people can't imagine building a house without a blueprint; implementing a performance improvement process also requires a plan. The development of a quality plan should follow the guidelines for any strategic planning process.

- First, the executive group should develop broad organizational goals and the means to achieve them.
- Second, assign responsibility and create the resources to meet the responsibilities.
- Third, develop the educational curriculum to support the required changes and create a reward and recognition process to reinforce the new behaviors.

Ernst & Young developed a process called policy development. Through this process, improvement activities are tied to the organization's long term vision. This type of planning integrates strategic

direction and improvement initiatives. There should be broad organizational participation in setting goals and then a process to link departmental and organizational goals.

Top management is responsible for developing and communicating a vision, then building an organization-wide commitment to its achievement.

- The vision is deployed through the development and execution of annual policy statements or annual plans.
- All levels of employees actively participate in generating a strategy and action plans to attain the vision.
- At each level, progressively more detailed and concrete means to accomplish the annual plans are determined. There should be a clear link to common goals in activities from the bottom to the top.
- The plans are hierarchical, cascading downward from top management's plans.
- Plans include significant levels of improvement, and emphasize concentrate on activities that are the most highly related to the vision.
- Implementation responsibilities, timetables, and progress measures are determined.
- Frequent evaluation and modification based on feedback from regularly scheduled audits of the process are provided.
- Plans and actions based on analysis of the root causes of a problem/situation, rather than only on the symptoms, are developed.
- Planning has a high degree of detail, including the anticipation of possible implementation problems.
- Emphasis is on the improvement of the process, as opposed to a results only orientation.

This is a way to create organizational focus on four or five top priority goals. Everyone in the organization knows the critical goals and can decide the best way to meet them at their level. The level of detail of plans increases as you go down through the organization, with the intent to achieve a priority focus. This is also a way to create energy for change. Critical success factors for the smooth implementation of quality/performance improvement include: a clear vision, the organizational capacity for change, a managed threshold for change, and a plan for change.

Steps of Strategic Quality Planning

Strategic planning is a systematic approach to integrating customer-focused organization-wide improvement efforts with the strategic plan of an organization. It is a systematic process by which an organization defines its long term goals with respect to quality and integrates them with financial, human resources, marketing, and research and development goals equally into one cohesive business plan which is then deployed throughout the organization. As a component of the total quality management system, strategic quality planning enables the organization to plan and execute strategic organizational breakthroughs. Over the long term, the intended collective effect of the breakthroughs is to achieve competitive advantage. Strategic quality planning is part of the foundation of the organization that supports the broader system of managing total quality in the organization. To be effective, strategic quality planning should be used as a tool, a means to an end, not the goal itself. It should be a process that involves people throughout the organization and capture existing activities, not just add workload to already overworked staff. Strategic quality planning should help senior managers face difficult decisions, set priorities, start new initiatives, and eliminate current initiatives which add no value to the organization.

The strategic quality planning process requires that organizations incorporate customer focus into the organization's mission, vision, values, policies, long and short term goals, objectives, and projects. Projects are the day to day, month to month activities that link performance/quality improvement activities, reengineering efforts, and quality planning teams to the organization's business efforts.

Steps in Strategic Planning

1. Step One - Getting Ready: To get ready for strategic planning, an organization must first assess if it is ready. While a number of issues must be addressed in assessing readiness, the determination essentially comes down to whether an organization's leaders are truly committed to the effort, and whether they are able to devote the necessary attention to the "big picture". For example, if a funding crisis looms, the founder is about to depart, or the environment is turbulent, then it does not make sense to take time out for strategic planning effort at that time.

An organization that determines it is indeed ready to begin strategic planning must perform five tasks to pave the way for an organized process

- a. Identify specific issues or choices that the planning process should address
- b. Clarify roles (who does what in the process)
- c. Create a Planning Committee
- d. Develop an organizational profile
- e. Identify the information that must be collected to help make sound decisions.

The product developed at the end of the step one is a work plan.

2. Step Two - Articulating Mission and Vision: A mission statement is like an introductory paragraph: it lets the reader know where the writer is going, and it also shows that the writer knows where he or she is going. Likewise, a mission statement must communicate the essence of an organization to the reader. An organization's ability to articulate its mission indicates its focus and purposefulness. A mission statement typically describes an organization in terms of its:

Purpose - why the organization exists, and what it seeks to accomplish

Business - the main method or activity through which the organization tries to fulfill this purpose

Mission: A mission statement is designed to address the question "What business are we in?" A mission is often confused with a vision. A mission statement should clarify the organization's purpose or reason for existence. Together, a vision and mission provide a common agreed-upon direction for the entire organization that can be used as a basis for daily decision making.

Veterans Healthcare Administration (VHA) Mission: Honor America's veterans by providing exceptional health care that improves their health and well-being.

Whereas the mission statement summarizes the what, how, and why of an organization's work, a vision statement presents an image of what success will look like.

Vision: A desired future state of the organization. Imagination and inspiration are important components of a vision. Typically, a vision can be viewed as the ultimate goal of the organization, one that may take years to achieve.

Is there a clear, customer-focused vision statement?

Is the organizational strategic plan aligned with that vision?

Is the vision positive, motivating, and inspiring? People can't become motivated by a basically negative vision such as cost reduction. The vision should provide a view of the future of the organization.

To develop the vision:

What kind of organization do you want to be?

What will the organization be like for customers and staff when the vision is achieved?

What does the organization want people to say about it as a result of its work?

What values are most important to the organization?

How does the vision represent the interest of customers and values that are important to the organization?

What place does each person have in this vision of the future?

The vision statement should emphasize how the organization will differ from past performance and focus on what the organization will become in the future. The visioning process starts with divergent thinking, capturing as many ideas as possible; then convergent thinking is used to narrow down the list. The vision statement is then crafted from the remaining key statements. This vision should start at the top and be shared with all levels of the organization for feedback to comment and provide insight for changes. The final vision statement must be communicated at all levels throughout the organization.

Each section of the organization must review the organizational vision and plan how they will contribute to making it a reality. When the organization communicates the vision and aligns the staff behind it, a powerful force is created, with synergy and a common purpose. The energy of the employees is focused on achieving common goals. The vision must be seen as attainable by the people and be communicated frequently. A clear vision by itself will not accomplish the goals of the organization. The vision requires appropriate strategies for goal achievement and staff who commit to the vision and wish to make it a reality. Strategic deployment begins with a vision that is customer focused. A vision should define the benefits a customer, employee, shareholder, or society at large can expect from the organization. The vision should offer a view of the direction and character of the organization, conveying a general image to customers and employees of where the organization is headed.

For the organization, the vision provides a clear picture of where it is headed and why it is going there. Good vision statements should also be compelling and shared throughout the organization. Visions are often a stretch for the organization but achievable in 3-5 years. Visions should have measurable achievements, such as being the best or first, etc. In creating the vision, organizations should take into account its customers, the markets in which it wants to compete, the environment within which the organization operates, and the current state of the organization's culture. Merely publishing a vision statement doesn't tell people in the organization what they need to do differently. The strategic deployment process and strategic plan become the basis for making the vision a reality.

Veterans Healthcare Administration (VHA) vision:

VHA will continue to be the benchmark of excellence and value in health care and benefits by providing exemplary services that are both patient centered and evidence based.

This care will be delivered by engaged, collaborative teams in an integrated environment that supports learning, discovery, and continuous improvement.

It will emphasize prevention and population health and contribute to the nation's well-being through education, research and service in National emergencies.

With mission and vision statements in hand, an organization has taken an important step towards creating a shared, coherent idea of what it is strategically planning for.

At the end of Step Two, a draft mission statement and a draft vision statement is developed.

Step Three - Assessing the Situation: Once an organization has committed to why it exists and what it does, it must take a clear-eyed look at its current situation. Remember, that part of strategic planning, thinking, and management is an awareness of resources and an eye to the future environment, so that an organization can successfully respond to changes in the environment, both internal and external. Situation assessment, therefore, means obtaining current information about the organization's strengths, weaknesses, and performance - information that will highlight the critical issues that the organization faces and that its strategic plan must address. Both the external environment and internal environment are assessed. These could include a variety of primary concerns, such as funding issues, new program opportunities, changing regulations or changing needs in the client population, and so on. The point is to

choose the most important issues to address. The Planning Committee should agree on no more than five to ten critical issues around which to organize the strategic plan.

The products of Step Three include: a data base of quality information that can be used to make decisions; and a list of critical issues which demand a response from the organization - the most important issues the organization needs to deal with.

Step Four - Developing Strategies, Goals, and Objectives: Once an organization's mission has been affirmed and its critical issues identified, it is time to figure out what to do about them: the broad approaches to be taken (strategies), and the general and specific results to be sought (the goals and objectives). Strategies, goals, and objectives may come from individual inspiration, group discussion, formal decision-making techniques, etc., but in the end the organization's leadership agrees on how to address the critical issues.

This can take considerable time and flexibility: discussions at this stage frequently will require additional information or a reevaluation of conclusions reached during the situation assessment. It is even possible that new insights will emerge which change the thrust of the mission statement. It is important that planners are not afraid to go back to an earlier step in the process and take advantage of available information to create the best possible plan.

Strategies: Strategies are the means to achieve the vision. Strategies are few and define the critical success factors such as price, value, technology, market share and culture that the organization must pursue. The first step in converting the vision into an achievable plan is to break the vision into a small number (4-5) of strategies. Strategies represent the most fundamental choices that the organization will make about how it will go about reaching its vision. Each strategy must contribute significantly to the overall vision. Responsibility for executing these strategies is distributed or deployed to key executives within the organization, the first step in a succession of subdivisions and deployments by which the vision is converted to action. In order to determine what the strategies should be, an organization should assess five areas

1. Customer loyalty and customer satisfaction
2. Costs related to poor quality
3. Organization culture/satisfaction
4. Internal business processes, including suppliers
5. Competitive benchmarking

The difference between where an organization is (current status) and where it wants to be (vision and goals) is what the organization does (target objectives and action plans).

Goals: An organization sets specific, measurable strategic goals that must be achieved for the broad strategy to be a success. These quantitative goals will guide the organization's efforts toward achieving each strategy. A goal is aimed at target. Goals must be specific, quantifiable (measurable), and time limited. At first, an organization may not know how specific the goal should be. Over time, the measurement systems will improve and the goal setting will become more specific and measurable. There are seven areas that are minimally required to assure that the proper goals are established:

- Product performance: response to customer need, such as promptness of service, courteousness, mean time between failures
- Competitive performance: performance compared to other organizations
- Quality improvement: improving product deficiencies or process failures
- Cost of poor quality: reducing costs due to waste or poor quality

- Performance of business processes: performance of major processes
- Customer satisfaction: specific goals related to increasing satisfaction and decreasing dissatisfaction
- Customer loyalty and retention: measure of customer purchasing power for a certain supplier

The goals selected for the annual business plan are chosen from a list of nominations made by all levels of the organization.

VA Goals

- Become the national benchmark for quality, safety, and transparency of healthcare, particularly in those health issues associated with military service.
- Provide timely and appropriate access to health care and eliminate service disparities.
- Transform VHA’s culture through patient-centered care to continuously improve Veteran and family satisfaction.
- Ensure an engaged, collaborative and high-performing workforce to meet the needs of Veterans and their families.
- Create value by leveraging scale and skill economies to achieve consistency and excellence in business practice.
- Excel in research and development of evidence-based clinical care and delivery system improvements designed to enhance the health and well-being of Veterans.
- Promote excellence in the education of the future workforce to drive health care innovation.
- Promote health within the VA, in local communities, and across the Nation, in collaboration with our academic affiliates, other government agencies and the private sector.

Objectives: While goals are broad, objectives are more specific. Objectives are specific, measurable results produced while implementing goals. While identifying objectives, organizations should keep asking “Are we sure we can do this?” Organizations should integrate the current year’s objectives as performance criteria in each implementer’s job description and performance review. Each objective should have responsibility and timeline assigned. The Organizations may include a grid similar to the following to list each strategy, goal, objective, responsibility, and timeline.

Strategy	Goal	Objective	Responsibility	Timeline
1. (Goal #1)	1.1 (first strategy to reach Goal #1)	1.1.1 (first objective to reach while implementing Strategy #1.1)	(who’s going to accomplish that objective)	(when the implementer is going to be accomplish that objective)

Values: Values are what the organization stands for and believes in. Some organizations create value statements to further define themselves. Values are what an organization stands for and believes in. A list of values must be supported with actions and deeds from management. Training and communication of values for all employees becomes a prerequisite to participation in the planning process. Organization policies must be changed to support the values of the organization.

- VA Healthcare System values: I CARE
- Integrity, Commitment, Advocacy, Respect, Excellence



Upper Management Leadership: A fundamental component in the establishment of any strategic plan is the participation of upper management acting as an executive council. Top level management must come together as a team to determine and agree upon the strategic direction of the organization. The quality council oversees and coordinates all strategic activities aimed at achieving the strategic plan. The quality council is responsible for executing the strategic business plan and monitoring the key performance indicators.

Activating the Strategic Plan: The activation of long and short term goals is the conversion of goals into operational plans and projects. A project can be defined as an activity of duration that addresses a goal, and whose successful completion contributes to assurance that the strategic goals are achieved. A project most usually implies assignment of selected individuals to a team which is given the responsibility and authority to achieve the specific goal. Subdividing the goals and allocating the sub goals to lower levels requires careful attention to such details as the actions needed to meet these goals, who is going to take the actions, the resources needed, and the planned timetables and indicators.

Key Performance Indicators: Key performance indicators are measurements that are visible throughout the organization for evaluating the degree to which the strategic plan is being achieved. To turn a vision into action, the vision must be broken apart and translated into successively smaller and more specific parts, such as key strategies, strategic goals, to the level of projects and departmental actions. The detailed plan for decomposition and distribution throughout the organization includes the assignment of roles and responsibilities and identification of resources needed to implement and achieve the project goals. Performance measures indicate the degree of accomplishment of objectives and quantify progress toward the attainment of goals. Performance measures are needed to monitor the continuous improvement process, which is central to the changes required to become competitive. Measures of individual, team, and business unit performance are required for periodic performance reviews by management.

Review: A formal, efficient review process will increase the probability of reaching the goals. When planning actions, the organization should look at the gaps between measurement of the current state and the target it is seeking. The review process looks at gaps between what has been achieved and the target. Frequent measurements in graphic form help identify the gaps in need of attention. The product of Step Four is an outline of the organization's strategic directions - the general strategies, long-range goals, and specific objectives of its response to critical issues.

Step Five - Completing the Written Plan: The mission has been articulated, the critical issues identified, and the goals and strategies agreed upon. This step essentially involves putting all that down on paper. Usually one member of the Planning Committee, the executive director, or even a planning consultant will draft a final planning document and submit it for review to all key decision makers (usually the board and senior leadership). This is also the time to consult with senior staff to determine whether the document can be translated into operating plans (the subsequent detailed action plans for accomplishing the goals proposed by the strategic plan) and to ensure that the plan answers key questions about priorities and directions in sufficient detail to serve as a guide. Revisions should not be dragged out for months, but action should be taken to answer any important questions that are raised at this step.

Benefits of Strategic Planning

- The goals become clear because the planning process forces clarification of any vagueness.
- The planning process then makes the goals achievable.
- The control process helps to ensure that the goals are reached.
- Chronic wastes are reduced through the quality improvement process.
- Creation of new wastes is reduced through revision of the business planning process.

Pitfalls and Problems with Strategic Planning

Pursuing too many objectives, long term and short term, at the same time will dilute the results and blur the focus of the organization. Excessive planning and paperwork will drive out the needed activities and demotivate managers. Trying to plan strategically without adequate data about customers, competitors, and internal employees can create an unachievable plan or a plan with targets so easy to achieve that the financial improvements are not significant enough. If the executive leadership delegates too much of the responsibility, there will be a real and perceived loss of leadership and direction. For an organization to elevate quality and customer focus to top priority creates the impression that it is reducing the importance of finance, which formerly occupied that priority. This perceived downgrading is particularly disruptive to those who have been associated with the former top priority financial goals.

At the highest levels of management, and among boards of directors, there is keen interest in financial measures such as net income and share prices on the stock markets. It is known that quality

influences these measures, but so do other variables. Separating out the effects of quality has as yet now been feasible other than through broad correlation studies.

Quality Outcomes

During the early 1990's, some of the financial press published articles questioning the merits of the Malcolm Baldrige National Quality Award, Total Quality Management, and other quality initiatives. These articles were challenged, and one result was analysis of stock performance of Baldrige award winners compared with that of industrial companies generally. The results were striking. From the dates of receiving the award, the stock price of the Baldrige winners had advanced 89%, as compared with 33% for the broad Standard & Poor's index of 500 stocks. In 1991, the General Accounting Office (GAO) published the results of a study of 20 finalist applicants for the Malcolm Baldrige award. These were the companies that received a site visit. The report concluded that in nearly all cases, companies that used total quality management practices achieved better employee relations, higher productivity, greater customer satisfaction, increased market share, and improved profitability.

Quality in Healthcare

Few industries have changed so radically in structure, focus, and process as health care has in recent years. Integrated delivery systems have replaced hospitals as the powerful force in health care delivery. The aim of the system has moved from caring for patients with disease and injury to improving the health of entire communities. Process redesign has produced changes in the kinds of care provided, the site in which care is received, and the extent to which the patient is an active participant in the plan of care. Discontent with the high cost and variable outcomes of health care has led to a number of initiatives in public policy, finance, and organization of care, in an effort to measure, control, and improve the value of care, and to increase the accountability of health care providers to the public and to insurers. These include:

Prepaid financing of care: Provider organizations are given a prospective annual budget to meet the needs of enrolled populations of patients. This is supposed to change the incentives for providers of care from doing more to conserving resources.

Health maintenance organizations: Managed care systems are designed as systems of health care linked to provide health services to members for a periodic fee regardless of the extent of the services. There is an emphasis on improving health status of the members.

Gatekeeping and other forms of utilization review: Providers of care must justify to insurers their choices to use expensive tests, surgery, specialty referrals, etc., especially if patterns of use deviate from that of peers.

Innovations in programs of care: A major shift in site of care has occurred as procedures and tests formerly only one in inpatient settings are now performed safely and at lower costs in outpatient offices and clinics. Outreach programs extend care into patients' homes, and there are new communications methods to involve patients more directly in decision making about their own care. Telemedicine links specialists with rural providers in remote areas and allows for the latest diagnostic capabilities to reach patients who no longer have to travel.

Report cards and measurement systems: The performance of health care organizations is assisted by standardized instruments, and often the results of measurement are made public to help inform the choices of payers and patients. Health care leaders are also using these comparative data and internal balanced score cards to define organizational priorities for change and to demonstrate progress to key stakeholders.

Health services research has demonstrated major opportunities for improvement of the performance of health care processes in at least four areas: health status outcomes, service characteristics (measures of satisfaction and ease of use of the system), breadth of access (including equity among racial and socioeconomic groups), and levels of waste. Eleven potential areas of potential improvement include:

1. Increase appropriateness of practice
2. Increase effective preventive practices
3. Reduce cesarean section rates
4. Reduce unwanted care at the end of life
5. Rationalize pharmaceutical use
6. Involve patients in decisions
7. Reduce wait states
8. Reduce, consolidate, and regionalize high-technology services
9. Reduce wasteful and duplicative recording
10. Reduce inventory costs
11. Reduce racial and economic health status inequities

Balanced Scorecards

The current environment for healthcare organizations contains many forces demanding unprecedented levels of change. These forces include changing demographics, increased customer expectations, increased competition, and intensified governmental pressure. The balanced scorecard can be used by healthcare organizations to meet these challenges.

A balanced scorecard is a customer-based planning and process improvement system aimed at focusing and driving an organization's change process. It is an integral part of the mission identification, strategy formulation, and execution processes, with a focus on translating strategy into an integrated set of financial and non-financial measures. The balanced scorecard plays a major role in communicating the organizational strategy to members and providing feedback to guide actions toward the attainment of objectives.

A balanced scorecard is a management decision tool intended to be a framework for linking strategy with operational performance measures. In practice, it's an integrated report, usually showing diverse areas of performance an organization values most. The balanced scorecard differs from traditional management tools such as financial, sales, production, and customer survey reports. Each of these traditional tools focuses on performance along a single dimension. The result is something akin to the blind man's understanding of the attributes of an elephant when the only part he can touch is the trunk or tail.

The term balanced in the scorecard suggests that objectives and measures along different dimensions, assembled together on one sheet or screen, offer a multidimensional and qualitatively better view of organization success. The balance scorecard method generally addresses performance in the management of finances, processes, customers, and employee development.

A well designed scorecard should not exceed 20 measures, all connected to strategic objectives. It helps management make good, fast decisions on what to improve or celebrate. Its purpose is to show what the whole elephant looks like so you can put food where it's mouth is. In practice, many organizations are still not seeing the whole elephant. As in most organizational change models, evolutionary improvement has certainly occurred in the balanced scorecard, but the improvement remains incomplete.

The popularity of scorecards reflects a general growth of interest in performance measurement and improvement tools. Balanced scorecards can sometimes suffer from the “ready, fire, aim” syndrome. Organizations often identify how to measure performance before they have defined either what or why to measure at all. It is possible to create a truly balanced scorecard that reflects priorities of both the organization and its customers. This requires categories of measure that reflect the key values of both parties. A good scorecard includes measures covering processes, products, and outcomes. Both customer and organizational values center around these three topics. Outcomes refers to the results the organization wants to achieve. Customers also have outcomes they hope to obtain by doing business with the organization. Outcomes address why the organization exists.

Products are the deliverables created by the organization. These are what customers receive. It’s important to note that products include information products and service products. A balanced scorecard includes broad measures of product attributes such as quality, ease of use, and reliability. Scorecard measures of process performance emphasize activity or how work is done. The measures may include cycle time, productivity, and backlog. Process measures usually focus on operations, whereas outcome measures usually focus on strategic intent.

Three reasons organizations should measure their performance:

- To align mission, strategy, values, and behavior
- To improve the right things
- To numerically define the meaning of success

Eight areas to measure in a balanced scorecard:

- Customer desired outcomes
- Undesired outcomes customers want to avoid or eliminate
- Product and service attributes customers want
- Process characteristics customers want
- Producer desired outcomes
- Undesired outcomes producers want to avoid or eliminate
- Product attributes producers want
- Process characteristics producers want

Ten questions to answer for a balanced scorecard:

- What outcomes are to be achieved by the scorecard?
- According to the 8 categories of measures, how much balance does the scorecard represent?
- Have you identified which of the organization’s products and services are most critical in carrying out its mission? If yes, what are the 10 most vital?
- What specific numerical objectives and due dates have been established for improving customers’ and the organization’s priority outcomes, products, and services? Are they being met?
- Which of the 8 categories of measures gets the most attention and has the highest priority with management?
- What is currently given higher organizational priority than customer satisfaction?
- What method is used to uncover customers’ priority expectations?
- What formal processes ensure customers get outcomes and products they want?
- What are the rewards for measured success? What are the consequences for failure?
- What return on investment is expected from your scorecard initiative?

The scorecard can be used at different levels: throughout the total organization, in a subunit, or at the individual employee level as a personal scorecard. For each level, the balanced scorecard approach involves identifying the key components of operations, setting goals for them, and then finding ways to measure progress toward achieving these goals. The measures provide a holistic view of what is happening both inside and outside that organization or level, allowing constituents of the organization to see how their activities contribute to attainment of the organization's overall mission.

A typical balanced scorecard would include:

1. **Customer perspective:** How do customers see us?
2. **Internal business perspective:** At what must we excel?
3. **Innovation and learning perspective:** Can we continue to improve and create value for customers?
4. **Financial perspective:** How do we look to providers of financial resources?

While the balanced scorecard concept implies that all components are important to organizational success, many organizations consider customer satisfaction to be the overriding concern. The customer perspective measures how well the organization is meeting the current demands and needs of its customers, and anticipates what customers may require in the future. The focus of the internal business perspective is on the ability of the internal processes to satisfy current and future customer expectations. In the innovation and learning component, the focus is on improving the organization's ability to meet customer expectations. The financial perspective keeps tabs on how well the operational results are being translated into financial well-being, which is vital to the organization's continued viability.

The first step in designing the balanced scorecard is not identifying the measures themselves, but agreeing upon the organization's overall mission. Following this sequence is important because to be effective, the scorecard measures must support attainment of a common mission. After this crucial first step, the design and implementation process can be divided into four stages:

- 1) Translating the vision and gaining consensus;
- 2) Communicating the objectives, setting goals, and linking strategies;
- 3) Setting targets, aligning strategic initiatives, allocating resources, and establishing milestones; and
- 4) Feedback and learning.

Sample Balanced Scorecard

Customer Perspective

<u>Goals</u>	<u>Measures</u>
Prompt Service	Patient satisfaction surveys, emergency room & Admission times; scheduling flexibility
High quality care	Patient evaluations, patient referrals, number of Patients admitted, accurate diagnosis rate, External ratings, favorable press coverage, Market share, repeat patients
Prompt emergency room response	Time to respond; patient satisfaction survey
Staff attitude & friendliness	Patient satisfaction surveys, community Perception of staff, market share, repeat patients
Good food	Complaint rate, patient satisfaction survey
Quality nursing care	Patient surveys, number of complaints

Managed care satisfaction	Number of contracts, number of new contracts Per period, number of contracts renewed
Physician satisfaction	Number of contracts with key physician groups, Physician participation in decision making, Physician satisfaction surveys, retention rate of Physicians
Competent staff	Reputation, number of referrals, number of Contracts, accurate diagnosis rate, number of Complaints, patient satisfaction, favorable Press coverage featuring staff, perception Surveys
Staff satisfaction	Staff satisfaction surveys
Patient satisfaction	Patient surveys, managed care surveys

Internal Business Perspective

<u>Goals</u>	<u>Measures</u>
Cost control	Cost per patient day, cost per diagnosis, cost Per procedure, per case cost
Service excellence	Complaint rate, patient feedback, quality of Care, degree to which staff is professional, Friendly, & helpful
Efficiency	Cycle time, analysis of use of equipment & space, Degree of automation, degree of use of technology
Reengineering of departments	Cost reduction
Quality of care	Periodic evaluations of staff, patient satisfaction Surveys
Effective use of resources	Hiring & retention rate of quality workforce, rate of Improvement of business processes, degree of use Of technology
Effective contracting	Comparable capitated fees, managed care
Increase contracts	Number of managed care contracts, number of new Contracts
Physician satisfaction	Contracts with key physician groups
Friendly & helpful staff	Patient surveys
Selected specialization	Cancer, heart, (provide value for cost)

Innovation and Learning Perspective

<u>Goals</u>	<u>Measures</u>
Collaboration with Medical Groups	Physician referrals, cost/benefit analysis
Continuous innovation	Number & quality of new services Offered in past 5 years; number of new Programs; market response to initiatives
State of the art technology	Degree of use of technology, degree of Automation, expenditures on hardware & Software, benefits vs. cost; patient Capitation, rate of increase of outpatients, Fiber optics network; physician links
Physician research & creativity	Number of professional presentations & Publications by physicians; number of

Partnerships with research Institutions	New procedures; degree of usage of state Of the art equipment; quality of care; number Of ongoing instructional development programs
Relationships with physicians	Number of joint activities; number of institutions/agencies participating in joint Activities Benefit/cost analysis

Financial Perspective

<u>Goals</u>	<u>Measures</u>
Increase capitation contracts	Number of contracts received, percentage of Contracts relative to competition, dollars Generated from new contracts
Reduce emergency room use	Percent unnecessary usage; analysis of ER use
Expand community Philanthropy	Dollars raised; number & dollars of corporate gifts; donor support for special projects; level of fund Raising activity for the hospital; number & dollars Of external grants
Increase contracts	Contracts with managed care & other payers
Increase regular insurance Contracts	Market share
Partner with other medical groups	Referrals & use

Sample schedule for developing a balanced scorecard

1. Strategic planning retreat involving everyone in organization to identify strategic issues & discuss possible solutions; purpose is to form consensus regarding vision & strategic goals & objectives; second retreat may be needed
2. Strategic planning committee formed with charge to identify objectives for each perspective in the organization's balanced scorecard
3. Using balanced scorecard as communication tool, strategic planning committee seeks comments on & acceptance of organization's balanced scorecard
4. Based on comments, strategic planning committee revises balanced scorecard
5. Revised balanced scorecard communicated to organization members; department/individual balanced scorecards developed that support the organization wide scorecard
6. Strategic planning committee reviews individual & department scorecards & suggests possible revisions
7. Based on finalized scorecards, organization formulates a 3-5 year strategic plan; first year plan expanded into the operational plan for coming year
8. Both department progress and organization progress are reviewed quarterly to identify areas that require attention & additional effort
9. Based on individual balanced scorecards, organization evaluation committee evaluates individual performance for the past year & makes recommendations related to retention, promotion, salary increases, & other rewards
10. Strategic planning committee revises organization's balanced scorecard & plan based on internal & external scanning of the organization's conditions & changes in the environment; identifies as many strategic issues as possible & considers possible solutions.

Guidelines for selecting measures for the balanced scorecard

1. The performance measures selected should be positively related to degree of attainment of the related goal; as the latter increases, the former should also increase
2. Not all the performance measures should be focused on outcomes; outcome measures tend to be prepared only periodically, & often are not sufficiently timely to alert remedial action; performance drivers also need to be included to serve as leading indicators of outcomes
3. The number of performance measures should be kept low so as not to diffuse attention and create confusion

Maintaining Quality in Healthcare

Health care's traditional reliance on external and internal inspection to maintain quality has had its expected effects on performance. The extensive inspections are very costly, but are agreed to, by providers and outsiders alike, as the best they can do. Reviews do tend to call attention to serious problems, some of which are remedied correctly, and others which invite overreactions that have probably added to the cost and complexity of care without much gain in quality of efficiency. On the whole, quality assurance in health care is viewed as cumbersome, occasionally revealing, and a necessary evil. Medical care finds itself susceptible to forms of fragmented efforts that impede systemic vision and optimization of the whole. Physicians, nurses, and others trained in highly conservative modes of work often find quality improvement especially threatening. Like other industries that came new to improvement methods, health care organizations often simply do not seem to believe that significant improvement is possible. Yet, the promise of quality improvement in health care remains great.

Each organization should implement a total quality model based on its environment, organization, and history. The principles, tools, and techniques are generally applicable anywhere, but the specific approach and speed of implementation must be tailored to the organization. Implementation takes place in the context of existing knowledge, skills, and relationships of physicians, staff, management, and the community. A cookie cutter approach using the same exact implementation plan in different organizations will not be effective.

SAMPLE CORE PLANNING GROUP POLICY

1. **PURPOSE:** To establish policy, procedures, and outline the functions of a Leadership Core Planning Group. This group will work within the overall Strategic Goals/Targets identified by VHA (and VISN) and identify major medical center priorities which need to be addressed to facilitate education, research, and patient safety activities in the medical center. The goal is to create a dynamic goal-oriented environment.
2. **POLICY:** The Core Planning Group will work within the overall Strategic Goals/Targets identified by VHA (and VISN) and identify major medical center priorities which need to be addressed to create an organization that is Veterans' **1st choice in health care by being a model of clinical and organizational excellence**. This group will make recommendations to the Executive Leadership Council.
3. **PROCEDURES:**
 - a. The group will function under the Baldrige Model (Assessment, Correlation of Assessments, Development of Action Plans) (See Appendix A: Core Planning Group Model). Appropriate team processes will be utilized to identify Medical Center Business Drivers, goals and priorities.
 - b. Input from multiple sources will be utilized.
 - c. Performance Indicators / Measurements will be developed for each business driver and will be tracked on the Medical Center Dashboard.
 - d. The Business Drivers, goals and priorities will be reviewed/updated as necessary, but not less than annually.
4. **RESPONSIBILITIES:**
 - a. The Medical Center Director is responsible for overall planning in the medical center.
 - b. The Executive Leadership Council is responsible for setting the strategic direction for the medical center, creating an environment and climate for continuous quality improvement and for supporting medical center staff in

meeting internal and external standards. The leaders develop the Medical Center Strategic and Operating Plans. Each service line develops its operating plan for providing services based on those two plans.

c. Associate Chiefs of Staff (s)(ACOS)/Service Line Administrators are responsible to participate as medical center leaders when assigned to the Core Planning Group.

d. Quality Management Staff are responsible to support the efforts of the Core Planning Group, including use and development of measurable indicators for the Key Business Drivers on the Dashboard Report.

5. **MEETINGS:** Meetings will take place not less than annually at the call of the Chairperson. Recommendations will be taken to the Executive Leadership Council.

6. **MEMBERSHIP:** The membership will be kept small. Some members may be appointed ad hoc for specific projects or processes. The Chairperson will evaluate the membership annually.

Chairperson: Medical Center Director

Members: Associate Director

Chief of Staff

ACOS, Ambulatory Care Services

Administrator, Mental Health and Behavioral Sciences Services

Administrator, Resource and Financial Management Services

ACOS, Quality Management Department

Administrative Assistant to the Director

Staff to Committee: Quality Management staff as appointed.

SAMPLE OPERATIONAL-PLAN-FOR-PROVISION-OF-SERVICES

1. **PURPOSE:** To establish policy and procedures related to provision of services, including both clinical and non-clinical support services, within the medical center.

2. **POLICY:**

a. The Medical Center Operational Plan for the Provision of Services describes the organization, functional relationships and responsibilities of service lines/departments within the medical center as well as the services delivered. All service line leaders (Associate Chiefs of Staff and Administrators) are responsible clinically and administratively to the Executive Leadership Council. Together they form the Executive Leadership Council. Some service lines contain a number of departments, with the Department Chairs/Assistant Administrators reporting to the service line leaders.

(1) Patient care clinical services are provided by the following service lines:

(a) Ambulatory Care Services

(b) Inpatient Care Services

(c) Mental Health and Behavioral Science Services

(d) Clinical Services

(e) Geriatrics and Extended Care Services

(f) Education and Research Services

(2) Non-clinical support services are provided by the following service lines:

(a) Facilities Service

(b) Resources and Financial Management Services

(c) Informatics Services

a. Human resources support services are provided by the Human Resources Management Service, which is aligned under the Office of the Director

b. Patient care services are integrated throughout the medical center.

c. The operational plan (scope of services) provided by each service line/department is defined in writing and is approved by the medical center's leaders.

d. The leaders are responsible for providing for the uniform performance of patient care processes, for providing appropriate services, for coordinating processes with those of other service lines and for participation in concerted efforts to improve the medical center's overall performance.

3. **PROCEDURES:**

a. The service lines identified in paragraph 2a(1) will develop operational plans using the attached templates (Appendixes A and B).

b. These individual operational plans will be combined in an overall medical center operational plan.

4. **RESPONSIBILITIES:**

a. The Executive Leadership Council (medical center leaders) is responsible for medical center planning which includes defining a mission, a vision and values for the medical center and creating the strategic, operational, programmatic and other plans and policies to achieve the mission and vision.

b. ACOSs, Administrators, Department Chairs, Assistant Administrators and other leaders are responsible for:

(1) Assuring that delivery of key patient care support functions in their service line or department is accomplished and is appropriate to the scope and level of care required by the patients served

(2) Assuring that delivery of services is based on identified patient care needs and is consistent with the medical center's mission

(3) Collaborating with one another and other relevant personnel in decision making.

(4) Developing programs for recruitment, retention, development and continuing education of all staff members.

(5) Considering clinical practice guidelines for use in designing or improving processes.

(6) Integrating their department's services with the medical center's primary functions.

(7) Coordinating and integrating services within their department and with other departments.

(8) Developing and implementing policies and procedures that guide and support the provision of services.

(9) Recommending a sufficient number of qualified and competent persons to provide care.

(10) Determining qualifications and competence of department personnel who provide patient care services and who are not licensed independent practitioners.

(11) Continuously assessing and improving their department's performance.

(12) Maintaining appropriate quality control programs.

(13) Providing for orientation, in-service training, and continuing education of all persons in the department.

(14) Recommending space and other resources needed by the department.

(15) Participating in selecting outside sources for needed services.

(16) Participating in budget planning and review.

c. Individual employees are responsible for carrying out their individual responsibilities and assignments.

5. **REFERENCES:** Joint Commission Standards, current version; and current Carl T. Hayden VA Medical Center Organizational Chart.

6. **RESCISSION:** Policy Memorandum No. 00-62

7. **ATTACHMENTS:** Appendix A - Template for Clinical Services

Appendix B - Template for Non-Clinical Services

OPERATIONAL PLAN FOR PROVIDING SERVICES--Patient Care Service Line: _____

I. Description of Service/Programs (Scope of Services):

1. Types of patients (diagnoses)

2. Ages of patients (breakdown adult, geriatric)

3. Frequent procedures/services/processes

4. Needs analysis: Methods used to assess and meet patients' care needs

5. Scope and complexity of patients' care needs

6. Appropriateness, clinical necessity, and timeliness of support services provided directly by the medical center or through referral contacts

7. Extent to which the level of care or service provided meets patients' needs (describe future plans to meet unmet needs as appropriate)

II. Purpose: Overall Purpose of Department - What types of patients are appropriate for care/services in your department/service line, based on needs/acuity?

III. Service Line Goals/Objectives:

1. Planning Process

2. Short-Term Goals

3. Long-Term Goals

IV. Administration and Organization of the Service Line:

1. Organizational Units

2. Organizational Chart (attachment)

3. Narrative of Organizational Chart (describe the components)

4. Management of the Department

5. Organizational Relationships

- V. Hours of Operation
- VI. Service Delivery Process
- VII. Staffing:
 - A. Quantity: (#FTEE and breakdown)
 - B. Levels and Responsibilities
 - C. Delivery of Care
 - D. Preparation of Staff
 - 1. Selection Process or Criteria
 - 2. Orientation
 - 3. Continuing Education
 - 4. Credentialing/Competency
 - E. Allocation Plan for Variance
- VIII. Budget/Resources
- IX. Plan to Improve Quality of Care:
 - A. Performance Indicators (dashboard performance measures)
 - B. PITs and their status
 - C. Other quality initiatives (i.e., assessing customer needs, customer satisfaction, etc.)
- X. Any Additional Standards of Practice Adopted/Adapted by Department/Service Line

OPERATIONAL PLAN FOR PROVIDING SERVICES--Non-Patient CareService Line:

- I. Description of Service/Programs (Scope of Services):
 - Customers (internal and external)
 - Frequent procedures/services/processes
 - 1. Needs analysis: Methods used to assess and meet customers' needs
 - 2. Extent to which the level of care or service provided meets medical center's needs (describe future plans to meet unmet needs as appropriate)
- II. Purpose: Overall Purpose of Department - What types of services are appropriate for your customers based on needs?
- III. Service Line Goals/Objectives:
 - A. Planning Process
 - B. Short-Term Goals
 - C. Long-Term Goals
- IV. Administration and Organization of the Service Line:
 - A. Organizational Unit
 - B. Organizational Chart (attachment)
 - C. Narrative of Organizational Chart (describe the components)
 - D. Management of the Department
 - E. Organizational Relationships
- V. Hours of Operation
- VI. Service Delivery Process
- VII. Staffing:
 - A. Quantity: (#FTEE and breakdown)
 - B. Levels and Responsibilities
 - C. Delivery of Services
 - D. Preparation of Staff
 - 1. Selection Process or Criteria
 - 2. Orientation
 - 3. Continuing Education
 - 4. Competency
 - E. Allocation Plan for Variance (staffing standards/emergency staffing plans)
- VIII. Budget/Resources
- IX. Plan to Improve Quality of Care:
 - A. Performance Indicators (dashboard performance measures)
 - B. PITs and their status

- C. Other quality initiatives (i.e., assessing customer needs, customer satisfaction, etc.)
- D. Any Additional Standards of Practice Adopted/Adapted by Department/Service Line

Performance Improvement Models

There are many different models for implementing performance improvement models, although most of them include similar characteristics. Examples:

FOCUS-PDCA (Hospital Corporation of America)

- Find a process to improve
- Organize a team that knows the process
- Clarify current knowledge of the process
- Understand causes of process variation
- Select the process improvement
- Plan: improvement, data collection
- Do: improvement, data collection, data analysis
- Check: data for process improvement and customer outcome, lessons learned
- Act: to hold gain, to reconsider owner, to continue improvement

Joint Commission Ten Step Model

- Assign responsibility
- Delineate scope of care and service
- Identify important aspects of care and service
- Identify indicators
- Establish means to trigger evaluation
- Collect and organize data
- Initiate evaluation
- Take actions to improve care and service
- Assess the effectiveness of actions and assure improvement is maintained
- Communicate results to relevant individuals and groups

Joiner Associates

- Understand the process. Describe the process, identify the customer needs and concerns, and develop a standard process.
- Eliminate errors. Work to eliminate errors in the process.
- Remove slack. Streamline the process and eliminate steps that do not add value.
- Reduce variation. Reduce variation in measurement systems and processes and bring both the measurement systems and processes into statistical control.
- Plan for continuous improvement. Conduct the PDCA process on the changes made.

Juran Institute

- The Diagnostic Journey
 - Understanding the symptom. This step requires not only noting the words and findings that indicate a problem exists, but also investigating to learn, as specifically as possible, the symptoms.
 - Theorizing as to causes. Juran suggests that those affected by the problem brainstorm and organize the various theories that result.
 - Testing the theories. This testing may require small scale or large scale data collection and analysis and should result in identifying the symptoms' cause or causes.

The Remedial Journey

Stimulating the establishment of a remedy. Although the project team itself may not establish the remedy, Juran suggests that the team follow up and stimulate until the remedy has been established.

Testing the remedy under operating conditions. This activity involves implementing and observing the remedy under day to day conditions. Juran encourages project teams to make sure the cure is not worse than the disease.

Establishing controls to hold the gains. Some changes are reversible. Whatever procedures are necessary to make sure improvement is maintained should be implemented.

FADE (Organizational Dynamics)

Focus. Generate a list of problems, select one problem, and verify/define problems, which lead to a written statement of the problem.

Analyze. Decide what you need to know, collect data on baselines and patterns, and determine influential factors, which lead to baseline data and a list of most influential factors.

Develop. Generate promising solutions, select solution, and develop implementation plan, which lead to a solution for the problem and a plan for implementation.

Execute. Gain commitment, execute the plan, and monitor the impact, which lead to organizational commitment, an executed plan, and a record of impact.

Qualtec Seven Step QI Process

Reason for improvement. Identifies a theme or problem area & the reason for working on it.

Current situation. Selects a problem and sets a target for improvement.

Analysis. Identifies and verifies the root causes of the problem.

Countermeasures. Plans and implements countermeasures that will correct the root causes of the problem.

Results. Confirms that the problem and its root causes have been decreased.

Standardization. Standardizes to prevent the problem and its root causes from recurring.

Future plans. Plans what to do about any remaining problems and evaluates the team's effectiveness and how to replicate the countermeasures elsewhere.

UMMC Seven Step Process (ROADMAP)

Recognize the process. To identify customers and major work processes and to analyze those work processes.

Organize the data. To collect and stratify data to identify specific problems resulting in a detailed statement reflecting the quality gap.

Analyze root causes. To identify and analyze contributing factors (causes) to the process flow (effect).

Determine options. Select options (proposed solutions) that will decrease or eliminate the identified significant root causes of the quality gap.

Measure the change. Measure results and success of the proposed options.

Apply to workplace. Standardize and maintain successful options from quality improvement process to prevent recurrence of root causes.

Plan for the future. Generalize improvements to other areas, investigate additional improvements, and celebrate achievements.

Six Sigma

Six Sigma is a results-oriented, project-focused approach to quality. It's a way of measuring and setting targets for reductions in product or service defects that is directly connected to customer requirements. These reductions in the cost of poor quality translate into cost savings and competitive advantage.

Sigma represents one standard deviation from the average or mean. Most control charts set their range at +/- 3 sigma, but Six Sigma extends three more standard deviations. At six sigma, there are only 3.4 parts per million (ppm) defective. In statistics, a sigma refers to the standard deviation from the mean of a population. Standard deviation describes the likelihood of your next data point deviating from the mean of the whole data set. The sixth sigma refers to the likelihood that only 3.4 out of every one million data points will appear outside the sixth standard deviation. That translates into fewer than 4 errors per mission transactions.

The statistical representation of Six Sigma describes quantitatively how a process is performing. To achieve Six Sigma, a process must not produce more than 3.4 defects per million opportunities. A Six Sigma defect is defined as anything outside of customer specifications. A Six Sigma opportunity is then the total quantity of chances for a defect. Process sigma can easily be calculated using a Six Sigma calculator.

One of the guiding principles behind Six Sigma is that variation in a process creates waste and errors. Eliminating variation, then, will make that process more efficient, cost-effective and error-free. This may sound like a relatively straightforward concept, but its application in a complex and highly integrated business environment can be far from simple. The term *Sigma* refers to a scale of measurement of quality in processes such as manufacturing. When using this particular scale, *Six Sigma* equates to just under 3.4 defects per million opportunities (DPMO).

Sigma Level	Defects per million	Defects percentage
1	691,462	69%
2	308,538	31%
3	66,807	6.7%
4	6,210	0.62%
5	233	0.023%
6	3.4	0.00034%
7	0.019	0.0000019%

The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction through the application of Six Sigma improvement projects. This is accomplished through the use of two Six Sigma sub-methodologies: DMAIC and DMADV.

The Six Sigma DMAIC process (define, measure, analyze, improve, control) is an improvement system for existing processes falling below specification and looking for incremental improvement.

The Six Sigma DMADV process (define, measure, analyze, design, verify) is an improvement system used to develop new processes or products at Six Sigma quality levels. It can also be employed if a current process requires more than just incremental improvement. Both Six Sigma processes are executed by Six Sigma Green Belts and Six Sigma Black Belts, and are overseen by Six Sigma Master Black Belts.

According to the Six Sigma Academy, Black Belts save companies approximately \$230,000 per project and can complete four to 6 projects per year. (Given that the average Black Belt salary is \$80,000 in the United States, that is a fantastic return on investment.) General Electric, one of the most successful companies implementing Six Sigma, has estimated benefits on the order of \$10 billion during the first five years of implementation. GE first began Six Sigma in 1995 after Motorola and Allied Signal blazed the Six Sigma trail. Since then, thousands of companies around the world have discovered the far reaching benefits of Six Sigma.

Six sigma is all about variance reduction. This refers to the amount of control you have over processes. Another way to look at it is how good you are at predicting or forecasting the future outcomes of a given process. Variance is a symptom of waste. So, the higher the sigma, the greater the control you have over your process, which means greater forecasting accuracy and less error. Processes that exhibit a lot of variance mean they have a lot of waste. Six sigma is very problem focused. It uses a scientific approach called DMAIC to analyze a specific problem for an existing process.

DMAIC (for existing processes)

Define—Initiate, scope, and plan the project

Measure—Understand customer needs and specify CTQs (critical to quality); measure defects or deviation

Analyze—Analyze root causes; develop design concepts and high level design

Improve—Improve the process; develop detailed design; implement countermeasures; and control/test plan

Control—Test design and implement full-scale processes; measure and monitor to sustain new level of improvement

DMAIC is used to apply the principles of Six Sigma to existing business processes. For instance, if you are trying to find out how to make a particular process more effective, you would use DMAIC to break down the process into its component parts. Using this Six Sigma model, you would start by defining the problems and project goals, measuring data relating to the current process and analyzing your findings to identify cause-and-effect relationships. The next step involves improving existing processes based on your data analysis. Finally, you need to implement controls to avoid variation in the process going forward.

Define: The main objective of this stage is to outline the borders of the project.

- Stakeholders agree on the parameters that will define the project
- Scope and budgetary items, as well as customer needs, are aligned with project goals
- Team development takes place as the project begins to take shape

Measure: The main objective is to collect data pertinent to the scope of the project.

- Leaders collect reliable baseline data to compare against future results
- Teams create a detailed map of all interrelated business processes to elucidate areas of possible performance enhancement

Analyze: The main objective is to reveal the root cause of business inefficiencies.

- Analysis of data reveals areas where the implementation of change can provide the most effective results
- Groups discuss ways that the data underscores areas ripe for improvement

Improve: The main objective at the end of this stage is to complete a test run of a change that is to be widely implemented.

Teams and stakeholders devise methods to address the process deficiencies uncovered during the data analysis process

Groups finalize and test a change that is aimed at mitigating the ineffective process

Improvements are ongoing and include feedback analysis and stakeholder participation

Control: The objective of the last stage of the methodology is to develop metrics that help leaders monitor and document continued success.

- Six Sigma strategies are adaptive and on-going.
- Adjustments can be made and new changes may be implemented as a result of the completion of this first cycle of the process.

At the end of the cycle, additional processes are either addressed or the initial project is completed.

Six Sigma methodologies can be rolled out in a matter of months or over the course of years. From large international companies to mid-size firms, many high-profile companies have implemented Six Sigma strategies as a way of saving corporate dollars, increasing quality and leveraging the competitive edge.

DMADV (for new processes)

Define
Measure
Analyze
Design
Verify

While DMADV shares some steps in common with DMAIC, it is used for Six Sigma projects that create new product or process designs. Using the DMADV Six Sigma model, you would start by defining your design goals. The next step is to measure the required quality characteristics, product or production process capabilities, and associated risks. You would then conduct an analysis of your findings to develop an appropriate solution. After that, you're ready for the design phase of the new product or process. Once the design is complete, you must test it and verify that it works. Following these steps will result in a successful Six Sigma implementation.

The application of DMADV is used when a client or customer requires product improvement, adjustment, or the creation of an entirely new product or service. The application of these methods is aimed at creating a high-quality product keeping in mind customer requirements at every stage of the game. In general, the process can be outlined as:

Define: Project leaders identify wants and needs believed to be considered most important to customers. Wants and needs are identified through the historical information, customer feedback, and other information sources.

- Teams are assembled to drive the process
- Metrics and other tests are developed in alignment with customer information

Measure: The second part of the process is to use the defined metrics to collect data and record specifications in a way that can be utilized to help drive the rest of the process.

- All the processes needed to successfully manufacture the product or service are assigned metrics for later evaluation
- Technology teams test the metrics and then apply them

Analyze: The result of the manufacturing process (i.e. finished product or service) is tested by internal teams to create a baseline for improvement.

- Leaders use data to identify areas of adjustment within the processes that will deliver improvement to either the quality or manufacturing process of a finished product or service
- Teams set final processes in place and make adjustments as needed

Design: The results of internal tests are compared with customer wants and needs. Any additional adjustments needed are made.

- The improved manufacturing process is tested and test groups of customers provide feedback before the final product or service is widely released

Verify: The last stage in the methodology is continuous. While the product or service is being released and customer reviews are coming in, the processes may be adjusted.

- Metrics are further developed to keep track of continuous customer feedback on the product or service
- New data may lead to other changes that need to be addressed, so the initial process may lead to new applications of DMADV in subsequent areas

The applications of these methodologies are generally rolled out over the course of many months or even years. The end result is a product or service that is completely aligned with customer expectations, wants and needs.

Leadership opportunities are abound for Six Sigma professionals in today's competitive business environment. As an in-house expert or as an independent consultant, those with Green Belt, Black Belt, or Master Black Belt certification can be on their way to a more rewarding career path. Career development is available through reputable online programs, like Villanova University, providing professionals with flexible options designed to develop the leadership skills needed to edge above the competition and move into top Six Sigma positions across the industry.

Measures, counts, and data about defects and their origins drive Six Sigma's defect reduction process. Without data about defects or deviation, Six Sigma just doesn't work.

Three key tools in reducing defects, errors, and mistakes:

Control Charts – To measure customers' critical to quality (CTQ) requirements

Pareto Charts – To focus the root cause analysis

Fishbone (Ishikawa) Diagrams – To analyze the root causes of the problems or symptoms

With these three tools, you can solve 90% of the problems associated with defects, mistakes, errors, or cost. The Six Sigma model focuses on identifying problems, determining their root causes, and implementing countermeasures that will reduce or eliminate the waste, rework, and delay caused by these problems.

1. Define a problem for improvement using measurements shown as control charts and pareto charts to select elements for improvement.
2. Use the cause and effect diagram to identify root causes. Then analyze, verify and validate the root causes.
3. Select countermeasures to prevent the root causes, and evaluate results from implementing the countermeasures.
4. Sustain the improvement using control charts.
5. Replicate the improvement.

Levels of Six Sigma Mastery

What is Six Sigma from a hierarchical perspective? Taking a cue from martial arts, Six Sigma uses a colored-belt system – with some modifications – to denote an individual's level of Six Sigma expertise or role in an organization's Six Sigma strategy:

- Green Belt is the foundational level of Six Sigma expertise. Team members with this training integrate Six Sigma implementation into their primary job duties. Green Belts are guided by those at the next Six Sigma level, Black Belts.
- Working under Master Black Belts to apply Six Sigma methodology to designated projects, Black Belts dedicate all of their professional efforts to Six Sigma.
- Master Black Belts mentor Black Belts and Green Belts. Like Black Belts, they concentrate on Six Sigma implementation. In addition to spending time on statistical duties, Master Black Belts help ensure that Six Sigma processes are applied consistently throughout an organization's numerous

departments and functions.

- Six Sigma Champions are individuals chosen from upper management by Executive Leadership. Champions are also concerned with enterprise-wide Six Sigma implementation as well as mentoring lower-level Six Sigma practitioners.
- At the top of the Six Sigma “food chain” is Executive Leadership. This includes a company’s CEO and other members of top management. Executive Leadership determines the overall strategy for the organization’s Six Sigma implementation. They also set the parameters for duties of more junior practitioners.

Developed by Motorola in the 1980s, this improvement methodology was created to reduce errors, waste and variations, and increase quality and efficiency in manufacturing. It has since been adapted for use in other types of business processes, and is today in practice in some of the top companies around the globe, including General Electric, Honeywell and Allied Steel. Six Sigma-driven companies use data to examine, manage, and enhance operational performance by eliminating and preventing flaws in goods and related processes, such as design, management, production, consumer satisfaction and service delivery.

Use Six Sigma when:

- You need measurable evidence of improvement
- Tuning/optimizing a process
- X’s are not so clear
- You need to know the functional relationship of X’s to Y
- Improvement has been tried before but failed or wasn’t sustained

Use Lean for Quick Turnaround when:

- Gross improvements are needed
- There is an obvious opportunity for improvement with basic tools (value stream mapping, etc.)
- You need to stabilize a process to get baseline data

Similarities of models

Focus on internal and external customers

Use scientific problem solving approach

Identify the root causes of problems or opportunities for improvement

Pilot new test approaches to improve quality

Include staff who do the work in the QI effort

Differences among models

Scope of the model. Some models focus exclusively on problem solving, while other models include a broader range of TQM activities.

Treatment of variation. Some models explicitly list steps to reduce variation of the process; others do not. However, underlying the improvements of all models will be reduced variation.

Removing slack or steps that do not add value.

Similarities to traditional clinical models

Medical practice model

Nursing care process

SOAPIER documentation process

Implementation Models/Processes

GOAL/QPC Ten-Element Model (GOAL/QPC)

- TQM decision
- Customer Focus
- Critical processes
- Initial teams
- Five-year plan
- Managing momentum
- Hoshin planning
- New teams
- Daily management
- Evaluating Progress

Juran Quality Improvement Journey

- Decide to pursue total quality
- Prepare for the journey
- Start the journey
- Expand effort
- Integrate the entire organization

Juran's Six Steps to Quality Improvement

1. Identify a project
 - a. Nominate projects
 - b. Evaluate projects
 - c. Select a project
 - d. Ask: is it quality improvement?
2. Establish a project
 - a. Prepare a mission statement
 - b. Select a team
 - c. Verify the mission
3. Diagnose the cause
 - a. Analyze symptoms
 - b. Confirm or modify the mission
 - c. Formulate theories
 - d. Test theories
 - e. Identify root causes
4. Remedy the cause
 - a. Evaluate alternatives
 - b. Design remedy
 - c. Design controls
 - d. Design for culture
 - e. Prove effectiveness
 - f. Implement
5. Hold the gains
 - a. Design effective quality controls
 - b. Foolproof the remedy
6. Replicate results and nominate projects
 - a. Replicate the project results

- b. Nominate new projects

FISH (Sustain the Improvement-Control)

<i>Focus</i>	1. Refine the process
Define measure	2. Identify the critical to quality indicators (CTQs)
<i>Improve</i>	3. Implement the critical to quality indicators
Measure	
<i>Sustain</i>	4. Check the process for stability and capability
Control	
<i>Honor</i>	5. Review, recognize, and refocus

Crosby 14 Steps

Management commitment—Make it clear that management is committed to quality.

Quality improvement team—Form quality improvement teams with representatives from each department.

Quality measurement—Determine where current and potential quality problems lie.

Cost of quality evaluation—Evaluate the cost of quality and explain its use as a management tool.

Quality awareness—Raise the quality awareness and personal concern of all employees.

Corrective action—Take actions to correct problems identified.

Establish ad hoc committee for zero defects program—Establish a committee for the zero defects program.

Supervisor training—Train supervisors to actively carry out their part of the quality improvement program.

Zero defects day—Hold a zero defects day to let all employees realize that there has been a change.

Goal setting—Encourage individuals to establish improvement goals for themselves and their groups.

Error cause removal—Encourage employees to communicate to management the obstacles they face in attaining their improvement goals.

Recognition—Recognize and appreciate those who participate.

Quality councils—Establish quality councils to communicate on a regular basis.

Do it all over again—Do it all over again to emphasize that the quality improvement program never ends.

ISO 9000—Provides quality management system fundamentals and vocabulary

ISO 9001—Used to document quality management system requirements

ISO 9004—Standard contains guidelines for performance improvements.

ISO 9001

Product conformity

Customer satisfaction

Continuous improvement

A quality management systems approach

Monitoring and measuring

Standard

Scope—standard specifies quality management system (QMS) requirements

Normative references

Terms and definitions

Quality management system

Requirements

Documentation

- Quality manual
- Control of documents
- Control of records
- Management responsibility
 - Management commitment
 - Customer focus
 - Quality policy
 - Planning
 - Quality objectives
 - QMS planning
 - Responsibility and authority
 - Management representative
 - Internal communication
 - Management review
- Resource management
 - Provision of resources
 - Human resources
 - Competence, training, and awareness
 - Infrastructure
 - Work environment
- Product realization
 - Planning
 - Customer related processes
 - Product requirements review
 - Customer communication
 - Design and development
 - Design planning
 - Design inputs
 - Design outputs
 - Design review
 - Design verification
 - Design validation
- Measurement, analysis, and improvement
 - Customer satisfaction
 - Internal audit
 - Process monitoring and measurement
 - Product monitoring and measurement
 - Data analysis
 - Continual improvement
 - Corrective action

VATAMMCS

Vision—Leaders identify potential areas for improvement reflecting an integration of the strategies, resources and performance goals identified at the VA, VHA, Network and Medical Center levels. These opportunity focus on the key drivers of VHA healthcare: Veteran-centeredness, quality, effectiveness, equity, and efficiency of healthcare.

Analysis—By narrowing the focus of the vision, leadership refines the broad opportunities into specific priorities most amenable to action and change. When indicated chartered teams assess and improve key processes to ensure implementation of change and sustain strategies.

Team—Teams plan and implement improvement plans and projects. Those who can best transform the work are the people who DO the work on a day-to-day basis. It is important to ask; “Does everyone who touches this process have a say in the process changes?” Teams work best with clear sponsorship from executive leaders, front-line staff who have integrity and are passionate about improvement, and a facilitator, or improvement professional, who has a deep knowledge and skill doing improvement work.

Aim—What is your team’s aim or goal? Team members should be able to describe the aim in one or two crisp sentences. If teams lose focus on their aim, they get lost and are ineffective. It is common for teams to invest a few hours, days, or even weeks clarifying and achieving buy-in around the real aim. They should write a clear, measurable aim statement that describes the WHAT and BY WHEN. Aim statements focus on VHA’s priority: the patient experience (in clinical services); or the support of patient experiences (in administrative services) – even if they are removed a step or two. Teams sometimes set more than one aim. In addition to clarifying the improvement work at hand, well-written aim statements help identify the end of the work.

- State the aim clearly
- Base the aim on data
- Include measurable goals
- Set stretch goals

Map—Have you drawn a picture of the process? Flow mapping clarifies the start, end, and key decision points for the process. The experience of flow mapping allows teams to agree on the process and discover value to the patient or customer, non-standard and unreliable processes, and the re-work involved. Flow mapping leads to ideas for measuring and improving the process. Flow mapping requires sustained discipline from every team member. Nothing should be taken for granted, and every team member must agree that the final map accurately represents the process as it really exists. Flow mapping can occur at a very high level, or at a much more detailed level. The facilitator and the team must choose the appropriate level of detail. An appropriate level of detail allows identification of mistakes, rework, and non-value added steps. Flow maps use circles to represent the start and end points of a process, rectangles to represent steps, and diamonds to represent decision points. The goal is to visualize and understand existing processes, while discovering improvement opportunities. The team uses the current state map to visualize an ideal process or future state map.

Measure—How do you know your change is an improvement? To recognize improvement and manage by fact, not feeling we are obligated to measure. Measurement must be good enough to support the team’s aim. Perfect measurement as would be required for a research study is not necessary. Use measurement to both diagnose the current state, including the constraints, and to visualize the general direction of change.

Change—What changes will result in improvement? Two critical issues affect this area of change: first, focus on considering change principles, not best practices or strategies; and second, use small tests of change as embodied in PDSA before attempting large, system-wide change.

Sustain—If everyone on your team retires, how do you know these change strategies will continue to be used? Sustain strategies require us to think about previous successful changes. Then, we think about the process and task changes that resulted in the success. Next, we must memorialize those changes by assigning responsibility, changing job descriptions, evaluations, reward systems, policies, and new employee training. Ongoing measurement of the key processes sustains change. Previous improvement efforts have failed because the appropriate system changes and safeguards were not in place to support the new processes.

Spread—How can we share what we have learned with persons who could apply this knowledge to improve services they provide? Spreading new developments can multiply the value of the improvement.

Lean Enterprise

Lean management principles have been used effectively in manufacturing companies for years, particularly in Japan. Lean thinking begins with driving out waste so that all work adds value and serves the customer's needs. Identifying value-added and non-value-added steps in every process is the beginning of the journey toward lean operations. In order for lean principles to work, leaders must first work to create an organizational culture that is receptive to lean thinking. The commitment to lean must start at the very top of the organization, and all staff must be involved in helping to redesign processes to improve flow and reduce waste. When applied rigorously and throughout an entire organization, lean principles can have a positive impact on productivity, cost, quality, and timely delivery of services.

The concept called lean management or lean thinking is most commonly associated with Japanese manufacturing, particularly the Toyota Production System (TPS). Much of the TPS way of thinking is based on Deming, who believed that managers should stop depending on mass inspection to achieve quality, and instead, focus on improving the production process and building quality into the product in the first place. Lean means using less to do more.

Lean Thinking is a management strategy that is applicable to all organizations because it has to do with improving processes. All organizations are composed of a series of processes, or sets of actions intended to create value for those who use or depend on them, such as customers and patients. The core of lean involves determining the value of any given process by distinguishing value added steps from non value added steps, and eliminating waste so that ultimately every step adds value to the process. Lean thinking is flexible and consequently adaptable to complex environments.

To maximize value and eliminate waste, leaders in health care must evaluate processes by:

- accurately specifying the value desired by the user;
- identifying every step in the process (or value stream),
- Continually eliminating non value added steps; and
- making value flow from beginning to end based on the pull, the expressed needs of the customer/patient;
- consistently delivering value

Unique Features

- Value stream mapping
- Improvement events
- Waste reduction tools
- Specific design principles

The value stream mapping used in lean thinking is a visual representation of how value flows to the customer. It captures activities at a macro level, both functional and cross functional processes. It highlights obstructions to flow and sources of waste.

A lean system emphasizes the prevention of waste: any extra time, labor, or material spent producing a product or service that doesn't add value to it. A lean system's unique tools, techniques, and methods can help your organization reduce costs, achieve just in time delivery, and shorten lead times. A lean enterprise fosters a company culture in which all employees continually improve their skill levels and production processes. Lean systems are customer focused and driven. Products and services are created and delivered in the right amounts, to the right location, at the right time, and in the right condition. Products and services are produced only for a specific customer rather than being added to an inventory. A lean system allows production of a wide variety of products or services, efficient and rapid changeover among them as needed, efficient response to fluctuating demand, and increased quality.

Power Laws of Quality

The wider your spread it, the thinner it gets.

To crease returns, narrow your focus.

Impact of Lean Principles in Industry

Direct Labor/Productivity Improved	45-75%
Cost Reduced	25-55%
Throughput/Flow Increased	60-90%
Quality (Defects/Scrap) Reduced	50-90%
Inventory Reduced	60-90%
Space Reduced	35-50%
Lead Time Reduced	50-90%

Key Concepts in Lean Thinking

Leadership: Those at the very top must lead. Implementing lean thinking requires major change management throughout the entire organization, which may be traumatic and difficult. CEO must be a visible, vocal champion of lean management, create an environment where it is permissible to fail, set stretch goals, and encourage leaps of faith.

Culture: A lean culture is a backdrop against which lean tools and techniques are implemented.

<u>Traditional Culture</u>	<u>Lean Culture</u>
Functional silos	Interdisciplinary teams
Managers direct	Managers teach/enable
Benchmark to justify not improving, just as good	Seek ultimate performance, no waste
Blame people	Root cause analysis
Rewards individual	Rewards group sharing
Supplier is enemy	Supplier is ally
Guard information	Share information
Volume lowers cost	Removing waste lowers cost
Internal focus	Customer focus
Expert driven	Process driven

Process: A set of actions or steps, each of which must be accomplished properly in the proper sequence at the proper time to create value for the customer or patient. Primary processes serve the external customer. Internal processes serve internal customers in support of the primary process. In a perfect process, every step is valuable (creates value for the customer), capable (produces a good result every time), available (produces the desired output, not just the desired quality, every time), adequate (does not cause delay, flexible, and linked by continuous flow). Failure in any of these dimensions produces some type of waste. TPS identifies seven categories of waste: overproduction, waiting, transporting, extra processing, inventory, motion, and defects/correction. A perfect process not only creates value, but is also satisfying for people to perform, managers to manage, and customers to experience.

Creating the Perfect Process

- Identify the key processes (value streams) in your organization; key processes are those that support core products (ED visit, inpatient stay, etc.)
- For each core product, identify key processes both primary & internal, that support them.
- Identify person responsible for thinking about each process as a whole, how it works, and how to make it better, specifying value from the customer's perspective
- Bring together key participants from a chosen process in a kaizen event, an intensive 3-5 day event or session focused solely on analyzing current processes and implementing changes; these are episodic workshops using a team based approach with 8-10 participants (Kaizen means continuous, incremental improvement of an activity to create more value with less waste).

- Team begins by mapping the process as it actually operates, specifying value from the standpoint of the customer (value stream map)
- Team next maps future state how the process should be; using future map, team reorganizes staff to match requirements of the process
 - Eliminate all stop and store points
 - Eliminate queues and waiting
- Use PDSA cycles
- Typical schedule
 - Monday-Event kickoff, team training, observe and document current state process
 - Tuesday-Design future state, brainstorm improvement ideas, select and prioritize ideas
 - Wednesday-Design improvements, create standardized work, test the new process, get input from other stakeholders
 - Thursday-Continue design and test cycles, gain buy-in from others, finalize standardized work, prepare training materials
 - Friday-Train other workers, create sustainability plan, complete report, hold presentation and celebration

Value stream

Value stream refers to all the activities your company must do to design, order, produce, and deliver its products or services to customers. A value stream has three main parts:

The flow of materials, from receipt from suppliers to delivery to customers.

The transformation of raw materials into finished goods.

The flow of information that supports and directs both the flow of materials and the transformation of raw materials into finished goods.

A value stream map uses simple graphics or icons to show the sequence and movement of information, materials, and actions in your company's value stream.

It helps employees understand how the separate parts of their company's value stream combine to create products or services.

Creating a value stream map is the first step your company should take in creating an overall lean initiative. A lean initiative begins with agreement among employees on the current state of your organization. Developing a visual map of the value stream allows everybody to fully understand and agree on how value is produced and where waste occurs. Creating a value stream map also provides the following benefits:

- Highlighting connections among activities and information and material flow that impacts the lead time of your value stream
- Helping employees understand your company's entire value stream rather than just a single function of it
- Improving the decision making process of all work teams by helping team members to understand and accept your company's current practices and future plans
- Creating a common language and understanding among employees through the use of standard value stream mapping symbols
- Allowing you to separate value added activities from non value added activities and then measure their lead time
- Providing a way for employees to easily identify and eliminate areas of waste

Current State Value Stream Map

Purpose of creating a current state map is to be able to create the Future State Value Stream Map

Mapping Tool: Supplier, Input, Process, Output, Customer (SIPOC): SIPOC is a process oriented tool to begin mapping and understanding any process. It pieces together the major elements of a process/value stream to allow participants the ability to view it at a high level and agree on it.

Suppliers to the process—Who or what provides information, materials, or services

Inputs provided by the suppliers—What actual information, materials, or service do they provide?

Process steps—What are the main steps of the process? What actions taken upon the inputs yield output and add value?

Outputs for the customer—What final product or service results from the process?

Customers of the process—Which person, process, or organization receives the output?

Steps to Completing SIPOC

General description of scope of the initiative from leader, process owner, or subject matter expert

Identify customers of the process

Identify outputs or final products to the customers

Identify high level steps to the process

The process must have a clearly identified start and stop point. The next steps will identify the suppliers and inputs to the process and then document the conclusions.



Steps to Use Value Stream Analysis to Target Improvements

- Develop current state value stream map
- Apply basic measurement tools to collect high level process timeliness, quality, and reliability data
- Identify high level process constraints within the current state value stream
- Utilize advanced measurement and process mapping tools to drill down into the high level processing constraints
- Using PDSA cycles, test the application of Lean Tools to reduce or mitigate the process constraints and improve process reliability
- Develop and utilize an implementation plan to improve processes

The right process will produce the right results:

- Create continuous process flow to bring problems to the surface.
- Use the pull system to avoid overproduction
- Level out the workload; work like the tortoise, not the hare
- Build a culture of stopping to fix problems, to get quality right the first time
- Standardization tasks are the foundation for continuous improvement and employee empowerment
- Use visual control so no problems are hidden
- Use only reliable, thoroughly tested technology that serves your people and processes
- Add value to the organization by developing your people and partners
- Grow leaders who thoroughly understand the work, live the philosophy, and teach it to others
- Develop exceptional people and teams who follow the organization's philosophy
- Respect your extended network of partners and suppliers by challenging them and helping them improve
- Continuously solving root problems drives organizational learning
- Go and see for yourself to thoroughly understand the situation
- Make decisions slowly by consensus, thoroughly considering all options; implement decisions rapidly

- Become a learning organization through relentless reflection and continuous improvement
- Lean principles hold promise for reducing or eliminating wasted time, money, and energy in health care. Lean is about getting the right things to the right place at the time in the right quantity while minimizing waste and being flexible and open to change. All of these concepts have to be understood, appreciated, and embraced by the actual employees who build the products and therefore own the processes. The cultural aspect of lean is just as important as the actual tools or methodologies.

Goals of Lean Enterprise

Goal 1: Improve quality

Quality is the ability of your products or services to conform to your customers' wants and needs (also known as expectations and requirements). Product and service quality is the primary way a company stays competitive in the marketplace.

Goal 2: Eliminate waste

Waste is any activity that takes up time, resources, or space but does not add value to a product or service. An activity adds value when it transforms or shapes raw material or information to meet your customers' requirements. Some activities, such as moving materials during product production, are necessary but do not add value. A lean organization's primary goal is to deliver quality products and services the first time and every time. As a lean enterprise, you accomplish this by eliminating all activities that are waste and then targeting areas that are necessary but do not add value.

Goal 3: Reduce lead time

Lead time is the total time it takes to complete a series of tasks within a process. Some examples are the period between the receipt of a sales order and the time the customer's payment is received, the time it takes to transform raw materials into finished goods, and the time it takes to introduce new products after they are first designed. By reducing lead time, a lean enterprise can quickly respond to changes in customer demand while improving its return on investment (ROI).

Goal 4: Reduce total costs

Total costs are the direct and indirect costs associated with production of a product or service. Your company must continually balance its products' and services' prices and its operating costs to succeed. When either its prices or its operating costs are too high, your company can lose market share or profits. To reduce its total costs, a lean enterprise must eliminate waste and reduce lead times.

Speedbumps of Lean (major types of waste)

Overproduction – Producing items for which there are no orders, which generates such wastes as overstaffing and storage and transportation costs because of excess inventory.

Too much inventory – Excess raw material, work in process (WIP), or finished goods causing longer lead times, obsolescence, damaged goods, transportation and storage costs, and delay. Also, extra inventory hides problems such as production imbalances, late deliveries from suppliers, defects, equipment downtime, and long setup times.

Waiting (i.e. delay or time on hand) – Workers merely serving to watch an automated machine or having to stand around waiting for the next processing step, tool, supply, part, etc., or just plain having not work because of stockouts, lot processing delays, equipment downtime, and capacity bottlenecks.

Unnecessary transport or conveyance – Carrying WIP long distances, creating inefficient transport, or moving materials, parts, or finished goods into or out of storage between processes.

Unnecessary, overprocessing, or incorrect processing – Taking unneeded steps to process the parts. Inefficiently processing due to poor tool and product design, causing unnecessary motion and producing defects. Waste is generated when providing higher-quality products than is necessary.

Unnecessary movement – Any wasted motion employees have to perform during the course of their work, such as looking for, reaching for, or stacking parts, tools, etc. Also, walking is waste.

Defects or rework to fix mistakes – Production of defective parts or correction. Repair or rework, scrap, replacement production, and inspection mean wasteful handling, time, and effort.

Unused employee creativity – Losing time, ideas, skills, improvements, and learning opportunities by not engaging or listening to your employees.

Redesigning the Work Flow

What is current flow?

What flow would reduce the seven speed bumps of waste?

What are the pull signals? (how do you know)

Lean Six Sigma

Lean: Eliminating delay from patient experience

Six Sigma: Eliminating defects and deviation from patient experience

Economies of Speed

To accelerate your speed, eliminate delay

25% reduction in delay will double productivity and increase profits 20%

Slash cycle time & enjoy growth rate 3X the industry average & 2X profit margin

5 S

Sort—Organizing, separating the needed from the unneeded

Straighten—A place for everything & everything in its place; visual & self explanatory

Shine—Cleaning and looking for ways to keep it clean

Standardize—Maintain and monitor the first 3 steps

Sustain—Discipline, stick to the rules & continuously improve all principles

Focus on mission critical problems involving delay, defects, and deviation

Set big hairy audacious goals; reduce defects, time or cost by 50% or more in six months or less

Count your misses to illuminate what to fix

Initiate root cause teams to analyze each problem and identify solutions

Implement solutions and verify results

Start with a small band of early adopters and ensure their success

Avoid the corporate immune system

Engage informal networks and adapt the process

To increase returns, reduce the number of people involved

To accelerate speed, eliminate delay

To increase your returns, narrow your focus

To engage your people, reduce the number of people involved and engage informal not formal network

Lean is a system designed to provide the tools for people to continually improve their work.

Lean Principles

1. Base your management decisions on a long-term philosophy, even at the expense of short-term financial goals.
 - a. Have a philosophical sense of purpose that supersedes any short term decision making. Work, grow, and align the whole organization toward a common purpose that is bigger than making money. Understand your place in the history of the company and work to bring the company to the next level. Your philosophical mission is the foundation for all the other principles.

- b. Generate value for the customer, society, and the economy. It is your starting point. Evaluate every other function in the company in terms of its ability to achieve this.
 - c. Be responsible. Strive to decide your own fate. Act with self reliance and trust in your own abilities. Accept responsibility for your conduct and maintain and improve the skills that enable you to produce added value.
- 2. Create continuous process flow to bring problems to the surface.
 - a. Redesign work processes to achieve high value added, continuous flow.
 - b. Create flow to move material and information fast as well as to link processes and people together so that problems surface right away.
 - c. Make flow evident throughout your organizational culture. It is the key to a true continuous improvement process and to developing people.
- 3. Use pull systems to avoid overproduction.
 - a. Provide your downline customers in the production process with what they want, when they want it, and in the amount they want. Material replenishment initiated by consumption is the basic principle of just-in-time.
 - b. Minimize your work in process and warehousing of inventory by stocking small amounts of each product and frequently restocking based on what the customer actually takes away.
 - c. Be responsive to the day-to-day shifts in customer demand rather than relying on computer schedules and systems to track wasteful inventory.
- 4. Level out the workload (**heijunka**). Work like the tortoise, not the hare.
 - a. Eliminating waste is just one third of the equation for making lean successful. Eliminating overburden to people and equipment and eliminating unevenness in the production schedule are just as important—yet generally not understood at companies attempting to implement lean principles.
 - b. Work to level out the workload of all manufacturing and service processes as an alternative to the stop/start approach of working on projects in batches that is typical at most companies.
- 5. Build a culture of stopping to fix problems, to get quality right the first time.
 - a. Quality for the customer drives your value proposition.
 - b. Use all the modern quality assurance methods available.
 - c. Build into your equipment the capability of detecting problems and stopping itself. Develop a visual system to alert team or project leaders that a machine or process needs assistance. **Jidoka** (making problems obvious) is the foundation for building in quality.
 - d. Build into your organization support systems to quickly solve problems and put in place countermeasures.
 - e. Build into your culture the philosophy of stopping or slowing down to get quality right the first time to enhance productivity in the long run.
- 6. Standardized tasks are the foundation for continuous improvement and employee empowerment.
 - a. Use stable, repeatable, methods everywhere to maintain the predictability, regular timing, and regular output of your processes. It is the foundation for flow and pull.
 - b. Capture the accumulated learning about a process up to a point in time by standardizing today's best practices. Allow creative and individual expression to improve upon the standard; then incorporate it into the new standard so that when a person moves on you can hand off the learning to the next person.
- 7. Use visual control so no problems are hidden. **Poka yoke** is a mindset and technique that creates devices or processes to detect and prevent errors from occurring in a process.

- a. Use simple visual indicators to help people determine immediately whether they are in a standard condition or deviating from it.
 - b. Avoid using a computer screen when it moves the worker's focus away from the workplace.
 - c. Design simple visual systems at the place where the work is done, to support flow and pull.
 - d. Reduce your reports to one piece of paper whenever possible, even for your most important financial decisions.
8. Use only reliable, thoroughly tested technology that serves your people and your processes.
- a. Use technology to support people, not to replace people. Often it is best to work out a process manually before adding technology to support the process.
 - b. New technology is often unreliable and difficult to standardize and therefore endangers flow. A proven process that works generally takes precedence over new and untested technology.
 - c. Conduct actual tests before adopting new technology in business processes, manufacturing systems, or products.
 - d. Reject or modify technologies that conflict with your culture or that might disrupt stability, reliability, and predictability.
 - e. Nevertheless, encourage your people to consider new technologies when looking into new approaches to work. Quickly implement a thoroughly considered technology if it has been proven in trials and it can improve flow in your processes.
9. Grow leaders who thoroughly understand the work, live the philosophy, and teach it to others.
- a. Grow leaders from within, rather than buying them from outside the organization.
 - b. Do not view the leader's job as simply accomplishing tasks and having good people skills. Leaders must be role models of the company's philosophy and way of doing business.
 - c. A good leader must understand the daily work in great detail so he or she can be the best teacher of your company's philosophy.
10. Develop exceptional people and teams who follow your company's philosophy.
- a. Create a strong, stable culture in which company values and beliefs are widely shared and lived out over a period of many years.
 - b. Train exceptional individuals and teams to work within the corporate philosophy to achieve exceptional results. Work very hard to reinforce the culture continually.
 - c. Use cross-functional teams to improve quality and productivity and enhance flow by solving difficult technical problems. Empowerment occurs when people use the company's tools to improve the company.
 - d. Make an ongoing effort to teach individuals how to work together as teams toward common goals. Teamwork is something that has to be learned.
11. Respect your extended network of partners and suppliers by challenging them and helping them improve.
- a. Have respect for your partners and suppliers and treat them as an extension of your business.
 - b. Challenge your outside business partners to grow and develop. It shows that you value them. Set challenging targets and assist your partners in achieving them.
12. Go and see for yourself to thoroughly understand the situation (**genchi genbutsu**).
- a. Solve problems and improve processes by going to the source and personally observing and verifying data rather than theorizing on the basis of what other people or the computer screen tell you.
 - b. Think and speak based on personally verified data.

- c. Even high level managers and executives should go and see things for themselves, so they will have more than a superficial understanding of the situation.
13. Make decisions slowly by consensus, thoroughly considering all options; implement decisions rapidly.
- a. Do not pick a single direction and go down that one path until you have thoroughly considered alternatives. When you have picked, move quickly but cautiously down the path.
 - b. **Nemawashi** is the process of discussing problems and potential solutions with all of those affected, to collect their ideas and get agreement on a path forward. This consensus process, though time consuming, helps broaden the search for solutions, and once a decision is made, the stage is set for rapid implementation.
14. Become a learning organization through relentless reflection (**hansei**) and continuous improvement (**kaizen**).
- a. Once you have established a stable process, use continuous improvement tools to determine the root cause of inefficiencies and apply effective countermeasures.
 - b. Design processes that require almost no inventory. This will make wasted time and resources visible for all to see. Once waste is exposed, have employees use continuous improvement process (**kaizen**) to eliminate it.
 - c. Protect the organizational knowledge base by developing stable personnel, slow promotion, and very careful succession systems.
 - d. Use **hansei** (reflection) at key milestones and after you finish a project to openly identify all the shortcomings of the project. Develop countermeasures to avoid the same mistakes again.
 - e. Learn by standardizing the best practices, rather than reinventing the wheel with each new project and each new manager.

Institute for Healthcare Improvement (IHI) (<http://www.ihl.org>)

The Institute for Healthcare Improvement (IHI), an independent not-for-profit organization based in Cambridge, Massachusetts, is a leading innovator, convener, partner, and driver of results in health and health care improvement worldwide. IHI believes everyone should get the best care and health possible. This passionate belief fuels their mission to improve health and health care. IHI has partnered with visionaries, leaders, and front-line practitioners around the globe to spark bold, inventive ways to improve the health of individuals and populations. To advance their mission, IHI's work is focused in five key areas:

Improvement Capability: Ensuring that improvement science drives their work and that extends the reach and impact of the improvement community

Person- and Family-Centered Care: Putting the patient and the family at the heart of every decision and empowering them to be genuine partners in their care

Patient Safety: Making care continually safer by reducing harm and preventable mortality

Quality, Cost, and Value: Driving affordability and sustainability through quality improvement

Triple Aim for Populations: Applying integrated approaches to simultaneously improve care, improve population health, and reduce costs per capita

IHI creates dynamic opportunities for health care professionals to learn from, collaborate with, and be inspired by expert faculty and colleagues throughout the world. Their professional development programs — including conferences, seminars, and audio and web-based programs — inform every level of the workforce, from executive leaders to front-line staff. The IHI Open School is committed to developing students, the next generation of improvers, through free online courses and an international network of chapters. For all who join in improving health care, they provide a wealth of free content

through their website, ihi.org and their audio program, WIHI.

IHI also works with a wide range of entities —health care facilities, entire health care systems, or governments — to help them achieve significant results in quality, safety, and innovation. They collaborate with these change agents on the front lines of care to accelerate improvement in vital areas, including maternal and neonatal health, end-of-life care, avoidable hospital readmissions, waste and cost reduction, person- and family-centered care, and the spread of the Triple Aim.

IHI Vision and Mission

Vision: Everyone has the best care and health possible.

Mission: Improve health and health care worldwide.

An Irish proverb says that “When you come upon a wall, throw your hat over it, and then go get your hat.” At IHI, the spirit of this one little saying has inspired many big outcomes. People who are drawn to IHI see beyond walls to the possibilities on the other side. They are inspired and energized by one unifying vision: a future in which everyone has the best care and health possible. Although the problems are big and daunting, they resolve to approach them with optimism grounded in rigorous science, hard work, and a relentless drive for results. IHI is a recognized innovator, convener, and generous leader, a trustworthy partner, and the first place to turn for expertise, help, and encouragement for anyone, anywhere who wants to change health care profoundly for the better.

Values: These operating values are our core principles. They guide the behavior and choices of all staff, faculty, and the board of directors.

Boundarilessness and One Team: The people of IHI work as a cohesive unit with common systems, common knowledge, and unconditional teamwork. When it comes to raising the quality of health and health care for all, IHI sees boundless possibilities. While we see the walls in front of us, we will not rest until we reach the other side.

Systems Direct Our Mission: We believe that every system is perfectly designed to achieve the results it gets, and only through continuous improvement of systems will we make a difference in the quality of health and health care the world over. Results for patients and communities define our success.

People Matter: Whether customers, faculty, the health care workforce, or our own staff, we recognize and value everyone’s knowledge, experience, and input. We interact with everyone with a spirit of cooperation, a sense of humor, and the utmost respect.

Inclusiveness and Diversity: We strive to have an organization that reflects the world we live in and embraces everyone in it, no matter where they come from, no matter what their point of view.

Honesty and Transparency: We work in the daylight. We tell the absolute truth about ourselves and our work, reporting both failures and successes with equal discipline, and seeing the views and opinions outside our organization. We are an institute without walls.

Vision and Agility: We strive for excellent execution of our plans. We anticipate changes in our own work and respond as quickly as the health care systems we serve need us to. Our past work need not be our future work. We are always willing to change.

Celebration and Thankfulness: Our mission is long, and our work is not easy. We take time to look back, as well as forward, to thank each other, and to take pride in what we do.

Quality planning

Quality planning, as defined by Juran, is a structured process for developing products (both goods and services) that ensures that customer needs are met by the final result. Quality planning has been

developed because organizations have consistently demonstrated a failure to produce the goods and services that unerringly delight their customers. Frequent, large quality gaps experienced by customers are really the compound result of a number of smaller gaps.

1. The first component of understanding the gap is lack of understanding of what the customer needs. Sometimes this gap opens up because the producer simply fails to consider who the customers are and what they need. More often, the gap is there because the supplying organization has erroneous confidence in its ability to understand what the customer really needs. Customers react to how they perceive the goods or services provided to them with a benefit.
2. The second component of a quality gap is a design gap. Even if there were perfect knowledge about customer needs and perceptions, many organizations would fail to create designs for their goods and services that are fully consistent with that understanding. Some of this failure is due to the fact that people who understand customers and the tools they use are often systematically isolated from those who actually create the designs. In addition, those who design often lack the simple tools that would enable them to combine their technical expertise with an understanding of the customer needs to create a truly superior product.
3. The third gap is the process gap. Many excellent designs fail because the process by which the physical product is created or the service is delivered is not capable of conforming to the design consistently time after time. This lack of process capability is one of the most persistent and confusing factors in the total quality gap.
4. The fourth gap is the operations gap. The means by which a process is operated and controlled may create additional deficiencies in the delivery of the final good or service.

Quality planning provides the process, methods, tools, and techniques for closing each of the above gaps.

Steps of the quality planning model:

- Establish the project
- Identify the customers
- Discover the customer needs
- Develop the product
- Develop the process
- Develop the controls and transfer to operations

Establish the project

A quality planning project is the organized work needed to prepare an organization to deliver a new or revised product or service, following the steps associated with quality planning. The following steps are involved:

- identify which projects are required to fulfill the organization's strategy;
- prepare a mission statement for each project;
- establish a team to carry out the project; and
- plan the project.

Identification of projects: Deciding which projects to undertake is usually the result of the strategic and business planning process of an organization. Typically, quality planning projects create new or updated products that are needed to reach specific strategic goals, to meet new or changing customer needs, to fulfill legal or customer mandates, or to take advantage of a new or emerging technology. Upper management must take the lead in identifying and supporting the critical quality planning projects.

Quality Council

Set up a quality council. The role of the quality council is to:

- Create the environment to support and promote continuous performance improvement.
- Understand and live by values, vision, mission, goals, and management expectations. Review the written statements related to values, vision, mission, goals, and management expectations and ask the following questions: When were they last updated? Are they understandable by all staff? Are they pertinent? Have staff ever seen them? Do they understand them? Encourage staff at all levels to participate in revision. Once revised, the statements should be broadly communicated to employees, customers, and suppliers. Only if each person knows the organization's common direction, can he/she perform and improve in that direction.
- Guide and monitor the quality process.
- Demonstrate commitment, sponsorship, participation, and common understanding for improvement of quality and cost effectiveness. Actions speak louder than words. Everyone is watching to see whether there is active participation and personal involvement by management to demonstrate real commitment.
- Develop strategic quality plans.
- Sets quality goals. Top management identifies opportunities and needs to improve quality and set strategic goals for the organization.
- Analyze the elements of the quality process. Evaluate the process and make changes as needed.
- Develop a customer focus.
- Prepare a preliminary budget.
- Assess the capabilities of internal staff.
- Develop the quality plan and timelines to measure progress.
- Develop managerial and staff competence in quality.
- Assess the culture.
- Support the development of the educational curriculum for teams.
- Nominates and selects projects. The quality council selects those major quality planning projects critical to meeting strategic quality goals.
- Selects teams. Once a project has been identified, the quality council appoints a team to see the project through the remaining steps of the quality planning process.
- Sponsor and support pilot teams. Approve new teams/appoint task teams. New techniques and processes are generally required to meet quality goals. It is up to the quality council to see that each quality planning team is well prepared and equipped to carry out its mission. The quality council's support to the team may include:
 - Providing education and training in quality planning tools & techniques
 - Providing a trained facilitator to help the team work effectively and learn the quality planning process
 - Have departments develop mission and goal statements.
 - Identify and understand functions and processes within departments and those involving other departments.
 - Reviewing team progress
 - Approving revision of the project mission
 - Identifying/helping with any problems
 - Coordinating related quality planning projects
 - Helping with logistics, such as meeting sites
 - Providing expertise in data analysis & survey design
 - Furnishing resources for unusually demanding data collection
 - Communicating project results

Mission Statements

The quality council is generally responsible for keeping the quality planning process on track, evaluating progress, and making midcourse corrections to improve the effectiveness of the entire process. Once the quality council has reviewed the sources for potential projects, it will select one or more for immediate attention. Next, it must prepare a mission statement for the project. Once the quality council has identified the need for a project, it should prepare a mission statement that incorporates the specific goals of the project. The mission statement is the written instructions for the team that specifies the intent or purpose of the project. The team mission describes:

- Scope of the planning project, including product & markets to be addressed
- Goals of the project, results to be achieved
- Writing mission statements requires a firm understanding of the driving force behind the project. The mission statement helps to answer the following questions:
 - Why does the organization want to do the project?
 - What will it accomplish once it's implemented?

A mission statement also fosters a consensus among those who either will be affected by the project or will contribute the time and resources necessary to plan and implement the project goals. In addition to the scope of the project, a mission statement also must include the goals of the project.

Quality Goals: An important consideration in establishing quality goals is the choice of the basis for which goals are set.

Technology: Quality goals can be established on a technological basis. Most of the goals are published in specifications and procedures that define the quality targets for the supervisory and non-supervisory levels.

Market: Quality goals that affect product stability should be based primarily on meeting or exceeding market quality. Because the market and the competition will be changing while the quality planning project is under way, goals should be set so as to meet or beat the competition estimated to be prevailing when the project is completed. Some internal suppliers are internal monopolies. Examples include payroll preparation, facilities maintenance, cafeteria service, and internal transportation. Most internal monopolies have potential competitors. There are outside suppliers who offer to sell the same service, so the performance of an internal supplier can be compared with the proposals offered by an outside supplier.

Benchmarking: Benchmarking is the concept of setting goals based on knowing what has been achieved by others. A common goal is the requirement that the reliability of a new product be at least equal to that of the product it replaces and at least equal to that of the most reliable competing product. Implicit in the use of benchmarking is the concept that the resulting goals are attainable because they have already been attained by others.

History: Historical performance has also been used to set goals when goals are based on past performance. Sometimes, this is tightened up to stimulate improvement. For some products and processes, the historical basis is an aid to needed stability. In other cases, such as those involving chronically high costs of poor quality, the historical basis helps to perpetuate a chronically wasteful performance.

Quality goals are a moving target: It is widely recognized that quality goals must keep shifting to respond to changes that keep coming: new technology, new competition, threats, and opportunities.

Project goals: Specific goals of the project, such as what the team is to accomplish, are part of an effective mission statement. In getting the job done, the team must mentally start at the finish. The more focused it is on what the end result will look like, the easier it will be to achieve a successful conclusion.

Measurement of the goal: In addition to stating what will be done and when, a project goal must show how the team will measure whether or not it has achieved its stated goals. It's important to define how success will be measured. The four things that can be measured are: quality, quantity, cost, and time. An effective quality planning project must have 5 characteristics for it to provide a team with enough information to guide the planning process. The goal must be:

- Specific
- Measurable
- Agreed to by those affected
- Realistic (can be a stretch goal, but it has to be realistic)
- Time specific (when it will be done).

Teams

“We trained hard, but it seemed that every time we were beginning to form up into teams, we would be reorganized. I was to learn later in life we tend to meet any new situation by reorganizing, and a wonderful method it can be for creating the illusion of progress while producing confusion, inefficiency, and demoralization.” (Petronius Arbiter, 66 AD)

Teams and teamwork are essential to the quality process. Organizations have to not just focus solely on the teams, but remember that the culture of the organization has to change to support the team effort. Teamwork can be productive only if the right climate exists. To build effective teams, barriers that prevent people from working effectively together must be removed. Whether problems take the form of a non-trusting we/they environment or a control oriented management group that wants to change but doesn't know how, issues must be identified and strategies developed to facilitate change. Teamwork leads to better ideas, improved job satisfaction, and improved organizational outcomes. Teamwork can achieve superior results. The complexity of healthcare dictates that no one person can have the answers to organizational success. To succeed, organizations must be creative and innovative with problem solving. The best way to enhance creative decision making is to increase brainpower and the minds of many to build synergy. There are many benefits to teamwork. Teams provide opportunities for learning and full participation of employees. Teams can:

- Improve productivity
- Encourage creativity
- Improve communication
- Enhance involvement
- Improve relationships
- Enhance problem solving
- Develop leadership potential
- Reduce errors
- Promote personal growth
- Provide linkages
- Share ideas & strong practices
- Facilitate learning about new tools
- Improve service delivered to customers
- Achieve efficiencies

Performance Improvement Teams

Performance improvement teams are established from groups of workers actually responsible for doing the work. People involved in a particular job know it better than anyone else. The quality process can give workers an opportunity to gain control over their jobs, as well as the ability to improve the organization overall. Teamwork improves communication between workers and management. With teams, people get involved, and involved people tend to resist change less. Involving people in the planning and design of change gives them the opportunity to think and solve problems, understand the plan, and develop a sense of ownership. Teamwork doesn't just happen. Every group of people is not a team and every team is not effective. There are several critical factors that support team formation. The right culture must be created to support the work of teams. Team should have adequate resources, the ability to implement decisions, the sponsorship of the managers, and an effective reward and recognition system. The appropriate training materials and time for skill building must be available during team formation. A standard problem solving process is also required for the team to stay on track. Leadership commitment to support the team effort is critical to success.

Types of teams

Improvement Teams (Quality Improvement Teams, Performance Improvement Teams)

Improvement teams are put in place to make organizational improvements. They have specific roles, team leader, member, and facilitator. They meet regularly and are approved the Quality Council or other group. They tend to focus on a defined issue and disband when the problem is addressed. They use a defined improvement process, tools, and techniques.

Natural Work Teams

These teams generally are already in place in certain areas. One type of a natural work team is a Self Directed Work Team. In the self-directed work team, employees can be responsible for functions that are usually done by management, such as staffing, scheduling, hiring, and evaluating work within their area. The supervisor assumes other roles than managing the department.

Functional Teams

These teams including members from a single functional area. They are part of a natural work group with a specific purpose or function. The classic functional team is a boss and his/her direct reports. This so called military model has been the staple of modern business. Despite all the talk about change, most organization charts still look like a pyramid. It may be a flatter pyramid, but it's a pyramid. Issues such as authority, relationships, decision making, leadership, and boundary management are simple and clear. They work well in traditional hierarchical organizations in stable, slow growth industries with predictable markers.

Cross-Functional Teams

These teams include members from multiple functional areas. Sometimes called multidisciplinary teams, they are part of the quiet revolution that is sweeping across organizations. A standard cross functional team is composed of those individuals from departments within the organization whose competencies are essential in achieving an optimal evaluation. Successful teams combine skills sets which no single individual possesses. They seem to be most effective in companies with fast changing markets, and industries that value adaptability, speed, and an intense focus on responding to customer needs. Advantages of cross functional teams include speed. Cross functional teams reduce the time it takes to get things done; especially in product development. They also improve an organization's ability to solve complex problems. Cross functional teams focus the organization's resources on satisfying the

customer's needs. By bringing together people with a variety of experiences and backgrounds, cross functional teams increase the creative capacity of an organization. Members of cross functional teams are more easily able to develop new technical and professional skills, learn more about other disciplines, and learn how to work with people who have different team player styles and cultural backgrounds than those who do not participate in cross functional teams. In addition, cross functional teams promote more effective cross team work by identifying one place to go for information and for decisions about a project or customer. The cross functional approach to quality planning is effective because team involvement promotes sharing of ideas, experiences, and a sense of commitment to being a part of helping the organization achieve its goal. The diversity of team members brings a more complete working knowledge of the product and processes to be planned. Planning requires a thorough understanding of how things get done in many parts of the organization. Representation from various departments or functions promotes the acceptance and implementation of the new plan throughout the organization. Products or processes designed with the active participation of the affected areas tend to be technically superior and accepted more readily by those who must implement them.

Self-Directed Teams

A self directed team is an intact group of employees who are responsible for an entire work process or segment that delivers a product or service to an internal or external customer. To varying degrees, team members work together to improve their operations, handle day to day problems, and plan and control their work. They are responsible not only for getting work done but for managing themselves. These can be used in some of the same industries as functional teams and in many others as well, particularly in start up sites or in organizations with an embedded base of participative management and a history of employee involvement.

Team Composition and Function

A team is generally composed of small numbers of people who have complementary skills. In a team, the team members are committed to a common purpose, goals, and objectives for which team members are mutually accountable. The small number of members on a team allows for more communication and time for everyone to be heard. Small numbers also reduce logistical problems of getting people together and finding adequate space, and allows for greater ease of interpersonal problem solving. Complementary skills will provide technical or functional expertise, problem solving and decision making skills, and interpersonal skills from among the members of the team. Because team members agree on a common approach, everyone is clear about how the work is to be done. Each member contributes unique skills for both task accomplishment and mutual learning. Each member has a role to play and a clear set of responsibilities. A common approach also provides mechanisms for problem solving, decision making, and setting priorities. Provision is made for internal turnover, introduction of new members, and allowance for new information. Because of mutual accountability, the team regards itself as sharing accountability for performance goals which become measures for accountability and evaluating the team's performance. Accountability develops commitment to purpose. Finally, trust and commitment develop from collaborative productivity.

Team player styles: Research has identified four types of team player styles, each with a unique set of strengths.

Contributor

Freely shares all relevant information and opinions with other team members

Helps the team use its time and resources

Pushes the team to set high standards and to achieve top level results; insists on high quality standards

Completes all team assignments other relevant homework necessary for the completion of team tasks

Accepts responsibility for all actions as a team member
Completes all work in his/her regular area and in other tasks not related to the team
Provides the team with clear, concise, and useful presentations at team meetings
Provides technical training for other team members and serves as a mentor for new team members

Collaborator

Helps the team establish long term goals and clarify its current objective or task
Helps the team see how its work fits into the total organization
Regularly reminds the team of the need to revisit the goals and action plans
Encourages the team to establish plans with milestones and appropriate task assignments
Pitches in to help out other team members who need assistance
Works hard to achieve team goals and to complete the current tasks, even though he/she may not agree
Does not gossip about other team members or share negative comments about team process with nonmembers
Is flexible and open to new ideas or data that may alter team goals
Often works outside his/her defined role to help the team achieve its goals
Is willing to share the limelight with other team members

Communicator

Steps in to resolve process problems, such as conflict among team members or lack of involvement by some
Listens attentively to all viewpoints while withholding judgment
Helps the team relax and have fun by joking, laughing, and discussing personal interests
Recognizes and praises other team members for their efforts
Communicates enthusiasm and a sense of urgency about the team's work
Periodically summarizes the status of a discussion or proposes a possible consensus
Encourages other team members to participate in the discussions and decisions on the team
Helps the people on the team get to know each other and to know what skills and resources each can contribute
Gives feedback to team members that is descriptive, specific, and intended to be helpful
Receives feedback from other team members without becoming defensive
Reminds the team to take the time periodically to assess team effectiveness & plan for improvement

Challenger

Candidly shares views about the work of the team
Is willing to disagree openly with the leadership of the team
Often raises questions about the team's goals
Pushes the team to set high ethical standards for work
Speaks out even when views are contrary to those of a vast majority of the team
Asks why and how and other relevant questions at team meetings
Sometimes is accused of not being a team player because he/she differs with conventional wisdom
Challenges the team to take well-conceived risks
Is honest in reporting team progress and stating problems facing the team
Is willing to blow the whistle on illegal and unethical activities of the team
Will back off when views are not accepted and will support a legitimate team consensus

Use of teams:

1. Provides better and more ideas
2. Involves the people who know best
3. Involves employees in solutions
4. Maintains pride and interest in work

5. Instills ownership of the process
6. Creates respect, cooperation, openness
7. Spreads quality
8. Gives everyone some air time
9. Provides strength in unity

Commitment to common purpose, goals, and objectives

1. Working together to shape a clear direction builds a common purpose and commitment.
2. Specific goals and objectives help define the results to be accomplished and the tasks needed.
3. Performance goals help the organization achieve its goals, but team goals are different.
4. Team goals are shorter term and account for small wins that are challenging, yet realistic.
5. Team purposes are achieved through accomplishment of specific team goals.

Team Work through Empowerment: Teams don't work effectively without empowerment. To be empowered, team members need to be given:

1. A clear role to play
2. The education and training required
3. The resources to get the job done
4. The freedom to be creative and innovative
5. The authority to exercise their best judgment
6. The responsibility to improve continuously
7. The recognition they deserve
8. A sense of ownership

Team roles

- **Team Leader**—guides the team to achieve successful outcomes and reach the established goals; concerned with what decisions are made; has specific responsibility for guiding the team through the meeting process to achieve the objective; involved in the meeting content as well as process; not responsible for making all decisions in a meeting or for the success or failure of the team; responsible for providing direction and support for the team; interested in driving change for the system.
- **Team Facilitator**—promotes effective group dynamics within the team; concerned with how decisions are made; is not a member of the team but a person outside the team who serves as a coach or consultant for the team; has specific responsibility for focusing on the meeting and improvement process; turns the light on; helps team come together; keeps the team on track; responsible for providing expertise regarding use of tools
- **Team Member**—shares knowledge and expertise of the process or issue addressed by the team; technical experts who understand processes; responsible for both the content and process of team meetings; shares responsibility for focusing on the objective, contributing information, analyzing data, staying on track, making decisions, managing time, continually improving the team

What a team leader should do:

- Conduct team meetings, staying focused on the agenda,.
- Provide direction and focus to team activities and team progress.
- Guide the team without dominating it, promote free exchange of ideas and involve all members in the problem-solving process.

- Use effective meeting skills & focus on tasks, time allocation,& work methods to ensure time is used productively.
- Coordinate arrangements and administrative details for team meetings.
- Ensure proper documentation of process & outcomes maintained for all team meetings/activities.
- Assist in tracking and measuring progress on team activities.
- Represent the team to the CQI council.
- Keep discussion focused on the topic and accomplishing objectives.
- Encourage participation and involvement from everyone.
- Maintain open, two way communication with the team and between team members.
- Assist the team in implementing action to accomplish result and meet goals.
- Standardize meeting time, place, and logistical arrangements.
- Restate opinions to show understanding.
- Learn to listen with the eyes, not just the ears.
- Summarize what has been said and/or suggested.
- Translate ideas into action steps.
- Clarify responsibilities and assignments.
- Develop mechanisms to follow up.

What a team facilitator should do:

- Seek opinions of team members, synthesize different ideas, test consensus and summarize key points during team meetings.
- Intervene if the discussion loses focus or moves off track.
- Consult with the team leader regarding team building, effective meetings, and other skills.
- Observe the team in action and help members of the team build strengths and overcome weaknesses.
- Assist the leader in processes such as team problem solving, decision making, & conflict management.
- Serve as a resource for team methods, tools, and techniques.
- Mediate and resolve conflicts among team members.
- Elicit opinions of less vocal members and make certain that more vocal members do not dominate team meetings.
- Suggest tools and techniques to assist team members in problem solving.
- Provide feedback & direction to team leaders on their ability to manage both team process & outcomes.
- Animate or inspire attention and commitment.
- Present information or demonstrate processes.
- Raise relevant questions, develop habits of self-questioning.
- Clarify difficulties or absurdities.
- Draw parallels or find relationships.
- Reflect feelings.
- Express agreement and support.
- Evaluate.
- Develop capacity for self-evaluation.
- Suggest specific tools to be used.

What a team member should do:

- Understand the team's mission and how to make a contribution to it.
- Offer perspective and ideas on issues addressed by the team;

- Participate in all team meetings, discussions, decisions and activities by attending meetings, listening, sharing ideas, and making suggestions.
- Adhere to meeting ground rules established by the team;
- Volunteer for action items and follow through with them.
- Perform assignments between meetings;
- Assist in preparing and presenting documentation and reports on team activities and outcomes;
- Share resources, knowledge, skills, and experience.
- Get along with team members by respecting their opinions and avoiding negative comments.
- Build team cohesiveness through participation.
- Represent work group.
- Communicate team activities to work group.
- Take part in setting goals and developing action plan for team; and
- Recommend agenda items for future meetings.

During the initial meetings, the roles of the team leader, team facilitator and team member are very distinct. As the team evolves into an effective team, the team roles begin to merge. For mature teams, team members begin to perform the responsibilities of the team leader and the facilitator.

Forming the team: Including the right people on a process improvement team is critical to a successful improvement effort. Teams vary in size and composition. Each organization builds teams to suit its own needs. First review the aim. Second, consider the system that relates to that aim: What processes will be affected by the improvement efforts? Third, be sure that the team includes members familiar with all the different parts of the process—managers and administrators as well as those who work in the process, including physicians, pharmacists, nurses, and front-line workers.

Guidelines for team selection ; When selecting a team, the quality council should identify those parts of the organization which have a stake in the outcome, including those who will be most affected by the results of the project, departments or functions responsible for various steps in the process, those with special knowledge, information, or skill in the design of the project, and areas that can be helpful in implementing the plan. Others include those who:

- Represent a piece of the process that is being studied for improvement.
- Identify with the team's goal.
- Gain from the team's efforts.
- Team players willing to forfeit individual needs for team objectives
- Have time for the project.

Team organization: The team organization does affect its effectiveness. Procedurally, all teams should have a team charter or mission statement and ground rules or rules of trust or conduct. The team should monitor its progress through minutes, agendas, team logs and process checks.

Team Charter: The team charter clearly identifies the team mission, expected improvements, boundaries and constraints, resources available and team representation:

- team mission—identifies what will be studied;
- expected improvements—outcomes that are to be accomplished by the team;
- boundaries and constraints—document where the team's mission starts or ends as well as the limits the team must face in addressing the mission;
- resources available—identifies who or what the team may access to accomplish its mission;
- team representation—states the major departments or areas represented on the team.

Sample Team Charter

Statement of problem:

Data to support problem exists: Yes No

Please explain how the problem impacts the process according to the organization's core values:

Quality or work or service

Customer satisfaction

Working environment

Cost effectiveness

Proposed name and title of team:

Team Leader:

Team Members:

Team Facilitator:

Ground Rules/Rules of Trust

The ground rules or rules of trust or conduct are the conditions established by the team members on acceptable behavior by the team members and how the meetings will be conducted. The ground rules should address attendance, time management, participation, communication, decision making and documentation.

- attendance—addresses the scheduling of meetings, legitimate reasons for missing a meeting and the process for informing the team leader of an absence;
- time management—identifies the start and end times for meetings, breaks, the number of members that need to be present to start a meeting and the timekeeper's role and responsibility concerning the meeting agenda;
- participation—states the members' responsibilities for meeting preparation and productivity during the meeting;
- communication—addresses criticism of others, confidentiality, interruptions and multiple conversations at the same time;
- decision making—identifies how conflict is handled and how consensus is reached;
- documentation—states how minutes are documented, where the minutes are stored and how agendas are prepared.

Enhancing team performance

Establish a sense of urgency with a message of high priority. The team should develop performance objectives that are clear, specific, measurable, and realistic. The team needs the authority and flexibility to establish and modify its own purposes, approaches, and priorities. The team should also have the opportunity to gather the information it needs and to deal with obstacles in its own way. This provides empowerment for the team. Base team membership on needed skills, not personalities. Selection of team members should focus on those with technical/functional skills, problem-solving/decision-making skills, and interpersonal skills. Potential teams should select individuals with potential skills for the project selected. Team training should be provided on a "just-in-time" basis. For team membership, strive for a balance between those with existing skills and those with skill potential.

Pay special attention to first meetings and activities. Recognize that beginning teams bring assumptions, values, beliefs, and attitudes about each other, especially those in authority. Team leader behavior will influence team climate and performance. Impressions are strongly developed at first meetings and are difficult to change later. The concept of shared team leadership needs to be established very early in the team's meetings. Be aware of reputations that others bring to the meetings. Establish clear behavioral standards and expectations for the team. Clarify expected interpersonal standards of behavior, ethics, and conduct. Determine functional rules regarding attendance, participation, taking

phone calls, confidentiality, and other factors the team agrees to live by (rules of trust). The adherence to rules determines internal and external team credibility. Establish a system for ensuring compliance with rules.

Identify opportunities for quick successes. Set challenging, achievable goals early on. Small successes are extremely important for building a team track record of success, which is essential for instilling confidence and growth. Keep goals flexible; not every goal is achievable. Subjective goals should be established after objective goals have been accomplished. Keep the team updated with new facts. New information helps keep the team's focus on performance goals and helps to maintain the sense of urgency. Team failures can be attributed to assuming that all necessary data and information is available to members. The team should establish mechanisms for receiving new information and hearing useful feedback. It's important that the team invests a lot of time together. Spending time together is particularly important during the team's initial forming stage. Provide both scheduled and unscheduled time for the team to meet if possible. Encourage informal interactions. Not all time together needs to be face to face; include creative activities like electronic mail or other communication avenues. More time together is needed when the group is having problems than when the group is doing well. Maximize positive feedback, recognition, and reward. Encourage interpersonal recognition among team members. Encourage team members to develop trust and support for each other. Provide special praise and appreciation as often as possible. The ultimate reward for the team will be outstanding team performance.

Stages of Team Growth

Stage 1: Forming

During the first stage the team agrees on the goal or vision, and tasks are delegated. The group is not yet a team, but members seek each other's input. The group orients itself to its assigned task. Discussions focus on how to accomplish its task and the information and resources that are needed. This is a period of testing and discovery to find out what kind of behavior is appropriate and members tend to defer to the leader or dominant member for guidance. This stage is relatively short if the task is clearly defined and easy to achieve.

Stage 2: Storming

The second stage is where conflict typically arises. Members try to express their individuality and resist group pressures and influence. There are often emotional responses to the demands being made, especially if the group is under pressure to achieve results. Some groups may get stuck in this phase as they face the discrepancy between initial expectations and the reality of the situation.

Stage 3: Norming

The norming stage is where conflict is resolved. During this stage, group cohesion develops and a sense of group identity begins to emerge. There is a willingness to listen to and accept the views of others. The group develops feelings of mutual respect, harmony and trust. Group standards and members' roles emerge.

Stage 4: Performing

The fourth stage is where the team works harmoniously towards a common goal. The group is highly productive during this stage and solutions to problems are found. The team develops a functional, but flexible structure and roles are interrelated. Interpersonal conflicts are resolved and the group is highly task-oriented.

General Team Guidelines

- Meet regularly

- Assign tasks and set deadlines
- Share workload equally
- Ask questions/never a stupid question
- Turn ideas into action steps
- Maintain positive attitude

Evaluating team performance

In addition to evaluating team outcomes, at the end of each team meeting the members should evaluate team effectiveness. During this process check the team should identify what the members like about the current team process as well as what could be done differently to improve the team meeting. The process check should address such issues as participation, climate, candor and criticism occurring during the meeting. By performing a process check at the end of each meeting, the team can continually improve its dynamics. A simple way to evaluate the effectiveness of performance improvement teams, is to review the characteristics of an effective team.

Effective teams exhibit the following characteristics

- Mutual agreement and identification with respect to primary task
- Open communications
- Mutual trust
- Mutual support
- Management of human difference
- Selective use of the team
- Appropriate member skills
- Leadership
- Values and goals of the group are interpreted as the needs and values of the members
- Group believes it can accomplish the impossible
- Understanding the nature and value of constructive conformity and when and how to use it
- Mutual influence between members and the leader
- Clear goals, purposes, individual steps, meetings, discussions, and decisions
- Agreement on workable mission
- Formally designated roles
- Improvement plan, revised as needed
- Flowchart or similar document describing project steps
- Effective use of member's talents
- Balanced participation with everyone involved
- Good, open discussions
- Clarification and/or elaboration on ideas
- Use of consensus decision making
- Use the scientific approach relying on good data for problem solving
- Resources and training throughout the project

Examples of Effective Teams

Effective teams include members representing three different kinds of expertise within the organization: system leadership, technical expertise, and day to day leadership. There may be one or more individuals on the team with each kind of expertise, or one individual may have expertise in more than one area, but all three areas should be represented in order to drive improvement successfully.

Teams need someone with enough authority in the organization to institute a change that has been suggested and to overcome barriers that arise. The team's system leader understands both the implications of the proposed change for various parts of the system and the more remote consequences

such a change might trigger. It is important that this person have authority in all of the areas that are affected by the change. This person must have the authority to allocate the time and resources the team needs to achieve its aim.

A technical expert is someone who knows the subject intimately and who understands the processes of care. An expert on the improvement methods can provide additional technical support by helping the team determine what to measure, assisting in design of simple, effective, measurement tools, and providing guidance on collection, interpretation, and display of data.

A day to day leader is the driver of the project, assuring that tests are implemented and overseeing data collection. It is important that this person understands not only the details of the system, but also the various effects of making changes in the system. This person also needs to be able to work effectively with the physician champions.

Ineffective teams exhibit the following characteristics

- Not distinguishing between facts, opinions and feelings
- Not separating the generation of ideas from the evaluation of those ideas
- Premature closure before all alternatives are identified
- Dominance by members with status of aggressive members
- Unproductive competition or conflict
- Failure to assign specific responsibilities
- No review of minutes, tasks or due dates
- Working on problems outside the scope of the group or too difficult to handle
- Uncertainty about the team's direction
- Launching many improvement projects without clear objectives
- Roles and duty assignments resulting from a pecking order
- Confusion over who is responsible for what
- People getting stuck with the same tedious chores
- Poor speaking skills
- Members unable to say what they really feel
- Hidden undercurrents with lack of reference to those issues
- Opinions expressed as facts or phrased as questions
- Failure to use discussion skills
- Reliance on one person to manage the discussion; no shared responsibility
- Discussions in the hallway after the meeting are more free and candid than those during the meeting
- People repeating points, unsure if anyone heard them in the first place
- Conceding to opinions that are presented as facts with no supporting data
- Decisions by one or two people in the group, without team members agreeing to defer to their expertise
- Too frequent recourse to majority rules or other easy approaches that bypass strong disagreement
- Decision by default; people don't respond to a statement and silence interpreted as consent
- Some team members have too much influence; others too little
- Participation depends on the subject being discussed
- Members too often contribute only at certain times in a conversation or meeting
- Some members speak only about a certain topic
- Certain important topics are avoided
- No one acknowledges the norms/ground rules
- Recurring differences about what is or is not acceptable behavior
- Behavior that signifies irritation
- Conflicting expectations
- Pushing ahead on the task when there are nonverbal signs of resistance, confusion, or disappointment
- Inattention to obvious clues and shifts in the group mood

- Members attributing motives to nonverbal behavior
- Remarks that discount someone's behavior or contribution, or group process issues
- Team members insist they don't need data before making decisions
- Wild stabs at supposed solutions, jumping to conclusions, too many inferences, and assumptions, shooting from the hip, hasty action

For a manager responsible for team development or the leader of a team:

- Insist on a clear team goal and a plan to achieve it
- Work hard to gain the commitment of team members & other stakeholders to the team's goal
- Emphasize collaborative efforts and team rewards
- Provide training on how to work with a diverse group of people
- Create a set of policies and procedures that support a team based environment

A Successful Team Needs

- Clarity in team goals
- An improvement plan
- Clearly defined roles
- Clear communication
- Beneficial team behaviors
- Well defined decision procedures
- Balanced participation
- Established ground rules
- Awareness of the group process
- Use of the scientific approach

Organizing Information for Committee Meetings

No one wants to sit through an inefficient meeting. Instead, people want to participate in meaningful sessions that get results. This is more likely to happen by following the basics of productive meetings.

- **Lay the foundation with good background**

Invest time up front to ensure the success of the meeting. Have important information available to members well in advance of the meeting. This could include information on the strategic plan, results of surveys, organization goals and objectives, policies, past minutes, agendas, and financial statements. To help people focus on changes that they may be dealing with, information on industry changes is always helpful. Other aspects to consider include frequency, location, duration, conflicts with other obligations, and group composition. Equally important is the need to document meeting results and ensure timely follow up.

- **Prepare a productive agenda**

Give participants the following information before the meeting:

- Meeting venue, date, and time
- A timed agenda focusing on the topics that need to be handled
- Participant roster
- All materials related to issues that will be discussed and need action
- Assign pre work
- Minutes of the last meeting
- Report or briefing document for every agenda item if possible
- Financials (if applicable)

- Use a consent agenda to handle routine business so people don't waste time discussing reports.

The agenda for the next meeting is established at the end of the team meeting. The agenda should include not only the agenda item but also the person responsible for the agenda item and the amount of time allocated to each agenda item. The minutes for each meeting should clearly document the date of the meeting, the members present, key discussion points and major decisions and action items. When developing the meeting agenda, consider whether the topics are intended for information, discussion and debate, or decision. In an ideal world, every topic on the agenda will be a report or similar documentation prepared in advance and included with the agenda. If the topic requires a decision, include a clear recommendation supported by sufficient information in the report so the team can make an informed decision during the meeting.

Pre-meeting checklist

Reserve meeting space, if necessary

Post or send meeting announcements

Gather flip chart pads, markers, masking tape, post it pads, paper

Establish a follow up process to reinforce the learning

Set aside first 5-10 minutes of next meeting to discuss connecting

- **Run the meeting right**

Reserve meeting time for items that support and advance the strategic plan. Use titles of strategic objectives as headers for the agenda. This allows you to at least review those strategic objectives that do not require in-depth discussion. Rank proposed topics by urgency and importance. Items that are both urgent and important should be addressed before the next meeting. Make sure the meeting begins and ends on time. Hold members accountable for having read the background information in advance. Make clear what the group's priority is for the meeting. Questions that can make meetings more productive include:

- **Is this item consistent with the strategic plan?**
- **Will this help in day-to-day business?**
- **Do we have the resources to handle this project?**
- **Is this ethical?**

It's the responsibility of the team leader to control and direct the meeting, supported by the meeting secretary, regarding points of order and respecting the time. The team leader must strike a balance between encouraging discussion and questions and ensuring that all topics receive the required attention. Another challenge for the team facilitator or leader is to have contributions from each of the meeting participants, while preventing one or two voices from dominating the meeting. If the leader/facilitator is sensitive to this issue, he or she can usually maintain control without offending or discouraging the participants. Strive to delegate tasks to different members of the group, distributing the workload and getting everyone involved. Keep the conversation moving forward and encourage everyone to contribute. From time to time, the team leader should check for understanding of the issue; you don't want to prolong or even ruin a meeting because people are unclear about what's being discussed. Ask the following questions:

- **Is anyone having a difficult time with any of the assumptions or opinions, and if so, why?**
- **Are there points about which you would like more feedback?**
- **Are there any gaps in the information we have?**

Allow sufficient time in agenda planning if discussion of contentious issues is required. It's best to position these early in the meeting schedule and during the first half of the day when minds are fresh. Some topics require more open discussion and are therefore harder to plan. You don't want to stop

discussion if the issue is important and a decision is required. Finally, the team leader should make certain that the information growing out of the discussions are accurate and meaningful.

- **Take time for good follow up and evaluation**

Meeting minutes should be clearly written to reflect the decisions made, the deadlines for next steps, and the person or people responsible for taking action. Once this information has been spelled out, use e-mails between meetings to track progress on these items. Periodically, the team leader should ask the following questions:

- **Is there anything we need to do to enhance our meetings?**
- **Have we succeeded at doing our work and keeping up with our strategic plan?**

There are many opinions about how to record meeting minutes. Minutes are not a verbatim record of a discussion, but they should reflect the decisions made during the meeting and action items to be performed. Be sure to designate a person to take the official minutes for the meeting. In no case, should the team leader take this role. It's difficult to participate in a meeting and accurately record minutes at the same time. Action items should clearly define the action to be taken, the deadline for completion, and the individual or individuals responsible for the action. It may be helpful to make a separate action-item grid to follow the assignments from one meeting to the next.

Without question, well-run meetings do take careful planning and continual effort. Nevertheless, the meeting process can be exhilarating when it's meaningful and the team feels that it's accomplishing true work.

General Tips

- Focus on a few priorities, document more
- Use work groups and content experts, document & use attachments
- Maintain an annual list for each workgroup of what must be covered, document through checklists
- Trend data, document
- Provide food
- Invite customers

Guidelines for committee chairs for conducting effective committee meetings

- Submit committee material to members in advance so that materials are reviewed prior to the meeting; this allows members to focus on recommendations and follow up actions in the meetings
- Prior to the meeting, contact committee members with reporting functions to ensure they are prepared and action items have received appropriate attention
- Assure follow up items from previous meetings are reviewed and actions taken
- Encourages members through modeling of such behavior to ask critical questions regarding outlier issues on performance measures
- Maintain focused discussions and work within a designated time period
- Whenever possible, have a recording person at the meeting to complete minutes so that the attention of the chair can focus on running an efficient meeting
- At the conclusion of a discussion non an agenda item, summarize the committee's recommendations and follow up plan; prioritize items identified for follow up; many items may need follow up, but given resources are finite, prioritization is essential; some items may need to be monitored longer before action is taken; document in the minutes rationale of the prioritization
- Use time limited workgroups composed of 2-3 individuals to review special concerns and to make recommendations to the committee
- Ensure minutes are signed, dated, and attachments specified

Meeting Example: Creating Agenda for Board Meeting

Be responsible

One of the primary responsibilities is the preparation for and facilitation of board meetings. Don't leave the effectiveness of the board meetings up to chance. You can't show up with a brief agenda and rely on the board to do the rest.

Help the board prepare

Preparation is critical for ensuring that boards are able to do their jobs well. Boards should be governing, not managing; overseeing, not doing. To achieve that, board members need to be informed. They need a fruitful forum for discussion, and they need help in elevating that discussion to the right level.

One of the best tools to help members arrive informed is the board preparation package. Remember that the main reason for this packet is to help members make informed decisions about important strategic and policy issues. If too many specifics are provided in the packet, the board will follow the lead and dive into questions that are overly detailed.

Specifics for creating useful board packets:

- Include the proposed meeting agenda
- Prepare high-level summaries of the information to be discussed; do not merely copy existing staff reports
- Use graphic, dashboard-type reports of key indicators such as financial status and program success
- Add executive-level reports from each committee
- Provide a proposed consent agenda
- Send the packets out at least one full week before the meeting

When determining what to include in the board packet, it's important to balance keeping the packet small with including required meeting information. Too much meeting time is wasted presenting materials that could have been provided earlier as background reading. On the other hand, make sure that all necessary materials are included in the board packet.

Create a great agenda

An excellent board packet alone will not guarantee a productive meeting. Take the time to prepare a focused agenda: Such an agenda will:

Help the members prepare

Send a message about the time to be devoted to each topic

Provide a guide for running the meeting and staying on time

Indicate the appropriate level of discussion on each issue, and

Ensure a focused discussion

At least two weeks before the board meeting, contact each of the board committee chairs and executive director regarding the topics to be discussed at the next board meeting. Then, write a one page agenda for a 2-3 hour meeting. Each agenda item should include:

The name of the presenter

An estimate of the time required for each discussion

The action being requested (information, decision, input)

The location of the relevant background materials in the board packet

Since board members should be focused on strategic & policy-level issues, make sure most of meeting is reserved for those discussions. One way to save time for important discussions is to use a consent agenda covering routine actions that require board approval. Any board member can request that an item be removed from the consent agenda and opened for discussion. The items that stay on the consent agenda are voted on together as a block, without any discussion. Once the entire board meeting agenda has been

drafted, go back over it and imagine having each discussion. If there is not enough time for all the discussions, some items must be deleted.

Be a Facilitator

Once the board packets have been distributed, next responsibility is to run a productive meeting. The most effective chairs are facilitators, not generals who tightly control everything. A facilitator introduces the topics, keeps the meeting on track, encourages appropriate participation by each member, manages conflicts, re-focuses the group on the issues at hand, and ensures that the discussions are strategic. Specific suggestions for facilitating a good meeting:

- Begin and end on time

- Start with a few, quick, easy items to get the board rolling (introduce new members and guests, approve agenda for this meeting)

- Discuss questions about the key indicator report

- Move to the substantive issues while the group is still fresh

- Allow time for committee chairs to highlight significant items in their reports or to ask for the board's approval of an item. Remember, a board should trust the work of its committees, not re-hash committee discussions.

Be flexible

Historically, boards have used Robert's Rules of Order to manage their deliberations and decision making. They may no longer be an appropriate tool for running board meetings. Although the Rules may still be needed when a very large group is convened to help keep order, they often cause a board to become highly rigid and formal. The Rules may inhibit openness and the free flow of conversation that are needed to ensure that important topics are discussed thoroughly. Well-facilitated discussions and decision making processes are much more important than the stiff deliberations forced by the Rules.

Learn from successes and mistakes

Many boards are now including time at the end of their meetings for a quick evaluation. The board chair facilitates a brief discussion in which the members state what they thought went well and what they would like done differently at the next meeting. This information is included in the meeting minutes, and the board chair uses the comments to help structure the next meeting.

Board meetings are most effective when the board is clear about its role as an oversight body; when it has received the appropriate level of preparation material in a timely fashion; when its meetings are well managed, and when its discussions are strategic, honest, and focused. Well crafted board preparation packages and agendas help boards do their work efficiently and effectively.

Sample board agenda

Name of Organization

Board of Directors Meeting

Board Room

Date, time

TIME AGENDA ITEM PRESENTER OBJECTIVE BACKGROUND MATERIALS

Welcome and Board Chair Information

Introductions

Approval of agenda

Executive director information

Key indicator report

Strategic plan review

Break

Committee chair reports
Consent agenda
Meeting evaluation
Adjournment

Customers

Identify the customers: The customer process contains the following elements:

- Identify customers & their requirements.
- Focus quality/performance improvement efforts on functions and processes as the customer see them, rather than to focus simply on departmental borders.
- Identify internal and external customers and suppliers for processes.
- Determine customer requirements.
- Interview customers about requirements. Use questionnaires & surveys. Ask questions & listen.
- Conduct focus groups of customers to determine customer requirements.
- Develop operational definitions.
- Ask key questions to define complete requirements: What? When? Who? For Whom? Where? Why? How?
- Suggest improvements: Define objectives. Determine priorities. Determine origin of work. Monitor customer opinion.

Customer Service

During the 1980's, customer service emerged as a critical success driver in many companies that pursue the management approaches of leading edge enterprise. The compelling logic behind the importance of customer service is simple. As rapid cycle times diminish the ability of providers to differentiate their products, customer service is one of the very few way. to motivate customers to enhance behaviors that affect the organization's profitability. Customer service includes transactions with customers and relationships with customers that occur before and after purchase of product or service.

Customer in healthcare is an all-inclusive term that is much broader than just the patient. It includes patients' families, physicians, nurses, other healthcare professionals, co-workers, professional associations, third party payers, and students. For any transaction involving a product, service, or information, the person or organization who provides that product, service, or information is the supplier. The person or organization who receives the product, service, or information is the customer. The customer at one step in the process normally becomes the supplier to another customer in the next step of the process. Everyone is a supplier and customer at different times. The supplier and customer relationship is different for each transaction and has nothing to do with money.

Customer requirements. Once your internal and external customers have been identified, the next step is to define valid customer requirements for each customer by talking directly with them. There may be some confusion among terms like needs, wants, expectations, and requirements. Valid customer requirements include any needs, wants, and expectations of customers for which an agreement has been reached between the supplier and the customer.

To establish customer requirements:

1. Encourage staff to identify all customers for each service.
2. Talk directly with customers.
3. Understand customer needs and desires.
4. Start with the most important requirements.

5. Negotiate, if appropriate.
6. Offer better alternatives.
7. Establish measures for requirements

Don't assume that you know customer requirements without asking. Don't assume that initial requirements are fixed; negotiation is generally always a possibility, and there are bound to be changes. Don't try to establish all requirements at once. Link internal and external customer requirements. Requirements of internal customers should be linked to those of external customers. If an internal requirement does not in some way help meet external customer requirements, then its value should be questioned. For example, if an internal management report doesn't include information relevant to meeting the requirements of patients, payers, referring physicians, or other external customers, it may not add value.

Link to needs and health status of community. The ultimate objective of a healthcare system is to improve health. Yet most healthcare organizations focus almost exclusively on treating sick patients that come to them for care. Using data from state or local health departments, the healthcare needs and health status of the community or service area should be estimated. These serve as indicators of the extent to which your organization and others are collectively improving health status. If a healthcare organization looks only at those people currently served, it may experience two major omissions. First, it may exclude people in its community or service area who are not served appropriately by any healthcare provider. The organization may be providing high quality high technology services to its patients, while others don't have basic services, such as prenatal care. Second, there may be opportunities to improve healthcare and health status that are outside of the organization's current scope of services. For example, providing obstetrical services in a predominantly senior citizen community. A comprehensive analysis of health status and needs may lead to the ability to serve customers better and to improve health within the service area.

Customers may not verbalize all requirements. When asked, customers will verbalize perceived requirements. Quality has been divided into 3 different dimensions; one-dimensional quality, attractive or unexpected quality, & must-be or expected quality. One-dimensional quality measures, such as waiting times, are readily perceived, & customers are often sensitive to such measures. As the measure is better fulfilled, customer satisfaction steadily increases. These measures are normally mentioned when customers are asked about requirements. On the other hand, the other two types of quality measures are usually not mentioned when customers are surveyed. Attractive or unexpected quality, such as a staff member stopping work to assist a lost visitor, is seldom mentioned during surveys or interviews because the customer may not have experienced this type of service before. However, this type of quality delights customers. Must-be or expected quality is also usually not mentioned during surveys or interviews because the customers expect this level of service. Patients usually don't mention the avoidance of a hospital-acquired infection during an admission, because they don't expect to experience one.

The philosophy, methods, and tools for the continuous improvement of customer service are similar to those for other functions. It's important to remember that continuous improvement involves incremental improvement when appropriate and discontinuous improvement when required. Part of the improvement process involves continual environmental scans in search of early warning signs of changing markets, new opportunities, and new competitive threats. In some cases, the improvement needs or opportunities will be customer driven, in some cases they will be competitor driven, and in some cases they will be driven by emerging technological capabilities. Generally there are two types of customers, the external customers (those outside the producing organization) and the internal customers (those inside the producing organization).

External customers

The term customer is often used loosely; it can refer to an entire organization, a unit of a larger organization, or a person. There are many types of customers, some obvious, others hidden.

Major categories include:

Purchaser: Buys the product for himself or for someone else.

End user/ultimate customer: Finally benefits from the product.

Merchants: Purchase products for resale, wholesalers, distributors, brokers; anyone who handles the product,

Processors: Organizations & people who use the product or input and output for producing own product.

Suppliers: Provide input to the process, i.e., manufacturer, etc. Suppliers are also customers who have information needs with respect to product specification, feedback on deficiencies, predictability of orders.

Original equipment manufacturers: Purchasers of a product to incorporate into their own.

Potential customers: Not currently using the product but capable of becoming customers.

Hidden customers: Different customers who are easily overlooked such as regulators, critics, opinion leaders, testing services, payers, media, public at large, those threatened by the product, corporate policymakers, labor unions, professional associations.

Internal customers

Everyone inside an organization plays three roles: supplier, processor, and customer. Each individual receives something from someone, does something with it, and passes it to a third individual. Effectiveness in meeting the needs of these internal customers can have a major impact on serving the external customers. Identifying internal customers requires analysis because many relationships tend to be informal, resulting in a hazy perception of who the customers are and how they will be affected. Most organizations try to set up a mechanism that will allow seemingly competing functions to negotiate and resolve differences based on the higher goal of satisfying customer needs. However, these mechanisms do not often work because the needs of internal customers are not fully understood, and communication among the functions breaks down. A major goal of the quality planning process is to discover who the internal customers are, what their needs are, and plan how those needs will be satisfied.

Discover customer needs:

Discover the needs of both internal and external customers for the product, including:

- Planning to collect customers' needs
- Collecting a list of customers' needs in their language
- Analyzing and prioritizing customers' needs
- Translating their needs into the organization's language
- Establishing units of measurement and sensors

Needs of human beings are both varied and complex, and actions of customers are often not consistent with what they say they want. The challenge for quality planning is to identify the most important needs from the full array of those needs expressed or assumed by the customer so that the product can delight the customer. When designing a product, there are two aspects to be considered, technology elements of what the product's or service's features will actually do or how it will function, and human elements of the benefits customers will receive from using the product or service. Both needs must be considered together.

Discovering customer needs is a complex task. Experience shows that customers usually do not state, in simple terms, exactly what they want; often they don't even mention some of their most basic needs. One of the ways customers express their needs is in terms of problems they experience and their expectation that a product will solve their problems. The art and science of discovering needs are to understand exactly the benefits that the customer expects. When a product or service meets the

customer's needs, it gives the customer a feeling of satisfaction. If the product or service isn't delivered defect free, the customer feels dissatisfaction. Even if a product functions the way it has been designed, a competing product, by virtue of superior service or performance, may provide customers with greater satisfaction.

Failure to grasp the difference between stated needs and real needs can undermine a quality planning project. Understanding the real needs doesn't mean that the organization can dismiss the customers' statements and substitute their own superior technical understanding as being the customers' real needs. Understanding the real needs means getting answers to the following questions:

- Why is the customer buying this product?
- What service does he expect from it?
- How will the customer benefit from it?
- How does the customer use it?
- What has created customer complaints in the past?
- Why have customers selected competitor products over ours?

Types of Customer Needs

Perceived needs: Customers understandably state their needs based on their perceptions. These may differ entirely from the supplier's perceptions of what constitutes product quality.

Cultural needs: Needs of customers go beyond products & processes and include primary needs for job security, self respect, respect of others, continuity of habit pattern, and other cultural values that are usually not stated openly. Any proposed change becomes a threat to those values.

Needs traceable to unintended use: Quality failures may occur because a customer uses a product in a different manner than that intended by the supplier. Questions to ask:

- What will be the actual use?
- What are the associated costs?
- What are the consequences of adhering only to intended use?

Safety needs: Effort must be put into reducing risks to human health, safety, and the environment.

User friendly needs: Product features should enable users to readily make use of products; information should be simple, unambiguous, readily understood, and broadly compatible.

Promptness of service needs: Services should be prompt.

Customer needs related to deficiencies: In the event of failure, customers need to get service restored and to get compensated for associated losses and inconvenience. The ideal solution is to plan quality so there are no failures.

Customer Complaints

Effects of complaint handling: While complaints deal primarily with product or service dissatisfaction, dissatisfied customers don't always complain. Research has shown that 70% don't complain because the effort to complain isn't worth it. They believe that complaining won't do any good, and they don't know how to complain. More than 40% of complaining customers were unhappy with the responsive action taken by the suppliers. Future product use is strongly influenced by action taken on complaints. An organized approach to complaint handling provides a high return on investment. This approach could include:

- A response center staffed 24/7 for access by customers and/or toll free telephone number
- Special training for employees who answer the phones and/or handle complaints
- Active solicitation of complaints to minimize loss of future customers

Keeping customers informed: Customers are quite sensitive to errors and mistakes and have a need to be kept informed regarding these. They want to be informed as to the nature of the problem and the likely solution.

Plan to collect customer's needs: Customer needs keep changing. There isn't a final list of needs. Even in the middle of a planning process, forces such as technology, competition, social change, and others can create new customer needs or may change the priority given to existing needs. It becomes extremely important to check with customers frequently and monitor the marketplace. Often customers do not express their needs in terms of the benefits they wish to receive from purchasing and using the product or service.

Ways to collect information on customer needs:

- Customer surveys, focus groups, and market research programs and studies
- Routine communications, management reviews, publications
- Tracking customer complaints, incident reports, letters, telephone contacts
- Simulated use experiments & planning processes that involve the customers
- Employees with special knowledge of the customer
- Customer meetings
- User conferences for the end user
- Information on competitor's products
- Government, independent laboratory data
- Changes in federal, state, and local regulations that will identify new needs or opportunities
- Competitive analysis & field intelligence comparing products with those of competitors
- Personal experience dealing with the customer
- Personal visits to customer locations with observations of
 - How product is used
 - Unintended uses
 - Service failures by others
 - What current or new features will relieve onerous tasks
 - Changes in habits and culture
 - Changes in sales
 - Changes in prices
 - Purchase of options

Collect lists of customer needs in their language: For customer needs to have significant meaning, they must be stated in terms of benefits sought. Capture needs in the customer's voice. Stating needs in terms of benefits sought also can reveal opportunities for improved quality that often can't be seen when concentrating on product or service features alone.

Complaints, Grievances, and Appeals

Example of Medicare complaint: Complaints are patient issues that can be resolved promptly or within 24 hours and involve staff who are present, (e.g., nursing, administration, patient advocates) at the time of the complaint. Complaints typically involve minor issues such as room housekeeping or food preferences that do not involve investigation or peer review processes. Most complaints will not require that the facility send a written response to the patient. Even if the patient's complaint is addressed quickly and informally, the facility should document the complaint and the actions taken to resolve it and maintain the records for quality improvement activities.

Example of Medicare grievance: A grievance is any complaint or dispute (other than an

organization determination) expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Medicare health plan, or its providers, regardless of whether remedial action is requested. The enrollee must file the grievance either orally or in writing no later than 60 days after the triggering event or incident precipitating the grievance. Listed below are some examples of problems that are typically dealt with through the plan grievance process:

- Problems getting an appointment, or having to wait a long time for an appointment

- Disrespectful or rude behavior by doctors, nurses or other plan clinic or hospital staff

Each plan must provide meaningful procedures for timely hearing and resolving both standard and expedited grievances between enrollees and the Medicare health plan or any other entity or individual through which the Medicare health plan provides health care services. The Medicare health plan must include in its grievance procedures:

- The ability to accept any information or evidence concerning the grievance orally or in writing not later than 60 days after the event; and

- The requirement to respond within 24 hours to an enrollee's expedited grievance whenever:

- A Medicare health plan extends the time frame to make an organization determination or reconsideration; or

- A Medicare health plan refuses to grant a request for an expedited organization determination or reconsideration.

Plans must notify all concerned parties upon completion of the investigation as expeditiously as the enrollee's case requires based on the enrollee's health status, but not later than 30 days after the grievance is received. For more information about the grievance process, see section 20.3 in Chapter 13 of the Medicare Managed Care Manual. A copy of the model notice plans may use to notify enrollees about their right to an expedited grievance is located in Appendix 5 (available on <http://www.medicare.gov>). Grievances about Part D prescription drugs are not processed using these procedures. For information on how to file a grievance about prescription drugs, click on the link to Chapter 18 of the Prescription Drug Benefit Manual (available on <http://www.medicare.gov>). Quality of care grievances (complaints about the quality of care received in hospital or other provider settings) may be reported through the plan's grievance procedures, the enrollee's Quality Improvement Organization (QIO), or both.

The Medicare website <http://www.medicare.gov> provides specific information.

For example, Medicare defines a grievance as a complaint about the way the Medical health plan or Medicare drug plan is giving care. Enrollees may file a grievance if they have problems call the plan or if they are unhappy with the way a staff person has behaved towards them. However, if they have a complaint about a plan's refusal to cover a service, supply, or prescription, they should file an appeal. An appeal is an action that enrollees can take if they disagree with a coverage or payment decision made by Medicare, a Medicare health plan, or a Medicare Prescription Drug Plan. Enrollees have the right to appeal if one of the following is denied:

- A request for a health care service, supply, item, or prescription drug that patients think they should be able to get

- A request for payment of a health care service, supply, item, or prescription drug that patients already got

- A request to change the amount patients must pay for a health care service, supply, item, or prescription drug

- Enrollees can also appeal if Medicare or a plan stops providing or paying for all or part of a health care service, supply, item, or prescription drug patients think they still need.

CMS Conditions of Participation - Patient Rights §482.13 - The Grievance Process

§482.13 Condition of Participation: Patient's Rights

A hospital must protect and promote each patient's rights.

Interpretive Guidelines §482.13

These requirements apply to all Medicare or Medicaid participating hospitals including short-term, acute care, surgical, specialty, psychiatric, rehabilitation, long-term, children's and cancer, whether or not they are accredited. This rule does not apply to critical access hospitals. (See Social Security Act (the Act) §1861(e).)

These requirements, as well as the other Conditions of Participation in 42 CFR 482, apply to all parts and locations (outpatient services, provider-based entities, inpatient services) of the Medicare participating hospital. Survey Procedures §482.13

Survey of the Patients' Rights Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.

A-0116

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a) Standard: Notice of Rights

Interpretive Guidelines §482.13(a)

The hospital must ensure the notice of rights requirements are met.

A-0117

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a)(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

Interpretive Guidelines §482.13(a)(1)

The hospital must inform each patient, or when appropriate, the patient's representative as allowed by law, of the patient's rights. Whenever possible, this notice must be provided before providing or stopping care. All patients, inpatient or outpatient, must be informed of their rights as hospital patients. The patient's rights include all of those discussed in this condition, as well as any other rights for which notice is required under State or Federal law or regulations for hospital patients. (See 42 CFR 482.11.) The patient's rights should be provided and explained in a language or manner that the patient (or the patient's representative) can understand.

In addition, according to the regulation at 42 CFR 489.27(b), (which cross references the regulation at 42 CFR 405.1205), each Medicare beneficiary who is an inpatient must be provided a standardized notice, "An Important Message from Medicare" (IM), within 2 days of admission. Medicare beneficiaries who have not been admitted (e.g., patients in observation status or receiving other care on an outpatient basis) are not required to receive the IM. The IM is a standardized, OMB-approved form and cannot be altered from its original format. The IM is to be signed and dated by the patient to acknowledge receipt. See Exhibit 16 for a copy of the IM. Furthermore, 42 CFR 405.1205(b)(3) requires that hospitals present a copy of the IM in advance of the patient's discharge, but not more than two calendar days before the patient's discharge. In the case of short inpatient stays, however, where initial delivery of the IM is within 2 calendar days of the discharge, the second delivery of the IM is not required.

The hospital must establish and implement policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights.

Survey Procedures §482.13(a)(1)

Determine the hospital's policy or notifying all patients of their rights, both inpatient and outpatient;

Determine that the information provided to the patients by the hospital complies with Federal and State law;

Review records and interview staff to examine how the hospital communicates information about their rights to diverse patients, including individuals who need assistive devices or translation services. Does the hospital have alternative means, such as written materials, signs, or interpreters (when necessary), to communicate patients' rights?;

Ask patients to tell you what the hospital has told them about their rights;

Does staff know what steps to take to inform a patient about their patients' rights, including those patients' with special communication needs?; and

Review a sample of inpatient medical records for Medicare beneficiaries, to determine whether the records contain a signed and dated IM provided within 2 days of the admission of the patient. For patients whose discharge

occurred more than 2 days after the initial IM notice was issued, determine whether the hospital provided another copy of the IM to the patient prior to discharge in a timely manner.

A-0118

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a)(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

Interpretive guidelines §482.13(a)(2)The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although 482.13(a)(2)(ii) and (iii) address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverage may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response. The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency. The hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process.

A "patient grievance" is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient's representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Hospital Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489.

"Staff present" includes any hospital staff present at the time of the complaint or who can quickly be at the patient's location (i.e., nursing, administration, nursing supervisors, patient advocates, etc.) to resolve the patient's complaint.

If a patient care complaint cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further actions for resolution, then the complaint is a grievance for the purposes of these requirements. A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.

Billing issues are not usually considered grievances for the purposes of these requirements. However, a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489 is considered a grievance.

A written complaint is always considered a grievance. This includes written complaints from an inpatient, an outpatient, a released/discharged patient, or a patient's representative regarding the patient care provided, abuse or neglect, or the hospital's compliance with CoPs. For the purposes of this requirement, an email or fax is considered "written."

Information obtained from patient satisfaction surveys usually does not meet the definition of a grievance. If an identified patient writes or attaches a written complaint on the survey and requests resolution, then the complaint meets the definition of a grievance. If an identified patient writes or attaches a complaint to the survey but has not requested resolution, the hospital must treat this as a grievance if the hospital would usually treat such a complaint as a grievance.

Patient complaints that are considered grievances also include situations where a patient or a patient's representative telephones the hospital with a complaint regarding the patient's care or with an allegation of abuse or neglect, or failure of the hospital to comply with one or more CoPs, or other CMS requirements. Those post-hospital verbal communications regarding patient care that would routinely have been handled by staff present if the communication had occurred during the stay/visit are not required to be defined as a grievance.

All verbal or written complaints regarding abuse, neglect, patient harm, or hospital compliance with CMS requirements are considered grievances for the purposes of these requirements.

Whenever the patient or the patient's representative requests that his or her complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, the complaint is considered a grievance and all the requirements apply.

Data collected regarding patient grievances, as well as other complaints that are not defined as grievances (as determined by the hospital), must be incorporated in the hospital's Quality Assessment and Performance

Improvement (QAPI) Program.

Survey Procedures §482.13(a)(2)

Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. Does the hospital adhere to its policy/procedure established for grievances?

Interview patients or the patient's legal representative to determine if they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance).

Is the hospital following its grievance policies and procedures?

Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger are resolved in a timely manner?

Does the patient or the patient's representative know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?

Has the hospital provided the telephone number for the State agency to all patients/patient representatives?

Are beneficiaries aware of their right to seek review by the QIO for quality of care issues, coverage decisions, and to appeal a premature discharge?

A-0119

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a)(2) (Continued)

[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.] The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

Interpretive guidelines §482.13(a)(2)

The hospital's grievance process must be approved by the governing body. The hospital's governing body is responsible for the effective operation of the grievance process. This includes the hospital's compliance with all of the CMS grievance process requirements. The hospital's governing body must review and resolve grievances, unless it delegates this responsibility in writing to a grievance committee. A committee is more than one person. The committee membership should have adequate numbers of qualified members to review and resolve the grievances the hospital receives (this includes providing written responses) in a manner that complies with the CMS grievance process requirements.

Survey Procedures §482.13(a)(2)

Determine if the hospital's governing body approved the grievance process.

Is the governing body responsible for the operation of the grievance process, or has the governing body delegated the responsibility in writing to a grievance committee?

Determine how effectively the grievance process works. Are patient's or the patient representative's concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities?

Is the grievance process reviewed and analyzed through the hospital's QAPI process or some other mechanisms that provides oversight of the grievance process?

A-0120

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§482.13(a)(2) (Continued)

[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.] The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

Interpretive Guidelines §482.13(a)(2)

Quality Improvement Organizations (QIOs) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a

beneficiary's request. The regulations state the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a complaint regarding quality of care, disagree with a coverage decision, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint. The hospital is required to have procedures for referring Medicare beneficiary concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request. This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR Part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Medicare patients have the right to appeal a premature discharge (see Interpretive Guidelines for 42 CFR 482.13(a)). Pursuant to 42 CFR 412.42(c)(3), a hospital must provide a hospital-issued notice of non-coverage (HINN) to any fee-for-service beneficiary that expresses dissatisfaction with an impending hospital discharge. Medicare Advantage (MA) organizations are required to provide enrollees with a notice of non-coverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), only when a beneficiary disagrees with the discharge decision or when the MA organization (or hospital, if the MA organization has delegated to it the authority to make the discharge decision) is not discharging the enrollee, but no longer intends to cover the inpatient stay.

Survey Procedures §482.13(a)(2)

Review patient discharge materials. Is the hospital in compliance with 42 CFR §489.27?

Does the hospital grievance process include a mechanism for timely referral of Medicare patient concerns to the QIO? What time frames are established?

Interview Medicare patients. Are they aware of their right to appeal premature discharge?

A-0121

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[At a minimum:]

§482.13(a)(2)(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

Interpretive Guidelines §482.13(a)(2)(i)

The hospital's procedure for a patient or the patient's representative to submit written or verbal grievances must be clearly explained. The patient or patient's representative should be able to clearly understand the procedure.

Survey Procedures §482.13(a)(2)(i)

Review the information provided to patients that explains the hospital's grievance procedures. Does it clearly explain how the patient is to submit either a verbal or written grievance?

Interview patients or patient representatives. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to submit a grievance?

A-0122

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[At a minimum:]

§482.13(a)(2)(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

Interpretive Guidelines §482.13(a)(2)(ii)

The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

Document when a grievance is so complicated that it may require an extensive investigation. We recognize that staff scheduling as well as fluctuations in the numbers and complexity of grievances can affect the timeframes for the resolution of a grievance and the provision of a written response. On average, a time frame of 7 days for the provision of the response would be considered appropriate. We do not require that every grievance be resolved

during the specified timeframe although most should be resolved. 42 CFR 482.13(a)(2)(iii) specifies information the hospital must include in their response.

If the grievance will not be resolved, or if the investigation is not or will not be completed within 7 days, the hospital should inform the patient or the patient's representative that the hospital is still working to resolve the grievance and that the hospital will follow-up with a written response within a stated number of days in accordance with the hospital's grievance policy. The hospital must attempt to resolve all grievances as soon as possible.

Survey Procedures §482.13(a)(2)(ii)

What time frames are established to review and respond to patient grievances? Are these time frames clearly explained in the information provided to the patient that explains the hospital's grievance process? On average, does the hospital provide a written response to most of its grievances within the timeframe specified in its policy?

A-0123

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[At a minimum:]

§482.13(a)(2)(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Interpretive Guidelines §482.13(a)(2)(iii)

The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative understands.

The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family.

The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances. However, in all cases the hospital must provide a written notice (response) to each patient's grievance(s). The written response must contain the elements listed in this requirement.

When a patient communicates a grievance to the hospital via email the hospital may provide its response via email pursuant to hospital policy. (Some hospitals have policies against communicating to patients over email.) If the patient requests a response via email, the hospital may respond via email. When the email response contains the information stated in this requirement, the email meets the requirement for a written response. The hospital must maintain evidence of its compliance with these requirements.

A grievance is considered resolved when the patient is satisfied with the actions taken on their behalf.

There may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf in order to resolve the patient's grievance and the patient or the patient's representative remains unsatisfied with the hospital's actions. In these situations, the hospital may consider the grievance closed for the purposes of these requirements. The hospital must maintain documentation of its efforts and demonstrate compliance with CMS requirements. In its written response, the hospital is not required to include statements that could be used in a legal action against the hospital, but the hospital must provide adequate information to address each item stated in this requirement. The hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate the grievance, resolve the grievance, or other actions taken by the hospital.

Survey Procedures §482.13(a)(2)(iii)

Review the hospital's copies of written notices (responses) to patients. Are all patients provided a written notice? Do the notices comply with the requirements?

A-0129

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§482.13(b) Standard: Exercise of Rights

Interpretive Guidelines §482.13(b)

The hospital must ensure that the exercise of patients' rights requirements are met.

Analyze and prioritize customer needs: Information collected from customers is often too broad, too vague, and too voluminous to be used directly in designing a product or service. Both specificity and priority are needed to ensure that the design really meets the needs and that time is spent on designing for those needs that are the most important. For the information collected:

- Organize, consolidate, and prioritize list of needs for both internal and external customers
- Determine the importance of each need for both internal and external customers
- Break down each need into precise terms so that a specific design response can be identified
- Translate those needs into the supplying organization's language
- Establish specific measurements & measurement methods for each need

Develop product or service: Once the customers and their needs are fully understood, the organization is ready to design the product or service that will meet those needs best. Product or service development isn't a new function for any organization, but the role of quality has to be emphasized. The overall quality objectives are to determine which product or service features and goals will provide optimal benefit for the customer, and identify what is needed so that the designs can be delivered without deficiencies. In the case of designing services, the scope of the activity is sometimes difficult to understand. In health care, where does the product of diagnosing and treating end and the processes of laboratory testing, chart reviews and other activities begin?

The product is the face to the customer. It is what the customer sees and experiences. The patient sees and experiences physician interaction, waiting time, clarity of information, courtesy, etc. The effectiveness and efficiency of moving blood samples to and around the laboratory have an effect on these product features but are really features of the process that delivers the ultimate product to the customer. The customer's needs are the benefits that the customer wants from the product or service, so the design includes not only the product or service but also helpful instructions on using that product or service. Important activities include grouping together related customer needs, determining methods for identifying product features, selecting high level product/service features and goals, developing detailed product/service features and goals, optimizing product/service features and goals, and setting and publishing final product and service design.

Prioritizing Customer Needs

There are generally a large group of customer needs that should be prioritized and grouped together, based on similar functionality. Prioritization ensures that the scarce resources of product development are spent most effectively on those items which are most important to the customer. The initial focus is on the components of the customer's needs, not the components of the product. The organization also needs to ensure that all relevant standards, regulations, and policies have been identified and addressed. The organization then needs to determine methods for identifying product features. The most common include benchmarking, basic research, market experiments, and creativity.

The team must agree on the explicit criteria to be used in evaluating alternative designs and design features. Designs must meet the customers' needs, meet the suppliers' and producers' needs, meet or beat the competition, and optimize the combined costs of the customers and suppliers. Team members should agree on the criteria that it will use to make the selection. In addition to the team's mission and goals, criteria might include:

- Impact of the feature on the needs
- Relative importance of the needs being served
- Relative importance of the customers whose needs are affected
- Feasibility and risks of the proposed feature
- Impact on product cost
- Relationship to competitive features uncovered in benchmarking

- Requirements of standards, policies, regulations, mandates

Teams must also decide whether to develop an entirely new functionality, replace selected old features with new ones, improve or modify existing features, or eliminate the unnecessary. Product feature goals should be measurable, optimal, legitimate, understandable, applicable, and attainable. To establish the measurement for a product feature goal, determine the unit of measure, determine how to measure the goal, and set the value for the goal. Once the initial detailed product features and goals have been developed, a preliminary design will be developed. This is a necessary step before a team can optimize models of product features using a number of quality planning tools and ultimately set and publish the final product features and goals.

Once the preliminary design is complete, it must be optimized. The design must be adjusted so that it meets the needs of both customers and suppliers while minimizing their combined costs and meeting or beating the competition. Finding the optimum involves balancing the needs. The following techniques can be used.

- Design review
- Joint planning
- Structured negotiation
- Create new options
- Competitive analysis
- Salability analysis
- Value analysis

After the design has been optimized and tested, it is time to select the product features and goals to be included in the final design. This is also the stage where results of product development are officially transmitted to other functions through various forms of documentation.

Develop process

Once the product is developed, it is necessary to determine the means by which the product will be created and delivered on a continuing basis, which is the process. Process development is the set of activities for defining the specific means to be used by operating personnel for meeting product quality goals. The major activities include:

Review product goals: Review of goals ensures that they are understood by those most affected by the process design. The review helps achieve the optimum. Process designers are able to present product designers with some realities relative to the costs of meeting the quality goals.

Identify operating conditions: Seeking to understand operating conditions involves identifying:

User's understanding of the end process: Those who actually contribute to processes to meet product goals, including internal customers responsible for running the process, operators or other workers, and process planners.

How the process will be used: What is actually done, based on direct observation and interviews.

Environments of use: Taking into account how factors such as temperature, vibration, noise level, and other environmental stressors can affect influence performance.

Collect known information on alternate processes: Once the goals and environment are clear, the planning team needs reliable information on alternative processes available for meeting those goals in the anticipated environment.

Select general process design: Begin by describing the overall process flow using a high level flow diagram. From this diagram, it will be possible to identify the sub processes and major activities that can then be designed at a more detailed level later. Once the initial process flow is completed, it should be reviewed for opportunities to improve it, including:

- Eliminating sources of error that lead to rework loops
- Eliminating or reducing redundant sub processes, activities, tasks
- Decreasing the number of handoffs
- Reducing cycle time
- Replacing tasks, activities, processes that have outputs with defects
- Correcting sequencing issues in the process to reduce the amount of activity or rework

Selected processes should be pilot tested. A pilot test tests the overall process on a small scale or with a small segment of the total population. The segment to receive testing will vary depending on the process itself. Testing may be limited to a particular function, location, or department.

Identify process features and goals: A process feature is any property or attribute that is needed to create the goods or deliver the service and achieve the product feature goals that will satisfy the customer need. A process goal is the numeric target for one of the features. Product features answer the question “What characteristic of the product do we need to meet customer needs?” Process features answer the question “What mechanisms do we need to create or deliver those characteristics and meet quality goals over and over again without deficiencies?” Collectively, process features design a process. The flow diagram is the source of many of those.

Identify detailed process features and goals: In most cases, it will be efficient and effective for the individual sub teams to carry out the detailed designs of sub processes and major activities. These will have the same process features and goals as their objectives and criteria. Each sub process team will develop the design to the level at which standard operating procedures can be developed.

Design for critical factors and human error: One key element of process design is determining the effect that critical factors will have on the design. Critical factors are those aspects which present serious danger to human life, health, and the environment, or risk the loss of very large sums of money. Planning for such factors should include ample margins of safety as to structural integrity, fail safe provisions, redundancy systems, and multiple alarms. Criticality analysis and failure mode and effect analysis are helpful tools in identifying those factors which require special attention at this point.

Optimize process features and goals: After the planners have designed for critical factors and made modifications to the plan for ways of reducing human error, the next activity is to optimize first the sub processes and then the overall process design. Optimization applies to both the design of overall processes and the design of individual sub processes.

Establish process capability: Before a process begins operation, it must be demonstrated to be capable of meeting its quality goals. Any planning project must measure the capability of its process specific to the key quality goals. Failure to achieve process capability should be followed by systematic diagnosis of root causes of the failure and improvement of the process to eliminate those root causes

before the process becomes operational. Process capability refers to the effectiveness of the process in meeting customer needs. One special class of needs may relate to the sub process cycle time, the total time elapsed from the beginning of a process to the end. Reducing cycle time has almost become an obsession for many organizations. Pressures from customers, increasing costs, and competitive forces are driving organizations to discover faster ways of performing their processes.

Set and publish final process features and goals: After the planning team has established the flow of the process, identified initial process features and goals, designed for critical processes and human error, optimized process features and goals, and established process capabilities, it is ready to define all the detailed process features and goals to be included in the final design. This is also the stage where the results of process development are officially transmitted to other functions through various forms of documentation, including the specifications for the product features and product feature goals as well as other supporting documents. The planning team must ensure that the following are also specified for each task within the process:

- Who is responsible for doing it
- How is the task to be accomplished
- Its inputs
- Its outputs
- Problems that can arise during operations and how to deal with them
- Specification of equipment
- Information required by the task
- Information generated by the task
- Training, standard operating procedures, job aids that are needed

Developing process controls/transfer to operations

In the planning phase, controls for the processes are developed, arrangements are made to transfer the entire product plan to operational forces if appropriate, and the implementation of the transfer is validated. Major activities include:

Identify controls needed: Process control consists of evaluating the actual performance of the process, comparing actual performance with the goals, and taking action on the difference. Control begins with choosing quality goals. Each quality goal becomes the target at which the team directs its efforts. All control is centered on specific things to be controlled, or control subjects. Each control subject is the object of a feedback loop. Control subjects are a mixture of product features, process features, and side effect features.

Design feedback loop: Once the control subjects are selected, it is time to design the remainder of the feedback loop by setting the standards for control, or the levels at which the process is out of control and the tools, such as control charts, that will be used to make the determination. The next step is deciding what action is needed when those standards are not met, i.e., troubleshooting, followed by designating who will take those actions. A detailed process flow diagram should be used to identify and document the points at which control measurements and actions should be taken.

Optimize self-control and self-inspection: Self-control takes place when workers know what they are supposed to do. Goals and targets are clearly spelled out and visible. Workers know what they are doing. Their output is measured, and they receive immediate feedback on their performance. Workers have the ability and the means to regulate the outcomes of the process. They need a capable process along with the tools, training, and authority to regulate it. In addition to providing the optimal

conditions for process operation and control, establishing self control has a significant, positive impact on the working environment and the individuals in it. Whenever possible, the design of quality control system should stress self control by the operating forces. Such a design provides the shortest feedback loop but also requires the designers to ensure that the process capability is adequate to meet the product quality goals.

Establish audit: Once self control is established, self inspection should be developed. This permits the worker to check that the product adheres to quality standards before it is passed on to the next step. This way, front line workers are made to feel more responsible for the quality of their work. Feedback on performance is immediate, facilitating process adjustments. Traditional inspection also has the psychological disadvantage of using an outsider to report the defects to the worker. Quality must be made the highest priority and workers must be trained and have unequivocally clear specifications.

Demonstrate process capability and controllability: While process capability must be addressed during the design of the process, it is during implementation that initial findings of process capability and controllability must be verified.

Plan for transfer to operations: In many organizations, an information package is prepared consisting of certain standardized essentials: goals to be met, facilities to be used, procedures to be followed, instructions, and cautions. Plans are made for briefing and training the operating forces in such areas as maintenance and dealing with crises.

Implement plan and validate transfer: The team needs to let go of the responsibility of the project and validate that the transfer of the project has taken place and everyone affected has all the information processes, and procedures in place to produce the final product. Validating that it all works well is worth the effort.

Quality Control

Quality control is a universal managerial process for conducting operations so as to provide stability, to prevent adverse change and to maintain the status quo. To maintain stability, the quality control process evaluates actual performance, compares actual performance to goals, and takes action on the difference. The Juran trilogy diagram describes the relationships between quality planning, quality improvement, and quality control, and the fundamental managerial processes in total quality management. Although the process is in control in the middle of the chart, the process is running at an unacceptable level of waste. What is necessary is not more control but improvement, actions to change the level of performance. After the improvements have been made, a new level of performance has been achieved. Now it is important to establish new controls at this level to prevent the performance level from deteriorating to the previous level or even worse, indicated by the second zone of control.

The term control of quality appeared early in the twentieth century. The concept was to broaden the approach to achieving quality, from the then prevailing after the fact inspection to what we now call defect prevention. The statistical quality control movement uses statistical methods. Total quality management is now used as the all embracing term, rather than quality control in the United States. Recently the European umbrella quality organization changed its name from the European Organization for Quality Control to European Organization for Quality. In Japan, the term quality control retains a broad meaning.

Feedback Loop

Quality control takes place by the use of a feedback loop. The feedback loop is a universal. It is fundamental to any problem in quality control. It applies to all types of operations, whether in service

industries or manufacturing whether profit or not. It applies to all levels in the hierarchy, from the chief executive officer to the work force.

The **first step** in the feedback loop is to choose the control subject. Each feature of the product/service or process becomes a control subject; a center around which the feedback loop is built. Control subjects are identified from multiple processes which include

- Stated customer needs for product features
- Technological analysis to translate customer needs into product and process features
- Process features which directly impact the product features
- Industry and government standards
- Needs to protect human safety and the environment
- Needs to avoid side effects such as irritations to employees or offense to the community

Establishing quality control goals

At the worker level, control subjects consist mainly of product and process features set out in specifications and process manuals. At managerial levels, the control subjects are broader and increasingly business oriented. Emphasis shifts to customer needs and to competition in the market place. This shift in emphasis then demands added, broader control subjects which have an influence on the remaining steps in the feedback loop.

After choosing the control subject, the **next step** is to establish the means of measuring the actual performance of the process or the quality level of the goods or services. Measurement is one of the most difficult tasks in quality management. In establishing the measurement, an organization needs to clearly specify the means of measurement, the frequency of the measurement, the way the data will be recorded, the format for reporting the data, the analysis to be made on the data to convert the data to usable information, and who will make the measurement.

Quality Goals

For each control subject, it is necessary to establish a standard of performance, a quality goal (also called targets, objectives). A standard of performance is aimed at achievement toward which effort is expended. The prime goal for products is to meet customer needs. Other goals for products and services are those for reliability and durability.

Processes which produce products and services have two quality goals;

- to produce products which do meet customer needs, and
- to operate in a stable and predictable manner.

Quality goals may also be established for departments or persons. Goals should be legitimate, measurable, attainable, and equitable. Quality goals are needed at the highest level. Goals should be established by the organization related to meeting customers' changing needs, meeting competition, maintaining a high rate of quality improvement, improving the effectiveness of business processes, and revising the planning process to avoid creating new failure prone products, services, and processes.

“Before you build a better mousetrap, it helps to know if there are any mice out there.”

Yogi Berra

Measuring actual performance

The critical step in quality control is to measure actual performance of the product, service, or process. After measurement is made, compare the measurement to standards and take action on the difference. The PDCA cycle is one method of dividing the feedback loop into elements and steps. An early version of the PDCA cycle was included in W. Edwards Deming's first lectures in Japan in 1950. Since then, additional versions have been devised and published.

Measurement

Obtaining needed information is time consuming, expensive, and difficult. Just as quality management is a never ending journey, so too is the task of learning of, obtaining, sorting through, synthesizing, and understanding all the data and information that could productively be used.

Information is considered in light of decisions that managers must make and the actions they take. The scientific method is essentially a process by which hypotheses are proposed, experiments are designed to test aspects of those hypotheses, data collected and analyzed, and the hypotheses either advanced, discarded, or modified. The system of measurement for quality parallels the scientific method, but the standards are different. Caution is the watchword in the scientific method while success is the watchword for quality.

In some cases, the manager is presented with well defined choices. For example, is this process in control? The manager can either decide that the process is in control and take no action, or decide that the process is not in control and take action to find and eliminate a special cause. In other situations, the range of options is ill defined and/or with unlimited boundaries. In many cases, the manager may choose to gather more data. For nearly all cases, the better the information, the better the decision. Better information includes more complete, more accurate, more relevant, more current, from a more reliable source, more precise, organized in a more convincing way, or presented in a format easier to understand.

A critical step in obtaining more information is measurement. Measurement involves collection of raw data, including searching a library, obtaining data originally gathered for other purposes, or talking to customers. The choice of what to measure and the analysis, synthesis, and presentation of the resultant information are just as important as the act of measurement itself. High quality information results from high quality and integrated design, data collection, and analysis/synthesis/presentation. The act of measurement is data collection. The measurement process includes design, data collection, and analysis/synthesis/presentation.

Steps in the Measurement Process

- Developing the framework
- Planning measurement,
- Collecting and storing data,
- Analyzing,
- Synthesizing,
- Formulating recommendations,
- Presenting results and recommendations,
- Making decisions and
- Taking action.

Decision Making

Decision making is often a complicated political process in and of itself. The framework in which information is produced is critical. At a high level, the framework defines the overall context in which decisions are to be made, including such diverse considerations as the organization's business goals, its competitive position, and its available resources; customer requirements, the goals and biases of decision makers, and any relevant constraints on the measurement process or decision making. For any particular decision, the framework includes the specific issues to be addressed. Taken together these five elements (framework, design, data collection, analysis/synthesis/recommendations/presentation, and decision/action) compose a measurement system.

Ultimately, the goal is to help the organization make consistently better decisions and take better actions. Better actions are defined in terms of results in achieving organization objectives. Good

measurement systems support a number of organization goals, not just a few. It is usually true that what gets measured gets managed. Those who define and operate a measurement process should consider the system as a whole, including the environment in which it operates. It's not sufficient to be technically excellent or to have one or two elements outstanding. Overall effectiveness is as much determined by how well the elements relate to each other and to other systems in the enterprise as by excellence in any area.

Who Will Make Decisions

The first step in defining a measurement system is to understand who will make the decisions and how. Many decisions, and most important ones, are not made by an individual, but by a committee or group. In some cases, this helps build support for implementation. In others, it's a vehicle for diffusing accountability. Some groups decide by majority rule; others by consensus. Most groups have a few key individuals. Few decisions makers are completely unbiased. Individuals intuitively make decisions based on different criteria.

Prior to determining what to measure and how to measure it, it is important to understand the overall framework in which the measurement system operates. Good measurement systems work in the context of the organization culture that defines acceptable directions, risks, behaviors, and policies to be followed. Defining a framework is similar to stakeholder analysis in strategic planning. Stakeholders include at least three groups, customers, owners, and employees.

One goal of organizations is to maintain and improve customer satisfaction, retention, and loyalty. Organization owners are concerned more with the economic viability, both short and long term, of the organization than with day to day considerations. Employees are stakeholders because they depend on the organization for their livelihood.

Range of Possible Decisions & Actions

A second aspect of understanding the framework involves the range of possible decisions and actions. A list of decisions/actions is called the decision/action space. Sample decisions:

- The process is in control and performing at an acceptable level and should be left alone.
- The process is out of control and must be brought under control.
- The process is in control but not performing at an acceptable level and must be improved.

The end result should be a framework document that captures the major points of the decision making. It should describe major business goals and strategies and customer requirements, define the decision/action space and decision makers, note important constraints (financial and other), and reference more detailed business plans and customer requirements.

Plans for the remaining steps of the process are then made. The output of this step is a measurement protocol, a document that describes the whos, whats, whens, wheres, hows, and whys of data collection, storage, and planned analyses.

	Data Collection	Data Storage	Analysis, Synthesis, Recommendations, Presentation
What			
Where			
When			
How			
How often			
Who			

Three aspects of quality

Measurable quality: compliance with standards (protocols, practice parameters)

Appreciative quality: comprehension and appraisal of excellence beyond minimal standards, (peer review, expert law opinion)

Perceptive quality: degree of excellence which is perceived by the recipient or the observer of care rather than the provider of care

What to measure: Most customer requirements are stated in subjective terms that have to be translated into a set of objective measurements. Many requirements will never lend themselves to objective measurements, such as data gathered by customer satisfaction surveys and customer feedback. In some cases, it's pretty clear what you should measure but you can't measure it. In almost all cases, literally dozens of measurements are available and the problem is to select the critical few. There are decreasing returns as measurements are added, and too many measurements can overwhelm the measurement system. Possible measurements can be listed and rank ordered, selecting only the essential few. Measure not only each step of the process but also the overall process. Measuring only the steps doesn't ensure a successful outcome because too many problems can arise between steps in a process. Precise definitions of what is measured are essential, as slight changes in definition can produce very different results.

Where to measure: Determine where to make measurements. In quality management, the usual evolution is from inspection at the end of a production process to measurement of in process performance. Immature systems place greater weight on inspection, more mature ones on in process measurement.

When, how, how often to measure: In some cases, no new data are collected, but rather existing data are used. Data collected from one purpose may not always be used for something else. Specify how, when, and how often measurements are to be made. Each should be spelled out in full detail. How involves not only how a particular measurement is to be made but also how the measurement equipment should be calibrated and maintained and how accurate data are to be obtained if appropriate to the measurement. When and how often need to be addressed to ensure that enough data are available.

Who measures: Just as important as the what, where, when, and how is the who. Who collects data, who stores them, who plots points on control charts, who looks at data in other ways.

Data storage and access: Data storage and retrieval must be planned.

Data analysis, synthesis, recommendations, and presentation: Consider the analysis, synthesis, formulation of recommendations, and presentation step. While all the analyses that will be carried out can't be planned, certain basic ones should be.

Measurement protocol: Define the sub-processes of the measurement process to be followed in subsequent steps. Written protocols should be used and widely circulated.

Data collection: Data collection involves following the measurement protocol. Maintain careful records. Measuring devices don't always work as planned. Control data collection so that errors are prevented.

Analyze, synthesize, formulate results, and present results and recommendations: Once data are collected, they must be summarized and presented in a form that is understandable to decision makers. This step is often called data analysis. Analysis is defined as separating or breaking up of any whole into parts. Synthesis is composition, putting two or more parts together to form a whole, the opposite of analysis. Then specific recommendations for action are developed. Presentation involves putting the most important results and recommendations into an easily understood format.

Steps of analysis:

- Completing planned analysis
- Exploratory data analysis when required
- Formulation of results and recommendations
- Presentation of results and recommendations

Decisions are no better than the data on which they are based.

Sample decision maker's checklist:

1. Make decision/take action
 - Is the decision/action space specified as clearly as possible?
 - Are the planned actions consistent with the decision and the data that lead to them?
2. Define framework
 - Are customer requirements clearly defined?
 - Are the requirements of the owners clearly defined?
 - Are employee requirements clearly defined?
 - Are any other major stakeholders identified? Are their requirements clearly defined?
 - Are decision makers named?
 - Is the framework documented?
- Plan measurements
3. Are plans for making measurement clearly laid out, including?
 - What is to be measured?
 - When are measurements to be made?
 - Where are measurements to be made?
 - How are measurements to be made, including calibration routines, data editing, and how a measurement log is to be used, if applicable?
 - How often are measurements to be made?
 - Who is responsible for measurement, including calibration?
4. Are plans for data storage clearly laid out, including:
 - What data are to be stored?
 - When are they to be stored?
 - Where are they to be stored?
 - How is storage to be accomplished?
 - How often are data stored? How often are data backed up?
 - Who is responsible for data storage and data management?
5. Are planned analyses and data presentations clearly defined, including:
 - What analyses are planned?
 - When are planned analyses conducted?
 - Where are analyses conducted?
 - How are planned analyses carried out?
 - How often are routine analyses made?
 - Who conducts the planned analyses?
6. Is the measurement protocol written?
7. Are those who make measurements familiar with the protocol?
8. Is the protocol under change management?
9. Collect and store data
 - Is the measurement protocol followed?
 - Is a measurement log of exceptions maintained?
10. Analysis, synthesis, present results
 - Is the measurement protocol followed?
 - Are presentation packages clear and understandable?
 - Are results presented in a comprehensive and fair manner?
11. Data quality program
 - Is the data quality program comprehensive? Does it cover all aspects of the measurement system?
 - Is the data quality program documented?

Measurement is a critical part of testing and implementing changes; measures tell a team whether the changes they are making actually lead to improvement. Measurement for improvement shouldn't be confused with measurement for research.

	Measurement for Research	Measurement for Process Improvement
Purpose	To discover new knowledge	To bring new knowledge into daily practice
Tests	One large "blind" test	Many sequential, observable tests
Biases	Control for as many biases as possible	Stabilize the biases from test to test
Data	Gather as much data as possible	Gather enough data to learn
Duration	Can take long periods of time	Small tests of significant changes to accelerate rate of improvement

Indicators

Structure, Process, Outcome

Avedis Donabedian, a University of Michigan physician, formulated the theoretical framework for patient care evaluation using structure, process, and outcome. His model suggests the importance of relating healthcare structures (the qualifications of practitioners and facilities, technology, buildings, equipment, etc.), processes (the activities involved in prevention, diagnosis, treatment, etc.), to outcomes (how patients actually fare as a result of their healthcare).

The Agency for Healthcare Research and Quality (AHRQ) is funding projects to define indicators that measure quality associated with various processes of patient care. The indicators rely solely on hospital inpatient administrative data to reduce the need for additional data collection. The first indicator set released by AHRQ in November, 2001 focuses on ambulatory care sensitive conditions for which evidence suggests that better outpatient preventive care could have avoided an inpatient hospitalization. Even though these indicators are based on hospital inpatient data, they provide insight into the quality of the health care system outside the hospital setting. For example, patients with diabetes may be hospitalized for diabetic complications if their conditions are not adequately monitored or if they do not receive the patient education needed for appropriate self management.

In July, 2002, AHRQ released a second set of indicators for inpatient care. These measures cover

- Inpatient mortality for select medical conditions and procedures;
- Utilization of procedures for which there are questions of overuse, underuse or misuse; and
- Volume of procedures for which there is evidence that a higher volume is associated with lower mortality.

The AHRQ has developed QI software that can be used to extract data from the hospital's administrative database to create the measurement results. This software is available free from AHRQ. It can be used by hospitals to help identify potential problem areas that might need further study. To use the AHRQ QI modules, users must have access to the SAS statistical software package and must apply the program modules to databases that contain information on hospital discharges.

A third set of indicators focusing on patient safety is currently under development by the UCSF-Stanford Evidence-based Practice Center. These indicators will also reflect quality of care inside hospitals, but focus on surgical complications and other iatrogenic events.

To learn more about the AHRQ quality indicator projects and the accompanying QI software go to: <http://www.ahrq.gov/data/hcup/>

This site contains links to various reports and download sites. In addition, you can obtain a copy of Stanford's full technical report on the development and validation of the preventive and inpatient indicators.

Indicators for a broad variety of populations and topics are available online indexed by topic using the CONQUEST System (Computerized Needs Oriented Quality Measurement Evaluation System). It is also free on the website: <http://www.ahrq.gov/qual/conqix.htm>

HCUPnet, on the AHRQ site enables users to identify, track, and analyze comparable statistics on the inpatient care of Americans. This site provides easy access to national statistics and trends, and selected state statistics about hospital stays. <http://www.ahcpr.gov/data/hcup/>

Examples of patient-centered outcome indicators: (condition of the patient; how is the patient)

- Pressure ulcer prevalence
- Falls
- Falls with injury
- Urinary tract infection
- Central line catheter infection
- Ventilator acquired pneumonia
- Restraint prevalence
- Death

Examples of structure indicators: (buildings, supplies, staff, credentialing, etc.)

- Skill mix (RN, LPN, NA)
- Nursing care hours per patient day
- Turnover

Examples of process indicators: (activities such as admission, discharge, transfer, medication administration, surgery, chemotherapy, physical therapy, lithotripsy, etc.)

- Smoking cessation counseling for acute myocardial infarction
- Influenza vaccine administered
- Pneumovax administered

HCAHPS is a tool used for public reporting of major areas of hospital performance to support consumer choice. HCAHPS provides an apples to apples metric for public reporting—additional measurement may be needed for ongoing quality improvement activities and monitoring. Deficit Reduction Act of 2005 included language that hospital quality measures should be expanded to include more clinical measures and measures of patient perspectives of care in order for hospitals to receive a full market basket update.

The intent of the HCAHPS initiative is to provide a standardized survey instrument and data collection methodology for measuring patients' perspectives on hospital care. While many hospitals have collected information on patient satisfaction, prior to HCAHPS there was no national standard for collecting or publicly reporting patients' perspectives of care information that would enable valid comparisons to be made across all hospitals. In order to make "apples to apples" comparisons to support consumer choice, it was necessary to introduce a standard measurement approach: the HCAHPS survey, which is also known as the CAHPS® Hospital Survey, or Hospital CAHPS. HCAHPS is a core set of questions that can be combined with a broader, customized set of hospital-specific items. HCAHPS survey items complement the data hospitals currently collect to support improvements in internal customer services and quality related activities.

Three broad goals have shaped the HCAHPS survey. First, the survey is designed to produce comparable data on the patient's perspective on care that allows objective and meaningful comparisons between hospitals on domains that are important to consumers. Second, public reporting of the survey results is designed to create incentives for hospitals to improve their quality of care. Third, public reporting will serve to enhance public accountability in health care by increasing the transparency of the quality of hospital care provided in return for the public investment. With these goals in mind, the HCAHPS project has taken substantial steps to assure that the survey is credible, useful, and practical.

This methodology and the information it generates are available to the public.

In May 2005, the National Quality Forum (NQF), an organization established to standardize health care quality measurement and reporting, formally endorsed the CAHPS® Hospital Survey. The NQF endorsement represents the consensus of many health care providers, consumer groups, professional associations, purchasers, federal agencies, and research and quality organizations.

There are seven domains:

- Communication with doctors

 - MD respect

 - MD listen

 - MD explain

- Communication with nurses

 - RN respect

 - RN listen

 - RN explain

- Responsiveness of hospital staff

 - Help when call button

 - Help using bathroom

- Pain control

 - Pain controlled

 - Do all help pain

- Communication about medicines

 - Tell what medicines were for

 - Effects of medicines

- Cleanliness and quiet of physical environment

 - Room clean

 - Room quiet

- Discharge information

 - Help for you at home

 - Symptoms/problems to be reported

<http://www.hcahponline.org>.

Core Measures

In early 1999, The Joint Commission solicited input from a wide variety of stakeholders (e.g., clinical professionals, health care provider organizations, state hospital associations, health care consumers and convened a Cardiovascular Conditions Clinical Advisory Panel about the potential focus areas for core measures for hospitals. In May 2001, the Joint Commission announced four initial core measurement areas for hospitals, which included acute myocardial infarction (AMI) and heart failure (HF).

Simultaneously, The Joint Commission worked with the Centers for Medicare & Medicaid Services (CMS) on the AMI, and HF sets that were common to both organizations. CMS and the Joint Commission worked to align the measure specifications for use in the 7th Scope of Work and for Joint Commission accredited hospitals. Hospitals began collecting AMI measures for patient discharges beginning July 1, 2002.

In November of 2003, CMS and The Joint Commission began to work to precisely and completely align these common measures so that they are identical. This resulted in the creation of one common set of measure specifications documentation known as the Specifications Manual for National Hospital Inpatient Quality Measures to be used by both organizations. The Manual contains common (i.e.,

identical) data dictionary, measure information forms, algorithms, etc. The goal is to minimize data collection efforts for these common measures and focus efforts on the use of data to improve the health care delivery process.

Core Measure Sets http://www.jointcommission.org/core_measure_sets.aspx

- Heart Failure
- Pneumonia Measures
- Acute Myocardial Infarction
- Immunization
- Children's Asthma Care
- Surgical Care Improvement Project
- Perinatal Use
- Substance Use
- Tobacco Treatment
- Hospital-Based Inpatient Psychiatric Services
- Venous Thromboembolism
- Stroke
- Emergency Department
- Hospital Outpatient Department

ORYX is The Joint Commission's performance measurement and improvement initiative, which integrates outcomes and other performance measure data into the accreditation process. ORYX measurement requirements are intended to support Joint Commission accredited organizations in their quality improvement efforts. Performance measures are essential to the credibility of any modern evaluation activity for health care organizations. ORYX data are publicly reported on The Joint Commission website at Quality Check®, <http://www.qualitycheck.org>. The public availability of performance measure data permits user comparisons of hospital performance at the state and national levels.

Computerization

Quality improvement brings with it the need for enormous amounts of data that need to be interpreted to be used. The gathering of volumes of information can be labor-intensive. As the request for information continue to expand, the ability to provide data becomes an increasing challenge that requires automation and the use of computer systems. Automation allows a program to function in greater volume and at a faster pace. Quality improvement, with its accompanying monitors, indicators, and data elements, needs to be appropriately organized, developed and integrated to gain the most benefit from computerization.

Computerization can assist organizations in controlling and planning management functions. Collecting data and analyzing information are major and critical parts of planning. Data needs to be transformed into a meaningful form to manage daily operations, whatever the setting. Computers can be useful for the following functions:

- Monitoring acuity and adjusting staffing
- Planning and maintaining a budget
- Recording and updating educational programs
- Providing integrated patient information
- Providing patient education tools
- Assisting with patient management
- Providing information for planning patient care

Computer programs may stimulate new thoughts and approaches. They provide immediate reward with a printout if desired. Computers can help staff use resources wisely. Computers are most useful to integrated performance/quality improvement. Risk and safety data can be collected and trended. Quality/performance improvement data can be aggregated for analysis and improvement of care. Infection control surveillance reports become more manageable with computerization. Labor intensive reports that were once manually prepared can be produced more often for better use in management and operations. Computers can also help improve utilization management by providing computerized services that access data rapidly, freeing staff for patient care, which allows better plans of care and improved patient care outcomes.

Computers can simplify the task of drawing charts and making the calculations. Graphics programs can provide a format for constructing any number of charts and graphs. When considering a graphics package, be sure it allows flexibility, especially in editing. Some packages offer more flexibility than others. A graphics program will not perform calculations. That requires a statistical package, one with graphics capabilities. What these packages offer is graphics capabilities along with the ability to calculate such things as upper and lower control limits for control charts based on raw data.

The exponential growth of computers will continue. The computer revolution has been a primary force in the expansion of quality activity into service businesses and functions. Breakthrough technology in communications and data storage has already begun the powerful transition from powerful stand alone machines back to large, virtual machines of unlimited potential. The Internet and its derivatives are an important part of this revolution.

Definition

A computer system is defined as a group of interlocking hardware equipment and software that performs an independent function. Computer systems can be as small as appliance or automobile type microprocessor chips with large mainframe computers running specialized database management software. Personal computers running commercial word processing and spread sheet software programs are generally considered as productivity tools rather than computer systems unless the commercial software is specifically developed and tested to perform a unique function, such as spread sheet programs that analyze financial, statistical, or engineering data, and word processing programs that present forms for entry of specialized information on data. Those commercial software applications are called templates and macros.

Computer systems have experienced a rapid evolution in recent years, from stand alone processing systems dominated by central mainframe processors to widely distributed architectures that provide almost unlimited communication capabilities. The explosion in popularity of systems such as the Internet has opened up tremendously new opportunities for information access. Almost any subject can be researched through the use of Internet search engines. Systems such as the Internet also present new quality challenge. Of increasing popularity are Intranet applications. Intranet is a private corporate network using Internet technologies. The Internet and Intranet, combined with the increasing power of on line document management systems, have transformed the way that companies communicate and perform work. The future will be characterized by automated on line services that provide unlimited access to and rapid retrieval of information from huge databases of specifications and reference materials.

Quality implications of computers

- Increased privacy concerns about access to personal information, such as salary and evaluation data.
- Increased security concerns about external access to corporate information, such as financial and product development data.
- Accuracy and currency of information available.

Also of concern is the potential for the introduction through these channels of programs that may cause corruption or destruction of data. The most familiar corrupter is called a virus. A virus is computer code that executes when an infected program is run. This has traditionally meant that only stand alone programs (executable files) can be infected. Recently, viruses have been inserted into programs that can allow nonexecutable files to propagate a virus. The threat of viruses is real. The number of new viruses is growing at a steady pace. Viruses can infect data on computers from mainframes to laptops. Viruses can be distributed across phone lines from bulletin boards or can enter computers via a floppy disk. A virus infection can destroy files and cost countless hours to remove the virus and recover lost data from affected programs. Quality practices must address the growing virus risk, which is a consequence of the increasing interconnection of computer systems.

In purchasing computer software, consider the following:

Testing for satisfaction of requirements supports the software quality model. However, this approach alone no longer is practical. Each significant piece of new off the shelf commercial software can be assumed to contain errors, even after thousands of millions of executions.

While fitness for use recognizes the importance of the satisfaction of defined requirements, there may be errors in the defined requirements themselves.

Freedom from errors is only one of many attributes which add up to fitness for use. The success of software developers is based on the realization that customers will tolerate bugs in software as a trade off for timely product enhancements, increased functionality, and low cost. This is in direct contrast to the reactions of the same customers to errors experienced in hardware quality where zero defect performance is expected.

For many software developers, a result of these customer attitudes is that structured design is subordinated to early coding and arduous testing. There is an attempt to accelerate the release of new products by investing tremendous hours in early coding and testing and subsequent debugging. The unending pressure to increase the complexity of emerging computer and software systems is forcing the industry to rethink the cost and risk of this brute force strategy. This complexity may dictate the gradual development of new software development tools and a shift by successful developers back to more structured design techniques.

Programming attributes of software include the following:

Correctness: Extent to which a program satisfies its specifications and fulfills the user's mission objectives

Reliability: Extent to which a program can be expected to perform its intended function with required precision

Efficiency: Amount of computing resources and code required by a program to perform a function

Integrity: Extent to which access to software or data by unauthorized persons can be controlled

Usability: Effort required to learn how to operate, prepare input, and interpret output of a program

Maintainability: Effort required to locate and fix an error in an operational program

Testability: Effort required to test a program to ensure that it performs its intended function

Flexibility: Effort required to modify an operational program

Portability: Effort required to transfer a program from one hardware configuration and/or software system environment to another

Reusability: Extent to which a program can be used in other applications; related to the packaging and scope of the functions that programs perform

Interoperability: Effort required to join one system to another; ability to share information

Open Source Software: Ability to implement, modify, apply, reconstruct, and restructure libraries of source codes

Steps in acquiring a computer application package

1. Identify present and future requirements. Involve appropriate members of administrative, clinical, and medical staff leadership in the process to gain support for the system.
2. Survey available packages.
3. Examine documentation and manuals, including promotional materials. Vendors can provide onsite presentations. Visit a facility that uses the proposed software if possible.
4. Determine data and communication interoperability with existing programs.
5. Survey existing users as to product acceptability. (Internet queries provide an optimal way to obtain this information). Look for system networking capability, integration of the key areas of quality, the ability to control and determine specific areas for data collection software.
6. Request quality assurance and testing information from the developer.
7. Request a list of known bugs.
8. Review copyright and licensing requirements.
9. Obtain programs for internal trial execution.
10. Negotiate contract to include maintenance services and upgrades.

Take into account the facility's budget cycle. A budget expenditure for capital equipment is the first cost of the system. However, the annual cost for servicing the system hardware and the service contract for the software vendor are additional annual expenditures. Contract negotiation includes hardware purchasing, interfacing costs, training/education costs, service contracts, and ongoing enhancements and upgrades to the system. The service responsibilities of the vendor should take into account not only the service of the equipment but also the issue of initial installation and training of personnel on use of the system. The long term commitment of the vendor to systems support should be discussed. Each of these issues should be taken into account in the contract negotiations with the vendor.

A key clause in the contract should concern the multiple deadline dates for implementation of the system. Once the contract is signed, hardware decisions and purchases can be made, and electrical department personnel can make appropriate connections for local area network use. Once the hardware is in place, the next major activity is installation of the software for access by the network locations.

Implementation

After the installation of hardware and software has been completed, the real work of implementation begins. Dictionary definitions, security, and facility specific software adjustments must be dealt with. Special requirements of the facility specific program must be met. Data element dictionaries and definitions must be built around the existing quality improvement program. Individual names need to be accurately incorporated into the software, including things like hospital locations, for accurate data retrieval. At this critical time, involvement by the quality improvement staff, administration, clinical and medical staff leaders is crucial. Vendor interaction and support are important parts of this process.

The next major component of any good quality improvement software system is the ability to capture data already collected in other hospital systems. By setting up appropriate interfaces, duplication of data entry by multiple areas of the hospital can be eliminated. Those involved in developing the interface should have a vision of what the quality improvement system can become so that appropriate information from other systems can be captured. A good interface can streamline the data intensive process of quality improvement, while a poor interface can lead to diminished performance and contribute to failed expectations.

The software vendor should train and educate the staff on the use of the new automated system. This training can take place in house, at a local facility, or on site at the vendor's location. Once the training has been completed and a period of test data collection has been accomplished, the official start date for the collection of accurate live data can be set.

Keep in mind that full implementation of an automated program will take from 6 to 18 months depending on the size of the facility, and the elements the facility wants in the program. Massive amounts of time, energy, and resources must be expended to automate the quality improvement process before any data has been captured and kept for future use. Data flow encompasses three major areas:

- Data collection
- Data access
- Report generation

With the completion, of hardware, software, dictionary definition, security, and the interface, data collection can actually begin. Many systems use laptop computers or other point of care devices that can be used to collect data which is then downloaded into the computer system. If this isn't available, is the development and testing of an appropriate data collection sheet must be accomplished. Those collecting data will use the form for gathering information and should test its usefulness and accuracy by keying information into the system through the computer. Once the pilot test has been completed and proven successful, full implementation can take place. Data collection and storage needs to occur for a long enough time period to provide trending of data, appropriate to the indicator. It's important to ensure that enough data has been collected for accurate interpretation of results.

Information System

For continuous improvement, information systems' role is that of support, providing data collection, analysis, and decision support functions. Considering the fundamental importance of statistical data to quality improvement initiatives, information technology, with its ability to capture, process, and disseminate data, must play a key role in continuous improvement. In making significant process change, information technology is often an essential enabler without which the process could not be reengineered. It has the potential to reduce organizational complexity, eliminate unnecessary paperwork, simplify and streamline communications and coordination, and facilitate teamwork. Many reengineered processes make use of information systems in replacing outmoded processes that originated before the advent of modern computer and telecommunications technology.

In addition to the important role of information systems in improving processes, they also are critically important in many other aspects of managing for quality. These include gathering customer satisfaction data and disseminating them throughout the organization; establishing effective communications processes such as electronic data interchange between the organization and its customers, suppliers, and other stakeholders; and enabling effective internal communications among individuals and teams with email, team based groupware, and other computer networking vehicles.

Information systems collect, process, and distribute patient-centered data to aid in managing and providing care. Together they create a comprehensive record of the patient's medical history and support organizational processes. Each of these systems is unique in the way it functions and provides information to clinicians and administrators.

Types of Healthcare Information Management Systems

Case Management Information Systems

Identify resources, patterns, and variances in care to prevent costly complications related to chronic conditions and to enhance the overall outcomes for patients with chronic illness

Span past episodes of treatment and search for trends

Once trend identified, provide decision support promoting preventive care

Care plans: common tool found in case management systems; set of guidelines that outline the course of treatment and the recommended interventions that should be implemented to achieve optimal

results; by using standardized plan of care systems present clinicians with treatment protocols to maximize patient outcomes and support best practices

Communication Systems

Promote interaction among healthcare providers and between providers and patients

Examples: call light systems, wireless telephones, pagers, email, instant messaging, patients accessing electronic chart via Internet

Core Business Systems

Enhance administrative tasks within healthcare organizations

Support management of health care within an organization

Provide framework for reimbursement, support of best practices, quality control, resource allocation

Four common types: Admission, discharge and transfer; financial systems; acuity systems; scheduling systems

Clinical Information Systems

Systems are designed to collect patient data in real time; enhance care by providing data at the clinician's fingertips and enabling decision making where it needs to occur, at the bedside. Systems are often easily accessible at the point of care for caregivers interacting with the patient. Systems are patient centered, containing observations, interventions, and outcomes noted by the care team. Team members enter information, such as the plan of care, hemodynamic data, laboratory results, clinical notes, allergies, and medications. All members of the treatment team use clinical documentation systems; pharmacists, allied health workers, nurses, physicians, and support staff.

Examples include:

Order entry systems: automate the way orders are initiated for patients

Computerized Physician Order Entry (CPOE) systems: provide decision support and automated alert functionality that was unavailable with paper-based orders

Patient Care Support Systems: clinical documentation systems including Bar Code Medication Administration (BCMA), pharmacy information systems, laboratory information systems, radiology information systems (RIS)

Information systems assimilate massive amounts of information and track care from one medical visit to the next. Information collected by information systems is processed in a way that helps to reduce risks, ensure quality and decrease costs. As healthcare begins to introduce more of this technology into practice the value of information systems is recognized. Integrating technology systems provides a real-time approach that facilitates care among the entire healthcare team, patients, and families. Information systems enhance the flow of information within an organization and promote an exchange of information to better care for patients. Information systems also play a pivotal role in determining the strategic direction for an organization, forecast future trends to allow an organization to successfully strategize on how to meet upcoming market demands, and track resources within a facility while managing the frequency and distribution of those resources.

Data Warehouse

Many organizations are aggregating data in a data warehouse for the purpose of mining the data to discover new relationships and to build organizational knowledge. A data warehouse is an extremely large database or repository that stores all of an organization's data and makes this data available for data mining. The data warehouse can combine an organization's many different databases to provide management personnel flexible access to data.

There are many ways to access and retrieve information in databases. Searching information in databases can be done through the use of a query, as is used in Microsoft's Access database. A query asks questions of the database to retrieve specific data and information. Structured Query Language (SQL) is a database querying language, a standard language for accessing and managing databases.

SAMPLE MANAGEMENT OF INFORMATION POLICY

1. **PURPOSE:** To establish policy and procedures regarding the coordination and integration of information management activities at this medical center in order to continuously improve the processes that obtain, manage, and use information. The medical center's goal is to enhance individual & organizational performance & improve care.
2. **POLICY:** The medical center will utilize effective information management to establish and monitor key processes to meet internal and external information needs.
3. **PROCEDURES:** The Management of Information (MOI) Function Lead Team (FLT) has oversight responsibility for assessing, planning and coordinating information management processes. As part of the coordination, the following committees/task teams/functions provide information and report to the MOI FLT: Information Security Officer; Automated Data Processing Application Coordinator (ADPAC) Subcommittee; Senior ADPAC Subcommittee; Clinical Informatics Committee; Data Validation Committee; Decision Support; and the Library.
 - a. A comprehensive assessment of information management needs will be completed periodically to evaluate the following:
 - (1) Type, structure, and complexity of the medical center's information;
 - (2) Needs of the customers using the information and any additional information needed to support customer and supplier relationships;
 - (3) Support required for planning and executing information management;
 - (4) VHA and other applicable guidelines for data parity and connectivity in interfacing information systems;
 - (5) Requirements for internally and externally generated data and information to support both clinical and administrative cost analysis, decision making, continuous performance improvement, enhancement of work flow;
 - (6) Requirements for comparing the medical center's performance with prior internal performance, other organizations, and published criteria (i.e., practice guidelines, standards of practice); and
 - (7) Appropriateness and cost versus benefit of technologies for information management.
 - b. The MOI FLT reviews the information management program direction to assure that staffing and material resource allocations are based on the medical center's scope and complexity of services provided, strategic plan and goals.
 - c. Appropriate staff participate in assessing, selecting, and integrating health care information technology.
 - d. The medical center has established policies to ensure the confidentiality, security, and integrity of information. These policies identify the individuals' obligation to keep information confidential; the release of health information and/or removal of the medical record; and the mechanisms designed to secure information against unauthorized intrusion, corruption, and damage. (Reference Policy Memorandum Numbers: RMS/IRM-1, ADP Security - Personnel Management; RMS/IRM-2, ADP Security Violations; RMS/IRM-5, Personal Computers; RMS/IRM-6, Computer Access Procedures; RMS/IRM-7, AIS Contingency Planning; RMS/IRM-9, AIS Security Training; RMS/IRM-11, AIS Virus Prevention.)
 - e. Individuals in the medical center who generate, collect, and analyze data and information are educated and trained in the principles of information management. Each ACOS/ Administrator/Chair/Assistant Administrator is responsible for training appropriate employees. (Reference: Policy Memorandum No. RMS/IRM-9, AIS Security Training)
 - f. The Information Resources Management (IRM) Department and the service lines/ departments are responsible for enabling the combination of data and information; making information from one system available to another; providing reports; clarifying and interpreting data and information; organizing data for analysis; and enabling linkage of patient care and non-patient care data and information over time among medical center service lines.
 - g. The Library Department and IRM Department are responsible for the management of knowledge-based information (authoritative, up-to-date print and nonprint information resources). The Library and the Informatics Service Line plan and provide access to clinical and managerial literature, reference information, and research data to meet identified needs. Relevant, current and accurate information is provided to medical center staff, affiliated students, patients and families within appropriate time frames and in formats appropriate to recipient's needs.

h. Components of Information Management - The timely collection of information and data in an economical and efficient manner, with the degree of accuracy, completeness, and discrimination necessary for their intended use:

(1) Accurate patient information in a timely manner: There is a medical record for every individual assessed or treated and entries are only made by authorized individuals. All significant clinical information pertaining to a patient is entered or scanned in the computerized patient record system (CPRS) as soon as possible after its occurrence. CPRS organizes and presents patient data to support clinical decision-making and provides increased accessibility and availability to the clinical staff.

(2) Patient-specific data and information (currently available in a combination of electronic and paper): Paper documentation that lends itself to scanning is being scanned into the electronic record. A paper record is maintained for patient-specific data that cannot be scanned. Medical record issues are addressed by the Medical Records Task Team, which has responsibility for the medical record process.

(3) Knowledge-based information: The Library Department maintains the medical center's knowledge-based sources. Knowledge-based information consists of systems, resources, and services to help health care professionals acquire and maintain the knowledge and skills to care for patients, support clinical and management decision making, and provide needed information and education to patients and families. Knowledge-based information is accessible in a variety of formats: books, journals, serials, audiovisual software programs (audio cassettes, slides/tapes, video cassettes), vertical file materials, anatomical models, computer software and CD databases, and connections to external databases through the Intranet and Internet.

(4) Aggregate and comparative data: Resource management information is available from Human Resources Management; Payroll/Fiscal Sections, Resources and Financial Management; Facilities; and Clinical Services for internal aggregation, comparative activities and organizational decision-making. Information and databases from external sources such as VHA, VISN, other VAMCs and health care facilities are utilized for benchmarking and comparative resource utilization. Data sources utilized include Decision Support System, Patient Treatment File and VA databases.

(5) Performance Improvement and Risk Management: Information gathered from performance improvement activities (service line and function lead team indicators, performance measures, external peer reviews) are assessed and evaluated in continuous improvement initiatives. Patient incidents reports are evaluated and root cause analyses are initiated when appropriate.

(6) Utilization review information: Workload and utilization data from internal and external sources are used for operational and managerial decision making. The Decision Support System and the Oracle project provide management with data related to resource utilization and costs and provider profiles. VISN data provide extracts for benchmarking with other facilities within the network.

(7) Marketing/Public Relations: The Public Relations marketing tools and communication activities with internal and external sources are done to provide information on the medical center's mission, goals, directions and services. The Desert Sun, all-employee e-mails, Health Trends provide information to veterans and employees.

4. **RESPONSIBILITIES:**

a. The Medical Center Director has responsibility for ensuring that the facility has a systematic approach and necessary resources to effectively implement a comprehensive information management system. b. Members of the Executive Leadership Council and Chairs/Assistant Administrators are accountable for the identification, implementation, and evaluation of information management initiatives. c. The ACOS and Administrator, Informatics Service Line ensure that information management processes and activities meet the medical center's information needs through coordinated participation by all service lines. d. The Assistant Administrator, Health Information Management Department has responsibility for ensuring all patient-specific data is maintained and used in accordance with applicable federal rules and regulations. The Assistant Administrator, Information Resources Management Department has responsibility for ensuring all automated systems in use within the medical center meet established standards for data integrity, security and confidentiality. f. The Library Department has responsibility for providing timely access to knowledge-based data to clinical practitioners, researchers, management and other staff through automated and printed material, utilizing technology to retrieve and distribute information based on users' needs, patient education literature, videos and reference materials. The Information Security Officer has responsibility for administering a comprehensive security program.

h. Information management process activities are frequently interdisciplinary and will require integrated efforts on the parts of individuals and service lines within the medical center.

Data

Data—documented observations or the results of performing a measurement process. The concept of data refers to strings or patterns of characters that describe some aspect of the world. The availability of data offers opportunities to obtain information and knowledge through inquiry, analysis, or summarization of these strings or characters. Data can be obtained by perception (observation), or by performing a measurement process.

Observations come from unique perceptions using senses of sight, taste, smell, hearing, and touch. Weaknesses of relying only on observations:

Recent observations tend to be more heavily weighted

New observations depend on previous observations

Perceptions are filtered; observe what is expected

Improvement teams learn better from data based on measurements than on observations. Sometimes observations are useful, as in patients' perceptions of pain. Combining observation and measurement data is a useful approach.

Guidelines for Collecting Data for Improvement

Have a few key measures that clarify the aim of the improvement in a tangible way.

Regularly report data throughout the project.

Don't overdo process measures. A balance of outcome, process, and balancing measures is important.

Show data visually on the key measures over time.

Make use of existing databases and data already collected for developing measures.

When possible, integrate data collection for measurement into the daily work routine.

Improvement projects generally require more than one measure.

Data questions

1. Where did the data come from? This should be the first question asked. You want an identifiable source for the data.
2. Have the data been peer-reviewed? This tells you that the data is minimally reliable.
3. How were the data collected? What kind of sample was used? Was it appropriate for the population?
4. Be skeptical when dealing with comparisons.
5. Be aware of numbers taken out of context.

Research

Quantitative Research: Formal, objective, systematic process implemented to obtain numerical data for understanding aspects of the world

Qualitative Research: Systematic, interactive, subjective, holistic approach used to describe life experiences and give them meaning

Applied or Practical Research: Scientific investigation conducted to generate knowledge that will directly influence or improve clinical practice; purpose is to solve problems, to make decisions, or to predict or control outcomes in real life practice situations

Inductive Reasoning: Moves from the specific to the general

Deductive Reasoning: Moves from the general to the specific

Hypothesis: Formal statement of the expected relationship or relationships between two or more variables in a selected populations; translates the problem and purpose into a clear explanation or prediction of the expected results or outcomes of the study

Null Hypothesis (Statistical Hypothesis): Used for statistical testing and interpretation of these results; implied if not stated because it is the opposite of the research hypothesis

Data Analysis: Reduces, organizes, and gives meaning to the data.

Descriptive analysis techniques to describe demographic variables and study variables
Statistical techniques to test proposed relationships among variables
Analysis techniques to examine group differences

Qualitative Data Analysis: Process of examining and interpreting data in order to elicit meaning, gain understand, and develop empirical knowledge

Statistical Tests Assumptions

Data are at least at the interval level
Sample was randomly obtained
Distribution of the scores was normal

Coding: In quantitative studies is the process of transforming data into numerical symbols that can be entered easily into the computer; means of naming and labeling

Code: Symbol or abbreviation used to label words of phrases in the data

Types of Variables

Data are collections of numbers gathered for the purpose of assessing some activity. Values are the actual numbers obtained when measuring variables. The two major types of variables used to categorize data are categorical (or count) and continuous (or measurement).

Measurement: Process of assigning numbers to objects, events, or situations in accord with some rule

Data Collection: Precise, systematic gathering of information relevant to the research purpose or the specific objectives, questions, or hypotheses of a study. Data collected in quantitative studies are usually numerical. Data collection involves obtaining numerical data to address the research objectives, questions, or hypotheses.

Categorical/Count Variables

Categorical variables contain data that can be counted. Categorical variables have pre-assigned units or categories, with the number of events in each category counted. The two types of categorical variables are **ordinal** and **nominal**. For ordinal categorical variables, the number in each category is counted and the categories are displayed in a particular sequence or order. A 5 point Likert scale would have all responses counted for each number, 1,2,3,4,5. For nominal categorical variables, the relative order of the categories is unimportant. Examples include gender, race, religion. A **binomial** is a special type of categorical variable. This variable has two categories. Examples include variables with the following categories: yes/no, normal/abnormal, present/absent. The results of these variables are usually reported as a proportion or a percentage.

Count or Categorical Data (Attributes Data)

Nominal: Lowest (first) of 4 measurement categories; used when data can be organized into categories of a defined property but the categories cannot be ordered

Diagnoses of Chronic Diseases
Hypertension
Type 2 Diabetes
Dyslipidemia

Categories differ in quality but not quantity; can't say that one category is higher than another or possesses more of the property being categorized

1. Categories must be unorderable

2. Categories must be exclusive

Examples of nominal data: ethnicity, gender, marital status, religion, diagnoses

Ordinal: Second level of measurement; data that can be measured at the ordinal level can be assigned to categories of an attribute that can be ranked; categories must be exclusive and exhaustive; with ordinal level data; quantity of the attribute possessed can be identified; but it cannot be shown that the intervals between the ranked categories are equal; ordinal data are considered to have unequal intervals; scales with unequal intervals are sometimes referred to as ordered metric scales

Examples of scales with ordinal levels of measure include: intensity of pain, degrees of coping, levels of mobility, ability to provide self-care, daily amount of exercise

Continuous/Measurement Variables

Continuous quantitative variables, usually referred to as continuous or measurement variables, are commonly used in healthcare. These variables have an infinite number of possible values within a range; with decimal points, the numbers approach infinity. Examples include blood pressure, temperature, weight, height, time, money (scaled data).

Measurement or Scaled Data (Variables Data)

Interval: Third level of measurement; distances between intervals of the scale are numerically equal; measurements also have mutually exclusive categories, exhaustive categories, and rank ordering; assumed to be a continuum of values; absence of a zero point on an interval scale

Examples of interval scales: Fahrenheit and Celsius temperatures; a difference between a temperature of 95.6 degrees F and 95.7 degrees F is the same as the difference between 101.4 degrees F and 101.5 degrees F; can measure changes in temperature precisely; impossible to say that temperatures of 0 degrees C or 0 degrees F means the absence of temperature because these indicate very cold temperatures

Ratio: Fourth (highest) level of measurement; meets all rules of lower forms of measures; mutually exclusive categories, exhaustive categories, rank ordering, equal spacing between intervals, and a continuum of values; in addition, ratio level measures have absolute zero points

Examples of ratio scales: Weight, length, money, and volume; each has an absolute zero point at which a value of zero indicates the absence of the property being measured; in addition, because of the absolute zero point can indicate that object A weighs twice as much as object B

Use the highest level of measurement possible. The level of measurement is associated with the types of statistical analyses that can be performed on the data.

Variables: Qualities, properties, or characteristics of persons, things, or situations that change or vary in a study; characterized by degrees, amounts, and differences within a study; concepts of various levels of abstraction that are concisely defined so that they can be measured or manipulated within a study

Types of Statistics

Descriptive statistics describe the summary results of the values from some variable, such as mean, standard deviation, or other statistic. They are computed to reveal characteristics of the sample and to describe study variables

Inferential statistics draw conclusions about a population based on information obtained from a sample from the population. **Inferential statistics** are used to make inferences about populations based

on samples. **Inferential statistics** aren't necessary if the data from the entire **population** are available. A **population** is the largest collection of entities that is being studied at a particular time. In most healthcare situations, the entire population is not available, so a sample is taken, and the findings are generalized from the sample to the population. Estimates are made about a population based on a **random sample** taken from that population. The sample must accurately reflect the population. All statistical theory and testing are based on the assumption that a proper random sample has been obtained. They are computed to draw conclusions and make inferences about the greater population; based on the sample data set. Inferential statistical analyses are based on the assumption that the sample from which data were derived has been obtained randomly

Population: All the elements (individuals, objects, or substances) that meet certain criteria for inclusion in a given universe; particular group of people or type of element that is the focus of the research. The researcher needs to determine which population is accessible and can be best represented by the study sample.

Target population: Entire set of individuals or elements who meet the sampling criteria

Accessible population: Portion of the target population to which the researchers have reasonable access

Sampling

Sampling is electing a group of people, events, behaviors, or other elements with which to conduct a study; process of selecting subjects, events, behaviors, or elements for participation in a study. A sample is a part of a whole. A sample is used in research when it's not feasible to study the whole population from which it is drawn. Other factors, such as cost, limited time, and lack of accessibility, prohibit a direct study of the total population. How far can a researcher generalize from any given sample? How far can the researcher stretch the conclusions from the sample findings to describe the total population? Generalizations can be made from findings if the data can be reasonably regarded as a fair sample of the universe to which it is generalized. Sampling defines the process for selecting a group of people, events, behaviors, or other elements with which to conduct a study.

Sampling Variation: the process by which sampling is done

Sampling Plan: Process of making the sample selections; strategies used to obtain a sample for a study

Sampling Frame: Listing of all potential participants that make up the population; listing of every member of the population

Sampling Method: Process of selecting a group of people, events, behaviors, or other elements that represent the population being studied

Sampling (Eligibility) Criteria: List of characteristics essential for membership or eligibility in the target population

Representative Sample: Similar to the target population in as many ways as possible

Sample: Selected group of people or elements included in the study; subset of the population that is selected for a particular study.

Probability Sampling: Every member (element) of the population has a probability higher than zero of being selected for the sample

Random (probability) sampling: Increases the probability that subjects with various levels of an extraneous variable are included are randomly dispersed throughout the groups within the study; each individual in the population should have a greater than zero opportunity to be selected for the sample; sample is representative of a population; each member of the population has a probability greater than zero of being selected for a study; random samples are more likely to represent the population than samples obtained with nonprobability sampling methods; all subsets of the population have a chance to be

represented in the sample; random assignment is important because it assumes that any important variables will be equally distributed, keeping variation to a minimum. The process of allowing every member of the population equal chance to be included in the sample representing the total population. Methods of random sampling include: roulette wheel, assigning a number to each member of the population, putting all the numbers in a container, mixing them up, and drawing one at a time until the desired sample size is obtained, using a random number table/computer program.

Simple Random Sampling: Most basic type of random sampling; allows everyone in the group from which the sample is being drawn to have an equal chance of being selected for the final sample; elements are selected at random from the sampling frame; draw names out of a hat; use a computer to select random numbers; each person in the population is chosen by chance and is as likely to be selected as anyone else. Selection is chosen by chance.

Stratified Random Sampling: The researcher initially selects a stratification variable. The researcher knows some of the variables in the population that are critical to achieving representativeness. Values commonly used for stratification include age, gender, ethnicity, socioeconomic status, diagnosis, geographical region, type of institution, type of care, care provider, site of care. Subjects within each stratum are randomly selected on the basis of their classification into the selected strata. A specific group is selected from the larger population and a random sample is then chosen from that group. Stratified random sampling involves dividing a population into sections, then taking a random sample from each section.

Cluster Sampling: Cluster sampling is similar to stratified random sampling but takes advantage of natural clusters or groups of population units that have similar characteristics. It is used when simple random sample would be prohibitive in terms of travel time and cost, or when individual elements making up the population are unknown, preventing the development of a sampling frame. States, cities, institutions, organizations are selected randomly as units from which to obtain elements for the sample. The researcher randomly assigns research subjects to groups within a much larger population, then research subjects within the assigned group are surveyed.

Systematic Sampling: Systematic sampling involves electing every n th individual on the list, using a starting point selected randomly; uses a sampling interval randomly selected; subjects to be included are selected at specific intervals within the population. This occurs by taking every n th number (number is selected randomly).

Nonrandom (nonprobability) sampling: Not every element of the population has an opportunity to be included in the sample

Convenience Sampling: This method selects people most easily located or most available for participation or easiest to recruit. Subjects are included in the study because they happen to be in the right place at the right time. Researchers simply enter available subjects into the study. It is also known as an incidental sample (sample of convenience) and means taking anyone available.

Quota Sampling: This method uses convenience sampling with a strategy to ensure the inclusion of subject types or strata in a population that are likely to be underrepresented in the convenience sample, such as women, minority groups, elderly adults, etc., but the initial sample is not random. It offers an improvement over convenience sampling; sets quotas and uses convenience sampling to select participants to fill the quotas.

Purposive or Purposeful Sampling: Researcher specifies the characteristics of the population of interest and then locates individuals who match those characteristics; researcher consciously selects certain participants, elements, events, or incidents to include in the study; select information-rich cases or critical cases, or cases that make a point; specific population is selected and only its members are surveyed. For both **Quota or purposive sampling**, some special group is selected because there is good evidence that it is representative of the total population .

Network or Snowball Sampling: Network sampling takes advantage of social networks and the fact that friends tend to have characteristics in common; Snowball sampling asks participants to find other participants; each subject in the study is asked to identify other potential research subjects

Theoretical Sampling: Researcher gathers data from any individual or group that can provide relevant data for theory generation.

Sampling Error: Difference between a sample statistic and a population parameter; large sampling error means that the sample is not providing a precise picture of the population; is not representative; sampling error is usually larger with small samples and decreases as sample size increases; sampling error reduces the power of a study, or the ability of the statistical analyses conducted to detect differences between groups or to describe the relationships among variables; sampling error occurs as a result of random variation and systemic variation

Power: Probability that a statistical test will detect an effect when it actually exists; capacity of the study to detect differences or relationships that actually exist in the population; capacity to reject a null hypothesis; minimum acceptable power for a study is commonly recommended to be 0.80 (80%)

Power Analysis: Performed to determine sample size; includes standard power (usually 80%), level of significance (usually set at 0.05), effect size (a determination of the effectiveness of a treatment on the outcome (dependent) variable or the strength of the relationship between two variables), and sample size

Statistical Power: Low statistical power increases the probability of concluding that there is no significant difference between samples when actually there is a difference.

Type I Error: Rejecting a true null hypothesis

Type II Error: Failing to reject a false null hypothesis; most likely to occur when the sample size is small or when the power of the statistical test to determine differences is low

Sample Size

Adequacy of sample size is an important factor only if a small sample is used. In order to be adequate, a sample must be only large enough to allow the investigator to have confidence in the inferences he makes after selected statistical techniques are used. The more homogeneous the population, the smaller the sample size needs to be in order to be classes as representative.

Regardless of the shape of the original population distribution, as sample size increases, the shape of the sampling distribution becomes normal. With a sample size of at least 30, the sampling distribution appears almost normal. However, there is no perfect minimum sample size that can be applied to any study. A power calculation or analysis is used to determine the appropriate sample size. Calculating sample size depends on four variables: the population size, an estimate of the population standard deviation, the desired level of significance, and the bounds of the error estimate. The following website will calculate the appropriate sample size from a population:

http://www.macorr.com/ss_calculator.htm or <http://www.stattek.com>

Sample Size: Determined with a power analysis

- The more stringent the significance level (e.g., 0.001 vs. 0.05), the greater the necessary sample size
- Two-tailed statistical tests require larger sample sizes than one-tailed statistical tests
- The smaller the effect size, the larger the necessary sample size
- The larger the power required, the larger the necessary sample size; study requiring a power of 90% requires a much larger sample than a study with a power of 80%
- The smaller the sample size, the smaller the power of the study

Factors to be considered in decisions about sample size because they affect power include: effect size, type of study, number of variables, sensitivity of the measurement methods, and data analysis techniques.

Effect: Presence of a phenomenon

Effect Size: Extent to which a phenomenon is present in a population; easier to detect large differences between groups than to detect small differences.

Number of Variables: As the number of variables under study grows, the needed sample size may also increase.

Random Variation: Expected difference in values that occurs when one examines different subjects from the same sample

Systemic Variation: Consequence of selecting subjects whose measurement values are different or vary in some specific way from the population

Generalizing: Findings can be applied to more than just the sample under study because the sample is representative of the target population

Reliability

How consistently the measurement technique measures a concept; determining the instrument is consistent and will give the same results if the research is replicated; reliable measure gives the same result each time the same situation or factor is measured; reliability of an instrument denotes the consistency of the measure obtained of an attribute, item, or situation; the greater the reliability or consistency of the measures of a particular instrument, the less random error in the measurement method.

Reliability is defined as the extent to which measurements are free from random-error variance.

Reliability is the proportion of accuracy to inaccuracy in measurement. **Reliability** is the accuracy of a measuring instrument. There are two basic sources of inaccuracy.

A deficiency (error) in the instrument itself

Inconsistency between different individuals who are taking readings from the instrument

A questionnaire with high reliability allows the user to be confident that observed scores on a questionnaire accurately reflect a respondent's true opinions.

Reliability needs to be determined before validity is tested; need instruments that are reliable and provide values with only a small amount of error; reliable instruments enhance the power of a study to detect significant differences or relationships actually occurring in the population under study; need to perform reliability testing on instrument before performing other statistical analyses.

Reliability Testing: Examines amount of measurement error in the instrument being used in a study. Reliability is concerned with the dependability, consistency, stability, precision, reproducibility, and comparability of a measurement method.

There are three general forms of reliability:

- Test-retest reliability: Assumes that the factor to be measured remains the same at the two testing
- Equivalence reliability: Compares two versions of the same instrument or two observers measuring the same event; alternate forms or parallel forms reliability
- Split-half reliability: Split instrument items in odd-even or first-last halves and correlate scores between the two halves

Intra-rater reliability: Multiple readings of a measurement assessed from the same person

Inter-rater reliability: Multiple readings of a measurement are assessed from several people

For test-retest reliability, a test is administered to the subjects, and after a period of time, it is administered again. If the test is reliable and the trait being measured is stable, the results will be consistent and essentially the same both times.

For equivalent testing, two forms of the test are developed using the same specifications but requiring separate samples of behavior in the area under study. Both tests contain the same types of items based on the same kinds of material, but the particular references and items are different.

For internal consistency, the split-half method is used. This is carried out at the time of scoring the results. Separate scores are given for the even numbered and odd numbered items. The results from each half of the test are compared to determine how accurately the test is measuring the subject. This test has generally been replaced by the Kuder-Richardson test. This is a measure of internal consistency or the homogeneity of the items in a test.

The **reliability** required for surveys is internal consistency among the questions dealing with a particular dimension of patient experience, such as nursing care or physician care. To ensure good **reliability** in the sense of internal consistency, a survey should have multiple-item scales, not merely stand-alone items, because the internal consistency of stand-alone items or questions can't be estimated. To assess patient opinion on a particular dimension, such as nursing, one question "How would you rate nursing overall?" would be used to keep the questionnaire as brief as possible. Or, the survey might ask several questions regarding various aspects of nursing care, for example, how well nurses answered questions, how promptly they responded to call lights, how much time they spent with patients, etc. The use of two or more questions to describe a dimension of care is referred to as a scale.

Scales

Combining the ratings of individual questions that make up a scale is called a scale score. Because internal consistency can be estimated only with scales that have more than one item, people who use one-item measures to assess the level of satisfaction of nursing care run the risk of obtaining information that is not highly reliable. The extent to which the observed score on the one-item measure is related to the true level of patient satisfaction can't be estimated in these cases. Many questionnaires have this weakness. ORYX measures, used by Joint Commission, are examples of scales with good reliability and validity. Scales with high reliability are critical to measuring for improvement because they enable the organization to better distinguish between respondents on a continuum of patient satisfaction. If an organization can't accurately detect differences in satisfaction levels, it can't demonstrate improvement.

Reliability Coefficient

A reliability coefficient applies to an individual patient's score. There are several methods to estimate the degree of reliability, which is generally reported as a coefficient between zero (no reliability) and one (perfect reliability). The most common method is Cronbach's alpha coefficient. There is no rigid rule in determining an acceptable level of reliability; there are differences with individuals and groups. For scales that measure individuals, such as personality tests, .90 is an appropriate minimum. For scales that compare groups instead of individuals, a minimum of .50 is generally considered acceptable. If the reliability coefficient of ratings assigned by a single rater is .50, nine raters would be needed to have a reliability coefficient of .90.

Cronbach's Alpha coefficient: Statistical procedure used for calculating internal consistency for interval and ratio data; can range from 0.00 indicating no internal consistency or reliability, to 1.00 indicating perfect internal reliability

Strong reliability: 0.80 or >

Moderate reliability: 0.60 – 0.79

Low reliability: <0.60

Validity

Validity refers to the degree to which a scale measures what it is designed to measure. Unlike reliability indices, such as the Cronbach alpha coefficient, no one statistic provides an overall index of validity of scale scores. It is much more difficult to establish validity than to establish reliability. A research instrument must have validity if the study is to be meaningful and worthwhile. Determines the extent to which it actually reflects or is able to measure the construct being examined; ensuring that the instrument measures what it was intended to measure; extent to which it actually reflects the abstract

concept being examined. Validity is considered a single broad measurement evaluation that is referred to as construct validity, and includes various types; examines the fit between the conceptual definitions and operational definitions of variables; theoretical constructs or concepts are defined within the study framework (conceptual definitions); these conceptual definitions provide the basis for the operational definitions of the variables; operational definitions (methods of measurement) must validly reflect the theoretical constructs; ;given that the relationship is probably causal and is reasonably known to be from one variable to another, what are the particular cause and effect constructs involved in the relationship? Validity, similar to reliability, is not an all or nothing phenomenon but a matter of degree. No instrument is completely valid; validity is an ideal state, similar to integrity, character or quality.

Content/Face validity: Face validity is simply a group of experts determining by looking (i.e. at face value) and making judgments whether items belong in certain scales. Face validity, or logical validity, involves an analysis of whether the instrument appears to be a valid scale. This procedure calls for a high degree of subjectivity. By just looking at the instrument, the researcher decides if it has face validity. Content/face validity refers to the extent to which the instrument samples the types of factors or situations under study. The content of the instrument must be closely related to that which is to be measured. Someone must judge if the content of the instrument is appropriate. Face/Content validity is an important characteristic of inventories, checklists, evaluation instruments, questionnaires, and interview schedules.

Face Validity: Face validity verifies basically that the instrument looks like it is valid or gives the appearance of measuring the construct it is supposed to measure; subjective assessment

Content Validity: Examines extent to which the measurement method includes all the major elements relevant to the construct being measured; determining whether the instrument and its items are representative of the content the researcher intends to measure

Criterion Related Validity: Requires the comparison of the measure in question with the best existing measure of the variable

Predictive Validity: Ability to predict future performance or attitudes; an instrument possesses predictive validity to the extent that its predictions of future behavior are later found to be accurate. Predictive validity is future oriented.

Concurrent Validity: Ability to predict the current value of one measure on the basis of the value obtained on the measure of another concept; concurrent validity, or status validity is present oriented. The behavior that is revealed can be demonstrated at the present time. There is always association with the present behavior of the individual being studied.

Internal Validity: Extent to which the effects detected in the study are a true reflection of reality rather than the result of extraneous variables; given that there is a relationship, it is possibly causal from the independent variable to the dependent variable, or would the same relationship have been obtained in the absence of any treatment or intervention; ability to infer that the independent variable is truly related to the dependent variable

External Validity: Concerned with the extent to which study findings can be generalized beyond the sample used in the study ;given that there is probably a causal relationship from construct A to construct B, can this relationship be generalized across persons, settings, and times? Generalizability of results obtained to other populations.

Specificity

Ability of an instrument to identify non-cases.

Sensitivity

Ability of an instrument to correctly identify a change

Responsiveness

Ability of an instrument to measure a meaningful or important change in clinical state

Bias

Two primary types of bias can affect survey data, interviewer bias and nonresponse bias.

Interviewer bias is often associated with personal interviews and telephone surveys. For example, a patient who is being interviewed by a nurse before being discharged may be reluctant to respond negatively for fear of being considered rude or confrontational. Discharged patients contacted by telephone at home may be reluctant to answer questions about physician care for fear that their comments will be shared with their personal physicians and possibly damage their relationships with the physician. Interviewer bias tends to inflate patient satisfaction scores and, as a result, obscure opportunities for improvement.

Nonresponse bias, which is more typical of mailed surveys, occurs when there is a systematic difference between those who respond and those who do not respond. There is no consensus on the percentage required for a negative response rate. Some researchers argue that a 50% or better response rate is necessary to generalize from data. Others recommend 30%, as noted in a study of 19,556 patients from 76 hospitals, in which researchers found that results of individual scale scores and subsequent improvement priorities had a 50-50 chance of being different when the first 30% of responses were compared with all respondents. There was no way for an individual hospital to know whether its satisfaction scores would be higher or lower with additional respondents; a low response rate was as likely to result in overstated patient satisfaction as understated patient satisfaction.

Measures of Central Tendency: Mean, Median, and Mode

Mean

A mean can be calculated from population or sample data. The mean is the average of all the values for a variable in a data set. All the values are summed and then divided by the total number of values. Whenever the frequency distribution is fairly symmetrical, the mean is the statistic of choice. All the scores must be added together before the sum can be divided by the number of scores. In published research, the description of samples is more common than that of populations.

The mean is the balance point of any distribution of scores. The positive and negative deviations from the mean will always cancel each other, bringing their sum to zero. As the balance point of a distribution, the mean is the only measure of central tendency that is sensitive to all of its scores. Its most important application is to other measures. Because of that balance point feature, it is compatible with many more complex measures. Calculating a mean is an integral part of a standard deviation, a product moment coefficient of correlation, and all of the various standard errors. A related advantage of the mean over other measures of central tendency is its usefulness in making inferences from a sample to a population.

The mean of a sample is the best estimate of that of the population. But even the best estimate will probably miss the mark, and it is important to know the probability of the extent of the error. The mean lends itself well to error estimation. It is the only average that utilizes all available information, and, in addition, when distributions are approximately normal it is the one that serves as an essential component of other measures.

The mean is the most often used descriptive statistic. It's a particularly informative measure of the central tendency of a variable if it is reported along with its confidence intervals.

To find the mean of the following numbers:

1 2 3 4 5 6

Add the numbers

$$1 + 2 + 3 + 4 + 5 + 6 = 21$$

Divide by the how many numbers you have, 6

$$21 \text{ divided by } 6 = 3.5$$

Median

The median of a sample (or a population) can be thought of as a measure of location for the mid-point of a data set. If the values are ordered from highest to lowest, the median is the value at which point there are equal numbers of entities in the data set with larger values on one side and smaller values on the other side. Another way of indicating central tendency is to tell which point on the baseline divides the distribution into two parts. In every case, the median is the point between the lower and upper halves of the distribution, and helps determine which scores are in what half of the distribution.

Although the median is not sensitive to the exact location of every score in the distribution, it can be used in situations where the mean would be inappropriate. The median should be used in preference to the mean whenever the shape of the distribution departs radically from perfect symmetry. Extreme scores or outliers have very large or very small values compared to other values in the data set. Outliers have too much influence on the mean, resulting in the mean being skewed toward these values. They don't affect a median. Other cases include when the scale is not long enough to accommodate all of the scores at one end of the distribution. There is also the rare array of categories that are essentially non-quantitative but nevertheless appear in a universally recognized order, such as military ranks. There are no scores to support the calculation of a median.

It is the point at which a distribution can be cut in half. The median is used when the precise location of the two halves is a prime concern, when data are ordered but not quantitative, or when a distribution of quantitative data is far from normal. It can supplement or even supplant the mean.

To find the median of the following numbers:

1 2 3 4 5 6

Remove one from each end at the same time, as you move toward the middle. Eliminate the 1 and 6; next eliminate the 2 and 5. You are left with 2 scores, 3 and 4. Add them together ($3 + 4 = 7$) and divide by 2 to get the median which is 3.5. If you had an odd number, the median is the score in the middle. First remove, the 1 and the 5, next remove the 2 and the 4, leaving the median, which is 3.

1 2 3 4 5

Mode

The mode is simply the point with the greatest frequency. It is used when a quick estimate is needed. It is also used specifically for identifying the typical, or most common score. If data are qualitative and not ordered, the mode is really the only central tendency that can be used. The mode can be used where the mean and median cannot; it can supplement but not replace either or both. The mode is the place where the greatest number of cases occurs. If the data are quantitative, it is the most common score.

To find the mode of the following numbers:

1 1 2 3 3 3 4 4 5 6 6

The mode is 3, the number that occurs most often. If two numbers appear most often, the set of numbers is bi-modal, with each being the mode.

In a skewed distribution, the arrangement of these measures of central tendency is predictable. If the skew is negative, the arrangement from left to right is mean, median, mode. If the skew is positive, the order is just the opposite, mode, median, mean. If the order of the three averages is known, the direction of the skew can be predicted.

Outlier: Value in a sample data set that is unusually low or unusually high in the context of the rest of the sample data

Measures of Variability or Dispersion: Variance, Standard Deviation, Interquartile Range, and Range: Different populations and samples have different central tendencies, and they differ in another significant respect as well. The variability of a set of scores, or the spreading of the scores means that the scores in the distribution vary more than those squeezed together. There are many occasions when it is important to have some kind of numerical index of the variability of a set of scores.

Variance: The variance is a computed amount that reflects the amount of dispersion that exists among the values of a data set with respect to the mean; measure of dispersion; always a positive value and has no upper limit; the larger the calculated variance for a study variable, the larger the dispersion or spread of scores for the variable. The Standard Deviation is the square root of the variance;

Variance Analysis: Used to track individual and group variance from a specific pathway

Normal (bell) curve: Frequency distribution of a variable that is perfectly normally distributed

Standard Error of the Mean: Calculated to determine the magnitude of the variability associated with the mean. A small standard error is an indication that the sample mean is close to the population mean; a large standard error yields less certainty that the sample mean approximates the population mean. (standard deviation divided by the square root of the sample size)

Standard Deviation

The **standard deviation** is equal to the square root of the variance. The numerical sizes of the standard deviation and variance increase as more of the data values are larger or smaller than the mean. To calculate the variance for sample data:

- Calculate the mean (average) of the sample.
- Subtract the mean from each value in the data set.
- Each of the resulting differences is then squared (results are then all positive numbers)
- Add the squares of the differences.
- Divide that number by the sample size minus 1 ($n-1$), that number is the **variance**

Using $n-1$ (referred to as **Degrees of Freedom**) provides a more accurate amount when the variance for a sample is being computed. If you are figuring the variance for an entire population, the sum of the squared differences is divided by the entire population. The **standard deviation** is equal to the square root of the variance. The size of the variance depends on the difference between each value in the data set and the mean. Both variance and standard deviation reflect the amount of dispersion or spread in the data set.

Normal Distributions

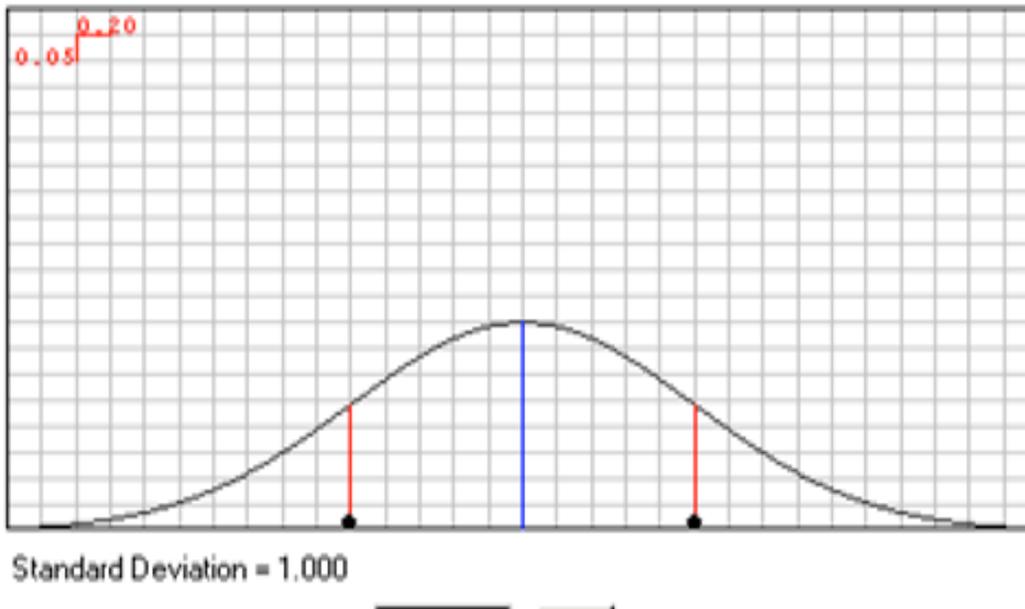
Normal distribution (bell-shaped curve) is a statistical term, also known as Gaussian distribution. Most biological measurements of a continuous variable, when formatted into a frequency distribution, will have the appearance of a normal distribution.

Frequency distribution from data only has to approximate a normal curve, for the properties of the normal distribution to be used in the calculations. An approximately normal distribution means that the **frequency distribution** has a hump in the middle with a tail extending to either side. Normal distributions are symmetrical and bell-shaped, but vary in width and height. They differ in shape due to the relative size of the mean and standard deviation. A certain percentage of values from a normal distribution fall within the intervals represented by 1, 2, or 3 standard distributions from the mean.

68.3% of the values are within the mean plus or minus 1 **standard deviation**

95.4% of the values are within the mean plus or minus 2 **standard deviations**

99.7% of the values are within the mean plus or minus 3 **standard deviations**



It's possible to calculate the multiple of the standard deviation for any value in the data set of values in a frequency distribution. The resulting multiples of the standard deviations are called **z-values**. **Z-values** represent a unique normal distribution called the **standard normal distribution**, which has a mean z-value = 0 and a standard deviation = 1. A unique normal distribution is the standard normal distribution of the variable z with a mean of 0 and a standard deviation of 1. There are tables to use to find the probability of any z-value in the standard normal distribution.

The standard deviation is to measures of variability what the mean is to measures of central tendency. It is sensitive to the value of every score, and in a normal distribution is an integral component of many other useful statistics. In scientific work, it is the prevalent measure of dispersion. The **standard deviation** is the mean of the mean. A normal distribution of data means that most of the

examples in a set of data are close to the average, while relatively few examples tend to one extreme or the other. The **standard deviation** is a statistic that tells you how tightly all the various examples are clustered around the mean in a set of data. When the examples are pretty tightly bunched together and the bell shaped curve is steep, the standard deviation is small. When the examples are spread apart and the bell curve is relatively flat, that tells you that you have a relatively large standard deviation.

Range: There is another measure of variability that is easy to compute. In some cases, information is required specifically on the most extreme cases in a sample. On these occasions the total range, or simply **range** is reported, **which is the distance from the lowest score to the highest**. The range is unreliable, extremely unstable, and is determined by only two scores. **Range and mode are each the quickest to calculate;** each is less stable than the alternatives, although the range is much worse. Both are used to answer questions related directly and very simply to their definitions.

Interquartile Range: If a distribution is cut into four equal parts, the upper end of each of those quarters is a point on the baseline called a quartile. The first quartile is above the lowest quarter (Q1), the second above the lowest two quarters (Q2), and the third above the lowest three-quarters (Q3). The point just above the highest score in the distribution would logically be the fourth quartile (Q4), but that expression is seldom if ever used. The interquartile range, like any measure of variability, is an interval. The interquartile range extends from Q1 to Q3. The difference between the two measures, the IQR, like the median is insensitive to the precise values of most of the scores in a distribution. If it is used instead of the standard deviation, information is discarded. But if the distribution is skewed, some important information, such as the direction of the skew, can be identified by reporting not only the difference between Q1 and Q3, but also their exact locations. If Q2-Q1 is longer than Q3-Q2, the skew is negative. If Q3-Q2 is longer, the skew is positive.

The interquartile range is to measures of variability is what the median is to measures of central tendency. Although insensitive to the exact values of many scores in a distribution, it's preferred to standard deviation in the same kinds of situations in which the median is preferred to the mean, such as situations in which distributions are radically asymmetrical. It is the perfect companion to the median.

Interquartile range – A measure of dispersion calculated by breaking the ordered data-set into four equal sections, known as quartiles, as shown in the graph below. The point at which the first break is made is known as Q1, the second Q2, and so on. The interquartile range is defined as $Q3 - Q1$. A related statistic, known as the semi-interquartile range, is given by dividing the interquartile range by two.

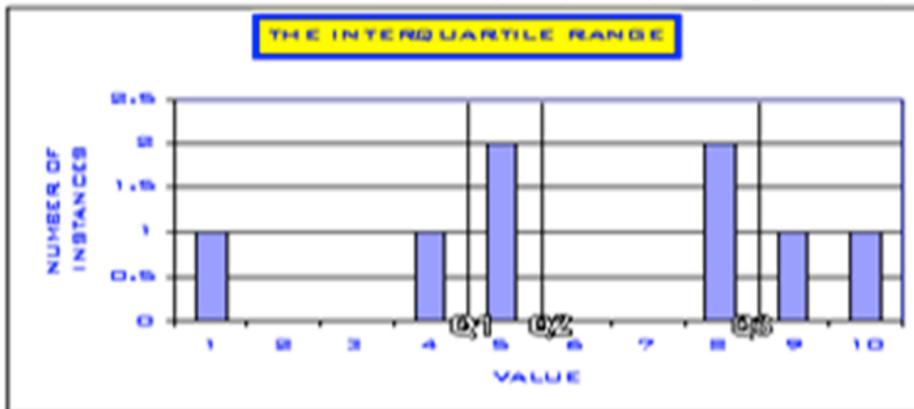


Figure 1: Graph showing a distribution and the positions of Q1, Q2, and Q3.

Standard Error and Estimation

The ultimate goal is to estimate the mean of a population. Because it's usually impossible to study an entire population, researchers take a sample and calculate the sample mean to **estimate** the population mean.

Because the sample mean is only an **estimate** of the population mean, a range and probability can be associated with the range. A researcher could say that there is a 95% probability that the population mean is between two values. This is called **interval estimation**, and the range is called a **confidence interval**.

One way to estimate a population mean is to take several sample means. A frequency distribution of these sample means would show a near-normal distribution. Because the sample means have a near-normal distribution, a variance and standard deviation can be calculated. With a mean of the means and a standard deviation of the means, it's possible to project a smooth normal distribution curve.

With the normal distribution of the sample means and standard deviations, a range for the 95% probability can be obtained. This interval represents the 95% probability that any sample mean taken from this population would fall between these values. Because there is a 95% probability that a sample mean would fall in this interval, the true population mean should be of similar value. It can be inferred from this that there is a 95% probability that the true population mean lies in that same interval. The researcher has 95% confidence that the population means lies between these values. Based upon the single sample mean, the researcher has 95% confidence of the true mean of the population. This range is called a **confidence interval**. The **z-value for $p=.05$** represents the **95% confidence interval**.

Confidence Interval:

The extent to which the sample statistic, such as mean, deviates from the population parameter; sample size calculator will tell the researcher that x number of research subjects should be sampled in order to have a 95 percent level of confidence, plus or minus 5 percent; in order to ensure a smaller confidence interval, such as plus or minus 2 percent, a larger sample size will be required

When the probability of including the value of the parameter within the interval estimate is known, this is referred to as a confidence interval. Theoretically, you can produce a confidence interval for any parameter of a distribution; confidence intervals can also be developed around correlation coefficients. Estimation can be used for a single population or for multiple populations.

To determine how closely the sample mean approximates the population mean, the standard error of the mean is used to build a confidence interval.

A confidence interval has a lower and upper limit value. A 95% confidence interval is interpreted as there is a 95% probability that the population value lies between the lower limit and the upper limit.

Researchers also use a **90% confidence interval**. The **90% confidence interval** represents a narrower range because the researcher has only 90% confidence that it contains the population mean. The **z-value for the 90% confidence interval is $p=.10$** . Researchers who want to be 99% confident that the population mean is contained within that interval, would use the z-value for $p=.01$.

Independent Variable (X): Intervention or treatment manipulated by the researcher to create an effect on the dependent variable; manipulated or varied by the researcher to have an effect on the dependent variable; leads to the effect produced in the dependent variable.

Dependent Variable (Y): Outcome the researcher wants to predict or explain; outcome or response variable measured to examine the effect created by the independent variable; changes measured in the dependent variable are presumed to be caused by the independent variable; actually the one the researchers is primarily concerned with understanding more thoroughly.

Difference Between Two Means

Often in research, it is important to know whether two populations are different from each other. Are the two samples measured merely two random samples from the same population? The probability that the true answer is yes, that the two samples have been drawn from a single population, depends on two factors. The first is the size and direction of the obtained difference between the two means, and the second is the variability of a hypothetical distribution of differences between means when pairs of samples are taken at random from a single population. To find out if one method is truly better than another, two samples are taken from the population, making sure that the two are initially random samples from a single population. The traditional method is used on one group, which is then known as the control group, and the new method is used on the other, or experimental group. Then, test both groups are tested and mean scores are compared. The objective of the study is to determine whether the two are still random samples of the same population as it related to the outcome of the intervention. The hope is that now there are two populations, one superior to the other with respect to the outcome of the intervention, and that the experimental group represents the superior population.

The basic formula for the **significance test**, or **z test**, uses the relation between the difference and the standard error of the difference. Unless the entire population has been measured, however, it is not the z ratio that is used to test for significance, but a ratio called t. The **t ratio** is essentially the same as z, but it is referred for significance testing to a distribution that changes its shape. When n is very large, the difference between z and t distributions is negligible; when n is as large as the population, the two are identical. These tests are used with continuous variables.

Tests of Significance:

t-test: One of the most common parametric analyses used to test for significant differences between group means of two samples is the t-test. A t-test is formulated to compare two sets of data or two groups at one time. The independent t-test analysis technique was developed to examine differences between two independent groups. For example, in a study examining the levels of depression among elderly long term care residents, differences between residents with and without dementia were investigated. The independent variable in this case was the level of dementia, and included two levels, a no dementia group and a severe dementia group. The dependent variable was the score of the long term care resident on a geriatric depression scale. The results of the test were significant; $p < 0.05$, demonstrating that long term residents with no dementia had significantly higher depression scores than long term residents who had severe dementia.

The paired or dependent t-test analysis technique was developed to examine differences between two matched or paired groups; or a comparison of a pretest and posttest measurements. Samples are independent if the study participants in one group are unrelated to or different from the participants in the second group; sample groups do not have to be equal. If the value is < 0.05 , the t-test is significant and represents a real difference between the two groups. For example, a study examined the level of functional impairment among adults receiving rehabilitation for a painful injury, looking at changes over time. The independent variable in this example was treatment over time, meaning that the whole sample received rehabilitation for 3 weeks. The dependent variable was functional impairment, which was represented by patients' scores on a pain scale which were done at the beginning and the end of the 3-week treatment period. The t-test was statistically significant revealing that the patients undergoing rehabilitation had significantly lower functional impairment levels from baseline to post treatment.

Level of Significance (P value): Level of Significance or cutoff point is used to determine whether the samples being tested are members of the same population (nonsignificant) or different populations (significant); commonly set at 0.05, 0.01, or 0.001.

The **significance level** represents only that much of a probability that the proclamation is wrong; that a true null hypothesis is being rejected. That means that the lower the significance level, the higher is the confidence that the observed effect is real and reliable. A significant difference is one that would occur only five times or fewer in 100 comparisons if every sample were taken at random from the same population; a very significant difference is one that would occur only once in 100 comparisons. These are sometimes referred to as the .05 and .01 levels of significance, or as $p < .05$ and $p < .01$, respectively. The p stands for probability.

Chi-Square

For categorical variables, the chi-square statistic may be used. In the general formula for the chi square, the greater the deviation from the expected frequency, the larger chi-square is likely to be. Squaring each difference allows negative differences to augment rather than reduce the total. Since the expected frequency is derived from the hypothesis of no difference, chi-square is an index of deviation from that hypothesis. Tables are available in which one can find the significance level of any chi-square.

Chi-Square Test of Independence: The chi-square test compares differences in proportions of nominal level variables. When a study requires that researchers compare proportions (percentages) in one category versus another category, the chi-square is a statistic that reveals if the difference in proportion is statistically improbable. A one-way chi-square is a statistic that compares different levels of one variable only. For example, a researcher may collect information on gender and compare the proportions of males to females. If the one-way chi-square is statistically significant, it would indicate that proportions of one gender are significantly higher than proportions of the other gender than what would be expected by chance. A two-way chi-square is a statistic that tests whether proportions in levels of one variable are significantly different from proportions of the second variable. For example, the presence of advanced colon polyps were studied in three groups of patients: patients having a normal body mass index; patients who were overweight, and patients who were obese. The results of the chi-square analysis indicated that a larger proportion of obese patients fell into the category of having advanced colon polyps compared with normal weight and overweight patients.

One Way Analysis of Variance (ANOVA): ANOVA is a statistical procedure that compares data between two or more groups or conditions to investigate the presence of differences between those groups on some continuous dependent or outcome variable. ANOVA is the better statistical technique for examining differences among more than two groups. ANOVA computes differences among (within) the data and differences between the groups or conditions. ANOVA tests whether group means are different but also considers the variation that will be present among all of the groups. For example, medical costs per month for women receiving treatment for a chronic pain condition were examined. The independent variable in this example was the type of study treatment or intervention. Patients received multidisciplinary treatment, standard care with primary care physician only, or pharmacotherapy by an anesthesiologist. The dependent variable was medical costs per month during the year. The ANOVA revealed that there was a statistical difference among the groups but does not tell you which group was different. Further testing, usually Post Hoc is required to determine all the significant differences between groups.

An experimental design may call for more than one independent variable, for example, several teaching methods. It may also assess the effects of those variables in various combinations, for example, combinations of methods and teachers. One technique that is appropriate to use is the **analysis of variance (ANOVA)**.

A design may feature one treatment variable but more than two categories of that variable. For example, a researcher may have six groups and six different methods to compare. Eventually, the researcher wants know which of the six methods is the most effective. The researcher could proceed by

comparing all possible combinations of groups, but that would be tedious since it would require, in this case, fifteen tests to check all the possibilities. What is needed is some kind of survey test that will tell whether there is any significant difference anywhere in an array of categories. If the answer is no, there is no point in searching further.

Whenever there are several categories of the treatment variable, an overall test of significance is needed. This test is called the **F test** or the **F ratio**. The **F** is a ratio of two variances. The variance of any distribution is the square of the standard deviation. The F test is a ratio between two variance estimates. In this example, there are six groups. The mean of each group differs by some amount from every other group. The question is whether those are significant differences or whether there is at least one significant difference among them. The researcher wants to know whether the observed variability of the means is greater than could be expected by chance. The null hypothesis in analysis of variance is that all of the groups being compared are samples taken from the same population. The F ratio is a quantitative test of the null hypothesis for analysis of variance. The null hypothesis is rejected if the probability of its occurrence by chance is sufficiently low, usually $p < .05$. When an F test turns out to be significant, the researcher knows, with some specified degree of confidence, that there is a real difference somewhere among the means. But the researcher doesn't know where it is.

Analysis of variance offers three advantages over the z or t type of significance test. The first advantage is that it can compare the effects of more than two categories of a treatment variable. The second is that it can compare the simultaneous but separate effects of two or more variables, and the third is that it can assess the interaction effects of two or more variables.

Customer surveys in healthcare: Reviewing Patient Satisfaction and Complaints

Why measure patient satisfaction?

Feedback for performance improvement

Feedback for staff retention

Engage customers

As a marketing strategy

For benchmarking

Understand the patient/family experience

A good evaluation releases the voice of the participants. It helps them to be heard, which for many people is a rare opportunity. It is through listening to this voice that the providers can understand the real needs and learn what activities and support would be most relevant and appropriate.

Surveys have evolved through a number of stages. Historically, the typical patient survey was designed by and for a healthcare organization marketing department. Early examples in the scientific literature tended to focus on general perceptions and attitudes toward health care. Later, surveys began to focus on patients' experiences in specific health care encounters. More recently, much has been made of surveying patient perceptions rather than patient satisfaction. A defining feature of perception surveys is the inclusion of both evaluative ratings and patient reports, the patient reporting that something did or did not happen.

Healthcare organizations need information that accurately reflects patients' perceptions of the health care delivery process. They want to use patient feedback for more than just gathering report card data to satisfy purchasers' or accrediting agencies' requirements. They also want to be able to identify opportunities for improvement, to measure the effect of efforts to improve patient satisfaction, and to be able to use patient satisfaction as a financial incentive for managers. A single generic survey will usually not meet all the managers' needs for patient satisfaction data. Surveys are also required for specific populations, such as inpatients, outpatients, emergency room patients, patients waiting for tests or therapy, and patients making physician office visits. To meet all those needs, the organization needs a high quality survey system with different kinds of surveys.

Healthcare organizations may consider developing their own survey systems, but this option is very expensive, requiring a staff of survey experts to develop customized questionnaires from scratch that would satisfy all its requirements. Even if an organization did develop its own questionnaires, the organization wouldn't have benchmark data to evaluate its results in comparison with other providers. This is why many healthcare organizations make the decision to select an outside survey provider that has scientifically sound questionnaires, a national database, and understandable report formats. The organization doesn't want to select a survey provider based on personal, political, or pricing considerations rather than scientific merit.

Although references and pricing are important criteria for a healthcare organization to consider, they should be applied only after some basic scientific criteria have been met. This is similar to the approach for choosing and evaluating clinical guidelines and outcomes measure. Because no patient questionnaire will ever assess patient satisfaction with perfect accuracy, the true level of patient satisfaction probably will never be known. So, the organization needs to assess the degree of accuracy of a questionnaire by measuring its reliability and validity. Survey providers should offer documentation to back up claims of reliability and validity for its scale scores.

Turning patient satisfaction data into meaningful PI measures

- Align patient satisfaction data with organizational goals and initiatives

- Select appropriate patient satisfaction data as PI measures of success

- Use PI tools and methodology to drill down to help understand underlying processes and identify solutions

 - Concentration on a few target areas and achieve success before moving to other areas

 - Set realistic goals and expectations

 - Organize appropriate staff mix and numbers to work on the target area

 - Communicate feedback to all organizational staff

 - Congratulate staff on their efforts and success

What to measure

- Service

- Care

- Experience

- Outcome and quality of life

Factors that influence patient satisfaction scores

- Age

- Illness

- Prior experience with satisfaction

- Patient/professional relationship

- Choice of service provider

- Gender/ethnicity and socioeconomic status

Traditional patient satisfaction topics

- Overall rating

- Admissions

- Meals-food temperature, diet explained

- Nurses-caring and respectful, response to call light

- Tests and treatments- received results in a timely manner, waiting time

- Pain management

- Visitors and family

- Noise level
- Cleanliness of room
- Physician-caring and respectful, patients included in decisions regarding treatment
- Discharge-instructions regarding hospital care, help arranging home care services
- Personal issues-TV, call button, worked, etc.
- Overall assessment

Aspects of patient experience (CAHPS)

- Access to care
- Coordination of care
- Information and education
- Physical comfort
- Continuity and transition to home
- Emotional support
- Involvement of family and friends
- Respect for patient preferences

Types of Surveys

If the organization puts a high priority on quick turnaround, or if it is conducting a special purpose assessment, for example, to survey a new unit or service, and wants to ask open ended questions, that allow the surveyor to obtain fuller explanations from patients, a **telephone survey** should be used. Although achieving a high response rate is sometimes used as an argument for conducting telephone surveys instead of the less expensive mailed surveys, telephone surveyors have been known to inflate their reported response rate by reporting what is called cooperation rate instead of the actual response rate, eliminating those they weren't able to contact. All patients should be considered in the denominator, whether contacted or not.

However, if expense is a high priority, **mailing questionnaires** is the recommended method of data collection. Mailing can result in a 50% response rate or better, with less than half the expense of a phone survey and without the interview bias typical of telephone surveys. To achieve this response rate, the organization should have a brief questionnaire, 15 minutes or less to complete, with an esthetically appealing format, a motivating cover letter from the chief executive officer, a prepaid postage return envelope, and at least one effort to follow up on the original mailing. In addition, the questionnaire and cover letter should be mailed within a short time (one to two weeks) of a patient encounter.

Personally distributing a questionnaire to patients either in the hospital, outpatient setting, or physician offices is the least expensive method of data collection, but results in highly inflated responses that are virtually useless for identifying improvement opportunities. One method should be chosen for the data; don't mix data collection methods and then combine the data into one database.

The purpose of the study, **enumerative** or **analytic**, will determine three aspects of the survey: the sampling method, the frequency of the surveys, and the report format. An **enumerative** study is done on a static population for a given period and/or location to merely describe outcomes. For example, if the organization wants to identify and prioritize opportunities for improvement, it is conducting an enumerative study, the most common use of patient surveys. An **analytic** survey examines a process over time and seeks to determine why the outcomes were observed and/or whether planned improvements had any impact, for example. It requires ongoing surveying, not just an annual or biannual survey. An enumerative study is like a snapshot; an analytic study is like a video. Depending on whether the organization is using its patient survey as an enumerative or analytic study will determine how to sample and how often.

Frequency: The survey's frequency will also be determined by its purpose. Quarterly analysis is usually sufficient to identify and prioritize opportunities for improvement. An analytic study is more labor intensive and requires analysis of daily or weekly data points.

Reports: Report formats for enumerative studies should show data compared to an appropriate database. The charts should show where the organization's patients fit in relation to those in other facilities. Is the facility consistently above or below the norm? What confidence do you have in the findings? For an analytic study, the charts should be run or control charts that will tell the organization whether the variation in the process is common cause variation (a stable process) or special cause variation (an unstable process). The choice of sampling and report formats is complicated.

Performance Improvement Tools

Brainstorming

Brainstorming is a structured process for generating unconstrained ideas/solutions about an issue and gaining engagement/involvement in the improvement process in a short amount of time.

Brainstorming is not an end in itself; its products will have to be assessed and refined. Brainstorming is a way of getting started with ideas and facilitates the creative thinking process. Brainstorming separates idea generation from organizing and assessment of the ideas. Teams can brainstorm to generate lists of:

- Topics to assess
- Process components
- Topics for data collection
- Problems
- Potential solutions

Brainstorming stimulates creativity and encourages many perspectives on an issue. Because brainstorming involves the whole team, it also strengthens the team. Brainstorming provides a safe environment for team members to express ideas, and it helps a team gain consensus.

Steps for brainstorming:

1. Identify the topic for the brainstorming session. Without an identified topic, ideas may be too wide spread and not useful. Make sure the team knows that any idea is appropriate to contribute related to the topic, no matter how narrow or broad, serious or humorous. Clarify the topic and provide any relevant information. The key to brainstorming is to withhold judgment as a way of unlocking creativity. Unusual suggestions may lead to creative solutions.
2. Allow time to think briefly about the issue. Team members should be given a few minutes to think of ideas, but not so long that they start questioning their ideas
3. Set a time limit for brainstorming. Depending on the size of the group, it may be wise to set a 10 to 20 minute time limit. Too little time won't allow everyone to participate, but too much time might lead to early analysis of ideas, which is not part of brainstorming.
4. Have each group member call out ideas; this can be done randomly or in a pre-determined order. Ideas should be displayed so everyone can see them. People shouldn't react to the ideas or comment about them. Team members can pass if they run out of ideas.
5. When the brainstorming session is complete, clarify the ideas. This step still doesn't involve judgment. The goal is to make sure that the ideas are recorded accurately and are understood by the group. Too often, ideas are criticized and deleted at this stage; but there should be no attempt to remove duplications, put the ideas in sequence or rank them.

If team members are hesitant to call out ideas, they can be written on pieces of paper and passed to the leader who will write them for everyone to see. When brainstorming is finished, the team should have a varied list of possible ideas which can be refined by the technique of Multivoting.

Multivoting

Multivoting is a technique for narrowing down a broad list of ideas to those most important. Using this process, the best ideas rise to the top of the list. Multivoting doesn't leave the team with a single idea, but moves the team in the direction of consensus. Multivoting can be used after brainstorming or with any list of ideas and is appropriate for all phases of quality/performance improvement. After multivoting, the team should have the critical few ideas worthy of immediate attention. One benefit of multivoting is that while it limits choices, it still allows a range of choices.

Steps for multivoting:

1. Using a predetermined list of ideas, consider whether any are the same or similar. Nearly every list will have some overlap; this step identifies those cases.
2. Ask the group whether similar items can be grouped, particularly those who identified the items.
3. If the group agrees, combine duplicate or similar items. The group should agree on the new wording;.
4. You can number each item on the new list, making them easier to locate.
5. Each member gets a certain number of points and can use them to vote on different items. Determine the total number of points to be given to each member. How many items are on the list and how quickly you want to finish this process will dictate how many votes each person has, generally in the range of 3-10. Sometimes you can divide the total number of items by 4.
6. Allow time for the members to independently assign their points to one or more of the items on the list. There are no rules regarding how points have to be assigned.
7. Identify the points for each item.
8. Note the item(s) that received the greatest number of points. Sometimes, there is no clear leading item.
9. Choose the final group or multivote again.

Multivoting is a non-threatening way to choose the best ideas the team members offer.

Cause-and-Effect Diagram (Fishbone, Ishikawa)

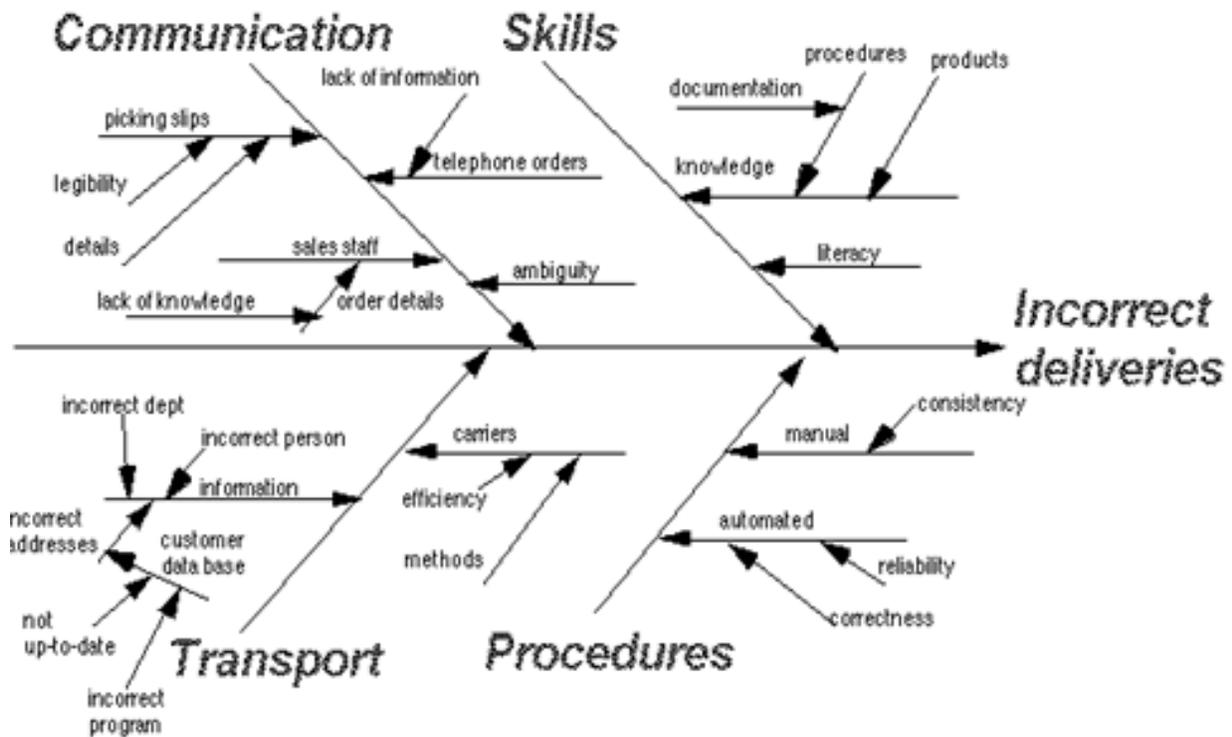
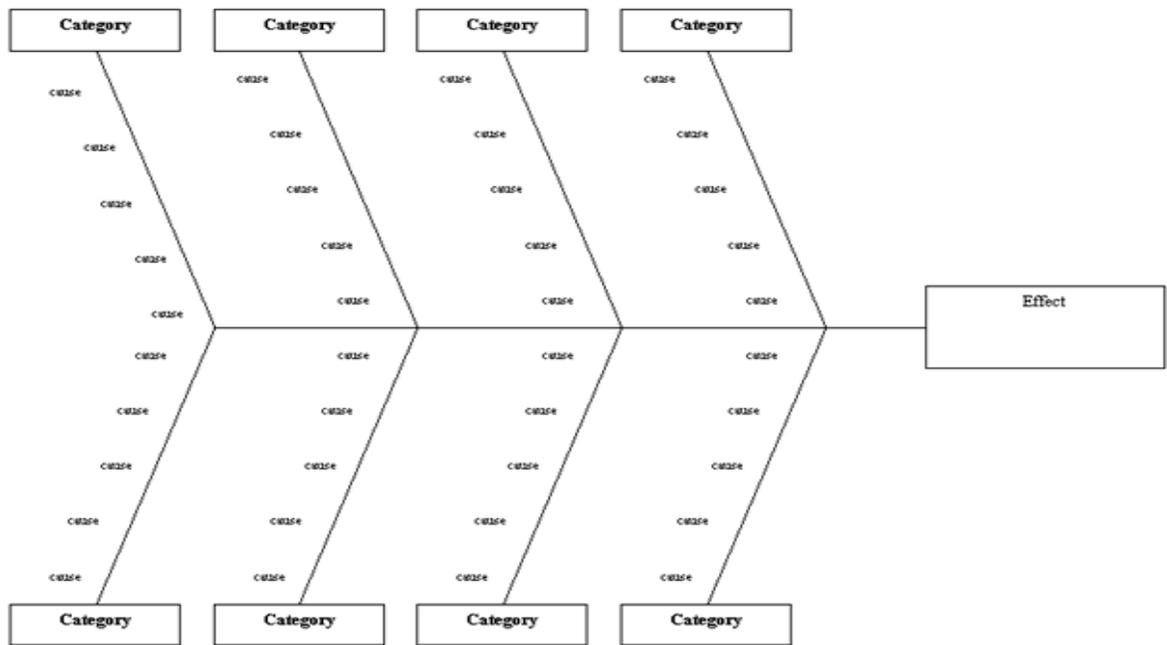
The Cause and Effect diagram is sometimes called a fishbone diagram because of its shape or an Ishikawa diagram after Kaoru Ishikawa, who created the diagram. The cause and effect diagram focuses on causality, showing a large number of possible causes of a particular outcome. The diagram can help a team get an overview of the causes for a particular outcome. In addition, it may help the team identify specific conditions requiring further attention and might even suggest appropriate actions. The process of developing the diagram can provide ideas for data collection. A caused and effect diagram helps teams:

1. Identify and define an outcome or problem
2. Determine causes of a given outcome or problem
3. Identify causes for variation in a process

An important attribute of a cause and effect diagram is its appearance. It can help team members quickly visualize the relationships of various components. Steps for a cause and effect diagram:

1. Place the outcome or problem statement on the right side of the paper, halfway down; draw a horizontal line across the paper with an arrow pointing to the outcome.
2. Determine major categories for causes; connect them to the horizontal line with diagonal lines. With categories, look for general categories, such as methods, machines, materials, people, to place specifics. Diagrams may also be done without major categories.
3. Note the major causes and place them under the general categories. Brainstorming is a good way to come up with causes. Ask the Why or How question five times. Place the main causes on horizontal lines that connect to the diagonal lines. If desired, list subcauses under main causes.

- Evaluate the diagram. When all ideas have been identified, study the diagram to determine obvious areas for improvement, causes that are readily solved or eliminated, and areas needing study to be better understood.



Flowchart

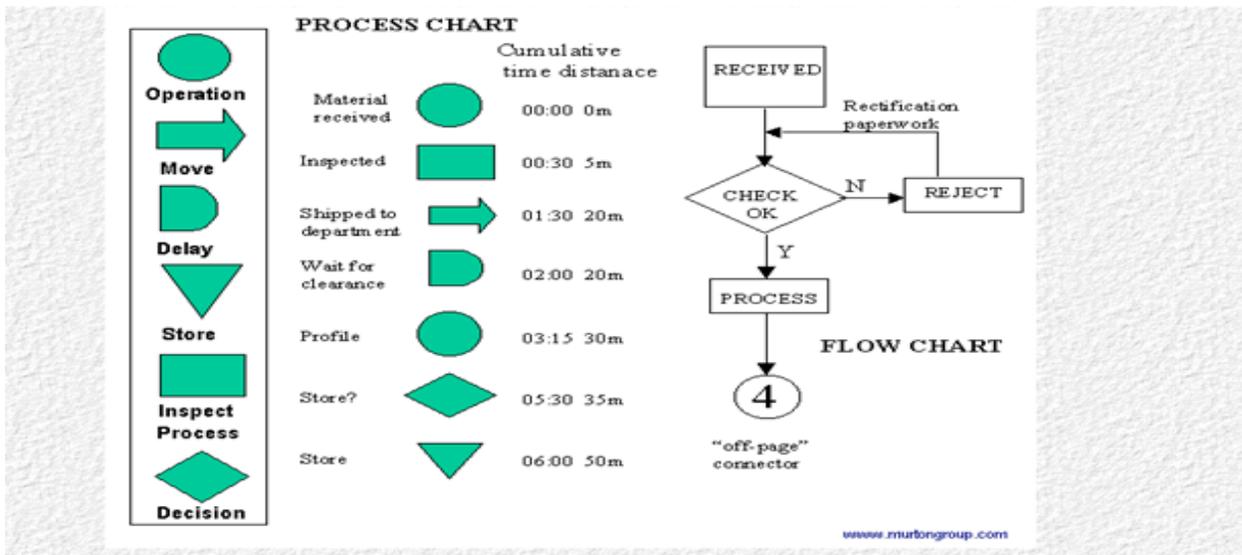
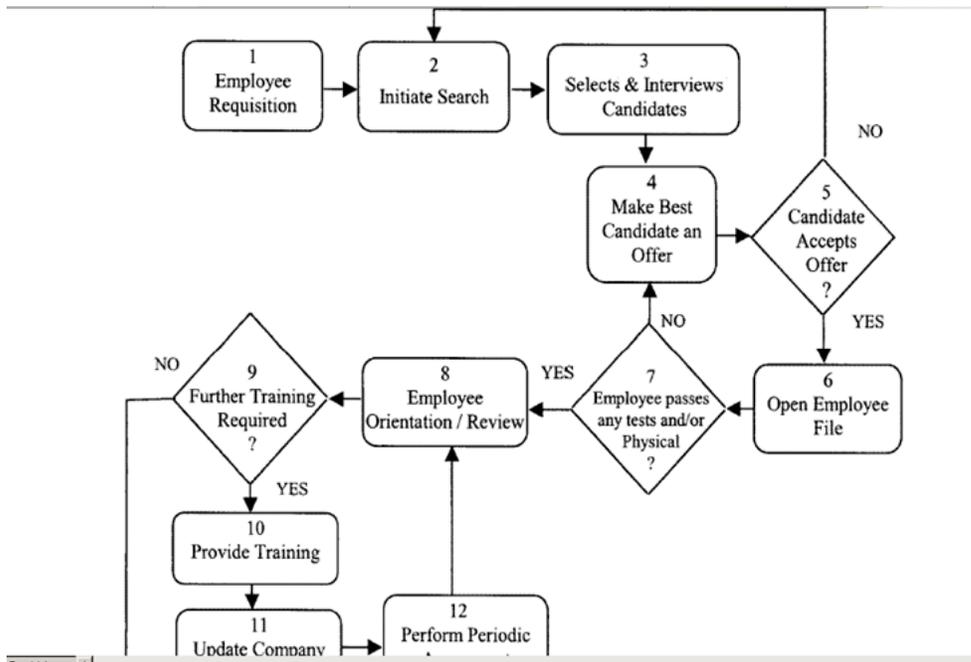
A flowchart depicts the sequence of steps performed in a specific process. The goal of a flowchart is to identify the actual path a process follows, as opposed to one defined in a procedure manual. By documenting a process with a flowchart, a team can identify redundancies, inefficiencies, misunderstandings, waiting loops, and inspection steps. These are the areas that create the problems in most processes. Another goal of creating a flowchart is to gain understanding of how the process should be performed. Once the actual process is illustrated on the flowchart, the team can create a flowchart showing how the ideal process should look.

Flowcharts can be used:

- When identifying problems
- When analyzing problems to determine causes, and
- When planning solutions.

To create a flowchart:

1. Decide on the starting and ending points of the process. These decisions are crucial in keeping the flowchart within manageable boundaries.
2. Brainstorm to record all activities and decision points involved in the process. This should be done by those most familiar with the process, with assistance from people outside the team as needed. The team is looking for exactly what activities are involved and what decisions must be made to keep the process moving to its conclusion
3. Arrange activities and decision points in sequence. Once the activities and decision points are gathered, the team must determine their sequence. Some activities may appear to occur simultaneously, while others may seem disconnected. Certain decisions may cause steps to be repeated
4. Using this information, create the flowchart. Place each activity within a rectangle and place each decision point in a diamond. Connect these with lines and arrows to show the flow of the process
5. Analyze the flowchart. The team can use the flowchart to evaluate the process as it currently exists, looking for redundancies, inefficiencies, misunderstandings, black holes, barriers, and any other problems. The team may also want to find spots where the process works well and consider these as models for improvement. The team can use this chart as the basis for designing an improved process. The team may want to follow the existing process, correcting isolated problems, or it may need to create an entirely new process if fixing the old one is too difficult. The team can use the failures of the old process as the rationale for the new design.

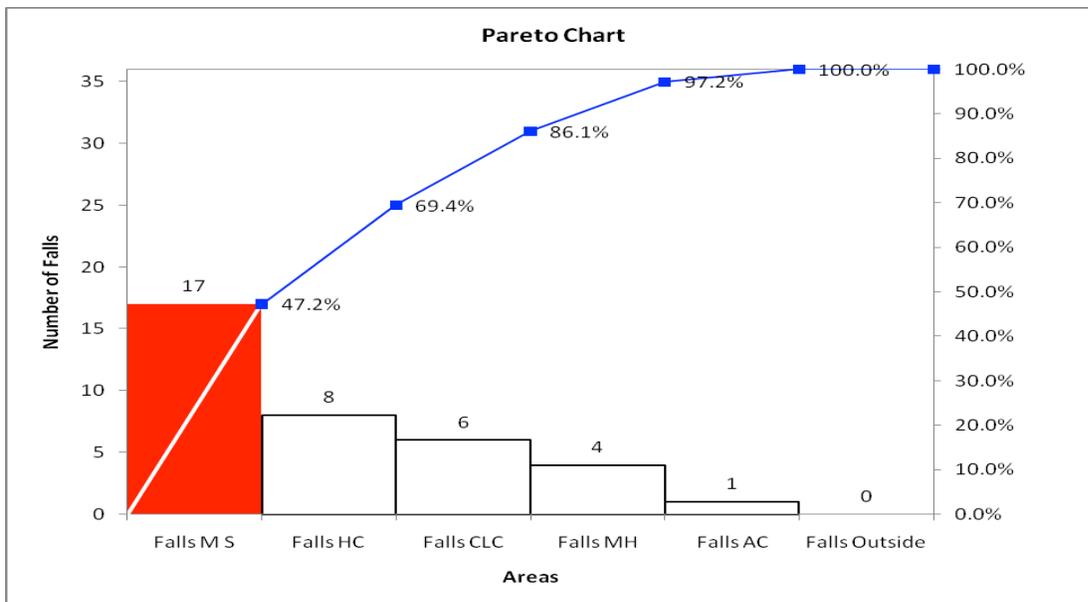
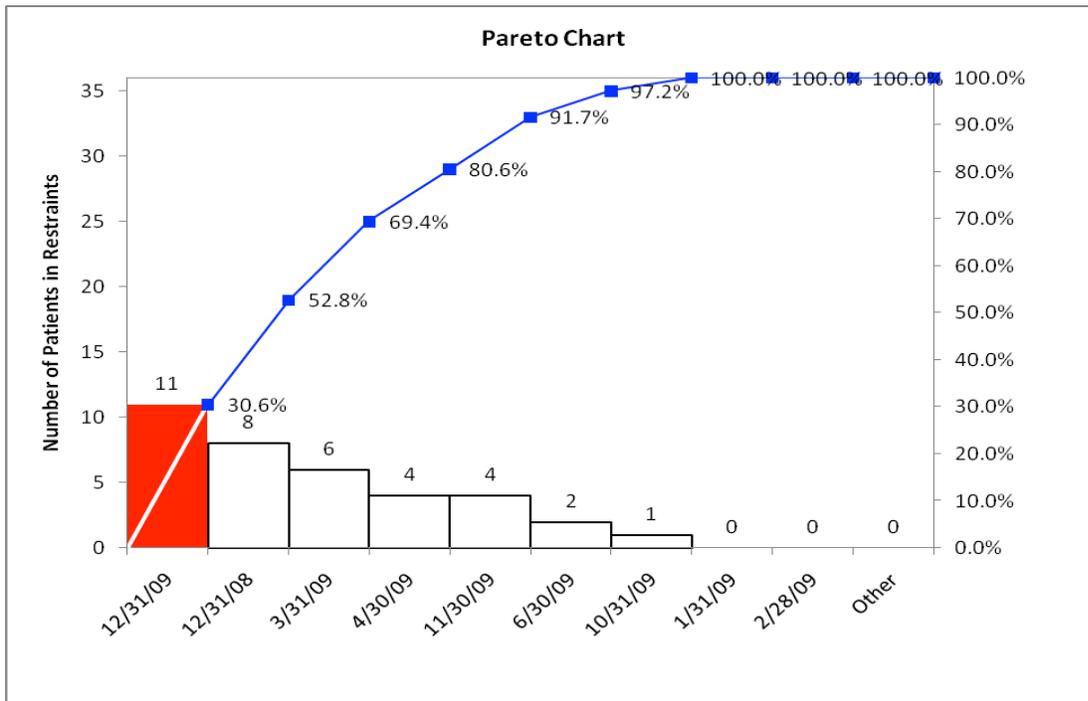


Pareto Chart

A Pareto chart depicts in descending order the frequency of events being studied. This useful chart allows teams to categorize occurrences and focus on those that are most frequent and most important. This chart might be a natural follow up to a cause and effect diagram. Having listed a number of causes, the team could collect data about the occurrence of each and then display them on a Pareto chart. The Pareto chart displays the relative frequency. This could be the most frequent causes that a team seeks to resolve. A Pareto chart can also be used to monitor the success of efforts to reduce the frequency of a particular occurrence. The Pareto chart can help a team to see when the causes it is measuring compose the majority of outcomes. Steps to develop a Pareto chart:

1. Decide on the data to be collected.
2. Select the type of causes or conditions to be compared.

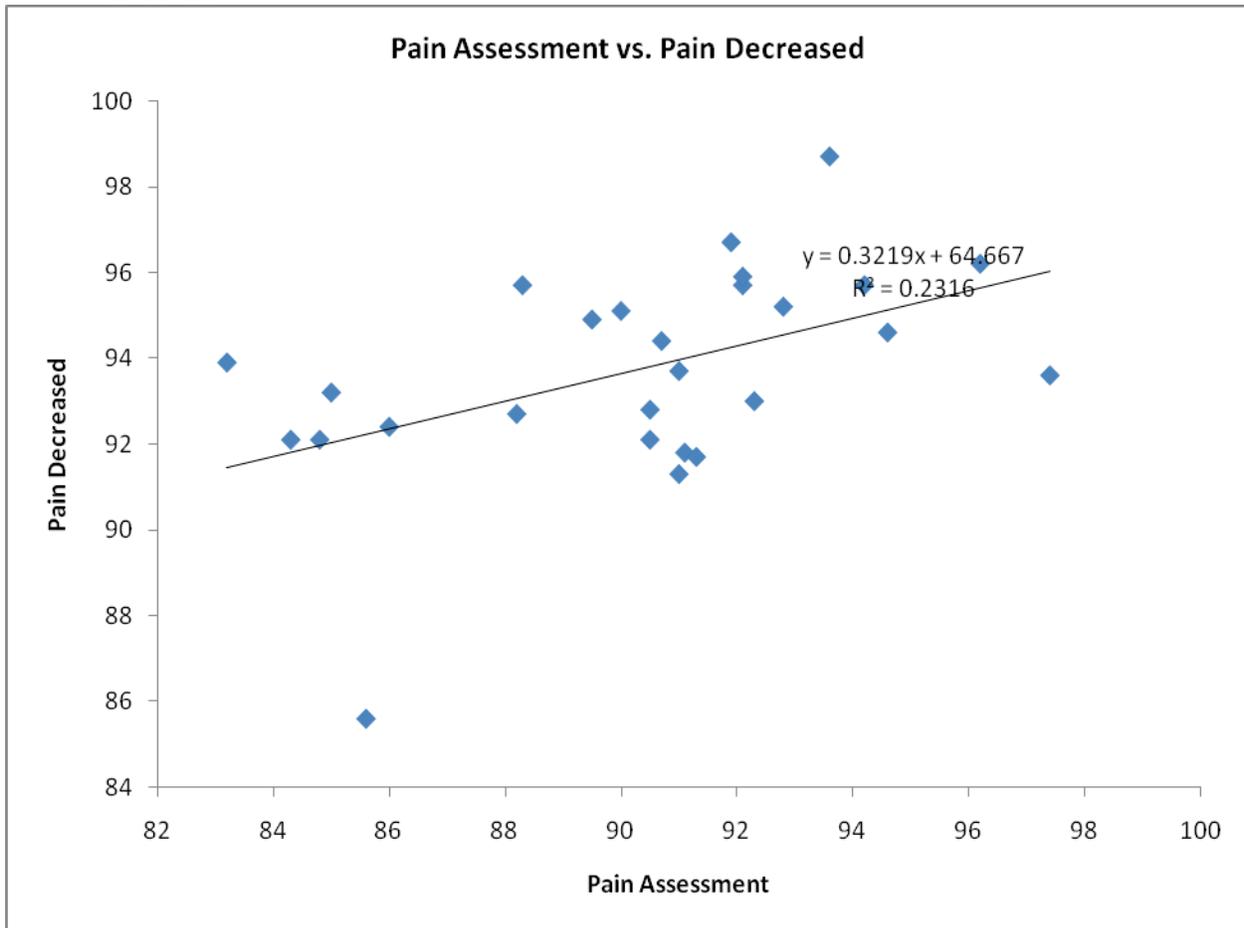
3. Collect data
4. Draw the vertical axis indicating the frequency in numbers on the left side. Draw a corresponding percentage line on the right vertical axis
5. Label the horizontal axis with each topic or factor in descending order
6. Draw bars to indicate the frequency of each factor. Identify the percentage of the first bar on the left with a point at the center of the bar which corresponds to the percentage line on the right vertical axis. Continue to draw a cumulative frequency line, adding the percentage of each succeeding bar until the last bar is reached, which corresponds to 100%.

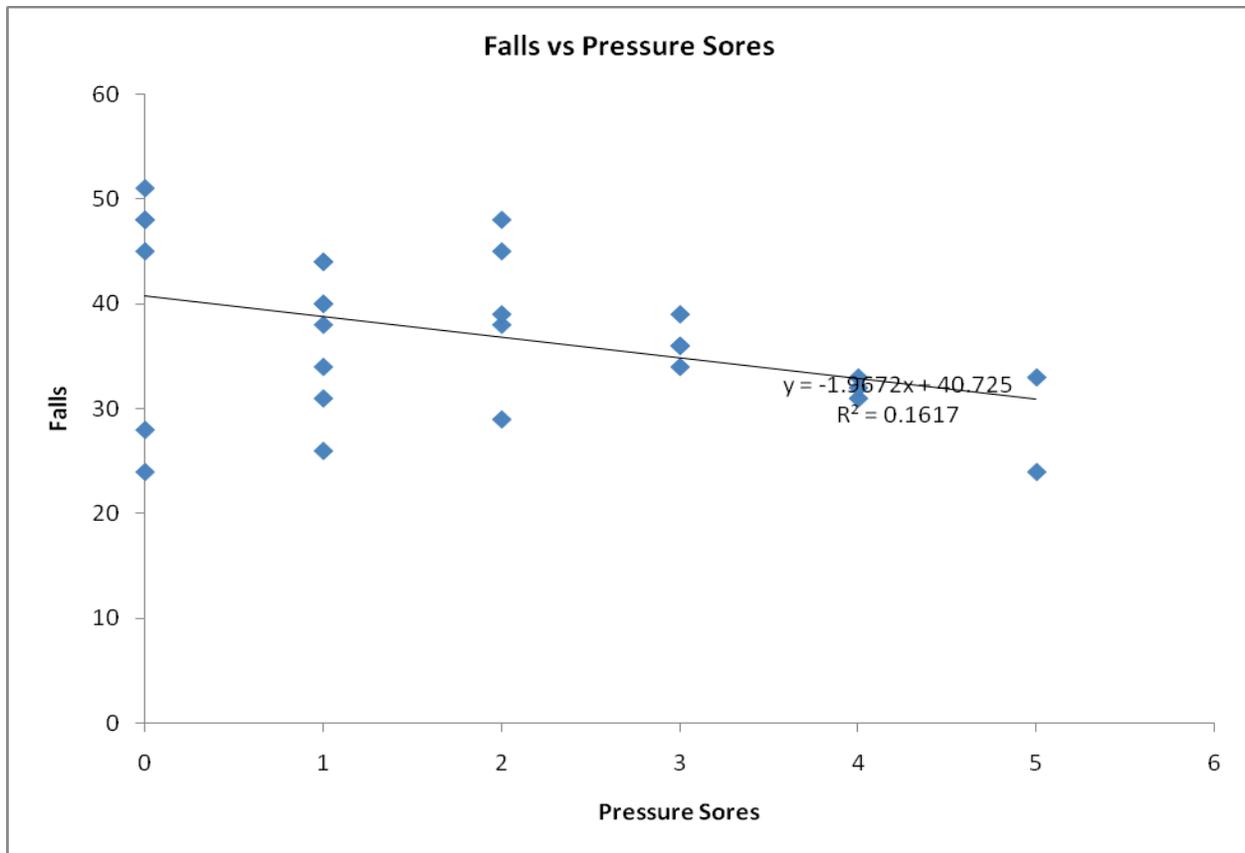


Scatter Diagram (Scattergram)

A scatter diagram illustrates the relationship between two variables. It is used to study the possible relationship between the variables. A scatter diagram can offer persuasive evidence of a relationship. Teams use scatter diagrams to test a theory about cause and effect data, when they analyze raw data, or when monitoring an action taken to improve performance. Steps to a scatter diagram:

1. Decide which two variables will be tested.
2. Collect paired samples of data.
3. Draw the horizontal and vertical axes, noting which variable is represented by each. The horizontal (x axis) is the independent variable; the vertical (y axis) is the dependent variable
4. Plot the variables on the graph. Mark the appropriate intersecting points on the graph; for repeated values, you can circle the number of times the point is repeated
5. Interpret the diagram by noting the clustering of points on the graph. If the points are scattered all over the diagram, the two variables have no correlation. If points cluster in an area running from lower left to upper right, the two variables have a positive correlation. If points cluster in an area running from upper left to lower right, the two variables have a negative correlation. In general, the more clusters form a straight line, the stronger the relationship between the two variables.





Run Chart

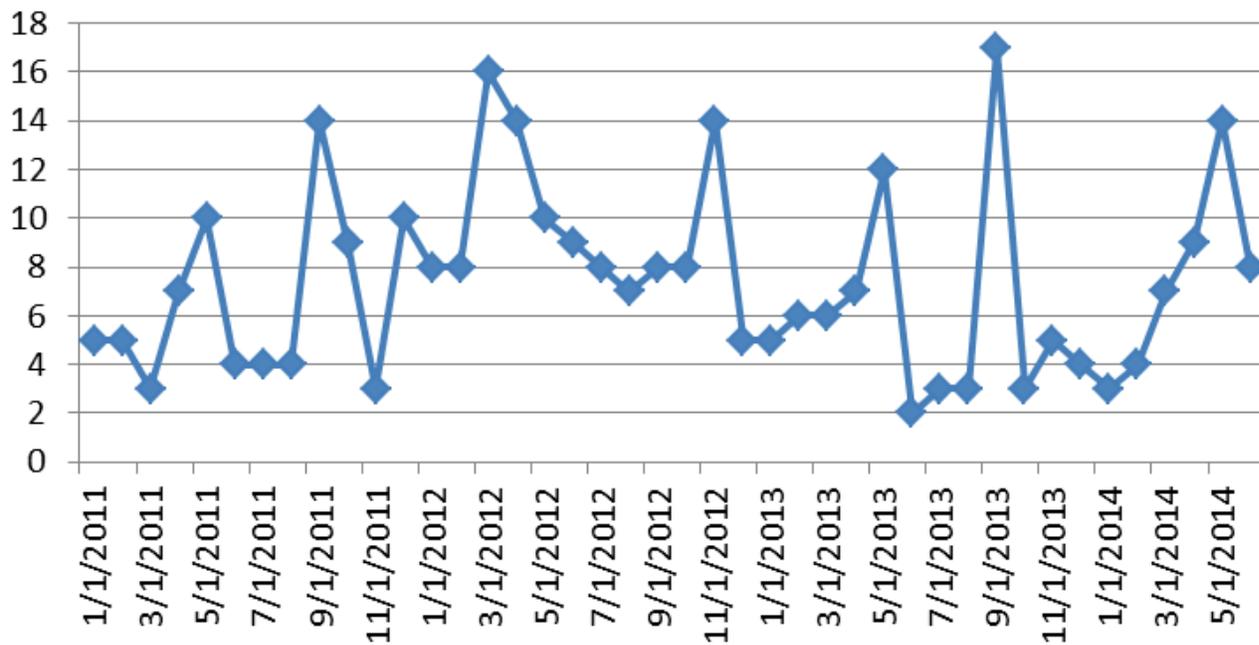
A run chart plots points on a graph to show levels of performance over time. A run chart identifies trends, including movement away from the average. A run chart can show performance needing improvement and performance experiencing improvement or decline. A run chart can be used to analyze performance data and to monitor actions taken to improve performance. Steps for a run chart:

1. Decide what data will be collected and over what period of time. The time period should be long enough to show patterns and trends.
2. Draw a graph, the horizontal (x axis) indicates the time sequence and the vertical (y axis) indicates the increments of measure.
3. Plot the data points for the designated time period on the graph and connect the points with a line.
4. Evaluate the run chart to identify meaningful trends or shifts. A run of (7-8) points on one side of the average indicates a statistically unusual event or shift, as does a trend of 6 or more steadily increasing or decreasing points.
5. Investigate the findings from the run chart.

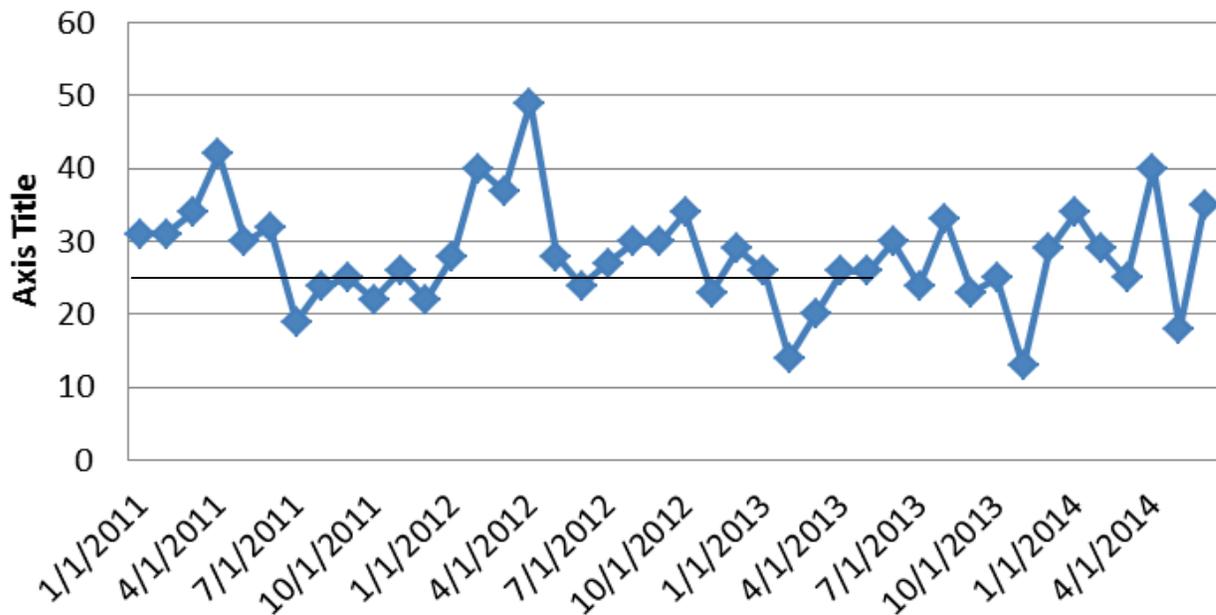
Think of data running across the page, over time.

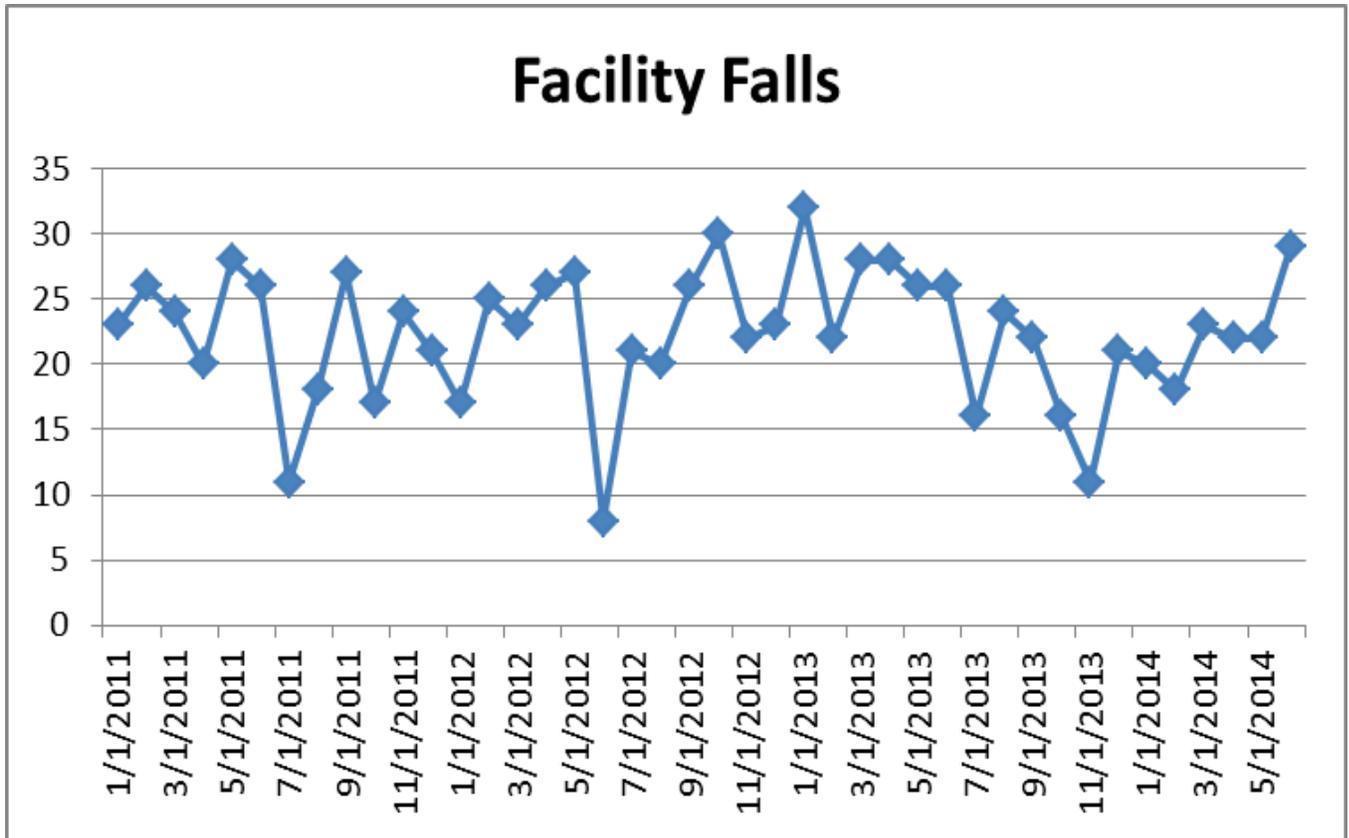
- A simple line chart
- X axis (horizontal) is time
- Y axis (vertical) is the measure
- Plot time as hourly, daily, weekly, monthly, etc.
- Displays data in order of occurrence

Medication Errors



RRT





Control Chart

A control chart is a run chart with an upper and lower control limit on either side of the average. The limits are statistically determined; generally 3 standard deviations from the mean. Donald Wheeler refers to them as natural process limits, because they designate the natural limits of the process. The limits don't represent desired limits, those would be specification limits. A control chart shows variation in a process and suggests what type of causes may underlie the variation.

Common Cause

When performance variation stays within the upper and lower control limits, the causes of the variation are common or random causes. Common causes will always be present, just as variation will always be present. These are the random, everyday occurrences that individually have little demonstrable consequence. To affect the common causes, the process itself must be changed, which may move performance to a different average. At the new level, variation and new common causes will still exist. Common causes are a valid subject for improvement activities when the team wants to improve the process as a whole. Don't make the mistake of tampering or trying to fix common cause as if it were special cause.

Special Cause

When performance jumps outside the upper or lower control limits, the cause is called special cause or an assignable cause. One or only a few special causes will have a significant effect. Special causes require immediate attention; however fixing a special cause doesn't necessarily improve the overall level of performance. Although control charts can be done manually, they are generally done with computer programs.

- Prescribes the proper decision for the manager
- Graphical and visually appealing
- Easy to create
- Empowers those who use or create it
- Provides basis for predicting the future

Control chart starts with a run chart

- Shows if a process is out of control
- Shows impact of process changes
- Mean (average) is usually calculated for 12 months (prior fiscal year) of data
- What type of data do you have?
 - Variable: measures and compares data by units such as time, process capability or process costs
 - Attribute: counts data by categories such as number or percentage of patients, errors, etc.
- Creating a control chart can help with process inspection, tracking the process over time, periodic adjustment of a process, or visual data display, which can identify an immediate improvement opportunity
- Once a control chart is used to stabilize a process, it can be used to predict the future performance of the process
- Control charts recognize sources of variation in a process and are used to monitor, control, analyze, and improve process performance over time by studying variation and its causes
- Out of control refers to a process that is outside normal variances (control limits)
- Control limits are calculated based upon the standard deviation, above and below the mean
 - Upper control limits UCL are 1, 2, or 3 standard deviations above the mean
 - Lower control limits UCL are 1, 2, or 3 standard deviations below the mean
- Mean (average) represented by \bar{X} , is the sum of the data (total) divided by the number (N) of data points. For example, $1,3,4,5,7 = 20$ (divided by 5 data points) = 4 (mean)
- Standard deviation measures the variation of the data from the mean (above and below). The less variation of the data, the closer the standard deviation is to zero.
- Variation is a normal part of any process and is expected to occur. Variation results from common and special causes within the process. Too much variation leads to an out of control process.
- Stability is a process in control. This is true if all of the data points are within the control limits and the process does not meet the out of control rules.
- Common causes are expected to occur. Improving common causes and variation requires changes to the process. Elimination of common causes will help a process perform consistently over time. Common causes can be trends or patterns identified in the data.
- Special causes are shown as data points outside the control limits. They are the result of special circumstances or conditions such as human error, unplanned events, freak occurrences, etc., that are not a part of the way the process normally operates. They may also occur because of an unlikely combination of events, including the breakdown of an entire process or system. Special causes must be addressed immediately to bring the process into control.

- Don't be misled by data that looks too good to be true. You may have data errors or underreporting of problems. You need to ask why your data has changed.

Control Chart Analysis: After creating a control chart, apply these seven rules to determine if your process is out of control

- One or more data points fall outside of the control limits (beyond 3 UCL or 3 LCL)
- Two data points, out of three consecutive data points, are on the same side of the mean between UCL 2 and 3 or between LCL 2 and 3
- Four data points, out of five consecutive data points, are on the same side of the mean between ULC 1 and 2 or beyond or between LCL1 and 2 or beyond
- Nine consecutive data points are on the same side of the mean
- Six consecutive data points are increasing or decreasing
- Fourteen consecutive data points alternate up and down
- Fifteen consecutive data points are between UCL 1 and LCL 1, above and below the mean

Remember that a process can be out of control even if the data represents a positive change. Ask why your data has changed. For the last two rules, this will apply only if data collection is frequent and many points are plotted.

Questions to ask when your process is out of control:

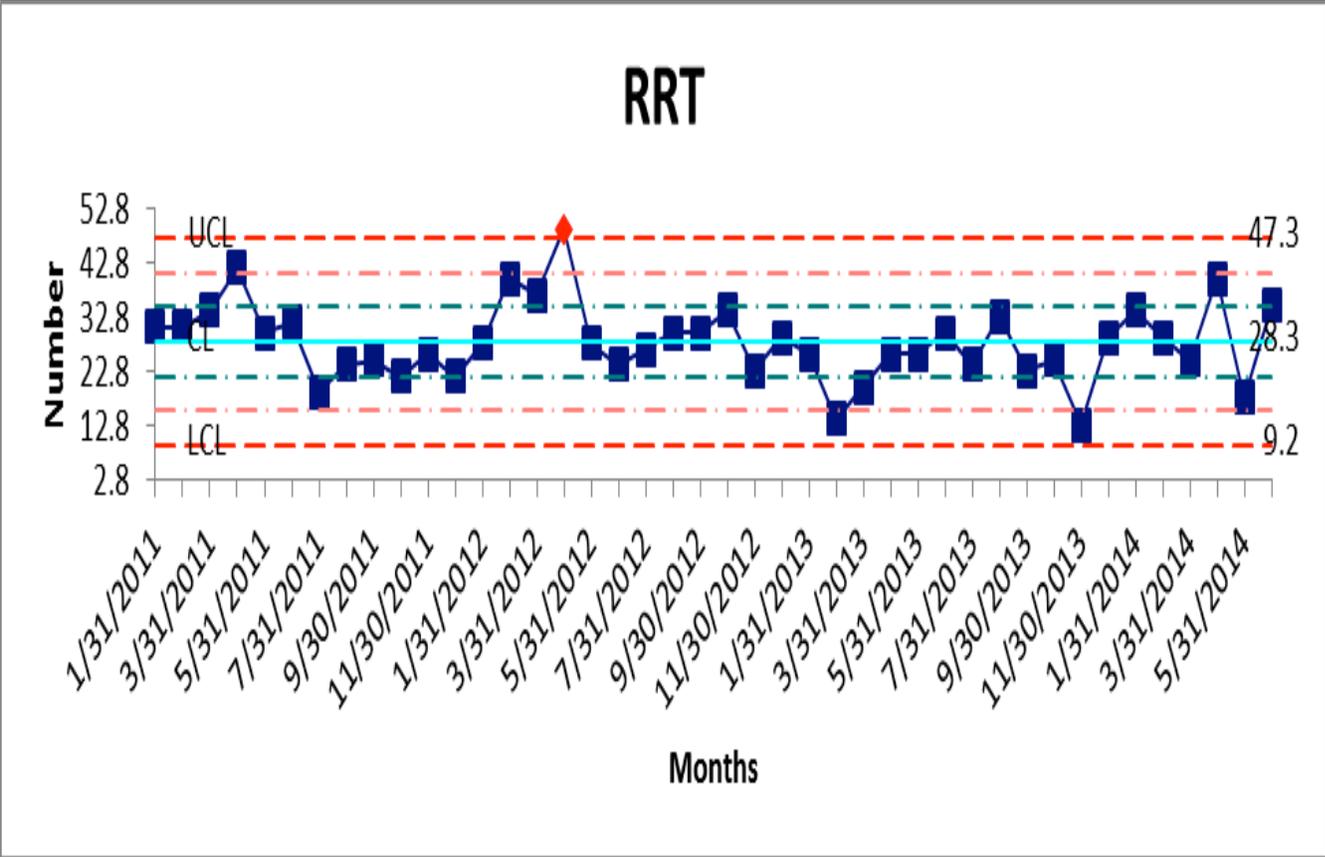
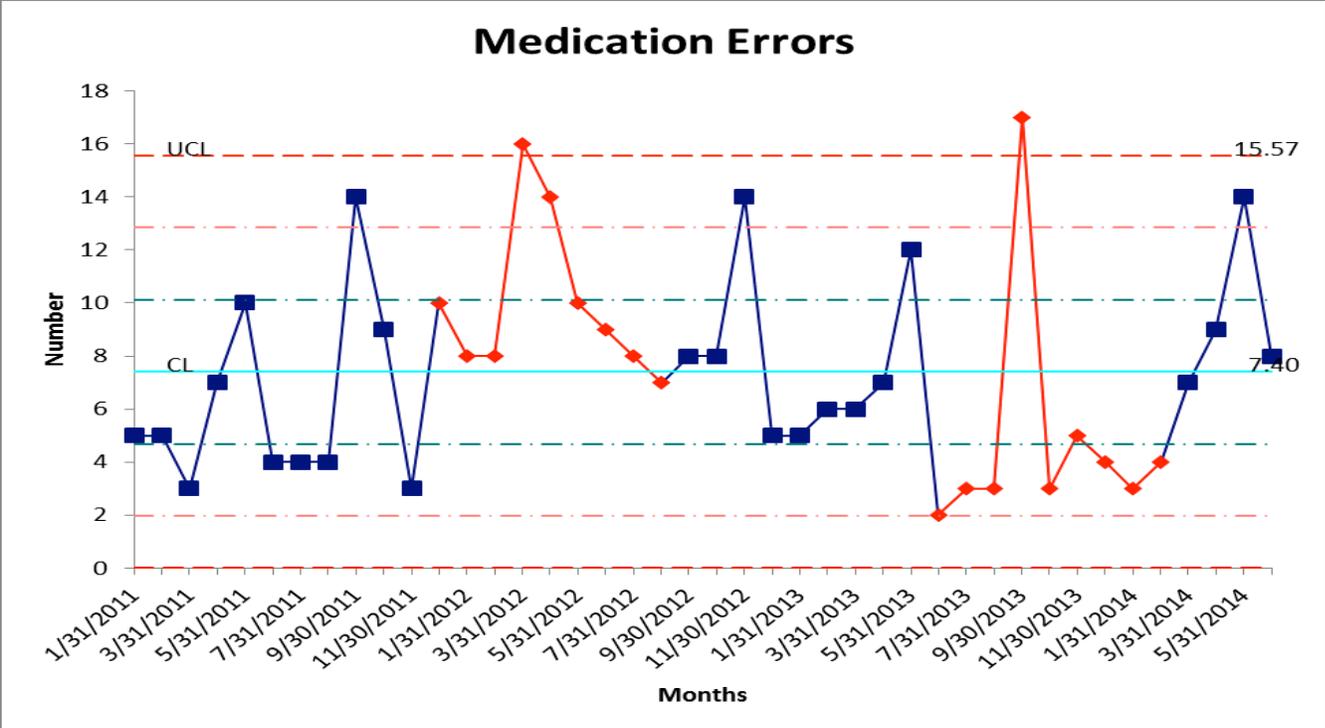
- Has the input to the process changed? (materials, supplier, etc.)
- Do different people use different data collection methods?
- Is the process impacted by predictable conditions? (machine out of service)
- Has the environment affected the process? (space, temperature, weather, etc.)
- Has there been a change in the environment? (relocation, weather, etc.)
- Has there been a change in policies or procedures?
- Has new technology or equipment been introduced?
- Is the process adjusted or changed frequently?
- Did the data come from different individuals, shifts, departments, or areas?
- Are employees reporting all incidents?
- Were any new (untrained) employees involved in the learning process at the time?
- Are employees working overtime, has workload increased, or are there position vacancies unfilled? (employee fatigue)

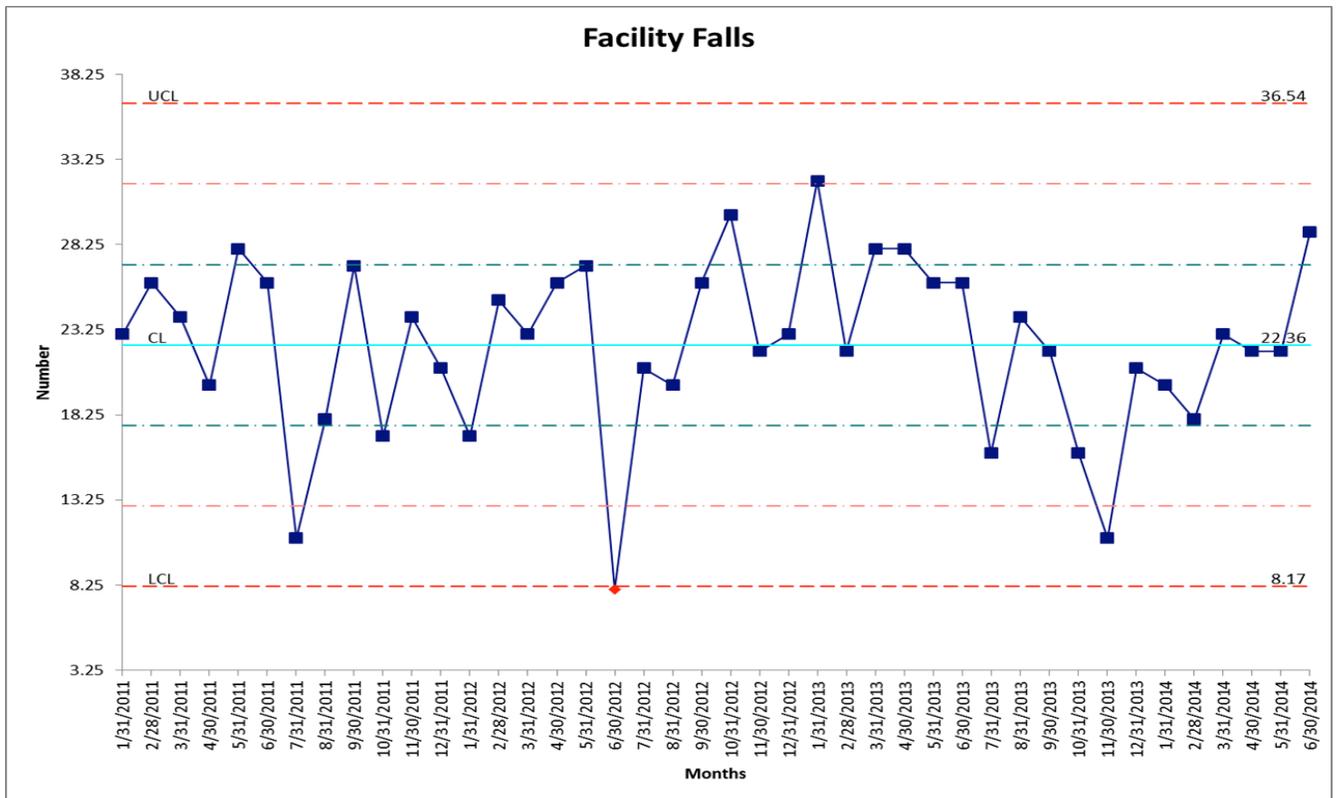
If you answered yes to any of the above questions, the next step is to find out what happened and why. Identify if this is common or special cause.

If a common cause is identified, use the PDSA model and consider a team to improve the process.

If special cause is identified, take immediate action to detect and address the cause.

A change in data needs to be identified, explained, and action taken.





Stratification

Separation and classification of data according to selected variables or factors.

Find patterns that help in understanding the causal mechanisms at work

Gain clues as to the causes of variation

Stratify by time periods; organization; unit; demographics such as age, gender, socioeconomic group, ethnic group; treatment location; treatment method; provider, etc.

Risk, Severity, Case-Mix Adjustment—Process of trying to account for different levels of complexity or illness between groups of patients; make comparisons of outcomes across different providers or organizations

Two types of ratios using denominator, percentage and rate

Percentage

Number of events of interest divided by total population of interest (numerator cannot be larger than denominator)

Number of patients who fell/Number of patients on unit

Rate

Number of events over a specified time/population at risk for that event over time (numerator can be larger than denominator)

Number of infections/Number of patients on unit

Statistical and non-statistical methods for studying, measuring, and improving performance are critical tools in the improvement process. They can help unlock creativity, encourage participation, capture objective data, document processes, measure performance, and analyze cause and effects. Their visual quality is part of their power; for many people a simple visual presentation of information elicits a much more potent response than just narration or tables of numbers. Another part of their power is objectivity; improvement teams no longer rely on hunches, intuition, or anecdotal evidence.

Planning for Control--PDCA Model

Plan includes choosing quality control subjects and setting goals

Do includes running the process

Check includes checking measurement against standards

Act includes taking action

Planning for control is the activity which provides the system, including the concepts, methodology, and tools, through which organizations can keep the operating processes stable and produce the product or service features required to meet customer needs. Planning for quality control of critical processes has traditionally been the responsibility of those who plan the operating process. The methodologies of quality control are built around various concepts such as the feedback loop, process capability, and self control. The important steps in the quality control process are:

- Systematic planning for quality control, with extensive participation by operating personnel.
- Formal application of the feedback loop, and establishment of clear responsibility for the associated decisions and actions.
- Delegation of decisions to work force through self control and self inspection.
- Wide application of statistical process control and the associated training of the operating personnel.
- A structured information network to provide a factual basis for decision making.
- A systematic process for corrective action in the event of sporadic adverse change.
- Standard methods for organizations for quality control, with periodic audits to ensure that they are current.

Quality Control Process

The quality control process is a universal managerial process for conducting operations to provide stability, prevent adverse change and maintain the status quo. Quality control takes the place by use of the feedback loop. Each feature of the product or process becomes a control subject, a center around which the feedback loop is built. As much as possible, human control should be done by the work force. The flow diagram is used widely during the planning of quality controls. The design for process control should provide the tools needed to help the operating forces distinguish between real changes and false alarms. The proper sequence for managing is first to establish goals and then plan how to meet those goals, including the choice of appropriate tools. Managers should make the vital few decisions, provide criteria to distinguish the vital few from the rest, and delegate the rest under a decision making process.

Quality Improvement History

Better quality is a form of beneficial change. One of the issues in quality today is the growth of chronic waste. Chronic waste doesn't seem to have been a major problem during the early days of artisanship. The artisan typically carried out many tasks to complete a unit of product. During each of these tasks, he was his own customer. His client lived in the same village, so the feedback loops were short and prompt.

The Industrial Revolution of the mid-eighteenth century greatly reduced the role of artisans while creating large factories and complex organizational structures that developed enormous amounts of chronic waste. The Taylor system of the early twentieth century improved productivity but had a negative effect on quality. To minimize the damage, companies expanded product inspection. This helped to shield customers from receiving defective products, but encouraged the resulting chronic waste, which became a huge problem.

The widespread practice of relying on inspection was shattered by the Japanese quality revolution that followed World War II. That revolution greatly reduced chronic waste, improved product features, and contributed to making Japan an economic superpower. In addition, it greatly intensified international

competition in quality. This competition soon created a growing crisis in Western countries, reaching alarming proportions by the 1980's.

In response to the crisis, many companies, especially in the United States, undertook initiatives to improve their quality. For various reasons, most of these initiatives fell far short of their goals. However, a relatively few companies made stunning improvements in quality and thereby became the role models. The methods used by these role models have been analyzed and have become lessons learned, what actions are needed to attain quality leadership and what processes must be devised to enable those actions to be taken.

- Lessons learned: Analysis of the actions taken by successful organizations shows that most of them carried out many or all of the following strategies:
- Enlarge the business plan at all levels to include goals for quality improvement
- Design a process for making improvements and set up special organizational machinery to carry out that process
- Apply the improvement process to business processes as well as to manufacturing processes
- Train all levels of personnel, including upper management, in how to carry out their respective missions of managing for quality
- Empower the work force to participate in making improvements
- Establish measures to evaluate progress against improvement goals
- Review progress against improvement goals
- Expand use of recognition for superior quality performance
- Revise the reward system to recognize the changes in job responsibilities

The most important lesson learned was that the annual rate of performance/quality improvement determines which organizations emerge as quality leaders. In the twenty-first century, competition in quality has intensified and has become a permanent fact of life. A major needed response is a high rate of quality improvement, year after year. Customers are increasingly demanding improved quality from their suppliers. These demands are then transmitted throughout the entire supplier chain. The demands may go beyond product improvement and extend to improving the system of managing for quality. Chronic wastes are still known to be huge. In the United States during the early 1980's, about third of what was done consisted of redoing what was done previously, due to quality deficiencies. Wastes should not continue, since they reduce competitiveness in costs. Quality/performance improvement should be directed at all areas that influence an organization's performance, business processes as well as operational processes. Quality/performance improvement should not be left entirely to voluntary initiatives; it should be built into the system. Attainment of quality leadership requires the upper managers personally take charge of managing for quality.

Quality Improvement Process

The quality/performance improvement process is designed around basic concepts. Improvement differs from control. There is no such thing as improvement generally. All improvement takes place project by project. The huge numbers of projects carried out in the 1980's and 1990's demonstrated that quality/performance improvement is applicable to service industries as well as manufacturing industries, business processes as well as manufacturing processes, support activities as well as operations. Quality improvement was applied to virtually all industries, including government, education, and health. In addition, quality improvement has been applied successfully to the entire spectrum of organization functions, including finance, product development, marketing, and legal. While the role modeling organizations achieved amazing results through quality improvement, most organizations did not.

Some of their failures were due to ignorance of how to mobilize for improvement, but there area also some inherent inhibitors to establishing improvement on an annual basis.

Disillusioned by failures: Lack of results for all organizations has led to conclusions that improvement initiatives are inherently doomed to failure. These conclusions ignore the stunning results achieved by the role model organizations.

Higher quality costs more: Some managers hold to a mind set that higher quality costs more. This may be based on the outmoded belief that the way to improve quality is to increase inspection so that fewer defects escape the customer. Higher quality in the sense of improved features usually requires capital investment, and does cost more, but higher quality in the sense of less chronic waste costs a great deal less.

Illusion of delegation: Managers are busy people, yet they are constantly bombarded with new demands on their time. They try to keep their workload balanced through delegation. Going into annual quality improvement adds minimally about 10% to the workload of the entire management team, including the upper managers. Most upper managers have tried to avoid this added workload through sweeping delegation. However, in role model companies, the upper managers took charge of the initiative and personally carried out certain non-delegable roles.

Employee apprehensions: Going into performance/quality improvement involves profound changes in an organization's way of life. It adds new roles to the job descriptions and more work to the job holders. It requires accepting the team concept for tackling projects. It raises the priority of quality, with damaging effects on other priorities. It requires training on how to do all this. To employees, there is the threat to jobs and/or status.

In spite of these concerns, quality improvement is essential to remaining competitive. Lessons learned during the 1980's and 1990's included the major finding that personal participation by upper managers is indispensable to getting a high rate of annual quality improvement. Presentations to upper managers should focus on the goals of upper managers. Upper managers are faced with meeting the needs of various stakeholders, customers, owners, employees, suppliers, the public, including safety, health, and the environment. The needs for quality improvement go beyond satisfying customers or making cost reductions. New forces keep emerging, such as growth in product liability, the consumerism movement, foreign competition, and legislation.

Mobilizing for quality improvement

The first step in mobilizing for quality improvement is to establish the organization's quality council. As noted earlier, the basic responsibility of this council is to launch, coordinate, and institutionalize annual quality improvement. Council membership is usually drawn from the ranks of senior managers. Experience has shown that quality councils are most effective when upper managers are personally the leaders and members of the senior quality councils. In large organizations, there may also be councils established at divisional levels, as well as the corporate level. Organizing quality councils solely in the lower levels of management is ineffective. This limits quality improvement projects to the useful many while neglecting the vital few projects that can produce the greatest results. In addition, this sends a message that the quality council is not a priority for top management.

Each council should define and publish its responsibilities so that members can agree on what is their mission and the rest of the organization can become informed about coming events.

Responsibilities of Management

- Establish quality councils
- Select projects
- Write mission statements
- Assign teams
- Review progress
- Provide recognition & rewards

Responsibilities of Teams

- Analyze symptoms
- Theorize as to causes
- Test theories
- Establish causes
- Stimulate remedies & controls

Activities of quality councils

Formulate the quality policies. These include things like focusing on the customer, giving top priority to quality, sustaining quality improvement annually, universal participation, and rewarding performance on improvement.

Estimate the major dimensions, such as status of quality compared with competitors, extent of chronic waste, adequacy of major business processes, or results achieved by prior improvements.

Establish processes for selecting projects, such as soliciting and screening nominations, choosing projects to be tackled, preparing mission statements, or creating a favorable climate for quality improvement.

Establish processes for carrying out the projects, such as selecting team leaders and members or defining the role of project teams.

Provide support for project teams, such as training, time for working on projects, diagnostic support, facilitator support, or access to facilities for tests and tryouts.

Establish measures of progress, such as effect on customer satisfaction, effect on financial performance, or extent of participation by teams.

Review progress, assist teams in the event of obstacles, and ensure that remedies are implemented.

Provide for public recognition of teams.

Revise the reward system to reflect the changes demanded by introducing annual quality improvement.

Quality Improvement Goals

Organizations that have become the quality leaders or role models all adopted the practice of enlarging their business plan to include quality oriented goals. The goals are clear, quantified, and have a timetable, for example reduce the cost of poor quality by 50% over the next five years.

Goals need to be broken down into specific projects to be carried out and assigned to specific individuals or teams who are then provided with the resources needed to take action. The broad strategic goals are established by the quality council and become part of the organization business plan. The goals are then divided and allocated to lower levels to be translated into action. In large organizations, there may be further subdivisions before the action levels are reached. The final action level may consist of individuals and teams.

The action levels select improvement projects that will collectively meet the goals. These projects are then proposed to upper management along with the estimates of the resources needed. The proposals and estimates are discussed and revised until final decisions are reached. The end result is an agreement on which projects to tackle, what resources to provide, and who will be responsible for carrying out the projects. The aim of this process is to provide open discussion in both directions before final decisions are made. The concept of strategic quality goals involves the vital few matters, but it isn't limited to the corporate level. Quality goals may also be in the business plans of divisions and other lower level departments.

A project is a chronic problem scheduled for solution. The project is the focus of actions for quality improvement. Some projects are derived from the quality goals that are in the organization business plan. Most projects aren't derived from the business plan but are proposed up through the organization through a nomination or selection process.

A valuable aid to selection of projects is the Pareto principle. In any population that contributes to a common effect, a relative few of the contributors, the vital few, account for the bulk of the effect. Identification of the vital few is made easier when the data are presented in a pareto diagram. In addition to facilitation of analysis, presentation of the data in the form of a pareto diagram greatly enhances communication of the information. Under the pareto principle, the vital few projects provide the bulk of the improvement, so they receive top priority. Beyond the vital few are the useful many projects.

Collectively, they contribute only a minority of the improvement, but provide most of the opportunity for employee participation.

Projects can be chosen through the nomination and selection process, which involves project nomination, project screening and selection, and preparation. Nominations for projects can come from all levels of the organization. At the higher levels, the nominations tend to be extensive in size and multifunctional in scope. At lower levels, the nominations are smaller in size, and tend to be limited in scope to the boundaries of a single department. Nominations arrive from many sources, including:

- Formal data systems (reports on product performance, customer complaints, claims, returns)
- Special studies (customer surveys, employee surveys, audits, assessments, benchmarking)
- Reactions from customers
- Field intelligence (visits to customers, suppliers & others, actions taken by competitors, stories in the media)
- Impact of quality on society (new legislation, extent of government regulation, growth of product liability lawsuits)
- Managerial hierarchy (quality council, managers, supervisors, professional specialists)
- Work force (ideas presented to supervisors, formal suggestions)
- Proposals

To encourage nominations, organizations can put out calls for nominations, make rounds approaching people for their ideas, seek ideas from quality council members, and have brainstorming meetings.

Project Selection

A call for nominations can produce a large number of responses. An essential further step is screening to identify those nominations which promise the most benefits for the effort expended. To screen the suggestions, it's necessary to have criteria. For selecting the first project:

- The project should be a winner.
- The project should be feasible.
- The project should be significant.
- The results should be measurable.
-

For other projects, the following criteria are useful:

Return on investment—all other things being equal, this factor has great weight

Amount of potential improvement—One large project would take priority over several small ones

Urgency—Need to respond promptly to pressures associated with safety, employee morale, customer service

Each of technological solution—Projects for which technology is well developed will take precedence over projects that require research to discover the needed technology

Probable resistance to change—Projects that will meet with a favorable reception take precedence over projects that may meet strong resistance

The end result of the screening process is a list of recommended projects in their order of priority. Each recommendation should be supported by the available information on the project in relation to the criteria and potential benefits, resources required. The quality council reviews the recommendations and makes the final determination on which projects to be tackled. These projects then become an official part of the organization's business. Other projects are outside the scope of the quality council and are recommended to appropriate sub-councils, managers, etc. Local projects can still be undertaken at local levels by supervisors or the work force.

Types of Projects

During the 1980's, some organizations completed numerous projects, but had no noticeable effect on the bottom line. Investigation showed that the reason was project selection. The projects actually selected had consisted of:

Firefighting projects: These are special projects for getting rid of sporadic spikes in the control chart data. Such projects didn't attach the chronic waste and couldn't improve financial performance.

Useful many projects: These have only a minor effect on financial performance.

Projects for improving human relations: These can be quite effective in their field, but the financial results are usually not measurable.

Project Selection

To achieve a significant effect on the bottom line, vital few projects as well as the useful many must be selected. The vital few are major contributors to quality leadership and to the bottom line. The useful many projects are the major contributors to employee participation and the quality of work. Each is necessary; neither is sufficient. They can be carried out simultaneously because they require the time of different categories of organization staff.

Projects selected should be accompanied by a mission statement that sets out the intended result of the project. The mission statement defines the intended end result and helps the team know when it has completed the project. The mission establishes clear responsibility and becomes an addition to each member's job description. It provides legitimacy, the project becomes official business. The team members are authorized the time to spend on the project. It also confers the right to hold meetings, ask people to attend, and assist the team, and request data and other necessary information. The ideal mission statement should also include the intended amount of improvement and the timetable. Publication of the mission statement makes a project an official part of the organization's business. As work on the project progresses, the emerging new information may suggest needed changes in the mission statement. The quality council should make it clear that the team should recommend revision of the mission statement as needed. For each project, a team is selected that then becomes responsible for completing the project.

Universal sequence for performance/quality improvement

The universal sequence for performance/quality improvement defines the actions to be taken by the team to accomplish its mission. It seems obvious that diagnosis should precede remedy, but biases or outdated beliefs can get in the way. Untrained teams often try to apply remedies before the causes are known (Ready, fire, aim.) The symptoms of the chronic quality problem must be analyzed. It's important to understand the words used in written or oral descriptions of problems. A frequent source of misunderstanding is the use of generic words to describe multiple problems or defects.

Teams should generate theories about the causes of a problem. One systematic way to generate theories is brainstorming. Experience has shown that brainstorming can have a useful effect on team members who carry strong opinions. Another systematic approach is nominal group technique. Similar to brainstorming, members generate their theories silently in writing. Each then offers one theory at a time, in rotation. After all ideas have been recorded, they are discussed and prioritized by vote. Multivoting is one way to vote. The theories shouldn't be limited to those which relate to errors on specific products or processes. In some cases, the cause may lie in some broader system that affects multiple products.

Orderly arrangement of the brainstorming list helps the team to visualize the interrelation of the. An orderly arrangement is required for choosing which theories to test. Several types of arrangements are available:

Storyboarding: A supplement to brainstorming, this is a form of orderly arrangement of theories. As each theory is proposed, it is recorded on an index card. The cards are then appropriately arranged on a board to form a visual display of the theories.

Tabular arrangement: Another form of arrangement is a table showing a logical hierarchy, with theories, sub-theories, sub-sub theories, etc.

Cause and effect diagram: This popular diagram has the effect written at the head of an arrow, with potential causes added to diagonal lines coming off the arrow. A common set of major causes includes personnel, work methods, materials, and equipment. These diagrams are applicable to all kinds of industries, processes, and problems. (Cause and Effect Diagram)

A cause and effect diagram can be combined with a **force field analysis**. The team identifies situations and events that contribute to the problem (restraining forces). The actions necessary to counter the restraining forces are then identified (driving forces). A diagram combining the restraining and driving forces is prepared to assist in the diagnosis. (Force Field Analysis)

Testing theories

Theories are numerous, yet most turn out to be invalid. As a result, project teams have learned to discuss priorities for testing theories and arrive at a consensus. A matrix may be used to arrive at a quantitative score for each theory. Ask each member to rank all theories in order of importance. The totals of the rank then become an input to the final consensus on priorities. A critical question is whether to test one theory a time, one group of interrelated theories at a time, or all theories simultaneously. Decisions should be based on fact, not theory. Teams must learn to distinguish theory from fact. Facts are supported by evidence. Theories are unsupported assertions.

For many products or services, the anatomy of the producing process is a procession, a sequential series of steps, each performing a specific task. Most team members are familiar with some of the steps, but few are familiar with the entire process. Preparing a flow diagram helps all members understand the progression and the relation of each step to the entire process.

One of the most frequent questions raised by improvement team members refers to process capability.

Is the process capable of meeting the specifications?

Or is the process capable but not being carried out correctly?

A common test of process capability is the control chart. Having established by control chart analysis that the process is inherently stable, the data can then be compared with the specification. This comparison provides a measure of the ability of the process to consistently product output within specified limits. Many processes in health care consist of a procession in which the work is performed in a sequence of steps as it moves from department to department. It may take days, weeks, months to complete cycle, yet the time required to do the work has taken only a few hours. The remaining time has consisted of waiting for its turn at each step, and redoing work. For such processes, the theoretical process capability is the cumulative work time.

Process dissection

A common test of why a capable process isn't being run right is process dissection. This strategy tries to trace defects back to their origins in the process. When defects are found at the end of a procession, it isn't known which operational step did the damage. In such cases, a useful strategy might be to inspect or test the product at intermediate steps to discover at which step the defect first appears. Successful discovery of this step can drastically reduce the effort of testing theories.

Source to source analysis: High volume products often require multiple sources of production, multiple suppliers, workers, and customers. The sources may seem to be identical, but the resulting products may not be. Source to source analysis consists of separating the production into sources of origin and testing for source to source differences in an effort to find the source of the problem.

Time analysis: The purpose is to discover if production of defects is concentrated in specific spans of time. This type of analysis has been used to study time between abnormalities, effects of change of work shifts, influence of seasons of the year, and other potential causes. The control chart is an

example of time to time analysis, which can show whether the variability in a process is due to assignable causes. The product is measured at equal time intervals. Graphic presentation of the data aids interpretation, such as a control chart.

Some forms of process dissection can test multiple theories simultaneously, such as use of the Multi-Vari chart, which can show the range of variation within a single unit of product, as compared with specification tolerance limits.

Defect correction analysis: The purpose is to discover concentrations that may point to causes. For manufactured products, defect locations can be plotted on drawings of the product. In World War II, the United States Air Force studied the damage done to aircraft returning from combat missions. One form of analysis was to prepare diagrams to show where enemy bullet holes and other forms of damage were concentrated. The diagrams seemed to show that some areas of the aircraft never received damage. The conclusion was that the damage to those areas had destroyed the planes and that redesign was needed to reduce the vulnerability of those areas.

Relating data to theory: Some diagnosis consists of relating data on symptoms to some theory of causation such as design, process, or worker. Possible relationships are examined using various statistical tools such as correlation, ranking, and matrices. Some processes are tested only after completion of all the steps. These can be tested differently by making measurements at intermediate stages of the process. Theories can also be tested by experiment, producing trial samples of product under specially selected conditions.

Diagnosis: Some of the work of diagnosis consists of the discussions that take place during project team meetings, analyzing symptoms, theorizing about causes, and selecting theories for test. In addition, the work of diagnosis involves test of theories, which consists mainly of data collection and analysis and is done largely as homework outside of team meetings. For some projects, the home work consists of data collection and analysis on a small scale. In some cases, the project team members themselves may be able to do the homework. Other projects require extensive data collection and analysis. In such cases, the project team may delegate or subcontract much of all of the work to people who have the needed time, skills, and objectivity. Despite such delegation, the team remains responsible for getting the work done.

Identifying solutions

Once causes have been discovered, solutions to problems are sought. Many quality professionals of wide experience have observed that about 85% of quality problems are management or systems problems and only 15% are worker problems (Pareto principle). While each solution is unique to the project, the managerial approach to selecting and applying solutions is common to all projects. For most projects, there are multiple proposals for solutions. Choice of solution depends on the extent to which the proposals meet certain essential criteria. The proposed solutions should remove or neutralize the cause(s), optimize the costs, and be acceptable to upper management.

Proposed solutions must be accepted by the project team based on logical reasoning, on its belief that the proposed solution will meet the criteria. The proposed solution should be tested on a small scale, whether in operations or in a simulated situation and then tested in operations. Some teams can only recommend solutions and have no responsibility to follow through. In such cases, many recommendations are not acted on. Results are much better in organizations that make the teams responsible for ensuring that the remedies are in fact applied and that they are effective under operating conditions. Many solutions consist of technological changes, but in many cases, the solution is to make better use of existing facilities. The solutions with the highest return on investment generally have involved managerial changes rather than technological changes. Dramatic evidence of this was seen when teams from the United States visited their Japanese counterparts to learn why Japanese quality was superior. The Americans were astonished to find that the Japanese facilities were identical to those used in the United States. The difference in quality had resulted from making better use of the existing

facilities. Other solutions consist of revising broad organizational issues such as policies, procedures, standards, plans, and organization. These solutions have effects beyond the specific project under study. Occasionally, solutions can be remarkably imaginative. In a plant for making chips for integrated circuits, a vibration problem caused by a nearby railroad was solved by constructing a swimming pool between the plant and the railroad. Another problem was due to cement dust from an adjacent concrete mixing plant. The solution was to buy the plant and demolish it. For some chronic quality problems, the solution consists of re-planning some aspect of the process or product.

Complex Processes

In complex processes, it is easy to apply a solution that reduces costs in one department but raises costs in another. The project team needs to make sure that the costs are optimal for the organization. Checks should also be made of external customers' costs. Any solution involves a change of some kind, redesign of the product or process, revision of the tool, and/or retraining the worker. Each change falls within the jurisdiction of some department that then becomes the change department for the project in question. Normally, the responsibility for making the change lies with the department, not the project team. Someone from the involved department is usually a member of the project team and helps keep communication open with the department. It's more difficult if no one from the involved department is on the project team.

Keep in mind that a solution developed for one problem may have applications to solve other problems as well. There may be generic solutions that apply to an assortment of problems. Solutions to problems may be developed in a laboratory or pilot setting, based on assumptions that are never tested. The testing may be done only on small samples or under closely controlled conditions. These and other limitations create the risk that the solution, despite working well during a testing phase, won't prove adequate under normal operating conditions.

Holding the Gains

To enable organizations to hold the gains requires a successful transfer of the solution from the pilot to the actual setting, and a systematic means of holding the gains. Ideally, the change should be irreversible. If this isn't the case, periodic audits need to be done to ensure that the change is continuing. To ensure that a new process takes place, appropriate revisions need to be made in operating standards, procedures, and policies supporting the change so that training can be provided in the use of the new processes. Training should include not only information related to the change but reasons behind the change, resulting new responsibilities for decisions and actions, and the significant findings that occurred during the project. Organizations should spell out what criteria should be met and what the consequences will be if they are not met. The final step involves holding the gains. This is done through the feedback loop, a cyclic process of evaluating actual performance, comparing this with the standard, and taking action on the difference. Once a solution has been developed, it needs to be applied, but obstacles are often raised by various sources. There may be delaying tactics or rejection by a manager, the work force, or other parties, such as unions.

Change

Laws of change

- Things are the way they are because they got that way.
- Unless things change, they are likely to remain the same.
- Change would be easy if it weren't for all the people.

Why does healthcare have to change? It's clear that the public is not satisfied with the healthcare industry. Everyone recognizes that the healthcare industry is experiencing major changes. The concept of a paradigm shift is helpful in understanding both the changes and how to address them. According to

Joel Barker, a paradigm is “a set of rules and regulations that defines boundaries and tells you what to do to be successful within those boundaries. Success is measured by the problems you solve using these rules and regulations.

Paradigm Shift

The way that organizations saw events and acted in the past may have been a successful paradigm at the time, but may not be right for the future. Given the current and future workforce, a major paradigm shift is required. Managers must become leaders and focus on developing new skills. To create a work environment in which everyone in a more diverse workforce contributes to his/her potential, the manager should shift from controlling to coaching, from quantity to quality, and from opinion to data-based decisions. Managers who are resistant to change must become open to change and see people as resources instead of commodities. The culture of the organization must shift from fear to trust, with commitment replacing compliance, and everyone in the organization moving from an internal focus to a customer focus. Finally, individual thinking and actions is replaced by team, moving the organization from detection to prevention.

The paradigm shift is very difficult to accomplish because people who have been successful with the old style will see no reason to change. In addition, new paradigms put everyone practicing the old paradigms at great risk; the higher the position, the greater the risk. The better a manager is at his/her paradigm, the most he/she has invested in it and the more he/she has to lose. Yet, managers must recognize the need for changing their own behaviors first in order to lead the change. This is extremely difficult.

Motivation for Change

People are not motivated by a negative vision of the future. Motivation is an inherent incentive to do something. People are motivated to do something if it makes them feel better or makes a situation better. When something motivates people, they want to do it more. Yet many of the changes that are implemented today in healthcare represent negative visions for most people, such as cutting costs, increasing productivity, and searching for the unacceptable few who caused the problem or fail to meet the quality standards. People do things because they have to, but are not inherently motivated to do them. For most people, these are considered necessary evils and represent negative visions of the future.

People can be motivated to positive visions. People want to improve quality for their patients and other customers, as well as for themselves. They are also motivated to reduce rework and waste and to improve the working environment. These are common goals of TQM. Another aspect of the future is a different role for managers, as reflected by the paradigm shift from managing to leading. The challenge is to communicate this vision so that it is viewed positively rather than negatively.

Support System for Change

Change won't happen without a support system that provides people with the capacity and capability for change. Most organizations don't change until they have to. They wait until they are in a declining phase then try to adapt. The most constructive and best time to change is when you do not have to, when things are going well, before a crisis occurs. When change is planned and gradually implemented, the organization can adjust more easily. Unfortunately, it is more difficult to initiate change when the need is not so obvious. To create the energy necessary for a change, a threshold of pain has to be reached and recognized. There must be a felt need for change or the change will not occur. To create this energy, you should clearly indicate the rationale for change.

One strategy is to find out from successfully changed programs what stimulated them to change. Begin the process of examining the current situation of the organization. There is a limit to the rate of corporate change an organization can tolerate; the threshold of corporate change. If the rate of change is too fast, the organization can become dysfunctional, and if the rate is too slow, people lose sight of the

vision, and enthusiasm may significantly decrease. There should be a balanced approach. While goals should provide stretch objectives that cause people to reach a little further, the organization must be able to view them as attainable. Too much change can be threatening. If people believe the change is beyond their capability, change can immobilize people.

An understanding of resistance to change starts with the realization that every change actually involves two changes, the intended change and the social consequences of the intended change. The social consequence is the most difficult to deal with. It consists of the impact of the intended change on the cultural pattern of the human beings involved, on their pattern of beliefs, habits, traditions, practices, and status symbols. The social consequence is at the root of the resistance to change. Dealing with this resistance requires an understanding of the nature of cultural patterns.

Ideally, advocates of change should be aware that all human societies evolve cultural patterns that are fiercely defended as part of the way of life. In addition, there is a need for the organization to discover exactly what is threatened, which habits, whose status, what beliefs. Those who resist change often state their reasons as objections to the merits of the intended change, whereas their real reasons relate to the social consequences. The stated reasons are not the real reasons for resistance.

To deal with cultural resistance:

Provide participation: This is the most single important rule for introducing change. Those who will be affected by the change should participate in the planning as well as the execution. Lack of participation leads to resentment, which can harden into a rock of resistance.

Provide enough time: How long does it take for members of a culture to accept a change? They need enough time to evaluate the impact of the change. Even if the change seems beneficial, they need to learn what price they must pay in cultural values.

Start small: Conducting a small scale tryout before going all out reduces the risks for the advocates as well as for members of the culture.

Avoid surprises: A major benefit of the cultural pattern is its predictability. A surprise is a shock to this predictability and a disturber of the peace.

Choose the right year: There are right & wrong years or decades, for timing a change.

Keep the proposals free of excess baggage: Avoid cluttering the proposals with extraneous matters not closely related to getting the results. The risk is that the debates will get off the main subject and into side issues.

Work with the recognized leadership of the culture: The culture is best understood by its members. They have their own leadership, and this is sometimes informal. Convincing the leadership is a significant step in getting the change accepted.

Treat the people with dignity: Relay assemblers in the Hawthorne experiments kept increasing productivity in good light or bad, because in the lab they were treated with dignity.

Reverse the position: Ask the question, "Which position would I take if I were a member of the culture?"

Deal directly with the resistance: Try a program of persuasion. Offer quid pro quo, something for something. Change the proposal to meet specific objections. Change the social climate in ways that will make the change more acceptable. In some cases, the change won't work and the correct alternative is to drop the proposal. Human beings can't always plan to be 100% successful.

Resolving differences

Sometimes resistance to change reaches an impasse. One method of resolving differences starts with having each side identify their areas of agreement and disagreement, so that the major point of disagreement can be identified. Then, both sides need to agree on why they disagreed. Then, they have to agree on what they are going to do about it.

Models of Change

A paradigm shift is commonly described as an experience in which someone sees a picture in a totally different light. Paradigm shifts are also described as a break in tradition with the old ways of thinking into seeing the world with a new way of thinking. A paradigm shift involves seeing, thinking, feeling, and behaving differently than one did before. The paradigm shift can be instantaneous or a slow, difficult and deliberate process. The power of a paradigm shift is the essential power of quantum change. Such change is a major endeavor.

Models of change show movement from a current state or old system. This involves first unfreezing or changing the old system and pushing it out of a comfort zone so change can occur. This progresses to a transition state, or middle ground, through which the now unfrozen process travels. Finally, a new system or future state of equilibrium emerges. This new state must be refrozen. These models have been used to integrate human system change with technology and work systems changes. The change process can be used to create new systems to foster the new activities needed by redesigned or reengineered work processes. The focus of the change effort is to invent a new status quo by directing, tracking, and recording all the activities and people involved in the change process.

Change has been viewed as a disruption of existing activities, a redirection of organizational energies. The change in work relationships and duties in a health services organization can create resistance and a sense of personal risk at all levels. The introduction to change must be compatible with the organization's culture. Involvement of leaders and clear, consistent, communication are key to an effective change process. Change occurs with a variety of results, some more permanent than others. Frequently, people change their behavior only to return to the original behavior after a short period of time. In order for change to become permanent, the new action must become a part of every day life. To achieve the desired results of change, change must be managed effectively.

Reaction to Change

Reaction to change varies; one model compares it to a process similar to that of death and dying. A person experiences ten phases prior to investing permanently in the changed process. Equilibrium is the first phase where the person feels satisfied with the status quo. Once the person is made aware of the necessary change, he begins the denial phase, which progresses to anger. Bargaining follows anger and leads into feelings of chaos. Feelings of longing for the past and of depression must follow prior to moving into the phase of resignation. At this point, the person is no longer resisting the change process, and he or she then moves into an openness phase and actively begins working towards the change. As the person enters the readiness phase, management can begin to direct the person in how to accomplish the new goals. Finally, the person is able to let go of past behaviors and to accept the new behavior in this re-emergence phase. At this point, the person returns to phase one of the cycle where there is a status quo.

Most change models used in health service organizations are based on an image of the universe that assumes people can manage by breaking the change process into its component parts and then by objectively measuring the system inputs and outputs for each part. For this type of model to work, the better measurement can be done objectively, the better accurate results can be predicted. These models depend upon an orderly universe, in which objects move in predictable ways and new information can fit into existing structures. A traditional organizational chart shows a series of boxes that relate to each other in the same ways. A change will become a new box added to the existing chart.

Wheatley's Model for Change

Another description of change can be viewed through a model that is based on quantum physics, as identified by Wheatley. This model suggests that there is no objective reality; there is only what we create through our interaction with others and with events. The basic premise of this model is that nothing is predictable because everything changes and adapts as new information is gained and integrated. The change, or new reality, is created by the interactions.

Although change is generally about moving people from a current state through a transition state to a future state, no one model will work in all cases. People will be influenced by other people and interactions as they move through the change process. This type of change is best managed by focusing on each person involved in the change at the same time that the overall change is occurring within the organization. This is important because the final success of any change will be based on perception, or how well all of the people think the change is working. If people view the change as positive, they will probably like the results. On the other hand, if people are not a part of the change process, they probably won't like the changes that result. Health care services are in a constant state of change, and the success of the health care organization in the future will depend on the acceptance of major change.

The following is breakdown of the stages within the change process:

Awareness stage: The person knows something about the change and may have heard it mentioned before and explained. However, the individual generally does not have a strong opinion about it or denies that the change will affect him or her.

Curiosity stage: The person expresses concern or asks questions about the effect of the change on himself or herself, and may be defensive, resistant, or in denial about the change.

Visualization stage: The person seeks to understand the relationship & effect of change on himself/herself or on organization as a whole by asking questions & seeking information.

Learning stage: The person takes part in learning how to implement or use the change and may offer opinions and concerns about specifics of the change.

Use stage: The person actively uses the change and integrates the change into his or her daily work habits and can describe or explain the change to others.

Individuals go through these stages at different rates and can revert to previous stages at any time. Some never make it through all of the stages. The change agent cannot force people into later stages if they have not dealt with the earlier stages. Whatever is done to help people through the change process will need to be repeated many times for many groups of people. Some individuals may need to have the same process repeated several times. This is because whatever is done the first time only really catches the people who were predisposed to change in the first place. Others will need more time and more examples before they can become committed to a change.

There are specific strategies for each stage. Those who are implementing changes in health services organizations can perform specific tasks at each stage of the change process. For the awareness stage, use advertising in various media to let people know the change is coming. Take the opportunity to highlight the positive effects of the change, and link the change to meeting staff needs and eliminating problems. Strategies for the curiosity stage include providing frequent, clear, concise explanations and answering all questions. Take the time to elicit staff concerns and acknowledge the difficulties that the change may cause. At the same time, present a viable approach to the change that acknowledges staff concerns.

For the visualization stage, demonstrate the change for people and conduct user testing and reviews of the proposed changes. The learning stage should focus on educating staff regarding the change. Conduct workshops for as many staff as is possible, giving them the opportunity for hands-on involvement, if appropriate. Provide materials that will make the change easier to use, such as quick reference guides or help desks. Finally, for the use stage, provide whatever technical assistance may be needed to make the change happen quickly and efficiently, and provide enough reference documentation to enable people to become experts.

People will be at different stages of change. Early in the change process, staff who are promoting or making the change should meet with all groups to discuss the change, especially why it is needed at this time. It is important for them to take the time to elicit reactions to the change, and be sure to clear up any misunderstandings. Also, it is important to acknowledge people's objections to the changes. They should not apologize for making the change, but should ask for suggestions that will help overcome the

objections. In summary, those making the change should do everything possible to gather support for the change, including promising to keep people informed about the change process, and keeping that promise.

Acceptance of Change

As the change is taking place, it is important to continually try to assess the degree of its acceptance on people's behalf. Watch people's behavior and note what they say. Then, try to figure out where they are in the change process. People will use many different methods to demonstrate resistance to change, and some may try to sabotage the change. Reengineering projects do not have a good success rate. Those in support of the change need to try to find ways to help people identify with the change and understand it, and also deal with their concerns. Organizational change is composed of the total changes that are developed by individuals, and these same individuals can sabotage the changes at any stage. For change to succeed in a health services organization, every individual must think, feel, or do something different.

People generally fall into three groups, those who are on each side of the fence and those who are on the fence. If the organization focuses its efforts on individuals who are already positively disposed to the change, they can, in turn, help encourage those who are sitting on the fence, thereby allowing the organization to amass critical support. At this point, individuals who are on the other side of the fence should see the inevitability of the change and also accept it.

Early in the change process, the organization should develop a communication plan to ensure that everyone becomes aware of the changes that will occur. Try to envision what concerns people may have, and do not ignore these concerns. Provide a forum for individuals to express their concerns and receive reliable information. Involve supportive people early in a demonstration of the change. Include enough time for people to deal with the emotions of the change. Help people let go of the past and embrace the future. Change is transitory at best. Unless the changed behavior is constantly reinforced, the person typically reverts to the old behaviors. This is the main reason that behavior modification programs fail once the participant leaves the program and strikes out on his or her own. Therefore, for change to be incorporated into everyday life, it needs constant reinforcement.

Organization Structure

Organizations are distinguished by a combination of the following: goal orientation, specialization of individuals and units, interdependence of individuals and units, and formalized hierarchy. These characteristics are generally acquired as an organization develops in the order listed above.

Goal Orientation: Organizations can accomplish some things that individuals and groups cannot do by or for themselves. For example, the task goals of individuals and groups may evolve into such complex and sizeable endeavors that more complex entities are necessary to accomplish them. Expanded business requires more space, more inventory, and more employees. The goal orientation of the business has changed to the point where individuals or groups could not achieve those goals by themselves.

Specialization of individuals and units: With specialization, more employees and skills become required. To exercise the necessary control over the wide range of activities, management organizes its personnel into functional units called departments. Within departments, further specialization occurs. It is this specialization that leads to the next characteristic of the large organization, interdependence of individuals and units.

Interdependence of individuals and units: Because of the specialization in the large, formal organization, each of the departments is dependent on each of the others to some extent. Within departments, specialization of people leads to interdependence of individuals. Therefore, the dependence of units on one another in the large organization is also a characteristic of the internal structure of the smaller units. The large organization is now composed of smaller units, and these units are composed of individuals. All however, are organized so that the goals of the organization can be achieved. The

organization grew or matured in step with changes in goals. Keep in mind, however that in the everyday work of the organization, the task goals of the total organization exist side by side with the group maintenance goals of the departmental units, and the self maintenance goals of the individuals involved. The interdependence characteristic of units and individuals applies equally to both task goals and maintenance goals.

Formalized hierarchy: To achieve its goals, the organization needs to direct and coordinate the interdependence of units and individuals toward a desired end. Formal organization structure results from efforts to achieve coordination. The formalized hierarchy ensures that communication occurs effectively as an element in coordination. Coordination results from effective communication and well-organized programs or systems. As goals expand beyond the capacity of the current organization, additional specialization is necessary to achieve these goals. As specialization increases, interdependence also increases. As interdependence of individuals and units increases, there is a greater need for a formalized structure or hierarchy to ensure communication and hence coordination.

Traditionally, organization charts have been used to describe the authority structure of the organization. People included in positions high in the chart appear to have greater authority than those located at lower levels. If used to describe communication in the organization, however, the chart may be entirely inadequate. Nor does the chart necessarily define the role structure, the relative importance of each department or individual participating in the organization. Organization charts help define the scope of the organization and assist people in getting a total view. Because people generally occupy roles and perform functions in all those spaces in the organization chart, the pictured structure could seldom be considered a final answer.

The organization structure does affect the behavior of individuals and units within it. Most organizations are pyramid shaped. The higher a person is on the pyramid, the greater the apparent authority and rewards. Most people probably strive for a higher position on the pyramid, and this striving may determine relationships with peers, subordinates, and superiors. Competition has become a characteristic of the American way of life. People and organizations compete for a greater share of scarce resources, for a limited number of positions at the top of organizations, and for esteem in their professions. Such competition is a healthy sign of the human desire to succeed; and in terms of economic behavior, competition is fundamental to the private enterprise system. At the same time, when excessive competition replaces the cooperation necessary for success, communication may be diminished, if not eliminated.

Just as people want to look good in the eyes of peers, superiors, & subordinates, units within organizations want to look good to one another. Behavior may then take the form of I win, you lose, & replace cooperative behavior, which could be characterized by I win, you win. As a result, excessive competition may have a negative influence on organization performance or everybody loses. At the same time, the organization may change behavior when effective communication takes place. Most conflict among people & groups results from a lack of understanding. When one unit is uninformed about the importance or function of another, needless conflicts may occur as the groups attempt to better themselves at the expense of others.

Interestingly enough, groups engaged in competition tend to solidify & become more cohesive with great internal group morale. As a consequence, competitive spirit of the group may intensify & lead to further deterioration of communication with other groups. It's easy to visualize what such activity may do to cooperative efforts in total organization. Although competition is appropriate & desirable in many situations, management must take steps through open communication to reduce competition & increase cooperation. When competitors have an understanding of others' importance & functions, cooperation is more likely. This statement is as true of cooperation among individuals as it is of cooperation among groups within organizations.

Eight Steps to Produce Needed Change

1. Create a sense of urgency, not panic. Take the issue to the right people.
2. Pull together the guiding team. This team must be strong enough to guide the change. They must possess leadership skills, credibility, communications ability, authority, analytical skills, and a sense of urgency. If you look at the companies that are good at initiating a major change, increasingly, you'll find that it doesn't work if the top few try to do all the heavy lifting.
3. Develop the vision and change strategy. Too many change initiatives might indicate that you haven't done this step well. You'll get change burnout and more resistance.
4. Communicate for understanding and buy-in.
5. Empower others to act. Remove barriers so that people can act on the new direction. Get the junk out of the way to get the momentum. Empowerment, but not a free for all, competent training may be called for.
6. Produce short term wins. It's critical because you always have skeptics. Tangible success will help to drain the power from these people and bring them on board.
7. Don't let up. Even after the win, keep the pressure up to keep the momentum going. Be relentless until you reach the end goal.
8. Create a new culture. Make sure that it sticks; it's internalized.

Spread of Change and Innovation

Important to spread change throughout organization

Rogers' Diffusion of Innovation Model to facilitate spread of change

Elements of Rogers Diffusion Model

- Change
- Communication channels about the innovation
- Time (time span from the point of someone first hearing of a change to the point of decision to accept it or reject it; the number of individuals in a social system who adopt a change in a given period, and the ability of the individual or agency to change determine the time needed to achieve adoption)
- Social system in which a change is adopted

Decision Process to Adopt a Change– 5 Stages

1. Knowledge – socioeconomic characteristics, personality variables, communication behavior
2. Persuasion – attending to the perceived characteristics of the change; relative advantage, compatibility, complexity, trialability, observability or visibility, reversibility, uncertainty
3. Decision – adoption or rejection
4. Implementation – direct application, reinvention, indirect application, or effect
5. Confirmation – evaluation of the change's effectiveness in order to determine whether it will be continued or discontinued

Change is affected by 3 major influences

Perceptions of the change

Perceived benefit

Compatibility of the change with values, beliefs, past history, and current needs

Complexity of change or innovation

Trialability of change

Observability of change

Characteristics of individuals

Innovators (2.5%)

Early adopters (13.5%)

Early majority (34%)

Late majority (34%)
Laggards (16%)
Managerial and contextual factors
Communication
Incentives
Leadership & management

Benchmarking

Benchmarking is the continuous process of measuring products, services, and practices against the organization's toughest competitors or those renowned as industry leaders. It is an ongoing investigation and learning experience. It ensures that the best practices are uncovered, adopted, and implemented. Benchmarking is a process of industrial research that enables managers to perform organization to organization comparisons of processes and practices to identify the best of the best and to attain a level of superiority or competitive advantage. Benchmarking is a method of establishing performance goals and quality improvement projects based on industry best practices. It is an exciting tool in the quality field. Searching out and imitating the best can improve everyone's motivation, often producing outstanding results. It is a positive, proactive process to change operations in a structured fashion to achieve superior performance. The purpose of benchmarking is to gain competitive advantage.

Benchmarking is the process of measuring a characteristic of your organization against the same characteristic of another organization. Benchmarking is the continuous process of measuring products, services, and practices against the toughest competitors or those companies recognized as industry leaders. The purpose of benchmarking is to improve processes and outcomes. Benchmarking helps organizations see the need to change, determine the priorities for change, and develop a model for changes. It helps an organization become more externally focused. Benchmarking can also stimulate innovation and creativity as people see effective ideas in other organizations. Best results are achieved when an organization acts as a partner and explores processes in depth, learning, and improving over time.

Types of benchmarking

- Internal benchmarking to replicate best practices within the organization
- Competitive benchmarking to identify and benchmark the best practices among competitors
- Functional benchmarking to identify and benchmark comparable functions, even if in other industries
- Generic process benchmarking to identify most important business practices to achieve greatest gains

The purpose of benchmarking is derived primarily from a need to establish credible goals & pursue continuous improvement. It is a direction-setting process, but more important, it is a means by which the practices needed to reach new goals are discovered and understood. Benchmarking legitimizes goals based on an external orientation instead of extrapolating from internal practices & past trends. Because the external environment changes so rapidly, goal setting, which is internally focused, often fails to meet what customers expect from their suppliers.

To be successful in benchmarking, understand the organization and its processes before benchmarking to others. Search widely for benchmark processes and organizations. Look beyond a single geographic area, competitors, and the healthcare industry. Don't overlook small organizations who are often very skilled in specific processes. It's helpful initially to benchmark similar processes within the organization. Expand thinking of managers beyond only one way to do something. Benchmarking can involve comparison of outcomes or results. Which organizations had the best outcomes and what are those outcomes. Organizations can also benchmark the processes that produce outcomes. Benchmarking is like reverse engineering. You need to dissect the processes to understand them correctly to apply that knowledge to your organization. Benchmarking is an evolving process, not a one time look. Strategic

benchmarking involves establishing long term benchmarking relationships. Benchmarking can be a two way process, with both organizations willing to share detailed information about processes and results. The purpose of benchmarking is to learn how a process may be adapted to an organization, not simply to copy the process because another process may not be totally appropriate in a different organization.

Steps to successful benchmarking include:

- Secure leadership commitment to benchmarking as a first step, defining how benchmarking contributes to the organization's goals.
- Identify what will be benchmarked, the information required, and who will use the organization. This should be tied to the organization's strategic planning process.
- Form and train a team familiar with the process to be benchmarked.
- Identify measures of results and processes to be used.
- Document current process and results in detail, including goals, priorities, processes, operational definitions, customers, customer requirements or expectations, quality and other performance indicators, and trends of results measured for reach of the major organizational goals, such as customer satisfaction, issues, strengths, and weaknesses.
- Benchmark internally to similar processes within your organization first.
- Identify organizations to be benchmarked by doing research including information about processes, past performance, planned changes, and projections.
- Research benchmark organizations, including its processes, customers, and results.
- Perform external benchmarking to one or more external organizations, including phone conversations to discuss process & data elements, personal meetings & interviews & surveys to understand in detail the results & characteristics of processes that produce results.
- Analyze gaps focusing on key processes benchmarked by comparing baselines process with the process benchmarked.
- Develop action plans based on the analysis of gaps and on the strategic plan for the organization, including a plan for change with objectives, priorities, actions, responsibilities, schedule, and expected results.
- Implement action plans and monitor the progress of process changes and results.
- Repeat the benchmarking process, refining it and repeating it periodically, so that both benchmark partners will continue to learn.

Customer expectations are driven by the standards set by the best suppliers in the industry as well as by great experiences with suppliers in other industries. The ultimate benefit of benchmarking is to help achieve the leadership performance levels that fully satisfy these ever-increasing customer expectations. Benchmarking is an important ingredient of strategic planning and operational improvement. To remain competitive, long range strategies require organizations to adapt continuously to the changing marketplace. To energize and motivate staff, an organization must:

- Establish that there is a need for change
- Identify what should be changed
- Create a picture of how the organization should look after the change

Benchmarking achieves all three. By identifying gaps between the organization and the competition, benchmarking establishes that there is a need. By helping understand how industry leaders do things, benchmarking helps identify what must be changed. By showing what is possible and what other companies have done, benchmarking creates a picture of how the organization should look after the change. The steps of benchmarking are:

1. **Identify benchmark subject:** Identify the product or output of the business process or function. This depends on development of a clear mission statement detailing the reason for the organization's existence, including key outputs expected by its customers and critical to fulfilling

the mission successfully. Successfully completing benchmarking depends on selecting a worthwhile topic.

2. **Identify benchmark partner:** It's difficult to identify which leading edge organizations possess processes that genuinely have the best practices. This is a search process that starts with consideration of an operation's primary competitors and then extends itself to leading companies that are not competitors. The goal is to identify and understand where things done differently can produce breakthrough results. Internal benchmarking identifies subjects within the organization.
3. **Determine data collection method:** Determine available sources including internal, such as libraries, with online computer searches to cover everything published on the topic during the last 5 years. Other sources are internal market research or competitive studies. External sources includes professional associations, public seminars, lectures, trade shows, and speeches.
4. **Collect data:** The actual data collection can be done through phone or mail surveys, or by site visits. A site visit report should be prepared after the visit, ideally on the same day. Onsite consults can be hired to perform this work, however when outside consultants are used, there is little organizational learning.
5. **Determine competitive gap:** Analyze all the information collected to determine if the processes benchmarked are at parity, ahead of, or behind others. The team needs to identify gaps or differences in performance that exist between the team's process and that of the best in class and that of world class organizations.
6. **Project future performance:** It's necessary to not only analyze the gap that exists at the time of measurement but also project where the benchmark and gap are likely to be in the future. Questions to ask include: How does the organization compare today with the industry's best? How will this organization gain a performance advantage? What will it mean to the operation? The organization? How much will it cost to convert? What are the historical performance trends? What is the current performance gap? How will industry performance change? Will the performance gap narrow, widen, or remain the same? What are the implications for the subject business? How can the organization gain a significant performance advantage?
7. **Communicate results:** Collecting and analyzing the best practices data and projecting the operational implications are important and necessary, but are not enough to attain improved organizational performance. The team's task is to communicate its findings in such a way as to obtain acceptance. The team must ensure that management understands the findings, thinks the team is credible, and accepts its recommendations.
8. **Establish functional goals:** After management approves the recommendations, the impacts of practice changes must be identified and communicated to all affected individuals. The organization must revise operational goals, and analyze the impact on others.
9. **Develop action plans:** The benchmarking team must develop an action plan, obtain approval, and proceed to implementation. Implementation priorities must be set, reflecting effects on the performance gap. Describe specific tasks that must be complete and results expected. Sequence the tasks chronologically and designate a targeted completion date for each. Assess the resources required to implement the best practices. Assign specific responsibilities to specific individuals. Establish a monitoring system to track progress and alert the team when corrective action is needed.
10. **Implement plans and monitor results:** The team needs to establish measurements to gauge implementation progress. These efficiency measures include cost, time, quality, and a series of effectiveness measures to determine customer satisfaction. Use quality tools to help the team.
11. **Recalibrate benchmarks:** Benchmarks must be planned and recalibrated to ensure success and effectiveness. One way is to recalibrate benchmarks annually. More frequently is not usually worthwhile since practices generally do not change that rapidly.

Benchmark Data

Comparative reference data, or benchmark data helps place the survey in perspective. A number that has no reference is impossible to interpret. If 60% of patients can get an appointment within a week, is that good or not? There has to be some basis for comparison to answer the question. Using an organization's own internal benchmark data is often useful. An organization can compare nursing units, emergency room shifts, physician groups, or sites or look at the results of any one of them over time.

Internal benchmark data is generally high quality because the organization can ensure that everybody is using the same instrument and collecting data in the same way and in the same time intervals.

External benchmark data are more difficult to obtain. To make appropriate comparisons, data from other facilities should be obtained by using the same valid and reliable instrument, from similar patients at similar hospitals or facilities, with a representative response rate. If any of these requirements are not met, the external benchmark data will be questionable. If you add or remove any survey items, modify the wording of items, or change the order in which they appear in the survey, then the reliability and validity of the scales will be affected to an unknown degree. If changes are made, a pilot study should be done with the revised questionnaire and obtain new samples of reliability and validity. Surveys shouldn't be done unless the organization is going to use the results. Obtaining valid and reliable patient survey feedback is a complex and difficult undertaking.

Sequence for Quality Improvement

- Selection of a project
- Identification of a mission statement
- Identification of project team
- Team meetings
 - Review progress made since previous meeting
 - Agree on actions to be taken prior to next meeting
 - Assign responsibility for actions

Teams work their way through the universal sequence, establishing causes and defining solutions, then establishing controls to hold the gains. During this time, minutes and periodic progress reports detail the progress of the team. The final report contains a summary of the results achieved, along with a narrative of the activities that led to the results. With experience, teams identify lessons learned that can be applied to other projects.

Continuing Quality Improvement

Many organizations initiate quality improvement but few have succeeded in institutionalizing it so that it goes on year after year. Methods to make quality improvement continuous:

- Enlarge the annual business plan to include goals for quality improvement.
- Make quality improvement part of the job description. In most organizations, the activity of quality improvement is regarded as incidental to the regular job of meeting the goals for quality, cost, and delivery. The need is to make quality improvement part of the regular job.
- Establish upper management audits that include review of progress on quality improvement.
- Revise the merit rating and reward system to include performance on quality improvement and give it proper weight.
- Create well publicized occasions to provide recognition for performance on improvement.

Roles for Upper Management in Continuing Quality

Upper managers must participate extensively in quality improvement. It's not enough to create awareness, establish goals, and leave everything else to subordinates. The following roles of management can't be delegated in an organization that is truly committed to quality:

Serve on the quality council: This is fundamental to upper managers' participation and also becomes an indicator of the priorities of the rest of the organization.

Acquire training in managing for quality: Upper managers risk losing credibility if they try to lead while lacking training in managing for quality.

Approve the quality vision and policies: Must be approved by upper management first.

Approve the major quality goals: Quality goals must be deployed to lower levels to identify what needs to be done and the resources.

Establish the infrastructure: This includes the means for suggesting and selecting projects, preparing mission statements, appointing team leaders and members, training teams and facilitators, reporting progress.

Provide resources: Provide resources for training in managing in quality, and for setting up infrastructure for quality improvement.

Review progress: Maintain a regular review of progress in making quality improvements. If this isn't done, quality improvement can't compete with the traditional activities that did receive progress reviews from upper management.

Give recognition: Upper managers should seize opportunities to offer highly visible support for quality activities.

Revise the reward system: Traditional award systems need to be revised to give proper weight to performance on quality improvement.

Serve on project teams: Lead by example.

Face up to employee apprehension: Communicate openly with employees regarding changes.

Scheduled, periodic review of progress by upper managers is an essential part of maintaining annual quality improvement. Activities that don't receive such review can't compete with priority with activities that do receive such review. Subordinates understandably give top priority to matters that are reviewed regularly by their superiors.

Results take multiple forms, and these are reflected in the design of the review process. Certain projects are of such importance individually that the upper managers want to follow them closely. The remaining projects receive their reviews at lower levels, but are summarized for collective review by upper management. There is also a need for regular review of the quality improvement process. One of the objectives of progress review is evaluation of performance. This evaluation extends to individuals as well as projects. Evaluation of individuals runs into the complication that the results are achieved by teams. The problem becomes one of evaluating individual contribution to team efforts. At higher levels of the organization, the evaluations extend to judging the performance of supervisors and managers. Such evaluations must necessarily consider results achieved on multiple projects.

Recognition and Reward

Recognition means public acknowledgement of superior performance. Recognition tells recipients that their efforts are appreciated, adds to their self respect and to the respect received from others. Most organizations are effective at providing recognition. Recognition is given for superior performance, which is voluntary.

Rewards refers to salaries, salary increases, bonuses, and promotions resulting from the annual review of employee performance. This review in the past has focused on meeting goals for traditional parameters, costs, productivity schedule, and quality. A new parameter, quality improvement must be added to recognize that quality improvement is to become a part of the job description. Rewards given for mandated performance, doing work defined in job description.

Quality improvement is time consuming, adds a new function to the job, and invades the cultural pattern. It is critical to the organization's ability to remain competitive. If employees are only judged based on traditional goals, quality will suffer due to lack of priority.

Keys to Successful application of quality/performance improvement in health care:

1. In health care, as in all other known examples of successful improvement, role of leaders is crucial.
2. Breaking down barriers among functional areas is necessary for effective system changes.
3. Sound data, soundly analyzed, are as important in improving health care as in any other industry.
4. Customer focus is as meaningful in health care as in any other industry.
5. Cost containment through improvement is attainable in health care.
6. Benchmarking is useful.
7. Involvement of all staff in improvement is powerful.
8. Financing systems can be a major barrier to improvement.

Quality Problem Solving

- Select a problem solving process.
- Develop a final budget for quality.
- Select a team training methodology for and train team leaders, facilitators, and members.
- Create institutional indicators.
- Choose key measures/indicators. If it isn't measured, it isn't managed. There are an infinite number of things that could be measured, but it's important to select a few critical measures indicators to monitor the degree to which the organization meets customer requirements and process expectations.
- Involve your suppliers.
- Develop and publish a rollout plan.
 - What is the action step?
 - Why is it necessary?
 - How will it be accomplished?
 - Who is accountable for its completion?
 - When must it begin and end?
 - What indicators will determine and/or measure achievement?
- Measure and understand process capabilities. Operational definitions are very important.
- Develop quality at the department level
 - Identify key services and customers.
 - Develop a departmental mission statement.
 - What do you do?
 - Who do you do it for?
 - Why do you do it?
 - How do you do it?
- Flowchart critical processes.
- Interview customers to validate requirements.
 - Gather data from customers. Customer requirements should drive mission statements.
- Identify service gaps.
- Establish and monitor quality indicators.
- Set up teams to improve or redesign processes to close these gaps.
- Include the concept of innovation and creativity in processes. Include benchmarking.

- The key to substantial continuous improvement of quality, customer satisfaction, cost effectiveness, working environment, and other organizational goals is to encourage ideas and theories of how to improve from all employees, customers, and suppliers.
- Use brainstorming. Ask for ideas in meetings and privately. Give full attention to a person, and listen carefully when an idea is being presented. Smile and be encouraging. Schedule another time to listen to the idea if you do not have time now. Recognize people who propose ideas, even if some ideas do not work out.
- Implement improvements. Reduce steps that do not add value. Investigate methods to manage workload/demand. Evaluate and prioritize opportunities.
- Gather additional customer performance data.
- Assess process of what's been done.
- Measure and collect data.
- Evaluate usefulness of ideas and theories.
- Define prioritization criteria, such as: within your control, solvable within a time frame, importance to patients or other customers, cost importance.
- Listen to customer and employees concerning their prioritization criteria and why.
- Identify best similar approaches in existence, through benchmarking.
- Involve people doing activities because they know the current processes best.
- Use the most knowledgeable, skilled people to design improved processes in a quality/performance improvement team. Test alternative methods if they exist.
- Review potential impacts.
- Develop backup procedures if required.
- Standardize the process. Develop standard, approved methods to perform each function.
- Obtain approval if required.
- Document and communicate standard methods to everyone involved.
- Begin the cycle again.
- Check ideas for improvement.
- Take action, if within your control.
- Define actions needed to implement changes and identify people responsible for those actions.
- Describe implementation procedures.
- Define a time schedule for testing the options or proposed solutions.
- Define the measures and methods of measurement to be used to evaluate the proposed options. Define the study/pilot period for testing the options.
- Define the data analysis methods to be used.
- Describe the education and training required.
- Identify the resource requirements, including people, facilities, equipment, dollars, and any other internal and external resources required for successful testing of the options.
- Define approvals required, internally and externally.
- Identify any external coordination and support required.
- Develop updated stretch goals to sustain momentum.
- Gain any necessary approvals and assistance to perform pilot test. Pilot test, measure, and compare results to predictions from theory.
- Measure results.
 - Ask: What happened? Did workloads increase or decrease? Did quality measures increase or decrease? Did productivity go up or down? How did productivity compare to expectation?
 - Ask why it happened? What were reasons for change?
 - Are changes major or minor? Broad or narrow impact? Temporary or long term?

- Ask customers, suppliers, and employees how they feel about the new process, in addition to the analytical measures.
- Evaluate results and perceptions to see if benefits are greater than costs and disadvantages.
- Make changes based on results.
- Continue to measure & monitor results of processes, to find & resolve special cause as necessary.

Quality Awards

One of the most useful recent trends has been the self assessment activities of many organizations throughout the world. Companies worldwide are using the criteria of the Malcolm Aldridge National Quality Award, the European Quality Award, the Deming Application Prize, and many other national quality awards to assess their current performance against a reasonable set of guidelines for total quality. These assessments can provide senior managers with a clear baseline of current quality performance levels. When these managers are willing to take the time to understand the criteria, understand what their own assessment scores mean, and to understand what is necessary to improve these scores, they can develop meaningful and realistic action plans for improving their organizations. A very important step in this process is to first understand one's own organization's performance level and compare it to the performance level of another organization.

One of the most striking benefits of these national and international quality awards has been the stunning increase in senior management contact with true leaders in total quality. Senior managers are hearing what other companies have achieved in quality, how they obtained these results, and what the executive leadership's role in these achievements was. This benchmarking, both on a personal level and an organizational level, is one of the most important trends in modern quality management.

Malcolm Baldrige National Quality Award (MBNQA)

During the 1980's, there was growing interest in the United States in promoting what is now called total quality. Many leaders in the United States felt that a national quality award, similar to the Deming Application Prize of the Union of Japanese Scientists and Engineers, would help stimulate the quality efforts of U. S. companies. In On January 6, 1987, the Malcolm Baldrige National Quality Improvement Act of 1987 was passed and signed by President Reagan on August 20, 1987, and became Public Law 100-107. This act provided for the establishment of the Malcolm Baldrige National Quality Award Program. The purpose of the award was to help improve quality and productivity by:

Helping stimulate American companies to improve quality and productivity for the pride of recognition while obtaining a competitive edge through increased profits;

Recognizing the achievements of those companies which improve the quality of their goods and services and provide an example to others;

Establishing guidelines and criteria that can be used by business, industrial, governmental, and other organizations in evaluating their own quality improvement efforts, and

Providing specific guidance for other American organizations that wish to learn how to manage for high quality by making available detailed information on how winning organizations were able to change their cultures and achieve eminence.

This national quality award was first awarded in 1988 to emphasize and recognize quality improvement among organizations in the United States. It was revised in 1998 to focus on quality results rather than quality systems. The actual applications are full of charts, graphs, tables, and other forms of results. The winning companies are well on the way to management by fact and report their activities in fact rich documents. The examiners expect this and often refuse to score any examination item highly that doesn't have convincing data to support a statement. One of the most common statements on an application is "Lack of evidence to support claim of ..." The scores, individual categories, and total, are mainly used in the early stages of the awards. High scoring applications are selected for the consensus

review stage. High scoring applications after consensus scoring are selected for site visits. After site visits, scores are not recalculated. The actual findings of the site visit teams are submitted to judges and the judges get further information from the site visit team leader or members. At this stage of judging, scores have become less important and are rarely used. The site visit teams concentrate a great deal of their activity on finding the evidence to support claims in the applications, verifying results, and examining supporting documents. These visits focus very much on results, not just approach or deployment. The focus is on whether the company's approach is working and is working across the company and across all functions. Examiners verify data, interview employees, and review actual operations and facilities.

During the site visit, examiners look for measurements of both internal and external quality. They look for measures of suppliers' quality levels. They interview employees and ascertain the results of the training, teamwork, and quality improvement processes. They look at customer satisfaction data, competitive evaluations, and benchmarks. They look for evidence of actual, sustained improvement and world class performance. The checklist of items to win the MBNQA is more than 23 pages.

- Core values and concepts that underlie all requirements include:
- Customer driven quality: Quality is being judged by the customer.
- Leadership: A company's senior leaders must create a customer orientation, clear and visible quality values, and high expectations.
- Continuous improvement: Achieving the highest levels of quality and competitiveness requires a well-defined and well executed approach to continuous improvement.
- Employee participation and development: A company's success in meeting its quality and performance objectives depends increasingly on work force quality and involvement.
- Fast response: Success in competitive markets increasingly demands ever shorter cycles for new or improved product and service introduction.
- Design quality and prevention: Quality systems should place strong emphasis on design quality— problem and waste prevention achieved through building quality into products and services and into the processes through which they are produced.
- Long range outlook: Achieving quality and market leadership requires a company to have a strong future orientation and a willingness to make long term commitments to customers, employers, suppliers, stockholders, and the community.
- Management by fact: Pursuit of quality and operational performance goals of the company requires that process management be based upon reliable information, data, and analysis.
- Partnership development: Companies should seek to build internal and external partnerships to better accomplish their overall goals.
- Corporate responsibility and citizenship: A company's quality system objectives should address corporate responsibility and citizenship.

The application guidelines provide very useful evaluation criteria in the categories of:

- Leadership
- Information and analysis
- Strategic quality planning
- Human resource development and planning
- Management of process quality
- Quality and operational results
- Customer focus and satisfaction

European Quality Award (EQA)

The European Quality Award shares many concepts and criteria elements with the Malcolm Baldrige National Quality Award, but the two awards differ in some important ways. The local model of

the EQA is quite clear. The first element is leadership which drives people management, policy and strategy, and resources. These, in turn, drive all processes which drive people satisfaction, customer satisfaction, and impact of society. These three drive business results. One of the major differences between the Malcolm Baldrige Quality Award and the EQA is the emphasis the EQA puts on assessment. The EQA makes the principle of self assessment an entry requirement for companies applying for the award. A second difference is that EQA doesn't have a fundamental internal results category. Some people argue that internal results are implicit in other categories. Another difference is the way the awards are administered. The MBNQA is competitive; it is given to a maximum of two companies in each category, and the maximum number has never been reached. The EQA is essentially non-competitive, every company that reaches the mark receives a prize. The Award is given to the best prize winner. In some ways this makes the EQA even more competitive, since companies have a great desire to win the award, not just a prize.

Deming Prize

Another contribution to the development of total quality has been the Union of Japanese Scientists and Engineers' Deming Application Prize. In recognition of Deming's friendship and contributions to Japan, the Deming Prize was established in 1951 to encourage the development of quality control in Japan. The prizes were originally funded with Deming's general gift of the royalties from transcripts of his 8 day Quality Course lectures and the Japanese translation of one of his books. There are two types of Deming Prize, the Deming Prize for Individuals and the Deming Application Prize for companies and divisions. Deming Application Prizes are awarded to companies or operating divisions that have achieved outstanding results through the skillful application of company wide quality control based on statistical methods, and are considered likely to continue to do so in the future. Company wide quality control is defined as the activity of economically designing, producing, and supplying products and services of the quality demanded by customers, based on customer focused principles, and with full consideration of the public welfare. In over the 40 year existence of the Deming Application Prize, there have been many modifications and improvements to the prize criteria and the administration of the prize. The Deming Application Prize is not competitive; every company whose application is accepted may win. There are several differences between the MBNQA and the Deming Application Prize. There is no limit to the number of companies that may win a Deming Application Prize in any one year. There is a stronger emphasis on the use of statistical methods than in the MBNQA. The company itself decides when it is to receive an objective assessment of whether its activities have reached the level capable of passing the Deming Application Prize examination.

SAMPLE PERFORMANCE-IMPROVEMENT-(PI) POLICY

1. **PURPOSE**: To establish policy and procedures for a planned, systematic, unified, collaborative, organization-wide approach to process design, performance measurement, analysis and improvement and patient safety. This includes development of a strategy and structure to measure, analyze and continuously improve the key systems and processes impacting patient care, directly or indirectly, at this medical center. The Program will be guided by the medical center's Mission/Vision and Value Statements
 - a. **Mission**: The Mission of the new VA is to improve the health of the served veteran population by providing primary care, specialty care, extended care and related social support services in an integrated health care delivery system.
 - b. **Vision**: Our vision is to be Veterans' 1st choice in health care by being a model of clinical and organizational excellence.
 - c. **Values**: Just as our values guide our behavior, organizational core values provide the compass that gives direction to its efforts. Values are the basis upon which the organization orients its strategies. We need values in place as part of the infrastructure in order to develop medical center goals and priorities for our quality activities. The VHA Core Values are adopted by this medical center and include (See Appendix A: Definition of Values):
 - (1) Trust
 - (2) Respect

- (3) Commitment
- (4) Compassion, and
- (5) Excellence

d. Network Strategic Targets: The annual Network Strategic Targets are utilized as beacons in guiding performance improvement activities. The FY '2001-2006 VHA Goals/Network Strategic Targets include the following:

- (1) Put Quality First Until First in Quality
- (2) Provide Easy Access to Medical Knowledge, Expertise and Care
- (3) Enhance, Preserve and Restore Patient Function
- (4) Exceed Patients' Expectations
- (5) Save More Dollars to Serve More Veterans
- (6) Build Healthy Communities

e. Patient Safety: The Medical center Comprehensive Patient Safety Program is under the Quality Management/ Performance Improvement umbrella. The Patient Safety/Risk Management program is proactive, and reviews, analyzes, reports, tracks, trends and evaluates patient/visitor incidents (adverse events, near misses, etc.), as well as other safety related events. The goal of the program is to improve the quality and safety of care by designing or redesigning patient care systems to prevent the likelihood of injuries that can harm patients, visitors and employees. The program is a system approach that emphasizes prevention, not punishment and focuses efforts toward creating a culture of safety. For more information please see Medical Center Policy Numbers 11-33 (Integrated Patient Safety/Risk Management Program) and 00-58 (Reporting of Adverse Events Involving Patients - Special Incidents Involving a Beneficiary) regarding the overall safety programs.

2. **POLICY**: The medical center's Performance Improvement Model is based upon Total Quality Improvement (TQI), which promotes a collaborative, interdisciplinary, systematic, organization-wide approach for continually improving all processes that deliver care or services directly to, or in support of, patient care. The medical center's mission, vision and values should guide all TQI efforts.

a. In pursuing a TQI environment throughout the medical center, four basic principles must be adhered to:

- (1) Develop a strong customer focus (both internal and external);
- (2) Continually improve all processes (using the four-step approach);
- (3) Involve employees (encourage teams, support them, use their work and celebrate their accomplishments); and
- (4) Mobilize both data and team knowledge to improve decision making (use TQI tools as appropriate).

b. The TQI Model used at the Carl T. Hayden VA Medical Center includes four steps (see Appendix B: A.P.I.E. Model of Process for Improvement):

- (1) Step 1 - Assess/Diagnose: Identify the process to be improved and state it in clear terms. Describe and analyze the current process quantitatively, using quality tools (e.g., use of flow chart). Use the data and other information to determine if there is a process problem and identify root causes (e.g., use cause/effect diagram).
- (2) Step 2 - Plan: Develop a plan to address the issues identified. Design new processes as needed.
- (3) Step 3 - Implement: Make the needed changes (i.e., pilot a different process and change a policy). Build in quality indicators.
- (4) Step 4 - Evaluate: Through the process of monitoring, show change in process performance (data-oriented results). Evaluate the improvements made and describe plans for ongoing monitoring in order to achieve and sustain further performance improvement.

c. Domains of Quality: VHA has put forth five domains of quality: access, technical quality/ safety, customer satisfaction, cost-effectiveness, and functional status.

d. Data Collection, Aggregation and Analysis

- (1) Data are collected to monitor the stability of existing processes, identify opportunities for improvement, identify changes that will lead to improvement, and sustain improvement. This includes collecting data to monitor:
 - (a) Organizational performance;
 - (b) Processes that involve high risk, problem prone, affecting large populations or risks which may result in sentinel events;
 - (c) Performance of areas targeted for further study; and
 - (d) Improvements in performance.
- (2) Data are systematically aggregated and analyzed as appropriate on an ongoing basis.
 - (a) Appropriate statistical techniques are used to analyze and display data;
 - (b) The organization compares its performance over time and with other sources of information (benchmarking);
 - (c) Undesirable trends in performance and sentinel events are intensively analyzed; and

(d) The organization identifies changes that will lead to improved performance and reduce the risk of sentinel events.

3. **PROCEDURES:** The Executive Performance Improvement Council (EPIC) oversees the medical center's Performance Improvement Program. The role of the EPIC and other components of performance improvement are depicted by the chart in Appendix D (Performance Improvement Organizational Structure), and described in Appendix E (Performance Improvement Organizational Quality Groups: Overview). Reports are submitted to the EPIC as outlined on Appendix F (Performance Improvement Reporting Schedule).

a. **Executive Performance Improvement Council:** Council membership includes representatives from leaders, medical staff, other staff and labor/union (partnership). The role and responsibility of the Council includes the following:

- (1) Providing oversight for medical center improvement activities;
- (2) Supporting a philosophy of continuous improvement;
- (3) Development/implementation of an appropriate performance measurement system which benchmarks against industry leaders and best practices in health care;
- (4) Overseeing and evaluating the effectiveness of the medical center's performance improvement activities;
- (5) Identifying changes that will lead to improved performance and improve patient safety.
- (6) Overseeing, coordinating and integrating improvements relating to patient care and patient safety;
- (7) Identifying priorities for improvement. Priorities for improvement are determined as they relate to network/medical center strategic targets and goals;

b. **Function Lead Teams and Medical Staff Committees Related to Quality Improvement:** Membership of the Function Lead Teams (FLTs) includes interdisciplinary experts representing areas related to the individual functions. A variety of Functional Lead Teams have been established to facilitate the interdisciplinary approach to process improvement. The charge to these teams is to continuously improve the performance of the key processes that constitute the function overseen by the team. The specific "scope" of these functional teams includes the following:

- (1) **Management of Information (MOI):** Identification of the organization's information needs, structural design of the information management system, definition and capture of data and information, transmission and reporting of data and information, and assimilation and use of information. The MOI FLT has oversight for the **Medical Records Task Team**: This task team reviews the completeness, accuracy, and timely completion of information in medical records concurrently.
- (2) **Management of Human Resources:** This FLT has oversight of the processes related to planning by the organization that defines the qualifications, competencies and staffing necessary to fulfill the organization's mission; providing competent staff members (either through traditional employer-employee arrangements or contractual agreements with other entities), developing and implementing processes designed to ensure that the competence of all staff members is assessed, maintained, improved and demonstrated throughout their association with the organization; providing a work environment that promotes self-development and learning.
- (3) **Ethics Advisory Committee:** The presence of functioning processes and mechanisms to address ethical issues. Other responsibilities include organ donation procedures, organization ethics policy, and policy and mechanism to protect patients and respect their rights during research, investigation, and/or clinical trials involving human subjects.
- (4) **Medication and Clinical Nutrition Management Committee:** The review, monitoring, and initiation of methods for improvement relative to: drug preparation and dispensing systems; availability of medications; use of parenteral nutrition; and medication usage. The group also provides oversight for the nutrition committee.
- (5) **Patient Assessment:** The processes involved with gathering patient data initially and throughout the patient's contact with the medical center. Analyzing the data to create information about the patient's needs and the actual decision making to select appropriate and efficacious care and treatment intervention. This function has been incorporated by the patient care (clinical) service lines with documentation oversight by the Management of Information FLT through the Medical Records Task Team.
- (6) **Operative and Invasive Procedures (Surgical Case Review Committee):** Provision of operative and other invasive procedures that are necessary for diagnosis, cure or palliation of disease or impairment, restoration or improvement of function, and relief of symptoms. The processes to be monitored and improved include the selection of appropriate procedures, preparation of the patient for the procedures, performing the procedures, and monitoring the patient before, during, and after the procedure. This group also provides oversight for moderate sedation.
- (7) **Management of the Environment of Care:** Provision of a functional and safe environment for patients, staff and others in the following areas: safety; fire prevention, security; hazardous materials and waste; emergency preparedness; life safety; medical equipment; and utilities systems. For each of these areas, the following activities are involved:

planning and designing consistent with the organization's mission and vision; education of staff about the role of the environment in safely, sensitively and effectively supporting patient care; development of standards to measure staff and hospital performance in managing and improving the environment of care; implementing plans to create and manage the organization's environment of care; An Information, Collection and Evaluation System (ICES) is developed and used to continuously measure, assess, and improve the status of the environment of care.

(8) Surveillance, Prevention and Control of Infections: Activities related to the direct patient care, support and ancillary levels to reduce risk of nosocomial infection to patients; reduction of the risk for transmission of infection among patients, employees, visitors and others, and linkage with support systems to reduce risk of infection from the environment (food and water sources)

(9) Continuum of Care: Activities related to five phases of the care process:

(a) Before Admission - The medical center identifies and uses available information sources about the patient's needs; the medical center communicates with other care settings and organizations.

(b) During Admission - Medical center services are consistent with its mission, population served, and setting. The medical center makes arrangements with other organizations and settings to facilitate the patient's admission. The patients are referred and transferred to meet their needs based on intensity, risk, and staffing level. Clinical consultants and contractual agreements are used for referrals and transfers, when appropriate.

(c) In the Medical Center - Services flow continuously from assessment through treatment and re-assessment. The patient's care is coordinated among practitioners.

(d) Before Discharge - The patient's status and need for continuing care are assessed. Education prepares the patient for discharge.

(e) At Discharge - The patient is directly referred to practitioners, settings, and organizations to meet his/her continuing needs. The use and value of continuing care to meet the patient's needs are re-assessed. The medical center provides information or data to help others meet the patient's continuing care needs.

(10) Education of Patients and Family: Education of the patient and family in order to improve patient health outcomes, ensuring that the education received is specific to the patient's assessed needs, abilities and readiness; and ensuring that any discharge instructions given to the patient are provided to the organization or individual responsible for the patient's continuing care.

(11) Medical Records Task Team: This task team reports to the MOI FLT. It reviews the completeness, accuracy, and timely completion of information in medical records at least quarterly.

(12) Clinical Safety Work Group: This committee reports to the EPIC. Its purpose is to facilitate education, research, and patient safety activities to enhance patient safety and to reduce risks/losses to the medical center. The Clinical Safety Workgroup will promote and support processes that identify and address selected high-risk areas related to patient care. (*See Medical Center Policy Numbers 11-33 (Integrated Patient Safety/Risk Management Program) and 00-58 (Reporting of Adverse Events Involving Patients - Special Incidents Involving a Beneficiary), regarding the overall safety programs)

c. Process Improvement Teams (PITs):

(1) Teams may be chartered by departments, service lines, FLTs, EPIC, ELC or other groups. Teams should report periodically to the parent group.

(2) Issues that involve cross service lines or multiple service lines need to have adequate representation by stakeholders to ensure optimum communication and coordination.

(3) PIT activities should be summarized to show their accomplishments

d. Service Line Performance Improvement Activities: Each service line will be involved with performance improvement activities. Additionally they will contribute to the Medical Center Strategic Plan by developing strategic targets/goals. An operating plan which incorporates scope of services and a business plan is developed as appropriate. Service lines will develop the following:

(1) Operational Plan For Providing Services - Each service line will develop an Operating Plan for providing services (See medical center document, "Operational Plan for Provision of Services."). This plan will then be incorporated into the Medical Center Operating and Strategic Plans. The components of Service Line Plans include:

(a) Description of Service/Programs (Scope of Services)

(b) Purpose of Department

(c) Service Line Goals/Objectives

(d) Administration and Organization of the Service Line

(e) Hours of Operation

(f) Service Delivery Process

- (g) Staffing
- (h) Budget/Resources
- (i) Performance Improvement/Quality of Care Initiatives
- (2) Service-Line/Departmental Monitoring Activities - In order to identify issues or performance that are not meeting customer expectations, it is necessary for all service lines/departments to continually monitor their performance in key areas. The results of these monitoring activities should be tracked and documented in a manner that identifies trends that require further review or intervention.
- (3) Service Line Teams - Teams are chartered by the service line to address improvement of processes within the service line, department, section or unit.
- e. Organizational Programs: Organizational Programs related to quality and performance improvement (Utilization Management, Patient Safety/Risk Management, Customer Satisfaction and Public Relations) report to the EPIC quarterly.
- f. Ongoing Evaluation: The Executive Performance Improvement Council will provide ongoing evaluation/review of organizational performance improvement activities.

4. **RESPONSIBILITIES**:

- a. The Medical Center Director is responsible for overall quality in the medical center and as such, chairs the Executive Performance Improvement Council (EPIC).
- b. The Executive Leadership Council is responsible for setting the strategic direction for the medical center, creating an environment and climate for continuous quality improvement and for supporting medical center staff in meeting internal and external standards. The leaders develop the Medical Center Strategic and Operating Plans. Each service line develops its operating plan for providing services based on those two plans.
- c. The Executive Performance Improvement Council is responsible for providing oversight for medical center improvement activities, supporting a philosophy of continuous improvement, and development of an appropriate performance measurement system which benchmarks against industry leaders and best practices in health care. The EPIC is responsible for overseeing and evaluating the effectiveness of the medical center's performance improvement activities and identifying priorities for improvement.
- d. Service Line Administrators/ACOSs:
 - (1) Are responsible for ensuring that performance improvement activities in the service line, department or program occur through an interdisciplinary council or group, that a summary of findings is communicated to their staff, and to medical center leaders in a service line report card. Documentation of service line performance improvement activities can be through reports to the leadership, project books, minutes or storyboards.
 - (2) Assure that ongoing monitoring of key functions in their areas is accomplished and results of ongoing monitoring will be documented and reported to the Director, Chief of Staff, EPIC or medical center committee/teams as appropriate. These leaders will also support the related concepts and practice continuous quality improvement in their operations throughout the medical center to meet internal and external standards.
- e. Department Chairs and Assistant Administrators assure that there is ongoing performance improvement activity in their department, including monitoring of key indicators. Results of performance improvement activities are reported through Service Line Administrators/ ACOSs. They oversee that staff meets internal and external standards which apply to their departments, and assure follow-up when deficiencies are identified.
- f. Employees are responsible for identifying opportunities for improvement in their work areas, actively participating on Process Improvement Teams, and participating in data collection efforts to measure our performance in a variety of areas.

Quality Management/Performance Improvement Staff are responsible for education and training of medical center employees, leaders, team leaders and team members in the TQI concepts and tools. The Quality Management Department will report findings of key performance measures on a "Dashboard of Performance Measurements" for the EPIC to utilize in determining priority areas for improvement efforts, as well as to monitor the continued success of performance improvements. Quality Management Staff serve as internal consultants throughout the medical center, working with teams and service line quality groups. They staff the EPIC, conduct periodic internal organization-wide quality audits, and utilize appropriate self-assessment tools.

5. **REFERENCES**: Joint Commission Manual, current year. CAMH – All Standards. Oakbrook, Ill; Medical Center Policy Numbers 11-33, Integrated Patient Safety/Rick Management Program and 00-58, Reporting of Adverse Events Involving Patients (Special Incidents Involving a Beneficiary)

6. **RESCISSION**: Policy Memorandum, 00-3

VHA CORE VALUES DEFINITION: The VHA Core Values adopted by this medical center are: Trust, Respect, Commitment, Compassion, and Excellence. (See Appendix A: Definition of Values). To promote a common understanding, these terms shall be understood to mean the following

“**TRUST**” means having a high degree of confidence in the honesty, integrity, reliability and sincere good intent of those with whom we work, the services that we provide, and the system that we are a part of. Trust is the basis for the caregiver-patient relationship and is fundamental to all that we do in healthcare.

“**RESPECT**” means honoring and holding in high regard the dignity and worth of our patients and their families, our co-workers, and the system we are a part of. It means relating to each other and providing services in a manner that demonstrates an understanding of and a sensitivity and concern for each person’s individuality and importance.

“**COMMITMENT**” means dedication and a promise to work hard to do all that we can do to provide service to our co-workers and our patients that is in accordance with the highest principles and ethics governing the conduct of the healthcare professions and public service. It is a pledge to assume personal responsibility for our individual and collective actions.

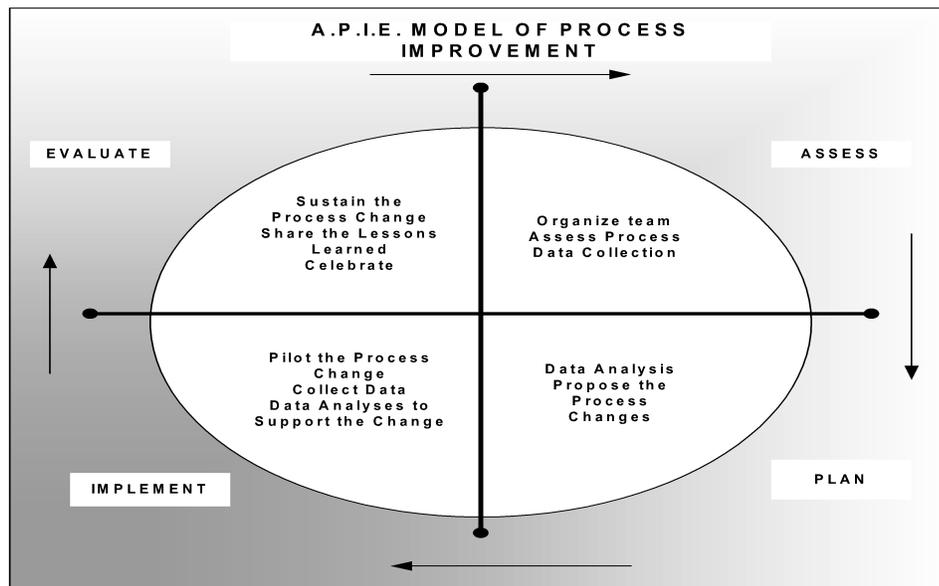
“**COMPASSION**” means demonstrating empathy and caring in all that we say and do. It means sharing in the emotions and feelings of our co-workers, our patients and their families, and all others with whom we are involved.

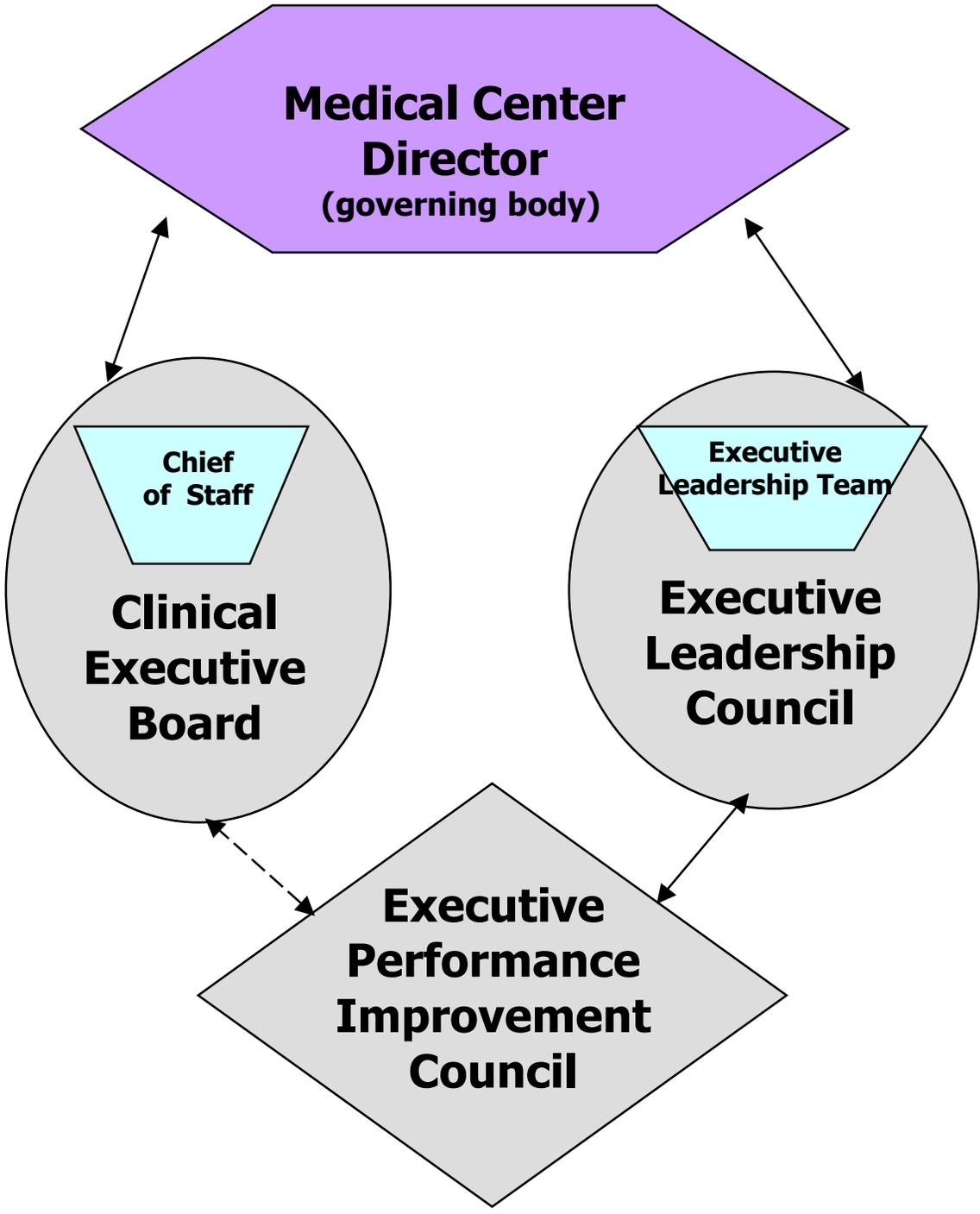
“**EXCELLENCE**” means being exceptionally good and of the highest quality. It means being the most competent and the finest in everything we do. It also means continually improving what we do.

Carl T. Hayden VA Medical Center

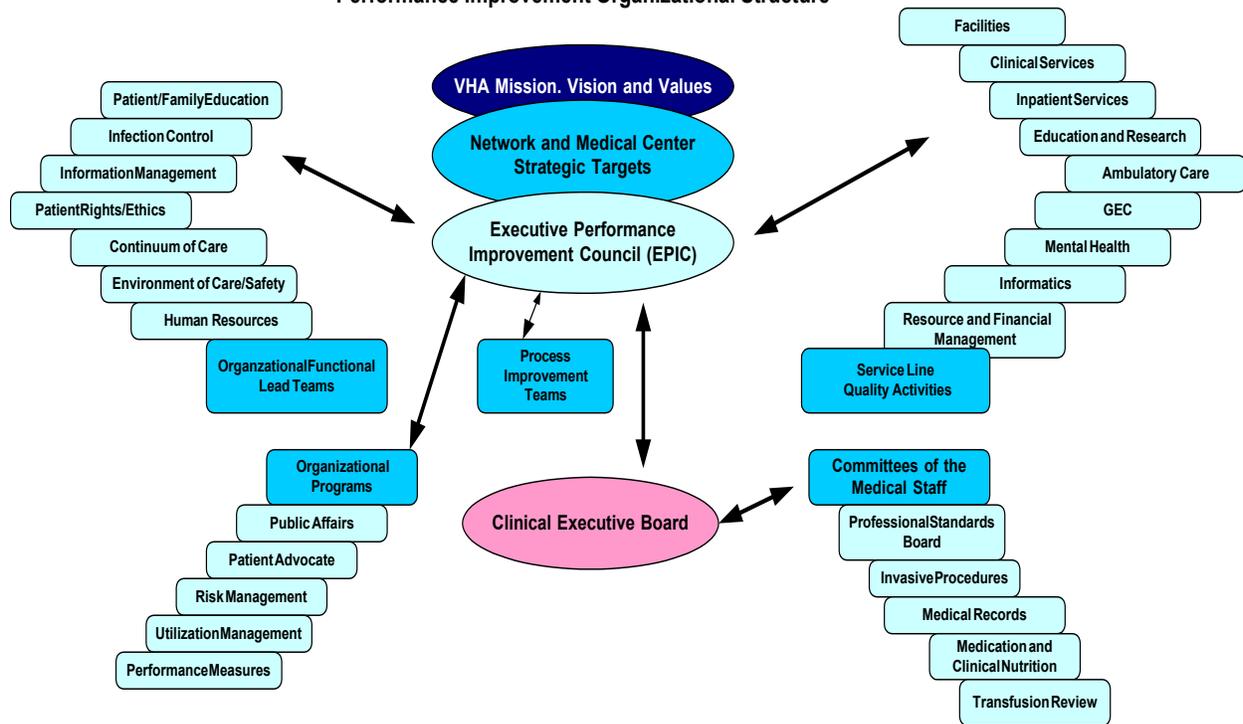
Attachment B

MEDICAL CENTER PROCESS IMPROVEMENT MODEL





**Carl T. Hayden VAMC
Performance Improvement Organizational Structure**



ORGANIZATIONAL PERFORMANCE IMPROVEMENT GROUPS: OVERVIEW

<i>FLT/Committee</i>	<i>RESPONSIBILITIES</i>
<i>Executive Leadership Committee (ELC)</i>	<ul style="list-style-type: none"> Leadership Standards including Safety Improving Organizational Performance Standards Leaders are required to develop framework for planning, directing, coordinating, providing and improving health care services that are responsive to community and patient needs and that improve health care outcomes Leaders need to develop strategic plan that clearly communicates mission/vision and plan Fulfill the organization's vision by providing framework to accomplish goals of strategic plan
<i>Executive Performance Improvement Council (EPIC)</i>	Organizational Performance Improvement: involves developing and utilizing a framework for performance measurement looks at organizations ability to design, measure, assess and improve performance. Considers dimensions of performance as outlined by Joint Commission.
<i>Management of Information</i>	Involves organization's collective information needs. Goal is to obtain, manage, and use information to improve organizational and individual performance in patient care, governance, management and support processes. Also involves review of completeness, accuracy and timely completion of medical records by oversight of Medical Records Task Team.
<i>Assessment</i>	<ul style="list-style-type: none"> Assessment activities are incorporated into the functions of mainly the Management Of Information FLT's medical records task team. Assessment addresses means by which pt needs are assessed in order to determine treatment. Includes <ol style="list-style-type: none"> Gathering data to assess pt needs Analyzing these data to provide information necessary for informed decision making re: pt needs Making decisions re: pt care or treatment based on analysis. Assessments should include relevant data re: physician, psychological

FLT/Committee	RESPONSIBILITIES
	<i>and social status needs. Chapter encompasses assessments performed by physicians, registered nurses, social work professionals and others.</i>
Continuum of Care	<ul style="list-style-type: none"> • <i>Involves coordinating the patient's care among practitioners, across organizations (geographic locations, services, or various levels of care) and over time. Major reference to discharge planning and documentation of appropriate information in the medical record.</i> • <i>Involves determining where the pt is to receive care (e.g., inpatient, home, intensive care, and emergency care). Entry is related to the organization's mission, patient needs and to organization's resources, among other factors.</i>
Care & Tx of the Patient	<p><i>Covers full range of processes involved in caring for pt, including operative and invasive procedures including Medication Administration (P&T functions) and Drug Interactions. Also includes procedures;</i></p> <ol style="list-style-type: none"> <i>1. Selection of appropriate procedure</i> <i>2. Preparation of pt</i> <i>3. Performance of procedure and monitoring of pt discharge from setting/service</i> <i>4. Focus is on performance rather than policies/procedures (key area is conscious sedation)</i> <i>5. Standards include roles of various disciplines involved in these procedures.</i> <i>6. Also includes standards related to Pt Restraints.</i>
Ethics Advisory Committee	<i>Covers mechanisms to address ethical issues, policies and procedures: pt rights, consideration of psychosocial and cultural variables, care for the dying pt, effective management of pain. Addresses medical center wide policies on withholding of resuscitative services from pts and forgoing or withdrawing of life-sustaining treatment and use of advance directives. Includes organizational ethics.</i>
Patient Education	<i>Addresses educating the pt and family to improve pt health outcomes. Effective education can help promote recovery and healthy behavior, return to function and involve pts in the care and decision making.</i>
Safety Management/ Environment of Care	<i>Covers environmental management, plant technology, facility and all related standards. Safety Committee covers Safety and is chaired by Paul West.</i>
Clinical Safety Committee	<i>To minimize the chance of occurrence of untoward outcomes consequent to medical care by preventing and managing injuries to patients, visitors, and personnel through the use of procedures, methods, and feedback loops at all levels of the medical center.</i>
Human Resources	<i>Standards related to competence assessment and performance and qualifications of staff. Includes standards related to orientation and training of staff.</i>
Infection Control	<i>Infection control standards. Surveillance and monitoring of infections.</i>
Clinical Executive Board	<i>Executive Committee of the medical staff.</i>
Medication & Clinical Nutrition Management Committee	<i>Performs all required functions of Pharmacy & Therapeutics, medication usage and nutrition management</i>
Transfusion Review	<i>Performs all required functions related to transfusion review</i>

<i>FLT/Committee</i>	<i>RESPONSIBILITIES</i>
<i>Invasive Procedures Review Committee</i>	<i>Performs all required functions related to surgical case review and review of operative invasive procedures. Oversight for moderate sedation.</i>
<i>Mental Health & Behavioral Services</i>	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
<i>Geriatrics & Extended Care (Home Care, Contracts, DME, etc.)</i>	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
<i>Ambulatory Care</i>	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
<i>Clinical Services</i>	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
<i>Facilities Services</i>	<i>Service Line Administrator ensures that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
<i>Inpatient Services</i>	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
<i>Informatics</i>	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>

<i>FLT/Committee</i>	<i>RESPONSIBILITIES</i>
Resources & Financial Management	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>
Education, Research & Training	<i>Service Line Administrators/ACOSs ensure that performance improvement activities in the service line or program occur through a council or group, that they are communicated to their staff, to medical center leaders and that they are documented in performance improvement reports, project books, minutes or storyboards. Focus is two-fold: a) ongoing quality monitors and b) process improvements). Reports need to be data oriented and utilize external benchmarking when possible.</i>

EXECUTIVE PERFORMANCE IMPROVEMENT COUNCIL REPORTING SCHEDULE			
	OCTOBER	NOVEMBER	DECEMBER
1st Quarter	Human Resources FLT Ethics FLT EC/Safety Mgt. Comm. Facilities Services (FS) Mgt. of Information FLT Informatics Services (IS)	Infection Control FLT Continuum of Care FLT Resources/Fin. Mgt. (RFMS) Education/Research (ERS) Clinical Services (CS) Geriatrics/Ext. Care (GECS) Risk Mgt./Patient Safety	Public Relations Customer Satisfaction Ambulatory Care (ACS) Mental Health/BS (MHBSS) Inpatient Care (ICS) Patient Education FLT Utilization Review
2nd Quarter	JANUARY Human Resources FLT Ethics FLT EC/Safety Mgt. Comm. Facilities Services (FS) Mgt. of Information FLT Informatics Services (IS)	FEBRUARY Infection Control FLT Continuum of Care FLT Resources/Fin. Mgt. (RFMS) Education/Research (ERS) Clinical Services (CS) Geriatrics/Ext. Care (GECS) Risk Mgt./Patient Safety	MARCH Public Relations Customer Satisfaction Ambulatory Care (ACS) Mental Health/BS (MHBSS) Inpatient Care (ICS) Patient Education FLT Utilization Review
3rd Quarter	APRIL Human Resources FLT Ethics FLT EC/Safety Mgt. Comm. Facilities Services (FS) Mgt. of Information FLT Informatics Services (IS)	MAY Infection Control FLT Continuum of Care FLT Resources/Fin. Mgt. (RFMS) Education/Research (ERS) Clinical Services (CS) Geriatrics/Ext. Care (GECS) Risk Mgt./Patient Safety	JUNE Public Relations Customer Satisfaction Ambulatory Care (ACS) Mental Health/BS (MHBSS) Inpatient Care (ICS) Patient Education FLT Utilization Review

	<i>JULY</i>	<i>AUGUST</i>	<i>SEPTEMBER</i>
4th Quarter	<i>Human Resources FLT</i> <i>Ethics FLT</i> <i>EC/Safety Mgt. Comm.</i> <i>Facilities Services (FS)</i> <i>Mgt. of Information FLT</i> <i>Informatics Services (IS)</i>	<i>Infection Control FLT</i> <i>Continuum of Care FLT</i> <i>Resources/Fin. Mgt. (RFMS)</i> <i>Education/Research (ERS)</i> <i>Clinical Services (CS)</i> <i>Geriatrics/Ext. Care (GECS)</i> <i>Risk Mgt./Patient Safety</i>	<i>Public Relations</i> <i>Customer Satisfaction</i> <i>Ambulatory Care (ACS)</i> <i>Mental Health/BS (MHBSS)</i> <i>Inpatient Care (ICS)</i> <i>Patient Education FLT</i> <i>Utilization Review</i>

SAMPLE PATIENTS' RIGHTS AND RESPONSIBILITIES POLICY

1. **PURPOSE**: To establish policy and procedures regarding the rights and responsibilities of all patients receiving care at this medical center.
2. **POLICY**: a. It is the policy of this medical center to ensure that patients are provided quality health care in a respectful and courteous manner and receive the benefits and rights for which they are entitled. Patient rights and responsibilities apply to inpatients and outpatients as applicable to their patient care settings.
3. **PROCEDURE**: Patients will be advised of their rights and responsibilities via "Information Booklet on Patients' Rights and Responsibilities," VA Form 10-7991A (Appendix A), which will be given to inpatients at the time of admission and will be made available to outpatients in clinic treatment areas. In addition, patients' rights information will be posted in public areas. When appropriate, patients may be referred to a Patient Advocate for assistance. (Policy Memorandum No. 00-43, "Management of Patient Complaints and Inquiries," should be referred to for information on processing grievances.)
4. **PATIENT RIGHTS**: Patients will have rights in accordance with Title 38, Code of Federal Regulations, Chapter 17, Section 17.34a and the "Information Booklet on Patients' Rights and Responsibilities," with modifications and additional rights based on local programs and policies and Joint Commission standards, as follows.
 - a. Each patient has the right to:
 - (1) Reasonable response to requests and access to treatment or service, within the medical center's capacity, its stated mission, and applicable laws and regulations.
 - (2) Care that is considerate and respectful of his/her personal values and beliefs, as well as access to pastoral counseling and/or spiritual services. This includes the opportunity for the patient to express these beliefs to the extent this does not harm others or interfere with treatment.
 - (3) Be informed about and participate in decisions involving his/her health care, which include ethical issues of conflict resolution, withholding resuscitative services, foregoing or withdrawal of life sustaining treatment, end of life care, and participation in investigational studies or clinical trials.
 - (4) Access to protective services, as appropriate. Patients may be referred to a social worker for assistance with guardianship or fiduciary services.
 - (5) Information necessary to enable him/her to make treatment decisions, including expected benefits, potential discomforts, risks, alternatives, and possible results of nontreatment, as appropriate.
 - (6) Be informed about, consent to, or refuse recommended treatment to the extent permitted by law and to be informed of the medical consequences of such refusal. Refusal to participate in investigational studies will not compromise a patient's access to services.
 - (7) Be advised of advance directives and the opportunity to execute an advance directive. Patients may give directions about future medical care verbally or in writing or may designate one or more persons to make medical decisions if he/she loses decision-making capacity. Advance directives may include living wills, durable powers of attorney, or similar documents expressing the individual's preferences. The patient has a right to change his/her mind regarding any written or verbal advance directive.
 - (8) Be provided reasonable privacy based upon the current physical environment and VA resources. Staff will demonstrate respect for patient privacy.
 - (9) Confidentiality of information. Each patient and/or legally designated representative will have access to the information contained in the patient's medical record, within limits of the law.
 - (10) Respectful, responsive care in the event of terminal illness. Care is directed to fostering the patient's comfort and dignity, providing appropriate treatment for primary and secondary symptoms that respond to treatment, as

desired by the patient or designated representative; aggressively managing pain by establishing a treatment plan and providing supportive care. The staff will respond to the patient and family's emotional, psychosocial, spiritual, and cultural concerns related to dying and expressions of grief. The staff will also demonstrate sensitivity in addressing issues such as tissue and organ donations.

(11) Expect reasonable safety insofar as the hospital practices and environment are concerned.; (12) Know the names of his/her caregivers. Staff must wear ID badges and should identify themselves. (13) Present grievances without fear of repercussion. (14) Timely and appropriate responses to inquiries or complaints. (15) Visit and communicate with others inside and outside the medical center. Restrictions will apply, if in the opinion of the professional staff, visitation and/or communication will be harmful to other patients, visitors, or the safe operation of the medical center. Restrictions will be evaluated for their therapeutic effectiveness, explained to the patient and family, and determined with their participation.

(a) Patients and/or designees who have a language barrier will be referred to the Medical Center Language Bank program (contact persons: EEO Officer and telephone operators) for assistance in language translation. In addition, Spanish language resources will be available in the medical center library. (b) For the hearing impaired, the Telecommunications Device for the Deaf (TDD) will be made available via the telephone operator. Closed-captioned videos and compatible televisions will be available in the medical center library. Patients will be referred to Audiology and Speech Pathology Department for additional assistance, such as sign language interpretation. (c) For the visually impaired, large print material, talking books, and information on Braille will be available in the medical center library

(16) Access the Ethics Advisory Committee to address ethical dilemmas related to their health care services. This also applies to family members or representatives of the patient. (17) Family participation in their health care. In addition, the patient may exclude any and all family members from participating in his/her care decisions. (18) To information about organ and tissue donation and may accept or decline the opportunity to become an organ or tissue donor. (19) Perform or refuse to perform tasks in or for the hospital in regard to a work therapy program.

b. Each resident/inpatient has the right to (1) Wear his or her own clothing, except where this conflicts with treatment policy; (2) Keep and use personal possessions, consistent with local ward management; (3) Regular and frequent exercise as well as to be outdoors at regular and frequent intervals. Facilities and equipment for such exercise shall be provided, consistent with local ward management.

c. Restrictions: Patients have the right to be free from physical restraint or seclusion except in situations in which there is a substantial risk of imminent harm to himself/herself or others and less restrictive means of preventing such harm have been determined to be inappropriate or insufficient.

d. Medication: Patients have a right to be free from unnecessary or excessive medication. Patients requiring emergency medication for control of behavior and deemed dangerous to themselves or to others, should be evaluated by a physician prior to the ordering of such medication. If this is impractical, a written order may be entered on the basis of telephone authority received from a physician. In such an event, the physician must countersign the written order within 24 hours of the ordering of the medication or, if the physician is serving as Medical Officer of the Day, by the end of his/her tour of duty. The attending physician shall review the drug regime of each patient under his or her care at least every 30 days, or more frequently if necessary. Medication shall not be used as punishment, for the convenience of the staff, or in quantities that interfere with the patient's treatment program.

4. Service Line Associate Chiefs of Staff/Administrators and Department Chairs/Assistant Administrators are responsible for ensuring their staff members are given a copy of the statement of rights and these rights are discussed with those employees by their immediate supervisors.

d. The Medical Center Director has overall responsibility for the administration of this policy

6. REFERENCES: a. Title 38, Code of Federal Regulations, Chapter 17, Section 17.34a, Patients' Right

SAMPLE MANAGEMENT OF PATIENT COMPLAINTS AND INQUIRIES POLICY

1. **PURPOSE**: To establish policy and procedures for the management of patient complaints and inquiries.

2. **POLICY**: It is the policy of this medical center to receive, act upon and respond to complaints and inquiries in a positive and timely manner. All responses shall substantively address the issue(s) of concern. Each patient or his/her representative has the right to present grievances on behalf of himself/herself or others to staff members, other Department of Veterans Affairs (DVA) officials, non-DVA government officials, members of Congress, or other persons, without fear of reprisal. Information gained through patient complaints and inquiries will be reviewed, evaluated and utilized by staff in quality and customer service improvement efforts.

3. **PROCEDURES**:

a. Informing Patients of the Complaint Process:

(1) Signs will be posted in patient waiting areas and lobbies, advising how to report a complaint.
(2) Information on how to resolve complaints will also be provided in brochures and booklets such as “Our Commitment to Your Health Care” (outpatient areas) and “Guide to Medical Center Services” (inpatient rooms).
b. Conflict Resolution: From time to time, conflicts will arise among those who participate in hospital and patient care decisions. Whether this conflict involves members of administration, medical staff, employees, or patient caregivers, and the patient (or the patient’s family/significant other), we will strive to resolve all conflicts fairly, objectively and at the level most directly involved with the conflict in a timely manner. In cases where mutual satisfaction cannot be achieved, it is the policy of the medical center to involve the Patient Advocate, Office of the Director; the appropriate Associate Chief of Staff and/or Administrator or designee(s); or the medical center Ethics Advisory Committee Chairperson to oversee the conflict. Other staff and second opinions will be sought as needed to pursue a mutually satisfactory resolution.

c. Patient Advocacy:

All staff will assist patients to the best of their ability and within the scope of their positions, to ensure patients’ concerns are addressed quickly and at the lowest possible organizational level. All staff will promote high quality health care through communication, consideration and courtesy. If staff members are unable to provide the requested assistance, referral will be made to an appropriate Department-level Patient Advocate. One or more staff from each Department will be designated as a Department-level Patient Advocate and, along with the Patient Advocates in the Director’s Office, will form a “Patient Advocacy Network” (see Patient Advocate Directory on the Phoenix Home Page). Each Patient Advocate will serve as a liaison between the patients and staff to ensure that patients receive the maximum benefits of their interaction with the medical center. Departments will provide back-up coverage during the absence of a Patient Advocate and will advise the Patient Advocacy Network Coordinator of changes in designations. Department-level Patient Advocates will be responsible for listening to concerns, facilitating resolution of issues and documenting the issue(s) and resolution. Resolution may involve reviewing files or records and discussing the matter with staff within or outside the Department to ensure seamless care. Department-level Patient Advocates will also be responsible for timely advisement to Department management of unusual circumstances and trends. Staff will assist, as appropriate, when called upon by a Department-level Patient Advocate (NOTE: The Administrative Officer of the Day (AOD) is the only designated Patient Advocate during irregular hours (evening/night tours of duty and weekends). Matters that cannot be resolved by the involved staff and cannot wait until regular business hours should be referred to the AOD.) Complex or “difficult” issues (i.e., allegations of abuse or malpractice, potential tort claims, or situations requiring coordination between two or more Departments) will be referred to the Patient Advocate, Office of the Director. Department-level Patient Advocates should accompany the patient at the initial referral, when possible. Concerns presented to the Director’s Office that have not been addressed by the Department may be referred back to the Department for resolution. A patient or his/her representative who wishes to write a letter regarding concerns, should address the letter to the Medical Center Director. Upon receipt of a written complaint or notice of a verbal complaint, including anonymous, obscene, and threatening communications, the Correspondence Control Officer, Office of the Director, will forward the letter to the appropriate Department for response. The Correspondence Control Officer will attach VAF 70-4583, Correspondence Control, to the correspondence indicating the suspense date and action required. The suspense date for answering complaints will be in accordance with VHA directives and based upon the judgment of the Correspondence Control Officer. When a person has been repeatedly and adequately furnished information he or she requested, and continues to make the same inquiry, the Director may authorize discontinuance of further responses.

d. Documentation of Complaints, Inquiries and Compliments:

(1) Department-level Patient Advocates will utilize the VISTA Patient Advocacy Tracking Program to document information relating to complaints, inquiries, and compliments received by the Department, including letters to which the Department has responded. The determination of which personal contacts should be documented in the tracking program is at the discretion of the Department; however, in order for collected data to be a true reflection of patient satisfaction, “selective” practices should be avoided. Documentation should be within 24 hours of the contact.
(2) Patients who request a copy of their “complaint” should be directed to the Release of Information Office (ROI), where a report of contact generated from the data entered into the VISTA Patient Advocacy Tracking Program, may be provided. The tracking program’s report of contact is NOT to be placed in the patient’s medical record and, therefore, is not to be used as a substitute for reports of contact which should be placed in the medical record. (A copy of the report of contact released through the ROI office will be placed in the patient’s administrative record.)
(3) Patient Advocates, Office of the Director, will review all data entered into the tracking program by

Department-level Patient Advocates, assign codes to categorize information, and close the reports of contact when resolved. (It is recognized that complaints may be deemed resolved despite the patient's dissatisfaction.)

e. Tracking, Trending and Reporting Compliments, Complaints and Inquiries:

(1) Patient Advocates, Office of the Director, will analyze, trend and report data regarding patient encounters. Unusual circumstances will immediately be reported to upper management. (2) Quarterly reports will be provided to upper management to identify areas of high and low patient satisfaction and opportunities for improvement. Reports will be provided by the first business day of the second month following the close of the quarter (February, May, August, November). Management will discuss quarterly reports with staff and document an action plan for improvement in staff minutes. (3) Feedback will be provided to patients, on at least an annual basis, in regard to areas of dissatisfaction and improvements made as a result of the dissatisfaction.

f. Meetings/Training:

(1) Members of the Patient Advocacy Network will meet quarterly for discussion and training regarding management of patient concerns. (2) Patient Advocates, Office of the Director, will attend Department staff meetings to discuss issues relating to customer service, i.e., patient concerns, methods for handling complaints, and ideas for improvements.

4. **RESPONSIBILITY:**

- a. Each medical center employee is responsible for knowing and respecting the rights of our patients and providing assistance in a compassionate, understanding and timely manner.
- b. Each Patient Advocate is responsible for being knowledgeable of policy memorandums and brochures regarding patients' rights and responsibilities and the management of patient complaints and inquiries. This includes appropriate and timely documentation of complaints and follow-up with the patient or other source of contact and reporting of events to management.
- c. Department Chairs/Assistant Administrators are responsible for developing a prompt and effective mechanism by which complaints/inquiries originating within their Department are resolved expeditiously and compassionately by involved staff and/or designated Department-level Patient Advocates. Department Chairs/Assistant Administrators are also responsible for informing staff of customer-generated feedback about patient satisfaction and for developing plans to improve quality of service and customer satisfaction.
- d. Service line ACOSs/Administrators are responsible for creating and supporting an environment which promotes high standards of customer service.
- e. The Secretary to the Director is designated as Correspondence Control Officer.
- f. The Patient Advocate (supervisor), Office of the Director, is designated as Patient Advocacy Network Coordinator
- g. The Director has oversight responsibility for the management of patient complaints and inquiries.

5. **REFERENCES:** M-2, Part I, Chapter 37; Joint Commission on Accreditation of Healthcare Organizations, current edition; M-1, Part I, Chapter 1, Section VI, paragraph 1.40; MP-1, Part I, Chapter 2.

Population Health

Since the late 1800's work has been taking place to make improvements in the quality of health care for individuals, families, and aggregates, including populations and communities. Important changes in health care have been taking place since the early 1990's, continuing with the reform due to the Affordable Care Act. The areas in health care that have posed the greatest problems for patients over the years have been access, quality, and cost. These problems are still present. Too many people either have no insurance or inadequate insurance, access to quality care is unevenly distributed across the country, and the cost of health care is still an issue.

Some of the key areas of emphasis in the current efforts to reform health care include preventing disease, coordinating care, and shifting care from the hospital to the home or community facilities where possible. Over the years, funding for public health has decreased while the needs for population based services have increased. The new emphasis on health care reform focuses on prevention, community-oriented care, continuity, and the important role of health care workers. There are some early indicators that health care reform will increase support for prevention. The government website [Http://www.healthcare.gov/learn/index/html](http://www.healthcare.gov/learn/index/html) provides easy to understand information about health care changes, specifically the sections "Health Finder" and "Let's Move."

A population or aggregate is a collection of individuals who have one or more personal or environmental characteristics in common. Members of a community who can be defined in terms of geography (e.g., a county, a group of counties, or a state) or in terms of a special interest or circumstance (e.g., children attending a particular school) can be seen as constituting a population. Often there are subpopulations within the larger population, for example, high-risk infants under the age of 1 year, unmarried pregnant adolescents, or individuals exposed to a particular event such as a chemical spill. In population focused practice, problems are defined by assessments or diagnoses and solutions or interventions such as policy development or providing a particular preventive service, and are provided for or with a defined population or subpopulation.

Epidemiology

Epidemiology can be defined as the study of factors that contribute to the incidence, distribution, and control of disease, defect, disability, and death. Historically epidemiology focused on understanding and control of epidemic diseases. Epidemiology now focuses on control of health problems and applies epidemiologic techniques to health problems, as well as communicable diseases. Theories regarding the cause of illness have evolved over time. During what is described as the religious era, disease was believed to be the result of divine intervention as punishment for misdeeds. Following this period, disease was believed to be caused by various physical forces such as harmful mists or miasmas. The bacteriologic era began with the discovery of specific organisms as the reason for specific diseases. From 1850 to 1880, disease was believed to be due to uncleanness. From 1880 to 1920 the emphasis on disease control was based on bacteriology. The health promotion phase occurred from 1920 to 1960, and even until the present, emphasis on health as a right has increased technology and accessibility. Because initial epidemiology focused on acute communicable disease, as the incidence of communicable disease declined, epidemiologists began to concentrate on chronic diseases. The ultimate concern for epidemiology is prevention of disease and maintenance of health.

Infection Control

Nosocomial infections contribute significantly to the morbidity and mortality of institutionalized patients. The probability and risks of serious infections are greater in areas where critically ill patients are subject to multiple invasive procedures and therapies. Nosocomial infection rates vary from 5% to 40% for inpatient hospital units. There is a direct correlation between infection and length of stay. Nosocomial infections increase morbidity and mortality. An infected surgical patient has an estimated 55% chance of survival. In multiple-trauma patients, 80% of late deaths are associated with infection. In the United States, 75,000 patients die each year as a result of septicemia. In addition, the costs of treating nosocomial infections are extremely high. Studies have found that critical care unit patients have disproportionately more nosocomial infections. The rate can be three times higher than that of general medical-surgical patients.

A **nosocomial infection** is an infection that occurs in an institutional setting such as a hospital. It is not present or incubating at the time of admission, except when related to a previous hospital admission. An infection that occurs 48 to 72 hours after admission is usually categorized as nosocomial.

Colonization is isolation of the same microorganism from two or more consecutive samples from the same site, in the absence of clinical signs of infection. It is primarily a microbiological observation.

Infection is a clinical diagnosis suggested by fever, chills, leukocytosis, acute adenopathy, myalgias, and local symptoms such as dysuria, cough, and pharyngitis.

Goals of an Infection Control Program

Goals of an infection control program include

1. Identifying trends in infection rates, sites, risk factors, patient outcomes, nosocomial pathogens, and antimicrobial resistance

2. Providing comparative data on nosocomial infections to be used to evaluate prevention and control efforts
3. Developing efficient and effective data collection and analysis methods of nosocomial infection control
4. Conducting collaborative research studies to describe the epidemiology of emerging infections and pathogens, assessing the importance of potential risk factors, and further characterizing mechanisms of antimicrobial resistance in nosocomial pathogens.

Surveillance

Surveillance has been advocated as an essential step for recognizing nosocomial infection problems and developing effective preventive measures. Its usefulness in helping to reduce nosocomial infections has been reported. However, there are methodological problems related to the identification of nosocomial infections and to data collection techniques that affect the reliability of data. These include wide observer variability in determining infections, lack of laboratory documentation of many infections, and lack of adherence to the surveillance protocol. Organization wide, **comprehensive or total surveillance** is no longer recommended or carried out by most organizations. In this type of surveillance, all nosocomial infections that occur in every area of the organization are reviewed.

Preferred methods of surveillance meet the goal of calculating infection rates that will identify potential infection problems in specific areas. Appropriate analyses should include collection of appropriate denominators and reports of sufficiently specific infection rates to pinpoint infection problems.

Priority-directed, targeted surveillance may be conducted for specific units, specific patient populations, or specific procedures. Unit specific surveillance might involve all patients in a surgical intensive care unit. Surveillance that is patient population specific might involve all patients who develop pneumonia while on a ventilator. A targeted patient outcome surveillance might be conducted when patients who receive enteral feedings suffer a higher incidence of diarrhea than expected, for example. Planning for targeted surveillance depends on the objections of the infection control program. **Problem oriented or outbreak response surveillance** is conducted to measure the occurrence of specific infection problems.

A method other than total organization surveillance is preferred because the overall infection rate is likely to be insensitive to important changes in the incidence of infections and patient risk, but it can be affected by changes unrelated to the quality of care. Such as rate is unable to account for factors that contribute to infections in patients, such as exposure to high risk procedures, and differences in surveillance methods and patient mix.

An infection surveillance system should include the following:

1. Criteria for defining nosocomial infections and for differentiating them from community acquired infections
2. Rationale for selecting a specific surveillance approach or a combination of approaches and the time frame for their use
3. Patient population studies
4. Data collection methodology employed
5. Quality improvement procedures to assure accuracy and completeness of care findings
6. Assignment of responsibility for data collection, evaluation, and follow up
7. Method for reporting and follow up
8. As required, the reporting of infections to public health authorities
9. Documentation of infections of epidemiologic significance among employees

Data collection on infected patients should be uniform. Summary or denominator data, which include number of patients exposed or number of patient days of exposure to selected risk factors are different. Calculation of site specific infection rates can be based on the appropriate denominator.

Denominators that may be used include number of patient days, admissions, discharges, discharges by diagnosis related group, number of patients, urinary catheter days, central line days, or ventilator days, as appropriate. Distribution of infections, as well as site specific rates for each service or unit and diagnosis groups may be calculated. Patient days are generally used. When admissions or discharges are used, every patient is assumed to be at equal risk of infection. With the use of patient days, a partial accounting is made for the influence of duration of exposure to certain important risk factors.

The number of infections identified will depend on the intensity of surveillance efforts, which include frequency and variety of sources used for case finding. This will require an adequate number of personnel who are trained, available for surveillance, and provided with required support. Culture reports are reviewed daily, with positive cultures reviewed for additional information. Post discharge surveillance is also usually in place to detect surgical wound infections. Benchmarking (comparing infection rates) provides clinical practitioners with valid epidemiological measures of the risks of infection in their patients and allows them to take action to reduce those risks and decrease infection rates. A comparison of infection rates within each department often has more impact than an overall hospital infection rate. The rates may need to be adjusted for patient risk in order to properly examine similar groups.

Risk Factors for Infection

It's important to assess the infection risk of the most severely ill patients, who are usually immunocompromised, when they are exposed to certain devices that increase the risk of infection, such as invasive lines or ventilators. Over 70% of multiple infections occur in intensive care units. Development of additional nosocomial infections can double the average length of stay. Patients with nosocomial infections should be considered at high risk to develop subsequent infections. If a patient has one infection, the chance of an additional one is 30%; if a patient has two infections, the chance of an additional infection is 40%, for three infections, the risk is 50%. More than half of all infections occur in patients with multiple infections. Factors that commonly predispose patients to colonization and subsequent infection include:

Age younger than 1 year or older than 70

Antineoplastic drugs

Antibiotics

Trauma

Diabetes mellitus, COPD, renal failure, hepatic failure, cancer, alcoholism, acute respiratory distress syndrome, malnutrition

Steroids

Major surgery

Underlying illnesses

The most accurate predictor of nosocomial infections is the compromise of the host defenses. Increasing severity of illness and subsequent intensified therapy correlate with increasing compromise of various host defenses. A severity of illness index can be used to help determine patient risk. Patients are assessed and assigned scores depending on the severity of illness.

There are two major sources for the organisms responsible for colonization and infection:

1. The patient's own microbial flora, which are found in the oral cavity, gastrointestinal tract, skin, and vagina, and
2. The patient's immediate environment (inanimate and animate surroundings).

Percentages of nosocomial infections reported to be caused by endogenous colonization range from 30% to 50%.

The inanimate environment is defined as all the patient's surroundings except for hospital staff and the patient's family. Objects that have direct access to blood must be sterile (surgical instruments, IV fluids, catheters, irrigation fluids, etc.). Objects that touch only mucous membranes must be free of vegetative bacteria, and items such as respiratory, bronchoscopy, and gastroscopy equipment require a high level of disinfection. Non-critical items, such as bedpans, beds, and blood pressure cuffs, require a low level of disinfection cleaning protocol. Fomites (particles found on surfaces around the bed)

contribute to infection to a negligible degree. Cleansing of surfaces around the bed once a day is sufficient. Hospital food can also be contaminated with large amounts of microorganisms, so feeding should be handled with aseptic technique. Epidemics of nosocomial infection have been associated with contaminated infusion fluids, contaminated medical equipment and products, and breaks in aseptic technique

Nurses, physicians, respiratory therapists, and other hospital staff members are considered the medium by which nosocomial bacteria may spread. Contamination transferred in this way is termed cross-infection. Hands play the main role in this transfer. Hand washing is the single most important procedure for preventing nosocomial infection. However, even with all these precautions, control of the patient's environment can prevent only up to 25% of all hospital infections. The incidence of secondary nosocomial infections can best be reduced by adequate staffing with personnel well trained in the basic principles of preventing cross-infection. The most important factors in preventing nosocomial infections are the use of standard precautions, strict aseptic technique, avoidance of known high risk practices, and an active infection control program.

Wearing gloves and gown for all patient contacts significantly reduced the risk of nosocomial infections in a group of high risk patients. However, successful control of infections is impossible unless health care workers comply with the precautions. To be effective, infection control precautions must be followed. Although hand washing has been shown to be an effective means of reducing the nosocomial spread of pathogens, it is not always followed. A decrease in compliance with infection control measures has been identified as the nurse to patient ratio decreased. Busy nurses assigned to multiple complex tasks are likely to forgo precautions more readily than less busy nurses. This effect of the nursing shortage could impact adversely on patient care.

In addition to high mortality and morbidity, the cost of treating nosocomial infections is high. A rational approach to decrease the cost would be preventive rather than therapeutic. Preserving host defenses may actually be a cost saving procedure if catheters and other invasive hardware are removed as early as indicated rather than left in place. The organization should ensure that staff members wash their hands after removing gloves or contacting blood or body fluids. Personal protective equipment must be available whenever blood or other infectious materials might reach an employee's work clothes, skin, eyes, mouth, or other mucous membranes. The creation of a healing environment will be aided by the development and implementation of practices, policies, and procedures that promote safety and decrease or eliminate risks for patients, personnel, visitors, and the public.

SAMPLE INFECTION CONTROL POLICY

1. **PURPOSE:** To establish policy and procedures regarding a multidisciplinary team to oversee the surveillance, prevention, and control of infections for all services and programs both inpatient and outpatient at this medical center, including specialized patient care treatment and diagnostic services.
2. **POLICY:** The Infection Control FLT will serve as the review authority regarding infection control practices and procedures, and will recommend appropriate action to the Executive Performance Improvement Council (EPIC) to ensure compliance with applicable survey and accrediting bodies, governmental regulations and guidelines and accepted standards of medical care. In urgent circumstances, where there is reason to consider there is a danger to any person, the FLT leader, or designee, will initiate appropriate action or control measures.
3. **SCOPE:** The scope of the Infection Control FLT is broad and involves activities at the direct patient care level to reduce the risks for nosocomial infections in patients. It also involves preventing and reducing risks related to person-to-person transmission of all infectious diseases among patients, employees, medical staff members, contract service workers, volunteers, students, and visitors. The FLT coordinates all activities related to the surveillance, prevention, and control of nosocomial infections. The FLT also links with support systems to reduce the risks of infection from the environment, including food and water sources.
4. **RESPONSIBILITIES:** Approval of the type and scope of surveillance activities, that include:
 - a. Approving definitions and criteria for identifying nosocomial infections
 - b. Reviewing microbiological reports.
 - c. Reviewing patient infections to determine whether an infection is nosocomial, and focusing on those that present the potential for prevention or intervention to reduce the risk of future occurrence.

- d. Review that is directed to surveillance data looking for:
 - (1) Epidemics;
 - (2) Clusters of infections;
 - (3) Infections due to unusual pathogens;
 - (4) Trends of nosocomial infections; and
 - (5) Continuous performance improvement of key processes falling under this function.
 - e. Direct prevalence incidence studies, process improvement or task teams, as appropriate, to prevent or control infection based on evaluation of surveillance data or other prioritized means.
 - f. Reviewing routine or special collection of other data, as recommended.
 - g. Directing the sampling of personnel or the environment for infective agents in accordance with applicable law or regulation.
 - h. Reviewing and approving all policies and procedures related to infection surveillance, prevention, and control of infection.
 - i. Providing a summary report of the FLT activities quarterly as presented to the EPIC to include:
 - (1) Surveillance, prevention and control of infection data, particularly as it relates to evidence of impact on patient outcomes, as measured by infection rates or other objective methods.
 - (2) Surveillance methods currently in use.
 - (3) Special studies, when conducted.
 - (4) The outcome of regular and special surveillance activities and actions taken by the FLT, which are documented in meeting minutes.
 - (5) Any formal outside consultation obtained.
 - (6) Educational activities.
 - (7) Any significant changes in policy and/or procedure, or infection control practice.
 - (8) Studies or organisms of epidemiological significance (for example, trends in antibiotic resistance patterns).
 - (9) A summary of infections of epidemiological significance among employees.
5. The authority of the FLT or its designee to institute any surveillance, prevention, and control of infection measures or studies when there is reason to believe that any patient or personnel may be in danger is defined in writing and approved by the Medical Center Director and medical staff every two years.

6. **MEMBERSHIP:**

- FLT Leader: Appointed Chairperson (CS/16)\
- Members: Infection Control Coordinators (11Q)
 Infectious Disease Physician (CS/111)
 Employee Health Representative (ACS/11C6)
 Environmental Management Representative (RMS/137)
 Surgical Department Representative (CS/112)
 Ambulatory Care Representative (ACS)
 Inpatient Care Representative (ICS)
- Ad Hoc Members:
 Industrial Hygienist (RMS/138)
 SPD Representative (FMS/90E)
 Microbiology Representative (CS113)
 Risk Management Representative (11Q)
 Nutrition and Food Service Representative (ICS/120)
 Pharmacy Representative (CS/119)

Any department, section, or program can submit a proposal for new improvement projects appropriate to the surveillance, prevention and control of infection function as outlined in Policy Memorandum 00-3, Performance Improvement.

7. **MEETINGS:** The FLT will meet at least bimonthly and at the call of the leader as necessary. A quorum must be present to formally conduct business. A quorum is considered to be 50% of the voting members of the FLT.
8. **FLT MINUTES:** Minutes of the Infection Control FLT will be maintained and distributed to the members before the next meeting.
9. **REFERENCES:**
 - a. Joint Commission on Accreditation of Healthcare Organizations: Standards, surveillance, prevention, and control of infection - Accreditation Manual for Hospitals, Chicago

- b. APIC: Infection Control and Epidemiology - Principals and Practice, Mosby
- c. Infection Control Committee Issues, Infection Control Today
- 10. **RESCISSION:** Policy Memorandum No. CS/111-2
- 11. **ATTACHMENTS:** None
- 12. **EXPIRATION DATE:**

SAMPLE STANDARD PRECAUTIONS - EXPOSURE CONTROL PROGRAM

1. **PURPOSE:** To establish policy and procedures to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals. Standard Precautions pertain to all blood and body fluids whether or not they contain visible blood and to all patients receiving care in the hospital. Transmission-based Precautions are designed for patients with diagnosed or suspected infections with a transmissible or epidemiologically important pathogen. There are three (3) types of Transmission-based precautions: Airborne, Droplet, and Contact. These may be combined for diseases that have multiple routes of transmission. Transmission-based Precautions are used in addition to Standard Precautions.

2. **POLICY:**

- a. Standard Precautions will be followed with every patient admitted to the Phoenix VAMC.
- b. All Department Chairs/Assistant Administrators shall review, annually, a list of all job classification procedures and tasks whereby an employee could be "reasonably anticipated," as a result of their job duties, to face contact with blood and other potentially infectious materials. Job classifications, procedures and tasks are as follows:
 - (1) Job classifications, procedures and tasks in which all employees have occupational exposures.
 - (2) Job classifications in which some employees have occupational exposures.
 - (3) Job classifications in which employees have no occupational exposure.

3. **PROCEDURES:**

a. Transmission Based Precautions are:

- (1) Airborne Precautions are used for diseases caused by small (5 microns or less) organisms that are carried by air currents and inhaled into the alveolar sacs. Airborne Precautions are used for patients with suspected Tuberculosis and Varicella.
- (2) Droplet Precautions are used for diseases that are transmitted by droplets produced from coughing.
- (3) Contact Precautions are used to reduce the risk of transmission of epidemiologically important microorganisms by direct and indirect contact.

b. **Hand Washing:** Employees must wash hands and any other parts of their body with soap and water, or flush mucous membranes with water immediately as soon as feasible following contact of such body area with blood or other potentially infectious material. In addition, hands must be washed immediately or as soon as feasible after removal of gloves or other personal protective equipment.

c. **Needle/Sharps Containers/Sharps:**

- (1) Labeled, puncture resistant, leak-proof containers shall be mounted and available for needle and sharp disposal in all patient care rooms, medication rooms, laboratories, examination rooms, or other high usage areas.
- (2) Needle and sharp containers shall be maintained upright and shall not be overfilled, creating a potential hazard for other personnel. Environmental Management personnel will be responsible for replacing needle and sharp containers when they are filled to the manufacturer's stated limits.
- (3) Used needles will not be recapped, cut, bent, broken, or sheared and will be placed promptly in labeled, puncture resistant, leak-proof containers.
- (4) Immediately, or as soon as possible after use, disposable sharps will be placed in labeled puncture resistant, leak-proof container.

(5) Immediately, or as soon as possible after use, reusable sharps shall be placed in appropriate containers until properly processed. The labeled containers shall be puncture resistant and leak-proof. Such sharps shall not be stored or processed in a manner that requires employees to place their hands in the container.

d. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. An acceptable exception is drinking from a can or a cup with a lid. Open cups or glasses are prohibited.

e. Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on counter tops or bench tops where blood or other potentially infectious materials are present or routinely handled.

f. All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, splattering, and generation of droplets of these substances.

g. Mouth pipetting/suctioning of blood or other potentially infectious material is prohibited.

h. Transportation of Specimens:

(1) All specimens of blood or other potentially infectious materials shall be transported in a well-constructed container with a secure lid, placed in a ziplock bag, with the requisition outside of the bag, before transporting. Color-coding or biohazards labeling of specimens is not necessary intra-hospital.

(2) Specimens transported/shipped to laboratories or other facilities, outside the VA, shall be placed in a closed container(s) which prevents leakage during transport/shipping and shall be labeled with a biohazardous label.

(3) All specimens of blood or other potentially infectious materials shall be placed in containers which prevent leakage during collection, handling, processing and storage. Containers for storage shall be closed prior to storage.

(4) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, and transport/shipping. If the specimen could puncture the primary container, then the primary container shall be placed within a secondary container which is puncture resistant.

4. EQUIPMENT:

a. Equipment that may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary by the requesting department.

b. Equipment that cannot be decontaminated and must be shipped back to the manufacturer or servicing representative, shall be labeled as potentially contaminated with a biohazardous label and shall state which portions of the equipment remain contaminated. This information shall be conveyed to all affected employees, the servicing representative or the manufacturer, as appropriate, prior to handling, shipping or servicing so that appropriate precautions may be taken.

5. PPE (PERSONAL PROTECTIVE EQUIPMENT):

a. All employees with exposure to blood or other potentially infectious fluids shall be provided appropriate personal protective equipment.

b. All PPEs shall be provided to employees at no cost and shall be readily available when needed.

c. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's clothing, skin, eyes, mouth or other mucous membranes under normal conditions of use and for the duration of time which the PPE will be used.

d. All PPE shall be removed prior to leaving the work area.

e. If blood or other potentially infectious material penetrates a garment, it shall be removed immediately or as soon as feasible.

f. When PPE is removed, it shall be placed in an appropriate designated area or container for storage, washing, decontamination or disposal.

g. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood or other potentially infectious materials, or contact with mucous membranes or non-intact skin. Gloves are worn to reduce the likelihood of transmission of organisms from the hands of personnel to the patient or environment. Hands will be washed after glove removal.

(1) Gloves must be worn in the following circumstances:

(a) If the employee has cuts, abraded skin, chapped hands, or dermatitis.

b) During procedures where hands may be potentially contaminated with blood or other potentially infectious materials.

(c) During instrumental examination of oropharynx, gastrointestinal tract or genitourinary tract.

(d) When examining abraded or non-intact skin, or a patient with active bleeding.

(e) During an invasive procedure.

(f) During all cleaning of blood or potentially infectious materials, and during decontaminating procedures.

(g) During the processing of blood or potentially infectious specimens.

(h) While hanging units of blood or blood products.

(i) Performing or assisting with postmortem procedures.

(2) Gloves of appropriate material will be provided for procedures performed, and gloves shall be of appropriate size for health-care workers.

(3) Surgical or examination gloves shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured or when their ability to function as a barrier is compromised.

- (4) Employees will not wash or disinfect surgical or examination gloves for reuse.
- (5) General purpose utility (rubber) gloves, worn by Engineering, Environmental Management, Laundry, or other non-medical personnel may be decontaminated and reused after they have been properly disinfected.
- (6) Gloves should not be used if they are peeling, cracked, discolored, or if they have punctures, tears, or other evidence of deterioration or when their ability to function as a barrier is compromised.
- (7) If the Employee Health Physician determines that an employee may have a latex allergy, then hypoallergenic gloves, glove liners, powderless gloves, or other similar alternative will be provided by SPD.

h. Masks, Eye Protection, and Face Shields:

- (1) Masks in combination with goggles, glasses, shall be worn in situations in which splattering with blood or other potentially infectious materials is possible (e.g., during surgical or dental procedures, suctioning, intubation, bronchoscopy, endoscopy, dialysis, or contact with droplets of blood or other potentially infectious materials).
- (2) Masks that cover the nose and mouth, and goggles are worn by hospital personnel during procedures that may cause splattering of body fluids on to mucous membranes.
- (3) Masks shall be worn by persons having direct contact with a coughing or intubated patient and in situations in which splashes or aerosolization of blood and other potentially infectious materials is possible.

i. Aprons/Gowns:

- (1) Aprons or gowns shall be worn if skin or clothing may be splashed, sprayed splattered with blood or other potentially infectious materials.
- (2) Aprons shall be made of fluid-proof or fluid-resistant material.
- (3) Gowns will be worn by personnel during the care of patients infected with epidemiologically important microorganisms to reduce the possibility of pathogen transmission. Gowns worn for this purpose are to be removed before leaving the patient's room.

j. Surgical Caps/Hoods and Shoe Covers/Boots/Beard Covers: Surgical caps/hoods and shoe covers/boots shall be worn in instances when gross contamination can be reasonably anticipated (e.g., autopsies, orthopedic surgery).

k. Resuscitation Equipment:

- (1) Resuscitation bags and mouthpieces for patient resuscitation (CPR) shall be made available for use.
- (2) The equipment should be located on or in the following:
 - (a) Code carts.
 - (b) Life Support rooms.
 - (c) Special care units (MICU-SICU-PACU).
 - (d) Operating room suites as designated by OR Supervisor

6. HOUSEKEEPING PROCEDURES:

- a. During departmental orientation and on an annual basis, Environmental Management personnel will be instructed in precautions to be taken for cleaning blood and other potentially infectious materials.
- b. Personal protective equipment as described under the VA PPE guide (VA National Engineering Service Center, St. Louis, MO) will be provided for Environmental Management Department personnel.
- c. An EPA (Environmental Protection Agency) registered tuberculocidal disinfectant/detergent will be used to decontaminate spills of blood or other potentially infectious materials.
- d. Environmental Management Department personnel will follow the clean up procedures set forth in Policy Memorandum No. RMS/137-13, Hazardous Spill Response and Cleanup.
- e. The schedule for cleaning and method of decontamination shall be a written part of the Environmental Management Infection Control Policy for those surfaces maintained by Environmental Management Department.
- f. Each individual Department will develop a schedule for cleaning and method of decontamination of work surfaces and counters that are likely to become contaminated with blood or other potentially infectious materials as a result of routine work performed by employees of the Department. Such schedule and methodology shall be a written part of the Departments' Infection Control Policy.

7. SIGNS/LABELS:

- a. Red-colored plastic bags indicate regulated medical waste that is also known as "contaminated" or "infectious" waste. Red-colored plastic bags do not require signs, labels, or biohazard symbols to further identify the contents.
- b. Waste containers that are lined with red-colored plastic bags shall have red-painted tops, or be painted fully red if they have no tops, to signify that the containers are for regulated medical waste.
- c. Waste collection carts utilized to collect and transport red-bagged regulated medical waste shall be equipped with red colored signs marked "Regulated Medical Waste" and have the biohazard symbol on them.

- d. Signs/Tags are not used on containers used to store, transport or ship specimens intra-hospital, as employees are instructed that blood or other potentially infectious materials from all patients are considered hazardous and must be handled using Standard/Universal Precautions.
- e. Biohazard symbols will be affixed to all containers of regulated medical waste and to freezers or refrigerators used for the storage of blood, specimens, or other potentially infectious materials.

8. **WASTE DISPOSAL:**

- a. Any disposable items that are blood soaked or substantively contaminated with blood or other potentially infectious material shall be red bagged and ultimately disposed of by incineration. The determination as to whether the item is blood soaked or substantively contaminated should include consideration as to whether blood or other potentially infectious materials (OPIM) are:
 - (1) Liquid or semiliquid blood or other potentially infectious materials;
 - (2) Items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semiliquid state if compressed; and
 - (3) Items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling.
- b. All red-bagged trash shall be carefully handled; protective apparel such as gloves, or cover-ups should be worn if the outside of the bag appears contaminated with blood or other potentially infectious materials.
- c. Receptacles that are used to contain regulated medical waste shall be constructed in such a way as to prevent leakage of fluids during handling, storage, transport and shipping and shall be closable.
- d. Broken glassware that may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means and placed in a receptacle marked "For Glass Only."
- e. All sweeping shall be performed, and all solid or liquid wastes, refuse and garbage shall be removed, in such a manner as to avoid creating a menace to health and as often as necessary or appropriate to maintain the place of employment in a sanitary condition.
- f. The outside compound, where red-bagged trash may be stored, must be kept locked, unless under direct supervision.
- g. Needle and sharp containers will be removed and replaced by Environmental Management personnel when filled to the manufacture's fill line.
- h. Contaminated materials used in laboratory tests shall be decontaminated before reprocessing or be bagged and disposed of in accordance with Laboratory Infection Control Policy.
- i. If the outside of a regulated medical waste bag becomes contaminated, it shall be placed in a second container that is constructed to contain all contents, prevent leakage of fluids, and capable of being permanently sealed.

9. **SOILED LINEN:**

- a. All soiled linen shall be placed in a material bag that prevents leakage or soak-through from the bag, and will be handled utilizing Standard/Universal Precautions.
- b. All linen shall be bagged at the location where it was used. It shall not be sorted or rinsed in patient care areas.
- c. Laundry workers assigned to sorting or washing of soiled linen shall be instructed in Standard Precautions/Exposure Control Program during orientation and on an annual basis.
- d. Protective clothing, gloves and appropriate masks shall be worn when sorting soiled laundry.
- e. Clean linen will be stored in an area separate from soiled linen. Clean linen on carts will be covered during transport and distribution.

10. **REUSABLE EQUIPMENT:**

- a. Standard sterilization and disinfection procedures recommended for Hepatitis B in healthcare settings are adequate to sterilize or disinfect instruments, devices or other items contaminated with blood or other potentially infectious materials. No special precautions are required for dishes, glasses, cups, or eating utensils. Reusable dishes and utensils can be used for patients in isolation.

11. **EMPLOYEE HEALTH SECTION:**

- a. Employees shall be instructed by their supervisor, to report blood or other potentially infectious material exposures as soon as possible following the incident. CA-1 will be initiated by employee, completed and signed by the supervisor and brought to the Employee Health Section or the Life Support when the Employee Health Section is closed.
- b. The following procedure shall be instituted if an employee has a specific eye, mouth, or other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials.

First, the route(s) of exposure circumstances under which the incident occurred will be documented and the employee will be asked for consent for base-line studies; secondly, the Employee Health Physician or his designee shall inform the source-patient's physician of the incident.

This physician shall inform the source-patient of the incident and obtain consent for HIV, HCV, or HBV testing.

c. If consent is obtained, the Employee Health Practitioner shall inform the Employee Health Clerk, who will institute confidentiality patient protocol procedure.

d. If the patient refuses, or the test is positive for HIV, the employee shall be informed of applicable laws and regulations regarding disclosure of the identification or infectious status of the source-patient. He/she will be placed on HIV protocol (e.g., base-line HIV test as soon as possible, and advised to report and seek medical evaluation of any acute febrile illness that occurs within 12 weeks after exposure). HIV seronegative employees shall be retested at 6 weeks, 12 weeks, and 6 months. An employee whose test is positive then becomes a Workers' Compensation claimant.

The employee shall be counseled and treated by the Employee Health Physician or referred to an appropriate physician

e. Follow-up procedures shall be taken for health care workers exposed or potentially exposed to HBV.

The type of procedure depends on the immunization status of the worker (i.e., whether HBV vaccination has been received and antibody response is adequate) and the HBV serologic status of the source patient

f. Hepatitis B vaccine will be offered at no cost to all employees, within 10 days of initial assignments who could be reasonably anticipated, as a result of their job duties, to have the potential for contact with blood or other potentially infectious materials

g. Employees that decline to accept the Hepatitis B Vaccine offer will sign a declination document but will have the opportunity to receive the vaccine at a later time, if they so choose.

h. Employee Health shall educate all pregnant employees regarding the dangers of HIV and Hepatitis B to the fetus. Employee exposure records shall be maintained for the duration of employment plus 30 years. These records will remain confidential and shall be available to employees on request.

2. TRAINING AND EDUCATION OF EMPLOYEES

a. All new employees shall be inserviced on Standard Precautions/Exposure Control Program during orientation

b. Training Topics: The topics covered in the training program include, but are not limited to, the following

(1) The Bloodborne Pathogens Standard(

2) The epidemiology and symptoms of bloodborne diseases as well as the modes of transmission

(3) The facility's Exposure Control Plan (and where the books are located).

(4) Appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.

(5) A review of the use and limitations of methods that will prevent or reduce exposure, including: engineering controls, work practice (administrative) controls and personal protective equipment.

(6) Selection and use of personal protective equipment including: types available, proper use, location within the facility, removal, handling, decontamination, and disposal.

(7) Visual warnings of biohazards within our facility including labels, signs and "color-coded" containers.

(8) Information on the Hepatitis B Vaccine, including: efficacy, safety, method of administration, benefits of vaccination and our facility's free vaccination program.

(9) Actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.

(10) The procedures to follow if an exposure incident occurs, including incident reporting.

(11) Information on the post-exposure, evaluation and follow-up including medical consultation that the facility will provide. Specific inservice training for the following areas will be conducted, as soon as possible after hire, and on an annual basis.(1) Nursing. (2) Laboratory. (3) Environmental Management. (4) Laundry.

d. All employees shall be inserviced annually regarding Standard Precautions and the Exposure Control Plan.

e. Each Department Chair/Assistant Administrator will designate specific trainer(s) for their Department. These trainers shall meet the following requirements:

(1) Attend a training session given by Infection Control.

(2) Demonstrate an understanding of Exposure Control Program.

(3) Ensure training of assigned personnel at least on an annual basis.

(4) Assist managers in the maintenance of training records.

f. Employee training records must be kept for a minimum of 3 years.

13. MONITORING OF STANDARD PRECAUTIONS:

a. Department Chairs/Assistant Administrators/supervisors or their designees will be responsible for the monitoring of Standard Precautions and the Exposure Control Plan.

b. Employees not following Standard Precautions and the Exposure Control Plan will be in violation of hospital policy and will be disciplined by their responsible supervisor.

14. **REFERENCES:**

a. OSHA, 29 CFR, Part 1910.1030, Bloodborne Pathogens Standard

b. APIC. Infection Control and Applied Epidemiology, Principles and Practice. Mosby, St Louis, MO. Garner, S. et al. (1996). HICPAC Guidelines for Isolation Precautions in Hospitals. Infection Control and Hospital Epidemiology; 17-53-80.

d. Jennings, J. and Manian, F. APIC Handbook of Infection Control, 2nd Edition APIC Publishing, Washington, D.C.

15. **RESCISSION:** Policy Memorandum No. 00-30.

16. **ATTACHMENTS:** Appendix A - Type and Duration of Precautions Needed for Selected Infections and Conditions.

17. **EXPIRATION DATE:**

SAMPLE TUBERCULOSIS CONTROL PROGRAM

1. **PURPOSE:** To establish a comprehensive policy and procedures for an effective tuberculosis infection control program for the prevention, detection, surveillance, and control of tuberculosis infection among patients, volunteers, and staff at the Phoenix VA Medical Center.

2. **POLICY:** The Phoenix VAMC provides a safe environment for tuberculosis care in accordance with CDC (Centers for Disease Control) and OSHA (Occupational Safety and Health Administration) Standards. The Tuberculosis Control Program applies to all employees, volunteers, visitors, students and patients. It is intended to prevent the transmission of Mycobacterium tuberculosis from infected individuals to susceptible hosts. All employees, volunteers, students, patients, and visitors must adhere to this plan.

3. **DEFINITIONS:** The following definitions are provided by the CDC:

a. "Acid-Fast Bacilli" (AFB) means bacteria that retain certain dyes even when washed with an acid solution. Most acid-fast organisms are mycobacteria. When seen on a strained smear of sputum or other clinical specimen, a diagnosis of TB should be considered; however, the diagnosis is not confirmed until a culture is grown and identified as M. tuberculosis.

b. "Exposure" means the condition of being subjected to something such as infectious agents, which may have a harmful effect. A person exposed to TB does not necessarily become infectious (see "Transmission").

c. "High-Efficiency Particulate Air Filter" means a specialized filter that is capable of removing 99.97% of particulate matter 0.3 microns in diameter or larger.

d. "Infectious" means capable of causing infection. In TB, a person is infectious only if he/she has clinically active TB and is aerosolizing organisms. TB patients whose sputum is AFB smear positive are often infectious.

e. "Transmission" is the spread of an infectious agent like M. tuberculosis from one individual to another. The duration and intensity of exposure to TB is directly related to the likelihood that transmission will occur and a person will become infected (see "Exposure").

f. "Tuberculin Skin Test" is a method to determine whether a person is infected with M. tuberculosis. A small dose of the antigen from M. tuberculosis is injected just beneath the surface of the skin and the area is examined 48-72 hours after the inoculation. A positive reaction is measured according to the size of the induration, not erythema. The classification for positive reactions depends on the patient's medical history and various risk factors.

g. Active "tuberculosis (TB)" means a clinically apparent active disease process caused by M. tuberculosis complex (usually M. tuberculosis or rarely, M. bovis or M. africanum).

h. "Tuberculosis Infection" means a condition in which living tubercle bacilli are present in the body, without producing clinically active disease. Although the infected individual has a positive tuberculin reaction, he/she has no symptoms related to the infection and is not infectious. The infected individual remains at lifelong risk of developing disease unless preventive therapy is given (at the appropriate time).

4. **PROCEDURES:**

a. **Risk Assessment, Tuberculosis Plan and Periodic Reassessment:** The purpose of the risk assessment is to evaluate the risk of TB transmission in each area and occupational group in the VAMC so that appropriate infection control interventions can be developed based on actual risk. The Phoenix VAMC has been classified as a low risk facility based on the number of Tuberculosis cases diagnosed and treated in the medical center and clinics.

- (1) The Infection Control Coordinators have the responsibility for the completion and review of the TB risk assessment. Employee Health assists the Infection Control Coordinators in the risk assessment.
 - (2) See Appendix A, Risk Assessment, which describes the procedures for performing the assessment in the VAMC.
 - b. Identification, Evaluation, Management and Treatment of Patients Who May Have Infectious TB:
 - (1) Early detection of potentially infectious TB patients (Identification): See Appendix B describes the Identification, Evaluation, Isolation and Treatment of Patients Who May Have Infectious TB.
 - (2) Evaluation procedures and isolation for persons with infectious TB are provided by the VAMC. Appendix B describes the evaluation procedures.
 - (3) Treatment for infectious TB is provided by the VAMC in accordance with the recommendations of the Arizona Department of Health Services and the CDC.
 - (4) Discharge Planning is provided by the VAMC for patients with infectious TB
 - c. Infection Control Practices:
 - (1) Patients with suspected or known infectious TB will be placed on Airborne Precautions.
 - (2) Ventilation requirements will be activated to prevent the aerosolization of droplet nuclei.
 - (3) Appendix C describes the infection control practices used at the VAMC.
 - d. Healthcare Worker Education:
 - (1) Employees will receive annual education and training from qualified instructors regarding tuberculosis.
 - (2) Appendix D describes the content of the education program.
 - e. Employee Health
 - (1) Health care worker counseling, screening and evaluation are provided by Employee Health.
 - (2) Appendix E describes employee health procedures.
 - f. Contact Investigation:
 - (1) The VAMC provides practices to be initiated when there is a possible infectious TB exposure.
 - (2) Appendix F describes the procedures to be initiated following an exposure to infectious TB.
 - g. Consideration for Special Areas:
 - (1) Several areas of the VAMC are required to provide care for the patient with infectious TB.
 - (2) Appendix G describes the procedures to be followed during care of the patient with suspected or confirmed infectious TB.
 - h. Program Evaluation:
 - (1) The effectiveness of the Tuberculosis Exposure Control Plan will be evaluated at least annually by the Infection Control Function Lead Team (FLT) and revised/modified as necessary.
 - (2) The program evaluation will include a review of information from Employee Health on PPD conversion within the VAMC by department and category of workers and a review of the occupational risk.
- 5. RESPONSIBILITIES:**
- a. The Infection Control FLT has overall responsibility for the Tuberculosis Control Program.
 - b. The Medical Center Director has overall responsibility for implementing this policy
 - c. The triad (Medical Center Leaders) is responsible for creating a safe environment and climate for patients, volunteers, students, visitors, and employees.
 - d. Service Line ACOSs/Administrators and Department Chairs/Assistant Administrators and other leaders will support a commitment to a safe environment for all occupants of the medical center and will ensure employee compliance in the utilization of practice to prevent the transmission of tuberculosis in the medical center.
 - e. Individual employees are responsible for:
 - (1) Utilizing administrative measures intended to reduce the risk of exposing uninfected persons to persons who have infectious TB;
 - (2) Using engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei; and
 - (3) Using personal respiratory protective equipment in situations in which the risk of infection with M. tuberculosis may be relatively high. Each employee is required to report to Employee Health, Room 3141, when notified for annual PPD (Purified Protein Derivative) testing and to wear proper protective gear in airborne precautions areas.
 - f. The Pathology and Laboratory Medicine Department is responsible for reporting sputum smear results to the Infection Control Coordinators.
 - g. The Infection Control Coordinators are responsible for conducting a risk assessment to evaluate the risk for transmission of M. tuberculosis in all areas of the medical center; for developing a written TB infection control program based on the risk assessment to evaluate the effectiveness of the TB infection control program.
 - h. Employee Health will provide PPD skin testing for employees and volunteers, track all PPD

conversions, and report this information to the Infection Control FLT.

i. The Industrial Hygienist will coordinate the TB Respirator Program, Policy Memorandum No. RMS/138-48.

6. **RECORD KEEPING:**

a. Employee Health will maintain records of skin testing results, medical evaluation, and treatment for the duration of employment plus 30 years.

All training session records, whether computerized or hard copy, will be maintained for three years from the date on which the training occurred

c. A tuberculosis infection (positive skin test conversion) and TB disease are recorded on the OSHA Accident/Injury Log

7. **REFERENCES:**

a. Center for Disease Control, Guidelines for Preventing the Transmission of Mycobacterium tuberculosis on Health Care Facilities (MMWR Vol. 43, NORR-13).

b. Center for Disease Control, Core Curriculum on Tuberculosis.

c. Control of Communicable Disease Manual, American Public Health Association,

EXPIRATION DATE:

SAMPLE RISK ASSESSMENT

A risk assessment will be conducted at least annually and at an interval indicated by the most recent risk assessment and will include the following:

a. An annual review of the community infectious TB profile (obtain from the Maricopa County TB Control Program);

b. A continual review of the number of infectious TB patients treated in each area of the facility (laboratory and discharge diagnosis based);

c. A continual review of the drug susceptibility patterns of the TB isolates of patients who were treated at the VAMC;

d. A review of the TB patient medical records;

e. Frequency is based on the previous risk assessment and follows the CDC Guidelines:

Minimal Risk - Not Applicable Very Low Risk – Optional Low Risk - Every 12 months Intermediate Risk - Every 12 months High Risk - Every 6 months

f. An analysis of PPD tuberculin skin test results of Health Care Workers (HCW) by area or by occupational group for HCWs not assigned to a specific area. Frequency is based on the results of the previous risk assessment.

Minimal Risk – Baseline Very Low Risk - Baseline and exposure follow-up Low Risk - Baseline, exposure follow-up, and high risk groups every 12 months Intermediate Risk - Baseline, exposure follow-up, and every 12 months High Risk - Baseline, exposure follow-up, and every 6 months

g. Observational review of TB infection control practices. Frequency is based on the results of the previous risk assessment. Minimal Risk - Not Applicable Very Low Risk – Optional Low Risk - Every 12 months Intermediate Risk - Every 12 months High Risk - Every 6 months

h. A review of current engineering controls. Frequency is based on the results of the previous risk assessment. Minimal Risk – Optional Very Low Risk – Optional Low Risk - Every 12 months Intermediate Risk - Every 12 months High Risk - Every 6 months

i. The results of the risk assessments are communicated to the Infection Control FLT, Patient/Employee Safety Subcommittee, Employee Health, and the Safety Management Committee.

j. The risk assessment from the VAMC includes the following information:

(1) **Minimal Risk:**

(a) No patients with infectious TB have been admitted to inpatient or outpatient areas in the previous year; and

(b) No infectious TB cases reported in the community or county in the previous year.

(2) **Very Low Risk:**

(a) No patients with infectious TB have been admitted to the inpatient area in the previous year but patients with infectious TB may have received initial and Diagnostic assessment or outpatient management in the previous year; and

(b) Patients with infectious TB who needed inpatient care were promptly referred to another inpatient facility.

(3) **Low Risk:**

(a) The current PPD test conversion rate is not greater than in areas or groups without occupational exposure to TB patients or than previous rate in the same area or group; or

- (b) There are no clusters (2 or more) PPD test conversions; or
- (c) There is no evidence of person to person transmission of infectious TB; or
- (d) There are less than six (6) TB patients examined or treated per year
- (4) Intermediate Risk:
 - (a) The current PPD test conversion rate is not greater than in areas or groups without occupation exposure to TB patients or than the previous rate in the same area or group;
 - (b) There are no clusters (2 or more) PPD conversions;
 - (c) There is no evidence of person to person transmission of infectious TB; or
 - (d) There are six (6) or more TB patients examined or treated per year. (Even if there is no evidence of Mycobacterium tuberculosis transmission, areas or groups encountering six or more TB patients per year still have a potential for transmission and should be classified as “intermediate risk.”)
- (5) High Risk:
 - (a) The PPD skin test conversion rate is significantly greater than areas without occupational exposure to TB patients or than previous rates in the same area or group;
 - (b) There is a cluster of PPD skin test conversions and the epidemiologic evaluation suggests nosocomial transmission of TB; or
 - (c) There is evidence of person to person transmission of M. tuberculosis.

**SAMPLE DENTIFICATION, EVALUATION, ISOLATION AND TREATMENT
OF PATIENTS WHO MAY HAVE INFECTIOUS TB**

1. IDENTIFICATION:

a. Early identification of patients with possible infectious TB:

- (1) Triage of patients in the outpatient setting will include efforts to quickly detect patients with suspected or confirmed infectious TB.
- (2) Health Care Workers (HCWs) who are the first point of contact serving patients at risk for infectious TB will ask appropriate questions to help them to recognize patients suggestive of infection with signs and symptoms of infectious TB.
- (3) Patients with signs or symptoms of infectious TB will be evaluated promptly to minimize the time spent in general waiting areas.

b. All patient waiting areas should be supplied with waste receptacles.

- (1) Instruct patients who are coughing or sneezing to cover both mouth and nose with tissues to contain secretions.
- (2) Provide a surgical mask to those patients who are unable or unwilling to use tissues to contain secretions. Instruct the patient how to put on the surgical mask. Instruct the patient to keep the surgical mask on while in the facility.

2. EVALUATION: Patients who have infectious TB will have the following precautions instituted while the diagnostic evaluation is being conducted:

- a. A surgical mask will be immediately placed on the patient;
- b. The patient will be instructed to keep the mask on while in the facility unless in a negative pressure room;
- c. The patient will be given tissues and will be instructed to cover his/her mouth and nose when coughing or sneezing. Used tissues will be disposed of in a waste receptacle;
- d. The physician in charge of the patient and the appropriate staff will be notified;
- e. The patient will be place in a separate waiting area apart from other patients;
- f. All TB precautions will be documented in the patient record;
- g. Notify the Infection Control Coordinators;
- h. If a patient with suspected or confirmed infectious TB requires treatment and/or admission, the patient must be placed in an appropriate TB isolation;
- i. Avoid scheduling patients with infectious TB at the same site or time with room severely immunocompromised or HIV positive patient; an
- j. Patients with known infectious TB who have not completed drug therapy should wear a surgical mask over the nose and mouth when receiving care, except when in a negative pressure room, until it is determined that they are non-infectious.

3. DIAGNOSIS: Diagnostic measures for identifying infectious TB Patients include:

a. History and Physical Examination:

- (1) Complete medical history should be obtained including risk factors.

- (2) Risk factors include
- Communal living, i.e., nursing homes, homeless shelters, chemical dependency, treatment centers, correctional facilities;
 - HIV positive or other immunosuppressive disease; and
 - Immigrant status.
- b. The diagnosis of active pulmonary TB should be considered for all patients with specific clinical profiles, including patients with:
- Productive or persistent cough (>2 weeks duration), night sweats, anorexia, unexplained weight loss, or hemoptysis;
 - A chest x-ray with pulmonary cavitation or hilar/mediastinal adenopathy, with or without pleural/pericardial effusion;
 - Known human immunodeficiency virus (HIV) infection with cough or fever, even in the absence of “classic” TB x-ray examination abnormalities;
 - Cough and fever, if the patient also has a significant response to a tuberculin skin test, a history of previous tuberculosis, or a history of exposure to infectious tuberculosis, or
 - Pulmonary systemic signs and symptoms that are initially ascribed to other etiologies, but which do not respond to therapy appropriate for the presumed etiology.
- c. Administration of tuberculin skin test:
- 0.1 ml of PPD is injected intradermally (Mantoux) into the volar or dorsal surface of the forearm just below the antecubital fossa (preferably the left arm).
 - A discreet, pale elevation of the skin (a wheel) 6-10 mm in diameter should be produced when correctly injected. If a wheel does not form, reinject the patient at a different site at least 1-2 inches from the first injection.
- d. Reading the skin test
- Reading of the test should be performed by trained personnel between 48-72 hours after injection. If uncertain about the results, or a positive reading is made, consult the Infection Control Coordinator.
 - The presence or absence of induration is the basis for determining a significant reaction. Redness or erythema should not be measured
 - Record the transverse diameter (across the arm) of the induration in millimeters.
 - Interpret the results using current definitions for a significantly positive reaction as follows:

<u>RISK FACTORS</u>	Positive Result by mm Duration
<ul style="list-style-type: none"> • HIV infection • Risk factors for HIV infection & unknown HIV status • Recent close contact with persons • Presence of abnormal CXR consistent with old healed TB 	5 mm
<ul style="list-style-type: none"> • IV drug users known to be HIV seronegative • Persons with medical conditions making them susceptible to conversion to active disease • Immigrants from Asia, Africa, Mexico & Latin America • Low income status • Long-term care facilities • Correctional and residential facilities 	10 mm
<ul style="list-style-type: none"> • Persons with none of the above risk factors 	15 mm

- All positive PPD’s should be reported to the Infection Control Coordinators.
- Chest X-Ray.
 - A chest x-ray should be done on anyone with a significantly positive PPD or with signs and symptoms of infectious TB.
 - Although active pulmonary TB can present radiographically as any infiltrative process, a chest x-ray characteristic of active TB may show:
 - Upper lobe infiltrate with or without cavitation
 - Patchy or nodular apical infiltrates or other infiltrates in the apical or subapical posterior upper lobe or the superior lower lobe

(7) Sputum Smear.

(a) AFB (acid-fast bacilli) smear and culture of sputum or other appropriate specimen should be collected on anyone with signs or symptoms of pulmonary or laryngeal tuberculosis or with an abnormal chest x-ray suggestive of TB.

(b) Early AM sputum specimens collected on three consecutive days are preferable.

(8) Laboratory response in AFB testing.

(a) The most rapid methods available should be used to detect TB and these methods should be updated, as more rapid or sensitive tests become available.

(b) Specimens should be sent to the Arizona Department of Health Services, Bureau of State Laboratory Services for processing.

(c) AFB smear results should be available within 24 hours of receipt of the specimen in the laboratory.

(d) Susceptibility tests should be performed on all TB isolates.

(e) Bronchoscopy or biopsy, if indicated.

(9) Initiation of Treatment.

(a) Patients with confirmed infectious TB or highly likely to have infectious TB should be started on appropriate treatment promptly in accordance with current guidelines.

(b) Inpatients should be administered anti-tuberculosis drugs by directly observed therapy (DOT).

(c) Initiation of isolation for suspected or confirmed infectious TB** .

4. ISOLATION AND MANAGEMENT:

a. All patients with suspected or confirmed infectious TB should be evaluated for potential infectiousness and should remain in isolation for TB until infectivity is ruled out. This includes:

(1) Patients with known or suspected HIV infection who have undiagnosed pulmonary infiltrates;

(2) Any patient who has an AFB smear or culture from a respiratory source that is positive for AFB;

(3) Any patient with a history of exposure to and clinical symptoms suggestive of infectious pulmonary or laryngeal tuberculosis;

(4) Any patient with previously diagnosed infectious TB who is readmitted to a facility before confirmation of complete cure should be placed on Airborne Precautions until infectiousness is ruled out.**Patients meeting the above criteria must be placed on Airborne Precautions until it is specifically documented in the patient's medical record by the Infection Control Coordinator or the Infectious Disease Physician why the patient does not need isolation.

b. Patients on Airborne Precautions should:

(1) Be educated about TB transmission and the reasons for isolation.

(2) Be instructed to cover their mouth and nose with a tissue when coughing and sneezing.

(3) Remain in the isolation room with the door closed at all times.

(4) Be transported outside of the isolation room only for medically essential procedures that cannot be performed in the isolation room.

(5) Wear a surgical mask whenever it is necessary to leave the isolation room. The person transporting the patient does not need to wear a mask outside the isolation room once the patient is masked properly. The timing of transport should be planned to occur when the procedure can be performed promptly and the patient does not have to experience delays in a common area.

(6) If treatment and procedure rooms are not separately ventilated or do not meet ventilation recommendations for TB isolation, the patient should remain masked and be returned promptly to the isolation room when the treatment or procedure is completed.

(7) Persons entering the Airborne Precautions (TB isolation) room should be kept to a minimum and all that enter should wear appropriate respiratory protection.

c. Discontinuation of Isolation for suspected or confirmed infectious TB:

(1) For persons with suspected infectious TB, isolation for TB can be discontinued when:

(a) Sputum smears collected on three consecutive days are negative for AFB;

(b) A single BAL (bronchoalveolar lavage) is negative for AFB;

(c) A single biopsy smear is negative for AFB; or

(d) An alternative diagnosis has been established.

(2) For persons with confirmed infectious TB, isolation for TB can be discontinued when:

(a) The patient is on effective therapy, and

(b) Is clinically improving, and

(c) Sputum smears collected on three consecutive days are negative for AFB.

(3) For patients with suspected or confirmed infectious multi-drug resistant TB (MDR-TB) isolation is to be continued throughout the hospital stay. |

d. Public Health Department Reporting:

(1) All persons with suspected or confirmed infectious TB should be reported to the Maricopa County Health Department immediately for initiation of contact Investigation, follow-up, and continuation of therapy by the Infection Control Coordinator.

(2) Confidentiality will be maintained as prescribed by state and local laws.

e. Discharge Planning:

(1) Appropriate discharge plans are to in place before discharge. At a minimum this includes:

(a) A confirmed appointment with the provider who will follow the patient and with the local health department to ensure continuation of therapy.

(b) A sufficient supply of medication to take until the first appointment at the county health department.

(c) Follow-up appointment with the VAMC primary care provider.

(2) TB patients who are infectious should only be discharged to facilities with the capacity of providing isolation for TB or to home.

(3) When discharging to home, consideration should be given to the presence of uninfected persons or high risk persons in the household and the ability to protect these persons from becoming infected.

f. Cough Inducing Procedures: General guidelines for cough-inducing procedures for patients with suspected or confirmed infectious TB:

(1) Procedures that involve instrumentation of the lower respiratory tract or induced cough may increase the probability of droplet nuclei being expelled in the air. These cough-inducing procedures include, but are not limited to, endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (including pentamidine therapy), and bronchoscopy. Other procedures that may generate aerosols (e.g., irrigation of tuberculous abscesses, homogenizing or lyophilizing tissue) are also included in these recommendations.

(2) Do not perform these procedures on patients who may have infectious TB unless absolutely necessary.

(3) Perform these procedures using local exhaust ventilation devices, (e.g., booths or special enclosure) or in a room that meets the ventilation requirements for TB isolation. HCWs present during the cough-inducing procedures should wear appropriate respiratory protection.

(4) Keep patients who may have infectious TB in the isolation room or enclosure until coughing subsides. Give patients tissues and instructions to cover their mouth and nose when coughing. If these patients must recover from sedatives or anesthesia they should be monitored in a TB isolation room, NOT in a general recovery area with other patients.

(5) Before the booth, enclosure, or room is used for another patient adequate time should be allowed to pass so that the droplet nuclei that have been expelled in the air are removed (for booth or enclosure follow manufacturers instructions; for an average size treatment or patient room with ≥ 12 air exchanges per hour (ACH) allow $\frac{1}{2}$ hour).

5. **AIRBORNE PRECAUTION ROOM MONITORING**

a. The negative pressure is monitored daily when these rooms are in use as a TB isolation room and monthly when not in use as a TB isolation room.

b. An ante room may increase the effectiveness of the TB isolation room by minimizing the potential for droplet nuclei escape into the corridor when the door is opened. Ante rooms are not required.

c. TB isolation areas are available in the VAMC to appropriately isolate patients with suspected or confirmed infectious TB. Within the Carl T. Hayden VAMC the following TB isolation rooms are available:

(1) ED (2) 2-C (3) 4-C (3) (4) 4-D (4) (5) SICU (1) (6) MICU (1)

6. **RESPIRATORY PROTECTION:**

a. Personal respiratory protection is used by:

(1) All persons entering a room in which known or suspected infectious TB are being isolated. (Consideration can be given to excluding household contacts--consult with the Infection Control Coordinators.)

(2) All persons present during cough-inducing or aerosol-generating procedures performed on patients with known or suspected infectious TB.

(3) All persons in settings where administrative and engineering controls are not likely to protect persons from inhaling infectious airborne droplet nuclei.

b. The TB Respirator Program, Policy Memorandum No. RMS/138-48, describes the respirator program at the Carl T. Hayden VAMC. The Industrial Hygienist is responsible for the respirator program.

INFECTION CONTROL PRACTICES

Whenever possible, the medical center will use engineering controls to prevent the spread of infectious TB and reduce the concentration of infectious droplet nuclei in the air.

a. General ventilation (general use areas) system designs should meet any applicable federal, state, and local requirements. Airflow should be designed, constructed and maintained so that air flows from clean to less clean areas.

b. TB isolation rooms separate persons likely to have infectious TB from other persons, prevent the escape of droplet nuclei from the room to the surrounding areas, and provide an environment that allows for the reduction of the concentration of droplet nuclei. These rooms are:

(1) Maintained under negative pressure with respect to the hallway and surrounding areas.

(2) Maintained with a minimum of ≥ 12 ACH.

c. Exhaust air directly to the outside in accordance with federal, state and local regulations, or if it is impossible to exhaust the air from the room directly to the outside, HEPA (high efficiency particulate air filter) filters must be used in the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulates the size of droplet nuclei from the air before the air is returned to the general ventilation system.

d. The negative pressure is monitored daily when these rooms are in use as a TB isolation room and monthly when not in use as a TB isolation room.

e. Negative pressure room - Occupied Negative Pressure Room Daily Recordings - Appendix H are sent to the Industrial Hygienist when completed.

HEALTH CARE WORKER EDUCATION

1. All health care workers at risk for occupational exposure to infectious TB at the VAMC should receive education about TB that is appropriate to their position description

2. Specific information and training about occupational hazards and required protective measures should be provided to new employee orientation

3. The following elements should be included in the education of all HCW's, although the level and detail of this education may vary according to job description

a. The basic concepts of tuberculosis transmission, pathogenesis, and diagnosis, including difference between latent tuberculosis and active disease; the signs and symptoms of tuberculosis, and the possibility of re-infection and/or reactivation in persons with a positive tuberculin skin test (PPD).

b. The potential of occupational exposure to persons with infectious TB in the VAMC, including the prevalence of tuberculosis, the ability of the VAMC to appropriately isolate patients and situations with increased risk of exposure to tuberculosis.

c. The principles and practices of infection control that reduce the risk of transmission of tuberculosis. Including the hierarchy of tuberculosis infection control measures, and written policies and procedures. Site-specific control measures should be provided by the department manager/ supervisor to personnel in areas needing measures in addition to the basic control program.

d. The purpose of PPD skin testing, the significance of a positive result and the importance of participation in the skin test program.

e. The principles of drug therapy for latent or active tuberculosis infection. Indications, use, and effectiveness, including the potential adverse effects of the medications.

f. The responsibility of the health care worker to seek medical evaluation promptly if:

(1) Symptoms develop that may be associated with tuberculosis; and/or

(2) If PPD test conversion occurs in order to receive appropriate evaluation and therapy to prevent transmission of tuberculosis to patients and other health care workers.

g. The necessity of notifying Employee Health if diagnosed with active tuberculosis so early contact investigation can be initiated.

h. The responsibilities of the VAMC are to assure that the health of the health care worker with tuberculosis receives appropriate therapy and is non-infectious before returning to duty.

i. Explanation of the higher risk posed by tuberculosis to individuals with specific medical conditions such as HIV infection, including:

- (1) The more frequent and rapid development of clinical tuberculosis after infection with *M. tuberculosis*;
 - (2) The difference in the clinical presentation of disease; and
 - (3) The high mortality rate associated with multidrug resistant tuberculosis (MDR-TB) disease in such individuals.
- j. Confidentiality shall be maintained.

EMPLOYEE HEALTH

1. HEALTH CARE WORKER COUNSELING, SCREENING, AND EVALUATION:

TB screening and prevention program for HCWs has been established for the protection of HCWs. Personnel with significantly positive PPD skin test conversions, or symptoms suggestive of TB shall be identified, counseled, evaluated or rule out infectious TB, and provided options for therapy or preventive therapy, as indicated.

a. Counseling HCWs Regarding TB:

- (1) All HCWs should know if they have a medical condition or are receiving a medical treatment that may lead to severely impaired cell-mediated immunity. These HCWs should be aware of their PPD skin test status prior to and subsequent to immunosuppression.
- (2) All HCWs, especially those who are severely immunocompromised, should seek counseling about the potential risks associated with taking care of patients with some infectious disease, including TB. Options for severely immunocompromised HCWs to voluntarily transfer to areas and activities in which there is the lowest possible risk of exposure to TB should be available. This shall be a personal decision for the HCW and must be requested by the HCW.
- (3) The confidentiality of the worker shall be maintained.

b. Screening HCWs for infectious TB

- (1) Any HCW with persistent cough (> 3 weeks duration), especially in the presence of other symptoms or signs compatible with infectious TB, such as weight loss, night sweats, bloody sputum, anorexia, or fever, should be evaluated promptly for TB
- (2) The HCW will not return to work until infectious TB is excluded or the HCW is on therapy and documented to be non-infectious.

c. Screening HCWs for Latent TB Infection: Administer a tuberculin skin test (Mantoux 5 TU PPD) to all HCWs including those with a history of vaccination with BCG at the time of employment. Use a documentation of PPD skin testing within the previous two years. Note: Tine test is not an acceptable method of screening

d. Any employee with a documented history of a positive PPD test, adequate treatment for disease or adequate preventative therapy for infection, should be exempt from further PPD screening.

e. Initial and follow-up PPD tests should be administered, read, and interpreted according to current guidelines.

f. Employees will be informed of the interpretation of PPD test results, whether positive or negative, at the time of testing.

g. All PPD negative employees should be screened at intervals determined by the risk assessment.

h. Immunocompromised HCWs should be referred to Employee Health for confidential individual counseling regarding his/her risk of TB and appropriate follow-up.

i. PPD skin test results are to be recorded both in the individual employee health record and in a retrievable aggregate database of all HCWs PPD test results, so they can be periodically analyzed to estimate the risk of acquiring new infections in each area or group of the VAMC.

2. MEDICAL REVIEW

a. Evaluate for clinically infectious TB with a chest radiograph and clinical evaluation (history and physical)

b. If a HCW's PPD test converts from negative to positive, a history would be obtained which would include: (1) previous PPD skin test results; (2) history of exposure to known TB infected person; (3) previous medical and surgical history; (4) current use of medications; and (5) TB symptoms currently being exhibited.

c. Attempt to determine the potential source of the TB exposure. The drug susceptibility pattern of the TB isolate from the known source patient will determine appropriate prophylaxis.

d. Notify the Infection Control Coordinators of any clinically infectious TB case in employees.

e. All HCWs with a history of positive PPD should be reminded that they should be evaluated promptly for any pulmonary symptoms suggestive of infectious TB.

f. Employee is referred to the Maricopa County TB Control division by the Infection Control Coordinator after a chest x-ray is obtained.

3. ROUTINE FOLLOW-UP CHEST RADIOGRAPHS:

- a. HCWs with significantly positive PPD skin tests shall have a CXR as part of the initial evaluation of their positive PPD skin test; repeat CXRs are not needed unless symptoms develop that may be due to infectious TB.
- b. Routine repeat CXRs are not necessary for asymptomatic PPD positive HCWs.

4. **WORK RESTRICTIONS:**

a. Infectious TB:

- (1) HCWs with infectious pulmonary or laryngeal TB shall be excluded from work until they are no longer infectious
- (2) Before returning to work, the HCW shall provide proof
 - (a) Of receiving adequate therapy;
 - (b) That sputum smears collected on three consecutive days are negative for AFB; and
 - (c) That the cough has resolved.
- (3) After work duties are resumed and while the HCW remains on antituberculosis therapy, the HCW shall provide proof that they have:
 - (a) Been maintained on effective drug therapy for the appropriate time period; and
 - (b) Remained AFB sputum smear negative.
- (4) HCWs with infectious TB who discontinue treatment before the recommended course of therapy has been completed will be excluded from work until:
 - (a) Treatment is resumed; and
 - (b) Have negative AFB sputum smears on three consecutive days.

b. Latent TB infection:

- (1) HCWs receiving preventive treatment for latent TB infection shall be allowed to continue their usual work activities.
- (2) HCWs with latent TB infection who cannot take or do not accept or do not complete a full course of preventive therapy shall not be excluded from work but they shall be counseled about the risk of developing infectious TB, especially if they have exposure to high risk patients (i.e., patients at high risk for developing infectious TB disease, such as patients with HIV infection).

5. **PROBLEM INVESTIGATION/EVALUATION:**

a. PPD conversions and active TB in employees :following steps should be taken if a skin test conversion is identified:

- (1) Evaluate the HCW promptly for infectious TB.
 - (a) Obtain a thorough history of possible exposure and risk factors in an attempt to determine the potential source of the TB infection;
 - (b) Perform a physical examination if indicated either by history or current symptoms review;
 - (c) Obtain a CXR; and
 - (d) Perform other diagnostic procedures as indicated.
- (2) Place HCW on preventive or curative therapy (if appropriate and according to current guidelines). When the source of infection is known, the drug susceptibility pattern of TB isolate will be determined in order to determine appropriate preventive therapy.
- (3) Administer PPD skin tests to HCWs in same area or group who may have similar exposure to determine if there is additional evidence of transmission.
- (4) The contact investigation will extend to possibly exposed patients, by the Infection Control Coordinators, if indicated.
- (5) The Infection Control Coordinators will initiate problem evaluation, if indicated. If a problem with patient detection, TB isolation practices, or engineering controls, is identified, implement the appropriate corrective interventions.
- (6) Consult, if needed, with TB Control Division of Maricopa County if a problem with patient detection, TB isolation practices or engineering controls is identified.

b. If employee develops TB, the following steps should be taken by the Infection Control Coordinators:

- (1) Conduct contact investigation including other employees, patients, and visitors who had significant exposure to source employee.

(2) Notify Maricopa County TB Control Division immediately for consultation and investigation of community contacts.

6. PATIENT-TO-PATIENT TRANSMISSION:

a. Review employee PPD test and patient surveillance data from the area where transmission is suspected to detect additional patients for employees with PPD conversions or active disease.

b. Investigate possible exposure of the “new” TB patient with the patient with TB during admission (e.g., admitted to same area/room, received same procedures, were in same treatment room on same day, etc.).

c. If above steps suggest transmission has occurred, the following steps should be taken:

(1) Investigate possible causes of transmission. Possible causes may include:

(a) Problem with patient detection;

(b) Problem with engineering controls; and

(c) Problem with implementation of appropriate TB isolation practices.

(2) Determine which additional patients or employees have been exposed and evaluate with PPD skin tests.

(3) Consult with Maricopa County TB Control Division for assistance in community contact investigation.

CONTACT INVESTIGATION

The following steps should be taken when a patient is seen in the VAMC without being recognized as having TB and promptly isolated, but is subsequently diagnosed as having infectious TB:

a. Identify employees and other patients who were exposed to the TB patient.

(1) Review the patient’s medical record to determine which areas and persons may have been exposed to the patient prior to appropriate isolation, such as:

(a) Outpatient Clinics

(b) Hospital Rooms

(c) Treatment, radiology, and procedure areas

(d) Patient lounges

(e) Persons providing direct care

(f) Other personnel such as therapists, clerks, transportation personnel, housekeepers, social workers

Note: Contact investigation follows a concentric circle, expanding from closest to less close contacts, if transmission to the former is found.

(g) Administer PPD to all employee and patients with documented exposure as soon as possible after exposure unless a known positive PPD (If PPD skin testing has been done in the previous three months then a repeat baseline test is not needed.).

1. If initial test is negative, a second test should be administered 12 weeks after last day of exposure.

2. If the initial test is significantly positive, conduct appropriate follow-up. The positive skin test, however, is not related to the current exposure.

3. Promptly evaluate exposed persons with PPD skin test conversion or with clinical symptoms suggestive of infectious TB.

4. Asymptomatic persons with previously known positive PPD, who have been exposed to an infectious patient do not routinely require a repeat PPD or CXR. If these persons have symptoms suggestive of infectious TB, a CXR and further evaluation for infectious TB disease is indicated.

5. An investigation should be conducted to determine why TB was not recognized in the patient or, if recognized, why the patient was not isolated promptly and appropriate corrective action taken.

CONSIDERATION FOR SPECIAL AREAS

ADDITIONAL CONSIDERATION FOR SELECTED AREAS

1. OPERATING ROOMS (ORS):

a. Elective procedures on patients with infectious TB should be delayed until the patient is no longer infectious.

b. Elective procedures on patients with suspected TB should be delayed until infectious TB has been ruled out.

c. If a surgical procedure must be performed on patients with suspected or confirmed infectious TB, it should be performed in OR rooms with ante-rooms (if possible), with the door to the room closed at all times and traffic in and out of the room kept to a minimum. If possible, procedures should be done when other patients are not present in the operating suite (e.g., end of day) and when a minimum number of personnel are present.

d. A bacterial filter placed on the patient’s endotracheal tube or on the expiratory side of the breathing circuit of the anesthesia machine may be useful in reducing the risk of contamination of anesthesia equipment or discharge of

tubercle bacilli into the ambient air when anesthesia is being administered to a patient with known or suspected infectious TB.

e. The patient with known or suspected infectious TB should be monitored during recovery in a room meeting TB isolation room ventilation requirements, NOT in the general recovery room area with other patients.

f. Personnel present when operative procedures (or other procedures requiring a sterile field) are performed on patients who have suspected or known infectious TB should wear appropriate respiratory protection. Valved or positive-pressure respirators are not appropriate for use during procedures requiring surgical masks (these masks have exhalation valves).

2. AUTOPSY ROOM

a. Due to the probability of the presence of infectious aerosols, autopsy rooms should

(1) Be maintained under negative pressure with respect to the hallway and surrounding areas.

(2) Be maintained with a minimum of ≥ 12 ACH.

(3) Exhaust air directly to the outside in accordance with federal, state, and local regulations.

(4) If it is impossible to exhaust the air from the room directly to the outside, HEPA filters must be used in the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulate the size of droplet nuclei before the air is returned to the general ventilation system

b. The negative pressure is monitored daily when these rooms are in use as a TB isolation room and monthly when not in use as a TB isolation room.

c. Respiratory protection should be worn by personnel performing autopsies on deceased persons who may have had infectious TB at the time of death.

d. Ultra Violet (UV) lighting may be used as an adjunct.

3. **LABORATORY**: The laboratory processing specimens for mycobacterial studies (e.g., AFB smears and cultures) should conform to criteria previously specified by CDC (Centers for Disease Control and Prevention) and NIH (National Institute for Health).

OCCUPIED NEGATIVE PRESSURE ROOM DAILY RECORDINGS

<i>DIGITAL PRESSURE READINGS</i>						
WARD	ROOM #	DATE	DOOR CLOSED	DOOR OPEN	DIFFERENCE (Y/N*)	INITIALS
* If no pressure differential is evident 10 seconds after opening door, call Engineering Department (Ext. 6428)						

NOTE: To be used only during AFB isolation. Send completed forms (when full or patient discharged) to FS/138E. Alarm should sound (after 30 seconds) when pressure drops to less than -.002.

Safety Programs--Creating a Culture of Safety

Medical error affects people from all walks of life.

35% of physicians report that they or family members have experienced error..

25% of patients experienced medical or drug errors in the United States

50% of these report that these caused serious problems

84% of adults have heard of a situation where a medical mistake was made

42% of adults said they have been personally involved in a situation where a medical mistake was made

31% of patients leave the doctor's office without getting all their questions answered

40% of patients don't follow the doctor's advice, don't agree with the advice, or it's too difficult to follow

84% of physicians and 62% of nurses report they have seen co-workers take shortcuts that could harm a patient

20% of physicians said they have seen patients injured as a result of a negligent colleague

10% of physicians said they would confront colleagues or discuss with supervisors

There is one hospital deal for every 750 admissions.

Role of leadership in establishing a culture of safety

Normal accident theory asserts that errors result from system failures. An important element of this perspective is the need for a system that collects, analyzes, and disseminates information from incidents and near misses as well as regular proactive checks on the system's vital signs. Four subcultures are important in supporting this kind of environment.

Reporting culture

Just culture

Flexible culture

Learning culture

High-reliability organization theory suggests that accidents occur because individuals who operate and manage complex systems are themselves not sufficiently complex to sense and articulate the problems generated by the system. Lessons learned from high-reliability organizations indicate that a safety culture is supported by migrated distributed decision making, management by exception or negotiation, and fostering a sense of the big picture.

Only by viewing the health care continuum as a *system* can truly meaningful improvements be made. A systems approach that emphasizes **prevention, not punishment** is the best method to accomplish this goal. Other high-risk industries/companies such as airlines and nuclear power have used this approach to accomplish safety. For healthcare to make the prevention effort effective, it's important to use methods of gathering and analyzing data from the that allow the formation of the most accurate picture possible.

Because people on the frontline are usually in the best position to identify issues and solutions, Root Cause Analysis teams in each organization should formulate solutions, test, implement, and measure outcomes in order to improve patient safety. Findings from these teams should be shared nation-wide. This is really the core of building a *culture of safety*. This kind of cultural change does not happen over night. It can only happen as a result of effort on everyone's part to take a different approach to the way we look at things. Organizations must constantly question if they can do things in a better, more efficient, and safer manner. 'Good enough' can never be good enough. Organizations must be relentless in their pursuit of finding ways to improve our systems.

Most people don't come to work to do a bad job or make an error, but given the right set of circumstances, anyone can make a mistake. Organizations must force themselves to look past the easy answer that it was someone's fault - to answer the tougher question as to why the error occurred. It's seldom a single reason. Through understanding the real underlying causes, organizations can better position themselves to prevent future occurrences. As has been said, "Experience is the best teacher" but is also one of the most expensive teachers as well. One of the best ways to reduce the expense is to take advantage of lessons present in *close calls* where things almost go awry, but no harm is done. Establishing a culture of safety where people are able to report both adverse events and close calls without fear of punishment is the key to creating patient safety.

Patient and Family Wishes in the Aftermath of Error

- Disclosure

- Non-abandonment of patients and families
- Non-abandonment of clinicians
- *Find root cause and prevent the same mistake from happening again*

The current focus on patient safety and health care quality issues stems in large part in the United States from the IOM Committee on the Quality of Health Care in America published To Err is Human: Building a Safer Health System in which the committee reported that deaths due to medical errors approximate as many as 98,000 per year in the United States.

A four tiered approach to enhancing patient safety was recommended in the report:

1. Establishment of a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety
2. Identifying and learning from errors through immediate and strong reporting efforts, with the aim of making sure the system continues to be made safer for patients
3. Raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups
4. Creating safety systems inside health care organizations through the implementation of a safe practices at the delivery level, the target level of all recommendations

The National Quality Forum (NQF), the principle product of President Clinton's Quality Commission, has been assigned responsibilities to define those adverse events for which, at a minimum, there is reporting accountability. This assignment, referenced in the IOM report, also asks NQF to set the standards for the recommended state based mandatory reporting systems. NQF published a Call to Action which details ten recommendations to health care organizations, leaders, and purchasers:

1. Make patient safety a leadership and management priority
2. Make an unequivocal organizational commitment to patient safety
3. Create a health care culture of safety
4. Initiate routine audits for patient safety hazards
5. Implement recognized safe practices
6. Increase education about patient safety
7. Be accountable for patient safety
8. Recognize and deal with professional misconduct
9. Make patient safety a research priority
10. Support efforts to create a non-punitive environment for health care error reporting

Acknowledging that the findings in To Err is Human accounted for only the tip of the iceberg in the larger story about quality care, the IOM in 2001 issued a second report titled Crossing the Quality Chasm: A New Health System for the 21st Century. This report states that the United States health care system is in need of fundamental change, indicating that other defects beyond safety are even more widespread. The principle concern relates to the gap or chasm between performance and potential in American health care. The report recommends a five part agenda to cross the quality chasm:

1. A strong commitment on the part of every health care institution, professional, purchaser, and regulator to make significant improvement in six specific areas:
 - a. Patient safety
 - b. Effectiveness of care
 - c. Patient centered care
 - d. Timeliness of care
 - e. Efficiency of care
 - f. Equitable nature of care
2. Ten rules should guide patient-clinician relationships:
 - a. Care should be based on continuous healing relationships
 - b. Care should be customized based on patient needs and values
 - c. Control should reside with the patient

- d. Knowledge and information should be shared with the patient
 - e. Clinical decisions should be evidence based
 - f. The care system should be safe
 - g. The health system should be more transparent by making information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing alternative treatment
 - h. The health system should anticipate patient needs rather than simply reacting to events
 - i. The health system should not waste resources or patient time
 - j. There should be more cooperation among clinicians to ensure an appropriate exchange of information and coordination of care
3. The health care system must focus greater attention on the development of evidence-based approaches to care for the common conditions that afflict many people.
 4. Health care organizations, clinicians, and patients must work together to redesign how care is delivered.
 5. There must be changes in the broader environment in four key areas:
 - a. Development of more effective processes for the diffusion of clinical knowledge to providers and patients
 - b. Commitment to build an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education
 - c. Examination by private and public purchasers of their payment methods to remove barriers that currently impede quality improvement and to build in incentives for quality enhancement
 - d. Development of strategies for restructuring clinical education, and assessment of the implications for provider credentialing and the funding and sponsorship of education programs for health professionals

AHRQ's report "Making Health Care Safer: A Critical Analysis of Patient Safety Practices," identified safety practices offering the greatest gains from more widespread implementation and those most promising areas for future research.

Top Opportunities for wider implementation

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality (noncardiac surgery)
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections
- Asking that patients recall and restate what they have been told during the informed consent process
- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator associated pneumonia
- Use of pressure relieving bedding materials to prevent pressure ulcers
- Use of real time ultrasound guidance during central line insertion to prevent complications
- Patient self management of warfarin to achieve appropriate outpatient coagulation and prevent complications
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients
- Use of antibiotic impregnated central venous catheters to prevent catheter related infections

Top opportunities for research

- Improved perioperative glucose control to decrease perioperative infections

- Localization of specific surgeries and procedures in high volume centers
- Use of supplemental perioperative oxygen to decrease perioperative infections
- Changes in nursing staffing to decrease overall hospital morbidity and mortality
- Use of silver alloy coated urinary catheters to prevent urinary tract infections
- Computerized physician order entry with computerized decision support systems to decrease medication errors and adverse events primarily due to the drug ordering process
- Placement of limitations on antibiotic use to prevent hospital acquired infections due to antibiotic resistant organisms
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections
- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk
- Appropriate provision of nutrition with a particular emphasis on early enteral nutrition in critically ill and post surgical patients
- Use of analgesics in the patient with an acute painful abdomen without compromising diagnostic accuracy
- Improved handwashing compliance via education/behavior change, sink technology and placement, or use of antimicrobial washing substances

National Quality Forum Set of Safe Practices

- Create a healthcare culture of safety: There is a need to promote a culture that overtly encourages and supports the reporting of any situation or circumstance that threatens, or potentially threatens, the safety of patients or caregivers and that views the occurrence of errors and adverse events as opportunities to make the health care system better.
- For high risk procedures, refer to high volume institutions: Patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that have demonstrated superior outcomes and should be referred to such facilities in accordance with the patient's stated preference.
- Explicit protocol for nursing staffing levels: Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix, and the experience and training of its nursing staff.
- Intensivists in the ICUs: All patients in general intensive care units (both adult and pediatric) should be managed by physicians having specific training and certification in critical care medicine.
- Pharmacists should participate in all stages of medication use process: This includes, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications.
- Verbal orders should be recorded and read back: A health care provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard.
- Use standardized abbreviations and dose designations.
- Patient care summaries should not be prepared from memory.
- Ensure that care information, especially changes in orders and new diagnostic information, is transmitted in a clearly understandable form to all of the patient's current health care providers who need that information to provide care.
- Ask patients to recount what they were told during informed consent.
- Display advanced directives: Ensure that written documentation of the patient's preference for life-sustaining treatments is prominently displayed in his/her chart.
- Implement computerized prescriber order entry

- Implement a standardized protocol to prevent the mislabeling of radiographs.
- Implement standardized protocols to prevent the occurrence of wrong-site or wrong-patient procedures.
- Evaluate each patient undergoing elective surgery for risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment for high-risk patients with beta blockers.
- Evaluate each patient upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.
- Evaluate each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis/venous thromboembolism. Utilize clinically appropriate methods to prevent both.
- Utilize dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.
- Upon admission, and regularly thereafter, evaluate each patient for risk of aspiration.
- Adhere to effective methods of preventing central venous catheter-associated bloodstream infections.
- Evaluate each pre-operative patient in light of his/her planned surgical procedure for the risk of surgical site infection, and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.
- Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.
- Evaluate each patient upon admission, and regularly thereafter, for risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.
- Whenever a pneumatic tourniquet is used, evaluate the patient for the risk of an ischemic and/or thrombotic complication, and utilize appropriate prophylactic measures.
- Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to, and after, direct contact with the patient or objects immediately around the patient.
- Vaccinate health care workers against influenza to protect both them and patients.
- Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
- Standardize the methods for labeling, packaging, and storing medications.
- Identify all high alert drugs (for example intravenous adrenergic agonists and antagonists, chemotherapy agents, anti-coagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics, and opiates)
- Dispense medication in unit dose or, when appropriate, unit of use form, whenever possible.

Safety Culture

According to the Institute of Medicine, the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm. Promoting a culture of safety has become one of the important tenets of the patient safety movement. In recent years, there has been increasing understanding within the healthcare industry that various factors, such as the emphasis on production, efficiency, and cost controls, organizational and individual inability to acknowledge fallibility, and professional norms for perfectionism among healthcare providers, combine to create a culture contradictory to the requirements of patient safety. Increasingly, the culture of the

healthcare industry is regarded as a potential risk factor threatening the patients for whom it provides care.

Professional and organizational cultures in healthcare must undergo a transformation in the interest of promoting safer patient care. Healthcare must come to see itself as a high hazard industry which is inherently risky. It must abandon the philosophy of requiring perfect, error free performance from individuals and focus instead on designing systems for safety. Healthcare systems must move away from the current blame and shame culture that prevents acknowledgement of error and therefore obstructs any possibility of learning from error. Safety improvement requires that healthcare systems have ready access to information that supports learning from experience in order to promote systems that both prevent errors and mitigate the impact of errors that occur. In contrast to a pathological culture where failure is punished or concealed and people refuse to acknowledge that problems exist, a positive safety culture recognizes the inevitability of error and proactively seeks to identify latent threats.

A fundamental culture change is necessary to ensure that innovations introduced to improve patient safety actually achieve their potential.

Five Steps to Create a Safety Culture

- Recognize that leadership owns the culture, whether the leaders want to or not
- Have a clear vision of the culture required
- Compare where the organization is with its stated values and goals
- Hardwire and create tools to reinforce the behavior and culture desired
- Link culture and performance and review every year

Work Processes for Safety Culture

- Strict procedural adherence/no workarounds
- Three point communication including readback
- Complete, accurate operating procedures
- Contingencies rehearsed, not trial and error
- Redundant safety systems
- Promote peer review of work and multi-level oversight

Safety Culture Employee Mindset

- Anticipatory and prepared for contingencies
- Questioning attitude
- Comfortable raising issues
- Feels included and treated as a stakeholder
- Strong corporate identity and organizational commitment
- Focus efforts beyond compliance
- Encourage peer review of work
- Willing to accept accountability and responsibility

Human Factors Principles for Safer Healthcare

Process

- Simplify work processes
- Standardize
- Reduce reliance on memory & vigilance
- Checklists, trigger tools
- Constraints & forcing functions
- Eliminate look alike/sound alike

Education and training
Design out failures
Use technology appropriately

Organization

Increase feedback and direct communication
Rounds
Teamwork and crew resource management
Drive out fear for reporting
Leadership commitment and safety culture
Training programs for staff on tools, techniques, technology
Environment adjustments
Adjust work schedules

Leadership Characteristics for a Safety Culture

Operating principles generated at the top and implemented from the bottom
Lessons learned in one part of the organization shared throughout and incorporated into operating procedures
Zero accident goals
Investigations focus on organizational processes not persons
Organization committed to continual training of all staff
All stakeholders involved in change management
Compliance is the base for focus of effort
Organization states its values strongly and maintains them as its identity

Practical Examples of Creating a Safety Culture

Set the expectation for all employees to speak up about safety programs
Identify and discuss barriers to speaking up
Identify the various ways in which employees can speak up
Introduce specific skills for effectively communicating concerns
Emphasize the use of chain of command as a patient safety tool
Use patient safety champions from each area
Monthly meetings with area champions

Fair and Just Culture

- Everybody makes mistakes & implements work-arounds; emphasis should be on importance of learning from mistakes & near misses
- Individual is accountable to the system & greatest error is to not report a mistake & prevent system & others from learning
- New culture of patient safety successfully created when everybody advocates for safety

Safety Culture

What is culture? What we do when no one is looking. Craig Clapper

The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management.

Organizations with a positive safety culture are characterized by communications focused on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

Organization reacts to error in a way that acknowledges error and balances individual with organizational responsibility

Creates processes that use information gleaned from error to improve systems

Designs systems that manage human choices for safety, stops errors from occurring, and permits recovery

Continually communicates its values and expectations

Safety Culture Assessment

Safety culture assessments are tools that can be used to measure organizational conditions that lead to adverse events and patient harm, and for developing and evaluating safety improvement interventions in healthcare organizations. They provide a metric by which the implicit shared understandings about the way we do things around here can be made visible and available as input for change.

Safety culture assessments can have multiple purposes:

Diagnosis of safety culture and raising diagnosis

Evaluation of patient safety interventions and tracking change over time

Internal and external benchmarking

Fulfillment of regulatory and or other requirements

Safety culture assessment should be viewed as the starting point from which action planning begins and patient safety changes emerge.

Sample Hospital Survey on Patient Safety Culture

Surveys on patient safety culture ask employees for opinions about patient safety issues, medical error, and event reporting. Some sample questions are listed below. Respondents are asked to indicate a numerical response on a Likert scale that ranges from strongly disagree to strongly agree.

1. People support one another in this unit.
2. We have enough staff to handle the workload.
3. When a lot of work needs to be done quickly, we work together as a team to get the work done.
4. In this unit, people treat each other with respect.
5. Staff in this unit work longer hours than is best for patient care.
6. We are actively doing things to improve patient safety.
7. We use more agency/temporary staff than is best for patient care.
8. Staff feel like their mistakes are held against them.
9. Mistakes have led to positive changes here.
10. It is just by chance that more serious mistakes don't happen around here.
11. When one area in this unit gets really busy, others help out.
12. When an event is reported, it feels like the person is being written up, not the problem.
13. After we make changes to improve patient safety, we evaluate their effectiveness.
14. We work in crisis mode trying to do too much too quickly.
15. Patient safety is never sacrificed to get more work done.
16. Staff worry the mistakes they make are kept in their personnel file.
17. We have patient safety problems in this unit.
18. Our procedures and systems are good at preventing errors from happening.
19. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.
20. My supervisor seriously considers staff questions for improving patient safety.
21. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.
22. My supervisor/manager overlooks patient safety problems that happen over and over.

23. We are given feedback about changes put into place based on event reports.
24. Staff will freely speak up if they see something that may negatively affect patient care.
25. We are informed about errors that happen on this unit.
26. Staff feel free to question the decisions or actions of those with more authority.
27. In this unit, we discuss ways to prevent errors from happening again.
28. Staff are afraid to ask questions when something does not seem right.
29. When a mistake is made, but caught and corrected before affecting the patient, it is reported.
30. When a mistake is made, but has no potential to harm the patient, it is reported.
31. When a mistake is made that could harm the patient but does not, it is reported.
32. Hospital management provides a work climate that promotes patient safety.
33. Hospital units do not coordinate with each other.
34. Things fall between the cracks when transferring patients from one unit to another.
35. There is good cooperation among hospital units that need to work together.
36. Important patient care information is often lost during shift changes.
37. It is often unpleasant to work with staff from other hospital units.
38. Problems often occur in the exchange of information across hospital units.
39. The actions of hospital management show that patient safety is a top priority.
40. Hospital management seems interested in patient safety only after an adverse event happens.
41. Hospital units work well together to provide the best care for patients.
42. Shift changes are problematic for patients in this hospital.

In a safety culture, leaders:

- Act in a way that communicates high personal standards
- Help others question and rethink their assumptions about safety
- Communicate the organizational vision through word and action
- Demonstrate willingness to consider and accept new ideas
- Consider the impact of their actions on the safety of others, and on the organization's safety culture
- Challenge and inspire people around the safety vision and values
- Describe a compelling picture of what the future could be
- Admit mistakes to self and others
- Go to bat for direct reports; represent and support the interests of people with higher management
- Give honest information about safety performance, even if it is not well received
- Ask for ideas on how to improve own performance
- Act constantly in setting and applying safety standards
- Willing to make safety-related decisions that are unpopular or involve some personal risks
- Demonstrate personal concern for employee well-being
- Follow through on commitments made
- Treat others with dignity and respect
- Encourage people to give honest and complete information about safety, even if the information is unfavorable
- Keep people informed about the big picture in safety
- Communicate frequently and effectively up, down, and across the organization
- Actively communicate and discuss safety information with direct reports
- Share with people the background and reasons for safety policies and procedures
- Listen actively and with respect to safety concerns that are raised and asks what others are thinking
- Make sure that others feel comfortable and safe in raising issues and concerns
- Promote collaboration and cooperation in safety

- Ask for and encourage input from people on issues that will affect them
- Help others resolve safety related problems for themselves
- Encourage others to implement their decision and solutions for improving safety
- Seek out and listen to diverse points of view
- Express confidence in the ability of others
- Support the decision that others make on their own
- Gain commitment of others before implementing changes
- Are proactive rather than reactive to addressing safety issues
- Give a timely, considered response to safety concerns
- Demonstrate a sense of personal urgency and energy to achieve safety results
- Deliver results with speed and excellence
- Focus safety efforts on the most important priorities
- Show persistence in solving safety problems
- Do whatever it takes to make safety improvement initiatives successful
- Seize safety improvement opportunities when they arise
- Are creative and innovative in improving safety
- Publicly recognize the contributions of others
- Readily recognize people for safety work well done
- Praise safety efforts more often than criticize them
- Give positive feedback and recognition for good performance
- Find ways to celebrate accomplishments in safety
- Give people a fair appraisal of their efforts and results in safety
- Clearly communicate people's roles in safety
- Foster a sense that people are responsible for the level of safety in their areas
- Set clear responsibilities in safety for direct reports
- Hold people accountable for meeting their commitments
- Regularly review with direct reports indicators of their safety performance

Changing to a safety culture is essentially about leadership.

Accountability: An agreement, a personal willingness, after the fact, to answer for the results of actions and behaviors regardless of how things turn out

Accepting accountability moves organizations from a victim mindset towards one of responsibility. Accountability is about keeping agreements and performing jobs. Blaming is more an emotional process. The accountability perspective focuses on a system level problem analysis. The blame perspective focuses on the individual. Accountability is about responsibility. It focuses attention to the problem & how to improve performance. Blame is more likely to focus on the person and punishment. Managers & staff should be trained in concepts of accountability and have the appropriate mindset. Responsibilities should be clearly defined and discussed in advance. Employees need to feel safe to report unsafe conditions and situations

Addressing Performance Problems as Systems Issues

First, focus on the issue or error, not the outcome

Second, interpret the error, intentional or unintentional

Third, identify contributing factors

- Health related issues

- Medical issues

- Mental illness

- Substance abuse

- Knowledge/skill deficit

System induced
Unacceptable or acceptable risk taking
Behavioral issue, reckless or inappropriate
Repeated unsafe acts

Shared accountability

To what extent is the system responsible for the conditions/events or series of conditions/events that led to the situation?

To what extent is the individual responsible for the conditions/events or series of conditions/events that led to the situation?

Both parties are accountable for the parts of the situation for which they are responsible. This does not mean that punishment follows.

Safety culture is a key determinant of the ability of health care organizations to address and reduce risks to patients due to medical care. A safety culture is necessary to encourage uniformly appropriate responses by frontline personnel.

Use of Red Rules to Foster a Culture of Safety-AHRQ

Red Rules - Rules that must be followed to the letter. In the language of non-health care industries, red rules "stop the line." In other words, any deviation from a red rule will bring work to a halt until compliance is achieved. Red rules, in addition to relating to important and risky processes, must also be simple and easy to remember.

An example of a red rule in health care might be the following: "No hospitalized patient can undergo a test of any kind, receive a medication or blood product, or undergo a procedure if they are not wearing an identification bracelet." The implication of designating this a red rule is that the moment a patient is identified as not meeting this condition, all activity must cease in order to verify the patient's identity and supply an identification band.

Health care organizations already have numerous rules and policies that call for strict adherence. So what is it about red rules that makes them more than particularly important rules? The reason that some organizations are using this new designation is that, unlike many standard rules, red rules are ones that will always be supported by the entire organization. In other words, when someone at the frontline calls for work to cease on the basis of a red rule, top management must always support this decision. Thus, when properly implemented, red rules should foster a culture of safety, as frontline workers will know that they can stop the line when they notice potential hazards, even when doing so may result in considerable inconvenience or be time consuming and costly, for their immediate supervisors or the organization as a whole.

Environmental Safety

Environmental health comprises those aspects of human health, including quality of life, that are determined by physical, chemical, biological, and social and psychological problems in the environment. It also refers to the theory and practice of assessing, correcting, controlling, and preventing those factors in the environment that can potentially affect adversely the health of present and future generations. Potential risks to health exist in all environments, homes, schools, workplaces, and communities. There are many ways in which environmental threats can occur. Chemical, biological, and radiological exposures may contribute to health risks via air quality (indoors and out), water, food, and products.

Environmental health is one of the priority areas of the Healthy People 2020 objectives. The federal government has long recognized the importance of the relationship between environmental risks and the underlying factors contributing to diseases. Healthy People 2020 objectives include the following:

Eliminate elevated blood lead levels in children.

Minimize the risks to human health and the environment posted by hazardous sites.

Reduce pesticide exposures that results in visits to the health care facility.

Reduce the amount of toxic pollutants released into the environment.

Reduce indoor allergen levels.

Decrease the number of U. S. homes that are found to have lead-based paint or related hazards.

The environment is radically different than a century ago. In addition to man-made pollutants contaminating air, water, and food, many of the same pollutants are now also found in human tissues.

Environmental Health Assessment

I Prepare

Investigate potential exposures

Have people ever felt sick after coming in contact with a chemical, such as a pesticide or other substance?

Do people have any symptoms that improve when you are away from your home or work?

Present work

Are people exposed to solvents, dust, fumes, radiation, pesticides, or other chemicals?

Are people exposed to loud noise?

Do people know where to find material safety data sheets/safety data sheets for chemicals with which you work?

Do people wear personal protective equipment?

Are work clothes worn home?

Are there similar health problems?

Residence

When was the residence built?

What type of heating is used?

Has the home recently been remodeled?

What chemicals are stored on the property?

Where is the source of drinking water?

Environmental concerns

Are there environmental concerns in the neighborhood (i.e., air, water, soil)?

What types of industries or farms are nearby?

Is a hazardous waste site or landfill nearby?

Past work

What are past work experiences?

What jobs were held for the longest period of time?

Have people ever been in the military, worked on a farm, or done volunteer or seasonal work?

Activities

What activities/hobbies do people pursue?

Do people burn, solder, or melt any products?

Do people garden, fish, or hunt?

Do people eat what they catch or grow?

Do people use pesticides?

Do people engage in any alternative healing or cultural practices?

Referrals and resources

Environmental Protection Agency <http://www.epa.gov>

National Library of Medicine—Toxnet Programs <http://www.nlm.nih.gov>

Agency for Toxic Substances and Disease Registry <http://www.atsdr.cdc.gov>

Association of Occupational and Environmental Clinics <http://www.aoec.org>
Occupational Health and Safety Administration <http://www.osha.gov>
EnviRN website <http://www.enviRN.umaryland.edu>
Local Health Department, Environmental Agency, Poison Control Center

Educate

- Are materials available for education?
- Are alternatives available to minimize the risk of exposure?
- Have prevention strategies been discussed?
- What is the plan for follow-up?

Environmental safety has the goal of providing guidance and direction in all phases of the safety program including occupational safety and health, environmental control, and chemical safety. The following are key components of environmental safety:

- Identify and control chemical hazards
- Monitor and administer hazardous chemical waste disposal program
- Conduct environmental sampling/monitoring
- Respond to chemical spills and accidents
- Investigate complaints related to workplace exposures
- Conduct training in the use, control, and disposal of hazardous chemicals
- Ensure Environmental Protection Agency (EPA) compliance
- Provide lifting guidelines.

Organizations that aspire to be better environmental stewards invest in strong environmental, health, and safety management. From an environmental standpoint, it involves creating a systematic approach to managing waste, complying with environmental regulations, or reducing the organization's carbon footprint. Successful programs also include measures to address ergonomics, air quality, and other aspects of workplace safety that could affect the health and well-being of employees. The corporate environmental safety function to oversee environmental, health, and safety began to merge at the management level around 1990. Environmental management emerged as a profession in the 1970's, following the creation of the U. S. Environmental Protection Agency (EPA) and other state-level regulatory systems. Safety and occupational health also grew in importance during this time, with the passage of legislation such as the Occupational Safety and Health Act of 1970.

Over time, organizations developed a systematic way of complying with environmental, health and safety regulations. Organizations began tracking key measures and looking for ways to improve their performance. Then, in the 1990's, improvements in data technology management made it easier for an organization to analyze its operations. Environmental safety programs administer policies and procedures for environmental management, ensuring compliance with federal, state and local laws, regulatory guidelines and industry standards. Environmental safety provides expertise in many areas including air resource management, contractor/construction management, oil storage and handling, and pesticide management. Environmental management serves the organization through technical support, regulatory reporting, training, and auditing of operational practices.

Industrial hygiene hierarchy of controls

Substitute less hazardous or non-hazardous substances (e.g., using water-based instead of solvent-based products)

Isolate the hazardous chemicals from human exposure (e.g., use closed systems)

Apply engineering controls (e.g., ventilation systems, including exhausts)

Reduce the exposures through administrative controls (e.g., rotating employees)

Use personal protective equipment (e.g., gloves, respirators, protective clothing)

Lifting Guidelines (Weight) For a Single Individual

Sex/Age	No Restriction?	Training Required?	Lifting Aids Required?	Not Recommended
Male <50	0-40 lbs.	41-60 lbs.	61- 130 lbs.	>130 lbs.
Male =>50	0-30 lbs.	31-50 lbs.	51-105 lbs.	>105 lbs.
Female* <50	0-25 lbs.	26-40 lbs.	41-80 lbs.	>80 lbs.
Female* =>50	0-20 lbs.	21-30 lbs.	31-60 lbs.	>60 lbs.
* females who are pregnant should not lift more than 25 lbs.				

Safety Culture Interventions

Safety behaviors for human error prevention for staff, leaders, and physicians - Specific behavior-based expectations & tools & techniques for human performance need to be identified for all staff, leaders and physicians. The expectations should be selected based on common causes of past events & current performance concerns identified during diagnostic assessment.

Education and training content should be crafted around the specific behavior-based expectations and error prevention techniques, and is delivered by the organization’s employees who are prepared as program trainers. The best education and training format is a short lecture followed by a series of experiential learning stations.

Accountability systems to reinforce and sustain performance – At the core of the initiative is the understanding and aligning of accountability systems within the organization to drive individual compliance with the expectations across the organization and to the front-line depths of each department. Areas of focus include:

- ✓ Clearly defining the expectations, knowledge, and skill of operational leaders in reinforcing behavior-based expectations.
- ✓ Educating medical staff about the initiative and their role is supporting and participating in the behavior-based expectations
- ✓ Aligning goals, metrics, and performance incentives to reinforce behavior changes

Don Berwick’s Seven Roadblocks to Improving Patient Safety

Berwick identified seven areas of concern that health care leaders should heed in the effort to continue the progress of the patient safety movement.

1. **Displacement by other concerns:** As we go to boardrooms around the U.S. and hear what is being discussed, there are two topics: a changing reimbursement system and workforce morale. I personally believe there’s a strong connection between safety and cost reduction, but that conviction hasn’t been firmly established in 20 years.
2. **Illusion of completeness:** There’s an illusion that we’ve worked on safety — 'here are our scores on central line infections, pressure ulcers and here’s what’s happening on medication reconciliation' — on to the next problem. The concept of safety as a box-checking enterprise, where we start and finish, is lethal to patients of the future.
3. **Incentive theory:** Most of the workforce is already trying as hard as it can. Until we become scientists and give up the incentive-oriented approach to safety, we won’t make the systemic progress we have been calling on for years.

4. **Metrics glut:** In pursuit of incentives, we've glutted ourselves with metrics. I think we are way beyond a level of toxicity. It's not just safety. We have to go on a diet.
5. **Separation of safety from quality:** When people say 'quality and safety,' what I hear is 'fruit and bananas.' Quality improvement is the big tent. It's the enterprise of constant improvement to everything we care about. The quality of my car is dimensional. It has safety, durability and fuel economy and so does health care. I think reuniting our endeavors is crucial to our future. We don't have the resources to waste on tribalism. We have to think systemically.
6. **System literacy:** We need to become literate about the systemic properties that produce improvement.
7. **Academic attacks:** I'm not sure why, but I deeply regret that academic students who position themselves outside the safety movement have all too often become critics. Until our academic brethren join in the progression of safety instead of positioning themselves as critics of the good-hearted work going on, they'll be riding the breaks.

VA's Approach to patient Safety

Virtually all healthcare organizations prior to the 1999 publication of the Institute of Medicine's landmark report, *To Err is Human*, engaged in investigations of events that caused harm to patients. Few of these investigations, however, engaged in a systems-based approach to problem solving. The focus was on individuals and mistakes, rather than on the cluster of events that had combined in an unfortunate sequence to cause an incident to occur. Based on a "name and blame" culture, the emphasis of such investigations was not on prevention, but on punishment.

By shifting the goal from eliminating errors to reducing or eliminating harm to patients - through investigating the viability of medical care systems, rather than focusing on individual acts - much has been accomplished at VA. Our goal is simple: The reduction and prevention of inadvertent harm to our patients as a result of their care.

Reducing or eliminating harm to patients is the real key to patient safety. Efforts that focus exclusively on eliminating errors will fail. We'll never eliminate all individual errors. The goal is to design systems that are "fault tolerant," so that when an individual error occurs, it does not result in harm to a patient.

That's why we've based VA's patient safety program on a systems approach to problem solving? focused on prevention, not punishment. We use methods and apply ideas from "high reliability" organizations, such as aviation and nuclear power, to target and eliminate system vulnerabilities. For instance, the fault-tolerance principle has been used for years by high-reliability organizations when designing systems, and the safety records of such organizations far surpass those of healthcare. We don't target people; we don't want to participate in the "name and blame" culture of the past.

We look for ways to break that link in the chain of events that can create a recurring problem: those underlying systems-based problems that went ignored or unaddressed. One of the most important ways to do this is to learn from close calls, sometimes called "near misses," which occur at a much higher frequency than actual adverse events. Addressing problems in this way not only results in safer systems, but it also focuses everyone's efforts on continually identifying potential problems and fixing them. This doesn't mean that VA is a "blame free" organization.

We have a system that delineates what type of activities may result in blame and which don't. Only those events that are judged to be an intentionally unsafe act can result in the assignment of blame and punitive action. Intentional unsafe acts, as they pertain to patients, are any events that result from a criminal act, a purposefully unsafe act, or an act related to alcohol or substance abuse or patient abuse. The integration of these approaches across the organization creates a level of trust and a focus of efforts that helps perpetuate a culture of safety.

Practical issues in patient safety

Leadership is the key to creating a blame-free reporting culture and affecting change.

Leadership must provide their staff with the tools to foster communication about near misses and adverse events as they occur in real time.

Sample safety goals:

- Establish patient safety as a visible commitment to putting patients first philosophy
- Move from blaming people to improving processes
- Improve use of technology to prevent and detect error
- Use data to identify & measure improvements

Sample approaches to improving safety:

- Improving medication practices
- Improving emergency services
- Improving workplace safety
- Preventing nosocomial infections

Challenges in implementing a safety program

- Sustaining interest in the face of competing priorities
- Nurturing safety champions
- Communicating effectively
- Measuring improvement
- Accelerating the pace of change
- Integrating safety into the organizational culture

Role of Reporting in Safety

External reporting allows lessons to be shared so that others can avoid the same mishaps. External reporting can lead to improved safety

- Alerts about new hazards can be generated
- Information about the experience of individual institutions in using new methods to prevent errors can be shared
- Central analysis of reports can reveal trends and hazards that require attention
- Central analysis can lead to recommended best practices

Why Reporting Efforts Fail

Staff members

Time pressure

Fear of punishment

Lack of perceived benefit

Providers

Shame and fear of liability

Loss of reputation

Peer disapproval

Lack of leadership

Successful reporting occurs when

Culture is non-punitive

System is easy to use

System is responsive

Feedback is given as to use of information for improvement

Leadership is visibly committed

Communication

- A clear, consistent, & frequent message around error reporting & patient safety
- Change management process and plan
- Education
- Successful improvements are heralded
- Right tools given to the right staff
- Data is used to improve systems, processes, and quality
- Feedback is used to close the loop

Sample Outline for an Organization Safety Program

Program goals (consistent with organization mission)

Scope of the Program

- Activities & functions relating to patient safety
- Participating sites, settings, & service

Structure

- Management of the program
- Components (safety related offices, committees, functions)
- Interdisciplinary participation
- Oversight

Mechanisms for coordination

- Among the components of the program
- Among the professional disciplines
- Across the organization

Communicating with patients about safety

- Patient education
- Informing patients about their care

Staff education

- Safety related orientation and training
- Team training
- Expectations for reporting

Safety improvement activities

- Definition of terms
- Prioritization of improvement activities
- Routine safety related data collection and analysis
 - Incident reporting
 - Medication error reporting
 - Infection surveillance
 - Facility safety surveillance
 - Staff perceptions of, and suggestions for improving patient safety
 - Staff willingness to report errors
 - Patient/family perceptions of, and suggestions for improving patient safety

Identification, reporting, and management of sentinel events

Proactive risk reduction

- Identification of high risk processes
- Failure mode, effects, & criticality analysis

Reporting of results

- To the safety program
- To organization staff
- To executive leadership & the governing body

Sample National Patient Safety Goals

Goal 1 Improve the accuracy of patient identification.

NPSG.01.01.01 Use at least two patient identifiers when providing care, treatment, and services. --

Rationale for NPSG.01.01.01-- Wrong-patient errors occur in virtually all stages of diagnosis and treatment. The intent for this goal is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier.

Elements of Performance for NPSG.01.01.01

Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures. The patient's room number or physical location is not used as an identifier. (See also NPSG.01.03.01, EP 1)

Label containers used for blood and other specimens in the presence of the patient. (See also NPSG.01.03.01, EP 1)

NPSG.01.03.01 Eliminate transfusion errors related to patient misidentification.

Elements of Performance for NPSG.01.03.01

Before initiating a blood or blood component transfusion: - Match the blood or blood component to the order. - Match the patient to the blood or blood component. - Use a two-person verification process or a one-person verification process accompanied by automated identification technology, such as bar coding. (See also NPSG.01.01.01, EPs 1 and 2)

When using a two-person verification process, one individual conducting the identification verification is the qualified transfusionist who will administer the blood or blood component to the patient.

When using a two-person verification process, the second individual conducting the identification verification is qualified to participate in the process.

Goal 2 Improve the effectiveness of communication among caregivers.

NPSG.02.03.01 Report critical results of tests and diagnostic procedures on a timely basis.

Rationale for NPSG.02.03.01-- Critical results of tests and diagnostic procedures fall significantly outside the normal range and may indicate a life-threatening situation. The objective is to provide the responsible licensed caregiver these results within an established time frame so that the patient can be promptly treated.

Elements of Performance for NPSG.02.03.01

Develop written procedures for managing the critical results of tests and diagnostic procedures that address the following: - The definition of critical results of tests and diagnostic procedures - By whom and to whom critical results of tests and diagnostic procedures are reported - The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures

Implement the procedures for managing the critical results of tests and diagnostic procedures.
Evaluate the timeliness of reporting the critical results of tests and diagnostic procedures.

Goal 3 Improve the safety of using medications.

NPSG.03.04.01 Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. Note: Medication containers include syringes, medicine cups, and basins.

Rationale for NPSG.03.04.01-- Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of safe medication management, yet it is routine in many organizations. The labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications in perioperative and other procedural settings. Labels for medications and medication containers are also addressed at MM.05.01.09.

Elements of Performance for NPSG.03.04.01

In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used. Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process. Refer to NPSG.03.04.01, EP 5, for information on timing of labeling.

In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.

In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following: - Medication name - Strength - Quantity - Diluent and volume (if not apparent from the container) - Expiration date when not used within 24 hours - Expiration time when expiration occurs in less than 24 hours Note: The date and time are not necessary for short procedures, as defined by the hospital.

Verify all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.

Label each medication or solution as soon as it is prepared, unless it is immediately administered. Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.

Immediately discard any medication or solution found unlabeled.

Remove all labeled containers on the sterile field and discard their contents at the conclusion of the procedure. Note: This does not apply to multiuse vials that are handled according to infection control practices.

All medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting staff responsible for the management of medications.

NPSG.03.05.01 Reduce the likelihood of patient harm associated with the use of anticoagulant therapy. Note: This requirement applies only to hospitals that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis (for example, atrial fibrillation) where the clinical expectation is that the patient's laboratory values for coagulation will remain outside normal values. This requirement does not apply to routine situations in which short-term prophylactic anticoagulation is used for venous thrombo-

embolism prevention (for example, related to procedures or hospitalization) and the clinical expectation is that the patient's laboratory values for coagulation will remain within (or close to) normal values.

Rationale for NPSG.03.05.01-- Anticoagulation therapy can be used as therapeutic treatment for a number of conditions, the most common of which are atrial fibrillation, deep vein thrombosis, pulmonary embolism, and mechanical heart valve implant. However, it is important to note that anticoagulation medications are more likely than others to cause harm due to complex dosing, insufficient monitoring, and inconsistent patient compliance. This National Patient Safety Goal has great potential to positively impact the safety of patients on this class of medications and result in better outcomes. To achieve better patient outcomes, patient education is a vital component of an anticoagulation therapy program. Effective anticoagulation patient education includes face-to-face interaction with a trained professional who works closely with patients to be sure that they understand the risks involved with anticoagulation therapy, the precautions they need to take, and the need for regular International Normalized Ratio (INR) monitoring. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with heparin (unfractionated), low molecular weight heparin, and warfarin.

Elements of Performance for NPSG.03.05.01

Use only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available. Note: For pediatric patients, prefilled syringe products should be used only if specifically designed for children.

Use approved protocols for the initiation and maintenance of anticoagulant therapy.

Before starting a patient on warfarin, assess the patient's baseline coagulation status; for all patients receiving warfarin therapy, use a current International Normalized Ratio (INR) to adjust this therapy. The baseline status and current INR are documented in the medical record. Note: The patient's baseline coagulation status can be assessed in a number of ways, including through a laboratory test or by identifying risk factors such as age, weight, bleeding tendency, and genetic factors.

Use authoritative resources to manage potential food and drug interactions for patients receiving warfarin.

When heparin is administered intravenously and continuously, use programmable pumps in order to provide consistent and accurate dosing.

A written policy addresses baseline and ongoing laboratory tests that are required for anticoagulants.

Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families. Patient/family education includes the following: - The importance of follow-up monitoring - Compliance - Drug-food interactions - The potential for adverse drug reactions and interactions

Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions in a time frame determined by the organization.

Introduction to Reconciling Medication Information

The large number of people receiving health care who take multiple medications and the complexity of managing those medications make medication reconciliation an important safety issue. In medication reconciliation, a clinician compares the medications a patient should be using (and is actually using) to the new medications that are ordered for the patient and resolves any discrepancies.

The Joint Commission recognizes that organizations face challenges with medication reconciliation. The best medication reconciliation requires a complete understanding of what the patient was prescribed and what medications the patient is actually taking. It can be difficult to obtain a complete list from every patient in an encounter, and accuracy is dependent on the patient's ability and willingness to provide this information. A good faith effort to collect this information is recognized as meeting the

intent of the requirement. As health care evolves with the adoption of more sophisticated systems (such as centralized databases for prescribing and collecting medication information), the effectiveness of these processes will grow.

This National Patient Safety Goal (NPSG) focuses on the risk points of medication reconciliation. The elements of performance in this NPSG are designed to help organizations reduce negative patient outcomes associated with medication discrepancies. Some aspects of the care process that involve the management of medications are addressed in the standards rather than in this goal. These include coordinating information during transitions in care both within and outside of the organization (PC.02.02.01), patient education on safe medication use (PC.02.03.01), and communications with other providers (PC.04.02.01).

In settings where medications are not routinely prescribed or administered, this NPSG provides organizations with the flexibility to decide what medication information they need to collect based on the services they provide to patients. It is often important for clinicians to know what medications the patient is taking when planning care, treatment, and services, even in situations where medications are not used. A new requirement in this NPSG addresses the patient's role in medication safety: it requires organizations to inform the patient about the importance of maintaining updated medication information.

NPSG.03.06.01 Maintain and communicate accurate patient medication information.

Rationale for NPSG.03.06.01-- There is evidence that medication discrepancies can affect patient outcomes. Medication reconciliation is intended to identify and resolve discrepancies—it is a process of comparing the medications a patient is taking (and should be taking) with newly ordered medications. The comparison addresses duplications, omissions, and interactions, and the need to continue current medications. The types of information that clinicians use to reconcile medications include (among others) medication name, dose, frequency, route, and purpose. Organizations should identify the information that needs to be collected to reconcile current and newly ordered medications and to safely prescribe medications in the future.

Elements of Performance for NPSG.03.06.01

Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications. Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications. Note 2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.

Define the types of medication information to be collected in non-24-hour settings and different patient circumstances. Note 1: Examples of non-24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic settings. Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.

Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies. Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison. (See also HR.01.06.01, EP 1)

Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose). Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.

Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter. Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards MM.06.01.03, PC.02.03.01, and PC.04.01.05.)

Goal 6 Reduce the harm associated with clinical alarm systems.

NPSG.06.01.01 Improve the safety of clinical alarm systems.

Rationale for NPSG.06.01.01-- Clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multifaceted problem. In some situations, individual alarm signals are difficult to detect. At the same time, many patient care areas have numerous alarm signals and the resulting noise and displayed information tends to desensitize staff and cause them to miss or ignore alarm signals or even disable them. Other issues associated with effective clinical alarm system management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow. These issues vary greatly among hospitals and even within different units in a single hospital. There is general agreement that this is an important safety issue. Universal solutions have yet to be identified, but it is important for a hospital to understand its own situation and to develop a systematic, coordinated approach to clinical alarm system management. Standardization contributes to safe alarm system management, but it is recognized that solutions may have to be customized for specific clinical units, groups of patients, or individual patients. This NPSG focuses on managing clinical alarm systems that have the most direct relationship to patient safety. As alarm system management solutions are identified, this NPSG will be updated to reflect best practices. * Footnote *: Additional information on alarm safety can be found on the AAMI website <http://www.aami.org/htsi/alarms/>. Also, the ECRI Institute has identified alarm hazards as one of the top technology hazards for 2013; more information on this hazard list can be found at http://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

Elements of Performance for NPSG.06.01.01

As of July 1, 2014, leaders establish alarm system safety as a hospital priority.

During 2014, identify the most important alarm signals to manage based on the following: - Input from the medical staff and clinical departments - Risk to patients if the alarm signal is not attended to or if it malfunctions - Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue - Potential for patient harm based on internal incident history - Published best practices and guidelines (For more information on managing medical equipment risks, refer to Standard EC.02.04.01.)

As of January 1, 2016, establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following: - Clinically appropriate settings for alarm signals - When alarm signals can be disabled - When alarm parameters can be changed - Who in the organization has the authority to set alarm parameters - Who in the organization has the authority to change alarm parameters - Who in the organization has the authority to set alarm parameters to “off” - Monitoring and responding to alarm signals - Checking individual alarm signals for accurate settings, proper operation, and detectability (For more information, refer to Standard EC.02.04.03)

As of January 1, 2016, educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

Goal 7 Reduce the risk of health care–associated infections.

NPSG.07.01.01 Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

Rationale for NPSG.07.01.01-- According to the Centers for Disease Control and Prevention, each year,

millions of people acquire an infection while receiving care, treatment, and services in a health care organization. Consequently, health care–associated infections (HAIs) are a patient safety issue affecting all types of health care organizations. One of the most important ways to address HAIs is by improving the hand hygiene of health care staff. Compliance with the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines will reduce the transmission of infectious agents by staff to patients, thereby decreasing the incidence of HAIs. To ensure compliance with this National Patient Safety Goal, an organization should assess its compliance with the CDC and/or WHO guidelines through a comprehensive program that provides a hand hygiene policy, fosters a culture of hand hygiene, and monitors compliance and provides feedback.

Elements of Performance for NPSG.07.01.01

Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)

Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)

Improve compliance with hand hygiene guidelines based on established goals.

NPSG.07.03.01 Implement evidence-based practices to prevent health care–associated infections due to multidrug-resistant organisms in hospitals. Note: This requirement applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant staphylococcus aureus (MRSA), clostridium difficile (CDI), vancomycin-resistant enterococci (VRE), and multidrug-resistant gram-negative bacteria.

Rationale for NPSG.07.03.01-- Patients continue to acquire health care–associated infections at an alarming rate. Risks and patient populations, however, differ between hospitals. Therefore, prevention and control strategies must be tailored to the specific needs of each hospital based on its risk assessment. The elements of performance for this requirement are designed to help reduce or prevent health care–associated infections from epidemiologically important multidrug-resistant organisms (MDROs). Note: Hand hygiene, contact precautions, as well as cleaning and disinfecting patient care equipment and the patient’s environment are essential strategies for preventing the spread of health care–associated infections. Hand hygiene is addressed in NPSG.07.01.01. Contact precautions for patients with epidemiologically significant multidrug-resistant organisms (MDROs) are covered in IC.02.01.01, EP 3. Cleaning and disinfecting patient care equipment are addressed in IC.02.02.01.

Elements of Performance for NPSG.07.03.01

Conduct periodic risk assessments (in time frames defined by the hospital) for multidrug-resistant organism acquisition and transmission. (See also IC.01.03.01, EPs 1-5)

Based on the results of the risk assessment, educate staff and licensed independent practitioners about health care–associated infections, multidrug-resistant organisms, and prevention strategies at hire and annually thereafter. Note: The education provided recognizes the diverse roles of staff and licensed independent practitioners and is consistent with their roles within the hospital.

Educate patients, and their families as needed, who are infected or colonized with a multidrug-resistant organism about health care–associated infection prevention strategies.

Implement a surveillance program for multidrug-resistant organisms based on the risk assessment. Note: Surveillance may be targeted rather than hospitalwide.

Measure and monitor multidrug-resistant organism prevention processes and outcomes, including the following: - Multidrug-resistant organism infection rates using evidence-based metrics - Compliance with evidence-based guidelines or best practices - Evaluation of the education program provided to staff and licensed independent practitioners Note: Surveillance may be targeted rather than hospitalwide.

Provide multidrug-resistant organism process and outcome data to key stakeholders, including

leaders, licensed independent practitioners, nursing staff, and other clinicians.

Implement policies and practices aimed at reducing the risk of transmitting multidrug-resistant organisms. These policies and practices meet regulatory requirements and are aligned with evidence-based standards (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).

When indicated by the risk assessment, implement a laboratory-based alert system that identifies new patients with multidrug-resistant organisms. Note: The alert system may use telephones, faxes, pagers, automated and secure electronic alerts, or a combination of these methods.

When indicated by the risk assessment, implement an alert system that identifies readmitted or transferred patients who are known to be positive for multidrug-resistant organisms. Note 1: The alert system information may exist in a separate electronic database or may be integrated into the admission system. The alert system may be either manual or electronic or a combination of both. Note 2: Each hospital may define its own parameters in terms of time and clinical manifestation to determine which readmitted patients require isolation.

NPSG.07.04.01 Implement evidence-based practices to prevent central line–associated bloodstream infections. Note: This requirement covers short- and long-term central venous catheters and peripherally inserted central catheter (PICC) lines.

Elements of Performance for NPSG.07.04.01

Educate staff and licensed independent practitioners who are involved in managing central lines about central line–associated bloodstream infections and the importance of prevention. Education occurs upon hire, annually thereafter, and when involvement in these procedures is added to an individual’s job responsibilities.

Prior to insertion of a central venous catheter, educate patients and, as needed, their families about central line–associated bloodstream infection prevention.

Implement policies and practices aimed at reducing the risk of central line–associated bloodstream infections. These policies and practices meet regulatory requirements and are aligned with evidence-based standards (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).

Conduct periodic risk assessments for central line–associated bloodstream infections, monitor compliance with evidence-based practices, and evaluate the effectiveness of prevention efforts. The risk assessments are conducted in time frames defined by the hospital, and this infection surveillance activity is hospitalwide, not targeted.

Provide central line–associated bloodstream infection rate data and prevention outcome measures to key stakeholders, including leaders, licensed independent practitioners, nursing staff, and other clinicians.

Use a catheter checklist and a standardized protocol for central venous catheter insertion.

Perform hand hygiene prior to catheter insertion or manipulation.

For adult patients, do not insert catheters into the femoral vein unless other sites are unavailable.

Use a standardized supply cart or kit that contains all necessary components for the insertion of central venous catheters.

Use a standardized protocol for sterile barrier precautions during central venous catheter insertion.

Use an antiseptic for skin preparation during central venous catheter insertion that is cited in scientific literature or endorsed by professional organizations. * Footnote *: A limited number of National Patient Safety Goals contain requirements for practices that reflect current science and medical knowledge. In these cases, the element of performance refers to a practice that is cited in scientific literature or endorsed by professional organizations. This means that the practice used by the hospital must be validated by an authoritative source. The authoritative source may be a study published in a peer-

reviewed journal that clearly demonstrates the efficacy of that practice or endorsement of the practice by a professional organization(s) and/or a government agency(ies). It is not acceptable to follow a practice that is not supported by evidence or wide-spread consensus. During the on-site survey, surveyors will explore the source of the practices the hospital follows.

Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports.

Evaluate all central venous catheters routinely and remove nonessential catheters.

NPSG.07.05.01

Implement evidence-based practices for preventing surgical site infections.

Elements of Performance for NPSG.07.05.01

1. Educate staff and licensed independent practitioners involved in surgical procedures about surgical site infections and the importance of prevention. Education occurs upon hire, annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities.
2. Educate patients, and their families as needed, who are undergoing a surgical procedure about surgical site infection prevention.
3. Implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence- based guidelines (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).
4. As part of the effort to reduce surgical site infections: - Conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital. - Select surgical site infection measures using best practices or evidence-based guidelines. - Monitor compliance with best practices or evidence-based guidelines. - Evaluate the effectiveness of prevention efforts. Note: Surveillance may be targeted to certain procedures based on the hospital's risk assessment.
5. Measure surgical site infection rates for the first 30 or 90 days following surgical procedures based on National Healthcare Safety Network (NHSN) procedural codes. The hospital's measurement strategies follow evidence-based guidelines. Note 1: Surveillance may be targeted to certain procedures based on the hospital's risk assessment. Note 2: The NHSN is the Centers for Disease Control and Prevention's health care-associated infection tracking system. NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate health care-associated infections. For more information on NHSN procedural codes, see <http://www.cdc.gov/nhsn/CPTcodes/ssi-cpt.html>.
6. Provide process and outcome (for example, surgical site infection rate) measure results to key stakeholders.
7. Administer antimicrobial agents for prophylaxis for a particular procedure or disease according to methods cited in scientific literature or endorsed by professional organizations. * Footnote *: A limited number of National Patient Safety Goals contain requirements for practices that reflect current science and medical knowledge. In these cases, the element of performance refers to a

practice that is cited in scientific literature or endorsed by professional organizations. This means that the practice used by the hospital must be validated by an authoritative source. The authoritative source may be a study published in a peer-reviewed journal that clearly demonstrates the efficacy of that practice or endorsement of the practice by a professional organization(s) and/or a government agency(ies). It is not acceptable to follow a practice that is not supported by evidence or wide-spread consensus. During the on-site survey, surveyors will explore the source of the practices the hospital follows.

8. When hair removal is necessary, use a method that is cited in scientific literature or endorsed by professional organizations. * Footnote *: A limited number of National Patient Safety Goals contain requirements for practices that reflect current science and medical knowledge. In these cases, the element of performance refers to a practice that is cited in scientific literature or endorsed by professional organizations. This means that the practice used by the hospital must be validated by an authoritative source. The authoritative source may be a study published in a peer-reviewed journal that clearly demonstrates the efficacy of that practice or endorsement of the practice by a professional organization(s) and/or a government agency(ies). It is not acceptable to follow a practice that is not supported by evidence or wide-spread consensus. During the on-site survey, surveyors will explore the source of the practices the hospital follows.

NPSG.07.06.01

Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI). * Note: This NPSG is not applicable to pediatric populations. Research resulting in evidence-based practices was conducted with adults, and there is no consensus that these practices apply to children. Footnote *: Evidence-based guidelines for CAUTI are located at: Compendium of Strategies to Prevent Healthcare- Associated Infections in Acute Care Hospitals at, <http://www.shea-online.org/about/compendium.cfm> and Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2009 at http://www.cdc.gov/hicpac/cauti/001_cauti.html

Elements of Performance for NPSG.07.06.01

Insert indwelling urinary catheters according to established evidence-based guidelines that address the following:

- Limiting use and duration to situations necessary for patient care
- Using aseptic techniques for site preparation, equipment, and supplies

Manage indwelling urinary catheters according to established evidence-based guidelines that address the following:

- Securing catheters for unobstructed urine flow and drainage
- Maintaining the sterility of the urine collection system
- Replacing the urine collection system when required - Collecting urine samples

Measure and monitor catheter-associated urinary tract infection prevention processes and outcomes in high-volume areas by doing the following:

- Selecting measures using evidence-based guidelines or best practices
- Monitoring compliance with evidence-based guidelines or best practices
- Evaluating the effectiveness of prevention efforts

Note: Surveillance may be targeted to areas with a high volume of patients using in- dwelling catheters. High-volume areas are identified through the hospital's risk assessment as required in IC.01.03.01, EP 2.

Introduction to the Universal Protocol for Preventing Wrong Site, Wrong Procedure

The Universal Protocol applies to all surgical and nonsurgical invasive procedures. Evidence indicates

that procedures that place the patient at the most risk include those that involve general anesthesia or deep sedation, although other procedures may also affect patient safety. Hospitals can enhance safety by correctly identifying the patient, the appropriate procedure, and the correct site of the procedure.

The Universal Protocol is based on the following principles: - Wrong-person, wrong-site, and wrong-procedure surgery can and must be prevented. - A robust approach using multiple, complementary strategies is necessary to achieve the goal of always conducting the correct procedure on the correct person, at the correct site. - Active involvement and use of effective methods to improve communication among all members of the procedure team are important for success. - To the extent possible, the patient and, as needed, the family are involved in the process. - Consistent implementation of a standardized protocol is most effective in achieving safety.

The Universal Protocol is implemented most successfully in hospitals with a culture that promotes teamwork and where all individuals feel empowered to protect patient safety. A hospital should consider its culture when designing processes to meet the Universal Protocol. In some hospitals, it may be necessary to be more prescriptive on certain elements of the Universal Protocol or to create processes that are not specifically addressed within these requirements.

Hospitals should identify the timing and location of the preprocedure verification and site marking based on what works best for their own unique circumstances. The frequency and scope of the preprocedure verification will depend on the type and complexity of the procedure. The three components of the Universal Protocol are not necessarily presented in chronological order (although the preprocedure verification and site marking precede the final verification in the time-out). Preprocedure verification, site marking, and the time-out procedures should be as consistent as possible throughout the hospital.

Note: Site marking is not required when the individual doing the procedure is continuously with the patient from the time of the decision to do the procedure through to the performance of the procedure.

UP.01.01.01

Conduct a preprocedure verification process.

--Rationale for UP.01.01.01--

Hospitals should always make sure that any procedure is what the patient needs and is performed on the right person. The frequency and scope of the verification process will depend on the type and complexity of the procedure.

The preprocedure verification is an ongoing process of information gathering and confirmation. The purpose of the preprocedure verification process is to make sure that all relevant documents and related information or equipment are:

- Available prior to the start of the procedure
- Correctly identified, labeled, and matched to the patient's identifiers
- Reviewed and are consistent with the patient's expectations and with the team's understanding of the intended patient, procedure, and site

Preprocedure verification may occur at more than one time and place before the procedure. It is up to the hospital to decide when this information is collected and by which team member, but it is best to do it when the patient can be involved. Possibilities include the following:

- When the procedure is scheduled

At the time of preadmission testing and assessment
At the time of admission or entry into the facility for a procedure
Before the patient leaves the preprocedure area or enters the procedure room

Missing information or discrepancies are addressed before starting the procedure.

Elements of Performance for UP.01.01.01

Implement a preprocedure process to verify the correct procedure, for the correct patient, at the correct site. Note: The patient is involved in the verification process when possible.

Identify the items that must be available for procedures and use a standardized list to verify their availability. At a minimum, these items include the following: - Relevant documentation (for example, history and physical, signed procedure consent form, nursing assessment, and preanesthesia assessment) - Labeled diagnostic and radiology test results (for example, radiology images and scans, or pathology and biopsy reports) that are properly displayed - Any required blood products, implants, devices, and/or special equipment for the procedure Note: The expectation of this element of performance is that the standardized list is available and is used consistently during the preprocedure verification. It is not necessary to document that the standardized list was used for each patient

3. Match the items that are to be available in the procedure area to the patient.

Introduction to UP.01.02.01

Wrong site surgery should never happen. Yet it is an ongoing problem in health care that compromises patient safety. Marking the procedure site is one way to protect patients; patient safety is enhanced when a consistent marking process is used throughout the hospital. Site marking is done to prevent errors when there is more than one possible location for a procedure. Examples include different limbs, fingers and toes, lesions, level of the spine, and organs. In cases where bilateral structures are removed (such as tonsils or ovaries) the site does not need to be marked.

Responsibility for marking the procedure site is a hotly debated topic. One position is that since the licensed independent practitioner is accountable for the procedure, he or she should mark the site. Another position is that other individuals should be able to mark the site in the interests of work flow and efficiency.

There is no evidence that patient safety is affected by the job function of the individual who marks the site. The incidence of wrong-site surgery is low enough that it is unlikely that valid data on this subject will ever be available. Furthermore, there is no clear consensus in the field on who should mark the site. Rather than remaining silent on the subject of site marking, The Joint Commission sought a solution that supports the purpose of the site mark. The mark is a communication tool about the patient for members of the team. Therefore, the individual who knows the most about the patient should mark the site. In most cases, that will be the person performing the procedure.

Recognizing the complexities of the work processes supporting invasive procedures, The Joint Commission believes that delegation of site marking to another individual is acceptable in limited situations as long as the individual is familiar with the patient and involved in the procedure. These include: -Individuals who are permitted through a postgraduate education program to participate in the

procedure

-A licensed individual who performs duties requiring collaborative or supervisory agreements with a licensed independent practitioner. These individuals include advanced practice registered nurses (APRNs) and physician assistants (PAs).

The licensed independent practitioner remains fully accountable for all aspects of the procedure even when site marking is delegated.

UP.01.02.01

Mark the procedure site.

Elements of Performance for UP.01.02.01

1. Identify those procedures that require marking of the incision or insertion site. At a minimum, sites are marked when there is more than one possible location for the procedure and when performing the procedure in a different location would negatively affect quality or safety.

Note: For spinal procedures, in addition to preoperative skin marking of the general spinal region, special intraoperative imaging techniques may be used for locating and marking the exact vertebral level.

2. Mark the procedure site before the procedure is performed and, if possible, with the patient involved.

The procedure site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed. In limited circumstances, the licensed independent practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications: - An individual in a medical postgraduate education program who is being supervised by the licensed independent practitioner performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed - A licensed individual who performs duties requiring a collaborative agreement or supervisory agreement with the licensed independent practitioner performing the procedure (that is, an advanced practice registered nurse [APRN] or physician assistant [PA]); who is familiar with the patient; and who will be present when the procedure is performed. Note: The hospital's leaders define the limited circumstances (if any) in which site marking may be delegated to an individual meeting these qualifications.

The method of marking the site and the type of mark is unambiguous and is used consistently throughout the hospital. Note: The mark is made at or near the procedure site and is sufficiently permanent to be visible after skin preparation and draping. Adhesive markers are not the sole means of marking the site.

A written, alternative process is in place for patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (for example, mucosal surfaces or perineum). Note: Examples of other situations that involve alternative processes include: - Minimal access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice - Teeth - Premature infants, for whom the mark may cause a permanent tattoo

UP.01.03.01

A time-out is performed before the procedure.

--Rationale for UP.01.03.01--

The purpose of the time-out is to conduct a final assessment that the correct patient, site, and procedure are identified. This requirement focuses on those minimum features of the time-out. Some believe that it is important to conduct the time-out before anesthesia for several reasons, including involvement of the patient. A hospital may conduct the time-out before anesthesia or may add another time-out at that time. During a time-out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.

A designated member of the team initiates the time-out and it includes active communication among all relevant members of the procedure team. The procedure is not started until all questions or concerns are resolved. The time-out is most effective when it is conducted consistently across the hospital.

Elements of Performance for UP.01.03.01

1. Conduct a time-out immediately before starting the invasive procedure or making the incision.
2. The time-out has the following characteristics: - It is standardized, as defined by the a hospital. - It is initiated by a designated member of the team. - It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning.
3. When two or more procedures are being performed on the same patient, and the person performing the procedure changes, perform a time-out before each procedure is initiated.
4. During the time-out, the team members agree, at a minimum, on the following: - Correct patient identity - The correct site - The procedure to be done
5. Document the completion of the time-out. Note: The hospital determines the amount and type of documentation.

Sample Patient Safety Program

VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

1. **PURPOSE** This Veterans Health Administration (VHA) Patient Safety Improvement Handbook provides a roadmap that can be used to guide the VHA in the accomplishment of its goal of minimizing the chance of the occurrence of untoward outcomes consequent to medical care.
 - a. Regarding medical errors, in order to take actions that will improve this situation, it is necessary to have a clear picture as to what is actually happening so that appropriate steps can be taken to prevent such occurrences. For this prevention effort to be effective, it is necessary to establish methods of gathering and analyzing data from the field that allows the formation of the most accurate picture possible. It is believed that only by viewing the health care continuum as a 'system' can truly meaningful improvements be made. A systems approach that emphasizes prevention, not punishment, as the preferred method to accomplish this goal will be used. Armed with this type of information, the most appropriate conclusions can be drawn from which prudent solutions can be formulated, tested, and implemented. **NOTE:** Ultimately, this effort can be successful only if emphasis on safety and responsibility for improving it resides at all levels of the organization. This activity requires a true team effort.
6. Through the use of procedures, methods, clarifying examples, and appropriate feedback loops at all levels of the organization (with accompanying rationale), it is hoped that this overall goal can be achieved. Incorporation of a widely understood methodology for dealing with these safety-related issues allows for a clear and a more rapid communication of information up and down the

organization, thus speeding the process of safety improvement. *NOTE: For this to occur training must take place to complement the contents of this handbook; reading it alone is not sufficient.*

7. This handbook

a. Delineates what types of events are to be considered within the Patient Safety Program and how they should be dealt with, as well as defining the disposition of other Adverse Events resulting from a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind.

b. Specifies the method by which the need for conducting a Root Cause Analysis (RCA) will be determined and the procedure for communicating related findings throughout the organization. These procedures address the management component as well as the frontline needs. *NOTE: Directions in this handbook for reporting Adverse Events and Close Calls do not eliminate the need for the provider to document or report events related to a patient as applicable by other requirements.*

DEFINITIONS

a. Adverse Events. Adverse Events that may be candidates for an RCA are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility.

(1) Adverse Events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment).

(2) Some examples of more common Adverse Events include: patient falls, adverse drug events, procedural errors and/or complications, completed suicides, parasuicidal behaviors (attempts, gestures, and/or threats), and missing patient events. *NOTE: All Adverse Events require reporting and documentation in the Patient Safety Information System. However, the type of review required is determined through the Safety Assessment Code (SAC) Matrix scoring process, as outlined in Appendix D.*

b. Sentinel Events. Sentinel Events are a type of Adverse Event. Sentinel Events, as defined by the Joint Commission are unexpected occurrences involving death, serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase “risk thereof” includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes.

(1) Sentinel Events signal the need for immediate investigation and response. Immediate investigations may be an RCA, or, in the case of an intentionally unsafe act, administrative action.

(2) Some examples of reviewable Sentinel Events include:

(a) Death resulting from a medication error or other treatment related error;

(b) Suicide of a patient in a setting where they receive around-the-clock care;

(c) Surgery on the wrong patient or body part regardless of the magnitude of the operation; and

(d) Hemolytic transfusion reaction involving the administration of blood or blood products

having major blood group incompatibilities.

NOTE: Events considered to be Joint Commission reviewable “Sentinel Events” are included in the catastrophic severity category of the SAC Matrix; also see Appendix D.

c. Close Calls. A Close Call is an event or situation that could have resulted in an Adverse Event but did not, either by chance or through timely intervention (see App. A). Such events have also been referred to as “near miss” incidents.

(1) An example of a Close Call would be a surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification, but caught at the last minute by chance.

(2) Close Calls are opportunities for learning and afford the chance to develop preventive strategies and actions: they receive the same level of scrutiny as Adverse Events that result in actual injury; and they require reporting and documentation in the Patient Safety Information System. *NOTE:*

However, the same as for Adverse Events, the SAC Matrix scoring process and score determines the type of review.

d. Intentionally Unsafe Acts

(1) Intentionally unsafe acts, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind.

(2) Intentionally unsafe acts are to be dealt with through avenues other than those defined in this handbook (i.e., Administrative Investigation (AI) or other administrative methods as determined by the facility Director and by applicable directives and regulations). The goal of these investigations, as it is with RCAs, needs to focus on answering the questions of what happened, why did it happen, and what do we do to prevent it from happening again. *NOTE: Guidance on what to do when criminal or intentionally unsafe acts are suspected is described in paragraph 6.*

(3) Facilities must maintain a log of all such events, including the disposition of all these cases.

8. RCA. RCA is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with Adverse Events or Close Calls. An RCA is a specific type of focused review that is used for all Adverse Events or Close Calls requiring analysis. Consistent use of RCAs further refines the implementation and increases the quality and consistency of focused reviews. To avoid confusion, the term RCA is used to denote this type of focused review and will adhere to the guidelines provided in this Handbook. Root Cause Analyses need to be initiated with a specific charter memo, and the term “Root Cause Analysis” needs to be used in documents so that they will be protected and confidential under Title 38 United States Code (U.S.C.) 5705 and its implementing regulations.

(1) RCAs have the following characteristics:

(a) The review is interdisciplinary in nature with involvement of those knowledgeable about the processes involved in the event.

(b) The analysis focuses primarily on systems and processes rather than individual performance.

(c) The analysis digs deeper by asking “what” and “why” until all aspects of the process are reviewed and contributing factors are considered.

(d) The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes, or systems that would improve performance and reduce the risk of the Adverse Event or Close Call recurrence.

(2) To help adhere to these characteristics, the following five guidelines need to be considered when developing root cause statements:

(a) Root cause statements need to include the cause and effect.

(b) Negative descriptions are not to be used in root cause statements.

(c) Each human error has a preceding cause.

(d) Violations of procedure are not root causes, but must have a preceding cause.

(e) Failure to act is only a root cause when there is a pre-existing duty to act.

(3) To be thorough, an RCA must include:

(a) A determination of the human and other factors most directly associated with the event or Close Call and the processes and systems related to its occurrence (there is rarely only one underlying cause).

(b) Analysis of the underlying systems through a series of “why” questions to determine where redesigns might reduce risk.

(c) Identification of risks and their potential contributions to the Adverse Event or Close Call.

(d) Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

(4) To be credible, an RCA must:

(a) Include participation by the leadership of the organization (this can range from chartering the RCA team, to direct participation on the RCA team, to participation in the determination of the corrective action plan) and by individuals most closely involved in the processes and systems under review. In cases where the facility Director serves on the RCA team, final concurrence is to come from the Veterans Integrated Service Network (VISN) Director, or designee.

(b) Be internally consistent (i.e., not contradict itself or leave obvious questions unanswered).

(c) Include consideration of relevant literature.

(d) Include corrective actions, outcome measures, and top management approval.

(e) Meet the National Center for Patient Safety (NCPS) and Joint Commission requirements.

NCPS provides a computer-assisted tool that must be used to guide RCA teams, document the RCA, and communicate to NCPS and VISNs. It is referred to in this Handbook as the Patient Safety Information System.

f. Employee Rights. RCAs do not involve sworn testimony. They can generate written confidential quality assurance documents if this is appropriately indicated in writing at the outset of the review (as in the RCA charter memo). Facility staff represented by an exclusive representative must be afforded all rights in accordance with their collective bargaining agreement.

GOALS: The goal of the Patient Safety Program is to prevent injuries to patients, visitors, and personnel. This is accomplished by taking small steps in the way things are done so that the level of faith and trust in the VHA patient safety system is established and these behaviors become a part of all employee behavior. This is a never-ending process. In this way a “culture of safety” can be formed. The key building blocks for accomplishing these goals are:

a. Comprehensive identification and reporting of Adverse Events, Sentinel Events, and Close Calls (see par. 6).

b. Reviewing Adverse Events, Sentinel Events, and Close Calls to identify underlying causes and system changes needed to reduce the likelihood of recurrence (see paragraph 7). The determination of cause is aimed at the system issues and is not to be used as a punitive tool. The requirements for initiating a review is determined by the prioritization method defined by the Safety Assessment Code (see App. D).

c. Disseminating patient safety alerts and lessons learned regarding effective system modifications throughout VHA (see par. 7) in an effective manner.

d. Prospective analysis of service delivery systems before an Adverse Event occurs to identify system redesigns that will reduce the likelihood of harm. These would include potential system weaknesses that were identified through prospective hypothetical analyses (“what if” types of questions) using techniques such as Healthcare Failure Mode and Effects Analysis (HFMEA™).

IDENTIFICATION AND REPORTING OF ADVERSE EVENTS, SENTINEL EVENTS, AND CLOSE CALLS; HOW TO ADDRESS INTENTIONALLY UNSAFE ACTS

a. Each VISN must ensure that its designated facilities report at least the following events to NCPS (and to the local VISN, if this is the VISN policy):

(1) Adverse Events

(2) Sentinel Events

(3) Close Calls

b. Facility staff must report, as per local policy, any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an Adverse Event or Close Call.

c. Adverse Events and Sentinel Events shall be reported within the facility to the Patient Safety Manager (PSM), or designee. Facility staff are strongly encouraged to report Close Calls to the PSM, or designee. The PSM, or designee, then uses the Safety Assessment Code Matrix (SAC) to determine what action is required.

(1) This action could range from reporting to the VISN, NCPS, and Joint Commission with the associated RCA performed and corrective action plan, to a decision to do nothing at the present time due to the low priority accorded the event from its SAC score.

(2) Appendix D details how the SAC score is used and paragraph 7 and Figures 1 and 2 show the procedure that must be followed for handling events that are reported along with the associated time constraints and products required, as well as what actions will or may be taken. If a safety alert to other facilities seems needed, this needs to be indicated. Events affecting personnel or visitors that could reveal vulnerabilities that could cause Adverse Events to patients need to be reported within the facility to the PSM, or designee.

d. Any report of an Adverse Event, Sentinel Event, or Close Call, as defined in subparagraphs 4a, 4b, and 4c, received by the PSM, or designee, is protected from disclosure under 38 U.S.C. 5705, as part of a medical quality assurance program. The only exception to this protection would be in the case of an intentionally unsafe act as defined as a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind (see subpar. 4d).

e. If in the course of conducting an RCA it appears that the event under consideration is the result of an Intentionally Unsafe Act, the RCA team must refer the event to the facility Director for appropriate further consideration as described in subparagraph 4d. In such a situation the RCA team discontinues their efforts, since the facility Director has assumed the responsibility for any further fact finding or investigation.

(1) The RCA team still maintains the information they have already collected confidentially as per 38 U.S.C. 5705. This means that members of the RCA team in question could not serve on an Administrative Investigation (AI) team that might be convened by the Facility Director to consider this particular issue.

(2) All facilities must maintain a record of all events that have been referred to top management for consideration and the final disposition of the case.

f. If a crime is suspected to have been committed, appropriate officials (e.g., facility Director, Department of Veterans Affairs (VA) Police and Security) are to be notified as soon as possible by management (Title 38 Code of Federal Regulations (CFR) Sections 14.560 and 14.563, MP-1, Pt. I, Ch. 16, and MP-1, Pt. I, Ch. 2, subpar. 208.02). To the best extent possible, the surrounding area is not disturbed so that evidence is available for review by the police and other authorities. However, care needed by the patient is always to be provided as quickly as possible, regardless of its effect on the facility.

(1) As required by 38 CFR Sections 14.560 and 14.563, allegations of crimes against the person or property, or other non-fraudulent criminal matters must be referred to the Regional Counsel, who then refers the matter to the appropriate law enforcement agency.

(2) Serious crimes (felonies or misdemeanors) committed on hospital or domiciliary grounds must be reported directly to the United States Attorney, or a local agent of the Federal Bureau of Investigation.

(3) Allegations of fraud, corruption, or other criminal conduct involving VA programs and operations must be referred to the Office of the Inspector General. *NOTE: Notification is also to be given to the Deputy Assistant Secretary for Security and Law Enforcement and to the VISN office. The VISN office must inform the Assistant Deputy Under Secretary for Health (10N).*

g. If a crime is suspected to have been committed, facility security and medical staff may need to assist law enforcement agencies with preserving evidence (e.g., blood alcohol levels, weapons, controlled substances, etc.). Local policies and procedures for maintaining the chain of custody of evidence apply in these instances.

h. Staff who submit Close Call and Adverse Event reports that result in an RCA will receive feedback on the actions being taken as a result of their report. The feedback is to be of a timely nature and come from the PSM, or other appropriately designated party. Prompt feedback to reporters has been credited, in other reporting systems, with being one of the cornerstones that establishes trust in the system. It demonstrates the seriousness and commitment on the part of the organization to the importance of the reporting effort. Reporters are to be made acutely aware that their effort of reporting was not just a paperwork drill. The nature of this feedback can range from a simple acknowledgement that the event is under consideration, to providing information as to the corrective action that is planned or has been accomplished. *NOTE: Feedback should only be given to individuals that remain on staff at the time when the information from the RCA is available.*

i. Each VISN and facility is to adopt strategies to encourage and advocate staff identification and reporting of Adverse Events and Close Calls. Emphasis is to be placed on the value of Close Calls in identifying needed system redesigns. Identification and reporting of Adverse Events and Close Calls, including those that appear to result from practitioner error, need to be a routine part of everyday practice. Employees need to understand that events that are often referred to as human errors are commonly due to systems-type problems. They especially need to understand that even the most conscientious, knowledgeable, and competent professionals can make errors and that the goal is to understand these in order to prevent them from causing harm to patients.

j. VA medical centers with a Nuclear Regulatory Commission license or other authorization to use radioactive materials must ensure compliance with the license and pertinent regulations. The VHA National Health Physics Program (NHPP) is to be contacted for assistance, if needed, to clarify license or regulatory requirements. *NOTE: The NHPP can be contacted by telephone at (501) 257-1571, by e-mail at vhconhpp@med.va.gov.*

k. The Patient Safety Information System must be used to track and monitor reported events. Designated staff at VA medical centers will enter data into the Patient Safety Information System, thereby ensuring the accuracy of the data recorded. *NOTE: This may also avoid translation and transcription errors that could occur if others performed this function.*

REVIEW AND ANALYSIS OF REPORTED EVENTS

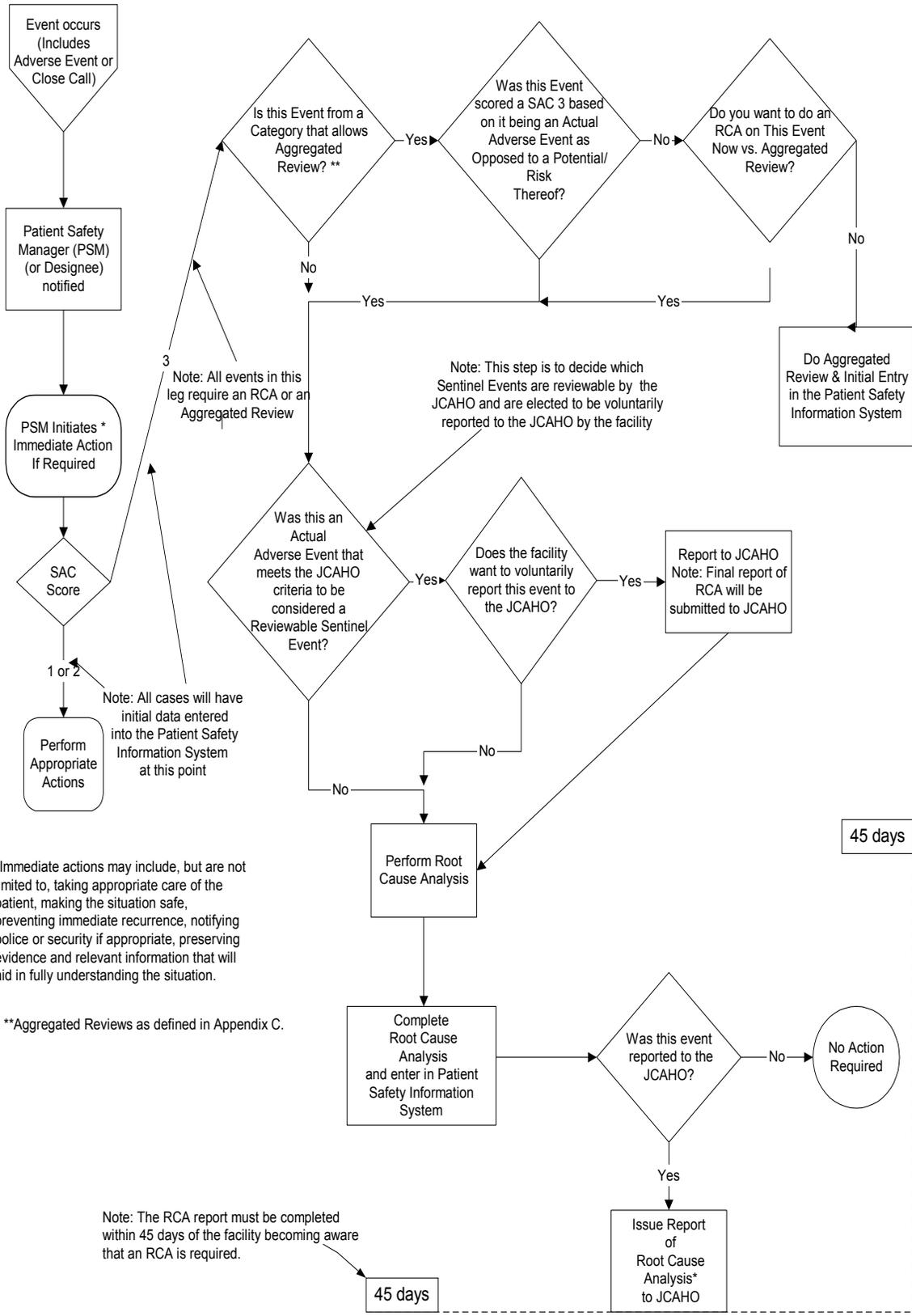
a. A procedure has been worked out so that the review and analysis system for handling reports proceeds in an understandable manner and takes into account the various requirements of VHA and accrediting organizations. The RCA process is detailed schematically in Figure 1, which provides a detailed view of the RCA process. The following description will ‘walk you through’ Figure 1:

(1) When an Adverse Event or Close Call occurs, VA personnel may use any available or locally accepted method to notify the PSM and begin the facility’s consideration of the event. The first step taken by the PSM after any required immediate action is to assign actual and potential SAC scores (see App. D) that then define what further actions are necessary.

(2) Events receiving a score of one or two will be acted on as thought appropriate by the facility. One needs to eliminate, control, or accept the risks associated with these events. These actions can range from performing an RCA to “no further action required.”

(3) All events receiving a SAC score of three will receive either a traditional RCA or an Aggregated Review as described in subparagraph 7a(4) and the initial report of the event must be entered into the Patient Safety Information System. Events that have received a SAC score of three based on what has actually occurred, must have an RCA performed; the aggregated approach may not be used.

(4) A quarterly Aggregated Review may be used for the events as described in Appendix C, Aggregated Reviews. The use of aggregated analysis serves two important purposes.



*Immediate actions may include, but are not limited to, taking appropriate care of the patient, making the situation safe, preventing immediate recurrence, notifying police or security if appropriate, preserving evidence and relevant information that will aid in fully understanding the situation.

**Aggregated Reviews as defined in Appendix C.

Figure 1. A Detailed View of the Root Cause Analysis Process

(a) First, this will provide a greater utility of the analysis as trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases.

(b) Second, it makes wise use of the RCA team's time and expertise. NCPS uses this information to compare with other data and to determine if any immediate action as far as the issuance of alerts or other action is indicated. NOTE: Any event may be subjected to a traditional RCA if this course of action is thought to be appropriate, even though it is in a category that permits an aggregated review.

(5) If the event in question is an actual Adverse Event meeting the Joint Commission definition of Reviewable Sentinel Event, the facility makes the determination to report it to Joint Commission. This may entail consultation with other entities such as the VISN as is defined by local policy. In either case, the event receives an RCA and results are reported to the Patient Safety Information System and if previously reported to Joint Commission, to them as well. The report of the outcome of the RCA must be completed within 45 calendar days and forwarded as described.

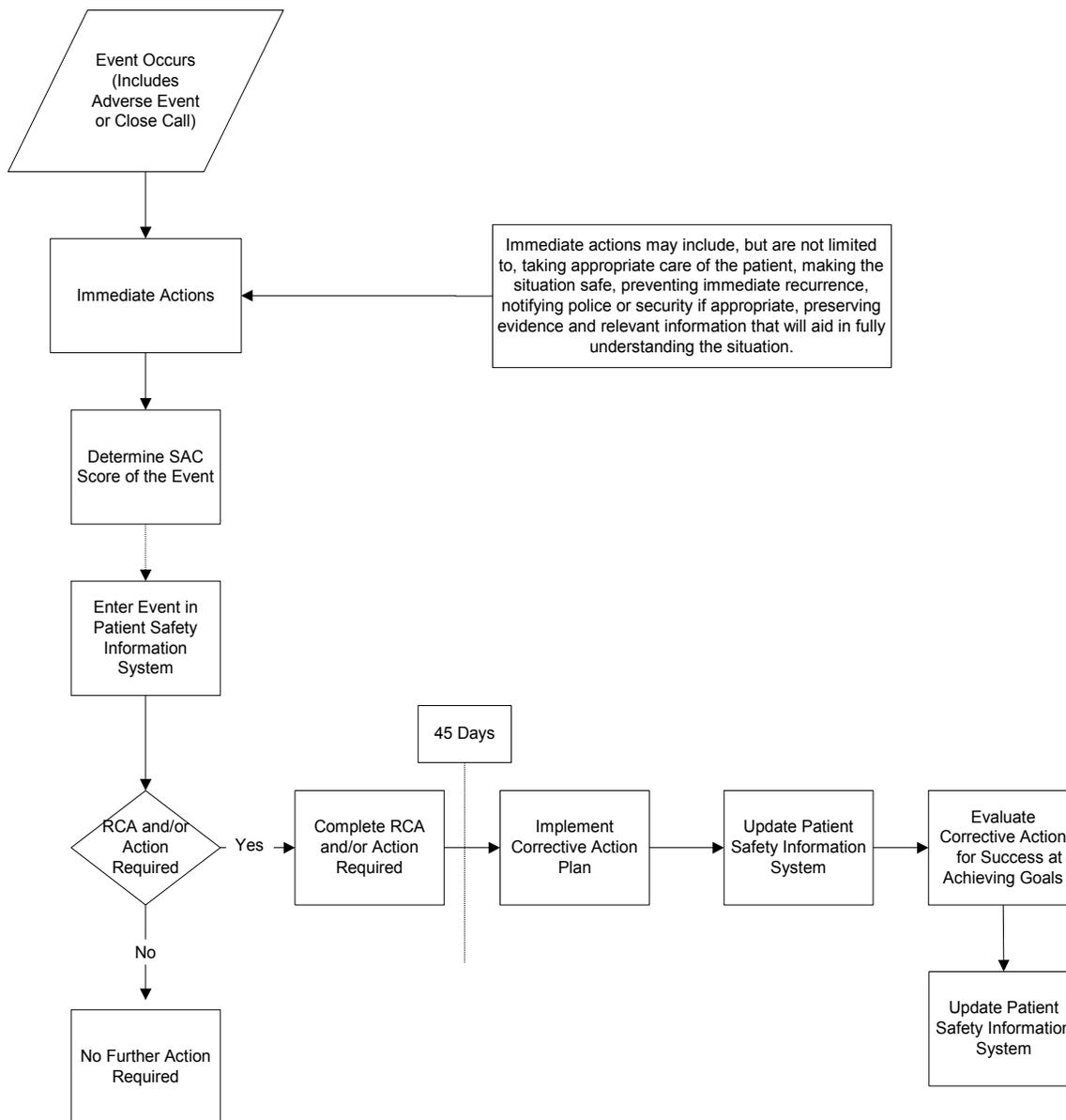
(6) To summarize, facilities have the option to report to Joint Commission as explained in policy. The RCA report will be retained by the facility even after the results have been entered into the Patient Safety Information System so that the report can be made available for future review and learning as appropriate.

(7) All events must be entered into the Patient Safety Information System. In this way all events reported are captured in the Patient Safety Information System even if they have SAC scores less than three. Those that receive a score of three (actual or potential) must receive RCA or aggregate review. Accordingly, the opportunity will then exist to better understand the system and appropriately focus attention in the future.

b. The real benefit of this review process is realized after the RCA is completed and the corrective actions are defined and implemented that prevent the future occurrence of similar events. These corrective actions are classified as eliminate, control, or accept based upon their projected impact on the identified system vulnerabilities. Once implemented, a plan for evaluating the effectiveness of the implemented change must be enacted to ensure that this change has the desired effect. The subsequent results must also be communicated to the VISN and NCPS through entry in the Patient Safety Information System or through other appropriate means. NOTE: Figure 2, provides a simplified view of the RCA process.

c. NCPS is responsible for disseminating important information learned from RCAs and the Patient Safety Information System. National Alerts and Advisories to VHA facilities are issued by the Office of the Assistant Deputy Under Secretary for Health in concert with NCPS.

d. The Office of Medical Inspector (OMI) monitors RCAs and AIs to assess their adequacy and to identify problems with processes of care that warrant attention. The OMI may conduct reviews and site visits at the request of the Secretary of Veterans Affairs, the Under Secretary for Health, the Deputy Under Secretary for Health, the Inspector General, veterans and their families, the VISNs and medical facilities, and to other stakeholders, such as Congress and Veterans Service Organizations. The OMI may also conduct reviews and site visits based on its own judgment.



INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. Background Information

(1) Clinicians and organizational leaders must work together to ensure that disclosure is a routine part of the response to Adverse Events. Telling patients that their health has been harmed rather than helped by the care provided is never easy, and disclosure must be undertaken with skill and tact. Nonetheless, VHA requires disclosure to patients who have been injured by Adverse Events.

(2) Disclosing Adverse Events to patients and their families is consistent with VHA core values of trust, respect, excellence, commitment, and compassion. Clinicians are ethically obligated to be honest with their patients. Honestly discussing the difficult truth that an Adverse Event has occurred

demonstrates respect for the patient and a commitment to improving care. Disclosure of Adverse Events can be combined with reaffirming VHA's commitment to continuing to provide health care.

(3) VHA policy requiring disclosure is consistent with Joint Commission requirements that hospitalized patients and their families be told of "unanticipated outcomes" of care (Standard RI 1.2.2, July 2001). Joint Commission's requirement demonstrates a policy commitment that clinicians and health care organizations are disclose Adverse Events to patients and families.

(4) Despite the general obligation to disclose Adverse Events to patients and families, there are legal restrictions that limit disclosures that violate patient privacy. Specifically, the Privacy Act limits disclosures to families, and 38 U.S.C. 7332 limits disclosures related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, and Human Immunodeficiency Virus (HIV) status even after a patient's death. Similarly, there are legal limitations on disclosure of information obtained from RCAs and other quality improvement activities protected under 38 U.S.C. 5705. VHA may not disclose information obtained from RCAs and other quality improvement activities protected under 38 U.S.C. 5705 to patients and families. NOTE: Questions about release of information to the patient and the patient's family are to be referred to the facility's Health Information Service; consultation with local or regional counsel may also be necessary.

b. Communication with Patients Regarding Adverse Events

(1) VISNs must ensure that their facilities have a process in place to promptly inform patients and their families about pertinent clinical facts associated with injuries resulting from Adverse Events. The patient and family need to be assured that measures have been taken to minimize the impact of the Adverse Event. The attending physician, or a designated member of the treatment team, needs to initially communicate the Adverse Event to the patient or family. Further disclosures and discussions of the Adverse Event need to be undertaken with input from regional counsel, risk management staff, patient safety officers, facility leaders, and members of the treatment team. Disclosure of Adverse Events to patients and/or family members need to be undertaken using methods similar to those used by clinicians to give other types of "bad news."

(2) VISNs and facilities must ensure that their staff provides appropriate and timely communication with patients and their families regarding Adverse Events that involve potential organizational liability. Potential organizational liability is to be assessed based on discussions with practitioners and the Regional Counsel. The patients and their families must be advised of appropriate remedial options. These options can include locally available interventions (e.g., arranging for second opinions, expediting clinical consultations, inpatient admission) and referral of patients to the 38 U.S.C. 1151 claims process and the tort claims process.

(3) A collaborative relationship between Regional Counsel and VA medical center staff is necessary to ensure appropriate and timely communication with patients. Each VISN needs to ensure that their staffs develop an understanding with its Regional Counsel regarding the procedures for obtaining Regional Counsel input prior to discussing an Adverse Event with a patient.

COMPENSATION FOR INJURED PATIENTS

a. The two primary options available to injured patients, or their survivors, are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, 28 U.S.C., Sections 1346 (b), 2671-2680.

(1) Claims under 38 U.S.C. 1151 can result in payment of monthly benefits for additional disability or death incurred as the result of VHA facility care, medical or surgical treatment or examination, if the disability or death was proximately caused by negligence or an unforeseen event. Claims under 38 U.S.C. 1151 provide for the payment of a monthly benefit based on the percentage of disability and eligibility for VA medical care. NOTE: Claims for 38 U.S.C.1151 benefits are processed by Veterans Benefits Administration (VBA) Regional Offices.

(2) Tort claims may result in a settlement by Regional Counsels, General Counsel, United States Attorney, or in a judgment by a Federal court which has determined that negligence by medical practitioners caused injury or death (and jurisdictional requirements are met). NOTE: Tort claims are processed by the Regional Counsels. In some cases subsequent review by the VHA Forensic Medicine Strategic Healthcare Group's (11F) Office of Medical-Legal Affairs may result in a recommendation that a practitioner be reported to the National Practitioner Data Bank based on a finding of substandard care, professional incompetence, or professional misconduct. Information contained in RCAs and other quality improvement materials is protected from disclosure in response to tort claims under 38 U.S.C. 5705 and may not be used by the VHA Office of Medical-Legal Affairs.

(3) Veterans and survivors may pursue both 38 U.S.C 1151 and tort claims. However, if both claims are successful, 38 U.S.C. 1151 benefits will be offset until the amount that would have been paid equals the amount of the tort claim settlement or judgment.

CLOSE CALL SYSTEM DEFINITIONS

What is a Close Call?

1. A Close Call is an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

2. All have experienced Close Calls on the job, whether they have recognized them or not. Two examples are listed as follows:

a. A nurse almost gives an overdose of insulin, but recognizes it and prevents the overdose when double-checking the order. NOTE: During the double-check, they realize that they had confused the "U" for units, with a "0."

b. An environmental management employee notices a jug of industrial strength cleaner mistakenly left in the shower stall on a locked psychiatric unit. They return it to proper storage before any patient can use it inappropriately.

THE JOINT COMMISSION DEFINITION OF REVIEWABLE SENTINEL EVENTS THAT MAY BE REPORTED TO THE JOINT COMMISSION.

The following criteria define the subset of Sentinel Events that are voluntarily reportable, at the facility's discretion to the Joint Commission. NOTE: As Joint Commission policies are dynamic, it is important to be sure that the most recent Joint Commission Sentinel Event Policies and definitions are used in making any determination. The text below was taken from the Joint Commission web page and this site should be checked periodically for updates or changes in policies.

1. Only those Sentinel Events that affect recipients of care (i.e., patients, clients, and Veterans Health Administration (VHA) nursing home and domiciliary residents) and that meet the following criteria fall into the subset of Sentinel Events that are voluntarily reportable to the Joint Commission:

2. The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. NOTE: A distinction is made between an adverse outcome that is related to the natural course of the patient's illness or underlying condition (not reviewable under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of that condition (reviewable). "Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When "major permanent loss of function" cannot be immediately determined, applicability of this policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.

Or

3. The event is one of the following (even if the outcome was not death or major permanent loss of function)

- a. Suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center).
- b. Infant abduction or discharge to the wrong family.
- c. Rape. NOTE: The determination of "rape" is to be based on the healthcare organization's definition, consistent with applicable law and regulation. An allegation of rape is not reviewable under the policy. Applicability of the policy is established when a determination is made that a rape has occurred.
- d. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

e. Surgery on the wrong patient or wrong body part. NOTE: All events of surgery on the wrong patient or wrong body part are reviewable under the policy, regardless of the magnitude of the procedure.

QUARTERLY AGGREGATED REVIEWS FALLS, ADVERSE DRUG EVENTS, MISSING PATIENTS, AND PARASUICIDAL BEHAVIOR

1. Quarterly Aggregated Reviews. Quarterly Aggregated Reviews completed within 45 days of the end of the quarter and conducted by a chartered Root Cause Analysis (RCA) Team, may be used for four types of reported Adverse Events or Close Calls (potential Safety Assessment Code (SAC) score of three). The four types of events that may be handled by Aggregated Reviews are falls, adverse drug events, missing patients, and parasuicidal behaviors. All Adverse Events with an actual SAC score of three require individual RCAs.

a. The use of Aggregated Reviews serves two important purposes. First, it provides greater utility of the analysis as trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise.

b. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any of these four types of Adverse Events or Close Calls that they think merits that attention, regardless of the actual SAC score

c. A tailored, real-time minimum data set (Aggregated Review Log) must be compiled for falls, missing patients, adverse drug events, and parasuicidal behaviors by designated staff in follow-up to reported events or Close Calls, during each quarter. Capturing this data may require medical record review, medication administration record review, and a brief discussion with staff members most knowledgeable about the events or Close Calls. The Aggregated Review Logs are to be provided to the designated RCA Teams as soon as they are convened, and serve as their initial data source. *NOTE: By using these logs the RCA teams may not routinely need to retrospectively consult individual patient profiles or individual medical records.*

d. It is anticipated that by utilizing this aggregated approach and building the reviews over succeeding quarters, common themes may be more readily identified enabling evaluation of the effectiveness of actions taken to prevent these events or Close Calls. *NOTE: Descriptions of each Aggregated Review Log are provided on the following pages. See the National Center for Patient Safety (NCPS) website for the most current form of the aggregate logs at <http://vaww.ncps.med.va.gov/training/AggRevLog.doc>.*

2. Falls. Falls are defined according to local or facility definition.

a. An individual RCA must be performed for any reported inpatient or outpatient fall occurring on facility property that results in an actual SAC 3, for all enrolled patients.

b. Reported falls and Close Calls (potential SAC score of 3) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

c. The following elements are included in the Falls Aggregated Review Log:

- (1) Case number.
- (2) Age.
- (3) Sex.
- (4) Event (day, date, time).
- (5) OPT or INPT/Unit (designation of outpatient or inpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event).
- (6) Functional and cognitive factors (a listing of factors related to falls, requires a "yes" or "no" response for all applicable items: prior fall; designation as "high risk" for falls; needs assistance with activities of daily living (ADLs) mobility, transfer, toileting, dressing, eating; gait or balance limitations; incontinence; confused or memory limitations; related medical conditions; medication effect, etc.).
- (7) Assistive Devices (a listing of devices related to falls, requires a "yes" or "no" response for all applicable items: cane; crutches; transfer device; walker; wheelchair; bathing device; mechanical lift; eye glasses; hearing aid, etc.).
- (8) Communication Issues (a short list of areas where communication or information exchange can break down, requires a "yes" or "no" response for all applicable items: staff to staff, staff to patient, and staff to family and/or other).
- (9) Environmental Factors (a listing of physical plant issues related to falls, requires a "yes" or "no" response for all applicable items: use of restraints, use of protective devices, inadequate footwear, bed side rails, floor condition, obstacles, fall while the patient was reaching for a needed item, inadequate patient or family or other education, unfamiliarity with the environment, inadequate lighting, and other).
- (10) A free narrative entitled "What Happened and Treatment Plan Changes."
- (11) Comments (free narrative).

NOTE: The current forms of the aggregated review logs can be seen at <http://vaww.ncps.med.va.gov/training/AggRevLog.doc>

3. Adverse Drug Events. The VHA report: "Consensus Report for Nomenclature and Taxonomy of Adverse Drug Events (ADEs)," issued December 27, 2000 defines an ADE as "an injury associated with the use or nonuse of a drug."

a. An individual RCA must be performed for any reported inpatient or outpatient ADE that results in an actual SAC 3, for all patients receiving pharmaceutical care from a Department of Veterans Affairs (VA) health care system provider.

b. Reported ADEs or Close Calls (potential SAC 3 score) involving patients receiving pharmaceutical care from a VA health care system provider will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

c. The following elements are included in the Medication Aggregated Review Log:

- (1) Case number.
- (2) Age.
- (3) Sex.
- (4) Event (day, date, time).
- (5) OPT or INPT/Unit (designation of outpatient or inpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event)
- (6) Processes related to the event (i.e., a listing of key steps in the medication process, requires a "yes" or "no" response for all applicable items: ordering, transcribing, dispensing, administering, and documenting).

(7) What happened? (A listing of ADEs, requires a "yes" or "no" response for all applicable items: medication given despite known allergy, omission, overdose, incorrect patient identification, incorrect medication identification, incorrect dose, incorrect route, incorrect schedule, and equipment failure.)

(8) Medication (name, dose, route, schedule for the correct medication, and the actual and/or Close Call medication).

(9) Treatment plan changes (free narrative).

(10) Comments (free narrative).

NOTE: The current forms of the aggregated review logs can be seen at

<http://vaww.ncps.med.va.gov/training/AggRevLog.doc>

4. Parasuicidal Behaviors. There are two primary categories of suicidal events: completed suicides, and parasuicidal events (any suicidal behavior with or without physical injury [i.e., short of death], including the full-range of known or reported attempts, gestures, and threats).

a. An individual RCA will be performed for any completed inpatient suicide (at the time it occurs) and for any completed outpatient suicide (at the time of facility notification) for all enrolled patients who have received clinic care services from VA. In other words, all actual known suicides of enrolled patients who have received clinic care services from VA must receive an RCA and must be reported in the Patient Safety Information System.

b. All reported parasuicidal events or Close Calls (potential score of three) involving enrolled patients who have received clinic care services from VA will be included in an Aggregated Review on a quarterly basis. The RCA Team will complete this within 45 days after the end of the quarter. These Aggregated Reviews must be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

c. The following elements are included in the Parasuicidal Aggregated Review Log:

(1) Case number.

(2) Age.

(3) Sex.

(4) Event (day, date, time).

(5) OPT or INPT/Unit (designation of outpatient or inpatient status at the time of event, and if inpatient, unit where the patient was assigned at the time of the event).

(6) Date of last OPT TX (date of most recent prior outpatient treatment; this does not include an appointment that was scheduled, but was a "no show").

(7) Diagnoses (a listing of current and active diagnoses).

(8) Tx Team (a short list of treatment team options for providers that were assigned to the patient at the time of the event; requires a "yes"/"no" response for all applicable items: mental health and/or psychiatry, specialty and/or sub-specialty, and primary care).

(9) What happened? (free narrative).

(10) Family and other supports (free narrative).

(11) Treatment plan changes (free narrative).

(12) Comments (free narrative).

NOTE: The current forms of the aggregated review logs can be seen at

<http://vaww.ncps.med.va.gov/training/AggRevLog.doc>

5. Missing Patients. A missing patient is "a high-risk patient who disappears from an inpatient or outpatient treatment area or while under control of VA, such as during transport." A high-risk patient is one who is "incapacitated because of frailty, or physical or mental impairment."

a. An individual RCA must be completed for any missing patient who is classified as an actual 3 using the SAC matrix. All missing patients that receive a SAC potential score of three must be included

in the Aggregated Review on a quarterly basis. The RCA Team must complete the Aggregate Review RCA within 45 days after the end of the quarter. The Aggregated Reviews must be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

b. The following elements are included in the Missing Patient Aggregated Review Log:

- (1) Case number.
- (2) Age.
- (3) Date reported missing (day, date).
- (4) Time reported missing.
- (5) Location reported missing from.
- (6) Length of time missing (days, hours).
- (7) Level of privileges (full, partial, none).
- (8) Previous episodes.
- (9) Order of treatment plan required supervision (Yes or No).
- (10) Primary diagnosis.
- (11) Person notified (name, date, and time).
- (12) Type of search conducted (general, grid).
- (13) Date found.
- (14) Location found.
- (15) Condition (injuries).
- (16) Barriers to prevent escape or elopement.
- (17) Activity at time of elopement or escape

NOTE: The current forms of the aggregated review logs can be seen at <http://vaww.ncps.med.va.gov/training/AggRevLog.doc>

Enterprise Risk Management

Enterprise risk management is recommended as a structured analytical process focusing on identifying and eliminating the portfolio of risks rather than risk avoidance. The portfolio includes:

Domains of operations (organization's systems & practices)

Financial resources (the earning, raising, or accessing of capital and the costs associated with transferring risk)

Human resources (recruitment, maintenance, and management of the workforce)

Strategic direction (the organization's ability to grow and expand)

Legal and technological resources (biomedical, health IT, equipment, and devices)

Using an enterprise-wide approach can help healthcare organizations manage risk. Organizations should also have established mechanisms for reviewing potential incidents of risk and safety concern. All members of the workforce are responsible for identifying, reporting, and documenting risk management and potential quality of care problems that can influence patient safety. Effective strategies for proactively reducing errors and ensuring patient safety require an integrated and coordinated approach to synthesizing knowledge and experience. Staff members should be encouraged to learn about errors and permit internal reporting of information without blame. Healthcare quality professionals should work with enterprise risk management and legal counsel to:

- Improve the effectiveness and efficiency of the organization's processes and operations through consistent identification of risks or threats to the enterprise
- Identify, evaluate and prioritize areas of risk that affect the operations of the organization
- Assess whether the identified risks are caused by internal (controllable) or external (uncontrollable) factors

- Develop and propose comprehensive strategies to minimize risks
- Establish action plans to address problems when identified
- Maintain a periodic evaluation of feedback to monitor the progress of strategies and actions

Risk Management

Risk management is the process of making and carrying out decisions that will minimize the adverse effects of accidental losses. In a climate of professional liability, risk management is important. Risks and their prudent management are viewed as matters of patient safety. Risk management is usually an administrative undertaking intended to protect the financial assets of a healthcare provider in three ways:

- By assuring adequate, appropriate insurance coverage against potential liability
- By reducing liability when untoward events occur
- By preventing those events that are most likely to lead to liability

Goals of risk management include identifying actual or potential causes of patient incidents and implementing programs and procedures to eliminate or reduce those incidents. Risk management efforts provide for and coordinate the collecting of internal and external data on potential risk. Risk management reports the analysis and reviewed findings of actual and potential risk to an entity and its respective departments, programs, and committees. The risk process incorporates the resources of the internal organization, insurance claims, management, legal counsel, external agencies, and databases.

There are similarities between performance/quality improvement and risk management. Poor quality care that creates risk of injury to patients also creates potential financial risks both to the health care practitioners and to health care facilities. Both performance/quality improvement and risk management emphasize identification and resolution of problems in patient care, which requires coordinated performance/quality improvement and risk management activities, and information systems. Both depend on establishing relevant screening criteria, collecting and analyzing data related to those criteria, and correcting problems through improvements in systems and in individual practices. A timely flow of information between performance/quality improvement and risk management will assist with the identification of problems and the evaluation of the success of corrective actions.

Risk management is a decision sequence for:

- Identifying exposures to accidental loss that may interfere with an organization's basic objectives.
- Examining feasible risk management techniques for dealing with these exposures.
- Selecting the apparently best risk management techniques.
- Implementing the chosen risk management technique.
- Monitoring the results of the chosen techniques to ensure that the risk management program remains effective.

The risk management process is both repetitive and self-reinforcing. It is repetitive because past choices of risk management techniques must be continually reevaluated in light of changes in an organization's activities and resulting loss exposures, changes in the relative cost of alternative risk management techniques, changes in legal requirements, and changes in an organization's basic objectives.

Risk identification

The first step in meeting the goals of reducing liability when untoward events do occur and preventing those events that are mostly likely to lead to liability is risk identification, to identify and analyze loss exposures. Identifying means to recognize the possibility of loss and to understand what

accidental losses could occur. Analyze means to estimate the likely significance of these possible losses. The significance increases as the actual losses from the exposure;

- Become more frequent,
- Become more severe,
- Interfere more substantially with an organization's ability to achieve its objectives.

Identifying and analyzing loss exposures is the most important step in the risk management decision process because an unrecognized loss exposure cannot be intelligently managed. Once an exposure has been identified and analyzed, however, the broad outlines of how best to manage it often become immediately apparent. Like any art, exposure identification and analysis requires imagination and insight. Recognizing exposures requires the ability to visualize how particular sets of circumstances may cause both routine and extraordinary accidental losses. To assist in the identification and analysis of loss exposure, the elements of any loss exposure are:

- Value subject to loss
- Peril causing loss
- Financial consequences of the loss
- Entity suffering the loss

To identify areas of risk, an organization's position in relation to licensing and regulatory laws is reviewed, generally by members of the risk management department. Areas of risk can be identified by a review of contractual relationships, particularly the medical staff bylaws, appointment processes, and physician insurance requirements. Other areas of risk include employee benefit plans, occupational exposures faced by employees, and the processes of personnel recruitment, hiring, credentialing, and training.

Information on areas of risk can also be obtained through patient questionnaires. Certain policies, procedures, and protocols can also identify risks and should be reviewed carefully, particularly those dealing with admission and discharge, management and organization, safety and security, equipment and supplies, clinical activities, emergency situations, informed consent, confidentiality, and documentation requirements.

Data Collection

The risk management department should have a process to collect risk management data. This includes liability claims, workers compensation claims, physical malpractice coverage, insured property, incident or event reporting, occurrence screening (identification of potentially adverse events such as unplanned readmissions, code arrests), that are routinely screened by the organization and information from other sources such as patient representatives, performance/quality improvement, and utilization review activities.

Identifying Loss Exposures

In general, most organizations providing health care services face four types of loss exposures:

1. Property
2. Freedom from liability
3. Personnel (life and health of key persons whose special talents are not easily replaced)
4. Net income

Types of perils:

1. Natural (windstorm, earthquake, flood)
2. Human (involving the actions of individuals, i.e. stealing or behaving carelessly)
3. Economic (unemployment or technologic change)

Property losses are most likely to occur because of theft, vandalism, or misuse of equipment and supplies. A liability loss occurs when a legal claim is brought against an institution because of a

corporate or employee-related action that may be perceived as a legal wrong. The financial and legal consequences of those losses will vary depending on the type of legal wrong committed—contractual, tortious, or criminal. The majority of personnel losses involve occupational illnesses, injuries related to improper body mechanics, or isolated accidents such as needle sticks, falls, injury by combative patients, and exposure to infectious disease. Losses in net income consist of either a reduction in revenue or an increase in expenses. Those that occur in relation to risk management often result from property, liability, or personnel losses.

Financial consequences of loss exposures vary with the frequency and severity of actual losses. Less severe losses are usually more frequent than severe losses. Many possible entities such as an organization, its employees, its suppliers, or its customers may be adversely affected by a loss causing event. In identifying and analyzing loss exposures, the organization needs to remain constantly aware of each of these four elements of loss exposure. A change in any element alters the fundamental nature of the exposure and may also change the indicated choice of appropriate risk management techniques.

Exposure identification and analysis is at least as much an art as a science because it relies both on insight and imagination. To aid in the practice of this art, a number of basic methods have been developed to search for loss exposures. These methods are particularly valuable whenever risk management professionals must rely on others to assemble basic exposure information. These methods include: standardized surveys/questionnaires, financial statement analyses, personal inspections, and consultations with experts within and outside the organization.

The risk management process is used basically to assess areas in which claims can be prevented. This process includes the identification, analysis, and treatment of risks.

Incident Reporting and Review

Data from incident reports can be used to identify patient care problems. The incident report form typically includes information about the person involved in an incident, the type of incident, the time and location of the incident, any hazards associated with the incident, treatment provided, and the outcome of the incident. A tracking mechanism for incident reports should be in place. Corrective action for an incident includes immediate care of the patient, and instructions to any health care provider involved. There should be an objective assessment of the problem's cause and scope. This problem assessment is followed by comprehensive corrective actions to reduce the possibility of similar incidents in the future. For example, guidelines may be developed, or changes made in policies, procedures, and equipment. The report is also referred to the appropriate organization mechanism for analysis and corrective action; i.e., safety incidents referred to the safety committee. In addition to the immediate review of an incident report, incidents should be summarized and analyzed, with conclusions drawn, and recommendations and corrective actions developed, with follow up on the results of the effectiveness of the corrective actions as part of the performance/quality improvement program.

Specific types of incidents often include patient falls and injury to patients' skin. A fall risk assessment program should be part of risk identification activities for organizations that have patient falls. The program involves developing policies and procedures for classifying patients according to the risk of falls. There is generally a protocol designed to guide classification of patients into levels of risk. Different levels of risk may be associated with different mandatory safety precautions. The higher the patient's classification, the greater the safety precautions to be implemented. Fall risk programs have built-in monitoring mechanisms as part of the performance/quality improvement program. Another area of risk involves skin integrity. Skin integrity risk assessment programs also identify patients at risk.

The most common loss exposures include:

- Criminal acts by employees
- Breach of contract
- Patient harm related to inability of contractors to perform services
- Clinical treatment by qualified or unqualified staff

- Improper utilization of equipment by staff, patients, or family
- Inappropriate discharge
- Falls
- Medication errors
- Civil assault and battery (lack of consent)
- Invasion of privacy (disclosure of confidential information)
- Problems with employer-employee relations
- Failure to meet regulatory or licensure requirements
- Restraint of competition (antitrust issues)
- Medicare or Medicaid fraud

Loss Prevention

Loss prevention deals with reducing the frequency of a particular loss or preventing the loss from occurring. Loss prevention techniques include:

- Developing clear, concise and legal staff bylaws
- Developing a clear, concise physician appointment process
- Setting appropriate physician insurance requirements
- Strengthening personnel recruitment, hiring, credentialing, and orientation and training practices
- Clearly defining the scope of services offered
- Developing specific criteria for referral, admission, and discharge
- Establishing policies and procedures related to employer-employee relations
- Developing strategies to promote professional growth
- Strengthening safety and security practices
- Educating employees with regard to personal safety and security
- Establishing clear practice standards with related policies, procedures, and protocols (particularly for documentation requirements, informed consent, confidentiality, and emergency situations)
- Establishing communication channels with appropriate backup systems
- Establishing a comprehensive biomedical preventive maintenance program that includes equipment utilization inservice for all employees, patients, and families
- Strengthening the patient education program
- Developing or strengthening performance/quality improvement and utilization management programs, including peer review of performance
- Testing equipment regularly
- Keeping routine maintenance records
- Maintaining periodic performance evaluations
- Requiring prompt notification of any problems
- Maintaining prompt, complete, accurate recording of data in patients' charts
- Offering staff development programs

Informed Consent

One of the most common methods of loss prevention is the use of informed consent. The requirement for informed consent in health care is based on the tort law of assault and battery. A battery consists of the touching of a first person by a second person or by any substance put in motion by the second person. The physician or other health professional performing any procedure that involves touching a patient should first obtain permission. The patient's understanding for informed consent is based on adequate information about his or her disease or condition, recommended therapy, available alternatives, and collateral risk. A signed consent form is evidence that the patient's informed consent has

been obtained. The purpose of this form is to provide evidence that the patient received all the information necessary from the physician or health care provider performing the procedure to make a considered decision about the course of treatment. The physician or other health care provider must obtain the patient's consent before he is legally entitled to commence treatment.

Loss Reduction

Loss reduction aims to lower the severity of a particular loss either before the loss occurred or after. This is accomplished through programs such as claims management and resource preservation. The following are loss reduction techniques:

- Utilizing outcome screens or reviews concurrently
- Implementing incident or occurrence screening reporting systems
- Developing patient-relations and advocacy programs
- Concurrently reviewing all documentation
- Establishing comprehensive claims management systems
- Developing and adhering to strict equipment or supplies recall programs
- Developing crisis intervention plans
- Documenting all medical staff appointments and recredentialing activities
- Documenting personnel recruitment, hiring, credentialing, and training practices
- Documenting employee evaluations that are based on performance criteria
- Establishing and documenting employee grievance procedures

Steps for Proactive Risk Reduction

- Identify a high risk process
 - Identified in the literature as high risk
 - Has characteristics of high risk processes
 - New process
 - Proposed redesign
- Flow chart process
- Assess the actual implementation of the process (different locations, shifts)
- Identify where there is, or may be, variation in the implementation of the process, i.e., what are the failure modes?
- For each identified failure mode, what are the possible effects?
- Assess the criticality of the possible effects (e.g., delay in treatment, temporary loss of function, patient death)
- For the most critical effects, conduct a root cause analysis to determine why the variation (the failure mode) leading to that effect occurs
- Redesign the process and/or underlying systems to minimize the risk of that failure mode or to protect the patient from the effects of that failure mode
- Conduct a failure mode and effects analysis on the redesigned process with special attention to how the redesigned steps will affect other steps in the process and whether they will continue to do the beneficial things that the previous design could do
- Consider simulation testing of the redesigned process
- Consider a pilot test of the redesigned process
- Identify and implement measures of the effectiveness of the redesigned process
- Implement a strategy for maintaining the effectiveness of the redesigned process over time

Risk avoidance includes avoiding high risks, such as high risk obstetrics services.

Risk financing describes methods, such as general liability and professional liability insurance, of paying for losses.

Risk evaluation is an ongoing evaluation of all risk management systems in the institution, such as incident or other types of event reporting; review of medical staff involvement, policies, and procedures; staff education; and organizationwide communications.

Risk Education

All staff should be educated about risks. Education programs related to risk management should contain information about legal aspects of healthcare, errors such as medication errors, patient confidentiality, and liability. All employees should have detailed risk management handbooks that include policy statements, legal forms, documents, opinions on key topics, a manual on informed consent, a guide to risk prevention for health care providers, and guidelines on reporting and resolving claims.

Patient Education

Much can be done to better inform patients about the benefits and risks associated with clinical services and programs. Generating more realistic consumer expectations will turn defensive claims prevention into loss prevention activities that directly involve the consumer in evaluating critical issues of potential risk and loss.

Successful risk management depends on early intervention, prevention, and use of available resources. Risk management is an organization-wide effort that increases awareness of the importance of prevention.

Sentinel/Unexpected Event Review

Accrediting bodies are concerned with sentinel events. Joint Commission views the current climate favoring self reporting of medical errors to learn about the relative frequencies and underlying causes of sentinel events, share lessons learned with other health care organizations, and reduce the risk of future sentinel event occurrences.

The Joint Commission's definition of a sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries specifically include a loss of limb or function. The risk thereof includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Any time a sentinel event occurs, the accredited organization is expected to complete a thorough and credible root cause analysis, implement improvements to reduce risk and monitor the effectiveness of those improvements. While the immediate cause of most sentinel events is human fallibility, the root cause analysis is expected to dig down to underlying organization systems and processes that can be altered to reduce the likelihood of human error in the future and to protect patients from harm when human error does occur.

Sentinel events may be subject to review by accrediting organizations. The Joint Commission only requires that only those sentinel events that affect recipients of care (patients, clients, residents) and that meet one of the following criteria are subject to review and may be reported on a voluntary basis. The criteria include:

- Event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition; or
- Event is one of the following (even if the outcome was not death or major permanent loss of function)
 - a. suicide of a patient in a setting where the patient receives round the clock care (hospital, residential treatment center, crisis stabilization center)
 - b. infant abduction or discharge to the wrong family
 - c. rape

- d. hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
- e. surgery on the wrong patient or body part

The Joint Commission requires a root cause analysis (RCA) for every sentinel event, whether it meets the above criteria or not; but the RCA doesn't have to be made available to the Joint commission.

A sentinel event or near miss is compelling. A response is demanded, driven in some cases by guilt, shame, or fear of retribution, in others, by a need to understand and fix. That response can be limited to the placement of blame and removal of the offending party, or, through the process of root cause analysis, can achieve an understanding of the factors that enabled the event to occur, and may lead to process redesign to reduce the risk of that type of event in the future. The best root cause analyses look not only at the factors surrounding the specific event, but at the entire process that was involved and its support systems, with the goal to minimize overall risk associated with that process, not just the risk of that specific type of event.

Sentinel events:

- Blood transfusion errors
- Concentrated KCL
- Fatal falls
- Infant abductions
- Infusion pumps
- Inpatient suicides
- Medication errors
- Operative and postoperative complications
- Restraint deaths
- Wrong site surgery

A process is a systematic series of actions directed to some end. A process is made up of actions or steps and their sequence, as well as how the parts interact, how the function of the process is affected. The parts work together to produce the desired effect. Characteristics of risk-prone processes:

- Variable input
- Complexity
- Inconsistency
- Tight coupling
- Human intervention
- Tight time constraints
- Hierarchical culture

Root Cause Analysis

Existing conditions lead to disastrous events. With patient safety an important focus in healthcare, the focus is placed on performance improvement to correct process failures and inadequate systems. The key is not to wait for a disaster but to redesign the process and system. The goal is to learn from experience and incorporate patient safety measures in order to prevent future failures. All events provide a learning opportunity, even those that do not produce a negative outcome. The integration of these concepts ensure an effective incident investigation and root cause analysis (RCA).

RCA has been used by other industries and has become part of a risk management tool in several formats. RCA is a way of looking at unexpected events and outcomes in order to determine all of the underlying causes of the events and recommend changes that are likely to improve the outcomes. Not all

events require TCA; its applicability depends on the severity and outcome of the event, as well as organization policy. However, if the healthcare quality professional determines that one is needed, chartering the RCA team would be the initial step. The team would define the scope of the investigation, identify the team members, establish the expectations and responsibilities of the team, determine the timeline for completion, and identify needed resources such as medical records, reports, or a literature review. After a team has been established, the RCA process can begin.

Root cause analysis is a technique used in determining the real cause of an event. Root cause analysis is also an important process for preventing near misses as well. Root cause analysis techniques are most often used in the reactive mode, to uncover the reason for problems that already have occurred. Root causes of problems must be clearly identified and addressed for any real improvement to occur. The root causes of current problems should also be considered when any changes are planned, to ensure that the same problems don't occur with the new systems. Learning from mistakes is a hard way to learn, but continuing to make the same mistakes is much riskier and certainly more costly. Healthcare professionals learn from mistakes only when they have some clear idea of why the mistake happened in the first place. Most errors occur from faulty systems rather than from human error. Poorly designed processes put people in situations in which errors are more likely to be made. Finding the real reason for the problem is the primary objective of root cause analysis. It is important to distinguish between the primary or root cause and the contributing causes to develop the corrective actions necessary to prevent the problem from recurring. A variety of tools can be used in the root cause analysis process. If the problematic situation is not thoroughly investigated, correction action that is taken may not eliminate or alleviate the problem, and waste valuable time and other resources.

Root cause is a process for identifying the most basic or causal factor or factors that underlie variation in performance. A root cause analysis identifies changes that could be made in systems and processes either through redesign or development of new systems or processes that would improve the level of performance and reduce the risk of a particular adverse event occurring in the future. Root cause analysis focuses primarily on systems and processes, not individual performance. The analysis progresses from special causes in clinical processes to common causes in organizational processes. The analysis repeatedly digs deeper by asking "Why" questions until no additional logical answer can be identified.

Root cause analysis techniques tend to prevent partial or incomplete solutions by examining completely the basic cause of a problem. Determining root cause usually requires thorough review and examination of the entire event. Root cause analysis requires personnel who are able to explore an issue and recognize when the most basic reason has been identified. Many root cause analyses fail because the personnel assigned the duties are unable to interpret data correctly, lack training in the techniques, or do not have the needed technical or operations experience. Program, operations, or system evaluations require staff with the knowledge, skill, and ability to effectively analyze complex system performance.

Root cause analysis can be an effective management tool for finding the true or actual cause of events, facilitating corrective action, and preventing recurrence. The usual inference is that management is somehow more responsible. The strong support of upper management is crucial to the success of root cause analyses being performed correctly. The results of any root cause analyses should be used for improving situations, not for assigning blame. Assigning blame to an individual who makes an error is not assurance that the same error will not be made again by a different person. Whenever human error is expected, it's important to trace the error to its root cause. The prevention and correction of problems is everyone's responsibility.

After the team has been identified, the next phases in the development and implementation of an effective root cause analysis program include the following:

- Setting up appropriate reporting mechanisms
- Defining criteria for problem selection
- Selecting individuals to conduct the analysis
- Selecting analysis techniques that will be used to identify and correct the root cause

Using Incident Investigations to Improve Patient Safety

Healthcare organizations have been performing root cause analysis investigations following a sentinel event, but sentinel events are still occurring. Hospitals are experiencing repeat events involving the same problematic process that was supposedly already fixed. Senior leaders must address the fundamental problems that limit the value of incident investigations.

- Find and resolve latent conditions as well as root causes

In the investigation of the 2003 Columbia Space Shuttle disaster, NASA discovered the cause to be an engineering defect. But the root cause analysis didn't end at that point. By questioning why this situation was allowed to exist, defects in the safety culture were discovered. Schedule pressures created strong incentives for people to disregard concerns and move forward with the launch. This latent condition would lead to more disasters if not resolved. Healthcare organizations must also dig more deeply to discover the problematic latent conditions. If the underlying factors that contribute to unsafe conditions are not resolved, patients will still be at risk of harm.

- Treat the cause rather than try to change people

Process redesigns are the strongest actions for eliminating unsafe conditions at the front lines. Often RCA actions are aimed at changing people's behavior through interventions such as retraining, memory aids or reminder memos. These may be the easiest actions to implement but they are the least effective. RCA teams must understand the process that needs changing and design more effective systems-based solutions.

- Get rid of the "oh wells"

Leaders must personally be engaged during the follow through phase of the RCA to prevent recurrence of adverse events. Do not let RCA action plans disappear into the woodwork. Senior leaders must hold process owners accountable for fulfilling their commitments, and if barriers exist, leaders should help clear those barriers. Use rapid cycle PDSA tests of process redesign and respond immediately if safety improvement interventions don't work out as expected. Encourage caregivers to relentlessly seek solutions.

Setting up reporting mechanisms

Organizations need methods to receive information about what is being done correctly or incorrectly or has opportunity for improvement. A problem or deficiency reporting system needs to be designed to be usable. Start simple and keep it that way, unless it isn't providing most of the necessary information. Computer programs may not provide all the necessary information. Patient satisfaction surveys or patient inquiries can provide insight into areas of potential or real problems before they occur. The time honored system of management of walking around can be a useful method for finding out what is happening in the organization. In areas needing attention, employees are a reliable source of information.

Identifying criteria for problem selection

These criteria are determined by the organization, and may be mandated by government or accrediting organizations.

Selecting problems for analysis

Based on previous root cause analyses, a pattern may occur. The same root cause may have precipitated other problems, which might then need to be addressed proactively to prevent similar events in the future.

Selecting analysis techniques

Selection of techniques that will be used is based on the specific problem to be analyzed. The amount of data needed to form accurate, defensible solutions will vary according to the problem and its

consequences. Statistical and nonstatistical tools can both be used in the analysis, i.e., cause and effect diagrams, Pareto chart, etc.

Collecting the right amount of the proper data increases with experience. Other techniques used in root cause analysis include brainstorming to obtain free flowing ideas about the cause of the event, flow charting to visualize the process leading to the event, and scatter diagrams to show the correlation between two variables.

Root Cause Analysis: A root cause analysis should have the following acceptable characteristics:

- Analysis focuses primarily on systems and processes, not individual performance
- Analysis progresses from special causes in clinical processes to common causes in organizational processes
- Analysis repeatedly digs deeper by asking “Why?”; then, when answered, “Why?” again, etc.
- Analysis identifies changes which could be made in systems and processes, either through redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future
- Analysis is thorough and credible

Root Cause Analysis Process

- Investigate events—Define the problem, collect pertinent evidence, conduct interviews, review event environment, determine contributing factors, and establish a chain of events.
- Reconstruct events—Define events preceding the adverse event or near miss, determine actions and conditions leading up to these events by developing a causal tree, and continue until you have identified underlying systems causes or until it is unreasonable to go any further.
- Analyze causes—Identify root causes within your causal tree and develop root-cause statements.
- Develop action plans—Identify strategies that are appropriate to the causes identified and acceptable to the organization and to those who will be involved in the change; develop a plan for addressing each root cause and for measuring the effectiveness of your intervention, and gain agreement from organizational leadership regarding actions to be taken.
- Report RCA processes and findings—Record the process and tools used, the cost of the process, a summary of the events, the investigation and analysis process, and findings.

To be thorough, a root cause analysis must include:

- A determination of the human and other factors most directly associated with the event, and the processes and systems related to its occurrence
- Analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk
- Inquiry into all areas appropriate to the specific type of event
- Identification of risk points and their potential contributions to this type of event
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist

To be credible, a root cause analysis must

- Include participation by leadership of the organization and by individuals most closely involved in the processes and systems under review
- Be internally consistent, i.e., not contradict itself or leave obvious questions unanswered
- Provide an explanation for all findings of not applicable or not a problem
- Include consideration of any relevant literature

The associated action plan should:

- Identify changes that can be implemented to reduce risk, or formulate a rationale for not undertaking such changes
- Identify who is responsible for implementation of planned actions, when the action will be implemented, including pilot testing, and how the effectiveness of the actions will be evaluated

Sample Root Cause Analysis

What happened? (Sentinel event)

What are the details of the event?

When did the event occur?

What area of service was impacted?

Why did it happen?

What were the most proximate factors?

Common cause or special cause variation?

What is the process or activity in which the event occurred?

What are the steps in the process as designed?

What steps were involved in/contributed to the event?

Human factors?

What human factors were relevant to the outcome?

Equipment factors?

How did the equipment performance affect the outcome?

Controllable environmental factors?

What factors directly affected the outcome?

Uncontrollable external factors?

Are they truly beyond the organization's control?

Other?

Are there any other factors that have directly influenced this outcome?

Why did that happen?

What systems and processes underlie those proximate causes?

Human resource issues: To what degree are staff properly qualified and currently competent for their responsibilities?

How did actual staffing compare with ideal levels?

What are the plans for dealing with contingencies that would tend to reduce effective staffing levels?

To what degree is staff performance in the operant processes addressed?

How can orientation and inservice training be improved?

Information management issues: To what degree is all necessary information available when needed?

Accurate?

Complete?

Unambiguous?

To what degree is communication among participants adequate?

Environmental management issues: To what degree was the physical environment appropriate for the processes being carried out?

What systems are in place to identify environmental risks?

What emergency and failure-mode responses have been planned and tested?

Leadership issues/corporate culture: To what degree is the culture conducive to risk identification and reduction?

Encouragement of communication: What are the barriers to communication of potential risk factors?

Clear communication of priorities: To what degree is the prevention of adverse outcomes communicated as a high priority?

How?

Uncontrollable factors: What can be done to protect against the effects of these uncontrollable factors?

A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. A particular root cause should be considered for an action and addressed in an action plan.

Ask why to find out why a particular finding occurred or didn't occur when it should have. Take action for any finding that can be considered a risk reduction strategy. For each of the findings identified in the analysis as needing an action, indicate the planned action, expected implementation date, and associated measure of effectiveness, or if after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time. If action is taken, check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action. Consider whether pilot testing of a planned improvement should be conducted. Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.

An effective root cause analysis system involves more than the application of analysis techniques. It involves the definition of the problem, gathering of appropriate information, development of potential solutions or changes, implementation of system improvements, process improvements, or both, and subsequent evaluation of these solutions. Adequate follow up and monitoring of changes to policy and procedures ensure appropriate implementation and the effective use of resources.

Selecting Events for Investigation

A scale for rating the severity of events aids in the selection of events for investigation. Catastrophic events like an unexpected death, permanent damage, or loss of function have a higher severity rating than a patient's receiving a wrong treatment and recovering without harm. For example, the Department of Veteran's Affairs uses a severity assessment code (SAC). An RCA is performed for any event with an SAC of 3 or above.

Understanding the Causes of Events

An effective investigation can be achieved when barriers to understanding what causes an event (such as reacting to failure with a judgmental attitude, stopping too soon in the investigation, or believing that there is only one root cause) are eliminated. Attention must also be given to the human factors and human errors involved in the development of an event. Human beings contribute to the breakdown of systems in two ways. One way, an active failure, is an intentional violation committed by an individual. The other, a latent condition, is a breakdown in processes or systems such as a lack of education, the failure to follow a procedure, an equipment defect, or a poor design.

Human error is not the cause of events; it is a symptom of deeper troubles in the system.

Human error is not the conclusion of an investigation; it is the beginning.

Events are the result of multiple causes.

By understanding that active failures and latent conditions are components of root causes, correction action with system redesign can be implemented as a means of reducing risk.

Human Factors—concerned with understanding and enhancing human performance in the workplace, especially in complex systems.

“Our systems are too complex to expect merely extraordinary people to perform perfectly 100% of the time. We as leaders have a responsibility to put in place systems to support safe practice.” IHI

Slips—things we do automatically without thinking

Lapses—a failure to remember a task

Mistakes—an error in judgment; decision based

- Inattention to detail
 - Unawareness-not paying attention to alarms, signals, precautions or information
 - Perceived pressure to complete task
 - Task too complex
 - On the job distraction

- Misjudgment
 - Cognitive overload-high volume of irrelevant information
 - Habit intrusion-performing tasks based on past experience without fully understanding current situation
 - Spatial misorientation-performing tasks on wrong system
 - Mindset-decision making without seeking facts
 - Wrong assumptions
 - Lack of information validation or verification
 - Misinterpretation of information
- Committed actions not carried out
 - Shortcuts evoked
 - Task too complex
 - Inappropriate order
 - On the job distraction
 - Inadequate tracking
- Inadequate skills or knowledge
 - Tunnel vision
 - Inadequate training
 - Not familiar with job performance standards
 - Not familiar with task
 - Not familiar with availability of information
- Inadequate mental state to complete task
 - Boredom
 - Lapse of memory
 - Reflex
 - Fear of failure
 - Illness, fatigue, injury, sickness
 - Overconfidence
 - Inadequate motivation

One of the basic goals of an investigation is to understand why people make certain decisions that cause an event. To do this successfully, all investigations must be performed methodically within the RCA process.

- Define the problem. What happened, when did the event occur, where did it occur, and what was the significance of the event in regard to patient harm or organizational liability?
- Collect pertinent data related to the event.
- Reduce any barriers that may hinder the investigation.
- Consider who should be interviewed, and prepare for interviews as soon as possible.
 - Clarify what happened versus what should have happened
 - Identify differences between the incident and previous successful completions of the same task/process
 - Identify barriers that were present and those that failed
 - Identify behaviors that met/did not meet standards of expectations
 - Identify interviewee's exact involvement, perspective on conditions/behaviors, and influence or modification from normal events and cause
- Develop questions to ask without putting pressure on the interviewee and without blame or reprisal.

- Review the involved individual's environment and the task that he or she was performing prior to the event.
- Evaluate the organizational norms affecting the individual's behavior.
- Review the organizational policies and procedures.

Improvement Strategy Checklist

- The strategy should be practical, cost effective, and based in reality.
- Actions should be supported by evidence.
- Internal and external requirements must be met.
- All factors must be considered (human, technological, etc.)
- Consider the impact to other systems or areas.
- Consult key stakeholders and involve them in development.
- Assign accountabilities.
- Develop interim milestones and target dates.
- Identify measures of effectiveness.

Root Cause Analysis Examples

Challenger disaster <http://www.gpo.gov/fdsys/pkg/GPO-CRPT-99hrpt1016/pdf/GPO-CRPT-99hrpt1016.pdf>

<http://dssresources.com/casesspaceshuttlechallenger/index.html>

Columbia Disaster http://www.nasa.gov/columbia/home/CAIB_Voll.html

Texas A&M Bonfire Collapse <http://archive.theeagle.com/bonfire/storyarchive/may2000/Final.pdf>

Failure Modes and Effects Analysis (FMEA)

Failure Modes and Effects Analysis is one of many analytical tools that are part of the broad management practice of system safety. FMEA was used as a tool in the aerospace industry in the 1960's and has been a key safety tool in the chemical process industries. System-safety processes aim to identify, assess, and control risks, or hazards before they cause harm. FMEA has recently been applied in the healthcare environment. FMEA is a proactive analysis tool used to reduce the likelihood or prevent poor outcomes or events.

FMEA is a powerful technique that offers a systematic way of examining a process prospectively for possible ways in which failure can occur and then redesigning the process to eliminate the possibility of the failure, stop the failure before it harms an individual, or minimize the consequences of the failure. FMEA has been a tool of industry outlining flaws in process flows. FMEAs are ideally completed when a new system or redesign of a system is in the early stages of development, but can also be used on existing processes or systems.

Cultural change, technical system enhancement, and applied process redesign are essential for protecting individuals receiving care in an organization. Process design for safety practices reduces the risk of failure. It recognizes that even with good preventive design, some failures will occur. However, the design should prevent the failure from reaching the individual and should mitigate the effects of those failures that do reach the patient.

Reforms or improvement actions are not easy to implement, yet their effectiveness as strategies to reduce risk has been proven in many industries other than health care. Failure mode and effects analysis is a straightforward, common sense approach to safety.

For each known or potential failure identified, an analysis is completed to determine the following:

The way the process/subprocess step may fail to function or

The manner in which the failure occurs (failure mode)

The effect of the failure mode
An estimate of the severity and probability for each mode-effect combination on healthcare or services
Evaluation of the actions that could be taken to reduce or eliminate the failure risk

FMEA: Failure modes and effects analysis, a systematic method of identifying and preventing product and process failures before they occur.

Failure (F): When a system or part of a system performs in a way that is not intended or desirable; the inability to function in a desired manner.

Mode (M): The way or manner in which something, such as a failure, can happen. Failure mode is the manner in which something can fail, the way in which failure occurs.

Effects (E): The results or consequences of a failure.

Likelihood or probability of harm; how likely the harm is to occur during an exposure interval.

Exposure Interval: A period of time for evaluation.

Severity of Harm: How serious the effects or harm would be if a given failure did occur. This estimation should be for the worst credible harm, a reasonable worst case, not the worse conceivable.

Risk Assessment: Risk is an expression of the degree of threat posed by a hazard. Risk can be defined as high, medium, or low. Risk is based on probability of harm and severity of harm, and guides team actions. A high risk code provides guidance for prompt action to suppress either the probability or severity of the risk, which may include the decision not to act, while a low risk code may prompt continued operations with long term tracking of the issue.

Hazard: An activity or condition posing threat of harm.

Countermeasures: Improvement or corrective actions to decrease the probability or severity of the risk.

Analysis (A): The detailed examination of the elements or structure of a process.

To perform FMEA:

- Identify each step in a process or sub-process and the relationships between process steps
- Identify potential failures involved in each process step in terms of failure modes or symptoms
- For each failure mode, study the effect on the total process, and also examine the interrelationships between the process under study and other processes that could be affected by change
- When potential effects are intolerable, devise and implement actions to eliminate the possibility of error, stop an error before it reaches people, or minimize the consequences of an error
- Then review and revise, as necessary, the action or actions being taken or planned to minimize the probability or effect of failure.

FMEA can be used to improve many types of processes or sub-processes. Almost any health care process or sub-process could benefit from FMEA, but in practice, no health care organization has the time or resources to use this technique with all processes occurring within the organization. Organizations leaders should focus on high risk processes. In high risk processes, a failure of some type is most likely to jeopardize the safety of the individuals served by the organization. How do leaders know which processes are high risk? The experience of the organization can signal a high risk process. High risk processes are known to be associated with sentinel events in health care organizations that provide similar services and care.

Processes benefiting from FMEA may be new to the organization or they may already exist and potentially cause problems. You can single out a sub-process or analyze the entire process through FMEA. Organizations might choose to use FMEA on the medication use process, or a number of sub-

processes, such as review of the dispensed medication and order by the nurses, assessment of the individual prior to administering, or the actual administering by the nurse. You can use FMEA proactively either before a new process is put into place or before a redesigned process goes live.

FMEA Process

1. Define the FMEA boundaries. Describe the process and its boundaries. Define individual and team responsibilities.
 - What processes occurring within the organization are high risk ones that are likely to impact the safety of individuals served by the organization? FMEA may be applied to issues reported at other medical centers, issues identified by regulatory or accreditation bodies, near misses, or high risk areas of healthcare delivery. Projects should be prioritized to clearly align with the organization's key business strategies. Leadership sponsorship is critical to FMEA project success. Resources must be allocated for team members to participate and for any actions required.
 - What sources can we use to identify such high risk processes?
 - What process is our first pick for FMEA and why?
2. Assemble the FMEA team. Assign the team leader and ensure adequate team make up
 - Who should be on the FMEA team? What role should each individual play? FMEA is a team function; it is not carried out by one individual. The purpose of the FMEA team is to bring a variety of perspectives and experiences on the project. FMEA teams are specifically designed for an individual project, are cross functional, and multidisciplinary. A team leader who understands FMEA will need to be assigned to coordinate the team. The team leader must possess excellent team facilitation skills. Team membership must include people who know the process best.
 - What training is needed to educate all team members about FMEA, additional performance improvement tools and techniques, and the process under study? Just in time training will be needed for the team members.
 - What is the scope of the FMEA? Define the boundaries. The FMEA leadership sponsors and the FMEA team leader work together to determine which aspects of the FMEA the team is responsible for. The process also needs to be clarified if the team needs to expand beyond these boundaries.
3. Review the process. Diagram/flowchart the process. Number process and subprocess steps.
 - What are the steps in the process? If an existing process, how does it currently occur and how should it occur? If a new process, how should it occur? Each step should be numbered consecutively to help identify the step with the work done. If the project is too complex, the scope must be narrowed to include only part or the process.
 - How are the steps interrelated? For example, are they sequential or do they occur simultaneously?
 - How is the process related to other health care processes?
 - What tools should we use to diagram the process?
4. Brainstorm potential failure modes and determine their effects. Brainstorming should include a review related to categories such as people, methods, equipment, materials, and the process environment, and also a consideration of policies and procedures. Other categories may be substituted according to project needs. Focusing on each of the categories will result in a more thorough list of potential failure modes. Determine all the ways each process/subprocess step could fail.
 - Which steps in the process or linkages between steps could fail?
 - What can go wrong with each step? (Examine each element of the process, including people, materials, equipment, methods, and environment)
 - What could happen if this failure mode occurred? What might the effects be?
 - What other processes or steps might be affected?
5. Prioritize failure modes
 - What is the likelihood that this failure would occur?

- What is the likelihood that the effects of the failure mode will reach an individual receiving care or services?
 - If this failure mode occurred, how severe would the effect be?
 - If this failure mode occurred, how likely is it that it would not be detected?
 - What system or tool should we use to prioritize and document prioritization of failure modes?
6. Identify root causes of failure modes. Determining potential causes of each failure mode is one of the most important steps of the FMEA. Causes can provide insight into the probability of failure and direct the team toward prevention and/or corrective actions. The more focused on the causes the FMEA is, the more successful the team will be in eliminating potential failure.
- What most likely could cause each failure mode? (What are the possible proximate causes and possible root causes?)
 - Might the possible root causes be due to human resource issues, information management issues, environmental management issues, or leadership and communication issues, among others?
 - How do we know whether we have identified all possible root causes?
 - How are the possible root causes related?
 - Would the potential failure mode occur if each possible cause were not present?
 - Will correction or elimination of the possible root cause prevent the potential failure mode's recurrence?
7. List potential effects on the patient.
- For each failure mode, identify potential effects. The effect is the outcome.
 - What happens when a failure occurs?
 - What are the consequences?
 - If this happens, then what happens? The effects can be localized or isolated (doesn't affect anything else or global (affects other functions or components). Global effects are generally more serious than isolated affects. For some of the failure modes, there may be only one effect, although there may be several effects for other failure modes.
8. Assign risk codes. The team evaluates the severity and likelihood of each failure mode-effect combination on the process of care. This step attempts to assign risk codes to all potential failure mode-effect combinations so they may be prioritized for actions or countermeasures to reduce or eliminate them.
- Assign a risk code from the risk matrix to each potential failure-mode effect combination.
 - As likely or probability requires an exposure interval to be decided. It may be easiest to think of a period of one year when thinking about the likelihood of harm. Likelihood of harm is the probability of this failure occurring during an exposure interval. Defining an exposure interval may be done in many ways, generally one year is used. Severity of harm is an estimation of how serious the effects or harm would be if a given failure does occur. In some cases severity of harm is clear based on past experience. In other cases, it is necessary to estimate the severity of a failure mode based on the knowledge & expertise of team members. Because each failure may have several different effects and each effect can have a different level of severity, it is the effect, not the failure, that is rated. The team should determine the likelihood of the worst credible outcome and the worst credible severity of harm. Worst credible is a reasonable worst case, not the worse conceivable case.
 - Review rating descriptions prior to rating so all team members have the same understanding of the definitions. Team should complete the rating for each failure mode identified, being careful to note that the scale is addressing the specific mode or effect, not the outcome of the entire process or product. The risk code is used to prioritize corrective actions or countermeasures to eliminate or reduce the potential failure modes. A high risk code provides guidance for prompt action to suppress either the probability or severity of the risk, while a low risk code may prompt continued operations with long-term tracking of the issue.

9. Develop actions of countermeasures to reduce risk. Identify countermeasures to reduce or eliminate the risk associated with the failure mode. Redesign the process

- How can we change the process to prevent this failure mode from occurring?
- What design/redesign strategies and tools should we use? How do we evaluate their likely success?
- Who should be involved in the design/redesign process? The team identifies feasible actions to eliminate or reduce the high risk failure modes. The team may want to prioritize, for action plan development, those effects that create the highest risk for patients. Although eliminating a failure mode is ideal, it may not be achievable.

10. Reassign risk codes. For each recommended action, the team determines what the risk code becomes after the planned actions have been implemented. Residual risk scores help the team examine the planned actions carefully to determine whether additional actions should be developed.

- With each recommended action, determine what the risk code would become after implementation, called residual risk.
- This code will assist in prioritizing actions and monitoring to determine if the actions were effective in reducing risk.

11. Assign responsibility for actions. Using the FMEA charter, the team determines whether the FMEA team or another group will be responsible for implementing the proposed actions or countermeasures. It is important to assign responsibility and project the completion date. Analyze and test the new process

- How will we measure if the change is successful in preventing future failure? What will be measured, by whom, and with what frequency?
- What strategy should we use to test the new process?

12. Monitor the actions and risk reduction. Implement and monitor the redesigned process. After the actions are implemented, the team or group assigned accountability for the actions should continue to document the FMEA actions as part of the FMEA documentation. The monitoring plan should include data to aid evaluation of the result of actions or determine whether new risks have been introduced with process changes. Staff members must evaluate whether the risk reduction strategies have actually reduced the failure mode to the predicted risk level and have not introduced new risks.

- How will the new process be implemented?
- How will the new process be monitored? What monitoring tools will we use?
- How is the new or revised process working?
- What modifications need to be made and why?
- What additional actions made need to be taken to further reduce risk?

Healthcare FMEA (HFMEA, Veterans Affairs)

Healthcare FMEA is a prospective assessment that identifies and improve steps in a process thereby reasonably assuring a safe and clinically desirable outcome. It is also a systematic approach to identify and prevent product and process problems before they occur. It is a concurrent review of a process to determine areas of inefficiency, improving the performance of existing processes and improving outcomes for the organization.

Step 1: Define the HFMEA topic. Define the topic of the healthcare FMEA along with a clear definition of the process to be studied.

Step 2: Assemble the team. The team is to be multidisciplinary including Subject Matter Experts and an advisor.

Step 3: Graphically describe the process.

- A. Develop and verify the flow diagram (this is a process vs. chronological diagram).
- B. Consecutively number each process step identified in the process flow diagram.
- C. If the process is complex, identify the area of the process to focus on (take manageable bites).

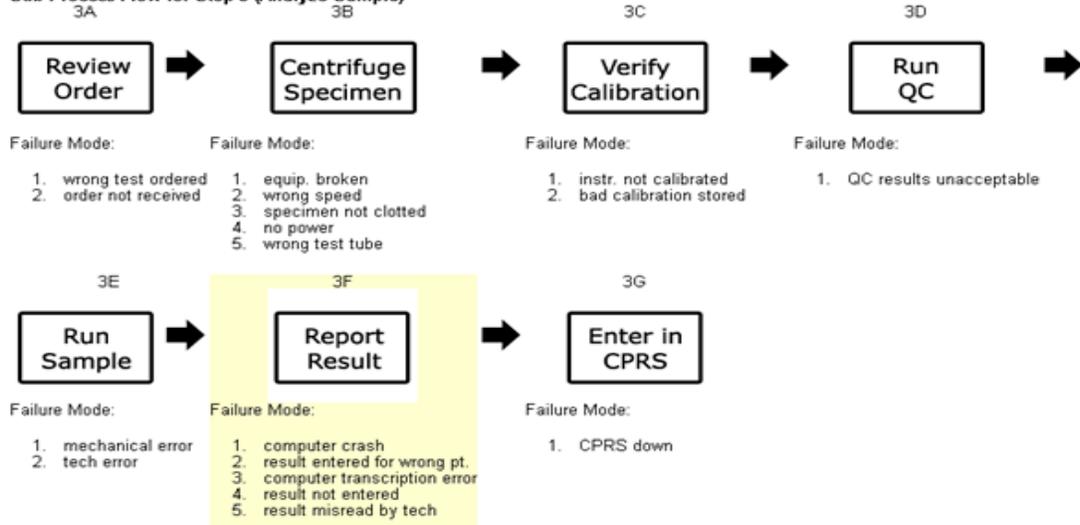
- D. Identify all sub-processes under each block of this flow diagram. Consecutively letter these sub-steps (i.e., 1a, 1b, 1c...3e, etc.).
- E. Create a flow diagram composed of the sub-processes. Consecutively letter these sub-steps. (It's extremely important that all process and sub-process steps be identified before proceeding.)

HFMEA™ Number _____	
Date Started _____	Date Completed _____
Team Members 1. _____	6. _____
2. _____	7. _____
3. _____	8. _____
4. _____	9. _____
5. _____	10. _____
Team Leader _____	
Are all affected areas represented?	YES / NO
Are different levels and types of knowledge represented on the team?	YES / NO
Who will take minutes and maintain records?	_____

Step 4: Conduct a hazard analysis.

- A. List all possible/potential failure modes under the sub-processes identified in the HFMEA Step 3. Consecutively number these failure modes. (i.e., 1a(1), 1a(2)...3e(4), etc.). Transfer the failure modes to a HFMEA worksheet. (This is the step in the process where the expertise and experience of the team really pays off. Use various methods including the National Center for Patient Safety triage/triggering questions, brainstorming, and cause and effect diagramming to identify potential failure modes.
- B. Determine the Severity and Probability of the potential failure mode and record these on an HFMEA worksheet. Look up the hazard score on the Hazard Score Matrix and record this number on a HFMEA worksheet.
- C. Go to the HFMEA decision tree. Use the decision tree to determine if the failure mode warrants further action. Record the action to proceed or stop on the HFMEA worksheet. If the action is to stop, proceed to the next sub-process identified in Step 4B. Note: if the score is 8 or higher, document the rationale for any stop decisions.
- D. List all of the failure mode causes for each failure mode where the decision is to proceed and record them on the HFMEA worksheet. Each failure mode may have multiple failure mode causes. Failure modes include anything that could go wrong that would prevent the sub-process step from being carried out.

Sub-Process Flow for Step 3 (Analyze Sample)



For teaching purposes we will focus only on sub-process step 3F.

The team would want to work through ALL of these sub-process steps in an actual proactive risk assessment

This will lead you to the Hazard Matrix Score.

The Severity and Probability Ratings that follow are the first step in identifying the potential effects of your identified failure modes and failure mode causes. Use the definitions to classify the severity of the failure as minor, moderate, major or catastrophic. Then classify the probable frequency of the failure as remote, uncommon, occasional or frequent. For consistency, remember to use the definitions provided. Once the Severity and Probability are known use the [HFMEA™ Scoring Matrix](#) to determine a numeric value for the mode or cause. When the hazard score is quantified proceed to the [HFMEA™ Decision Tree](#).

Step 4B: Severity Rating

Event Severity:	Catastrophic Event
FMEA Rating:	(Traditional FMEA Rating of 10 - Failure could cause death or injury)
Patient Outcome:	Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, surgery / procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family
Visitor Outcome:	Death; or hospitalization of 3 or more
Staff Outcome:	A death or hospitalization of 3 or more staff
Equipment or facility:	Damage equal to or more than \$250,000
Fire:	Any fire that grows larger than an incipient

Event Severity:	Major Event
FMEA Rating:	(Traditional FMEA Rating of 7 - Failure causes a high degree of customer dissatisfaction)
Patient Outcome:	Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients
Visitor Outcome:	Hospitalization of 1 or 2 visitors
Staff Outcome:	Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses
Equipment or facility:	Damage equal to or more than \$100,000
Fire:	Not Applicable - See Moderate and Catastrophic

Event Severity:	Moderate Event
FMEA Rating:	(Traditional FMEA Rating of 4 - Failure can be overcome with modifications to the process, but there is minor performance loss)
Patient Outcome:	Increased length of stay or increased level of care for 1 or 2 patients
Visitor Outcome:	Evaluation and treatment for 1 or 2 visitors (less than hospitalization)
Staff Outcome:	Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff
Equipment or facility:	Damage more than \$10,000 but less than \$100,000

Visitor Outcome:	Evaluation and treatment for 1 or 2 visitors (less than hospitalization)
Staff Outcome:	Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff
Equipment or facility:	Damage more than \$10,000 but less than \$100,000
Fire:	Incipient stage or smaller
Event Severity:	Minor Event
FMEA Rating:	(Traditional FMEA Rating of 1 - Failure would not be noticeable to the customer and would not affect delivery of the service or product)
Patient Outcome:	No injury, nor increased length of stay nor increased level of care
Visitor Outcome:	Evaluated and no treatment required or refused treatment
Staff Outcome:	First aid treatment only with no lost time, nor restricted duty injury nor illness
Equipment or facility:	Damage less than \$10,000 or loss of any utility without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning)
Fire:	Not Applicable - See Moderate and Catastrophic

Step 4B: Probability Rating

- Frequent
Likely to occur immediately or within a short period (may happen several times in one year)
- Occasional
Probably will occur (may happen several times in 1 to 2 years)
- Uncommon
Possible to occur (may happen sometime in 2 to 5 years)
- Remote
Unlikely to occur (may happen sometime in 5 to 30 years)

Step 4B: The HFMEA Scoring Matrix

The HFMEA Scoring Matrix

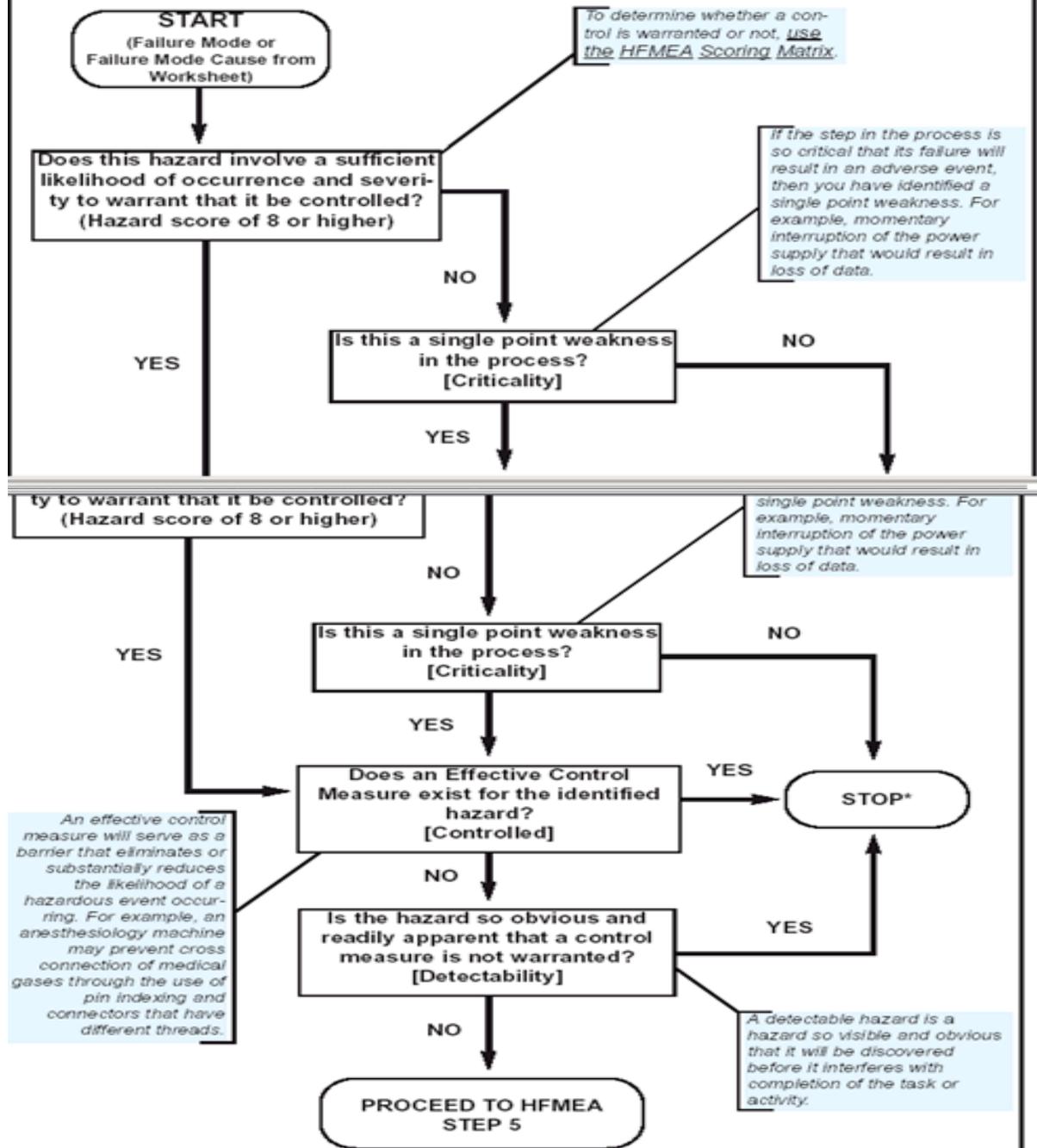
Probability	Severity			
	Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
Frequent (4)	16	12	8	4
Occasional (3)	12	9	6	3
Uncommon (2)	8	6	4	2
Remote (1)	4	3	2	1

Step 5: Actions and outcome measures.

- A. Determine if you want to eliminate, control, or accept the failure mode cause. Record this decision on the HFMEA worksheet.
- B. Identify a description of action for each failure mode that will be eliminated or controlled. Place the control measure in the process at the earliest feasible point. Multiple control measures can be placed in the process to control a single hazard. A control measure can be used more than one time in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facility-wide implementation.
- C. Identify outcome measures that will be used to analyze and test the redesigned process.
- D. Identify a single, responsible individual by title to complete the recommended action.
- E. Indicate whether top management has concurred with the recommended action.

HFMEA Decision Tree™

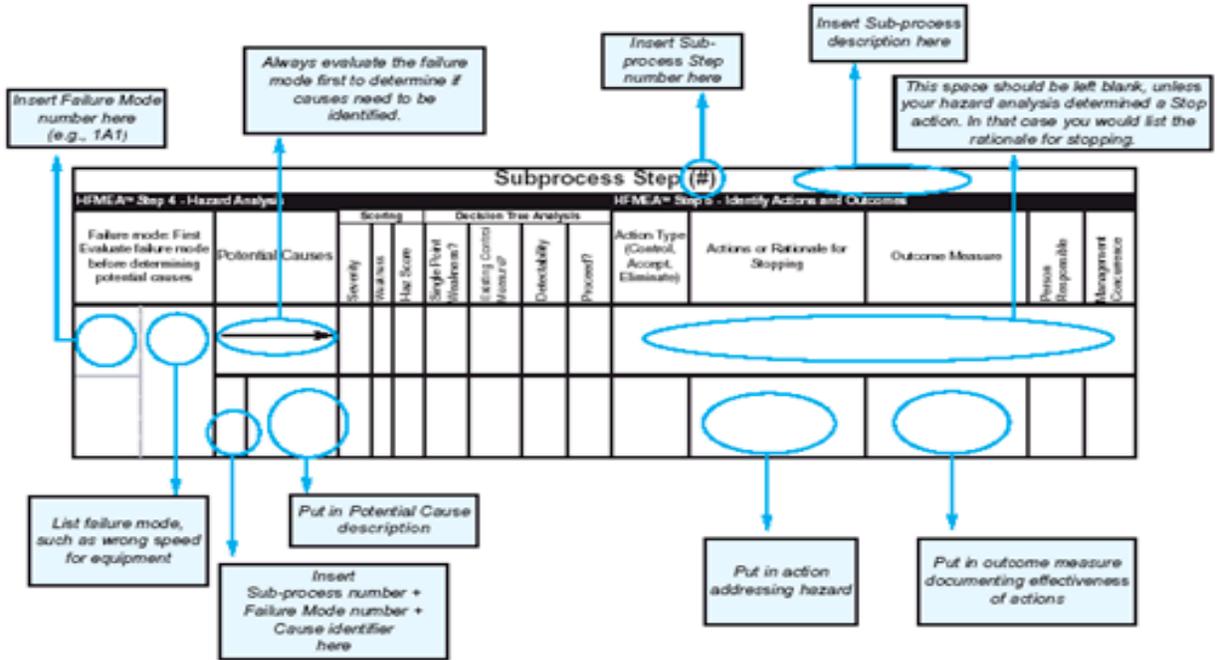
NOTE: THIS DECISION TREE IS TO BE USED AFTER THE HFMEA HAZARD SCORING MATRIX



*Document rationale for all Stop Decisions on the Worksheet

Step 4: Decoding the HFMEA Worksheet
 Decode the worksheet by viewing the [HFMEA Worksheet Guide](#) (pdf).

DECODING THE WORKSHEET



Next Section: [Step 5](#)

Sub-process Step 3F(1): Computer crash												
Failure Mode: First Evaluate failure mode before determining potential causes		HFMEA™ Step 4 - Hazard Analysis							HFMEA™ Step 5 - Identify Actions and Outcomes			
		Potential Causes		Scoring		Decision Tree Analysis			Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible
Severity	Probability	Max. Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?						
3F(1)	Computer crash	Major	Occasional	9	+	N	N	Y				
3F(1)a	Virus	Major	Occasional	9	+	N	N	Y	Control	Purchase and install virus protection software	Software installed	Chief IRM Y
3F(1)b	Old equipment	Moderate	Frequent	2	Y	Y	+	N	N/A	Ongoing program to replace existing equipment		
3F(1)c	Software license expired	Moderate	Occasional	6	Y	Y	+	N	N/A	Software licenses reviewed annually		

Definitions:

Effective Control Measure: A barrier that eliminates or substantially reduces the likelihood of a hazardous event.

Healthcare Failure Mode & Effects Analysis (HFMEA): A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome; a systematic approach to identify and prevent product and process problems before they occur.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

Failure Mode: Different ways that a process or sub-process can fail to provide the anticipated result.

HFMEA Process Steps 1 and 2

Step 1. Select the process you want to examine. Define the scope. Be specific and include a clear definition of the process or product to be studied.

Step 2. Assemble the Team:

HFMEA Number:

Date Started:

Team Members:

Team Leader:

Are all affected areas represented: Yes No

Are different levels and types of knowledge represented on the team? Yes No

Who will take minutes and maintain records?

Date Completed:

Severity:

<p>Catastrophic Event (Traditional FMEA Rating of 10 – Failure could cause injury or death)</p>	<p>Major Event (Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction)</p>
<p><u>Patient Outcome:</u> Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family <u>Visitor Outcome:</u> Death; or hospitalization of 3 or more <u>Staff Outcome:</u> A death or hospitalization or 3 or more <u>Equipment or Facility:</u> Damage equal to or more than \$250,000 <u>Fire:</u> Any fire that grows larger than an incipient</p>	<p><u>Patient Outcome:</u> Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients <u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors <u>Staff Outcome:</u> Hospitalization or 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses <u>Equipment or Facility:</u> Damage equal to or more than \$100,000 <u>Fire:</u> Not applicable</p>
<p>Moderate Event (Traditional FMEA Rating of 4 – Failure can be overcome with modifications to the process or product, but there is minor performance loss)</p>	<p>Minor Event (Traditional FMEA Rating of 1 – Failure would not be noticeable to the customer and would not affect delivery of the service or product)</p>
<p><u>Patient Outcome:</u> Increased length of stay or increased level of care for 1 or 2 patients <u>Visitor Outcome:</u> Evaluation and treatment for 1 or 2 visitors (less than hospitalization) <u>Staff Outcome:</u> Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff</p>	<p><u>Patient Outcome:</u> No injury, nor increased length of stay, nor increased level of care <u>Visitor Outcome:</u> Evaluated and no treatment required or refused treatment <u>Staff Outcome:</u> First aid treatment only with no lost time, nor restricted duty injuries nor illnesses</p>

<u>Equipment or Facility:</u> Damage more than \$10,000 but less than \$100,000 <u>Fire:</u> Incipient stage or smaller	<u>Equipment or Facility:</u> Damage less than \$10,000 or loss of any utility without adverse patient outcome (e.g., power, natural gas, electricity, water, communications, transport, heat/air conditioning) <u>Fire:</u> Not applicable
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Probability:

Frequent – Likely to occur immediately or within a short period (may happen several times in one year) Occasional – Probably will occur (may happen several times in 1 to 2 years) Uncommon – Possible to occur (may happen sometime in 2 to 5 years) Remote – Unlikely to occur (may happen sometime in 5 to 30 years)
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Hazard Scoring Matrix

<u>Severity Categories</u>	<u>Probability Ratings</u>
Catastrophic = 4	Frequent = 4
Major = 3	Occasional = 3
Moderate = 2	Uncommon = 2
Minor = 1	Remote = 1

Probability	Severity of Effect			
	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

To use above matrix:

1. Determine the Severity & Probability of the Hazard based upon the definitions included with matrix.
2. Look up the Hazard Score on the Matrix.

The Basics of Healthcare Failure Mode and Effect Analysis
VA National Center for Patient Safety
24 Frank Lloyd Wright Dr. M2100
Ann Arbor, MI 48106-0486

Healthcare Failure Modes and Effects Analysis (HFMEA) was designed by the VA National Center for Patient Safety specifically for health care.

HFMEA streamlines the hazard analysis steps found in the traditional Failure Modes and Effects Analysis (FMEA) process by combining the detectability and criticality steps of the traditional FMEA into an algorithm presented as a Decision Tree. It also replaces calculation of the risk priority number (RPN) with a hazard score that is read directly from the Hazard Matrix Table. This table was developed by NCPS specifically for this purpose.

Healthcare FMEA Steps

STEP 1 Define the HFMEA Topic Define the topic of the Healthcare FMEA along with a clear definition of the process to be studied. See Figure 1.

STEP 2 Assemble the Team (Team is to be multidisciplinary including Subject Matter Experts and an advisor. See Figure 1.

STEP 3 Graphically Describe the Process

- A. Develop and verify the flow diagram (this is a process vs. chronological diagram).
- B. Consecutively number each process step identified in the process flow diagram.
- C. If the process is complex identify the area of the process to focus on (take manageable bites).
- D. Identify all sub processes under each block of this flow diagram. Consecutively letter these sub-steps (i.e. 1a, 1b...3e, etc.).
- E. Create a flow diagram composed of the sub processes. Consecutively letter these sub-steps
(*Hint: It is very important that all process and sub-process steps be identified before proceeding.*)

STEP 4 Conduct a Hazard Analysis

- A. List all possible/potential failure modes under the sub-processes identified in HFMEA Step 3. Consecutively number these failure modes (i.e. 1a(1), 1a(2)...3e(4), etc.). Transfer the failure modes to the HFMEA Worksheet, Line 2. See Figure 2.
(*Hint: This is the step in the process where the expertise and experience of the team really pays off. Use various methods including the NCPS triage/triggering questions, brainstorming, and cause and effect diagramming to identify potential failure modes.*)
- B. Determine the Severity and Probability of the potential failure mode and record these on Lines 4 and 5 of HFMEA Worksheet. Look up the Hazard Score on the Hazard Score Matrix and record this number on Line 6 of the HFMEA Worksheet. See Figures 3, 4, and 5.
- C. Go to the HFMEA Decision Tree. Use the Decision Tree to determine if the failure mode warrants further action. Record the action to “Proceed” or to “Stop” on the HFMEA Worksheet, Line 7. If the action is to “Stop” proceed to the next sub-process identified in Step 4B. (Note: if the score is 8 or higher, document the rationale for any “Stop” decisions.) See Figure 6.
- D. List all of the failure mode causes for each failure mode where the decision is to “Proceed” and record them on the HFMEA Worksheet, Line 3.
(*Hint: Each failure mode may have multiple failure mode causes. Failure modes include anything that could go wrong that would prevent the sub-process step from being carried out. For example: if logging onto a laptop computer is the process step, possible failure modes are not being able to log in and delayed login. Possible failure mode causes would include the computer not being available, no power, no log in ID for the operator, etc.*)

STEP 5 Actions and Outcome Measures

- A. Determine if you want to “eliminate,” “control,” or “accept” the failure mode cause. Record this decision on Line 8 of the HFMEA Worksheet.
- B. Identify a Description of Action for each failure mode that will be eliminated or controlled. (*Hint: Place the control measure in the process at earliest feasible point. Multiple control measures can be placed in the process to control a single hazard. A control measure can be used more than one time in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facility-wide implementation.*)
- C. Identify outcome measures that will be used to analyze and test the redesigned process.
- D. Identify a single, responsible individual by title to complete the recommended action.
- E. Indicate whether top management has concurred with the recommended action.

Definitions:

Effective Control Measure – A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

Healthcare Failure Mode & Effect Analysis (HFMEA) - (1) A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome. (2) A systematic approach to identify and prevent product and process problems before they occur.

Hazard Analysis - The process of collecting and evaluating information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

Failure Mode - Different ways that a process or sub-process can fail to provide the anticipated result.

Probability – See the Probability Rating Scale, Figure 3.

Severity – See the Severity Rating Scale, Figure 4.

Healthcare FMEA™ Process Steps 1 and 2

Step 1. Select the process you want to examine. Define the scope (Be specific and include a clear definition of the process or product to be studied).

This HFMEA™ is focused on _____

Step 2. Assemble the Team HFMEA™ Number _____

Date Started _____

Date to be Completed _____

Team Members _____

Figure 2. Healthcare FMEA Worksheet

Step 4	1	Process Step					
	2	Potential Failure Mode					
	3	Potential Cause(s)					
	4	Severity					
	5	Probability					
	6	Hazard Score					
	7	Decision (Proceed or Stop) <i>(Note: If the score is 8 or higher and the decision is to “Stop,” document the rationale for this decision)</i>					
Step 5	8	Action (Eliminate, Control, or Accept)					
	9	Description of Action					
	10	Outcome Measure					
	11	Person Responsible					
	12	Management concurrence (yes or no)					

Figure 3. Severity Rating

<p>Catastrophic Event (Traditional FMEA Rating of 10 - Failure could cause death or injury)</p>	<p>Major Event (Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)</p>
<p>Patient Outcome: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family Visitor Outcome: Death; or hospitalization of 3 or more. Staff Outcome: * A death or hospitalization of 3 or more staff Equipment or facility: **Damage equal to or more than \$250,000 Fire: Any fire that grows larger than an incipient</p>	<p>Patient Outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients Visitor Outcome: Hospitalization of 1 or 2 visitors Staff Outcome: Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses Equipment or facility: **Damage equal to or more than \$100,000 Fire: Not Applicable – See Moderate and Catastrophic</p>
<p>Moderate Event (Traditional FMEA Rating of “4” – Failure can be overcome with modifications to the process or product, but there is minor performance loss)</p>	<p style="text-align: right;">Minor Event (Traditional FMEA Rating of “1”– Failure would not</p>
<p>Patient Outcome: Increased length of stay or increased level of care for 1 or 2 patients Visitor Outcome: Evaluation and treatment for 1 or 2 visitors (less than hospitalization) Staff Outcome: Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff Equipment or facility: **Damage more than \$10,000 but less than \$100,000 Fire: Incipient stage⁺ or smaller</p>	<p>Patients Outcome: No injury, nor increased length of stay nor increased level of care Visitor Outcome: Evaluated and no treatment required or refused treatment Staff Outcome: First aid treatment only with no lost time, nor restricted duty injuries nor illnesses Equipment or facility: **Damage less than \$10,000 or loss of any utility[†] without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning).</p>

Figure 4. Probability Rating

<p>Frequent - Likely to occur immediately or within a short period (may happen several times in one year)</p> <p>Occasional - Probably will occur (may happen several times in 1 to 2 years)</p> <p>Uncommon - Possible to occur (may happen sometime in 2 to 5 years)</p> <p>Remote - Unlikely to occur (may happen sometime in 5 to 30 years)</p>

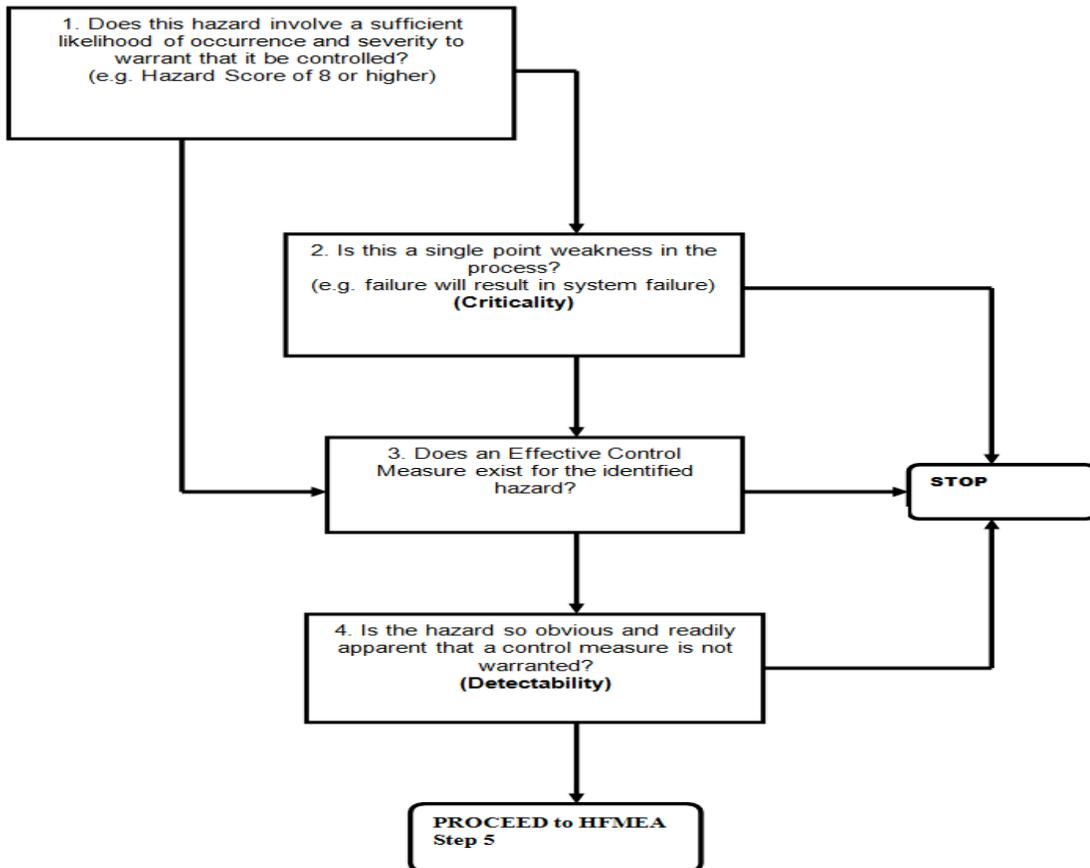
Figure 5. Hazard Scoring Matrix

Probability	Severity of Effect				
		Catastrophic	Major	Moderate	Minor
	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

How to Use This Matrix:

- (1) Determine the Severity and Probability of the Hazard based upon the definitions included with this matrix. (NOTE: These definitions are the same as those used in the Root Cause Analysis Safety Assessment Code.)
- (2) Look up the Hazard Score on the Matrix.

Figure 6. Decision Tree



You must document rationale for STOP decision.

HFMEA Subprocess Step Title and Number													
HFMEA Step 4 - Hazard Analysis						HFMEA Step 5 - Identify Actions and Outcomes							
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes	Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?					
	→												

Team Leader _____ Are all affected areas represented? YES _____ NO _____
 Are different levels and types of knowledge represented on the team? YES _____ NO _____
 Who will take minutes and maintain records? _____

SAMPLE POLICY INTEGRATED PATIENT SAFETY/RISK MANAGEMENT PROGRAM

1. PURPOSE:
 - a. To establish policy and procedures for the operation of the Patient Safety/Risk Management (PS/RM) program. The Patient Safety/Risk Management is a proactive program that oversees, reviews, analyzes, reports, tracks, and trends patient/visitor adverse events (incidents), as well as other safety-related events. Patient Safety data are analyzed to identify patterns, trends and improvement strategies. The Patient Safety/Risk Management Program is an integrated program which is consistent with the Mission of the medical center. It is located within the Quality Management Department in the Office of the Director
 - b. This policy applies to the entire medical center including Geriatrics and Extended Care Programs, and its remote clinics (CBOC's).
2. PHILOSOPHY: Human error is inevitable, even among the most conscientious professionals practicing the highest standard of care. Identification and reporting of adverse events, including those that result from practitioner error, are critical to our efforts to continuously improve patient safety. Likewise, medical managers have a duty to recognize the inevitability of human error and attempt to design systems and processes that make such errors less likely, and to avoid punitive reactions to honest errors.
3. POLICY: The Patient Safety/Risk Management Program is an interdisciplinary program which is designed to improve the quality of care by identifying system design flaws and other problems, and redesigning patient care systems to decrease the likelihood of system errors that can harm patients.
 - a. All employees and practitioners are responsible for fully cooperating in the efforts to improve patient safety and reduce potential risks. This may include: the reporting of events, which result in actual or potential injury and close calls to a patient or visitor, and participating in patient safety activities.
 - b. The attending physician or resident of the treatment team will promptly inform the patient or their family and the Risk Manager about injuries resulting from Sentinel or Adverse Events and the options available to them (See paragraph 5d., Procedures, for "Informing Patients About Adverse Events").
 - c. Risk Management is responsible for patient safety activity and programs: This includes: (See Patient Safety/Risk Management Responsibilities in paragraph 6)
 - (1) Overseeing mechanisms for coordination among components of the program, among the professional disciplines; and across the organization (See Appendix A: Patient Safety in the Medical Center: Mechanisms for Coordination and Communication);
 - (2) Initiating or recommending system and process improvements to improve the quality of patient safety;
 - (3) Overseeing the Peer Review Process and Death Review Screening;
 - (4) Coordinating and overseeing Administrative Tort Claims Analysis, including obtaining Expert Opinions;
 - (5) Coordinating Administrative Boards of Investigation related to patient safety; and(6) Providing oversight for Clinical Safety Workgroup.
 - d. Linkages With Other Programs: PS/RM actively reviews, analyzes, and takes action on data from many facility programs. Conceptually, the Patient Safety/Risk Management Program supports a framework for many medical center activities. While many of these activities may not directly align themselves under the Patient Safety/Risk Management Program, they have risk implications and therefore provide linkage with the Patient Safety/Risk Management Program. These activities include (but are not limited to), and have links with:
Safety Management Committee, Equipment and Utilities Committee (Safe Medical Devices Act)
 - (3) Safe Environment Committee (Safety Surveillance, Fire Safety and Training), (4) Patient Advocate Program, (5) Customer Satisfaction Group (National Customer Service Data), (6) Professional Standards, (7) Professional Standards Board (Credentialing and Privileging), (8) Credentials Office and Human Resources (Reporting of Practitioners to State Licensing Boards and National Practitioner Data Bank),(9) Utilization Review, (10) Tort Claim Analysis, (11) Infection Control Function Lead Team (FLT) (committee), (12) Safety and Health Program, and (13) Informed Consent.
 - e. High Risk Events: The Medical Center Patient Safety Program has identified four high risk events (falls, medication errors, para-suicidal behavior and missing patients) which will be reviewed in aggregate on a quarterly basis. f. Purposes: The purposes for the PS/RM Program include:
 - (1) Promoting a Culture of Safety in a non-punitive environment;
 - (2) Protecting patients from harm and preventing adverse events;

- (3) Identifying and reporting of adverse and potential events to patients, personnel, and visitors;
- (4) Protecting and securing facility assets through loss prevention, which includes monitoring, trending, analyzing, and reporting of problems identified in various clinical, administrative, and other review processes; and
- (5) Disseminating improvement teams recommendations and actions to relevant leaders.

g. Goals: The goals of the PS/RM Program currently include:

Focus on systems, not individuals; Focus on prevention, not punishment;

- (3) Emphasize open reporting of adverse events;
- (4) Facilitate continuous improvement in health care delivery systems;
- (5) Proactive in response to risk assessment; and
- (6) Promote shared learning.

5. PROCEDURES: a. Identification, Reporting And Review Of Adverse Events Involving Patients:

(1) Incident Reporting:

- (a) Whenever a patient is involved in an adverse event, sentinel event and or a close call, a VA Form 10-2633, (Report of Special Incident Involving a Beneficiary), will be completed by the first employee who becomes aware of the incident.
- (b) Electronic filing of VA Form 10-2633 in the VISTA system is the preferred method of reporting. For specific procedures see Appendix C: Flow Chart – Reporting of Adverse Events Involving Patients).
- (c) Other methods of reporting incidents (to ensure non-punitive concerns) include notifying Risk Management by a memorandum, Report of Contact, in person, and or voice message at extension 6362. If the employee feels the nature of the incident is so confidential he/she cannot report it through the regular incident reporting process, the incident may be directly reported to the Risk Manager at extension 6362.

(2) Actions: (a) The incident report will include a description of the (sentinel event, adverse event or close call) event, time and location of the event, pertinent factors such as the diagnosis, date of birth, mental status, medical evaluation and actions taken. Only factual information is recorded and no accusation of guilt or subjective opinion is to be included in the report or documented in the computerized medical record. (b) Appropriate actions need to be taken immediately following an adverse event, sentinel event, or close call. Actions taken are based on the assessment of the patient and event (not necessarily in this order)

1. Provide immediate care/treatment to individuals involved in the event (includes patients, staff, or visitors); 2. Make the situation safe and immediately prevent recurrence; 3. Physically remove specific equipment or supplies that malfunctioned; 4. Gather factual information for subsequent analysis; 5. Collect evidence (e.g., supplies, biological samples, equipment, etc.); 6. Notify Supervisor and Risk Management; and 7. Enter an incident report.

(c) The treating physician will assign a Severity of Injury Scale Level to each adverse event. The following Severity Scale (Appendix D) will be used:

- 1. Level 0 - No injury or disability;
- 2. Level 1 - Minor or Moderate (Injuries are minor or moderate in nature and if they do require medical intervention, it does not extend the patient's hospital stay except for observation or to obtain laboratory/radiology result);
- 3. Level 2 - Major (Injuries which require medical or surgical intervention, increased hospital stay or are disabling/ disfiguring to a degree that patient will have any degree or permanently lessened function or require surgical repair); & 4. Level 3 - Catastrophic – Death.

b. Review of Adverse Events: (1) The Risk Manager/designee reviews all incidents. Occurrences that do not meet the definition of an adverse event, sentinel event, or close call/near miss shall be assigned an appropriate disposition.

(2) The Risk Manager/designee, using the Safety Assessment Code (SAC) Matrix (Appendix F) and Probability Categories (Appendix G) assesses adverse events, sentinel events, and close calls. Based upon the severity level and the SAC score, appropriate action is taken based upon the Incident Report Review. In general, events with a score of 1 or 2 will be entered in the registry. Events with an Actual SAC score of 3 will be entered into the registry and evaluated with a Root Cause Analysis (RCA). A quarterly Aggregate RCA will be conducted on events with a Potential SAC score of 3, for falls, medication errors, para-suicidal behaviors, and missing patients.

(3) The Medical Center Director/designee and Chief of Staff are kept informed of individual events and investigations. Recommendations for corrective actions are forwarded to the Director through the investigative/review processes, through scheduled or ad hoc reports, and through minutes and/or reports of appropriate committee and services

(4) Root Cause Analysis is conducted for all events listed [paragraph 5c(2)] below. Final reports of RCA's are reported to VISN & National Center for Patient Safety within 45 days unless there are extenuating circumstances

c. Reporting Adverse Events to the VISN: Risk Management initiates VISN reports, which are submitted through the Office of the Medical Center Director.

The following incidents are reported to the VISN within 24 hours:

(a) Sentinel Events (adverse event that results in loss of life, limb or permanent loss of function); (b) Adverse events assessed with a severity level of 3 (c) Major or an event that would generate substantial negative publicity; (d) Event that may initiate an immediate VHA and or Joint Commission visit; (e) Unplanned clinical occurrences with a SAC Score of 3; (f) Allegations of patient abuse; (g) Potentially compensable events; and (h) Events suspected of criminal intent.

d. Informing Patients About Adverse Events

(1) The attending physician promptly informs Risk Management and patients and their families about injuries resulting from adverse events and the options available to them. There is evidence that patients desire acknowledgement of errors from their caregivers and that doing so reduces the likelihood that patients will take legal or administrative action. Regional Counsel may be consulted for input prior to discussing an adverse event with a patient and or their family.

(2) Medical Center staff will provide appropriate and timely communication with patients and their families regarding adverse events that involve potential organizational liability. Potential organizational liability can be assessed based on discussion with practitioners and the Regional Counsel (Actual liability can be determined only after consideration of a claim under the provisions of the Federal Tort Claims Act, 28 U.S.C.(1346 b), 2671-2680).

(3) The Patient Advocate may advise the patients and their families of appropriate remedial options. These options should include locally available interventions (e.g., arranging for second opinions, expedited clinical consultations, or inpatient admissions) and referral of patients to the 1151 claims process and the tort claims process.

e. Sentinel Event Alerts:

(1) The Joint Commission collects and analyzes data from sentinel events in healthcare organizations. Sentinel Event Alerts are issued by the Joint Commission to increase the general knowledge about sentinel events, their causes, and strategies for prevention. The alerts form the basis for future error-reduction and prevention for organizations.

(2) Sentinel event alerts are received by Risk Management/ Patient Safety and assigned to appropriate departments for response to the alert, root causes, risk reduction strategies, and recommendations that may need to be implemented (or no further action is needed).

(3) Responses back to Risk Management/Patient Safety to the sentinel event alert need to be completed within 60 days of notification of the alert.

(4) Risk Management/Patient Safety maintains a database to track follow-up actions to the alerts.

f. VHA Patient Safety Alert and Patient Safety Advisory:

(1) Veterans Health Administration Warning System for VHA Patient Safety Alert and Patient Safety Advisory are similar to Sentinel Event Alerts and are published by VA Central Office.

(2) The VHA alert and advisory purpose is the same for Sentinel event alerts; as stated above. The same process as described above applies for response to the alert and or advisory.

g. Healthcare Failure Mode and Effect Analysis (HFMEA):

(1) Healthcare Failure Mode and Effect Analysis (HFMEA) is a 5-step process that uses a multidisciplinary team to proactively evaluate a health care process. The team uses process flow diagramming, a Hazard Scoring Matrix, and a HFMEA Decision Tree to identify and assess potential vulnerabilities.

(2) An HFMEA Worksheet is used to record the team's assessment, propose actions, and outcome measures.

(3) HFMEA includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.

h. External Patient Safety Reporting System:

(1) The VA and the National Aeronautics and Space Administration (NASA) have developed a partnership for an external Patient Safety Reporting System (PSRS). The purpose of the reporting system is to identify hazards and safety issues, which will provide data for planning and improvements with other VA's and NASA. (It is expected that this system will be implemented during FY'03).

(2) The PSRS is a voluntary and confidential reporting system for adverse events and close calls.

(3) Any adverse events, sentinel events, and close calls/near misses that occur in this medical center must still be reported as directed in this policy FY'03.

i. Patient Safety Education:

(1) Patients are encouraged to report safety concerns and questions to staff (noted in the “Patient Guide to the Medical Center”).

(2) The Joint Commission Speak Up Program urges patients and their families to become involved in their care. The Speak UP program supports efforts to increase the veteran’s awareness and involvement in their health care that may prevent health care errors. Research shows that patients who take part in decisions about their health care are more likely to have better outcomes. The program includes the following “SPEAK UP” concepts for patients:

S - Speak up if you have questions or concerns, and if you don’t understand ask again.

P - Pay attention to the care you are receiving.

E - Educate yourself about your diagnosis, medical tests, and treatment plan.

A - Ask a trusted family member or friend to be your advocate.

K - Know what medications you take and why you take them.

U - Use hospital or clinics that meet standards of quality care.

P - Participate in all decisions about your treatment

(3) Concepts from the above program will be utilized as we develop new Patient Education Materials.

j. Staff Patient Safety Orientation and Training:

(1) Patient safety training is included during the hospital basic orientation.

(2) Ongoing safety training is provided to leaders and staff in a variety of ways; programs offered medical center wide; RCA “just-in-time training,” unit or department inservice programs, and Satellite training from remote centers

(3) Training focuses on the various aspects of the Patient Safety Improvement Program, including basic patient safety, Joint Commission Patient Safety Standards, National Center for Patient Safety Program, and other patient safety regulations

k. Review of Administrative Tort Claims

(1) The facility conducts peer reviews of all administrative tort claims & reports findings to Regional Counsel within 30 days of notification of the claim. Practitioners involved in administrative tort claims will be identified in peer reviews. Medical staff department chairs will notify involved practitioners of the medical malpractice claim

(2) After a tort claim settlement has been paid, the names of the involved practitioners are reported to the VHA Office of Medical Legal Affairs by Risk Management.

(3) The VHA Office of Medical Legal Affairs will conduct a second peer review panel to determine whether reporting to the National Practitioner Data Bank is required.

l. Expert Medical Opinions: Expert Medical Opinions are completed as requested by the VHA Office of Medical Legal Affairs. The Expert Medical Opinions will be completed within 30 days of receipt of notification.

m. Statistical Analyses Of Patient Safety/Risk Management Data:

(1) Risk Management staff reviews surgical mortality and morbidity data as it is made available by VA’s National Surgical Quality Improvement Program.

(2) Data is then shared with appropriate managers and staff.

(3) Risk Management staff reviews and trends mortality rate data for hospitalized and recently discharged (within 30-days) medical and psychiatric patients.

(4) Mortality data is reviewed annually by appropriate staff and explanations sought as appropriate for unusual trends. Among the explanations that should be considered are associations between mortality rates and specific locations, times, or practitioners.

(5) If an association with a practitioner is suspected, actions will be taken by the appropriate manager.

n. Adverse Events Involving Visitors:

(1) Visitors who are involved in an adverse event should be evaluated and treated on a humanitarian basis at the treatment facility, if medically appropriate.

(2) VA Form 10-10M, Medical Certificate, will be used in the evaluation of a visitor involved in an incident. Other appropriate forms will be used to create a record of the event, e.g., progress notes, etc. A copy of the VA Form 10-10M, and other forms used to record the events, will be filed in the Safety Office

6. RESPONSIBILITY a. All Employees are responsible for:

- (1) The highest standard of care to patients. Identification and reporting of adverse events, sentinel events, and close-call events are critical to the medical center's continuous effort to improve patient/visitor safety.
- (2) Reporting incidents immediately. All employees regardless of position or discipline, who first become aware of an actual or potential adverse event, sentinel event and or close call/near miss must initiate an automated incident report (10-2633) and document in the electronic medical record the facts relating to the event and the outcomes. See Appendix C, Flow Chart "Reporting of Adverse Events Involving Patients." If the employee feels the nature of the incident is so confidential it cannot be reported through the regular incident reporting process, the incident may be directly reported to the Risk Manager at extension 6362, or in writing to the Risk Manager.
- (3) Participating in Root Cause Analysis Team reviews, and or fact-finding reviews as indicated or requested.
- (4) Acknowledging that support will be extended to any employee who wishes assistance in dealing with their involvement in a sentinel or adverse event. Supervisors will contact Employee Assistance Program Coordinator who will provide assistance as necessary.

b. Physicians: Physicians are responsible for:

- (1) Evaluating the patient, documenting the event in the electronic medical record and completing the physician's portion of the incident report in VISTA (under Physicians Examination Findings/Actions) including Severity and Level of Injury (see Appendix D - "Severity of Injury Levels"). This is the responsibility of the physician that is responsible for the patient at the time of the event.
- (2) Promptly informing the patient or their family and the Risk Manager about injuries resulting from Sentinel or Adverse Events and the options available to the patient/family. (See paragraph 5d. "Procedures for Informing Patients About Adverse Events"). Attending physician or resident of the treatment team is responsible for above.
- (3) Participating in root cause analysis team reviews, risk assessments for patient safety activities, health care failure mode and effect analysis, and or fact-finding reviews as indicated or requested.
- (4) Completing peer reviews, administrative tort claim & expert medical opinions reviews as assigned within 30 days.

c. ACOS's/Administrators/Department Chairs and Assistant Administrators are responsible for:

- (1) Educating employees regarding sentinel events, adverse event and close-call reporting procedures.
- (2) Timely reporting of events to Risk Management;
- (3) Ensuring that employees participate in patient safety activities, such as root cause analysis teams;
- (4) Reviewing and completing recommendations/actions from RCA's (Root Cause Analysis), Administrative Boards of Investigations and Psychological Autopsies in collaboration with Risk Manager and the Chief of Staff; &
- (5) Ensuring that support is extended to employees who wish assistance in dealing with their involvement in a sentinel or adverse event. Supervisor is to contact Employee Assistance Program Coordinator who will provide assistance as necessary.

d. Chief of Staff: The Chief of Staff is responsible for:

Ensuring that actions are taken from findings of root cause analysis teams, administrative investigations, peer review process, and other reviews.

- (2) Providing guidance to improve the patient safety program.
- (3) Reporting of clinical providers to state licensure board and the National Practitioner Data Bank when indicated.

e. Medical Center Director/or Designee is responsible for:

- (1) Effectiveness of the Patient Safety/Risk Management Program.
- (2) Providing resources and support systems for the risk management functions.
- (3) Appointing review teams members for root cause analysis teams, Special Clinical Reviews, and Administrative Boards of Investigations.

f. Patient Safety/Risk Management is responsible for:

- (1) Coordinating & overseeing all activities related to adverse events including, but not limited to: data collection, review, analysis, follow-up recommendations, track implementation of corrective actions, & reporting of aggregate data analysis.
- (2) Informing leadership of adverse events and the need for RCA's, Administrative Boards of Investigations, Peer Reviews, and or Psychological Autopsy. Initiating and facilitating the process for the reviews. Serving as technical advisors for reviews and final reports.

- (3) Facilitating the root cause analysis process (See Appendix E: The Root Cause Analysis Flow Chart).
- (4) Complying with VHA, National Center for Patient Safety, and other regulatory agencies, which includes the integration of goals and activities with the medical center.
- (5) Maintaining the official files and data bases of all adverse events, related reviews, and investigations.
- (6) Maintaining the Patient Incident Reporting (PIR) database, tracking, trending, analyzing, and timely reporting to appropriate individuals and groups within the medical center and the VISN.
- (7) Coordinating, facilitating and communication of findings/root causes/recommendations of relevant events (sentinel and other events) and the mandated follow-up activities to appropriate individuals and groups.
- (8) Informing the Medical Center Director and Chief of Staff of adverse incidents, investigations and reports and reporting adverse events to the VISN.
- (9) Coordinating, developing, monitoring, implementing, and evaluating patient safety programs as outlined in the National Patient Safety Handbook and VHA Performance Measures
- (10) Preparing a quarterly report summarizing patient safety/risk management activities to Executive Performance Improvement Council (EPIC)/Executive Leadership Council (ELC). Sharing the report with other leaders and staff including the Clinical Executive Board (CEB), Nurse Managers and various committees.
- (11) Providing ongoing training to the medical center leadership and employees in the various aspects of the Patient Safety Improvement Program, including Joint Commission Patient Safety Standards, National Center for Patient Safety Program, and other patient safety regulations.
- (12) Coordinating Peer Review process and clinical review processes.
- (13) Reviewing and preparing statistical reports of surgical mortality and morbidity data from the VA National Surgical Quality Improvement Program.
- (14) Consulting Regional Counsel for guidance with related adverse patient events and Administrative Tort Claims
 - g. The RCA Team is responsible for: (1) Conducting RCA's utilizing the methodology prescribed in the Patient Safety Improvement Handbook. (2) Submitting a report in the format defined by the National Center for Patient Safety. The RCA will be completed within 45 calendar days. (3) Contacting the Risk Manager, if in the course of conducting an RCA, it appears that the event under consideration is the result of an Intentional Unsafe Act. The Risk Manager will refer the event to the Director for appropriate consideration. If an Administrative Investigation (AI) is subsequently appointed, the RCA will cease. The members of the RCA team may not serve as members of the AI team.
 - h. VA Police Service is responsible for:(1) Notifying appropriate individuals in management if a crime is suspected to have been committed (see Title 38 Code of Federal Regulations (CFR), Sections 14.560 and 14.563, and MP-1, Part I, Chapter 16 and MP-1, Pt.1, Chapter 2, Sub par. 208.02).
 - (2) Ensuring that to the extent possible, the surrounding area should not be disturbed, so that evidence is available for review by the police and other authorities. However, care needed by the patient should always be provided as quickly as possible

7. REFERENCES: Medical Center Policy No. FMS/90-9, Procedures for Recall of Potentially Hazardous Products and Medical Device Incident Reporting b. Medical Center Policy No. 11-68, Peer Review Process (formerly Occurrence Screening and Peer Review Program);c. DM&S Clinical Services Manual, M-2, Part VII, Pharmacy Service; d. VHA Patient Safety Handbook 1051/1 – current version;e. VHA Handbook 1100.17, National Practitioner Data Bank Reports – current version; f. Quality Management Activities Which Can Generate Confidential Documents, VHA Directive 98-016; and g. Clinical Safety Workgroup, Policy Memorandum 11-86 8. RESCISSION: Policy Memorandum No. 11-33

DEFINITIONS OF ADVERSE EVENT 1. ADVERSE EVENT: Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with the care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility. Adverse events may result from acts of commission or omission (e.g., administration of wrong medication, failure to make a timely diagnosis, or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.). Some examples of more common adverse events include: patient falls, medication errors, procedural errors/ complications, completed suicides, para-suicidal behavior (attempts, gestures/threats), and missing patient (s).

2. SENTINEL EVENT: Sentinel events are a type of adverse event. Sentinel Events as defined by Joint Commission are unexpected occurrences involving death or serious physical injury or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. Major permanent loss of function means sensory, motor, physiologic, or intellectual impairment not previously present that requires continuous treatment or life-style change. The phrase "risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome. Sentinel Events signal the need for immediate investigation and response. Some examples of sentinel events include: death resulting from a medication error or treatment-related error; suicide of a patient in a setting where they receive around-the-

clock care; surgery on the wrong patient or body part regardless of the magnitude of the operation; and hemolytic reactions involving the administration of blood or blood products where there are major group incompatibilities.

3. CLOSE CALLS/NEAR MISS: A Close Call/Near Miss is an event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. Such events have also been referred to as "near miss" incidents. For example: a surgical or other procedure almost performed on the wrong patient due to inconsistencies in verification of patient identification, but caught at the last minute by chance.

4. INTENTIONAL UNSAFE ACT: Intentional Unsafe Acts, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse, impaired provider/staff; or events involving alleged or suspected patient abuse of any kind. Intentional Unsafe Acts should be dealt with through avenues other than those defined in this policy memorandum (i.e., police investigation, Administrative Investigation, for allegations of patient abuse, etc.).

5. ROOT CAUSE ANALYSIS (RCA): Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. This specific type of review (RCA) will be the form of review that is used for all sentinel events, adverse events, close calls, and aggregated reviews for medication errors, patient falls, para-suicide behavior, and missing patients. The format for performance and reporting of the RCA is described in the VHA Patient Safety Improvement Handbook.

6. TYPES OF ADVERSE EVENTS:

a. SUICIDE AND SUICIDE ATTEMPT: A suicide and suicide attempt is a self-injurious acts (with or without serious injury) with the intent to die. Note that intent to die is judged by both *subjective* evidence (patient-reported) and *objective* evidence (behavior that suggests intent to die, such as: preparing a will, putting affairs in order, giving away prized possessions, inappropriate thanks/good-byes, and selection of highly lethal method of self-injury accompanied by efforts to prevent rescue).

b. SUICIDE GESTURE: A Suicide Gesture is a self-injurious act with a *goal other than death*, such as: seeking help, punishing others, gaining attention. Also known as "Instrumental Suicide-Related Behavior," such acts sometimes lead to death (accidentally) and carry a high risk of repetition.

c. SUICIDE THREAT: A Suicide Threat is communication that suicide behavior *might* occur

d. PATIENT ABUSE: Patient Abuse includes acts against patients that involve physical, psychological, or verbal abuse. The "intent" to abuse is not a requirement for patient abuse. Patient's perspective of how he/she is being treated is an essential component of the determination of a patient abuse. However, the fact that a patient has limited or no cognitive ability does not exclude the possibility of abuse. Allegations of patient abuse include: any action or behavior that conflicts with patients' rights, as identified in 38 Code of Federal Regulations (CFR) 17.34a; intentional omission of patient care; willful violations of the privacy of the patient(s); intimidation, harassment or ridicule of the patient(s); and or willful physical injury of a patient.

e. MISSING PATIENT: A Missing Patient who absents him/herself from the patient care area without knowledge and permission of staff for any length of time, even if found or returns. A patient is considered a high-risk patient if he/she meets one or more of the following criteria: patient is considered a danger to self or others; patient has a court-appointed legal guardian; patient is legally committed; or patient lacks the cognitive ability to make decisions. An incident report is completed regardless of severity level and the Police Service is notified.

f. HOMICIDE: Homicide is the taking of the life of a patient or staff member, either accidentally or intentionally. This includes homicides directly associated with the care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility.

g. FALL: An uncontrolled descent by a patient regardless of whether observed or whether or not there is an injury.

h. MEDICATION ERROR: A Medication Error is an incident where the patient received an erroneously prescribed medication or did not receive a medication as prescribed including: intravenous admixtures or an additive which do not meet the labeling requirements of DM&S Clinical Services Manual, M-2, Part VII, "Pharmacy Service." Medication does not have to be administered to the patient for it to be considered a medication error.

(1) Factors that constitute a prescribing error: Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy) -Wrong dose -Wrong frequency -Wrong route -Failure to continue needed medication

(2) Factors that constitute a dispensing error: Unauthorized drug use - Wrong patient - Wrong dose or dosage form - Wrong route of administration - Wrong rate - Wrong time - Wrong preparation of dose - Omission of medication

(3) Factors that constitute an administration error: Wrong patient - Wrong dose - Wrong medication - Wrong time - Wrong route - Administration of medication when known allergy exists - Unordered and or outdated/discontinued medication

i. FIRE - PATIENT INVOLVED: This includes the patient(s) involved in a fire (with or without injury); who are burned, or who are exposed to smoke or fire, i.e., smoke inhalation

j. ASSAULT - PATIENT TO PATIENT: Another patient injures a patient or a patient is assaulted by another patient including a rape or homicide

k. ASSAULT - PATIENT TO STAFF: A staff member is physically struck or injured by a patient(s).

l. SEXUAL ASSAULT: This includes un-consented sexual contact with or without penetration regardless of gender including cases of rape involving a patient.

m. UNEXPECTED DEATH: Reportable deaths are those which occur in the operating room; in the recovery room; during anesthesia induction (including in procedure room); deaths during or within 24 hours of a procedure; death due to equipment malfunction or during use of a medical device; deaths reportable to, and accepted by the medical examiner; death of patients who are on the medical center grounds, but who are not necessarily being treated at the time; or generally unexpected.

n. TRANSFUSIONS ERRORS: Errors exist when blood is administered to the wrong patient; administered when not ordered; administered using the wrong product; incorrectly administered; or if there was an error in the type/cross-match process. These errors include; blood and blood products. Errors are to be reported according to the medical center policy, College of American Pathology (CAP), Joint Commission and other accrediting bodies. Reports are to be made part of blood usage review process.

o. FAILURE TO OBTAIN INFORMED CONSENT: Consent is not obtained which includes: invasive procedures, procedures requiring anesthesia or moderate sedation, and for patients who are participating in research protocols.

p. ENVIRONMENT OF CARE EVENTS: Events, other than those previously defined, that might include: serious injury of employee or visitor; fatality; major utility failure; major property damage; fire; bomb threat; and or bio-terrorism (biological [airborne], chemical, nuclear, or radiological) attacks.

q. MEDICAL DEVICE INCIDENT: Any item or equipment that is used for the diagnosis, treatment, or prevention of a disease, injury, illness, or other condition; and is not a drug that may have caused or contributed to a patient death, serious illness, or injury

r. OTHER: Incident categories as determined by the Chief of Staff (COS) in consultation with the Risk Manager which are not previously listed, where a patient may not have sustained an injury; however, the incident may lead to compensable events, or may bring about substantial negative publicity; and any event which may initiate an immediate Joint Commission visit for cause. In the event, that any of the previously mentioned situations occur without direct patient involvement the incident will be reportable to the VISN.

7. TORT CLAIMS: a. Potential - A potential claim is an event, accident, or incident, which in judgment of Risk Manager in collaboration with Regional Counsel, may develop into a potentially compensable event.

Claim - A written demand by a patient or his/her representative for a sum of money as a result of alleged negligent care. The signed claim would be filed with the Veterans Administration by a patient or his/her legal representative.

SEVERITY OF INJURY LEVELS

Level 0: No injury or disability

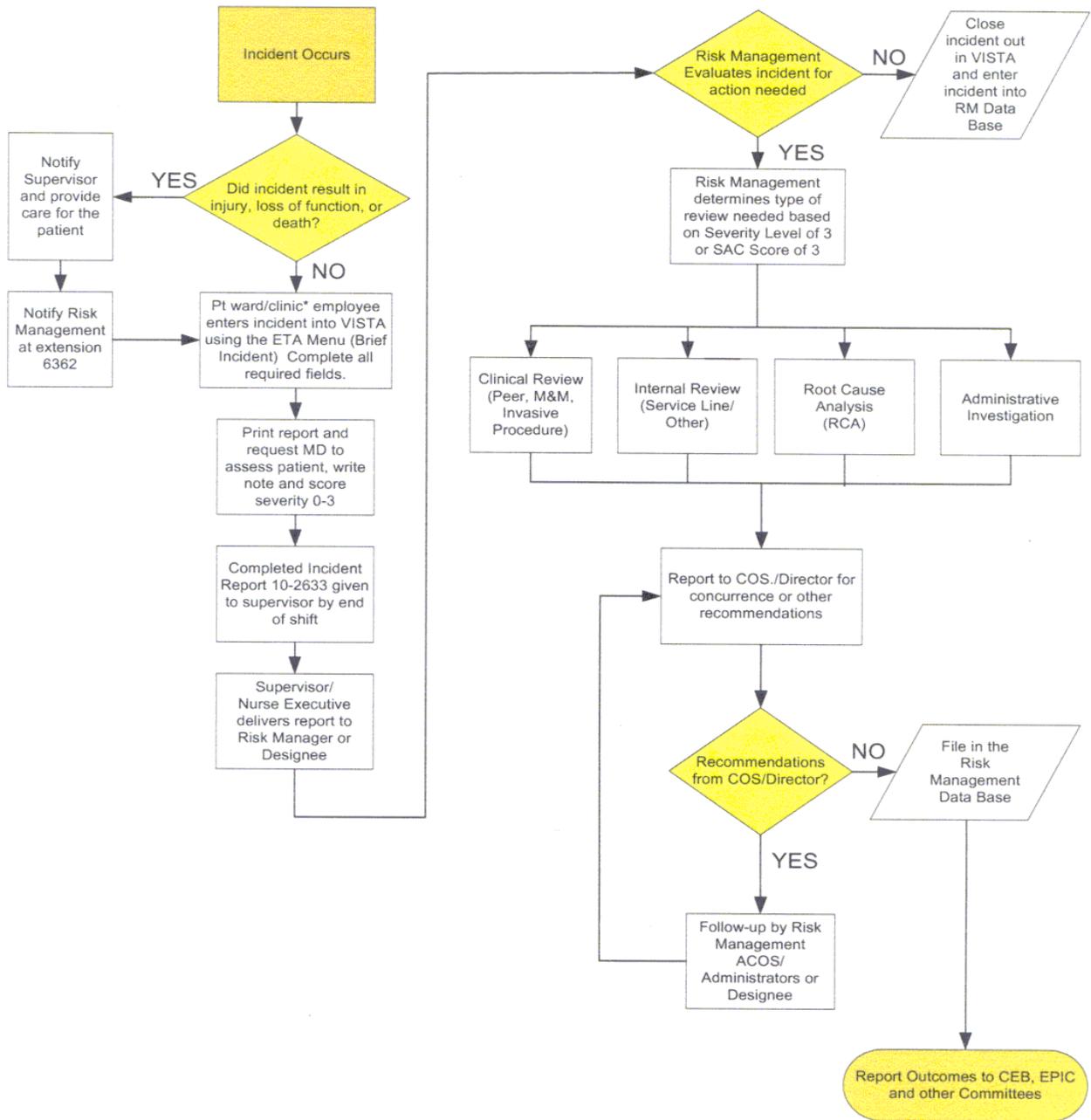
Level 1: Minor or Moderate injury: Injuries are minor or moderate in nature and if they do require any medical intervention, it does not extend the patient's hospital stay or outpatient treatments, except for observation or to obtain laboratory/radiology results. Examples: Fractures of fingers, bruises, abrasions, small lacerations requiring sutures, choking, bites, burns (those less than 1% of the body surface and 3rd degree smaller than ½ by ½”).

Level 2: Major: Injuries that require medical or surgical intervention, increased hospital stay or are disabling/disfiguring to a degree that the patient will have any degree of permanent dysfunction are sentinel event.

Examples: Laceration requiring extensive suturing, vital structure damage fractures of major bones, significant burns, organ loss, etc.

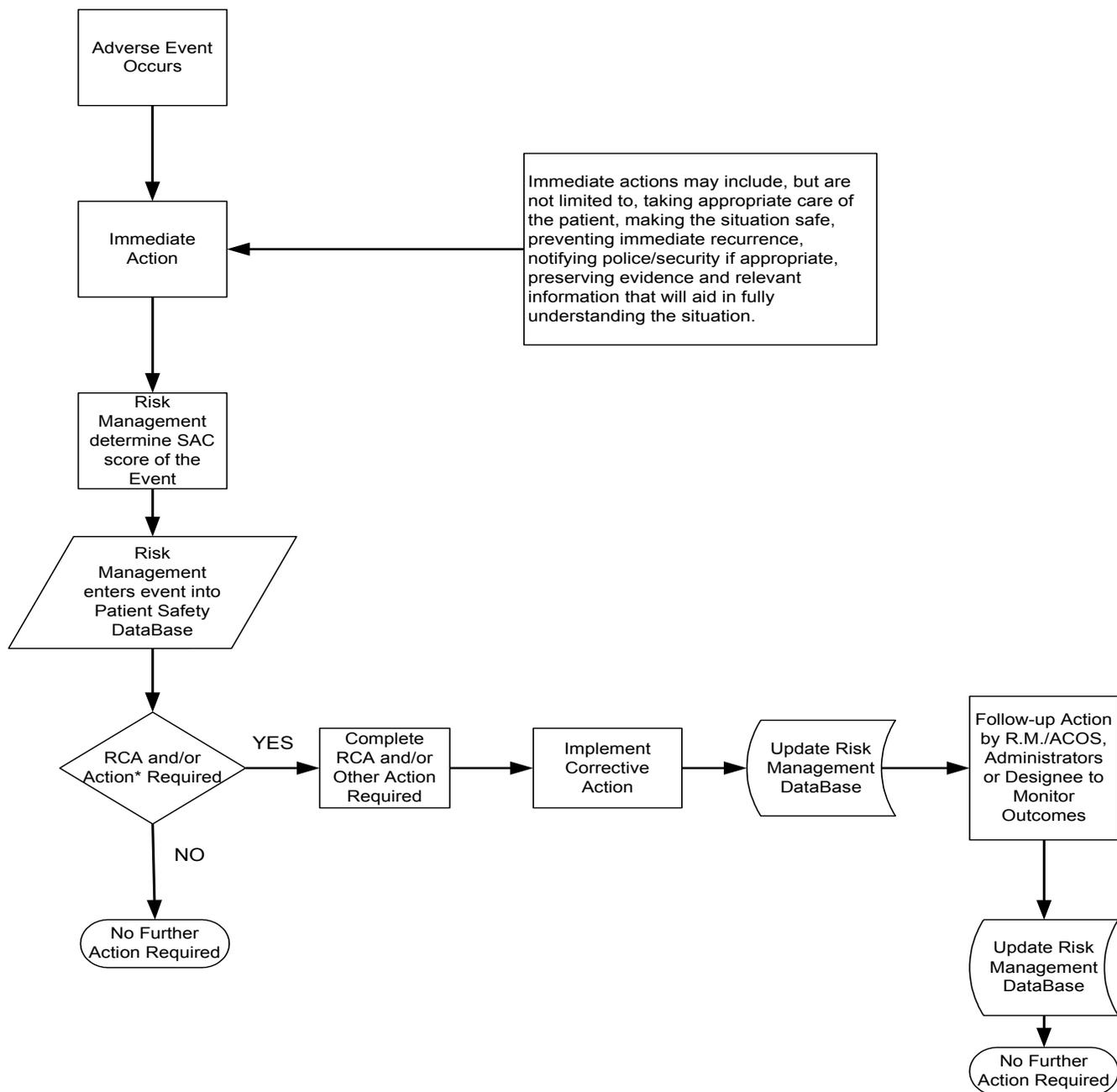
Level 3: Catastrophic - Death:

**Patient Safety/Risk Management (Incident Report Flow Chart)
Reporting of Adverse Events Involving a Patient.**



* Includes all specialty areas (ICUs, PACU, O.R., etc.)

Root Cause Analysis Flow Chart (Abbreviated)



* Falls, medication errors, para-suicidal events or missing patients. (high risk, high priority events) are aggregated and reviewed quarterly.

Root Cause Analysis

We use a multi-disciplinary team approach, known as Root Cause Analysis - RCA - to study health care-related adverse events and close calls. The goal of the RCA process is to find out what happened, why it happened, and how to prevent it from happening again. Because our Culture of Safety is based on prevention, not punishment, RCA teams investigate how well patient care systems function. We focus on the "how" and the "why" ? not on the "who". Through the application of Human Factors Engineering (HFE) approaches, we aim to support human performance. Because people on the frontline are usually in the best position to identify issues and solutions, RCA teams at VA health care facilities formulate solutions, test, implement, and measure outcomes in order to improve patient safety. See below to learn more about the RCA process ...

The goal of a **Root Cause Analysis** is to find out

- ***What happened***
- ***Why did it happen***
- ***How to prevent it from happening again.***

Root Cause Analysis is a *tool* for identifying prevention strategies. It is a process that is part of the effort to build a *culture of safety* and move beyond the culture of blame.

In **Root Cause Analysis**, basic and contributing causes are discovered in a process similar to diagnosis of disease - with the goal always in mind of preventing recurrence.

Root Cause Analysis is:

1. Inter-disciplinary, involving experts from the frontline services
2. Involving of those who are the most familiar with the situation
3. Continually digging deeper by asking why, why, why at each level of cause and effect.
4. A process that identifies changes that need to be made to systems
5. A process that is as impartial as possible

To be thorough a Root Cause Analysis must include:

1. Determination of human and other factors
2. Determination of related processes and systems
3. Analysis of underlying cause and effect systems through a series of *why* questions
4. Identification of risks and their potential contributions
5. Determination of potential improvement in processes or systems

To be Credible a Root Cause Analysis must:

1. Include participation by the leadership of the organization and those most closely involved in the processes and systems
2. Be internally consistent
3. Include consideration of relevant literature

Sample Joint Commission Sentinel Event Alert

Delays in treatment

While hospital Emergency Departments (EDs) are the source of just over one-half of all reported sentinel event cases of patient death or permanent injury due to delays in treatment, Joint Commission sentinel event data reveal that such serious problems can occur in any hospital unit, as well as in other health care settings. Of the 55 reported cases of delays in treatment, 29 were ED-related, while 26 cases originated in hospital intensive care units, medical-surgical units, inpatient psychiatric hospitals, freestanding and hospital-based ambulatory care services, the operating room and in the home care setting. Of the 55 cases of delays in treatment, 52 resulted in patient death. The reported reasons for the delays in treatment are many and varied with the most common factor being misdiagnosis (42 percent). Other delaying factors include: delayed test results (15 percent); physician availability

(13 percent); delayed administration of ordered care (13 percent); incomplete treatment (11 percent); delayed initial assessment (7 percent); patient left unattended (4 percent); paging system malfunction (2 percent); and unable to locate ER entrance (2 percent).

Of the 23 cases involving misdiagnoses, the most frequent missed diagnosis was meningitis (7); six of the seven cases were in children. Other missed diagnoses included various forms of cardiac disease, pulmonary embolism, trauma, asthma, neurologic disorder, and four cases of unknown diagnosis due to the patient leaving without being evaluated. Of the five cases that occurred in inpatient psychiatric hospitals, all were related to the delayed diagnosis or treatment of non-behavioral medical conditions.

Multiple root causes identified

Analyses of the cases reveal that multiple root causes contributed to each sentinel event, with most organizations (84 percent) citing a breakdown in communication, most often with or between physicians (67 percent).

Organizations also cited problems with patient assessment process (75 percent); continuum of care issues (62 percent), most often relating to discontinuity of care across settings or shifts; orientation and training of staff (46 percent); availability of critical patient information (42 percent); staffing levels (25 percent); and availability of physician specialists (16 percent).

Among the ED cases, the most commonly cited root causes were staffing (34 percent) and availability of physician specialists (21 percent); overcrowding was cited as a contributing factor in 31 percent of the cases.

According to an April 2002 American Hospital Association survey of hospitals¹, the majority of hospital EDs perceive they are at or over operating capacity with more than 90 percent of large hospitals (300 plus beds) reporting EDs at or over capacity. And, according to the survey, capacity constraints translate into longer waiting times for treatment, longer stays in the ED, and longer waiting times to get admitted to a general acute, critical care, or psychiatric bed.

"Delays have always been a source of concern for Emergency Departments, due in part to the inability to turn people away," says Michael T. Rapp, M.D., FACEP, past president of the American College of Emergency Physicians, and member of Joint Commission's Hospital Professional and Technical Advisory Committee.

"Providing timely treatment and avoiding delays is a constant challenge. Causes of delays tend to be multi-factorial, and both external and internal to the emergency department. Currently, issues of overcrowding are a threat to emergency departments everywhere, frequently stemming from insufficient inpatient beds. Other external factors can include slow turnaround of lab and X-ray results. Within the emergency department itself, there are a number of things that can be done to address delays, including simplifying and standardizing processes, and staffing at peaks of activity, not averages. It is also important to teach principles of teamwork which can both improve efficiency and enhance patient safety, and to communicate effectively, including read back of verbal orders."

Risk reduction strategies implemented

As a result of the sentinel events arising from delays in treatment and in response to the many identified root causes, health care organizations implemented multiple and varied risk reduction strategies. These strategies include a redesign of:

- Orientation and training processes (80 percent)
- Transfer procedures (27 percent)
- Staffing plans (25 percent)
- On-call specialist contact procedures (22 percent)
- Triage procedures (16 percent)
- Physical space (11 percent)

Other strategies include the implementation of formal oral communication procedures (25 percent); revised specialist on-call procedures (13 percent); and the revision or redesign of various other procedures such as initial assessment processes, patient information retrieval processes, credentialing and privileging processes, communication of abnormal lab or radiology results, and the implementation of voice recognition transcription software.

To help address communication issues, health care organizations can look to health information management (HIM) professionals who can assist in the development of lists of approved or prohibited abbreviations, optimize information availability, and avoid duplicate record production. "When health information availability issues are identified—whether oral, written or electronic—organizations are encouraged to include HIM professionals into the redesign processes to address problems at the source," says Beth Hjort, R.H.I.A., professional practice manager, American Health Information Management Association (AHIMA). "It is absolutely critical to create an environment and culture where individuals feel safe in asking questions and probing until there is complete understanding."

Joint Commission recommendations

In light of the number of organizations experiencing delays in treatment that cite problems with communication, the Joint Commission recommends that organizations:

1. Implement processes and procedures designed to improve the timeliness, completeness, and accuracy of staff-to-staff communication, including communication with and between resident and attending physicians.
2. Implement face-to-face interdisciplinary change-of-shift debriefings.
3. Take steps to reduce reliance on verbal orders and require a procedure of "read back" or verification when verbal orders are necessary.

In addition, Joint Commission recommends 4) that hospital EDs implement strategies to maintain a high index of suspicion for meningitis.

Resources

¹ *Emergency Department Overload: A Growing Crisis*. The Results of the American Hospital Association Survey of Emergency Department (ED) and Hospital Capacity, April 2002.

SAMPLE ENVIRONMENT OF CARE MANAGEMENT PROGRAM

1. **PURPOSE**: To establish policy and procedures regarding a Medical Center Environment of Care which provides protection to medical center patients, visitors and staff and complies with Joint Commission Standards, OSHA Standards and other regulatory organizations dealing with safety.
2. **POLICY**: The medical center will assure a safe environment for patients, employees, and visitors through the establishment and maintenance of an effective Environment of Care Program which includes life safety, equipment and utilities management, hazardous waste management, emergency preparedness, and security management. This program will be based on monitoring and evaluation of organizational experience, applicable laws and regulations, and accepted practice.
3. **RESPONSIBILITIES**:
 - a. The Medical Center Director is responsible for the overall Environment of Care Program, the quarterly review of summaries of the Medical Center Occupational Health and Safety Committee activities, and safety and fire protection issues. The Medical Center Director and the Chief of Staff shall be the approving official for all policies and procedures relative to the safety program, will approve the methodology for the annual review of the program, and will appoint a Safety Officer and a Safety Committee. As necessary, the Medical Center Director will act as the ultimate authority for modifications and conflicts directly associated with the program.
 - b. The Safety Officer (Assistant Administrator, Engineering Department) is responsible for:
 - (1) The development, implementation and monitoring of the medical center's safety and fire protection program.
 - (2) Implementation and maintenance of an ongoing hospital-wide system to collect and evaluate information for use by the Medical Center Safety Management Committee about hazards, safety practices and safety management issues.
 - (3) The annual review of all department safety plans and all medical center safety policies and procedures and the submission of a summary report to the Medical Center Safety Management Committee.
 - (4) Investigating all incidents that involve property damage, occupational illness and patient, personnel, or visitor injury.
 - c. Community Response/National Disaster Medical System (NDMS) Coordinator (Assistant Administrator, Medical Administration Department) is responsible for:

Working with federal, state and local agencies to coordinate this medical center's disaster planning efforts with those of the community. This individual will serve as this facility's liaison in planning, coordinating and executing this medical center's response to external drills and actual emergencies with outside agencies.
 - d. Department Chairs/Assistant Administrators are responsible for:
 - (1) Development and implementation of an ongoing and effective safety program in their department, including the assignment of a Safety Coordinator, and participating in and supporting the Environment of Care Program of the medical center including ensuring the reporting and review of all employee accidents and conducting safety inspections within the department.

- (2) Assuring that employees receive annual mandated training in general safety, fire or life safety, hazardous material safety, emergency preparedness, infection control, and security. Special department-specific training, as needed, will also be provided.
- (3) Preparing departmental safety policies and procedures that are distributed, practiced, and enforced.
- (4) Using safety-related information in the orientation of new employees and continuing education.
- (5) Reporting all security incidents that involve patients, visitors, personnel or property.
- (6) Educating and ensuring monitoring of personnel who manage or regularly come into contact with hazardous materials and wastes.
- (7) Identifying, evaluating, and preparing an inventory of hazardous materials and wastes used or generated in each department.
- (8) Reporting all hazardous materials or waste spills and exposures or other incidents that involve patients, visitors, personnel, or property.
- (9) Assessing and minimizing the clinical and physical risks associated with medical equipment through inspection, testing and maintenance of equipment and education of users.
- (10) Reporting and investigating equipment problems, failures, or user errors that may have an adverse effect on patient safety and/or the quality of care.
- (11) Developing department-specific policies that detail employee actions to be taken when equipment fails (Example: To cover department actions taken when a defibrillator fails - how to get backup - where is it, etc.).
- (12) Reporting all utility systems management problems, failures or user errors that are or may be a threat to the patient care environment (Example of an error is a 110V plug forcibly inserted in a 208V outlet).
- (13) Reporting all fire protection deficiencies, failures, and user errors.
- (14) Orienting and educating employees on the attached policies dealing with safety, life safety, security, hazardous materials and wastes, medical equipment and utilities with specific training on department or area processes for reporting deficiencies in any area (safety, life safety, etc.), specific area hazards (radiation, toxic materials, flammable storage, medical equipment usage, etc.), specific equipment assembly and operation, location of and proper use of emergency transport equipment, and operation procedures for emergency shut-off controls.
- (15) Establishing a department-specific process to review safety issues on a quarterly basis as outlined in Medical Center Policy Memorandums, Department Safety Meetings, and annually reviewing the effectiveness of the department level safety program and documenting this review in the respective minutes.

e. Assistant Administrator, Engineering Department, in addition to the responsibilities outlined in paragraph 3b., is responsible for:

- (1) The design and implementation of a medical equipment management program which assesses and controls the clinical and physical risks of fixed and portable equipment used for the diagnosis, treatment, monitoring and care of the patients and other fixed and portable electrically-powered equipment, according to medical center policy.
- (2) The design and implementation of a utilities management program which assures the operational reliability, assessment of special risks involved, and response to failure of any utility system which supports the patient care environment.
- (3) As the Safety Officer, ensuring adherence to the life safety standards as set forth by Joint Commission and the National Fire Protection Association (NFPA).

f. All employees are responsible for the prevention of accidents and injuries; for reporting all incidents that involve property damage, occupational illness, and patient, personnel or visitor injury; for reporting all unsafe conditions to their supervisor; and for attending safety training on an annual basis.

g. The Assistant Administrator, Police and Security Department is responsible for the development, implementation, and monitoring of policies and procedures for the appropriate identification of staff, visitors, and personnel; and the maintenance of a Police and Security Program which includes a Behavioral Emergency Management Plan for the medical center. h. The Radiation Safety Officer is responsible for advising the Medical Center Safety Management Committee of significant, identified radiation safety issues and of corrective actions taken; and managing the Medical Center Radiation Safety Program.

i. The Safety Officer is responsible for monitoring all aspects of fire safety including fire drills, compliance with the National Fire Safety Code, portable equipment checks, and liaison with Engineering Department to assure compliance with the Life Safety Code during construction and renovations.

- j. The Supervisor, Acquisition Section is responsible for promoting a hazardous surveillance program including response to product safety recalls.
- k. The Assistant Administrator, Human Resources Management Department (HRMD) is responsible for ensuring the use of safety-related information in the orientation of new employees and continuing education of all employees.

4. PROCEDURES:

- a. The Safety Officer for the medical center is granted the authority to immediately intervene or stop work, operation, project or acts which, in his/her opinion, may result in injury, impairment, sickness, or immediately endanger the life of patients, employees, or visitors, or threaten damage to equipment or buildings. The Radiation Safety Officer and Laser Safety Officer have the same authority in their respective areas of responsibility.
- b. The Safety Officer will establish a risk assessment program that proactively evaluates the impact on patient and public safety of buildings, grounds, equipment, occupants and internal physical systems.
- c. The Safety Officer will assure ongoing fire drills are conducted and documented.
- d. The Safety Officer will assure that annual inspection is done of Community Residential Care Homes and Contract Nursing Homes as required by VHA Headquarters' standards.
- e. The Industrial Hygienist will assure that an effective hazard surveillance program is conducted throughout the medical center and continuously improved, as appropriate.
- f. A Safety Management Committee (SMC) is established as required. The SMC shall prepare an annual evaluation of the objectives, scope, performance, and effectiveness of the documented Environment of Care Management Plan. The SMC is empowered through the approval of the Medical Center Director to direct service lines and specific departments to take appropriate action as required to address issues identified by the SMC and to meet the objectives of the Environment of Care Plan. If appropriate, departments shall include SMC directives in their Department Strategic Plans.

5. **REFERENCES:** Accreditation Manual for Hospitals, Joint Commission on Accreditation of Healthcare Organizations, current edition; OSHA Standards 29 CFR

6. **RESCISSION:** Policy Memorandum No. 00-45

7. **ATTACHMENTS:** Appendix A - List of Medical Center/Internal Departmental Policies and Procedures

8. EXPIRATION DATE:

REPORTING OF ADVERSE EVENTS INVOLVING PATIENTS(SPECIAL INCIDENTS INVOLVING A BENEFICIARY)

1. **PURPOSE:** To establish medical center policy and procedures on reporting, documenting, processing and systematically tracking and trending of untoward patient occurrences in order to prevent and minimize risks to patients and liability to the medical center, and to comply with the Total Quality Improvement (TQI) philosophy

2. POLICY

- a. In all instances where a beneficiary or visitor has been harmed, allegedly abused, physically or verbally, or involved in any event that could potentially be harmful, an incident report shall be entered in the VISTA Patient Incident Review (PIR) data base within 24 hours. The automated Incident Report Form 10-2633 is not part of the medical record (see Appendix A for definitions and a list of reportable adverse events)
- b. The patient's medical record will reflect a description of the event and pertinent medical factors, such as medical evaluation and intervention.
- c. An Incident Report shall also be initiated in the event a patient is inadvertently harmed during procedure (a "therapeutic misadventure"). Therapeutic Misadventures are defined as adverse events, which have caused, or have the potential of causing significant harm, discomfort, disability, or death, and occurred as part of the patient's diagnoses, care, or treatment while an inpatient or outpatient. If a "therapeutic misadventure" occurs, the patient or the patient's family, when appropriate, should be informed as soon as possible. The information provided is to be documented in the patient's medical record. Examples of a "therapeutic misadventure" are administering the wrong unit of blood, leaving a surgical sponge in the patient, or damage to tissue or organ during a procedure.
- d. Follow-up actions on each incident will be pursued by the Risk Management staff of the Quality Management Department.
- e. For adverse events involving personnel and visitors, see Appendix B

3. RESPONSIBILITY

- a. All Staff: Regardless of position or discipline, the employee who first becomes aware of an actual or potential adverse event, shall initiate an automated incident report or see to it that one is initiated (see Appendix C).
- b. Physicians: The physician responsible for patient care at the time of the incident will:
 - (1) Be notified immediately and promptly evaluate the patient and determine level of injury in accordance with Appendix D.
 - (2) In the case of therapeutic misadventure, inform the patient/family and document the discussion in the patient's medical record.
 - (3) If the adverse event resulted in injury or change in condition, inform the patient/family and document the change and the discussion in the medical record
- c. ACOSs/Administrators/Department Chairs and Assistant Administrators have the responsibility to
 - (1) Assure that employees are educated in adverse event/incident reporting procedures.
 - (2) Ensure timely reporting of incidents
- d. Chief of Staff is responsible for ensuring that appropriate action is taken and appropriate recommendations resulting from that action are implemented.
- e. Medical Center Director or Designee is responsible for appointing review teams for Focused Reviews, Reviews of Sentinel Events, Special Clinical Reviews and Administrative Boards of Investigations.
- f. Risk Management is responsible to:
 - (1) Coordinate and oversee all activities related to adverse events including, but not limited to: data collection, review, follow-up on recommendations, tracking of implementation of corrective action, and reporting aggregate data and individual-specific information.
 - (2) Ensure compliance with VA and other regulatory mandates, and integration of goals and activities with medical center mission and goals.
 - (3) Maintain the official files of all adverse events, related reviews and investigations.
 - (4) Ensure that there is timely reporting to the VISN of all sentinel events (24 hours), Level 2 and Level 3 occurrences (as soon as possible) and final reports of focused reviews (45 days).
 - (5) Maintain the PIR database, tracking, trending, analyzing and timely reporting to appropriate individuals and groups within the VISN.
 - (6) Coordinate and facilitate the mandated follow-up activities and communication of findings, root causes, recommendations of relevant events to appropriate individuals and groups.
 - (7) Track the status of follow-up actions on recommendations.
 - (8) Initiate and facilitate process improvements resulting from adverse events as appropriate.
 - (9) Educate medical center staff in the various aspects of the Patient Safety/Risk Management Program as indicated

4. PROCEDURES

- a. Ward staff notifies the immediate supervisor of the adverse event and enters incident reports on all inpatient and outpatient incidents as indicated.
- b. Sentinel events and other selected incidents are reported to Risk Management and management immediately. Analysis of sentinel events will include Root Cause Analysis.
- c. Risk Management and clinical staff will review all incidents entered on the previous days. Risk Management will determine appropriate follow-up in accordance with Appendixes C and E and initiate proper procedures.
- d. Risk Management initiates VISN reports which are submitted through the Office of the Director as follows
 - (1) The following are reported to the VISN within 24 hours
 - (a) Sentinel events (adverse event that results in loss of life, limb or permanent loss of function).
 - (b) Adverse events generating substantial negative publicity.
 - (c) Any event which may initiate an immediate Joint Commission visit for cause.
 - (2) Reports to VISN are sent within 24 hours via MS Exchange and include
 - (a) Facility ID number (644)
 - (b) Patient ID (initial of first name and last name and last four of SSN)
 - (c) Date of Incident

- (d) Type of incident and severity
- (e) Description of event
- (f) Outcome
- (3) The following adverse events should be communicated to the VISN as soon as possible
 - (a) All adverse events with Level 2 or 3 severity of injury
 - (b) Unplanned clinical occurrences – Level 2 and 3
 - (c) Allegations of patient abuse
 - (d) Potential compensable events
 - (e) Those events suspected of criminal intent
- (4) Focused reviews are conducted for all incidents listed above. Final reports of Focused Reviews and Root Cause Analysis are reported to the VISN office within 45 days unless there are extenuating circumstances
- e. Risk Management will initiate focused reviews as soon as possible, but no later than 10 days after initiation of the 10-2633 (see Appendix E, Focused Reviews)

5. REFERENCES: VHA Patient Safety Handbook 1051/1 and Medical Center Policy No. 11-33, Integrated Patient Safety/Risk Management Program

DEFINITIONS OF ADVERSE EVENTS

1. ADVERSE EVENT: Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other unexpected occurrences that have negative consequences. Sentinel events and unplanned clinical occurrences are the major categories of adverse events. They are distinguished according to the outcome or consequences of the event and are equivalent to occurrence screening elements. All adverse events require specific review in accordance with this policy.

2. SENTINEL EVENT: A sentinel event is an adverse event that results in the loss of life or limb or permanent loss of function. Examples of sentinel events include death resulting from a medication error or an assault and suicide by patients who received services from the medical facility within the prior thirty (30) days. In addition, the following incidents will be considered reportable regardless of severity level

- a. Rape (by another patient or staff)
- b. Hemolytic transfusion reaction
- c. Surgery on the wrong patient or wrong body part

3. UNPLANNED CLINICAL OCCURRENCES are adverse events that result in hospitalization, increased hospital stay (for more than observation), emergency intervention, or prolonged outpatient treatment. More likely than not, an unplanned clinical occurrence would have become a sentinel event if circumstances had been less fortuitous, e.g., an error had not been caught by chance rather than through a systematic monitoring process. An unplanned clinical occurrence may result from acts of commission or omission, e.g., administration of the wrong medication or failure to make a timely diagnosis of cancer

4. TYPES OF ADVERSE EVENTS

a. Suicide is the voluntary act of taking one's own life. Cases in which patients commit suicide are reportable if the patient is currently receiving inpatient care or within 30 calendar days of a VA clinic encounter or visit.

b. A suicide attempt is a self-destructive act requiring inpatient medical, psychiatric or surgical care, and carries a high risk for severe injury or death and may require the provision of additional care to respond to the patient's needs. A suicide gesture is a self-destructive act that is manipulative or attention seeking and does not require inpatient medical or surgical care to prevent serious injury or death. Self-destructive acts will be evaluated by a psychiatrist to determine if the act constitutes an attempt or gesture.

c. Patient abuse includes acts against patients that involve physical, psychological or verbal abuse. The "intent" to abuse is not a requirement for patient abuse. Patient's perspective of how he/she is being treated is an essential component of the determination of a patient abuse. However, the fact that a patient has limited or no cognitive ability does not exclude the possibility of abuse. An allegation of patient abuse includes any of the following

(1) Any action or behavior that conflicts with patients' rights, as identified in 38 Code of Federal Regulations (CFR) 17.34; (2) Intentional omission of patient care; (3) Willful violations of the privacy of the patient(s); (4) Intimidation, harassment or ridicule of the patient(s); and/or (5) Willful physical injury of a patient

d. Missing Patients: A patient who absents him/herself from the patient care area without knowledge and permission of staff for any length of time, even if found or returns. A patient is considered a high-risk patient if he/she meets one or more of the following criteria and will have an incident report completed regardless of severity level: (1) The patient is considered a danger to self or others; (2) The patient has a court-appointed legal guardian; (3) The patient is legally committed; or (4) The patient lacks the cognitive ability to make decisions.

e. Homicide: Homicide is the taking of the life of a patient or staff member, either accidentally or intentionally. This includes homicides that occur on medical center property in both inpatient and outpatient areas, while patients are being transported by self-destructive act that is manipulative or attention seeking and does not require inpatient medical or surgical care to prevent serious injury or death. Self-destructive acts will be evaluated by a psychiatrist to determine if the act constitutes an attempt or gesture.

c. Patient abuse includes acts against patients that involve physical, psychological or verbal abuse. The "intent" to abuse is not a requirement for patient abuse. Patient's perspective of how he/she is being treated is an essential component of the determination of a patient abuse. However, the fact that a patient has limited or no cognitive ability does not exclude the possibility of abuse. An allegation of patient abuse includes any of the following (1) Any action or behavior that conflicts with patients' rights, as identified in 38 Code of Federal Regulations (CFR) 17.34; (2) Intentional omission of patient care; (3) Willful violations of the privacy of the patient(s); (4) Intimidation, harassment or ridicule of the patient(s); and/or (5) Willful physical injury of a patient

d. Missing Patients: A patient who absents him/herself from the patient care area without knowledge & permission of staff for any length of time, even if found or returns. A patient is considered high-risk patient if he meets one or more of the following criteria and will have an incident report completed regardless of severity level:

(1) The patient is considered a danger to self or others; (2) The patient has a court-appointed legal guardian; (3) The patient is legally committed; or (4) The patient lacks the cognitive ability to make decisions.

e. Homicide: Homicide is the taking of the life of a patient or staff member, either accidentally or intentionally. This includes homicides that occur on medical center property in both inpatient and outpatient areas, while patients are being transported by medical center personnel for treatment; patient is out on pass, and those involved in medical center recreational activities.

f. Falls: An uncontrolled descent by a patient regardless of whether it was observed or whether or not there is an injury.

g. Medication Errors: A dose of medication that deviates from the physician's order as written in the patient's medical record or as written on an outpatient prescription form or which deviates from standard policies/procedures for administering and dispensing medications

(1) Inpatient Medication Error - If a medication is administered to the patient and one of the following conditions exist

(a) Wrong patient (b) Wrong medication (c) Wrong dose is given (d) Wrong route of administration (e) Wrong rate (f) Wrong time of administration (g) Omission of medication (h) Wrong labeling (i) Medication is not given as the physician ordered provided that it was ordered per established standards

(2) Outpatient Medication Error - If an incorrect medication is received by the patient (regardless of whether the patient actually takes any of the medication), the above principles of being wrong would apply.

(3) A medication error occurs when individual or specialized inpatient or outpatient prescriptions, including intravenous admixtures compounded by Pharmacy Department, do not meet the labeling requirements of DM&S Clinical Services Manual, M-2, Part VII, "Pharmacy Service." In these cases, the medication does not have to be administered to the patient for it to be considered a medication error. It is also considered an error when the additive to the intravenous (IV) mixture is incorrect, be it type of medication or dosage

h. Fire, Patient Involved: This includes the patient(s) involved in a fire (with or without injury); who are burned, or who are exposed to smoke or fire, i.e., smoke inhalation.

- i. **Assault - Patient to Patient:** A patient is injured by another patient or a patient assaulted by another patient.
 - (1) Regardless of the number of patients involved, a VA Form 10-2633, is to be completed for each patient involved and then reported as an individual case of patient on patient assault. This will allow a severity of injury assessment to be assigned to each patient involved.
 - (2) If the assault is a rape or a homicide it should be reported only in those categories
- j. **Assault - Patient to Staff:** A staff member is physically struck or injured by a patient(s).
- k. **Sexual Assault:** This includes unconsented sexual contact with or without penetration regardless of gender including cases of rape involving a patient.
- l. **Unexpected Death:** Reportable deaths are those which occur in the operating room; in the recovery room; during anesthesia induction (including in procedure room); deaths during or within 24 hours of a procedure; death due to equipment malfunction or during use of a medical device; deaths reportable to, and accepted by medical examiner; death of patients who are on the medical center grounds, but who are not necessarily being treated at the time; or generally unexpected.
- m. **Transfusions Errors:** Errors exist when blood is administered to the wrong patient; administered when not ordered; administered using the wrong product; incorrectly administered; or if there was an error in the type/cross match process. These errors include blood and blood products. Errors are to be reported according to medical center policy, College of American Pathology (CAP), Joint Commission and other accrediting bodies. The reports are to be made part of the blood usage review process.
- n. **Failure to Obtain Informed Consent:** Consent is not obtained for all invasive procedures, for all procedures requiring anesthesia, and for patients who are participating in research protocols
- o. **Environment of Care Events:** Events, other than those previously defined, that might include employee or visitor serious injury, fatality, major utility failure, major property damage, fire, and bomb threat/incident.
- p. **Medical Device Incident:** Any item that is used for the diagnosis, treatment, or prevention of a disease, injury, illness, or other condition; and is not a drug that may have caused or contributed to a patient death, serious illness, or injury.
- q. **Injury not otherwise listed:** Any injury to a patient not addressed specifically in this policy is included in this category including, but not limited to, surgery on the wrong patient or wrong body part; acts of self-mutilation or abuse inflicted by a patient which is not considered suicidal behavior; injuries incurred as a result of use of a medical device; and hemolytic transfusion reactions.
- r. **Other:** Incident categories as determined by the Chief of Staff (COS) in consultation with the Risk Manager which are not previously listed, where a patient may not have sustained an injury; however, the incident may lead to compensable events, or may bring about substantial negative publicity; and any event which may initiate an immediate Joint Commission visit for cause. In the event that any of the above situations occur, without direct patient involvement, the incident will be reportable to the VISN through appropriate channels

5. **TORT CLAIMS**

- a. **Potential:** A potential claim is an event, accident, or incident which, in the judgment of the Medical Center Risk Manager in collaboration with Regional Counsel, may develop into a potentially compensable event.
- b. **Claim:** A written demand by a patient or his/her representative for a sum of money as a result of alleged negligent care. The signed claim would be filed with the Veterans Administration by a patient or his/her legal representative

ADVERSE EVENTS INVOLVING PERSONNEL AND VISITOR

1. Employees who sustain an injury while on duty shall report immediately to their supervisor and then to the employee health unit, or their personal physician, for evaluation and treatment
2. The Office of Workman's Compensation (OWCP) Form CA-1, Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation, or CA-2, Notice of Occupational Disease and Claim for Compensation, needs to be completed as soon as possible. Department of Veterans Affairs (VA) Form 2162, Report of Occupational Injury or Illness, must be completed and a copy filed with the Safety Office

NOTE: Information about compensation for employees and other forms used to document these events are detailed in OWCP Pamphlet, CA-11.

3. Visitors who are involved in an adverse event should be evaluated and treated on a humanitarian basis at the treatment facility, if medically appropriate. VA Form 10-10M, Medical Certificate, will be used in the evaluation of a visitor involved in an incident. Other appropriate forms will be used to create a record of the event, e.g., progress notes, etc. A copy of the VA Form 10-10M, and other forms used to record the events, will be filed in the Safety Office

SEVERITY OF INJURY LEVEL

Level 0: No injury or disability

Level 1: Minor injury:

Injuries are minor in nature if medical intervention is not required and it does not extend the patient's hospital stay or outpatient treatments, except for observation or to obtain laboratory/radiology results. Examples: Fractures of fingers, bruises, abrasions, lacerations not requiring more than 12 sutures, choking, bites, burns (those less than 1% of the body surface and 3rd degree smaller than ½" by ½")

Level 2: Major:

Injuries which require medical or surgical intervention, increased hospital stay (unplanned clinical occurrence), or are disabling or disfiguring (to a degree that the patient will have any degree of permanent dysfunction) are sentinel events. Examples: Laceration requiring more than 12 sutures, vital structure damage, fractures of major bones, significant burns, organ loss, etc.

Level 3: Death:

FOCUSED REVIEWS:

1. Are conducted in the following circumstances:

- (a) Sentinel events - An adverse event that results in loss of life, limb or permanent loss of function (also conduct Root Cause Analysis)
- (b) Adverse events generating substantial negative publicity
- (c) Any event which may initiate an immediate Joint Commission visit for cause are reported to the VISN within 24 hours.
- (d) All adverse events with Levels 2 or 3 severity of injury
- (e) Unplanned clinical occurrences – Level 2 and Level 3
- (f) Allegations of patient abuse
- (g) Potential compensable events
- (h) Those events suspected of criminal intent

2. Final reports of Focused Reviews and Root Cause Analysis are reported to the VISN within 45 days unless there are extenuating circumstances.

3. The Medical Center Director, or designee, will appoint an appropriate reviewer or review team for each Focused Review. Appointees should be knowledgeable about the relevant clinical issues, quality improvement, and skilled in identifying system defects. Appointees shall not have direct involvement in the event nor have a direct supervisory role over any of the involved individuals. The written report from the Focused Review shall include the scope of the review (individuals interviewed and documents reviewed), answers to the 10 questions listed in appendix, conclusions, and recommendations for review and approval by the Medical Center Director. The Risk Manager submits a copy of each report (through the Office of the Director) to the VISN, after indicating actions taken as a result of the report. The report should use the patient's initials and last four digits of the social security number (SSN) as the identifier rather than the full name. Names of practitioners should not be included.

4. Focused Reviews will be considered confidential and protected as quality management information.

"Confidential" This document is confidential and privileged under provision of 38 U.S.C. & C.F.R. 17-500-511 which provides for fines up to \$20,000 for violations. This material shall not be transmitted to anyone without proper consent or other authorization.

RISK MANAGEMENT EXECUTIVE SUMMARY
FOCUSED REVIEW/BOARD OF INVESTIGATION

Pt Initials & #		Facility #	
Date of Incident		Pt Disposition	

Scope of Review: (Individuals interviewed, documents reviewed, etc.)	
What exactly was the adverse event?	
What was the chain of events that resulted in the adverse event?	
Was the adverse event preventable?	
Did any errors lead to the adverse event?	
What were the root causes (both direct and indirect) of each error?	
Did any errors and/or root causes involve inadequate systems or systems failure?	
Is there a need to redesign the relevant system?	
Were any actions taken by staff in responding to the adverse event particularly helpful?	
Should any personnel action be taken?	
Are there lessons that may be learned that may be helpful to other facilities?	
Conclusions:	
Recommendations:	
Literature:	
Reviewer	

SAMPLE COMPLIANCE PROGRAM

1. **PURPOSE:** To establish policy and procedures for a Compliance Program to ensure the highest levels of professional and ethical behavior in facility operations.

2. **POLICY:** This facility has a policy of maintaining the highest level of professional and ethical standards in the conduct of its clinical and administrative operations. High importance is placed on our reputation for honesty, integrity and high ethical standards.

a. These standards can be achieved and sustained only through the actions and conduct of all personnel. Each employee is obligated to conduct himself/herself in a manner to ensure the maintenance of these standards. Such actions will be factors in evaluating an employee's judgment, competence, performance rating or proficiency.

b. Every employee who is materially involved in any documentation, coding or billing activity has an obligation to familiarize himself or herself with applicable laws, regulations and VA policies and to adhere at all times to these requirements. Where any questions or uncertainty regarding these requirements exists, it is incumbent on each employee to seek guidance from a knowledgeable management official.

c. This policy prohibits managers and employees from:

(1) Making improper claims to any U.S. government agency or program official, or any other health care payer, including:

(a) Items or services not provided as claimed;

(b) Making a false claim(s); and

(c) Allowing services by an unlicensed physician; or was licensed as a physician, but the physician's license had been obtained through misrepresentation.(2) Providing services which are not medically necessary, except for research subjects with proper approval and consents;

(3) Refusing to treat, transferring or discharging any patient without first providing for an appropriate medical screening to determine if the individual has an emergency medical condition requiring stabilization prior to transfer or release;

(4) Soliciting or receiving remuneration in return for referring a patient(s) to another individual or organization for health care related services or procedures; and

(5) Failing to promptly report to the Compliance Officer, or other medical center official, any instance of non-compliant conduct, including violations of the standards described in the previous paragraphs.

3. **PROCEDURES:**

a. Performance Ratings/Proficiencies: Employee adherence to this policy and related activities, to include completion of mandatory group training, will be a performance rating/proficiency element of each employee who is involved in any documentation, coding, billing or other compliance related activities, including supervision or management of such activities.

b. Auditing and Monitoring:

(1) Audits: Pursuant to a VISN 18 audit plan and schedule, periodic compliance audits will be conducted by VISN 18 representatives, the Compliance Officer or other appropriate designees. Such audits shall evaluate the medical center's compliance with this Compliance Program, as well as VISN 18 Compliance Program requirements.

(2) Compliance audits may include:

(a) Interviews conducted with personnel involved in management, operations, and other related activities;

(b) Reviews of whether the Compliance Program elements have been satisfied (e.g., whether there has been appropriate dissemination of the Compliance Program standards, training, etc.);

(c) Review of records with special attention given to procedures relating to documentation, coding, billing and the giving and receiving of remuneration to induce referrals; and

(d) Other reviews determined appropriate.

(3) Audit reports will be submitted by the Compliance Officer to the Medical Center Director and VISN 18, as appropriate, to ensure that the Director and VISN 18 management are aware and can take necessary steps to correct/deter problems. Audits or other analytical reports should identify areas where corrective actions are needed and identify if any subsequent audits or studies are advisable.

(4) Retention of Records and Reports: All records and reports created in conjunction with the adherence to the Compliance Program are confidential and shall be maintained by the Compliance Officer, in a secure location until such time as the Compliance Officer determines that the destruction or retirement of such documentation is appropriate. Retention of compliance related records and documents would be consistent with applicable RCS 10-1 and other legal or regulatory requirements

c. Education and Training:

(1) The medical center will make available appropriate educational and training programs and resources to ensure employees are thoroughly familiar with those areas of law that apply to and affect the conduct of their duties, including the specific areas of documentation, coding and billing. Employees will sign from time to time an acknowledgement statement to the effect that the employee fully understands the Compliance Program and acknowledges his/her commitment to comply with the program as an employee of the medical center. The employee's appropriate supervisor shall retain this acknowledgement. Managers and supervisors of individual employees are responsible to ensure these forms are signed. Sample acknowledgment statements are shown as attachments (Appendixes A and B).

(2) The Compliance Officer, consistent with VISN 18 Compliance Education Plan, will be responsible for development and implementation of an effective Compliance Education Program. The program should provide each employee with an appropriate level of information and instruction regarding ethical and legal standards, including standards for documentation, coding, billing, and referral practices. Compliance education and training of employees shall be conducted at least annually. The VISN 18 education plan will identify necessary training by category of employee.

3) Different methods may be used to communicate information about applicable laws and regulations to employees. The medical center may conduct training sessions, regarding compliance, which will be mandatory for employees. The orientation for new employees will include discussions of the Compliance Program and an employee's obligation to maintain the highest level of ethical and legal conduct. Acknowledgment by employees and contractors of this Compliance Program Policy and the Compliance Program is an essential component of all training or education efforts.

d. Compliance Communication:

(1) While the medical center will make every effort to provide appropriate compliance information to all employees, and to respond to all inquiries, no educational and training program, however comprehensive, can anticipate every situation that may present compliance issues. Responsibility for compliance with this Compliance Program, including the duty to seek guidance when in doubt, rests with each employee.

(2) The medical center will maximize employee and patient awareness regarding its Compliance Program efforts. As a minimum, these efforts will include posted announcements with ways and means to contact the Compliance Officer. The Compliance Officer dedicated "Helpline" number will be included in such postings.

e. Violations: Documented compliance violations or offenses will be dealt with consistent with OPM/VA regulations regarding disciplinary policies and procedures and applicable union contract provisions.

4. **RESPONSIBILITIES:**

a. The Medical Center Director has overall responsibility for the operations of the medical center, including the Compliance Program.

b. The Compliance Officer is responsible for:

(1) Working with the Medical Center Director; Administrator, Resources and Financial Management Services; Chief of Staff; other Service Line Administrators and employees in the preparation and development of a Compliance Program, including documentation, coding, and billing practices with respect to requests for payments and/or reimbursements from Medicare or any other health insurer program;

(2) Consistent with VISN 18's Compliance Education Plan, developing and implementing an educational training program for personnel to ensure an understanding of laws and regulations involving ethical and legal business practices including, documentation, coding, and billing practices for requests for payments from Medicare or any other health care insurance program. Note: Documentation of employee awareness of this Compliance Program Policy and the Compliance Program is an essential aspect of this responsibility; see paragraph 3c(1);

(3) Handling inquiries by employees regarding any aspect of the Compliance Program;

(4) Investigating, or causing to be investigated, information or allegation(s) concerning possible unethical or improper business practices and recommending corrective action when necessary; with appropriate documentation including final disposition and preventative actions;

(5) Providing guidance and interpretation to the Medical Center Director and other personnel on matters related to the Compliance Program;

(6) Consistent with VISN 18 guidelines, planning and overseeing regular, periodic audits of the operations to identify and rectify any possible barriers to an effective Compliance Program;

- (7) Developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation;
- (8) Preparing regular reports for the Medical Center Director, VISN 18 or VHA, as appropriate, concerning the compliance activities and actions undertaken and any recommendations for changes in the Compliance Program;
- (9) Coordinating personnel issues with the Human Resources Officer, and the credentialing and privileging staff to ensure that the National Practitioner Data Bank and HHS Provider Exclusion lists have been checked with respect to all medical staff and independent medical providers (including contractors and consultants);
- (10) Ensuring that independent contractors and medical providers who furnish medical services are aware of the Compliance Program including its policies with respect to the specific areas of documentation, coding, billing, and referral practices. Such awareness will be appropriately documented;
- (11) Coordinating the Compliance Program with VISN 18 and VHA officials and program requirements, including participating on VISN 18 Compliance workgroups, task forces and committees, as appropriate;
- (12) Compliance Officer will have an open-door policy, including a dedicated compliance "Helpline," with respect to receiving reports of violations, or suspected violations, of law or policy and with respect to answering employee questions concerning adherence to law and to policy; and
- (13) Performing other duties and responsibilities as directed.

c. The Associate Director and Chief of Staff have responsibility to ensure successful implementation of the Compliance Program within their subordinate organizational elements and by their subordinate managers, supervisors and employees, including trainees and contractors.

d. Clinical Department Chairs and other managers and supervisors are responsible for adherence to Compliance Program Policy principles and procedures in their own behavior and in the behavior of their subordinate employees, including house staff, other trainees and contract employees.

e. Each employee, including house staff, trainees, and contractors who is involved in any documentation, coding, billing or competitive practices has an obligation to familiarize himself or herself with applicable laws and regulations and to adhere at all times to the requirements thereof. Where any questions or uncertainty regarding these requirements exists, it is incumbent on each employee to seek guidance from a knowledgeable management official. All employees are responsible to immediately report to the Compliance Officer or other management official suspected or actual violations of applicable law or regulations. All information that is reported by any employee in accordance with this policy would be kept confidential to the extent that confidentiality is possible; however, there may be a point where an employee's identity may become known or may have to be revealed in certain instances.

Under no circumstances shall the reporting of any such information or possible impropriety serve as a basis for any retaliatory actions to be taken against any employee making the report.

f. Compliance Committee: A Compliance Committee will be appointed by the Director to advise management and assist in the implementation of the Compliance Program.

(1) The purpose of the Compliance Committee is to allow the medical center to benefit from the combined perspectives of individuals with varying responsibilities, such as, operations, finance, audit, human resources, utilization review, social work, discharge planning, medicine, coding, as well as employees and managers of key operating units.

(2) The Compliance Committee's functions will include:

- (a) Identifying compliance risk areas;
- (b) Assessing existing policies and procedures to ensure that they facilitate the Compliance Policy;
- (c) Working with appropriate organizational elements to promote compliance;
- (d) Developing internal systems and controls to ensure success of Compliance Program; and
- (e) Determining appropriate approaches to promote compliance, including identification of improved reporting mechanisms and enhanced training.

(3) Members of the Compliance Committee will be as follows:

Chairperson: Compliance Officer (00C)

Members: Executive Administrative Support Staff Recorder

ACOS/Quality Management Dept./Ethics Committee Representative (11Q), Human Resources Specialist (HRMS/05), Assistant Administrator, Health Information Management (IS/HIMD), Medical Care Cost Recovery (MCCR) Supervisor (RFMS/136F), Coding Compliance Specialist (IS), Radiology Department Representative (CS/114), Surgical Department Representative (CS/112), Pathology and Laboratory Medicine Department (CS/113), Education and Research Services Representative (ERS), Mental Health and Behavioral Sciences Services Representative

(MH&BSS), Geriatrics and Extended Care Services Representative (GECS), Ambulatory Care Services Representative (ACS), Union Representative (AFGE Local 2382), Informatics Services Representative (IS)

5. **REFERENCES:** Veterans Health Administration, Billing and Coding Audit Report, January 1999; Stark Law 42 U.S.C. 1395; Proposed Stark II Regulations: 63 Federal Register 1659 (January 9, 1998); Office of Inspector General, Work Plan, Fiscal Year 1999; The False Claims Act, 31 U.S.C. 3729; and Compliance Program Guidance for Hospitals (Office of Inspector General (OIG) of the Department of Health and Human Services, February 1998).

6. **RESCISSION:** Policy Memorandum No. 00-61 *ACKNOWLEDGMENT*

I hereby acknowledge that I have received and reviewed the Carl T. Hayden VA Medical Center's Corporate Compliance Program, including its Statement of Policy on Ethical Practices. I fully understand that, as an employee, I have an obligation to fully adhere to these policies and principles. In particular, I hereby acknowledge and affirm that:

1. I fully understand the Compliance Program Policy and the Compliance Program, and I acknowledge my commitment to comply with the Policy and Compliance Program as an employee.
2. When I have a concern about a possible violation of Policy, I will promptly report the concern to the Compliance Coordinator in accordance with the Compliance Program.

Employee's Signature

Date

Printed Name of Employee

PHYSICIAN ACKNOWLEDGEMENT - COMPLIANCE

The undersigned physician (Physician) acknowledges that he or she has received and reviewed the Carl T. Hayden VA Medical Center's Compliance Program, including its Statement of Policy on Ethical Practices. Physician fully understands the Compliance Program Policy and the Compliance Program and is committed to comply with the Policy and Compliance Program as long as Physician has privileges at the facility. When Physician has a concern about a possible violation of this Policy, Physician will promptly report the concern to the Compliance Coordinator in accordance with the Compliance Program. Physician acknowledges that the Carl T. Hayden VAMC may furnish to all physicians and their staff, from time to time, training in the federal requirements for determining, accurately documenting, and supporting the principal and secondary diagnoses and the major procedures performed on the patient, as attested by Physician in the medical record pursuant to 42 C.F.R. § 412.46. Such training shall be furnished for one or more of the following purposes: (1) to promote compliance with the Physician's obligations under 42 C.F.R. § 412.46, (2) to promote compliance with the facility policy pursuant to the Compliance Program, and/or (3) to satisfy the training standard imposed on the Carl T. Hayden VAMC under proposed 42 C.F.R. § 482.125(c) for continued participation in the Medicare, Medicaid or other programs. Physician and the medical center each acknowledges that such training is not intended to, and will not, induce referrals from Physician to the medical center. To the extent that such training may be deemed to constitute remuneration or compensation under any applicable law or regulation, the benefit resulting from such training to the Physician is consistent with fair market value of the services rendered by the Physician in documenting and attesting the medical records which support the billings. The term of this arrangement is at least one year and shall continue thereafter as long as Physician has admitting privileges at the Carl T. Hayden VA Medical Center.

Physician's Signature

Date

Printed Name of Physician

Utilization Management Legislation

- Title XVIII Social Security Act 1965
 - Established Medicare Program
- Title XIX Social Security Act 1965
 - Medicaid Program
- Amendment to Social Security Act 1972
 - Established professional standards review organizations
- Federal HMO Act 1973

Omnibus Budget Reconciliation Act 1981 Diagnostic Related Groups (DRGs)

- Tax Equity & Fiscal Responsibility Act 1982
 - Prospective payment based on DRGs
 - Incentives to increase discharges, decrease LOS & ancillary services; shift care; HMOs
- Peer Review Improvement Act 1982
 - Peer Review Organizations
- Social Security Amendment 1983
 - Prospective payment system based on DRGs
- Consolidated Omnibus Reconciliation Act 1985
 - Payment denial substandard care
- Medicare Conditions of Participation 1986
- Patient Self Determination Act 1990 (Advance Directives)
- Safe Medical Devices Act 1990
- Americans with Disabilities Act 1990
- Occupational Safety & Health Administration 1991-bloodborne pathogens
- OSHA 1993-prevention TB transmission
- Healthcare Research & Quality Act 1999
- Needlestick Safety & Prevention Act 2000
- Medicare Prescription Drug Improvement & Modernization Act 2003
- Patient Safety & Quality Improvement Act 2005
- Safety of Seniors Act 2007 (reduce falls)
- Affordable Care Act 2010
- Public demand for more efficient use of resources while providing access created healthcare reform movement

Utilization management in healthcare can be defined as a series of actions to produce a quality health care product in a cost effective manner while contributing to the overall goals of an institution. Utilization management seeks to identify and resolve problems that can result in excessive resource utilization and inefficient care delivery. Utilization management is a critical component of an integrated quality management process and the key to a successful quality/performance improvement process.

Utilization review includes assessment, the process whereby the reviewer assesses the use of professional care, services, and procedures, and evaluation of the need and appropriateness of care. Utilization review intervenes and proposes solutions for situations in which cost and quality are jeopardized and screens patients for discharge needs and follow up care. Historically, factors that contribute to utilization problems are lack of incentives for controlling costs, lack of actual cost awareness by medical and professional staff, non individualized care such as ordering diagnostic tests out of habit, lack of community resources, and ineffective scheduling of tests or services.

In the United States, capitated payment systems and increased scrutiny of costs by the government with potential for punitive consequences forced hospitals to create a means by which practices of care providers and institutions could be monitored. In response, hospitals began developing

their own utilization management programs. The focus of these programs was to ensure that patients received the care needed in the most appropriate setting based on diagnosis and presenting condition. Programs were designed to evaluate professional medical care, services, and procedures against predetermined criteria and the facility as a whole.

Program development in hospitals included a written plan of utilization review and mechanisms to interact with medical and professional staffs on patients with UR issues. Utilization management programs typically dealt with denials of payment for perceived poor quality or overuse of resources and performed review activities based on objective criteria approved by the medical staff. Utilization management programs developed systems for identifying problem cases, practitioners, departments or services, and mechanisms for collecting, analyzing, and reporting data. Knowledge of laws and regulations and reimbursement or payer practices provided a basis for overall UR activities.

Basic Utilization Management Activities

Basic utilization management activities in acute care include review and assessment of the use of professional care, services, and procedures for need and appropriateness. In evaluation of need and appropriateness, staff members look for patterns of overutilization and underutilization of services, as well as inefficiencies in scheduling and lack of cost containment. UR intervenes in areas in which problems are identified that adversely affect the balance between cost effectiveness and quality and also works with discharge planning to identify a patient's needs after leaving the hospital. In the outpatient setting, utilization management seeks to assess the patient's continuity of care needs through a period of illness and patient and family ability and willingness to follow their treatment plan. Utilization management also provides input on referrals and access to available community resources.

Utilization management programs utilize a variety of techniques and approaches to monitor care. Prospective review involves review of proposed care related to level of care and setting. Financial assessment is made to determine patient's ability to pay for the treatment proposed. Concurrent review determines need and appropriateness of care on admission or within 24 hours. Need for continued stay is assessed at specified intervals throughout a hospital stay by reviewing use of ancillary services such as laboratory, x-ray, and level of care. Criteria used in concurrent review and continued stay are normative or empirical. Normative are based on the opinion of professionals; empirical are based on actual practice of professionals. Retrospective review is done after a patient is discharged from the hospital. In retrospective review, the reviewer gets an overall picture of the hospital stay, and patient outcomes and cost can be compared. Funds and practice patterns are more easily identified in retrospective review. Focused review focuses on singular issues and is often based on government reviews. Focused review is very specific, with case selections based on internally identified problems or outside agency requests.

Level of Care

Level of care refers to the continuum of care which includes various intensities of service levels such as acute, rehabilitation, sub-acute, Skilled Nursing Facility (SNF), Home Care, and Outpatient Rehabilitation, etc. The selection of the appropriate care setting is based on the review of an individual patient's severity of illness, co-morbidities, and complications.

Utilization Management Criteria

Criteria that will be used in the review process should be developed by UM staff and preapproved by the medical staff to meet the needs of the institution. Use of criteria is an attempt to establish the medical need for admission as an inpatient and the appropriateness and need for specific types of care, procedures, treatments, and readiness for discharge. Using the criteria, the UM staff compares all documented patient signs, symptoms, complaints, previous diagnoses, test results, treatment, and other available data. Documentation of nonspecific diagnoses, vague complaints, and systems is discussed with the attending physician, physician advisor, or both. The medical staff has an overall responsibility to act

on physician related utilization management problems. Intervention may be done with the physician advisor through a committee such as a utilization review committee or a medical executive committee.

Criteria systems

Different types of criteria systems are used in utilization management. Diagnosis specific review criteria involve the use of physician's history and physical and emergency room record. There are two distinct steps required in justifying admission. Using criteria, the reviewer verifies that a specific condition exists and validates need for inpatient admission. Severity of illness/intensity of service criteria make up a generic system used in many acute care facilities. Criteria are divided into major body systems and can be used on admission and throughout inpatient stay. Documentation of clinical findings is used to assign severity. Intensity of service refers to prescribed medical care that can be provided only in a hospital setting. Length of stay criteria are based on the data of patients with specific conditions and the number of days spent as an inpatient. Factors such as age, single, or multiple diagnoses, or surgeries are compiled and then aggregated as numbers of inpatient days. Norms are based on data in regions. Length of normal stay should not be used as the only guideline but should be balanced against clinical criteria.

Utilization management programs generally have a plan with stated program objectives and screening criteria. The program must have efficient mechanisms for physician referral to a physician advisor or UR committees to review and advise on questionable cases. Efficient and accurate data collection is essential, as well as review of quality/performance improvement data for trends in departments, services, or practitioners. Good intradepartmental communication is helpful in making referrals to groups such as social service, risk management, infection control, and discharge planning.

Patient classification systems are a means by which patient conditions are classified. Classification systems are used for utilization management, quality/performance improvement, and risk management, institutional planning and management, and reimbursement financial divisions of institutions. A diagnostic related group (DRG) is a patient classification system selected by HCFA for the Medical prospective pricing system. Principal diagnosis is the condition which is largely responsible for causing the admission of the patient to the hospital. Principal procedure refers to the procedure performed for treatment that is most closely related to the principle diagnosis. Provisional diagnosis is the preliminary or admitting diagnosis, the condition before study that caused the inpatient admission. Comorbidity is expected in 75% of cases to increase length of stay by at least 1 day. Case mix is a combination of clinical and financial information. Case mix information includes types and ages of patients and types of services and disease groups. The DRG system is a type of case mix classification. Data services for case mix include the patient's medical record, bill, patient acuity reports, and any available severity level indexes. Case mix is a combination of clinical and financial information but is based on charge data rather than actual cost. Case mix is affected by demographics, services offered, hospital and physician referrals, specialty composition of medical staff, and patient distribution across diagnostic and procedural categories.

Utilization management is integral to and greatly dependent on an effective quality/performance improvement program. UM attempts to determine at what point quality might be compromised as hospitals look to contain costs. Quality/performance improvement data is often used to review ancillary services and practitioners.

Over/Under Utilization of Resources

Underutilization of resources is a serious impediment of quality care. Underordering of resources such as diagnostic tests and drugs, although initially reducing costs, will likely cost the patient, facility, and care provider over time. If treatment or diagnostics are under ordered, patient illnesses may lengthen, which causes increased pain and suffering, as well as residual damage. That decreases patient productivity, which could result in institutionalization or even death. Quality is also compromised when underutilization results in prolonged physician care or need for rehabilitation. Prolonged illnesses

because of under utilization will create financial concerns for the patient and family. Under utilization can affect the speed with which health problems are detected and treatment initiated. Overutilization can be just as detrimental. Any test or procedure creates a potential for an adverse occurrence or a bad outcome. Therefore over ordering of tests, medications, and treatments can create a potentially harmful environment. Overutilization can create financial burdens. Overutilization may create financial burdens. Overutilization of resources can decrease the viability of the institution under capitated payment systems.

Diversion

Diversion is the status where patients are diverted to other medical facilities due to unplanned reasons such as the unavailability of beds, needed services that could not be provided, staffing, etc.

Appeal Process

The appeal process is the formal mechanism by which a service provider or a member, or both, can request reconsideration of a decision, with the goal of finding a mutually acceptable solution. There are 4 levels of appeals:

1. **Reconsideration** (first level review): A request by telephone for additional review of a UM determination not to certify; performed by the reviewer who reviewed the original decision and is based on additional information or peer to peer discussion.
2. **Expedited** (second level review): A request by telephone for additional review of a decision not to certify imminent or ongoing services requiring a review conducted by a clinical peer who was not involved in the original decision not to certify. The member or provider can request an expedited decision (no longer than 72 hours).
3. **Standard** (third level): A request to review a denial of an admission, extension of stay, or other health care service. It is conducted by a peer reviewer who was not involved in any of the previous determinations pertaining to the same episode of care. This is a formal written appeal process defined and handled by the payer.
4. **Arbitration** (final level): Mediation usually handled by objective outside parties; patient also handles this level.

Utilization management is defined as evaluation of medical necessity, appropriateness, and efficiency of use of health care services, procedures, and facilities under the auspices of the applicable health benefit plan. The goals of utilization management are to eliminate or minimize unnecessary care and promote the use of appropriate care. This includes hospital admissions, outpatient diagnostic procedures, and imaging studies and visits with specialists. It focuses on real time management of the process. Resource management encompasses processes that monitor appropriateness of resource utilization and delivery. Resources are monitored to be appropriate for the conditions presented, and the opportunity to maintain or improve care through the use of alternative solutions. Utilization management involves determining the appropriate level of care, which is the appropriate setting that enhances the appropriate resource delivery, and resources for the care to be delivered in order to maintain cost effectiveness and quality. Programs, processes, criteria, and screens are used to assist the provider in managing the quality delivery and cost of health care services. These avenues vary from health care settings and from country to country, and may be governed by specific rules and regulations for practice and payment. Examples of utilization management tools include practice guidelines, clinical pathways, benchmarks for care, and outcomes management. Average lengths of stay (LOSs) have been established by federal criteria in the United States, and private sector organizations in the U.S. have also offered guidelines for the average hospital stays for specific disease or conditional states.

In the United States, criteria have been developed by InterQual, Milliman and Robertson, Inc., and HCIA. Utilization management is primarily a cost containment activity. It's important because it allows services to be authorized by insurance companies for patients. Utilization modalities also

encourage fiscally responsible lengths of stay and offer an efficient aid for determining medical necessity as the patient moves through the healthcare continuum.

Preadmission Review

Preadmission review (precertification, prospective review) is a certification that takes place before services are rendered. The reviewer determines whether admission to the facility is reasonable and medically necessary. This may also be a review of whether diagnostic services and therapeutic modalities are appropriate and match the level of care.

Concurrent Review

Concurrent review is performed while the patient is in the facility. These reviews may be conducted in person or by telephone. Telephone reviews are generally less expensive, but poor or inadequate information can result from the reviewer's not knowing medically important questions to ask for a particular admitting diagnosis. This review is done to assess medical necessity and the appropriateness of the level of care, such as intensive care, step-down, telemetry, floor care, extended care, rehabilitation care, or home with home health. Medical appropriateness is gauged by monitoring and evaluating the medical condition of the patient against the services performed. Concurrent review consists of admission review which is performed within 24 to 48 hours and continued stay review, which is performed at specific points during the patient's stay. If the patient is critical, a review every 2 to 3 days may be an acceptable time frame, but a patient nearing a change in level of care might need daily reviews.

Subsequent Reviews

Subsequent reviews are done intermittently throughout the hospitalization with a 3-day interval between reviews considered maximum for InterQual's review process. The frequency is determined by the level of care, the severity of the patient's illness and other factors.

Retrospective Review

A retrospective review is performed after discharge. This can be a useful tool for looking at quality by identifying quality issues that could be prevented.

Insurance Authorizations

Prospective or precertification authorization is given prior to services rendered. Prospective payment usually refers to a diagnosis related group (DRG) payment, in which one amount is given for all services needed based on a specific diagnosis.

Concurrent authorization is generated at the time the service is rendered.

Retrospective authorization is approved after the services have been performed.

Pended (for Review) means that the organization doesn't know if an authorization will be given.

Denial refers to no authorization given for services. Grievance procedures may then be initiated.

Subauthorization refers to one authorization number that allows other services to be added.

Denial Management

Denial management is a process where all denied claims are appropriately appealed or declared uncollectible and reported in a manner that provides optimal information flow. It also includes a consistent approach to track and appeal denials and a reporting system that measures outcome and appeal status. Non-authorizing decisions may be based on medical appropriateness or benefit coverage.

Discharge Reviews

Discharge reviews determine stability for treatment and services at a lesser level of care.

Utilization Management Documentation

Utilization management data should include the following:

- Clinically pertinent data with exact objective data where possible, for example temperatures
- Patient's response or lack of response to treatments and services
- Accurate documentation of conversations with physicians, insurance reviewers, and others pertinent to services needed and treatment plans
- Times and dates of conversations
- Patient's status
- Discharge planning

Utilization Indicators

Inappropriate hospital days may occur at the beginning of a hospital stay (on admission), during, or at the end of a hospitalization in which a patient could have been discharged or transferred sooner than was actually done. These days are considered nonacute by insurance companies, representing overutilization of services. Insurance companies may deny portions of hospitalization they determine are due to avoidable delays.

Variations

Variations are deviations from normal, quality care. Unexpected occurrences that affect the course of an illness may be identified through an analysis of variance data. These data may also identify possible opportunities for improvement. Clinical pathways are excellent tools to trend variations. Variations are generally assigned to three categories, patient/family reasons, practitioner reasons, or institution/systems reasons. Variations can be caused by social factors, environmental factors, patient or family responses or lack of responses, physician-induced reasons, or institution responsibilities.

Length of stay is the number of days that a patient should stay in the hospital for a specific diagnosis or surgical procedure. Length of stay is the most well known and commonly used of all utilization parameters in the United States.

High Cost

High cost refers to an individual or group of patients that consume a significant amount of resources. Resources could be cost, time, or personnel related.

Utilization Management Indicators

- Number/percentage of admissions and continued stay days meeting criteria
- Reasons for days not meeting criteria
- Recommended level of care when criteria not met
- Analysis of physician approval and/or denials of the number of patients not meeting criteria during the first level of review
- Acute bed days of care rate
- Total cost per patient
- Thirty-day readmission rates for medicine, surgery, and behavioral health
- Comparison of length of stay for top ten most frequent diagnosis related groups
- Frequency of 1 day acute length of stay by department
- High cost cases
- Number of diversions and reasons for diversion
- Inter-rater reliability

SAMPLE POLICY UTILIZATION MANAGEMENT

1. PURPOSE: To establish policy and procedures for a Utilization Management Program that is consistent with VA guidelines and the Veterans Integrated Service Network (VISN) 18 policy.

2. POLICY: Utilization Management (UM) and Utilization Review (UR) activities are integral components of the medical center's performance improvement which is committed to improving efficiency, cost-effectiveness, coordinated patient-centered outcomes and patient satisfaction.

3. DEFINITIONS:

a. Utilization Management refers to the facility's overall program to increase the efficiency and appropriateness with which services are provided and resources are utilized. UM involves the analysis of relevant databases to evaluate under or over utilization.

b. Utilization Review is one process by which UM issues are identified, and involves assessing the appropriateness and level of care using written, measurable criteria.

c. Observation Beds: Use of "Observation Beds" provides full access to medical and nursing care for individuals whose need for care is very short (e.g., after ambulatory surgery) or when the decision to admit or not requires a period of observation and testing to determine the severity of the illness or injury. The length of stay in an observation bed should not exceed 23 hours (see Medical Center Policy ICS-3, Observation Policy).

4. PROCEDURES:

a. Preadmission, Admission and Continuing Stay Review: All patients admitted to the medical center will be screened for medical necessity, appropriate level of care and quality of care utilizing InterQual ISD (Intensity of Service, Severity of Illness and Discharge Screen Components) criteria (see Attachment B, Preadmission Review).

(1) Preadmission and admission review is performed on 100% of inpatient admissions and identifies each patient's most appropriate level of care.

(2) Preadmission review is conducted before admission whenever feasible and admission review is conducted by the UR nurses within 48 hours of admission.

(3) Continuing stay reviews are completed as required.

b. Use of Alternatives to Acute Hospitalization:

(1) Whenever feasible, outpatient alternatives will include scheduled appointments to primary care and specialty clinics.

(2) Temporary lodging that provides hotel type accommodations is available for patients who are undergoing evaluation or treatments.

(3) Another alternative to acute hospitalization is to admit the patient to an observation bed.

c. Patient-Centered Monitoring: These reviews consist of patient-centered monitoring which emphasize outcomes rather than processes. These include satisfaction, functional status, morbidity and mortality in addition to cost. Utilization of resources such as Pharmacy, Laboratory and Radiology is also monitored.

d. Medical Care Cost Fund (MCCF): This program incorporates insurance review activities aimed at recovering costs for medical care provided to all veterans treated for nonservice-connected conditions and those nonveterans treated on a humanitarian basis. The program includes the following activities:

(1) UR on preadmission, admission, retroactive, concurrent and initial precertified and certified insurance cases.

(2) Chart review for conditions resulting in an increased length of stay on identified insurance cases.

(3) Collaboration with the insurance carriers regarding appropriateness of admission and continuing stay reviews for inpatients as necessary.

(4) Collaboration with the facility Utilization Review Manager to incorporate information from MCCF cases into the UM Program.

(5) Submission of quarterly reports to MCCF.

e. Clinical Pathways: When Clinical Pathways are utilized for specific cohort of patients, compliance with the pathway should be monitored. The preadmission review and present schedule for review of continuing stay days may then be eliminated for that cohort of patients.

f. Long-Term Care Utilization Review: These activities include:

(1) Appropriateness of Nursing Home placement which is reviewed by the Nursing Home Care Committee.

(2) Evaluation of the severity of resident illness and use of available services.

(3) Reviews are carried out prior to admission (screening process) and concurrently at specified intervals.

g. Contract Nursing Home Review:

(1) The community health nursing staff determines the severity of the resident's illness, the appropriateness of care and environment.

(2) Social Services and the Community Council monitor and evaluate placement contracts, inspections and community resource referrals.

h. Interdisciplinary Discharge Planning ensures continuity of care and begins before or at the time of admission. Veterans are discharged when continued stay is determined no longer to be medically necessary. Appropriate medical center and community alternate levels of care and resources are used as appropriate to facilitate the discharge planning process. The InterQual Prerequisites Criteria (clinical and operational qualifiers to help reviewers assess whether the patient is a candidate for the proposed level of care) for home care are used when applicable to support clinical decisions to move patients from one level of care to another throughout the continuum. Discharge planning encompasses family and interdisciplinary team participation.

5. RESPONSIBILITIES:

- a. The Medical Center Director is responsible for overall quality in the medical center and the Utilization Management of all resources for the provision of quality patient care.
- b. The Executive Leadership Council is responsible for leadership in the medical center for supporting and participating in the UM Program to ensure appropriate utilization of resources.
- c. The Executive Performance Improvement Council (EPIC) is responsible for providing oversight for medical center improvement activities, and supporting a philosophy of continuous improvement.
- d. Utilization Management Program evaluation is ongoing through collaboration with the ACOS, Quality Management Department, Chief of Staff and the Executive Performance Improvement Council.

6. UM PROGRAM REPORTS: The VISN UM Quarterly Report (Appendix A) is presented to the Medical Center Director and Chief of Staff who in turn submit the report to the Executive Leadership Council and the VISN Network Office 30 calendar days following the end of each quarter.

7. CONFIDENTIALITY: Reports, documents, and minutes generated in the UM Program are protected in accordance with the HSRO Confidentiality Regulations (38 U.S.C. 5705).

8. REFERENCES:

9. RESCISSION: Policy Memorandum No. 00-7

10. ATTACHMENTS:

11. EXPIRATION DATE:

ADMISSION AND DISCHARGE PLANNING QUARTERLY REPORT

DATA FOR _____ QUARTER FROM _____ TO _____, FY _____.

FACILITY _____

Number of admissions	
Number of admissions reviewed	
Number of admissions meeting criteria	
Number of patients reviewed for continued stay	
Number of bed days of care	
Number of bed days of care reviewed	
Number of bed days of care meeting criteria	

Case Management

Case management is a system of health care delivery designed to facilitate achievement of expected patient outcomes within an appropriate length of stay. The goals of case management are the provision of quality health care along a continuum, decreased fragmentation of care across settings, enhancement of a client’s quality of life, efficient utilization of patient care resources, and cost containment. Case management is a collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual’s health needs, using communication and available resources to promote quality and cost-effective outcomes.

The purpose of care coordination is to work directly with clients and families over time to assist them in arranging and managing the complex set of resources that the client requires to maintain health and independent functioning. Care coordination seeks to achieve the maximum cost-effective use of scarce resources by helping clients get the health, social, and support services most appropriate for their needs at a given time. It guides the client and family through the maze of services, matches service needs with funding authorization, and coordinates with clinician and provider organizations.

Essential Activities

1. **Assessment**—The process of collecting in-depth information about a person’s situation and functioning to identify individual needs in order to develop a comprehensive case management plan that will address those needs.
2. **Planning**—The process of determining specific goals, objectives, and actions designed to meet the patient’s needs as identified through the assessment process.
3. **Implementation**—The process of executing specific case management activities and/or interventions that will lead to accomplishing the goals set forth in the plan.
4. **Coordination**—The process of organizing, securing, integrating, and modifying the resources necessary to accomplish the goals set forth in the case management plan.
5. **Monitoring**—The ongoing process of gathering sufficient information from all relevant sources about the case management plan and its activities or services to enable the case manager to determine the plan’s effectiveness.
6. **Evaluation**—The process, repeated at appropriate intervals, of determining the case management plan’s effectiveness in reaching desired outcomes and goals.

Case Management Models

1. **Acute Care Models**—Acute care models focus on one episode of care from admission to discharge in the acute care setting. In many cases, this model also includes utilization management and/or discharge planning functions. Typically, registered nurses or social workers provide case management services, and they may or may not function within an interdisciplinary environment or provide patient care.
2. **Community Based Models**—These models can provide case management services throughout the continuum of care or at a specific practice setting. This can be in either a provider or payer setting.
3. **Geriatric Case Management**—These models coordinate services that are not usually covered by insurance plans to prevent institutionalization.
4. **Independent Case Management**—In these models, the practitioner practices either independently or under the auspices of a case management organization. Case management interventions are provided throughout the continuum of care to reach mutually agreed on outcomes. There is no provision of direct patient care. The focus is on enabling the patient to make the needed transitions through the health care delivery system, monitoring resource utilization, managing costs, and providing quality services.
5. **Integrated Delivery System Model**—The case manager is assigned to the case at one of the defined access points, depending on where services were provided. The responsibility for case management resides at the location where the patient is receiving care, and continuity is maintained by providing referral and tracking services.
6. **Long Term or Chronic Case Management Model**—This model is similar to geriatric case management. This model provides for social and health needs, serving populations with long term care and chronic care needs.
7. **Managed Care Model**—This model controls costs by controlling utilization and coordinating care. There are two types of case managers. Financial case managers functions in a traditional

utilization management model, in a high volume/low intensity role. Clinical case managers focus on high intensity/low volume interventions with high risk patient populations.

8. **Provider Based Case Management Models**—These models provide coordination and management services to patients serviced by the agency. They function in home health, durable medical equipment, or home infusion companies.
9. **Generalist Case Manager Model**—This model is structured to provide direct service, access, planning, and monitoring activities to patients. The case manager acts as a broker and is involved in the intake, coordination, and evaluation of care provided.
10. **Primary Therapist Case Manager Model**—This model focuses on a therapeutic relationship between the case manager and the patient. The case manager is required to have a master's degree and training in psychology, social work, psychiatry, or psychiatric clinical nursing.
11. **Interdisciplinary Team Model**—This model focuses on providing case management services through a collaborative team approach. Responsibilities and functions are divided among the team members according to their area of specialization. One team member is responsible for maintaining overall service coordination and evaluation.

Selection of a Case Management Model

The following should be considered when selecting or adapting a case management model:

1. **Patient population**
 - a. Age
 - b. Educational level
 - c. Financial resources
 - d. Most frequent diagnoses
 - e. Geographic location (rural/suburban/urban)
 - f. Recidivism
2. **Organizational issues**
 - a. Mission
 - b. Vision
 - c. Long term and short term goals of the organization
 - d. Organizational structure
 - e. Strengths
3. **Funding source**
 - a. Reimbursement system
 - b. Regulatory agencies

Target Patient Populations

1. Diagnostic category
2. Potential for large consumption of resources
3. Frail and elderly
4. Hospitalized
5. Procedure

Purpose and Goals of Case Management

1. Inject objectivity and information where it is lacking.
2. Maximize efficiency in use of available resources.
3. Work collaboratively with the patient, physician, family/significant other, and the health care provider to implement a plan of care that meets the individual's needs.
4. Promote the optimal allocation of health dollars through effective and efficient use of resources.
5. Through early assessment, ensure that services are generated in a time and cost effective manner.

6. Assist patients to achieve an optimal level of wellness and function by facilitating timely and appropriate health services.
7. Assist patients to self direct care appropriately, self advocate, and make informed decisions to the degree possible.
8. Maintain cost effectiveness in the provision of health services.
9. Appropriate expenditure of claims dollars and timely claim determinations.
10. Enhance employee productivity, satisfaction, and retention, when applicable.
11. Return the patient to work or assess the patient's ability to return to work and develop a plan that will assist the patient in returning to work or becoming employable.
12. Enhancement of quality of care.

Functions of Case Management

- A. **Assessment**—Obtaining and evaluating relevant information (medical, psychosocial, functional, vocational, and financial) through interviews with all parties.
- B. **Planning**—From the information gathered, developing and prioritizing a needs list with input from all parties, keeping patient and family active decision makers in the process. Developing contingency plans and instituting them as necessary.
- C. **Facilitating**—Focusing on communication and collaboration with all parties to enhance patient care and maximize outcomes.
- D. **Advocating**—Until the patient is able, advocating for the services and funding to meet established goals; providing education and support to encourage patient empowerment and self-reliance; keeping the patient's best interests the most important factor.

Specific activities within functions

1. Reviewing and coordinating health care, worker's compensation, and government insurance benefits related to care needs of clients.
2. Reviewing medical records and employment related information.
3. Performing return to work functions.
4. Researching and securing funding, community resources, and support needed for community reentry.
5. Conducting home visits and on site visits with employers and physicians; inspecting and selecting facilities that provide specialized care services for clients.
6. Evaluating, purchasing, and coordinating the acquisition of appropriate assistive technologies for adaptive, accommodative, or job modification purposes.
7. Performing early intervention functions with disabled workers, treating physicians, and others to meet safe and timely return to work objectives.
8. Educating other stakeholders regarding the role and value of case managers in health care.
9. Monitoring and evaluating the impact of case management outreach, community living, return to work, and overall program outcomes.
10. Developing methodologies to measure case management outcomes meaningful to the payer (e.g., return to work rate, improved functional work status, improved health status, disability cost reduction, reduced lost time, disability cost savings, and worker and employer satisfaction).
11. Attending team conferences.
12. Networking for relationship building and resource development.
13. Negotiating cost effective rates for services purchased.
14. Performing program evaluation and research functions to document improvements in patient outcomes, cost savings, patient compliance, and return to productivity.
15. Coordinating and facilitating health promotion, illness and disability prevention, and health education activities.

16. Performing prevention and wellness program functions (e.g., health counseling and health education.)
17. Preparing a life care plan.
18. Conducting job analyses and job accommodation activities to facilitate prevention of disability or injury.
19. Performing administrative and coordination functions related to the operation of a case management program.
20. Promoting and marketing the case management program.
21. Performing job placement or outplacement services.
22. Performing utilization review functions.

Essential Components of Case Management

1. Assessing the patient (medical, psychological, social, environmental, vocational, financial).
2. Synthesizing assessment information to prioritize care needs and develop treatment plans.
3. Conducting and performing medical case management functions.
4. Communicating with clients, family, treating physicians, other service providers, attorneys, and payers.
5. Monitoring and evaluating the patient's response to treatment and revising treatment plans as needed.
6. Researching alternative treatment options and selecting and locating appropriate providers.
7. Providing education, information, direction, and support related to care goals of clients.
8. Acting as an advocate for the patient and family with third-party payers and service providers.
9. Implementing care and treatment plans.
10. Performing case management functions (i.e., coordinating community resource services, documentation, and functional assessments).
11. Performing case recording, documentation, and report writing functions.
12. Coordinating acquisition of medical equipment (including assessment, negotiation, proper use, and follow up).
13. Participating in professional development activities to keep current with state of the art case management practices.
14. Implementing conflict resolution strategies with clients.
15. Performing case identification, selection, and outreach functions.
16. Performing advocacy and intervention functions.
17. Preparing discharge plan.

Case Management Process

Each patient is unique, and the case management process needs to take into consideration the individual needs of the patient. Each case manager also has his/her own unique style of case management based on his/her experience, education, and creativity. Some stages of the case management process may vary significantly based on the case management setting and the population served. Stages that may vary based on these variables are case selection, implementation of the plan, and evaluation and follow up. Other stages of the case management process have universal principles that apply to several stages of case management. These stages are assessment/problem identification, development and coordination of the case plan, and continuous monitoring, reassessing and re-evaluation. The process of case management is much broader than the nursing process. The nursing process assesses the patient for changes in the physical, medical psychosocial, and safety needs; plans how to meet these needs; implements these plans; and evaluates the results of these plans. The case management process includes collecting assessment data before the onset of the current illness; assessing the environmental, financial, and support system available to meet the identified needs; and planning future care.

Assessment—This is the process in which the case manager obtains factual information about the patient and family. The scope of the assessment should be broad, covering personal and environmental factors as well as medical information.

Case Selection—This is the first step in the case management process in which the case manager appraises the need for patient intervention through gathering relevant data and the critical, objective evaluation of those data.

Continuous Case Management—In this process, the case manager uses a method of checking, regulating, and documenting the quality of care, services, and products delivered to the patient to determine if the goals of the care plan are being achieved or if those goals remain appropriate and realistic. This part may also be called the monitoring, reassessing, and re-evaluating phase of case management.

Coordination and Development of the Treatment/Discharge Plan—The case management plan identifies immediate, short term, and ongoing needs, as well as where and how these needs can be met. The plan sets goals and time frames for achieved goals that are appropriate to the individual and his/her family, and are agreed to by the patient/family and treatment team. The case manager also ensures that funding or community resources, or both, are available to implement the plan.

Final Evaluation or Post discharge Follow Up—The case manager employs a methodology designed to measure the patient's response to the health care services and products being delivered, while also measuring the effectiveness, necessity, and efficacy of the care plan itself; and the quality of services and products from the providers.

Implementation of the Final Plan—In this phase of case management, the patient's assessed needs have been linked up with private and community services, gaps are filled, there is no duplication of services, and the patient and support systems are in agreement with the plan. The goal of this phase is to maximize the safety and total well being of the patient.

Problem Identification—Utilizing objective data gathered through careful assessment and examination of the potential for effective intervention, the case manager selects a caseload reflecting practice patterns and trends so that patient outcomes can be positively influenced.

Stages of the Case Management Process

Case Selection is a process of evaluating individuals referred for case management services based on an established set of criteria. The criteria enable the case manager to determine whether the patient needs case management services and what services will be needed. No single condition or diagnosis, with the exception of reportable events, is automatically a problem that necessitates full case management services. With case selection, a case manager can reduce systematically the number of cases in his/her caseload. Case selection determines the need for case management and allows the specific needs of a patient to be matched to the specific skills of a case manager. Case selection requires at least a cursory assessment to determine if the patient needs a case manager. A case manager may not be necessary if:

1. Patients meet intensity of services or severity of illness criteria.
2. No major discharge barriers are identified.
3. Readmission is not a concern.
4. Financial barriers are not present.

Case management may be necessary if:

1. Complex medical issues or comorbidities exist.
2. Complex discharge needs exist.
3. Complex social issues exist.

Selection criteria may be specific to the goals of the organization and ideally should be based on the anticipated needs of the patient. Length of stay and claims data should not be exclusively used for criteria, as they are late indicators of case management needs. By the time the patient has

exceeded the established length of stay and maximum dollar expenditure for the diagnosis, a great deal of case management intervention could have already taken place.

Criteria (taken in conjunction with other criteria) may include, but are not limited to:

- Lives alone or with someone with a disability
- Age over 65 years
- Readmission with 15 days
- Diagnosis or diagnosis related group
- Overdose (intentional or unintentional)
- Eating disorder (e.g., bulimia, anorexia nervosa, failure to thrive)
- Chronic mental illness
- Uncooperative, manipulative, or aggressive behavior
- Miscellaneous conditions
- Socioeconomic indicators
 - Suspected child or elder abuse and/or neglect
 - Victim of violent crime
 - Homelessness
 - Poor living environment
 - No known social or family support system
 - Admission from an extended care facility or sheltered living arrangement
 - Need for transitional care
- Out of state or out of county residence
- Residence in rural community with limited or nonexistent services
- Limited or no financial resources
- No or inadequate health insurance
- Single parent
- Dependent in activities of daily living
- Repeated admissions to acute care
- Frequent visits to emergency room, family physician, or clinic
- Disruptive or obstructive family member/significant other

Assessment or problem identification begins after completion of the case selection process. A thorough assessment has to be done at this point in order to determine the needs of the patient, particularly as they relate to the discharge plan, because an inaccurate, or poor assessment can lead to an unsafe discharge plan. During the assessment, identification of actual and potential problems are identified and goals are established. Sources of assessment data include: patient, family physician, office and hospital medical records, ancillary staff, family, employer. Patient data to be collected includes: patient history and demographics, current medical status, nutritional status, medication assessment, financial assessment, functional assessment including environmental factors such as home environment assessment and ADL assessment, psychosocial assessment, and cultural and religious assessment. Family needs must also be assessed and addressed with the patient's family members to help them cope with illness and hospitalization. A key role of the case manager is communicating accurate information to the family to enable them to make informed decisions.

Development and coordination of the case plan occurs next with goals established, needs and goals prioritized, as well as beginning service planning and resource allocation. Case managers within a facility begin implementation of the plan preferably before discharge but no later than the day of discharge. Outside the facility, initial checks are done, with intermediate checks and case closure. Evaluate and follow up depends on the type of case management employed, and includes case evaluation and identification of case management outcomes. Continuous monitoring, reassessing, and re-evaluation

occur as needed depending on the site where case management is provided. For example, case management in a hospital may require more frequent follow up than that in a private home or extended care facility. Issues that are evaluated include changes in medical status, changes in social stability of the patient, quality of care, changes in functional capacity and mobility, and evolving educational needs. Termination of case management services is made when appropriate.

Transitions of Care

Patients face significant challenges when moving from one health care setting to another. As currently structured, the United States' health and long-term care system fails to meet the needs of most patients during transitions between health care settings. The vision of the National Transitions of Care Coalition (NTOCC) is to improve transitions of care, increasing quality of care and patient safety while controlling costs. Specifically, NTOCC suggests the following steps:

- Improve communication during transitions between providers, patients and caregivers;
- Implement electronic medical records that include standardized medication reconciliation elements;
- Establish points of accountability for sending and receiving care, particularly for hospitalists, SNFists (physicians practicing in skilled nursing facilities), primary care physicians and specialists;
- Increase the use of case management and professional care coordination;
- Expand the role of the pharmacist in transitions of care;
- Implement payment systems that align incentives; and
- Develop performance measures to encourage better transitions of care.

To successfully overcome the challenges of complex health tasks on top of mounting administrative and economic hurdles, patients require actively managed continuity of care. The changes cited above should alleviate the heavy burden of responsibility placed on patients and their families and caregivers, who are ill-equipped or unqualified to initiate their own follow-up care because they have a limited understanding of their conditions and the complexities of today's health and long-term care system. At the same time, patients often are the only constant in a series of care transitions, thus they must play an active role in ensuring the quality of care and should have the necessary tools and support to successfully interface with the complex health and long-term care system. Patients and caregivers must take active responsibility for and become involved in their health care to ensure seamless and safe transitions of care.

The United States health and long-term care system is plagued by problems of underuse, overuse, or misuse of health care. Many episodes of care for serious illness or conditions involve numerous settings, both acute and long-term, and many highly specialized professionals, frequently with little connection or communication between the various components. The one constant in all episodes of care is the patient, who needs sufficient knowledge to proactively facilitate necessary communication and interaction between providers. To improve health care in this country, patients and providers must ensure better information exchange at all stages of the health care process.

Certain groups of patients are particularly vulnerable when care between settings is not provided in a coordinated, seamless manner. For example, individuals who speak a different language or are of a cultural background that is infrequently encountered by the relevant health care provider; children with special health care needs; the frail elderly; persons with cognitive impairments; persons with complex medical conditions; adults with disabilities; people at the end of life; low-income patients; patients who move frequently, including retirees and those with unstable health insurance coverage; and behavioral health care patients require particular attention to transitions of care to protect their health. Concrete steps can improve the quality of care. Most individuals who have had an experience with the health and long-term care system are aware of the potential mishaps that can occur during a poor transition between care settings. Transition breakdowns or miscommunication between care providers can have multiple implications, including:

- Patient or caregiver confusion about the patient's condition and appropriate care;

- Lack of follow-through on referrals;
- Medication errors, overuse of narcotics, and sub-optimal use of medicines;
- Inconsistent patient monitoring; and
- Increased financial impact and duplication of resource utilization.

The following vignettes illustrate some of these implications and the types of issues that can arise as a result of poor communication and fragmented care:

An older man with atrial fibrillation who is taking warfarin for stroke prophylaxis is hospitalized for pneumonia. His dose of warfarin is adjusted during the hospital stay and is not reduced to his usual dose prior to discharge. The new dose turns out to be double his usual dose, and within two days he is rehospitalized with uncontrollable bleeding.

A woman with dementia is transferred from a skilled nursing facility (SNF) to the hospital. Upon arrival at the hospital, she is taken off her medication for dementia for two reasons: the medication is not on the hospital's formulary, and the hospital staff views her dementia as too advanced for her to benefit from continuation of her medication regimen. Neither the patient, the patient's caregiver, nor her other physicians are consulted prior to discontinuing the medication.

An older woman has back surgery and is sent home without instructions on how to care for herself without home health care services. She has great difficulty getting out of bed, cannot take care of the surgical wound on her back, and cannot prepare her meals. She is told that a visiting nurse will arrive along with dressing materials, but no one ever arrives. She returns to the emergency room by ambulance with a weeping, infected wound covered by unchanged dressings. She explains that she is frightened and that no one had told her whom to call for help.

A man goes to the neurologist to be evaluated for recurrent migraine headaches. The neurologist asks the patient to bring his MRI and, after multiple conversations with the radiologist's office, the patient obtains the films. When the patient arrives at the neurologist's office, films in hand, the neurologist says, "I need the written report to see what's really going on here."

Such scenarios make clear that much is at stake during transitions of care. Luckily, health care professionals and government leaders are increasingly aware that improving the coordination of care among the various care settings could improve patient safety, quality of care, and health outcomes and also may lead to significant savings. Making such improvements is a challenging task, however, and will require significant and meaningful collaboration among health care providers, community members, and government regulators. In addition, patients and their families and caregivers will need to take a more active role in their health care and facilitate communication during transitions.

After identifying key gaps and barriers to improving transitions of care, NTOCC details issues to consider, including:

- Improving communication during transitions between providers, patients and caregivers;
- Implementing electronic medical records that include standardized medication reconciliation elements;
- Establishing points of accountability for sending and receiving care, particularly for hospitalists, SNFists, primary care physicians and specialists;
- Increasing the use of case management and professional care coordination;
- Expanding the role of the pharmacist in transitions of care;
- Implementing payment systems that align incentives; and
- Developing performance measures to encourage better transitions of care.

By addressing these issues, health outcomes can be improved as well as the overall health care experience for patients and their families and caregivers. The goal is to improve transitions in a complex health care system that is challenged by: socioeconomic diversity and the need for cultural competency, barriers to accessing care, safety and quality concerns, the growth of technology, communication barriers, and other issues. Policy makers, payers, and advocates need to focus on a blueprint for change to move towards a more unified and integrated health and long-term care system.

Definitions

The term “transitions of care” connotes the scenario of a patient leaving one care setting and one episode of care such as hospital, nursing facility, assisted living facility, primary care physician care, home health care, or specialist care, and moving to another setting or to the patient’s home. The transition of care frequently involves multiple persons, including the patient, family or other caregiver(s), nurse(s), social worker(s), case manager(s), pharmacist(s), physician(s), and other providers. Transitions of care affect not only the patient but the health care professionals as well. An optimal transition should be well-planned and adequately timed. More often, however, a lack of communication from an episode of care in one setting to an episode of care in the next threatens the quality of care.

Care coordination is a related, but distinct, concept. Although a transition of care refers to the actual transition between two particular care settings, care coordination involves the interaction of providers and health plan administrators across a variety of care settings to ensure optimal care for a patient. Every transition of care will involve care coordination, but care coordination is a broader process that typically encompasses the assessment of a patient’s needs, development and implementation of a plan of care, and evaluation of the care plan.

Gaps in Care and the Costs of Fragmented Care

The lack of connectivity between providers in the health and long-term care system stymies the delivery of quality care. The Institute of Medicine (IOM) emphasizes that health care quality suffers due not to a lack of effective treatments, but to inadequate health care delivery systems that fail to implement these treatments. Fragmented care and inefficiencies in the current system unnecessarily increase costs to patients, providers, payers, and employers.

Poor transitions of care can compromise patient safety and quality of care. In 2001, the IOM issued a report that called for increased care coordination across the health care system to improve quality of care and reduce errors. Since that time, numerous studies have sought to examine the issue of fragmented care and its impact, including a recent study of Medicare patients after hospital discharge that found nearly one-quarter experienced complicated care transitions — a finding that has important implications for both patient safety and cost-containment efforts. Another study found 19 percent of discharged patients experienced an adverse event within three weeks of leaving the hospital and that simple strategies could have ameliorated or prevented 12 percent of these adverse events. Medication errors harm an estimated 1.5 million people each year in the United States, costing the nation at least \$3.5 billion annually. An estimated 60 percent of medication errors occur during times of transition: upon admission, transfer, or discharge of a patient. Medication errors result in readmissions to the hospital as well as greater use of emergency, post-acute, and ambulatory services and duplication of services that needlessly increase the cost of care. Such errors can involve underuse, overuse, or misuse of medication. In other words, an important therapy can be missed or a prescribed therapy can contribute directly to patient harm. Contributing factors may include patient misunderstanding of instructions, drug-drug interactions, drug-food interactions, and duplicative therapy.

Inefficient care transitions place a significant burden on patients and their families and caregivers. Potentially detrimental to patients, fragmented care can result in unnecessary suffering, prolonged illness, and even death. If a provider does not have all necessary information in advance of a patient’s visit, appointments may not address all relevant issues. Missing test results, discharge summaries, referrals, and medication lists may require patients to schedule redundant and avoidable appointments. In addition, copayments for patients may increase when they are placed on new medications duplicating drugs they already are taking. The financial burden of a new therapy can pose significant adherence barriers, potentially leading to therapeutic, safety, economic, and psychosocial problems. Finally, the lack of clear, consistent education, training, and instructions by providers decreases patient adherence to both medication therapy and lifestyle changes.

Providers and payers also incur costs due to poor transitions of care. Unnecessary hospital

stays occur when transitions are flawed, increasing costs to payers significantly. With hospital resources often spread thin, readmissions could be reduced significantly by increasing patient understanding of discharge medications, follow-up appointments, and expectations for recovery. Duplicate visits to physicians and repetition of laboratory or other tests either result in payment for identical services or are not covered by payers, meaning that providers or patients must cover the cost.

Employers also bear costs associated with a fragmented system. Often bearing the additional cost of lost productivity when care is not coordinated, employers also feel the burden of fragmented care. The health and long term care system's routine failure to provide appropriate care leads to nearly 66.5 million avoidable sick days. Poor quality health care caused by misuse, overuse, and waste costs employers an estimated \$1,700 to \$2,000 per covered employee each year, of which approximately \$350 to \$650 is due to indirect costs such as lost workdays.

Potential Areas for Improvement

Numerous reports have recommended changes to the existing system in order to improve transitions of care and improve the overall quality of care while reducing costs. For example, IOM recommended four key strategies for improvement of transitions of care:

- Provide educational supports, including multi-disciplinary health professions education, that teach care coordination principles in all health care and academic settings and development of care teams;
- Institute patient-centered health records, supported by information and communications technology;
- Ensure accountability and define roles for care; and
- Align financial incentives with quality measures.

Similarly, in late 2006, the Commonwealth Fund (CWF) released two reports on establishing a high performance health system in the United States. In the first report, CWF chronicles the fragmented, broken system of care that currently exists and recommends improved care coordination as a primary strategy to reduce inefficiencies such as waste due to duplication, poor processes, the provision of care that is known to be ineffective, and unacceptable variation in quality and safety. In addition, CWF calls for a system that is coordinated throughout the patient's life, with a single provider responsible for a patient's primary care as well as for serving as the coordinator for specialty and other care. The second CWF report provides results from a national scorecard on health care performance in the United States. Patients in this survey reported that 18 percent of physicians unnecessarily repeated tests, and test results and medical records were missing when needed at 23 percent of follow-up appointments. Similar to the IOM recommendations for addressing coordination, CWF's recommendations include strategies and policies regarding information technology, quality measurement, payment structures that encourage increased communication with other providers, and professional education.

Issues to Consider to Improve Transitions of Care in the Health and Long-term Care System.

Improve Communications During Transitions Between Providers, Patients, and Caregivers

The transfer of timely and accurate information across settings is critical to the execution of effective care transitions. Every episode of care involves various individuals, including patients, caregivers, professionals, and non-health care professionals, and transfers between care settings, increasingly a standard practice in the health and long-term care system. These transitions also include a variety of often disconnected systems (hospitals, home health care providers, insurance companies, pharmacies, physician offices, long-term care facilities, etc.).

- Between 41.9 and 70 percent of Medicare patients admitted to the hospital for care received services from an average of 10 or more physicians during their stay;
- Among hospitalized patients 65 or older, 23 percent are discharged to another institution, and nearly 12 percent receive home health care;
- Among patients discharged from a SNF, 19 percent are readmitted within 30 days; and

- On average, patients 65 or older with two or more chronic conditions see seven different physicians within one year, accounting for 95 percent of Medicare expenditures.

Clinicians throughout the continuum generally lack training on how to execute effective transfers of patients and often do not recognize their own role in transition planning. Effective communication between the patient and providers, between providers and family members or other caregivers, and between multiple providers is vital to achieving desirable health outcomes. As noted above, lack of communication can lead to poor outcomes, particularly from medication errors. A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such adverse drug events can cause injury or even death. Medication errors involve underuse, overuse, or misuse. Medication underuse means failing to provide a drug when it would have produced a favorable outcome for a patient. For example, failing to provide a steroid inhaler to an asthma patient or not giving aspirin, beta-blockers, or other proven medications to individuals after myocardial infarction. Medication overuse occurs when the potential harm is greater than the potential benefit. For example, prescribing antibiotics to a patient with a viral infection constitutes overuse and could lead to an increase in antibiotic resistant bacteria.

Finally, a preventable complication can reduce the benefit of an appropriate type of care if the treatment is misused. Thus, a patient with a known allergy to a drug will suffer a foreseeable complication and not benefit from receiving the usually effective treatment. If, on the other hand, medication is used appropriately, it can improve outcomes, shorten recovery time, and ultimately lead to cost savings due to more efficient treatment.

These types of errors are more common if a transition of care does not involve good communication. For example, if a patient enters a hospital and its formulary does not include the patient's current medications, the provider inadvertently may make substitutions while the patient is receiving care. Information regarding the medication substitution rarely gets to the patient or caregiver, potentially leading to dispensing duplicative medicines or too many forms of similar medications being used by a patient upon discharge. Another complication arises upon discharge from the hospital, when some patients will need to obtain a prescription. If the medication does not appear on their health insurer's formulary, patients may need to seek the intervention of a primary care physician to avoid discontinuing the treatment or failing to take a critically important drug. It is imperative that patients and their families and caregivers take an active role in understanding their medication regimen and following it to assist providers in preventing medical errors.

Issues for Consideration

To improve communication between providers, additional education of patients and their caregivers as well as of providers is critical. Further, certain transitions, such as from emergency department to outpatient care, require particular attention.

- Provide information to patients and caregivers

A significant gap in education exists at the patient and caregiver level. Most patients and families are not encouraged to play a more active role in their care during transitions. Actually, most patients and their caregivers mistakenly believe that as a standard practice, information about their care is transferred in advance of appointments. In addition, patients may not know what information is important for them to share with a new provider. Low levels of patient education and the unwillingness of many providers to release patient information directly to the patient present transition barriers. In addition, the patient's health literacy level, along with cultural and ethnic issues, can impede communication. All these factors need to be considered in ongoing efforts to engage patients and their caregivers because they are the only constant in every episode of care.

Improving education will make patients and caregivers more informed consumers of care and therefore permit them to serve as the linchpin in a successful transition of care. In addition, patients and their caregivers need to know how to access help in their own communities. To have a successful

transition of care, the first step is to identify, coordinate, and optimize existing resources. States, communities, and payers need to work together to alleviate the fragmentation of service delivery and the frustration among patients and their caregivers, extend services to patients and caregivers across the community, and develop partnerships with area educational institutions and service providers.

Patients without strong family and caregiver support and resources may need the assistance of a community team. A team that might include the case manager, the Department of Aging, the Department of Social Services, the discharge planner from the hospital, and representatives of the various agencies could help reduce duplicative efforts, collaborate on solutions for those needing support, and ensure access to available services at appropriate levels of care. Another avenue to explore is setting up telehealth programs for patients at a high risk. Telehealth services could be used to model disease management, provide cost-effective support, reduce the number of visits to the emergency department, and delay the need for more costly and intensive transitions. Regardless of the vehicle for providing community support, it should focus on providing patients with the knowledge and tools they need to better meet their health needs.

- Provide patients and caregivers tools and resources

Patients and caregivers are often the only constant in a transition of care. The patient and caregiver experience the processes and changes of providers, facilities, levels of care, and coverage constraints, yet they often lack the tools, resources, awareness, or knowledge to participate in and coordinate their care options. Navigating this fragmented process requires knowing what questions to ask about care options, how to work through the health and long-term care maze, what information to seek, and how to interact with the provider team in resolving health care needs. The use of a tool, a patient/caregiver transition of care checklist, to identify questions patients and caregivers should ask the care team during any transition will achieve a better level of care. The tool should identify key touch points that providers are coordinating during a transition and facilitate a dialogue between the patient and caregivers and all members of the care team. Several organizations and facilities have developed or are in the process of developing such tools. At minimum these types of tools should address:

- Patient/caregiver's understanding of who is responsible for doing what;
- Information that should be communicated and shared with other providers in what time frame;
- Care options and resources available;
- Follow-up care/visits;
- Medication reconciliation requirements; and
- Patient's personal medicine list.

Equipping patients and caregivers with understandable tools and resources will help them be responsible for and participate in their health care decisions with providers and their health care team. Integrating patient and caregiver tools with provider tools will improve consistent information exchange and support of the transition process.

- Improve education of providers

Recognized as a national priority for health care quality, patient safety, and efficiency, care coordination issues need more attention at the provider level. Provider education does not typically emphasize communication and teamwork. These topics are not included in the curricula for most accreditation or certification programs and are infrequently among the topics of continuing clinical education programs. In fact, a survey of over 1,000 physicians found that two-thirds thought they had received inadequate training in care coordination and patient education. Developers of university curricula and continuing education programs for all health professionals should place greater emphasis on transition of care issues.

- Improve the transition between settings, such as from emergency department and acute care to long-term, assisted living, home, or hospice care

Although all health care transitions require a certain amount of coordination, research indicates that certain transitions are particularly problematic. One example is the transition from emergency

department and acute hospital care to a long term care, assisted living, or home care setting. Emergency departments deal with high patient volume, high acuity of care, a significant number of patients seeking primary care, frequent shortages of clinicians, and limited access to care coordination resources. The round-the-clock care required by emergency department patients necessitates coverage by multiple physicians, nurses, social workers, and other professionals, resulting in handoffs and potential for numerous care coordination problems, including medication issues. Successful transitions of care for most emergency departments are limited by the time available for coordinating care and the lack of accurate information. To address the typical issues encountered in the emergency department setting, emergency department staff should consider the following questions:

- Do the patient and caregiver know what to expect regarding the hospital stay and post-discharge experience?
- Do the patient and caregiver know how to reach providers?
- Do the patient and caregivers understand and agree with the follow-up plan?
- Has the emergency department staff determined if patients and caregivers can afford prescribed medications?
- Do the patient and caregiver know how to take medications, handle equipment, or handle or manage wound care?
- Do the patient and caregivers understand their condition and treatment options?
- Have other functional arrangements been coordinated, including transportation, homemaker functions, and dietary counseling?
- Does the patient have the personal strengths or access to resources needed to carry through the plan of care?

Policy makers, health insurers, and hospital and other health care executives should provide emergency departments with the resources necessary to provide safe, high quality care by addressing these and other transition issues. The initial setup of services in the outpatient setting as a follow-up to emergency department care also requires specific attention to aid in the transition after discharge. Individual facilities should develop protocols or standards of practice to arrange the transition to outpatient care. To the extent possible, the emergency department should assist in setting up the transition to a nursing home or assisted living facility, or, if a patient is returning home, the department should schedule home visits, arrange for outpatient practitioner follow-up, plan for the acquisition of medications, and arrange the delivery of durable medical equipment and oxygen, if needed.

Emergency department providers or others could use a standardized universal transfer form to improve communication between settings. Facilities should encourage use of a standardized tool to facilitate the transfer of necessary patient information during transitions of care. Patient transfers are fraught with the potential for errors stemming from the inaccurate or incomplete information relating to medical history and a course of hospitalization or emergency department visit. Because it is extremely difficult to reach the hospital or emergency department once the transfer is complete, use of a standardized universal transfer form at the time of transfer can help ensure that the patient information is transmitted fully and in a timely fashion. Another tool to consider is the standardized patient assessment tool that CMS has developed for use at acute hospital discharge and at post-acute care (PAC) admission and discharge. The Continuity Assessment Record and Evaluation (CARE) tool measures the health and functional status of Medicare acute discharges as well as changes in severity and other outcomes for Medicare PAC patients. The tool is now being used to collect information from providers participating in the PAC payment reform demonstration.

An appropriate coordinator of care in the outpatient setting would greatly improve the transition out of the emergency department or acute hospital setting. A social worker, nurses, case managers, or discharge planner could initially coordinate care on the original unit. Facilities should appoint such a single point of contact to be responsible for such coordination until follow-up care is initiated. Determining who will oversee coordination of services once the patient arrives at a SNF, assisted living

facility, or at home is critically important. This may require periodic visits by a case manager, nurse, social worker or home health nurse, but currently the health care system is not designed to provide such long-term services. Once a patient is in a nursing home, assisted living facility, or at home, however, wound care and durable medical equipment management, preparation of meals according to dietary restrictions, respiratory care, physical and occupational therapy, and other issues may arise that require the attention of a coordinator of care.

Implement Electronic Medical Records that Include Standardized Medication Reconciliation Elements

Health care continues to be siloed, with different sets of professionals and settings focusing on specific types of care rather than a single team dealing with the patient in a holistic manner. This specialized approach to health care further exacerbates communication breakdowns. With few practices or tools in place to encourage communication across settings, this model of care is not ideal. Implementation of electronic health records can assist greatly in fostering better flow of information between providers and can improve the accessibility, accuracy, and completeness of clinical information. For information technology to help improve the flow of information between different care settings, it must be interoperable or uniform across providers. Although technology is evolving to contain point-of-care and follow-up reminders, the majority of primary care providers do not use electronic health record systems. As electronic medical records become more common, it is important to consider the elements needed to best facilitate communication and improve care among multiple providers. To be effective, health information technology must include common data standards for drug and other information, including sets of terms, concepts, and codes, safety alerts, and mechanisms for overrides. A complete electronic health record could aid in the important task of medication reconciliation, because it can help maintain accurate, current, and complete medication history and thus ensure patient safety. Developing standards for the elements of electronic medical records would ideally involve various key stakeholders, including CMS and the insurance industry. In addition, data contained in electronic medical records ideally would be used to populate a patient-centered Personal Health Record. Patient-centered records, fully accessible by patients, are critical to better communication.

In designing such a system of records, it is important to bear in mind the following issues:

- Vulnerable populations may not have access to computers and the Internet or may lack the necessary computer literacy skills to access and update their records;
- Aging people may have difficulty adjusting to changes in computers and develop usability issues over time; and
- Patient tools need to be sensitive to cultural and ethnic issues.

Patient records need to be standardized to facilitate communication between settings.

Standardized inclusion of and presentation of information would assist providers in quickly and effectively reviewing records. One mechanism for accomplishing uniformity is use of a universal transfer form. The standard form should include standard medication reconciliation data elements, codes sets and personal medicine list elements.

- Develop standard medication reconciliation elements

Every time a patient is exposed to a new care setting or level of care, a medication reconciliation form should be completed, and the new setting should receive key information about the patient's medication regimen. This listing would include prescription and non-prescription medications, dietary supplements, herbal remedies, a record of when the medication was taken and its route and frequency of administration, indication for use, patient allergies, and other medication-related information. Facilities accredited by the Joint Commission require that a complete list of the patient's medications be communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner, or level of care within or outside the organization. In addition, upon discharge from a facility, patients should receive a literacy-sensitive medications list.

All medication reconciliation forms and systems nationwide should incorporate a set of common, essential data elements for medication reconciliation. The key elements include:

- Demographics;
- Medications (active, taken chronically);
- Other medications — over the counter (OTC), herbal remedies, dietary supplements and time-limited medications;
- Medical history;
- Primary physician; and
- Validation.

All providers should ensure that their tools and systems include all the key medication reconciliation elements.

- Standardize patient's personal medicine list elements

It is not enough to have a standard form for medication reconciliation if patients are unaware of the medicines that they take and the dosage of those drugs. Facilities and providers should encourage widespread use of a personal medicine list by patients to track their own medication use. As with medical records generally, this list should have standard elements to increase its compatibility and comparability across providers. A literacy-sensitive list will facilitate its use as a tool to stimulate discussion between patients and caregivers and providers about their medicines. Use of standard elements and a uniform, easy-to-follow format will increase the likelihood that an individual patient and his or her caregiver will be able to manage medication therapy personally on an ongoing basis. It would be beneficial for this form to be a standard form.

Establish Points of Accountability for Sending and Receiving Care, Particularly for Hospitalists and SNFists

Given the number of professionals involved in successfully managing chronic conditions and difficult cases, each member of the healthcare team must have a clearly delineated role. Each team member then can be held accountable for fulfilling his or her role in managing the patient's care. The Robert Wood Johnson Foundation has supported the development of a chronic care model that defines roles, allocates care and follow-up tasks, provides for case-management as necessary, and ensures cultural sensitivity in care delivery. In determining a plan for care, it is important to include professionals, patients, caregivers, and community members because everyone's collaboration is important to successful outcomes. The key to higher quality care is accountability across all settings and individuals, including patients.

One of the emerging key team players involved in episodes of care occurring in hospital settings is the hospitalist. Hospitalists are physicians, often internists or family physicians, who spend the bulk of their time caring for hospitalized patients. In 2003, the United States had approximately 1,415 hospital medicine groups and 11,159 hospitalists, and about 20 percent of hospitals had a hospital medicine group (55 percent at hospitals with 200 or more beds). By 2010, the number of hospitalists grew to 30,000. The percentage of inpatients cared for by hospitalists varies, with some hospitals having up to 100 percent hospitalist coverage. Increased hospitalist use is driven by pressures affecting traditional hospital-physician relationships. As many physicians have increasing interest in sources of revenue besides inpatient care or emergency department consultations, primary care physicians and specialists have grown less dependent on hospital privileges, and hospital-based medicine has emerged as a new form of specialized practice.

Primary care physicians that practice specifically in skilled nursing facilities are called SNFists. They attend the chronically institutionalized patients found in nursing homes. Nearly four-fifths of elderly people in nursing homes are long-stay residents who are at high risk for care site transfers due to frailty and multiple disease processes. SNFists also attend the 10 percent of nursing home residents who

are post-acute and sub-acute patients, and who are predominantly (62 percent) admitted from the hospital. Only a few years ago, many of these post-acute and sub-acute patients would have been under treatment in a hospital setting. They are a population with complicated orders and treatments, prone to care transition complications from the hospital move as well as re-admission to the hospital. This segment, often frail elders, may only stay days to weeks in the SNF before another transfer home or to an assisted living setting. The SNFist, like the hospitalist, deals with a highly mobile, medically labile group. Their presence in the SNF enables consultation with nurses, interdisciplinary teams, patients, and caregivers. In addition to heavily involved physicians, such as hospitalists and SNFists, individual patients and their caregivers have a critical role to play in the success of transitions. As mentioned before, patients are the one constant throughout care, and thus they must take some level of accountability for ensuring the flow of information by asking questions or otherwise being active participants in their own care. Quality of care can improve through the clear delineation of responsibility. During times of transition, existing resources, such as institution-based physicians, should be used to coordinate care.

- Increase accountability

To improve the quality of care during transitions, each clinician involved should know his or her role in the process. Expectations need to be established for both the health care team sending a patient and the team receiving a patient, such as from a SNF to a hospital or vice versa. The teams should focus not on patient discharge as an endpoint, but rather view themselves as part of a continuum of care in which they are responsible for ensuring a successful transfer. By shifting focus in this manner, health care teams will assume responsibility for completing transfer forms, medication records, and medical records, assisting the receiving team and helping ensure patients and caregivers have a better understanding of their role in the process. Performance measurement focused on these issues and modification of existing payment systems can help encourage this shift in focus and ensure greater accountability.

- Make better use of hospitalists and SNFists

Research indicates that care by hospitalists improves clinical efficiency by reducing costs and shortening lengths of stay. Additionally, hospitalist care is associated with reduced patient mortality. Despite these advantages, the hospitalist model of patient care raises concerns. This new system, no longer directly involving the primary care physician as the point of contact in the hospital, can lead to disconnection in the timely transfer of information. No evidence indicates that hospitalists are the problem; rather, the hospitalist model creates transitions of care difficulties that may contribute to poor transitions. There is a need for strategies and interventions that help eliminate this chasm of care. Hospitalists and SNFists, along with primary care and emergency room providers, should be encouraged to coordinate care when transferring patients from one institution to another. They are equipped with the information necessary to ensure a successful transfer to the next care setting – whether it is home, long-term care, assisted living, hospice or other community settings.

Increase the Use of Case Management and Professional Care Coordination

Another important element in a successful transition of care is case management or other professional care coordination. Case management often is confused with discharge planning or other interventions. For purposes of this document, case managers are defined as licensed health care professionals responsible for providing patient assessment, treatment planning, health care facilitation, and patient advocacy. Case managers frequently arrange for the timely and accurate transfer of information as patients prepare to move from one level of care to another. When moving from one setting to another, the patient's medical information is usually not available to the receiving health care providers. Many patients require care facilitation support that case managers provide by navigating through the maze of health care resources, communication, and services. Yet case managers often have to start at the beginning with the patient at each level of care because there is not appropriate transfer of clinical factors, psychosocial factors related to the patient and those pertaining to the family, medication lists, or other related assessments. Case managers realize that patients usually are not prepared

for what to expect as they move from one level of care to another and therefore do not know what questions to ask or what information they should be prepared to share during the transition process.

Care coordination has resulted in positive outcomes for both patients and their caregivers. For example, many of the programs for older adults that include care coordination have produced positive outcomes for the patients served, such as improved functional ability, reduced hospital admissions, and fewer nursing home placements. Care coordination has been shown to decrease stress among informal caregivers and reduce the unmet needs of community-dwelling older adults. For example, hospital days for patients participating in the Wisconsin Partnership Program decreased from five days per year per thousand clients to 2.1 days, and reduced hospital utilization also has been reported in four other programs. Similarly, five programs reduced the length of nursing home stays. In addition, the rate of unmet needs among community-dwelling older adults was reduced in the demonstration project, and reduction of unmet needs has been achieved in state point-of-entry programs. Case management and professional care coordination can aid greatly in improving transitions of care. There should be increased use of case managers and other professionals to coordinate transitions of care.

- Increase use of case management

Case managers assist patients by providing support advocacy, adherence assessment, motivational intervention, resource coordination, enhanced patient self-management, and care planning to address many of the concerns identified in this paper. Because the patient is a constant factor in all transitions, it is appropriate to create a patient-centered model of integration with the medical team to assist with improved communication and information transfers. The issue then becomes who, how, and when this information gets communicated to the patient, the patient's caregivers, and other members of the patient's health care team in a consistent and reliable manner. Case managers can fill this role by ensuring that information related to the patient's current symptoms, medication list, advanced directives, adherence assessment, literacy, knowledge/comprehension, motivation, readiness to change, functional limitations, cognitive ability, coping ability, informal caregiver information, and professional caregiver contacts are provided in an accessible record. Case managers working in a collaborative practice model with emergency department physicians, residents, hospitalists, community practitioners, managed care administrators, health plans, pharmacists, and employers have the opportunity to coordinate care by overseeing the transfer of information throughout the transition.

- Introduce alternative professional care coordinators as needed

Other professionals also can be effective in assisting with discharge planning and home care. For example, an advance practice nurse supported by a physician has been shown to be effective in improving post-discharge outcomes among high-risk elderly patients. One study found this type of discharge planning to reduce hospitalizations for medical cardiac patients for six weeks post-discharge. A second major study on the subject demonstrated improved clinical outcomes and decreased hospital readmissions for common medical and surgical conditions. In addition to advanced practice nurses, similar models should be evaluated using other types of professionals, such as case managers, nurses, social workers, or pharmacists. A competent coordinator is particularly important given the specialized role of various clinicians, including medication management (pharmacists), nutrition (dietitians, pharmacists, and primary care physicians), rehabilitation (physical therapists, occupational therapists, and speech therapists), and wound care (nurses and physical therapists).

Dr. Eric Coleman, a member of the NTOCC advisory task force, directs the Care Transitions program (www.caretransitions.org) and has developed the Care Transitions Intervention. Unlike other models developed to date, the CTI is primarily a transitions self-management model that provides coaching skills and tools to help patients and caregivers assert a more active role during this vulnerable time. CTI not only prepares patients and caregivers for the immediate transitions but simultaneously prepares them for future transitions as well. The intervention is low-cost, low intensity and yet as been shown to produce a sustained effect reducing hospital readmissions significantly for five months

following the one-month intervention. This intervention is expected to result in nearly \$300,000 in savings for the care of 350 adults with care needs. Healthcare professional should work with models such as CTI. Although the Care Transitions model is one that is recognized as a quality tool, there are a number of emerging models of care that aim to enhance patient safety and care through transitions. Each model brings a set of interventions, tools, and resources that help to address the issues of communication, transfer of patient information, accountability for sending and receiving information, and improving quality of care. There is not one consistently accepted model, but use of the evolving models to break down the individual silos of care and address the needs of transition for patients and their caregivers is encouraged. Only through collaboration and aligned incentives will health care benefit from the excellent work in each of these models. NTOCC has developed an Elements of Excellence in Transitions of Care (TOC) Checklist. The adoption of a set of guidelines with checklists such as those included in the TOC Checklist can provide a framework for assessment and facilitate better communication, resulting in improved transitions of care.

Expand the Role of the Pharmacist in Transitions of Care

The role of the pharmacist has expanded to include a patient-centered care approach known as pharmaceutical care. The American Society of Health-System Pharmacists defines pharmaceutical care as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life. Pharmacists are an integral part of establishing a smooth transition of care and can provide expertise in a patient's drug therapy regimen. Many of the concerns about transitions of care include patient safety and efficacy as it pertains to medication use. When patients are moving from one care setting to another and are using different pharmacies, pharmacists are concerned with who is monitoring the patient's medications. Studies have shown that patient morbidity and indirect and direct costs may be reduced when pharmacists are actively involved in discharge planning. Pharmacists are not only an important component to the patient care team during transition, but also assume the responsibility for improving patient safety in regards to medications as patients move across the health care settings. Because a pharmacist is able to identify duplication in a medication regimen, drug-to-drug interactions, medication schedule, and multiple medications, he or she is a critical member of a patient's health care team.

There is a need for increased use of pharmacists as part of the patient care team during a patient's transition of care. The medication reconciliation should be a part of each pharmacist's responsibility. Pharmacists should have direct contact with patients and other health care providers to ensure medication information is transferred accurately and completely. Pharmacists should educate the patient and caregiver during the patient's discharge from one health care setting to another. Pharmacists also should be used to identify medication safety concerns and to prevent morbidity associated with improper drug selection, sub-therapeutic dosage, failure to receive medication, excessive dosage, drug interactions, and drug use without indication and treatment failures.

- **Managers of medication reconciliation**

Medication reconciliation is critical during transitions of care. This process includes a pharmacist review of all over-the-counter, prescription, vitamin, and herbal medications. If there are gaps that exist during the medication reconciliation process, it can lead to medication errors or rehospitalization due to adverse events. The process is particularly important given that a reported 46 percent of medication errors occurred when new orders were written at patient admission or discharge. According to the Joint Commission, every transition of care should include medication reconciliation. A report issued by the United States Pharmacopeia found that 66 percent of medication errors occurred during the patient's transition or transfer to another level of care, 22 percent occurred during the patient's admission to the facility, and 12 percent occurred at the time of discharge. The majority of these errors were due to omission and prescribing errors. Other types of errors reported were wrong drug, wrong time, extra

dose, wrong patient, mislabeling, wrong administration technique, and wrong dosage form. Medication reconciliation with a pharmacist managing the process may reduce errors and improve transitions of care. While other health professionals can conduct the initial medication reconciliation, the pharmacist should be responsible for overseeing the patient's medications, including all over-the-counter drugs, prescription drugs, vitamins, and herbal medications, and ensure that new orders are made and filled properly. It may be most effective to have a pharmacist serve as a counselor on all the patient medications. When a patient is admitted for acute or post-acute care, the pharmacist can review the medications that the patient was taking prior to admission. Once the patient is discharged, a pharmacist should perform the final review of current and discharge medications. The most important step is to ensure that the patient or caregiver understands how each medication is to be used, how to administer it, if or when to discontinue, and who to consult after discharge for questions or concerns. Also, pharmacists can include information on adverse events and what to do in case one occurs. This process should include a personal health record to ensure that the health care provider or pharmacist has a record of the patient's medication history. Encouraging a patient to have a medication therapy management session would allow the pharmacists to perform a complete medication review and identify any medication-related problems. A follow-up call with the patient should occur a few days later to ensure that patients understand their new or continued drug regimens.

Implement Payment Systems that Align Incentives and Include Performance Measures to Encourage Better Transitions of Care

Since the establishment of coordination of care as a national priority by IOM in 2001, some progress has been made to modify payment systems to align incentives that encourage improvements in transitions of care. In recent years, however, the federal government has focused on implementing quality reporting and moving towards a payment system based on pay-for-performance. The Department of Health and Human Services announced the creation of a National Health Care Quality Initiative that seeks to (a) empower consumers with quality of care information to make more informed decisions about their health care and (b) encourage providers and clinicians to improve the quality of health care. Through a greater emphasis on evidence-based medicine, the initiative aims to ensure that providers are delivering care according to national guidelines by developing and having different types of providers report sets of performance measures. These quality reporting efforts may result in improved care in point-of-service settings across the country, but they do not address the critical interruptions in patient care that occur at transitions across the continuum.

- Modify payment systems to encourage better transitions of care

According to the Joint Commission, poor communication continues to be the most frequent cause for sentinel events. The communication between staff in one setting is complex, but when adding communication across settings, the chances of a patient being treated according to national standards is further reduced. Although the guidelines tend to be very clear on how patients should be treated, they do not usually identify who will manage each aspect of care. Adopting both evidence-based medicine and process improvements will enhance care coordination and improve the variable rates of provider adherence to evidence-based therapies. The existing payment structure requires practices to move patients through quickly, with little time for working with team members, scheduling follow-up, developing a plan of care, and conveying changes to other providers. Pay for many patients are on a per visit basis, as opposed to episodic care across providers. No incentive exists for communicating, and there is no disincentive for not doing so. Duplicate tests are ordered and get reimbursed without having to consider whether another provider already has performed a similar service. A new approach will require a redesigned payment structure to change the behavior of providers.

Centers for Medicare and Medicaid Services (CMS) and private payers should implement performance measures relating to transitions of care and to develop payment systems that align incentives

for improvements in communication. IOM stated that Pay-for-performance mechanisms should recognize, promote, and reward improved coordination of care among a patient's multiple providers and during entire episodes of illness.

- Introduce performance measures relating to transitions of care

Part of creating a payment system that encourages better transitions of care involves the creation and implementation of performance measures relating to care coordination. The National Quality Forum (NQF), in its efforts to develop and implement a national strategy for health care quality measurement and reporting, has identified care coordination as a priority area and has endorsed both a standard definition of care coordination and a framework for measuring its quality. NQF has, to date, endorsed one such consensus standard. The federal government, including CMS, should encourage consensus organizations to develop care coordination measures to address the following areas, identified as essential by NQF:

1. Health care home. The source of usual care that functions as the central point for coordinating care around the patient. This is the clearinghouse of all patient information and is responsible for coordinating acute, episodic, and chronic care.

2. Proactive plan of care and follow-up. A care plan that ensures tracking of progress to goal is developed with the care team and patient, and includes information on evidence-based referrals, follow-up tests, self-management support, and community resources.

3. Communication. Medical and psychosocial information is available to all relevant team members, including the patient. Communication is encouraged and is reimbursed appropriately.

4. Information systems. Seamlessly interoperable systems available to all providers and patients, using evidence-based plan of care management, decision support tools, patient reminders, etc.

5. Transitions or hand-offs. Emphasis on medication reconciliation, follow-up tests/services, changes in plan of care, involvement of a team during hospitalization, communication between care settings, and transfer of current/past health information from old to new home in a timely manner.

With its primary focus on transitions of care, NTOCC has created and convened a Measures Work Group to review, assess, and make recommendations on how to improve and expand the current state of quality measurement within this more narrowly defined scope. The NTOCC Measures Work Group has been charged with the following tasks:

1. Developing a measurement framework specific to transitional care (as opposed to NQF's broader Care Coordination Framework);

2. Conducting an environmental scan for existing transitional care performance measures, evaluating these measures, and identifying existing measurement gaps; and

3. Developing recommendations on how to fill identified measurement gaps. A preliminary environmental scan has revealed several important measurement gaps for which NTOCC suggests that standards be developed for NQF endorsement consideration:

- The use of an integrated pharmacy data set to facilitate coordination and medication management;
- Success on therapeutic endpoints (such as Hemoglobin A1c);
- Monitoring for adverse drug events;
- Monitoring for medication adherence and persistence;
- Simplification of medication regimen to meet the patient's therapeutic, safety, and lifestyle needs;
- Assessment to ensure patient can afford medication;
- Assessment and teaching to ensure that patients understand how to use their medicines and identify adverse events; and
- Monitoring of the transfer of patients to higher levels of care due to failure to comply with treatment plan.

In addition to the measures noted above, the National Health Policy Group (NHPG) has made recommendations to CMS about performance indicators for coordination of care and care transitions specific to elderly populations and the National Committee for Quality Assurance (NCQA) Accreditation Standards includes several elements designed to measure care coordination practices from the health plan perspective. CMS and private plans should adopt these care coordination measures as part of their pay-for-performance systems.

To improve quality of care and medical outcomes in this country, a number of steps must be taken to improve communication during transitions of care. All stakeholders should consider:

- Improving communications during transitions between providers, patients, and caregivers;
- Implementing electronic medical records that include standardized medication reconciliation elements;
- Establishing points of accountability for sending and receiving care, particularly for hospitalists, SNFists, primary care physicians and specialists;
- Increasing the use of case management and professional care coordination;
- Expanding the role of the pharmacist in transitions of care;
- Implementing payment systems that align incentives; and
- Developing performance measures to encourage better transitions of care.

By addressing these critical issues, the health care system and the standard of care in this country can be greatly improved while also controlling costs.

Elements of Excellence in Transitions of Care (TOC)

TOC Checklist

The purpose of this checklist is to enhance communication—among health care providers, between care settings, and between clinicians and clients/caregivers—of patient assessments, care plans, and other essential clinical information. The checklist can serve as an adjunct to each provider’s assessment tool, reinforcing the need to communicate patient care information during transitions of care. This list may also identify areas that providers do not currently assess but may wish to incorporate in the patient’s record. Every element on this checklist may not be relevant to each provider or setting. For purposes of brevity, the term *patient/client* is used throughout this checklist to describe the client and client system (or patient and family). The *patient/client system* (or family), as defined by each patient/client, may include biological relatives, spouses or partners, friends, neighbors, colleagues, and other members of the patient/client’s informal support network. Depending on the setting in which this checklist is used, providers may wish to substitute *resident, consumer, beneficiary, individual*, or other terms for *patient/client*.

Overarching Concepts

Engagement

- Maximize patient/client involvement in all phases of intervention by promoting self-determination and informed decision-making.
- Provide educational information to support the patient/client’s participation in the plan of care.
- Protect patient/client’s right to privacy and safeguard confidentiality when releasing patient/client information.
- Affirm patient/client dignity and respect cultural, religious, socioeconomic, and sexual diversity.
- Assess and promote the patient/client’s efforts to participate in the plan of care.

Collaboration

- Define multidisciplinary team participants.
- Build relationships with all team members, with the patient/client at the center of the collaborative model.
- Communicate with other professionals and organizations, delineating respective responsibilities.

- Create awareness of patient/client and provider accountability for receiving and sending patient/client care information to and from care settings.
- Provide services within the bounds of professional competency and refer patient/client as needed.

Strengths-based assessment

- Use respect and empathy in patient/client interactions.
- Recognize patient/client's strengths and use those abilities to effect change.
- Help patient/client use effective coping skills and insights to manage current crises.
- Recognize and help resolve patient/client's difficulties.
- Distinguish cultural norms and behaviors from challenging behaviors.

Assessment as an ongoing process

- Keep assessments flexible, varying with presenting problem or opportunity.
- Regularly reassess patient/client's needs and progress in meeting objectives.
- Facilitate goal-setting discussion based upon the patient/client's needs during all phases of care.
- Assess effectiveness of interventions in achieving patient/client's goals.
- Communicate changes in assessment and care plan to the health care team.

Common Elements for Assessment and Intervention

Physiological functioning

- Assess patient/client's understanding of diagnosis, treatment options, and prognosis.
- Evaluate patient/client's life care planning and advance directive status.
- Evaluate impact of illness, injury, or treatments on physical, psychosocial, and sexual functioning.
- Evaluate patient/client's ability to return to or exceed pre-illness or pre-injury function level.

Psychosocial functioning

- Assess past and current mental health, emotional, cognitive, social, behavioral, or substance use/abuse concerns that may affect adjustment to illness and care management needs.
- Assess effect of medical illness or injury on psychological, emotional, cognitive, behavioral, and social functioning.
- Determine with patient/client which psychosocial services are needed to maximize coping.

Cultural factors

- Affirm patient/client dignity and respect cultural, religious, socioeconomic, and sexual diversity.
- Assess cultural values and beliefs, including perceptions of illness, disability, and death.
- Use the patient/client's values and beliefs to strengthen the support system.
- Understand traditions and values of patient/client groups as they relate to health care and decision making.

Health literacy and linguistic factors

- Provide information and services in patient/client's preferred language, using translation services and interpreters.
- Use effective tools to measure patient/client's health literacy.
- Provide easy-to-understand, clinically appropriate material in layperson's language.
- Use graphic representations for patients/clients with limited language proficiency or literacy.
- Check to ensure accurate communication using teach-back methods.
- Develop educational plan based upon patient/client's identified needs.
- Evaluate caregiver's capacity to understand and apply health care information in assisting patient/client.

Financial factors

- Identify patient/client's access to, type of, and ability to navigate health insurance.
- Identify patient/client's access to and ability to navigate prescription benefits.
- Evaluate impact of illness on financial resources and ability to earn a living wage.
- Provide feedback on financial impact of treatment options.
- Educate patient/client about benefit options and how to access available resources.
- Assess barriers to accessing care and identify solutions to ensure access.

Spiritual and religious functioning

- Assess how patient/client finds meaning in life.
- Assess how spirituality and religion affect adaptation to illness.

Physical and environmental safety

- Evaluate patient/client's ability to perform activities of daily living and meet basic needs.
- Assess environmental barriers that may compromise the patient/client's ability to meet established treatment goals.
- Determine with patient/client the appropriate level of care.
- Assess ability of family or other informal caregivers to assist patient/client.
- Assess for risk of harm to self or others.

Family and community support

- Identify patient/client's formal and informal support systems.
- Assess how patient/client's illness affects family structure and roles.
- Provide support to family members and other informal caregivers.
- Assess for, and if appropriate help resolve, conflicts within the family.
- Evaluate risk of physical, emotional, or financial abuse or neglect, referring to community social services as needed.

Assessment of medical issues

- Patient/client diagnosis
- Symptoms
- Medication list and reconciliation of new medications throughout treatment
- Adherence assessment and intention
- Substance use and abuse disorders
- Lab tests, consultations, x-rays, and other relevant test results

Continuity/Coordination or Care Communication

- Specific clinical providers
- Date information sent to referring physician, PCP, or other clinical providers
- Necessary follow-up care

Example of Assessment & Coordination of Care Communication Checklist & Tool**Medication Assessment:**

þ Review all prescribed medications, over-the-counter medications, and health/nutritional supplements

Name of Medication

Dose

Route

Frequency

Next Refill

Can the patient/client tell you:

Reason she or he is taking medication

Positive effects of taking medication

Symptoms or side effects of taking medication

Where the medication is kept at home

The next refill date for the medication

How long she or he needs to remain on the medication

Modified Morisky Scale – a validated, evidence-based tool (Morisky 1983)

Question Motivation Knowledge

1. Do you ever forget to take your medicine?

2. Are you careless at times about taking your medicine?
3. When you feel better do you sometimes stop taking your medicine?
4. Sometimes if you feel worse when you take your medicine, do you stop taking it?
5. Do you know the long-term benefit of taking your medicine as told to you by your doctor or pharmacist?
6. Sometimes do you forget to refill your prescription medicine on time?

Hand off all assessments to the next level of care coordination

CONTINUITY/COORDINATION OF CARE:

Does the patient/client have a primary care physician? (if appropriate) Send assessment information to PCP – Date

Does the patient/client have a specialty physician, e.g., cardiologist? (if appropriate)

Send assessment information – Date

Does the patient/client have a psychiatrist or other mental health provider? (if appropriate) Send assessment information – Date

Does the patient/client have an outpatient case manager who should be notified? Send assessment information – Date

Ensure all transition services and care (medications, equipment, home care, SNF, hospice) are coordinated and documented – Date verified

Ensure patient/client and caregiver understand all information and have a copy of the care plan with them – Date verified

Proposed Framework Outline for Measuring Transitions of Care

I. Structure

A. Accountable provider at all points of transition. Patients should have an accountable provider or a team of providers during all points of transition. This provider(s) should be clearly identified and will provide patient centered care and serve as central coordinator of his/her care across all settings, across other providers.

B. Plan of care. The patient should have an up-to-date, proactive care plan that includes clearly defined goals, takes into consideration patient’s preferences, and is culturally appropriate.

C. Use of health information technology (HIT). Management and coordination of transitional care activities is facilitated through the use of integrated electronic information systems that are interoperable and available to patients and providers.

II. Processes

A. Care Team Processes:

- Medication reconciliation.
- Test tracking (lab and diagnostic procedures).
- Referral tracking.
- Admission and discharge planning.
- Follow up appointment.

B. Information transfer/communication between providers.

- Timeliness, completeness and accuracy of information transferred.
- Protocol of shared accountability in effective transfer of information.

C. Patient education and engagement.

- Patient preparation for transfer.
- Patient education for self-management.
- Appropriate communication with patients with limited English proficiency and health literacy.

III. Outcomes

- Patient experience (including family or care giver).
- Provider experience (individual practitioner or health care facility).
- Patient safety (medication errors, etc.)
- Health care utilization and costs (reduced avoidable hospitalizations)
- Health outcomes (clinical and functional status; intermediate outcomes, therapeutic endpoints).

Transitions of Care Measures

Currently there is a large evidence base that demonstrates the existence of serious quality problems for patients undergoing transitions across sites of care. While there are transitions of care measures on the structure, process, and outcomes of care that are useful, measure gaps still exist. According to a report from the Agency for Healthcare Research and Quality (AHRQ)¹, there is a need to reach consensus on definition, conceptual model(s), and outcomes related to care coordination. There also exists a need to continue the conduct of research to evaluate the value of different care coordination efforts and tools. In order to measure the progress in improving care transitions, what is needed is a comprehensive, more robust set of measures that is applicable to all aspects of care transitions, to all populations across all care settings.

The Case Management Society of America (CMSA) convened the National Transitions of Care Coalition (NTOCC) to develop recommendations on actions that all participants in the health care delivery system can take to improve the quality of care transitions. The multi-disciplinary members of NTOCC worked collaboratively to develop policies, tools, and resources as well as recommend actions and protocols to guide and support providers and patients in achieving safe and effective transitions of care. The Measures Work Group is one of four work groups convened to focus on specific areas. The objectives of the Measures Work Group are:

1. To develop a framework for measuring transitions of care.
2. To conduct an environmental scan for existing transitions of care quality measures, evaluate these measures, and assess gaps in measures.
3. To develop recommendations on how to fill gaps in measures.

Care Coordination

Care Coordination is the deliberate organization of patient care activities among two or more participants (including the patient and/or the family) to facilitate the appropriate delivery of health care services. Organizing care involves marshalling personnel and other resources to carry out all required patient care activities, which is often managed by the exchange of information among participants responsible for different aspects of the care. Transitions of Care refer to the movement of patients between health care locations, providers, or different levels of care within the same location² as their conditions and care needs change. Specifically, they can occur:

1. Within settings; e.g., primary care to specialty care, or intensive care unit (ICU) to ward.
2. Between settings; e.g., hospital to sub-acute care, or ambulatory clinic to senior center.
3. Across health states; e.g., curative care to palliative care or hospice, or personal residence to assisted living.
4. Between providers; e.g., generalist to a specialist practitioner, or acute care provider to a palliative care specialist.

Transitions of Care

Transitions of care are a set of actions designed to ensure coordination and continuity. They should be based on a comprehensive care plan and the availability of well-trained practitioners who have current information about the patient's treatment goals, preferences, and health or clinical status. They include logistical arrangements and education of patient and family, as well as coordination among the

health professionals involved in the transition. In effect, transitions of care are a subpart of the broader concept of care coordination.

Measuring Transitions of Care

Measures are typically based on agreed upon standards of care and practice. They can be used to promote better health care processes and outcomes through internal quality improvement activities, public recognition, incentives from payers (e.g., pay for performance), and informed consumer decisions. Measures are most effective when the structure or process of care being measured is based on strong scientific evidence linked to good outcomes and when the outcome being measured is influenced or impacted by one or more specific clinical interventions. There is consensus in the quality measurement community that there are a few essential attributes and/or criteria for selecting and evaluating measures. These are importance, scientific soundness, usability, and feasibility. The Step Up to The Plate Alliance (SUTTP), convened by the American Board of Internal Medicine Foundation (ABIM), noted that transitions of care often involve interactions between unrelated parts of the health care delivery system, and that transitions occur in the white space between individuals and organizations that is neither owned nor claimed by anyone. This crosscutting nature of transitions of care necessitates particular attention in developing measures to areas that the work group has considered, including:

1. Patients: all or only those identified as high risk.
2. Applicability to all health care settings and providers or to a defined subset.
3. Types of measures: structure, process, outcome, patient experience, efficiency, effectiveness.
4. Focus of measures: patient's perspective or experience, provider's perspective or experience.
5. Feasibility of data sources and data collection.
6. Unit of measurement: organization/facility/practice, individual health care professionals, multidisciplinary teams, system level, communities, population.

Patients

A key issue to consider for the care transition measure set is the type of patients to include in the denominator population. Should the measure focus only on certain high-risk patients? Should there be multiple measures on care transitions focusing on specific disease conditions? Or should there be a set of care transition measures applicable to all patients undergoing transitions? Since care transitions are not unique to any specific condition or patient population, the work group recommends having care transition measures that apply to all patient populations.

Health Care Settings and Providers

Another key issue involves health care settings such as hospitals, nursing homes, physician offices, home health agencies, and the like. Should different care transition measures be developed for different health care settings or provider types? Or should there be a set of care transition measures that applies to the health care setting or provider types involved in the care transition activities? Since an important ingredient for successful, effective, and safe care transitions is teamwork across settings and providers, the Measures Work Group recommends that care transition measures apply to all health care settings and provider types. This will promote shared accountability across all providers who are involved with the patient's care transitions.

Types and Focus of Measures

An ideal set of care transition measures should evaluate the adequacy of certain structural elements in the health care setting, especially those that promote safe transitions of care. It should also have process measures that evaluate the timeliness and completeness of information transferred and received between care settings and/or providers. In addition, there should be process measures that evaluate the adequacy of the providers tracking vital information and acting on the information.

Moreover, the set of measures should include outcome measures that evaluate the adverse events occurring as a result of inadequate care transitions. Efficiency measures could include the inappropriate utilization of resources, such as unnecessary readmissions and duplication of tests. Patients' and providers' experience and perspectives should also be measured.

Feasibility of Data Sources and Data Collection

The data sources for producing the care transition measures are critical factors to consider. The use of standardized data sources such as patient demographics and discharge summaries is essential for comparisons across sites or providers, and for benchmarking. Outcome measures may be produced by claims data; however, simply having outcome measures is not sufficient to promote quality improvement in the area of transitions of care. An ideal set of measures should have structural and process measures as well. The use of medical record data abstraction or paper tracking tools to produce structural or process measures is quite burdensome. While the use of surveys is also resource intensive, they are ideal data sources for assessing patients' perspectives and feedback and should be used in every health care setting. Measures for care transitions should ideally be based on longitudinal, electronic health records. Electronic databases such as the use of the CMS CARE tool might serve as a valuable data source for future care transition measures.

Unit of Measurement

An additional issue to consider in developing or evaluating measures for care transitions is the unit of measurement. Should the measure be calculated at the individual provider level, the facility level, the team level, or the system level? Since care transition requires that all providers involved with the patient's care transition activities within a setting or between settings be cooperative and accountable, the ideal set of measures should apply to the providers as well as the teams. It should allow aggregation at the provider level, facility level, and the system level. Because the outcome(s) of a care transition activity may not be evident until after the transition has been completed—that is, after the handover from one care setting or provider to the next—it is important to consider measuring outcomes of care transitions applying a paired approach. This means that measures should be developed and examined in a way that would best link the impact of the two care settings and/or providers involved (i.e., the sending and receiving) in the care transition activities.

Many measures of transitions of care that could be particularly meaningful to communities or consumers may lack reliable data sources or specific units of measurement. For example, a measure that might make sense to consumers could look for evidence of medication reconciliation in an outpatient medical record at a given interval after hospitalization. In practice, however, this measure may be unworkable outside of vertically integrated delivery systems or managed care organizations. This is because the measure presupposes that all patients have a designated principal ambulatory care giver (a primary care provider, or PCP, a medical home, or a care coordination hub) known to the other parts of the delivery system. Having a central care coordination hub for all patients is one of the principles underlying effective care transitions, however this is not the current state for a majority of patients. One reasonable goal of transition of care measures would be to promote consumer engagement in designating a principal coordinating caregiver. In this example, data for the denominator —patients discharged from the hospital — would come from hospitals or from payers. The numerator would be derived either from medical record reviews at the ambulatory practice site or could come from payer data if a billing code were introduced to indicate post-hospital medication reconciliation. But who is being measured in this case? Is it the hospital? Is it the ambulatory care professional? Is it both? To implement such a measure would present a great challenge knowing that currently there is no shared sense of responsibility and accountability among the providers involved in the patient's care in both settings, and where the financial incentives are not aligned. An effective care transition requires a series of steps or actions that must be taken by the responsible providers along the continuum of care or the pathways the patient is traveling.

Appropriate, stepwise measurement of the accountable provider at each of these steps could not only help to assure that each step is taken responsibly but could also serve to promote better communication within the delivery system. Ultimately, these actions promote effective outcomes and safe patient care practices.

Evidence Based Practice

Evidence based practice is defined as conscientious, explicit, and judicious use of current best evidence in making decisions about the care of patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Evidence based practice promotes patient safety through the provision of effective and efficient health care, resulting in:

- Less variation in care
- Less unnecessary or non-therapeutic intervention
- Use the highest level of evidence possible.

Evidence based clinical decision making is the balance of evidence and clinical judgment based on experience. It includes patient preferences and values. The goal is not the “cookie cutter” approach to care or simply cost savings, but the best care and outcomes.

The reality of care today is that evidence does not exist for the majority of clinical situations. Most of what is known by research is not known by clinicians. Clinicians don’t always follow the evidence in practice.

The **goals** of evidence based practice are to provide:

- Care based on the best available evidence
- Most efficacious clinical management
- Best clinical outcomes
- Decreased unnecessary risks to patients
- Decreased unnecessary tests, procedures, & non-therapeutic practices

Optimal patient outcomes and patient safety is based on both evidence based practice and the best patient care outcomes.

Evidence-based practice

Evidence-based practice (EBP) is a problem solving approach to clinical practice that integrates the conscientious use of best evidence in combination with a clinician’s expertise as well as patient preferences and values to make decisions about the type of care that is provided.

Over \$50 billion dollars in new research is completed throughout the world each year. There has been approximately 60 years of biomedical research since World War II. Despite an aggressive research movement, the majority of findings from research often are not being integrated into practice. It takes approximately 17 years to translate research findings into practice.

Without current best evidence, practice becomes rapidly out of date to the detriment of our patients. Rule 5 of the Ten Rules for Healthcare in Crossing the Quality Chasm is evidence-based decision making. The 5 core competencies deemed necessary by the recent IOM Health Professions Educational Summit include employing evidence-based practice. In the near future, it can be expected that third party payors will only provide reimbursement for treatments of health care practices that are supported to be effective based on scientific evidence.

Physicians have been reluctant to follow protocols because, in many instances, the newer therapies were not part of their original training. Consequently, patients do not benefit from the latest, most effective therapies until many years after the original discovery. The average time from discovery to implementation of new and effective medical therapies ranges from 5 to 20 years. Substantial investments have been made in clinical research and development over the last 30 years, resulting in the medical knowledge base and the availability of many more drugs and devices. The lag time between the

discovery of more efficacious forms of treatment and their incorporation into routine patient care is unnecessarily long, in the range of about 15 to 20 years.

Numerous standardized protocols have been developed and proven for both medical and surgical treatment, and in spite of this effort and knowledge, marked variability in physician practice patterns remains, as seen in the attendant costs and morbidity associated with outmoded treatments, ineffective treatments, or prolonged hospital stays. Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

Why Evidence Based Practice?

Textbooks may be out of date by the time they are printed

Journals are voluminous; in order to keep up with journals relevant to practice, healthcare professionals should review 19 articles a day, 365 days a year

Knowledge and performance deteriorate over time

Traditional continuing education does not significantly improve performance

To advance healthcare professions

To facilitate better outcomes for our patients and their families

To enhance life-long learning

Five steps of Evidence-Based Practice

1. Ask the burning clinical question in **PICO** format

Patient population

Intervention or interest

Comparison intervention or comparison group

Outcome

2. Collect the best evidence

Search first for systematic reviews or evidence syntheses (e.g., Cochrane Database of Systematic Reviews) and evidence-based clinical practice guidelines (<http://www.guideline.gov>)

3. Critically appraise the evidence

What were the results of the study? Are the results valid (as close to the truth as possible)? Are the results important? What is the impact of the intervention (size of the effect)? Are the results clinically relevant/applicable?

- Were subjects randomly assigned to treatment groups and was the random assignment concealed from the individuals enrolling subjects?
- Was the follow up sufficiently long to study the effects of the treatment and were all patients accounted for at the end of the study?
- Were patients analyzed in the group to which they were assigned?
- Was the control group appropriate?

4. Integrate evidence, clinical expertise, and patient factors/preferences to implement a decision

5. Evaluate the outcome

Evidence Based Practice Priorities

- Cancer
- Diabetes
- Emphysema
- High cholesterol
- HIV/AIDS
- Hypertension
- Ischemic heart disease
- Stroke

- Arthritis
- Asthma
- Gall bladder disease
- Stomach ulcers
- Back problems
- Alzheimer's disease & other dementias
- Depression & Anxiety

Evidence based practice guidelines are available from the following:

- AHRQ (AHCPR)
- National Guideline Clearinghouse
- Cochrane Library
- CINAHL]
- TRIP
- ACP Journal Club
- Medline
- Medscape
- DARE
- Evidence Based Medicine
- Clinical Specialty Organizations

Efficient review of literature

- Systematic reviews/meta-analyses
- Clinical practice guidelines
- Randomized clinical trials
- Less rigorous studies
- PubMed filter for systematic reviews
- <http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.html>

Efficient determination of best practice

- Comprehensive search for information
- Critical appraisal of literature
 - Systematically reviewing the research evidence
 - Completing a critical appraisal checklist
 - Level of evidence
 - Study inclusion criteria
 - Target population
 - Currency of information
 - Consistency across guidelines
 - Fit with patients & setting
 - Determining the validity & relevance of the findings in order to influence practice
 - Interpretation of scientific evidence combined with
 - Clinical expertise
 - Knowledge of unique features of target population & references
 - Specific medical co-morbidities
 - Other relevant contextual factors
- Data synthesis

- Interpretation

Sharing your findings

- Translating data into understandable information
- Find innovative modes of sharing
- Focus on practice change implications
- Communicate horizontally & vertically

Implementing change

- Be sure there is sufficient research of adequate quality
- Identify specific outcomes to be tracked
- Identify how outcomes will be measured
- Identify who will track outcomes
- Identify when outcomes will be examined
- Address a specific clinical problem
- Address clinical, system, & provider components
- Use effective communication strategies
- Address identified barriers
- Incorporate the best evidence or research available to optimize patient outcomes.

Barriers to evidence based practice

- Getting practitioners to use definitive systematic review or guideline
- Resistance to change
- Hierarchical practice
- Lack of the perceived need
- Aversion to cookbook medicine
- Lack of awareness of evidence based practice guidelines
- Lack of confidence in the guideline developer
- Suspicion that the true goal is cost control
- Low comfort level with library and search techniques
- Too many journals
- Lack of time to search for the best evidence
- Challenges with understanding and interpreting research reports
- Negative attitudes toward research
- Lack of organizational support

Strategies to promote evidence based practice

- Use one of several research utilization models which have been widely used to promote each step of the EBP process, from practice question determination to evaluation
- Automate EBP, such as standing order sets, practice protocols, and computerized prompts
- Point of care access to the Internet based search engines & systematic reviews
- Initial & ongoing education of health care professionals
- Implementation of an EBP curriculum in the education of all health care professionals
- Evidence based practice rounds

Recommendations for advancing Evidence Based Practice

- Ask the following questions
 - To what extent is the practice that is delivered evidence based

- How much do staff believe that implementing and teaching EBP will lead to the highest quality of care for patients and families?
- How much knowledge of the EBP process do staff possess?
- Assess environment readiness
 - Does the philosophy & mission of the institution support EBP?
 - What is the personal commitment to EBP among clinicians and administration?
 - Are there healthcare professionals who have strong knowledge and skills related to EBP?
 - Do practitioners model EBP in their clinical settings?
 - Do educators and healthcare professionals have access to quality computer?
 - Are there librarians who have knowledge of EBP who can assist with EBP?

Requirements for implementing EBP

Champions in the environment at all levels (administrators, skilled EBP mentors)

Resources (committee & skilled mentors, computers, access to quality databases & Internet)

Evidence Based Practice Resources

- Evidence Based Practice Centers (Veterans Affairs)
- Agency for Healthcare Research & Quality
- Critical Appraisal Tools
- Systematic Reviews
- Clinical Guidelines
- Professional Organizations
- Virtual Communities

The following website includes guidelines with grading of the evidence.

http://www.icsi.org/knowledge/browse_bydate.asp?catID=29

Clinical Pathways

Clinical pathways are a multidisciplinary management tool that proactively depicts important events that should take place in a day-by-day sequence. Throughout the entire episode of illness, the key events change daily and move the patient and the healthcare team toward discharge. The overall goal is to achieve optimal quality of care while minimizing delays and resource utilization. Pathways can be used by all team members to coordinate, plan, deliver, and monitor care, and document and perform utilization review activities concurrently. Clinical pathways are generally written for specific patient populations. Some are based on diagnoses; others are written for patient conditions or surgical procedures. They can also be written for various timelines of care. The most common scope of care is the inpatient hospital pathway. Other pathways extend until post discharge follow up is completed. Pathways are also used for chronic conditions, such as ESRD or COPD, BPH, or Crohn's disease in the ambulatory setting. Pathways are usually set up in chart form, with hospital days stretching across horizontally and key categories vertically. Key categories include treatments, consults/referrals, diagnostic tests, medications, activities/mobility, diet/nutrition, discharge planning, and education.

When a patient's care doesn't meet the changes as outlined in the clinical pathway, a variance has occurred. The variances can be positive or negative, avoidable or unavoidable. A positive variance may show the patient progressing more quickly than the pathway anticipated. Negative variances usually resulted in an extended length of stay, and the patient takes longer to reach the desired outcomes. Because variances can be identified almost immediately, avoidable days can be reduced. The goal is to recognize and resolve the variances as quickly as possible and get the care back on the path in a timely manner. The causes of variances should be dealt with as quickly as possible, allowing corrective action to be taken. Analysis of variance data is directly related to performance/quality improvement activities.

Benefits of Clinical Pathways

- Utilization management and performance/quality improvement activities are all inclusive.
- The patient is the primary focus, resulting in improved patient/family satisfaction.
- Patients involved in day to day care have a decreased level of anxiety and an increased sense of involvement and control.
- Effective for decreasing length of stay and resource utilization.
- Quality of care is enhanced with continuous, concurrent attention to variances.
- Improves communication among team members.
- Serve as excellent guidelines for care for new staff members.
- Provide excellent documentation tools.
- Provide cues to staff for all aspects of care.

Pathways emphasize **coordination** of all clinical activities and can be presented in a number of formats.

1. Activity and precedent table format: Lists all the activities and shows their required precedents, duration, and resource requirements. Some may show start, finish, and slack times as well.
2. Gantt chart format: Shows the beginning and ending times for each activity to be done each day on a bar chart along a time scale. The activities are frequently grouped into consults, tests, patient activities, treatments, medications, diet, and patient and family education. Gantt charts clearly display when activities are to be done in each time period but do not show precedent relationships among activities.
3. Flowchart format: Graphically illustrates the precedent relationship among activities and shows the critical path. In general, flowcharts require more space than tables and can be quite large. This format does not work well in showing which activities have to be done on each day.

Clinical paths can be used to show the overall management of a patient across disciplines, so that activities can be coordinated. Dependencies are identified. Expectations of actions, timing, and outcomes are established and agreed on by the interdisciplinary team. Clinical paths are an effective tool to educate and orient health care staff, and clarify the recovery process and expectations for patient and family. Clinical paths can also reduce variances in care. Even though the individual user can tailor pathways, there is still a great amount of resistance from many health care professionals who reject the notion of “cookbook medicine.” This should be addressed by involving all clinical practice areas, including physicians, registered nurses, pharmacists, and therapists, in the creation of the pathways.

- Used for measuring outcomes and modifying treatments based on analysis Basis for creation of patient education tools Serve as the basis for creation of a disease management program

Disadvantages of Clinical Pathways

- Difficult to keep up to date with changing practice patterns
- Different pathways for the same condition can have conflicting recommendations
- No one pathway for any disease addresses the full continuum of care
- Difficult to evaluate the validity of the pathway without extensive outcomes testing
- Recommendations may be difficult to implement due to provider or patient noncompliance

Clinical Protocols

Clinical protocols, guidelines, or standards are sometimes used interchangeably with clinical pathways. They provide a list of the minimum standards of care and can be applied to nearly all patients assigned to a group because they are free of individual patient differences. Protocols can guarantee a

single standard of care. Goals, timelines, and resource allocation are not generally included in the definition of a protocol.

Sample: Effect of a Critical Pathway on Patients' Outcomes after Carotid Endarterectomy

The purpose of a clinical pathway or protocol is to provide a framework to coordinate care for a specific population of patients. Clinicians use pathways to integrate knowledge from current research and maximize efficiency while maintaining the quality of patients' care. In today's healthcare setting, clinicians are being held accountable for controlling the costs of providing quality healthcare. One way of doing so is to use clinical pathways that have been established and tested for their effects on patients' outcomes.

Carotid endarterectomy, removal of plaque from the inner lumen of the carotid artery, is the most frequently performed vascular surgical procedure in the United States. The procedure has become the standard therapy of choice for preventing debilitating strokes in patients with greater than 70% stenosis of the carotid artery, whether the patients have signs and symptoms of cerebral ischemia or not. The most significant risk factors associated with the procedure are stroke, acute myocardial infarction, and pulmonary complications. Improved technological capabilities and effective postoperative monitoring have reduced the risk of complications to acceptable levels compared with the risk of stroke due to significant stenotic lesions.

Several trends are apparent in the current management of patients undergoing elective carotid endarterectomy. A number of institutions are using clinical pathways or protocols to manage this population of patients. The purpose of most of the protocols is to reduce preoperative and postoperative lengths of hospital stay, decrease routine use of preoperative angiography, and use the intensive care unit (ICU) for selective admission of patients. Accessibility of specialized units for postoperative care of patients after carotid endarterectomy is an important factor that makes it possible to decrease the use of ICUs.

Outcome measures before and after implementation of a clinical pathway have been compared. Common outcome variables studied include total length of stay, preoperative length of stay, and postoperative length of stay. Other variables include hospital costs, morbidity and mortality rates, outcomes by type of anesthesia, and the use of preoperative angiography.

Inclusion and exclusion criteria differed among studies. Some studies included only patients undergoing elective carotid endarterectomy, whereas others included both elective and emergent cases. Information gained from these studies is that the length of hospital stay and costs can be reduced without increasing morbidity and mortality rates for these patients. The degree to which the use of general anesthesia versus regional anesthesia makes a difference in complication rates has been documented in several studies. In 1996, a multidisciplinary collaborative practice team developed an integrated plan of care for patients undergoing carotid endarterectomy at the Orlando Regional Healthcare System. This initiative was based on evidence found in the research literature about the management of patients undergoing this procedure. The major emphasis behind this initiative to improve performance was to address practice issues across the continuum of hospital care and to streamline care with coordinated efforts while maintaining quality.

Utilization of resources was addressed by use of specific protocols that reduced unnecessary use of oxygen and monitoring, routine preoperative use of cerebral angiography, and ICU stay. One goal was to reduce length of stay and costs by discharging patients who met set outcomes criteria on the day after surgery. In order to reduce ICU admissions, a step-down, monitored care unit was designed so that arterial monitoring could be used and the plan of care could be followed outside the traditional ICU. Evidence indicated that the protocol was successful in the first year of its introduction. During the first 6 months, adaptation to the protocol was variable, however, by the end of the first year, costs per case and length of stay had diminished. A research study was undertaken to determine if the goals of the project had been met and maintained over time. Records were reviewed retrospectively to determine if patients

who had carotid endarterectomy before implementation of the protocol had a different length of stay than patients who were managed according to the protocol. Lengths of stay were compared between groups.

The mean length of stay for patients not managed according to the protocol was 2.93; and 1.68 for those who were managed according to the protocol. Analysis of variance indicated a significant difference between group length of stay ($p < .001$). Preoperative length of stay also varied; from .29 days for patients not on the protocol; and .08 days for those managed with the protocol, another significant difference ($p < .001$). Seventy-seven per cent of patients who were not managed on the protocol spent time in ICU, contrasted with only 9% of patients managed with the protocol. Mean costs for the group not using the protocol were \$7798 per case; and \$5387 for those on the protocol, another significant difference ($p < .001$). The complication rate for myocardial infarction was 1.6% for the group not managed by protocol, and 1.5% for those on the protocol. Complication rates were also similar, 2.32% for the group not managed by protocol and 2.38% for the protocol group.

The use of a systematic clinical protocol reduced hospital costs and length of stay, and improved transfer of patients within the hospital. Using the protocol did not result in changes in the quality of patients' outcomes, and most patients were discharged to home without complications. The findings of this study support result from previous reports of similar initiatives for the management of patients undergoing carotid endarterectomy, thus supporting further initiatives of this type in comparable populations of patients.

Critical Elements of the Protocol

Preoperative Phase: Preadmission Testing/Preoperative Area	Immediate Postoperative Phase: Postanesthesia Care Unit	Postoperative Recovery Phase: Vascular Thoracic Unit	Discharge Phase: Vascular Thoracic Unit
Perform baseline neurological assessment & record findings	Assess incision for edema and/or hematoma	Perform same assessment as in postanesthesia care unit with hourly checks & documentation	Observe patient's ability to perform activities of daily living in the morning after surgery
Measure blood pressure in both arms	Perform neurological assessment	Monitor blood pressure & control with drugs specified in protocol, same as was done in postanesthesia care unit	Assess patient as his or her condition indicates
Provide patient with educational materials	Evaluate patient's comfort & treat as needed	Have patient get out of bed & into a chair the night of surgery	Remove arterial catheter if blood pressure has remained within parameters & no current IV vasoactive or inotropic drugs being used to control blood pressure
Review course of hospitalization	Assess airway & oxygen levels	Offer diet of choice	Assess if assistance at home is needed & make appropriate referral with case manager
Review laboratory results and notify physician if values not within expected range	Use oxygen only when oxygen saturation $< 93\%$	Assess swallowing	
Check pulse oximetry readings before administering oxygen	Monitor blood pressure with arterial catheter	Control nausea & vomiting	
	Follow protocol for administering drugs to control blood pressure when it is out of desired range	Assess patient's ability to void. If patient needs urinary catheter, attempt to remove catheter as soon as feasible	Educate patient & patient's family with instructions about discharge & follow up care with surgeon
	Control nausea & vomiting	Stop administering oxygen as soon as parameters indicate it is feasible to do so	

Sample Pediatric Asthma Pathway

Category	Day 1	Day 2	Day 3
Patient Outcomes	O2 saturation >93% Improvement in PEFR after nebulizers Asthma education initiated	O2 saturation >94%, RA Peak flow >70% Patient/family verbalizes asthma education	Patient discharged when: Peak flow >80% of personal best Tolerating PO's well Patient/family demonstrates understanding of asthma & its management Follow up appointments made
Medications	IV fluids or SL as ordered Begin Bronchodilator management protocol Begin steroids as ordered Begin anti-inflammatory MDIs Adjuvant medications as ordered	Continue bronchodilator protocol Continue oral steroids Continue anti-inflammatory MDI Decrease IV fluids or D/C if PO intake adequate	Discharge Bronchodilators Discharge oral steroids Discharge anti-inflammatory medications
Activity/Safety	As tolerated	Up as tolerated	Activity appropriate for age
Diagnostic Procedures	CBC if febrile CXR is febrile or first episode of wheezing Pulse oximetry if ordered	Wean O2 to keep saturations >94% Continue pulse oximetry if pt on O2 Peak flow monitoring	D/C O2 for saturations >94%
Diet	Age appropriate diet as tolerated	Age appropriate	Age appropriate
Education	Hospitalization plan discussed with patient/family Begin asthma education/give care plan to family	Review with patient/family asthma education care plan Discuss home management plans Instruct on home care equipment	Education complete
Nursing Assessment	Initiated pediatric asthma care plan Vital signs assessments as ordered Assess pain using grimace scale	Continue routine assessment & vital signs including grimace scale Assess changes in PEFR from day of admission	Routine assessments & vital signs including grimace scale Assess changes in PEFR
Consults/Therapy	Care management referral	Asthma center referral	
Discharge Planning	Home health referral if indicated	Initiation of home management plan	Home management plan complete
Patient Problems			

SAMPLE POLICY CLINICAL GUIDELINE

1. **PURPOSE:** To establish policy, define terminology, assign responsibility and outline procedures for the development, implementation and continuous improvement of Clinical Guidelines
2. **DEFINITIONS**
 - a. Clinical Guidelines is an umbrella term which includes Clinical Practice Guidelines, Clinical Pathways and Clinical Algorithms.

- b. Clinical Practice Guidelines are guidelines which function as recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach that includes the following:
- (1) Literature review to determine the strength of the evidence (based on study design), and
 - (2) Development and application of specific criteria such as effectiveness, efficacy and population benefit.
- Guidelines are frequently displayed in the form of an algorithm.
- c. Clinical Pathways are clinical management plans that organize, sequence and specify timing for the major patient care activities and interventions of the entire interdisciplinary team for a particular diagnosis or procedure. They define key processes and events in the day to day management of care.
- d. Clinical Algorithms are sets of rules for solving a problem in a finite number of steps. Typically, a clinical algorithm diagrams a guideline into a step by step decision tree. Algorithms function as guides to assist practitioner decision-making.
- e. Variances are patient outcomes or staff actions that fall outside the expected range.
- f. Action Team is an interdisciplinary work group responsible for developing and implementing specific Clinical Guidelines. The Team is led by a “Champion” who is a provider.
3. **POLICY:** It is the policy of this medical center to support the development of Clinical Guidelines as tools for assessment and improvement of patient care and resource utilization.
- a. It is the express policy of this medical center that adherence to Clinical Guidelines is purely voluntary. Except where a statement explicitly indicates otherwise, the suggested Clinical Guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate decision-making authority regarding the propriety of any specific procedure or course of care shall remain with the physician, who shall exercise professional judgment in light of the individual circumstances presented by the patient.
 - b. The goals of using Clinical Guidelines are to:
 - (1) Improve patient care.
 - (2) Decrease variance from identified best practices.
 - (3) Control or reduce cost while maintaining quality of care.
 - (4) Improve interdisciplinary communication and collaboration.
 - (5) Strive for consistency and predictability of care.
4. **PROCEDURES:**
- a. A VISN 18 Advisory Group has been established, consisting of the Chief of Staff, the Chairperson, physicians, the Utilization Manager or designee and other health care professionals. This group functions as the medical center advisory body in the area of Clinical Guidelines.
 - b. Clinical Guidelines can be used to improve many different types of clinical processes in the medical center and may be proposed by any individual or group in the medical center.
 - c. Action Teams develop specific Clinical Guidelines and include provisions for variance tracking.
 - d. A copy of the Action Team’s guidelines will be forwarded to the appropriate medical center Function Lead Team (FLT) and to the Quality Management (QM) Department. The QM Department will maintain an inventory of Clinical Guidelines. This inventory will help to avoid duplication of effort and to maximize interdisciplinary collaboration and communication.
 - e. The Action Team will collect appropriate performance data, analyze their findings at regular intervals and forward these results to the appropriate FLT or Service Line ACOS/Administrator. The QM representative to the FLT will forward these findings to the QM Department and local members of the VISN 18 Advisory Group.
 - f. The VISN 18 Advisory Group will participate in this process by consultation when requested by an individual or the group involved in this process.
5. **RESPONSIBILITIES:**
- a. The Chief of Staff is responsible for overall clinical guideline implementation in the medical center.
 - b. The Chairperson of the Local VISN 18 Advisory Group is responsible for coordinating the functions of the team and for reporting its ongoing activities to the Executive Leadership Council and the Clinical Executive Board.
 - c. Individual physicians are responsible to participate as appropriate.
6. **REFERENCE:** Office of Policy, Planning and Performance, Clinical Guidelines Directive, Department of Veterans Affairs, Veterans Health Administration, Washington, DC 20420, May 1996
7. **RESCISSION:** Policy Memorandum No. 11-59

Disease Management

Disease management is a comprehensive, integrated approach to care and reimbursement based on a disease's natural course, focusing on clinical and non-clinical interventions when and where they are most likely to have the greatest impact. Ideally, disease management prevents exacerbation of a disease and use of expensive resources, making prevention and proactive case management two important areas of emphasis. Disease management uses a set of prospectively determined interventions with the intent of altering the course of the disease, improving clinical and financial outcomes, as well as quality of life, while reducing health care costs. The goal is prevention of exacerbation of illness and reduction of the effects of comorbidities in order to avoid or delay the onset of acute episodes of illness. Disease management brings together outcomes research and clinical management of diseases to provide efficient care to patient populations in a continuous performance/quality improvement environment. Disease management is a continuous process focused on efficiency and is applied to selected patient populations. The ideal definition of disease management is a clinical management process of care that spans the continuum of care from primary prevention to ongoing long term maintenance for individuals with chronic health conditions or diagnoses. It is the process of caring for patients using standardized treatment strategies that ensure appropriate utilization and high quality care across the continuum.

For a successful disease management model, understanding the course of the disease and practice guidelines is critical. Disease specific clinical excellence is required in every aspect of management of the disease. Strategic data is examined to delineate issues such as what cost and quality drivers, causes, and patterns of symptom manifestation may be in any given disease. Judicious use is made of primary care physicians and specialists for disease specific care. Prevention of exacerbation of diseases is sought, with preventive measures used to avoid disease specific conditions. Evidence based practice guidelines are used, along with complementary and alternative medicine as it relates to disease specific conditions. Evidence based practice guidelines are defined by the Institute of Medicine as systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.

Members likely to benefit most from intervention are targeted. Prevention of an acute episode is an essential function of disease management. Educational efforts are an important component of preventive care. Demand management, which is the use of self management and decision support systems to enable, educate, and encourage people to improve their health and make appropriate use of medical care, is used as an education method and as a system to use medical resources wisely. Patients are encouraged to comply with prevention and treatment efforts through education and support groups. The patient educational component is critical to the success of the program. Topics may include:

- Etiology and progression of the disease, with instructions in how to monitor the disease to avoid exacerbation.
- Precipitating reasons and signs and symptoms of impending problems.
- Medication time tables, dosages, side effects, what to do about various side effects.
- Dietary considerations and other lifestyle modifications.
- A discussion about compliance with physician and clinic appointments.

Reimbursement may be limited for counseling, support groups, education, and many forms of preventive therapy. An important part of disease management is providing care across the continuum. The continuum of care must be geographically convenient to provide access to care and preventive services. In addition, measuring outcomes is important, because outcomes point the direction toward change; they show what works and what needs improvement. Sophisticated software systems that integrate care based in inpatient and outpatient settings are essential to elicit the information needed for a well-developed disease management program.

To develop a successful disease management program:

1. Define the target population.

- a. Consider the organization's case mix and location.
 - b. Evaluate criteria for the selection of conditions; decide which criteria will provide the most accurate data.
 - c. Evaluate the organization's current processes and programs that are in place.
 - d. Common diseases and conditions targeted for disease management programs include: asthma, cancer, cardiovascular diseases, COPD, depression, mental health disorders, diabetes, high risk pregnancy/neonates, HIV or AIDS, hypertension, pain management, pneumonia, infectious diseases, renal failure and hemodialysis, and transplants.
2. Organize a multidisciplinary, cross functional team.
 - a. Determine the goals, objectives, and expected outcomes for the team.
 - b. Determine who will be on the team.
 - c. Assign team tasks, including examination and evaluation of data; ongoing training required for team members and for those who will manage and implement the disease management program; potential development of clinical pathways, admission, or discharge orders.
 - d. Assess barriers to successful disease management programs, including system barriers, patient or provider barriers, economic barriers, and regulatory barriers.
 3. Define core components, treatment protocols, and monitoring and evaluation methods.
 - a. Determine how to monitor and evaluate the outcomes.
 - b. Design a continuous approach to performance/quality improvement.
 - c. Base the disease management program on best practices and current evidence based guidelines.
 - d. Consider a well respected physician champion to direct the disease management effort; this person would facilitate the medical advisory team.
 - e. Determine goals and objectives, including organizational, clinical and financial.
 4. Pilot the program.
 - a. Initially, conduct the program on a small scale.
 - b. Incorporate training as required.
 5. Measure the outcomes of the pilot disease management program. Review data for:
 - a. Clinical outcomes
 - b. Satisfaction outcomes (patient and provider)
 - c. Financial outcomes
 6. Implement the disease management program and plan continuous improvement.

DISEASE MANAGEMENT TEMPLATE

This describes a template for disease management that should be applicable, with modification, to most diseases. Disease management is a systematic population-based approach to health care that identifies persons at risk, intervenes with specific programs of care, and measures clinical and other outcomes. Disease management is closely related to clinical practice guidelines; for most diseases the intervention with specific programs *is* the practice guideline. Disease management differs from most clinical practice guidelines in that it is not limited to those with a disease but is applied to a broader population, including those *at risk* for the disease. Further, disease management requires specific monitoring of outcomes, which can then be analyzed and serve in turn to modify the interventions. Thus, disease management attempts to bring screening efforts, clinical practice guidelines, clinical pathways, and quality improvement under one roof.

The disease management approach, with the common exception of screening, is a familiar one in many specialty endeavors. Take for example a well-run renal transplant team. The team will probably not screen for candidates but rather will accept referrals. Once the patient is enrolled, he or she will be monitored in clinic according to a set of protocols. The team will have an agreed-upon set of interventions

and guidelines for pre-transplant evaluation, acute rejection, chronic rejection, acute infection, and other situations. Depending on the reason for the patient's admission, there will be a well-defined approach, akin to a clinical pathway, to the transplant procedure itself as well as other interventions. Through all this, the team is keenly interested in monitoring graft survival, average function at selected intervals, hospital-acquired infection, etc.

Add population-based screening and this approach becomes applicable to a broad range of diseases, including those common ones seen by primary care providers. When the number of patients is large, disease management becomes heavily dependent on modern information systems. It also needs a defined team to apply the elements described to a specific institution.

The elements of disease management can best be described by considering all the aspects of a disease, from screening through monitoring of performance measures. For a prototypical disease, these are:

- * screening/case finding for undiagnosed patients
- * prevention/complication finding for patients with the disease
- * education
- * inpatient management
- * outpatient management
- * emergency management
- * monitoring of outcomes

For each of the above areas there are elements that apply specifically to:

- * patients
- * providers
- * institutions (system)

There is a matrix of all the elements:

	Screening	Prevention	Education	Inpatient	Outpatient	Emergency	Outcomes
Patient							
Provider							
System							

The disease management elements of each box of the grid will vary depending on the specific disease in question and the resources available at each institution. For instance, for coronary artery disease, inpatient management would include a clinical pathway for PTCA or stent placement only where either procedure were available. Elements can be tasks, options, or structure. Let us consider each element in turn.

SCREENING for the disease is the first element.

The patient should have:

- the option for self-referral into the system;
- a connection to a primary provider; and
- identification through screening programs, either by the primary provider or open screening programs.

The provider should :

- be familiar with screening guidelines; and
- follow up the screened patients.

The system (medical center) provides:

- facilities for screening and prevention;
- easy geographic accessibility for patients to screening and prevention programs;
- database to identify patients appropriate for screening; and
- public relations capability for patient notification about screening and prevention opportunities.

PREVENTION and complication finding for those with the disease is the next element.

The patient should have access to counseling and preventive activities, e.g., wellness programs. The provider should:

- monitor disease progression and risk-stratify individual patients;
- intervene with accepted methods to modify risk; and
- refer to available resources for counseling and prevention

The system should:

- have a database of risk-stratification results that allows easy identification of individual and groups of patients for intervention;
- have resources available for disease modification; and
- have a team or teams, usually multidisciplinary, that “own” each disease.

EDUCATION is the next element.

The patient needs instruction in the care of their disease by a variety of means. Different patients learn best through different media. The provider gives basic instruction. The patient should further have available, according to the situation and need:

- classroom instruction;
- videos;
- written material such as pamphlets and books;
- individual instruction and feedback; and
- flow sheets, logbooks, etc., as he or she progresses.

Ideas for props to facilitate learning include reference cards, wallet cards, and refrigerator magnets. Each would contain salient points about the disease, e.g., phone numbers or the algorithm for emergencies.

The provider needs ongoing instruction. The values of the organization should encourage individual learning. The formal lecture (grand rounds, noon conference, etc.) is the traditional instructional format. Day-to-day application to patient care is facilitated by disease management grids. Details of each practice guideline should be readily available, in book format, on CD-ROM, or via the Internet. Computer reminders during clinic visits are enormously helpful. Each provider should have access to a subject matter expert for reference and perhaps mentoring.

The system needs education itself, to include most of the learning tools mentioned under patient and provider. The entire team involved with a given disease will need instruction, from those who organize screening efforts, through those in direct contact with patients, to those who extract and present data. The exact format and nature of the system’s education would come from an interplay between those who “own” a given disease and those who decide resource allocation and education efforts. As with patients and providers, all those in the institution who deal with a given disease should have a variety of learning tools available – all of the above as well as Internet access, interactive CD-ROM programs where available, and mentoring.

INPATIENT MANAGEMENT elements will vary widely from disease to disease.

For the most part the patient has less influence here than with other elements of disease management. Knowing when and how to access the system at the times of a critical exacerbation of his or her disease is probably the most critical issue.

The provider has access to criteria to aid in decision making. Such criteria are evolving as the evidence base for them grows, and are included in most clinical practice guidelines.

The clinical pathway is the most useful tool, and there are many available for specific elements of inpatient management. The provider needs to understand the nature of clinical pathways, their applicability, their limitations, and the requirements of each specific pathway in use.

The system provides for facile use of clinical pathways and inpatient elements of clinical practice guidelines. The tools to accomplish this best are:

- a process to regularly update the guidelines;
- case management;
- computer interaction by the whole care team, including:
 - electronic progress notes,
 - electronic reminders, and
 - data entry and retrieval;
- disease management grids;
- reference works readily available (copies of the full guidelines and pathways and relevant background material); and
- “owners” of the guidelines and pathways.

The data generated by use of guidelines and pathways are key elements in disease management. Data input, reporting, and analysis are necessary for improvement in the care of patients with a disease. Yet these functions come at a cost, so it is essential that these be done most efficiently. Important information comes from:

- activity reports;
- outcome measures; and
- variance analysis.

OUTPATIENT MANAGEMENT is the next element.

The patient should have knowledge about:

- how to access the system;
- when to use such access;
- names and numbers of people to contact for troubleshooting, appointments, medication refills, etc.;
- details of the activities (treatments, monitoring, etc.) in the home to manage his or her disease optimally; and
- resources available to help with the above, e.g., Mediset, home health care, etc., depending on need and availability.

The provider should have available detailed guidelines for ambulatory care interventions, monitoring, and procedures. Disease management grids, summary sheets, and flow diagrams are all helpful for direct patient care. The most fruitful aids to the provider are computer prompts that suggest interventions at key points in the disease course and that appear while the provider is interacting with the patient. These prompts should be coupled with names and phone numbers of the available resources. Of course, the electronic record allows easier data recording as well.

The system should set up and maintain all the above. This requires:

- a significant amount of infrastructure for information management;
- interdisciplinary teams to set up a management program for each disease;
- specific content for the disease management grid;
- data retrieval and analysis;
- a plan to phase in disease management concepts; and
- a plan to update guidelines and clinical pathways.

Current practice has many of these interdisciplinary teams already working together doing some, but not all, of these duties.

EMERGENCY MANAGEMENT is the next element.

Most of the tools for in- and outpatient management apply here as well. The patient, as in other areas, needs ease of access for emergency care as well as instructions for dealing with common emergencies related to a specific disease.

The provider should have emergency protocols and disposition criteria readily available. Further, there should be easy follow-up care for those sent home.

The system provides easy follow-up to both the primary provider and specialist care, depending on need. Patient instructions for emergency care are helpful.

OUTCOME monitoring is the last element.

This aspect of disease management is likely the most fruitful but also the most demanding of the information system. A proper information system provides for easy data entry in all the foregoing areas, from population screening through emergency management. Then the data can be queried for information that can tell of successes, trends, and difficulties. Since the details depend so highly on the disease in question as well as the specific information management system, each institution will have to develop its own means of data entry, retrieval, display and analysis. Following are lists of examples that might be applied to some diseases in the realms of patient, provider, and system. The number of other possibilities is enormous.

The patient could be queried concerning:

- satisfaction with care (by questionnaire);
- quality of life (by questionnaire);
- knowledge and skills required for self-care;
- compliance with the care plan; and
- functional status.

The provider could be queried concerning:

- knowledge and skills concerning different aspects of management;
- performance measures concerning processes and outcomes; and
- efficient use of tests, procedures, etc.

The system could be queried concerning:

- disease-specific morbidity and mortality;
- variances from established clinical pathways; and
- adverse events, such as drug reactions, unwanted outcomes, etc.

The data involved in outcome monitoring must be of sufficient reliability and of sufficient quantity to allow for meaningful analysis. The items evaluated must be of sufficient importance to merit the effort involved. One particularly difficult factor to account for is that of illness severity, which, by itself, will effect any outcome.

Outcomes Management

Outcomes are the qualitative measures or results of a process and performance. Outcome measures can assist in the definition assist in the demonstration of value by validating what is effective, what is not effective, the costs of an intervention, and whether the costs of the intervention are substantiated by the return on the investment. Outcomes cannot be managed; the structure and process that produced the outcome must be managed, and the outcome measured. A system is perfectly designed to produce the outcome that it produces. If you want different outcomes, you have to change your process. Measuring outcomes allows organizations to base improvement on measurement. Without effective outcome measurements, it's impossible to track improvements or declines in performance objectively. Measurement of outcomes provides a method for demonstrating value to the customers of a process. The ability to verify positive outcomes provides a powerful rationale for a service. Outcome measurements allow organizations to determine which processes and interventions are effective and which are not. Outcome data provide information to determine whether the results of a process or intervention yield the desired return on investment.

Clinical Outcomes

Morbidity
Mortality
Improvement or deterioration in symptoms
Absence of complications

Functional Outcomes

Maintain lifestyle
Complete required health related activities
Return to gainful activities
Perform vocational tasks (return to work)

Financial Outcomes

Cost savings
Recidivism costs
Job related injuries/disease cost
Satisfaction with care

Effective Outcomes Measurements Are

1. Valid—Effect seen is actually related to the intervention and is not a random occurrence.
2. Reliable—Measuring what is actually intended to be measured.
3. Objective and Quantifiable—Difficult to manipulate.
4. Dynamic—Measure can change to reflect changes in practice.
5. Flexible—Can demonstrate outcomes for more than one process, or demonstrate multiple outcomes.
6. Cogent—Makes sense to the user.

Incorporating Outcome Measurement into Practice

Build outcome measures into any new or revised intervention, process or program. Begin by considering the goals of the intervention, process, or program; then listing the problems to be solved and describing potential improvements, with methods to determine when goals have been reached. Describe the things that will occur when you have achieved the desired outcome, being as specific and descriptive as possible. Determine how you can measure the achievement or outcome.

Discharge Planning

Safe transfer to alternative levels of care is the major focus of discharge planning. Patients are being moved to lower levels of care sooner than ever, with more physiological needs. When beginning discharge planning, all levels of care options should be explored. Discharging home with family support is preferable in most cases. If family is unavailable, friends, neighbors, religious affiliation volunteers or community referrals can sometimes provide the needed link between the client's independence and his/her having to go to a supervisory setting. If more skilled care is required than can be provided by family or volunteers, the client may be safe to go home with the addition of home nursing services. Home care services may include RN care, teaching, and assessments; physical therapy, occupational therapy, speech therapy, psychiatric nursing or social services. If the patient is not homebound or can be transported easily by family or volunteers, outpatient services such as outpatient rehabilitation, providing physical, speech, and occupational therapies may be an option. Freestanding clinics also provide a variety of services ranging from wound care to the administration of intravenous antibiotics or chemotherapy. Although discharging clients home is often the best plan of care for the patient and is also the least

resource intensive plan, it is not always safe or possible. Early discharge planning, even in the preadmission phase is extremely important in providing patients with the appropriate level of care.

Long term care is targeted for clients with functional disabilities that may present as a physical or mental problem. The goal of long term care is to promote or maintain as much independence and quality of life as possible. If the client is terminally ill, the goal is to maintain comfort and dignity. A broad spectrum of services is provided, depending on the unique needs of the individual and family. Candidates for long term care and those requiring complex care and extensive convalescence such as a major trauma victim, or those with chronic and multiple medical, mental health, and social problems, who are unable to care for themselves. Some clients with severe mental retardation, cerebral palsy or spastic quadriplegia fall into the chronic category and may live in group homes.

Custodial care may also be referred to as personal care, supervisory care, or assisted living. Group homes and foster homes may also be included at this level of care. Custodial care is care that is primarily for the purpose of helping clients with their personal care needs such as activities of daily living. Custodial care requires the least skilled personnel of all the levels of extended care. These clients generally can ambulate independently with or without assistive devices, can transfer with standby assistance, and accomplish their own ADLs.

Intermediate care is provided to clients who need moderate assistance with ADLs and often restorative nursing supervision for some activities. These people are not as independent as those classified for custodial care. These clients generally need no more than one staff person for transferring from a bed to a chair or toilet; need assistance with ambulation but could self-propel a wheelchair; require a moderate amount of assistance in bathing, grooming, eating, and dressing; and may need restraints.

Skilled nursing or subacute care is provided for clients who may require a maximum of assistance with ADLs, may be totally incontinent of bowel and bladder, and may be disoriented, confused, combative, or even obtunded. In addition, they need care from a skilled licensed professional provided on a daily basis, and the assessment that this care must take place at the extended care facility level for reasons of patient safety and economy.

Monitoring Organizational Performance

Performance monitoring and improvement are data driven. The stability of important processes can provide the organization with information about its performance. Every organization must choose which processes and outcomes, including types of data, that are important to monitor based on its mission and the scope of care and services it provides. Data collection is prioritized by leaders based on the organization's mission, care and services provided, and populations served.

Processes to Monitor

- Medication use
- Operative and other procedures
- Use of blood and blood components
- Restraint use
- Seclusion use when it is part of care or services provided
- Care or services provided to high risk populations
- Staffing effectiveness
- Performance measures related to accreditation and other requirements
- Risk management
- Utilization management
- Quality control
- Staff willingness to report medical/health care errors

- Staff opinions and needs (perceptions of risk to patients, suggestions for improving patient safety)
- Behavior management procedures
- Outcomes of processes or services
- Autopsy results
- Performance measures from acceptable databases
- Customer demographics and diagnoses
- Financial data
- Infection control surveillance and reporting
- Research data
- Performance data
- Appropriateness & effectiveness of pain management
- Needs, expectations, and satisfaction of patients and families

Detail & Frequency of Data Collection

The detail and frequency of data collection are determined as appropriate for monitoring ongoing performance. Data are collected at the frequency and with the detail identified by the organization. Data collection should be incorporated into the day to day activities rather than a separate activity. The organization collects data to monitor the performance of processes that involve risks or may result in sentinel events. Organizations should select processes that are known to be high risk, high volume, problem prone areas related to the care and services provided. Organizations should select performance measures for processes that are known to jeopardize the safety of the individuals served or associated with sentinel events in similar health care organizations.

The organization needs to determine the detail and frequency of data collection that are appropriate for monitoring high risk, problem prone processes. Data should be collected at the frequency and with the detail identified by the organization. Performance measure data are used to evaluate outcomes or performance of problem prone processes. The organization has to provide rationale and adequacy of sampling for operative, other invasive, and non invasive procedures, and the use of blood and blood components.

For example, the Joint Commission has revised its recommendations for sample size and now recommends:

- 30 cases for a population up to 100 (if population is less than 30, sample all)
- 50 cases for a population of 101-500
- 70 cases for a population of over 500

Areas targeted for study

The organization should collect data to monitor performance of areas targeted for further study. A specific area for further study is identified by considering the information provided by the data about process stability, risks, and sentinel events, and priorities set by the leaders. Narrowing the focus of study allows the organization to better describe the processes related to the area of study, allows data collection to occur as processes are carried out, and allows the organization to identify potential changes that can lead to more significant improvement. The area targeted for further study can be a specific population, a specific diagnosis, a specific service provided, or an organization management issue, and is time limited. Performance measures should be chosen that address the topic area. The detail and frequency of data collection should be determined as appropriate for monitoring targeted areas of study. Data are collected at the frequency and with the detail identified by the organization. The data collected about specific performance measures help focus change or improvement activities for that specific area of study.

Selecting Populations

To select a population for targeted study, consider the data that has already been collected, such as an organization's top ten diagnoses treated based on volume, costs, charges, amount of time spent, and risk to patient. Criteria which can be used to focus include:

- Diagnoses with high volume and high cost
- A high potential for improvement per case
- Market competition
- A high probability of achieving change

Performance Measures

When an area of further study relates to a specific population or care issue, the team identifies very specific performance measures for which data will be collected. The organization should decide the types of performance measures to be chosen for a specific population or a care issue. The measures should relate to perception of care, outcomes, and costs. Measures could be developed in four categories:

Clinical measures: signs, symptoms, complications, diagnostic and laboratory test results

Functional measures: physical function, performance of activities of daily living, mental health, social/role function, health risk status, pain, stamina, and perceived well-being

Perception of care measures: satisfaction of individuals with various processes related to care and services provided, perceived health benefit from care and services provided

Costs: direct costs, indirect costs such as lost days from work, and caregiver costs

Operation Issues

Regarding organization operation issues, the organization should identify very specific performance measures for which data should be collected. Performance measures for a specific function or process should relate to employee satisfaction, outcomes, and costs. Measures include:

- Process or outcome measures related to organization processes
- Employee opinions
- Costs, such as salaries and benefits, supply costs, insurance premiums, capital expenditures, and purchased services

Changing Processes

Once data collection and analysis has been completed, ways to change the processes to get better results are identified. When planning for improvement, the organization identifies those areas needing improvement and identifies desired changes. Performance measures are then identified to determine whether the change results in an improvement and value is increased. Data on the performance measures are collected. The data are analyzed to determine the effectiveness of the change. Performance measures are used on a continuing basis to ensure continued improvement once the change is fully implemented. Data are collected for a period of time that allows the organization to ensure that sustained improvement continues.

Aggregating & Analyzing Data

Aggregating and analyzing data means transforming data into information. The organization can use this information to draw conclusions about its performance of a process or the nature of an outcome. Data analysis can answer the following questions:

- What is the current level of performance?
- How stable are the current processes?
- Are there areas that could be improved?
- Was a strategy to stabilize or improve performance effective?

- Did the organization meet design specifications for processes?

Comparisons

- With self
- With other comparable organizations
- With standards
- With best practices

Frequency of Data Aggregation

How often the organization aggregates and analyzes data depends on the process being measured and the organization's priorities. Conclusions about current performance based on data analysis may indicate a need for targeted study or more intense analysis of processes or outcomes. Such conclusions are based on comparison with

- Pre-established criteria
- Sentinel events
- Control limits]
- Review of all occurrences
- Other interpretation methods

Data analysis should be interdisciplinary when appropriate for the process or outcome under review. When the analysis focuses on an individual's clinical performance, the organization takes appropriate action. Data should be systematically aggregated and analyzed on an ongoing basis. The frequency of data aggregation should be appropriate to the activity or area being studied. Aggregation of data at points in time enables the organization to judge a particular process's stability or a particular outcome's predictability in relation to performance expectations.

Aggregated data are analyzed to make judgments about:

- Whether design specifications for processes were met
- Level of performance and stability of existing processes
- Opportunities for improvement
- Actions to improve the performance of processes
- Whether changes in processes resulted in improvement

Evaluating Performance

Performance can be evaluated from three perspectives:

- Compared internally over time
- Compared to performance of similar processes in other organizations
- Compared to external sources of information

These comparisons can be used to determine if there is excessive variability or unacceptable levels of performance of processes and outcomes. External sources should be as up to date as possible and include:

- Recent scientific, clinical, and management literature
- Well formulated practice guidelines or parameters
- Performance measures
- Reference databases
- Standards that are periodically reviewed and revised

Undesirable Patterns or Trends

Undesirable patterns or trends in performance and sentinel events are intensely analyzed. When the organization detects or suspects significant undesirable performance or variation, it should initiate intense analysis to determine where best to focus changes for improvement. The organization should initiate intense analysis when comparisons show that:

- Levels of performance, patterns, or trends vary significantly and undesirably from those expected
- Performance varies significantly and undesirably from that of other organizations
- Performance varies significantly and undesirably from recognized standards
- A sentinel event has occurred

When monitoring performance of specific clinical processes, certain events always elicit intense analysis. Based on the scope of care or services provided, intense analysis is performed for the following:

- Confirmed transfusion reactions
- Significant adverse drug reactions
- Significant medication errors
- Hazardous conditions
- Staffing effectiveness issues

Intense analysis should also occur for those topics chosen by the leaders as performance improvement priorities and priorities for proactive reduction in patient risk or when undesirable variation occurs that changes the priorities. Intense analysis involves studying a process to learn in greater detail about how it is performed or how it operates, how it can malfunction, and how errors occur.

Root Cause

A root cause analysis should be performed when a sentinel event occurs. An intense analysis should also be performed for:

- Major discrepancies or patterns of discrepancies between postoperative and preoperative (including pathologic) diagnoses, including those identified during the pathologic review of specimens removed during surgical or invasive procedures, and
- Significant adverse events associated with anesthesia use.

A root cause analysis may have:

- A cause and effect diagram to visually display the problem and identify as many proximate and underlying causes as possible
- Barrier analysis, which helps identify where failures in protective barriers occurred
- Change analysis, which helps focus on changes that have occurred between expected performance and the actual performance of a process

System Changes

The organization should use the information from data analysis to identify system changes that will improve performance or improve patient safety. Changes are identified based on the analysis of data from targeted study or from analysis of data from ongoing monitoring. A change should be selected, and the organization should plan to implement the change on a pilot test basis or across the organization. Performance measures should be selected that help determine the effectiveness of the change and whether it resulted in improvement.

When a change is selected for pilot testing, the following are identified:

- Who will be involved
- What their responsibilities will be

- What performance measures will be used to evaluate the pilot's success
- What data will be collected in relation to identified performance measures
- Who will collect and analyze the data
- What education of all affected staff about the change will be implemented

The planned change is implemented. Change management guidelines are used to manage successful implementation, and data are collected. The results of the change are analyzed and are compared to results before the change. The organization determines if the change led to the predicted improvement or met the objective. Unsuccessful changes are analyzed to determine whether the change itself did not work or whether it was not implemented properly. To sustain improvements, change is managed and implemented incrementally.

- The core team is expanded to include additional staff
- The team is educated about the redesigned processes and input is obtained
- The improvement is tested a second time
- The team is expanded again to include all providers affected by the improvement
- Team input is obtained and used where developing a protocol
- Performance measures are identified for use in determining whether the improvement is being sustained
- Implementation occurs
- Feedback is provided on a regular basis

When analysis and improvement activities lead to a determination that there are issues related to an individual's performance, appropriate action is taken by peer licensed independent practitioner leaders with relevant responsibility and authority, or through human resource processes for other staff.

Specific Examples

Medication use:

- Adverse Drug Events (ADEs)
- Medication use processes
- Prescribing/ordering—patients with positive cultures treated with antibiotic appropriate to sensitivity
- Preparing/dispensing—Pharmacy dispensing errors
- Administering—medication errors contributing to increased LOS and increased resource use
- Preoperative prophylaxis for hips
- Monitoring effects—adverse drug reactions
- Pharmacy intervention program
- Medication errors
- Pharmaceutical supplies and costs
- Pain Management

SAMPLE MEDICATION AND CLINICAL NUTRITION MANAGEMENT (P&T) COMMITTEE

1. **PURPOSE:** To establish policy and procedures for the Medication and Clinical Nutrition Management (MCNM) Committee and define its responsibilities and membership.
2. **POLICY:** The MCNM Committee will foster and promote appropriate drug utilization and establish policy and procedures pertaining to the appropriate use of drugs within the medical center. The MCNM Committee will support the medication formulary and medical use guidelines as defined by the VISN 18 Medication Management Work Group, and the VA National Formulary Policy.
3. **PROCEDURES:**
 - a. Meetings will be on the 2nd Wednesday of every other month at 2:30 p.m., in Room 4115. Additional meetings will be convened as necessary.
 - b. The VISN 18 Formulary Modification Request Form will be used for requests or recommendations for drugs to

be considered by the committee for addition to the formulary. When considering an agent for formulary placement, the following will be used as selection criteria in the consideration process.

- (1) The need for the agent to treat our patient population.
 - (2) The effectiveness of the agent in relation to other agents.
 - (3) The safety of the agent in relation to other agents.
 - (4) Acquisition costs and cost impact on the organization.
- c. The secretary will prepare and circulate an agenda at least 2 days prior to each meeting.
- d. The secretary will prepare minutes of each meeting for approval by the Chairperson.
- e. Minutes will be forwarded to:
- (1) All MCNM Committee members
 - (2) Clinical Executive Board members
 - (3) All Clinical Department Chairs
 - (4) Chair, Quality Management Department
- f. Access to formulary information will be provided via the following mechanisms
- (1) VISTA options available to all clinicians;
 - (2) Formulary changes will be communicated via MCNM Committee minutes (which are distributed to each Department) and through periodic pharmacy newsletters and/or intranet postings that are distributed/available to all prescribers; and
 - (3) Verbal requests to pharmacists.
- g. Approval for procurement and use of drugs or other significant actions taken by the Chairperson or other authorized members of the committee between committee meetings will be reported at the next meeting and included in the minutes.
- h. This committee has been granted confidential status and will comply with the VA Confidentiality Regulations.

4. **RESPONSIBILITIES:**

- a. To serve in an advisory capacity to management on policies pertaining to the use of drugs.
- b. To evaluate clinical data on drugs proposed for use in the medical center, outpatient clinic, or nursing home care unit, and make recommendations for stocking of those considered most useful and effective.
- c. To establish and provide for continuous revision of a Medical Center Drug Formulary consistent with the VISN 18 Medical Formulary and formulary approval procedures.
- d. To review and evaluate data on drugs brought to the attention of the committee and recommend, approve, or disapprove the use of such drugs in the medical center, outpatient clinic, or nursing home care unit.
- e. To establish mechanisms for the provision of "nonformulary" drugs.
- f. To coordinate and evaluate drug utilization reviews and recommend corrective action when necessary.
- g. To receive all reports of adverse drug reactions and assist the Chief of Staff in the collection of pertinent data, evaluation of each reaction and preparation of reports to the Food and Drug Administration.
- h. To prevent unnecessary duplication of drug products. (Emphasis placed on therapeutic categories and other groups that provide a common therapeutic index and major budget impact.)
- i. To periodically review medication errors for trends and severity. To advise, recommend and, when necessary, establish procedures pertaining to the prescribing, dispensing and administering of drugs to ensure rational use and patient safety.
- j. To review and evaluate requests for use of investigational drugs.

5. **MEMBERSHIP:**

Chairperson:	Associate Chair, Medical Department (CS/111)
Vice Chairperson:	Clinical Pharmacy Section Representative (CS/119A)
Secretary:	Chair, Pharmacy Department (CS/119)
	Chief of Staff (11)
	Dental Department Representative (CS/16)
	Neurology Department Representative (CS/127)
	Coordinator, Mental Health Clinic (MH&BSS/116A)
	Nurse Executive, Nursing Department (CS/118)
	Anesthesiology Section Representative (CS/112A)
	Clinical Pharmacy Section Representative (ACS/11C-8)

Surgical Department Representative (CS/112)
Ambulatory Care Services Representative (ACS/11C-2)
AA/Director (Director's Designee) (002)

6. **REFERENCES:** M-2, Part I, Chapter 3; and M-2, Part VII.
7. **RESCISSION:** Policy Memorandum No. CS/119-4
8. **ATTACHMENTS:** None
9. **EXPIRATION DATE:**

SAMPLE DRUG UTILIZATION EVALUATION

1. **PURPOSE:** To establish policy and procedures for Drug Utilization Evaluation (DUE).
2. **POLICY:** Drug Utilization Evaluation (DUE), a medical staff function, is the process of reviewing the prophylactic, empiric and therapeutic use of drugs through the analysis of individual or aggregate patterns of drug usage. Ongoing DUE will be conducted under the auspices of the Medication and Clinical Nutrition Management (MCNM) Committee. The MCNM Committee shall identify potential opportunities to enhance medication therapy management and shall be responsible for recommending any necessary corrective measures. The MCNM Committee shall support the DUE monitoring requests of the VISN 18 Medication Management Committee.
3. **PROCEDURES:**
 - a. **Daily Unit Dose Profile Review of All Inpatients by Pharmacists:** Problems identified will have appropriate corrective action taken either by direct communication with the prescriber or charge nurse, or by referral to the appropriate clinical pharmacist provider.
 - b. **Daily Outpatient Profile Review by Pharmacists:** Problems identified will have appropriate corrective action taken either by direct communication with the prescriber or patient, or by referral to the appropriate clinical pharmacist provider.
 - c. **Daily Ward Rounds and Concurrent Inpatient Profile Review by a Clinical Pharmacist Provider:** A formal statement will be submitted to the MCNM Committee only when specific action is required for problem resolution or corrective action.
 - d. **Daily NHCU New Admit Review and Monthly NHCU Patient Profile Review by Clinical Pharmacy Providers:** NHCU clinical pharmacist providers will present a formal statement to the MCNM Committee when specific action is required for problem resolution or corrective action.
 - e. **Drug Usage Evaluations:** Criteria-based, systematic reviews for monitoring and evaluating the prophylactic, therapeutic and empiric use of drugs to help assure that they are provided appropriately, safely, and effectively and are conducted in accordance with the established policy. The results will be reported to the MCNM Committee where they will be documented, and recommendations will be made regarding any necessary corrective actions. These reviews will focus on high-volume, high-risk and problem-prone drugs.
 - f. **Clinical Pharmacy Antibiotic Rounds:** Daily nonformulary antibiotic reviews will be conducted by the Clinical Pharmacy Staff. Formal statements will be submitted to the MCNM Committee only when specific action is required for problem resolution or corrective action
 - g. **Narcotic Usage:** Patients who exhibit drug-seeking behavior shall be identified by physician, nurse and clinical pharmacist providers. Precautionary warning narratives will be placed in the patient's computer medication file by a designated clinical pharmacy specialist(s) when appropriate. Patients who require more intense review and monitoring shall be referred to the multidisciplinary Drug Seeking Behavior Committee. Potential opportunities for medication therapy enhancement will be submitted to the MCNM Committee.
 - h. **Nonformulary Drug Usage Review:** In compliance with Policy Memorandum No. CS/119-10 (Medication Formulary Process), all requests for nonformulary medication shall be clinically evaluated and considered for approval by a clinical pharmacy specialist on a per-patient basis. A formal statement will be submitted to the MCNM Committee when specific action is required for problem resolution or corrective action.
4. **REFERENCES:**
 - a. M-2, Part VII, Chapter 9
 - b. Accreditation Manual for Hospitals, Joint Commission on Healthcare Organizations, current edition.
5. **RESCISSION:** Policy Memorandum No. CS/119-9
6. **ATTACHMENTS:** None
7. **EXPIRATION DATE:**

ADVERSE DRUG EVENTS (ADEs)

1. **PURPOSE:** To establish policy and procedures for the adverse drug event (ADE) program that will:
 - a. Monitor local trends in ADEs and identify opportunities to prevent future ADEs, with the ultimate goal of improving patient care.
 - b. Provide relevant and timely information to support the Food and Drug Administration's (FDA's) MedWatch system.
2. **SCOPE:** This policy applies to all personnel involved in the administration of drugs to patients whether used as diagnostic agents, therapeutic agents or investigational drugs. This policy also includes drugs used for unapproved indications (i.e. conditions not named in the official labeling.)
3. **POLICY:** Adverse drug events shall be reported, including those that result from administration of over-the-counter, prescription, herbal medicine or investigational/research drugs.
 - a. An adverse drug reaction/event (ADR/ADE) is any response by a patient to a drug that is noxious or unintended (excluding well-documented and common mild side-effects), and that occurs at doses normally used for prophylaxis, diagnosis, or therapeutic treatment. This definition includes significant or serious side effects, drug interactions, injury, toxicity, hypersensitivity and/or allergy.
 - b. A definite cause and effect relationship does not need to be established before an adverse drug event is reported. Possible or probable adverse drug effects should be recorded in the patient's records.
 - c. All serious, life-threatening or fatal adverse drug reactions will be reported by the local facilities through the FDA MedWatch program within 60 days of occurrence. Adverse reactions that are not life threatening, serious, or fatal for drugs marketed in the previous three years will also be reported to the FDA.
4. **EXCEPTIONS:**
 - a. Adverse events (reactions) caused by blood and blood plasma that are reported and reviewed by the Transfusion Committee.
 - b. Adverse events (reactions) to vaccines
5. **PROCEDURES AND RESPONSIBILITIES:**
 - a. Identification and Reporting of a Suspected ADE.
 - (1) All health care personnel observing an adverse drug event (ADE), or receiving a report of an ADE, shall promptly report the event in accordance with local facility policy. If the person reporting an adverse reaction is not the primary prescriber, that individual will be immediately notified of the adverse event
 - (2) The allergy-tracking program in VISTA will be used for the entry of all adverse reactions and allergies to facilitate national trending.
 - (3) Reactions will be entered into the VISTA allergy-tracking program as OBSERVED, if the reaction occurred during current therapy. HISTORICAL reactions will be entered if the reaction did not occur during current therapy.
 - (4) Reactions will be classified as
 - (a) **MILD** - Requires minimal therapeutic interventions and/or does not prolong length of stay.
 - (b) **MODERATE** - Requires significant therapeutic intervention and/or prolongs hospitalization by at least one day.
 - (c) **SEVERE** - Life threatening, contributed to death, permanently disabling, or recovery takes more than 15 days.
 - b. Monitoring and Evaluation of ADEs by the Medical and Clinical Nutrition Management (MCNM) Committee.
 - (1) The MCNM Committee is responsible for review of ADEs, determination of which ADEs require follow-up, determination of ADEs to be reported off station, review of ADE trends and the recommendation of appropriate action regarding drug use based on ADE trends
 - (2) Reports on drugs and biologicals that fit the criteria listed in paragraph 3b will be reported to the Food and Drug Administration (FDA). Reports will be submitted on FDA Form 3500, MedWatch Form. All reports sent to the FDA will be forwarded to the Executive Committee on Therapeutic Agents in the VA Central Office by the FDA.
 - (3) If alarming problems suspected to be related to drugs are identified (e.g., clusters of cases of serious ADEs), these will be communicated to VA Pharmacy Benefits Management.
 - (4) Facility-specific ADEs will be reported to the VISN consistent with VISN 18 Policy Memorandum No
6. **REFERENCES:**
 - a. VISN 18 Policy Memorandum No. 25
 - b. M-2, Part I, Chapter 3, Joint Commission Standards Current Edition

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 1/31/96
See OMB Statement on reverse

Mfr report #
UF/OIst report #
FDA Use Only

A. Patient information			
1. Patient Identifier	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
In confidence			
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> life-threatening	<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

PLEASE TYPE OR USE BLACK INK

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 _____			
#2 _____			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1 _____		#1 _____	
#2 _____		#2 _____	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 _____		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 _____		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 _____		#1 _____	
#2 _____		#2 _____	
8. Event reappeared after reintroduction		9. NDC # - for product problems only (if known)	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply		#1 _____	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply		#2 _____	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
D. Suspect medical device			
1. Brand name			
2. Type of device			
3. Manufacturer name & address		4. Operator of device	
_____		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____	
6. model # _____		5. Expiration date (mo/day/yr)	
catalog # _____		7. If implanted, give date (mo/day/yr)	
serial # _____		8. If explanted, give date (mo/day/yr)	
lot # _____		_____	
other # _____		9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)		_____	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
E. Initial reporter			
1. Name & address		phone #	
_____		_____	
2. Health professional?		3. Occupation	
<input type="checkbox"/> yes <input type="checkbox"/> no		_____	
4. Initial reporter also sent report to FDA		_____	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk		_____	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FDA Form 3500A (6/93)

Blood use:

- Significant transfusion reactions
- Blood drawing events
- Transfusion transmittal disease
- Blood administration audits
- Blood use audits
- Hemaphereis unit-adverse events
- Ordering
- Orders not meeting appropriate criteria
- Distributing/dispensing
- Stat turn around time
- Administering
- Blood administration review
- Monitoring effects
- Blood transfusion reaction

Operative and other procedures:

- All pre and post operative major discrepancies
- Operative and other procedures processes
- Selecting appropriate procedure
- Surgical case review-non tissue (embolectomy, femoral bypass, cardiac cath, colonoscopy, sigmoidoscopy, cataract, bronchoscopy, total knee, total hip, carpal tunnel)
- Difference pre/post diagnosis
- Preparation of the patient
- Patient without H&P entering surgical areas
- Risks, options, benefits, discussed by surgeon
- Risks, options, benefits of blood discussed by surgeon
- Performing the procedure
- Inatrogenic complications
- Incorrect surgical counts
- Post procedure care
- Returns to OR in 48 hours
- Admission following outpatient surgical procedure
- Post procedure patient education
- Additional questions on follow up calls
- Sedation outcomes/complications
- Adverse anesthesia events
- Inpatient deaths by ASA classification

SAMPLE SURGICAL SITE VERIFICATION OPERATIONAL GUIDELINES

Policy: Surgical site verification is required to minimize the risk of surgery on the wrong side or the wrong site. This will require coordination between the surgical team (attending and residents), Operating Room (OR) Same Day Surgery (SDS), nursing teams, anesthesia personnel, and the patient or surrogate. All personnel involved in the surgical process must take an active role in site verification.

Responsibility:

- a. Ultimate responsibility for verification of site and laterality rest with the attending surgeon. The attending surgeon or designated resident is responsible for documenting the correct site and laterality on the patient consent form, on the patient physically, and in the medical record.

Once the patient has been brought to the holding area, it is the responsibility of the attending surgeon or designated resident to confirm the site/laterality.

The Anesthesia practitioner is also responsible for confirming site/laterality.

The OR nurse is also responsible for confirming site/laterality.

Procedure: For the purpose of these guidelines the following definitions are to be used in conjunction with, and part of the procedures, which will be utilized by surgical personnel.

Laterality shall be defined as referring to the side of the patient's body as "right", "left", "bilateral" or "midline". Which could be right or left. As example: hernias or breasts.

Verification shall be defined as checking for consistency in laterality between the consent form, diagnostic studies, signed surgical site and the response of the patient or guardian.

1. The surgical site will be initialed with the surgeon's initials utilizing an indelible marker in the pre-procedure/holding area. The site should be initialed in a position that will be visible once the surgical site is prepped and draped and designated "right", "left", "bilateral" or "midline" when appropriate.
2. The surgeon will confirm the site/laterality through review of the patient's medical record, pertinent diagnostic studies and through discussion with the patient or surrogate. This process will be completed in SDS or pre-op holding on the day of surgery (for outpatients) or on the wards within 24 hours prior to surgery (for inpatients).
3. The Circulator will confirm the patient's identity and site/laterality through review of the patient consent form, medical record, and marked surgical site and through discussion with the patient or surrogate.
4. Prior to the surgical incision the operating room team will verbally confirm

Infection Control

- Nosocomial multi-drug resistant organisms (MRSA, VRE)
- Ventilator associated pneumonias
- UTI
- Central line bacteremias
- Primary bacteremias
- Nosocomial C. difficile
- Needle stick surveillance
- TB case surveillance
- Nosocomial rate
- MRSA
- VRE

Utilization management:

- Inappropriate admissions
- Readmission within 30 days
- Medically avoidable days
- Observation stays

Specific Department:

- Quality Control
- Clinical laboratory
- Diagnostic radiology
- Dietetics
- Nuclear medicine
- Radiation oncology
- Equipment in use
- Satisfaction (Inpatient/Provider/Outpatient)
- Clinical pathways

- Utilization management
- Annual competency report to governing board
- Completion of performance evaluations
- Timeliness of performance evaluations
- Performance improvement teams
- Department clinical services reports
- Medical staff committees
- Nursing
- Staffing turnover
- Nurse/patient ratios
- Acuity
- Pressure Sore Incidence and Prevalence
- Use of sick leave/unplanned leave
- Falls
- Use of restraints/restraint alternatives

Mortality Review

- Patients who die within 2 days of procedure involving anesthesia
- Patient mortality following cardiovascular/cardiothoracic procedures
- Pediatric inpatient deaths
- Expected (DNR)/unexpected
- Application of autopsy criteria with fall out

A goal of a mortality review system is to develop a better understanding of mortality by examining the causes and circumstances of individual deaths, and to evaluate the benefits of mortality review in providing information to the improvement of the organizational functions and processes. Inpatient mortality rates have been the focus of an enormous amount of attention, since there is the public perception that many of these deaths might have been avoided. Mortality review takes into consideration other factors, including severity of illness, disease specificity, and variances in patient populations. Quality of care issues may be identified in mortality reviews.

An initial mortality review that is conducted as soon as possible after the death will provide the most useful information. A database can be developed which can then be scrutinized for trends by department, physician, nurse, shift, and day of the week, for example. Quality issues identified by reviews can also be trended by category. Initial reviews may be done by screeners, with quality issues that seem to be related to the death flagged for further review.

A sample mortality review form might contain the following elements:

- Age
- Sex
- Date and time of death
- Admitting service, physician, discharging service
- Reason for death
- Brief summary of facts

Quality review indicators:

- Nonsurgical procedure was performed

- Surgical procedure was performed
- Procedure was performed within 24 hours of death
- Procedure was performed within 48 hours of death
- Procedure was cause of death
- Procedure contributed to death
- Indications for procedure were questionable
- Death occurred within 24 hours of admission
- Patient was DNR
- DNR protocol was followed
- Death was expected
- Death was unexpected
- Autopsy was performed
- Case was referred to risk management
- Case was determined to be medically futile
- Patient has advance directive or durable power of attorney for health care

If a quality issue is related to physician care, additional review should be carried out by a physician. If a systems issue is identified, the additional review could be conducted by a nurse or physician. The physician or nurse reviews should conduct an in-depth review of the case, including discussion with the attending physician, house staff physicians, and nurses; and review of radiologic and laboratory studies. Physician review is generally a two stage process, with a designee of the department director making an initial evaluation to determine whether the case warranted further evaluation. If a potential quality of care issue was identified, the case would be referred to a senior physician and then to a department chair. The department director would make a final judgment on behavioral and system performance based on the review of the medical record and related materials, and a discussion of the case with the involved physician and nurses. As a final check, the quality improvement coordinator may also review the case to determine that all substantive issues had been addressed. The department director is responsible for taking action to correct any lapses in quality of care. Common actions include working with administration to correct systems problems, discussing lapses with physicians and nurses, and placing letters detailing quality of care issues in credentials files.

Types of quality issues identified in mortality reviews include:

- Failures to initiate treatments and therapies
- Delays in initiating treatments and therapies
- Inappropriate initiation of treatments and therapies
- Problems with ordering and administering medications
- Problems with monitoring laboratory values
- Systems problems

Mortality reviews may be part of an existing risk management or utilization management programs in order to avoid duplication.

Mortality Review Worksheet

ADMISSION DATA

Patient Name: _____ Date of Death _____ Age _____ Sex _____

Security Number _____ **Ethnicity** _____

Date/Time _____ DX _____

Comorbidities/PMH _____

Cause of Death _____

Admitting Unit _____ ER Admit: Yes ★

Account # _____ Medical Record # _____

Attending Physician _____ Consultants _____

_____ Procedure Physician _____

Death Note by Physician Yes No

MORTALITY QUALIFIERS

Maternal death Yes No Neonatal Death Yes No (wt of baby _____)

Perioperative death Yes No (general anesthesia): within 24 hours within 48 hours within 3-10 post surgery

Intraoperative death: Yes No type of procedure _____

Invasive procedure death: Yes No type of procedure _____

Non surgical death Yes No Within 24 hours admit Within 48 hours admit

Death associated with ADR Yes No Death associated with Adverse Event Yes No

MORTALITY CATEGORY

ER Code in Progress Yes No

Was initial admission to an ICU? Yes No

Was the patient admitted for comfort care? Yes No

Code in House Yes No DNR Yes No Complete Yes No

ACD Yes No Copy on Chart Yes No

Withdraw Life Support Yes No

Mortality Box Category (circle) A B C D*

A ICU admission AND comfort care

B Non-ICU admission AND comfort care

C ICU admission NO comfort care

D Non-ICU admission No comfort care

*All Box D mortalities require physician review

Medical Examiner Case* Autopsy Requested: Yes No Autopsy Findings: _____

***Following types of cases should be reported to the M.E.:** deaths within 24 hours of admission/accidental, suicidal, homicidal inflicted trauma/anesthesia deaths/deaths as result of diagnostic or therapeutic procedures/death where the disease process is either work related or suspicious of being aggravated or accelerated at work/stillbirths and neonatal deaths when maternal injury has occurred/maternal deaths/death of a child <6yrs/deaths where the attending physician has no adequate or reasonable explanation for the cause of death

Death anticipated Yes _____ No _____

*Death expected **at the time of admission** as documented in the medical record and evidenced by S/S within the first 24 hours*

Death unanticipated Yes _____ No _____

*Death unexpected **at the time of admission** as documented in the medical record and evidenced by the absence of S/S within the first 24 hours*

Death unanticipated at time of admission but expected at time of death Yes _____ No _____

*Death unanticipated **at the time of admission** as documented in the medical record and evidenced by the absence of S/S within the first 24 hours but, during the hospitalization, the course of the illness caused the expectation of mortality to change from unanticipated to anticipated*

Global Triggers

CODE EVALUATION

For patients coding in general medical/surgical areas

Unit/location of code _____ Date/time of code _____

Was patient ever in an ICU prior to the Code? Yes _____ NO _____

If so, how long where they on the floor prior to the code? _____

PRE-CODE DATA

12 HOURS PRIOR TO CODE

VITAL SIGNS

TIME													
TEMP													
PULSE													
RESP													
B/P													
O2 SAT													
PAIN													

Other Critical Findings

Additional Comments _____

DISPOSITION OF CASE

Further Review Necessary **Yes** **No**

Referred to Department of Medicine Surgery OB/GYN/Pedi for further review.

Referred to Service for further review: _____

Referred to Hospital Department for further review: _____

Reviewer's Signature _____ Date _____

SAMPLE POLICY DEATHS REPORTABLE TO THE MEDICAL EXAMINER

1. **PURPOSE:** To establish policy and procedures for reporting the death of inpatients and those that are Dead on Arrival to the medical examiner's office.
2. **POLICY:** Applicable state and local laws will be followed in reporting deaths to the medical examiner.
3. **PROCEDURES:**
 - a. The following categories of death require reporting to the medical examiner:
 - (1) Death when not under the current care of a physician for a potentially fatal disease or when an attending physician is unavailable to sign the death certificate.
 - (2) Death resulting from violence.
 - (3) Death occurring suddenly when in apparent good health.
 - (4) Death occurring in a suspicious, unusual or unnatural manner.
 - (5) Death from disease or accident believed to be related to the deceased's occupation or employment.
 - (6) Death believed to present a public health hazard.
 - (7) Death occurring during anesthetic or surgical procedure.
 - b. In an instance requiring the reporting of a death, the attending physician will notify the Decedent Affairs Clerk during normal working hours, or the Administrative Officer of the Day (AOD) during other than normal working hours. The attending physician will be required to give all of the circumstances of the death. The Decedent Affairs Clerk or AOD will notify the Phoenix Police Department, telephone number 602-495-5883, who will notify the medical examiner.
 - d. The medical examiner will provide the appropriate instructions for compliance with the laws of the State of Arizona.
 - e. The Decedent Affairs Clerk will obtain a copy of the autopsy report from the medical examiner within 90 days following the death for filing in the patient's medical record.
4. **RESPONSIBILITY:** The Assistant Administrator, Medical Administration Department is responsible for the administration of this policy.
5. **REFERENCES:** Arizona Revised Statutes 11-593 and 11-594.
6. **RESCISSION:** Policy Memorandum No. FMS/136-17

Health Information Management

The federal Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) addresses the development, adoption, and implementation of health information technology policies and standards and provides enhanced privacy and security protections for patient information. It also addresses Medicare and Medicaid health information technology and provides significant financial incentives to healthcare professionals and hospitals that adopt and engage in meaningful use of electronic health record technology.

The HITECH Act seeks to provide each person in the U. S. with an electronic health record (EHR). In addition, a nationwide infrastructure will be developed so that access to a person's EHR will be readily available to every healthcare provider who treats the patient, no matter where the patient may be located at the time treatment is rendered.

The HITECH Act established the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services (HHS). The ONC is headed by

the National Coordinator, who is responsible for overseeing the development of a nationwide health information technology infrastructure that supports the use and exchange of information to achieve the following:

1. Improve healthcare quality by enhancing coordination of services between and among the various healthcare providers a patient may have, fostering more appropriate healthcare decisions at the time and place of delivery of services, and preventing medical errors and advancing the delivery of patient centered care
2. Reduce the cost of health care by addressing inefficiencies such as duplication of services within the healthcare delivery system, and by reducing the number of medical errors
3. Improve people's health by promoting prevention, early detection, and management of chronic diseases
4. Protect public health by fostering early detection and rapid response to infectious diseases, bioterrorism, and other situations that could have a wide-spread impact on the health status of many individuals
5. Facilitate clinical research
6. Reduce health disparities
7. Better secure patient health information

The HITECH Act also provides significant monetary incentives for providers who engage in meaningful use of health information technology. Meaningful use is defined as using electronic health records (EHRs) in a meaningful manner, which includes, but is not limited to electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating that information to help coordinate care, and initiating the reporting of clinical quality measures and public health information. Monetary incentives are available to clinicians and facilities which implement EHR systems that meet the specific standards. Providers that fail to adopt such systems within a specified time frame may be subject to significant governmental penalties.

CMS Meaningful Use

The Medicare and Medicaid EHR Incentive Programs provide financial incentives for the meaningful use of certified EHR technology to improve patient care. To receive an EHR incentive payment, providers have to show that they are meaningfully using their EHRs by meeting thresholds for a number of objectives. The EHR Incentive Programs are phased in three stages with increasing requirements. Eligible professionals participate in the program on the calendar year, while eligible hospitals and CAHs participate according to the federal fiscal year. Providers must attest to demonstrating meaningful use every year to receive an incentive and avoid a Medicare payment adjustment.

Eligible professionals must meet:

- 13 required core objectives
- 5 menu objectives from a list of 9
- 18 total objectives

Eligible hospitals and critical access hospitals must meet:

- 11 required core objectives
- 5 menu objectives from a list of 10
- 16 total objectives

Clinical Quality Measures

Eligible professionals, eligible hospitals, and critical access hospitals are required to report clinical quality measures (CQMs) during each year of participation in order to receive an incentive. Clinical quality measures, or CQMs, are tools that help measure and track the quality of health care

services provided by eligible professionals, eligible hospitals and critical access hospitals (CAHs) within our health care system. These measures use data associated with providers' ability to deliver high-quality care or relate to long term goals for quality health care. CQMs measure many aspects of patient care including:

- Health outcomes
- Clinical processes
- Patient safety
- Efficient use of health resources
- Care coordination
- Patient engagements
- Population and public health
- Adherence to clinical guidelines

Measuring and reporting CQMs helps to ensure that the health care system is delivering effective, safe, efficient, patient-centered, equitable, and timely care. To participate in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs and receive an incentive payment, providers are required to submit CQM data from certified EHR technology.

Information confidentiality and security

The collection, maintenance, and use of patient information in medical records or other data storage systems is based on applicable laws and regulations. Consistent with applicable laws and regulations, employees of the health care facility may have access to any information necessary to perform their assigned duties. In addition, there are generally uses of information that don't require prior approval for release to individuals or organizations that are not a part of the health care organization. These include:

- Physicians or organizations identified by the patient receiving ongoing medical updates
- Social service sharing information to assist patients with community resources and services
- Information regarding diagnostic problems/information shared with consultants
- Information shared with governmental agencies and/or released as required by law
- Information for statistical analysis may be released without identifiers
- Information may be shared with contractors so they can provide service

Confidentiality of data is stressed. All information systems should be limited to authorized personnel, with authorized uses defined for each segment or system. Security is provided through passwords and other security measures. Data are protected against loss, tampering or destruction. Safeguards are taken to protect data loss. Procedures are in place to ensure that data is recoverable in the event of hardware failures, software failures, viruses, accidents, and natural disasters. Data is saved and stored in secure locations, preferably off site, may be rotated, and backed up daily.

Health Insurance Portability & Accountability Acts (HIPAA)

HIPAA was signed into law in 1996 and was updated in 2002. The intent of HIPAA was to: curtail healthcare fraud and abuse, enforce standards for health information, guarantee the security and privacy of health information and ensure health insurance portability for employed persons. Consequences were put into place for organizations and individuals who violate the requirements of this act.

The privacy requirements went into effect April 14, 2003 and limit the release of protected health information (PHI) without the patient's knowledge and consent. Covered entities must comply with the

requirements. Among the necessary rules they must comply with, they must dedicate a privacy officer, adopt and implement privacy procedures, educate their personnel, and secure their electronic patient records. Most individuals are familiar with the need to notify patients of their privacy rights, having signed forms on interacting with healthcare providers.

There are certain rights provided to patients by the privacy rule. Some of the rights include the following: the right to request restrictions to access of the health record; the right to request an alternate method of communication with a provider; the right to receive a paper copy of the notice of privacy practices; the right to file a complaint if one believes his/her privacy rights were violated; the right to inspect and copy one's health record; the right to request an amendment to the health record; and the right to see an account of disclosures of one's health record. This places the burden on the healthcare system and not the patient.

Patients are entitled to a notice of privacy practices from their healthcare provider. Inpatients are entitled to opt out of the facility's directory, thereby protecting disclosure of information that they are even a patient in the facility. Under certain circumstances, patients must authorize disclosure of their PHI before it can be released by the provider. Patients can request and obtain access to their own healthcare records and may request that corrections and additions be made to their records. Providers must consider a patient's request to amend a healthcare record, but they are not required to make such an amendment if the request is unwarranted. Unauthorized access or use or any loss of healthcare information must be disclosed to any patient affected by the breach. Patients may request an accounting of anyone who accessed their healthcare information and the provider is required to provide that information in a timely manner. Finally, patients have a right to complain if they perceive that the privacy or security of their healthcare information has been compromised in some way. Complaints can be made directly to the provider or to the Office of Civil Rights (OCR).

On October 16, 2003, the electronic transaction and code set standards became effective. This does not require electronic transmission but mandates that if transactions are conducted electronically, they must comply with the required federal standards for electronically filed healthcare claims. CMS is responsible for enforcing the electronic transactions and code sets provisions of the law.

The security requirements went into effect on April 21, 2005 and require the covered entities to put safeguards that protect the confidentiality, integrity, and availability of protected health information when stored and transmitted electronically into place.

Health Insurance Portability & Accountability Acts

- Requirements for release of health information HIPAA 1996
- Policies for protection of personal health information HIPAA 2002
 - Names; all geographic subdivisions smaller than a state; street address, city, county, zip code, etc.
 - Birth dates, admission dates, discharge dates, date of death, all ages over 89 unless aggregated
 - Telephone/fax numbers
 - Electronic mail addresses; URLs, IP addresses
 - Medical record, health plan, beneficiary numbers
 - Certificate/license; vehicle ID; biometric identifiers

The American National Standards Institute (ANSI) X12N and Health Level 7 (HL7) standards organizations worked together to develop an electronic standard for claims attachments to recommend to HHS. ANSI was founded in 1918 and has served as the coordinator of the United States voluntary standards and conformity assessment system. HL7 is one of several American National Standards Institute-accredited Standards-Developing Organizations. HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity, and enhance knowledge transfer among

all of the stakeholders, including healthcare providers, government agencies, the vendor community, and patients.

Data Definition

Data definition is accomplished so that all common data items share the definition specified by the organization. The extensive interfacing of systems in either electronic or hard copy form assures continuity of the definitions throughout the organization. The commonality of data definition allows aggregation and use in support of various administrative, quality improvement, and patient care activities. The use of the organization's information system ensures the integrity of the data entered by the edits and validation. Listings of specific data items with format and definition is available.

Medical Records Management

Indicators: Medical Records

- Completeness and timeliness of medical record information
- Delinquency statistics

Medical records contain sufficient information to:

- Identify the patient
- Support the diagnosis
- Justify the treatment
- Document the course and results
- Facilitate continuity of care

To facilitate consistency and continuity in patient care, specific data and information are required. Administrative and direct patient care providers produce and use this information for professional and organizational improvement. The environment in which patient specific information is provided supports timely, accurate, secure, and confidential recording and use of patient specific information. The system recalls historical patient data and is able to furnish data about current encounters.

To facilitate consistency and continuity in patient care, the medical record should contain very specific data and information, including:

- Patient's name, address, date of birth, and name of any legally authorized representative
- Legal status of patients receiving mental health services
- Emergency care provided to the patient prior to arrival, if any
- Record and findings of the patient's assessment
- Conclusions or impressions drawn from the medical history and physical examination
- Diagnosis or diagnostic impression
- Reasons for admission or treatment
- Goals of treatment and treatment plan
- Evidence of known advance directives
- Evidence of informed consent, when required by policy
- Diagnostic and therapeutic orders, if any
- All diagnostic and therapeutic procedures and test results
- Test results relevant to the management of the patient condition
- All operative and other invasive procedures performed, using acceptable disease and operative terminology
- Progress notes made by the medical staff and other authorized individuals
- All reassessment and any revisions of the treatment plan
- Clinical observations
- Patient's response to care
- Consultation reports

- Every medication ordered or prescribed for an inpatient
- Every medication dispensed to an ambulatory patient or an inpatient on discharge
- Every dose of medication administered and any adverse drug reaction
- All relevant diagnoses established during the course of care
- Any referrals and communications made to internal or external care providers and to community agencies
- Conclusions at termination of hospitalization
- Discharge instructions to patient and family
- Clinical resumes and discharge summaries, or a final progress note or transfer summary

A concise clinical resume included in the medical record at discharge provides important information to other caregivers and facilitates continuity of care. For patients discharged to ambulatory care, the clinical resume summarizes previous levels of care.

The discharge summary contains:

- Reason for the hospitalization
- Significant findings
- Procedures performed and treatment rendered
- Patient's condition at discharge
- Instructions to the patient and family

Certain types of data and information need to be accumulated over time to support the hospital's clinical and management functions.

The information management function has the ability to collect and aggregate clinical and administrative data to support:

- Individual care and care delivery
- Decision making
- Management and operations
- Analysis of trends over time
- Performance comparisons over time within and with external sources
- Performance improvement
- Reduction in risks to patients

International Classification of Diseases ICD 10

The International Classification of Diseases (ICD) is the standard diagnostic tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. It is used to monitor the incidence and prevalence of diseases and other health problems, providing a picture of the general health situation of countries and populations.

ICD is used by physicians, nurses, other providers, researchers, health information managers and coders, health information technology workers, policy-makers, insurers and patient organizations to classify diseases and other health problems recorded on many types of health and vital records, including death certificates and health records. In addition to enabling the storage and retrieval of diagnostic information for clinical, epidemiological and quality purposes, these records also provide the basis for the compilation of national mortality and morbidity statistics by World Health Organization (WHO) Member States. Finally, ICD is used for reimbursement and resource allocation decision-making by countries. All member states use the ICD which has been translated into 43 languages. Most countries (117) use the system to report mortality data, a primary indicator of health status.

ICD-10 was endorsed by the Forty-third World Health Assembly in May 1990 and came into use in WHO Member States as from 1994. ICD is currently under revision, through an ongoing

revision process, and the release date for ICD-11 is 2017. ICD-10-CM and ICD-10-PCS are medical coding classifications that are slated to replace the highly antiquated American ICD-9-CM medical coding system - ICD-10-CM will be used for diagnosis coding and ICD-10-PCS will be used for procedural coding. On July 31, 2014 the U.S. Department of Health and Human Services (HHS) issued a rule finalizing October 1, 2015 as the new compliance date for health care providers, health plans, and health care clearinghouses to transition to ICD-10-CM/PCS. <http://www.ICD10Data.com> is a free website.

World Health Organization (WHO)

The World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. WHO fulfills its objectives through its core functions:

- providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
- shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
- setting norms and standards and promoting and monitoring their implementation;
- articulating ethical and evidence-based policy options;
- providing technical support, catalyzing change, and building sustainable institutional capacity;
- and monitoring the health situation and assessing health trends.

SAMPLE CONFIDENTIALITY REGULATIONS POLICY

1. **PURPOSE**: To establish policy and procedures regarding the confidentiality of specified documents resulting from Performance Improvement (PI) activities carried out by or for the Carl T. Hayden VA Medical Center
2. **POLICY**: It is the policy of the Carl T. Hayden VA Medical Center to appropriately maintain the confidentiality of PI documents
3. **SCOPE**: This medical center policy memorandum applies to PI documents initiated on or after January 23, 1995, the date on which the revised VA PI confidentiality regulations for 38 U.S.C. 5705 became effective. Guidance regarding the confidentiality of PI documents initiated before January 23, 1995 can be found in the previous confidentiality regulations originally published on October 22, 1982 as 38 C.F.R. §§17.500-.541. Documents covered under this policy may be retained in any storage medium (e.g., written, optical disk, electronic, photographic, etc.)
4. **PROCEDURES**:
 - a. The following PI activities generate confidential documents at all VA Medical Centers if criteria in Paragraph 4c. are met
 - (1) Monitoring and Evaluation Review
 - (a) Tort Claim Peer Review (including TCIS and local reviews)
 - b) Mortality and Morbidity Reviews (including Psychological Autopsies)
 - (c) Occurrence Screening
 - (d) Drug Usage Evaluation (including Adverse Drug Event Reports)
 - (e) Utilization Review (including admission and continued stay reviews, rejected applications and diagnostic studies)
 - (f) Surgical and Other Invasive Procedure Reviews (including Pre- and Post-op Diagnosis Reviews) (g) Medical Record Review
 - (h) Blood Usage Review (including Transfusion Errors and Reactions)
 - (i) Patient Risk Event Reporting - the reporting, review, or analysis of unusual or unexpected incidents involving patients which cause harm or have the potential for causing harm (Reports of Special Incident and follow-up documents unless developed during or as a result of a Board of Investigation)
 - (j) Infection Control and Surveillance
 - (k) Service and Program Monitoring (including service-specific and multi- and interdisciplinary activities including but not limited to focus reviews, psychological, autopsies, critical incident reports) (l) Autopsy Review (the review of pre- and

post-mortem diagnoses to assess diagnostic accuracy)

(m) Process Improvement Team

(2) Focused reviews which address specific issues in detail and are designated by the Medical Center Director at the outset as protected by 38 U.S.C. 5705 and its implementing regulations. A focused review will be terminated if it appears that disciplinary action may be indicated, and a board of investigation will be initiated so that evidence independent of the focused review may be developed and this evidence and the findings can be the basis of such disciplinary actions

(3) Contracted External Reviews of Care, specifically designated in the contract/ agreement as protected by 38 U.S.C. 5705 and its implementing regulations

b. Documents from the PI activities listed in Paragraph 4a. are, in general, confidential only if all of the following criteria are met

(1) The activity is performed for the purpose of improving the quality of health care or improving the utilization of health care resources and is either a form of monitoring and evaluation or a focused review

(2) The document identifies either implicitly or explicitly individual practitioners, patients or reviews; contains discussion relating to the quality of medical care or utilization of VA resources which occurred during the course of a review of Performance Improvement information or data; or was produced in deliberating on health care review findings or prepared for use in such deliberation

(3) The document does not meet any of the 15 exceptions listed in Appendix A

(4) The activity was performed at this medical center by staff of this medical center or there was prior written designation of the role of individuals who are not staff of this facility in performing the review

c. The following statement will be used on documents considered confidential: "Confidential and Privileged IAW 38 U.S.C. 5705." This statement will be helpful in retrospectively identifying confidential documents. However, the statement, by itself, does not assure confidentiality of a document. Documents are confidential if they meet the requirements of 38 U.S.C. 5705 and its implementing regulations (as summarized in Paragraph 4c.) even if no such statement is present; similarly, the use of this statement does not protect documents which do not qualify as being confidential

d. In order to ensure that access to and disclosure of all confidential information will occur only as authorized, the Department Chair/Assistant Administrator or designee will contact the Confidentiality Officer (Assistant Administrator, MAD)

e. Those documents which contain confidential material in one part, but not in others, such as Clinical Executive Board minutes, will be filed and maintained as if the entire document was protected (this is not required if the confidential material is removed)

f. Access to confidential PI records and documents within the medical center is restricted to VA employees (including consultants and contractors of the VA) who have a need for such information to perform their government duties or contractual responsibilities. All individuals granted such access have been informed of the contents of this policy statement including the penalties for unauthorized disclosure by their supervisor

g. Confidential PI documents can be shown to the practitioner for educational or process improvement purposes. To protect the integrity of the peer review process, the identities of the peer reviewers will not be disclosed to the provider, to the extent practicable

h. Other VA employees (and consultants and contractors) may have access to confidential PI documents if they need the information to perform their government duties or contractual responsibilities. This includes staff of the Inspector General, Medical Inspector, General Counsel and the Regional Counsel

i. Disclosure of confidential PI documents is authorized to the following non-VA requesters (See §17.509 of the revised confidentiality regulations for details).

(1) Department of Justice attorneys who are investigating a claim or potential claim against the VA or who are preparing for the litigation involving the VA

(2) A committee or subcommittee of either House of Congress if the document pertains to any matter within the assigned jurisdiction of the committee (e.g., House/Senate Veterans Affairs Committee, etc.)

(3) Accreditation agencies requested by VA to assess the quality of patient care (e.g., Joint Commission, CAP, etc.)

(4) The General Accounting Office if the document pertains to any matter within its jurisdiction

(5) Federal agencies charged with protecting the public health and welfare, federal and private agencies which engage in various monitoring and quality control activities, agencies responsible for licensure of individual health care facilities or programs and similar organizations (see Paragraph 4k.)

(6) A federal agency or provider of health care participating with VA in a health care program if disclosure of the document is necessary for VA to participate in the program (see Paragraph 4k.).

- (7) A criminal or civil law enforcement governmental agency charged under applicable law with protecting public health or safety if a qualified representative makes a qualifying written request for the record (see Paragraph 4k.)
- (8) Qualified persons or organizations that are participating with VA in a health care program if disclosure of the document is necessary for VA to participate in the program
- (9) Health care personnel to the extent necessary to meet a medical emergency affecting the health or safety of any individual
- j. PI documents, whether confidential or not, will not be disclosed to a requester outside VA until determining the applicability of other confidentiality statutes, i.e., the Freedom of Information Act, Privacy Act, U.S.C. 7332 "Drug and Alcohol Abuse, Sickle Cell Anemia, HIV Infection," and U.S.C. 5701 "Veterans Names and Addresses." This will require a collaborative review with the facility Release of Information Office
- k. A request for confidential PI documents listed under Paragraphs 4i(5) - (8) must:
- (1) Be made in writing on agency letterhead and be signed by the requester;
 - (2) Specify the nature and content of the information requested;
 - (3) Specify to whom the information should be transmitted or disclosed;
 - (4) Specify the purpose for which the information requested will be used;
 - (5) Specify, to the extent possible, the beginning and final dates of the period for which disclosure or access is requested
- l. The disclosure of confidential and privileged records and documents will always be by copies, abstracts, summaries, or similar records or documents. The original records and documents will not be removed from the medical center unless otherwise legally required. The only exception is that documents may be removed to the site where the General Counsel (or any attorney within the Office of General Counsel) or the Department of Justice attorney is conducting an investigation or preparing for litigation. Section 5705-protected documents which are disclosed to authorized individuals will bear the following statement: "These documents or records (or information contained herein) are confidential and privileged under the provisions of 38 U.S.C. 5705, which provide for fines up to \$20,000 for unauthorized disclosures thereof, and the implementing regulations. This material shall not be disclosed to anyone without authorization as provided for by that law or these regulations. The name of, and other identifying information regarding, any individual VA patient, employee or other individual associated with VA shall be deleted before any disclosure if disclosure would constitute a clearly unwarranted invasion of personal privacy
- m. When a request for PI documents is denied in whole or in part by the Carl T. Hayden VAMC Medical Center Director, the requester will be notified in writing of the right to appeal this decision to the General Counsel of the Department of Veterans Affairs within 60 days of the date of the denial letter
- n. Confidential PI documents will be maintained for three years.

5. **RESPONSIBILITIES:**

- a. The Medical Center Director has the ultimate responsibility for applying the confidentiality law (38 U.S.C. 5705) and the implementing regulation
- b. The Chief of Staff and Associate Director have the responsibility for implementing the confidentiality law and its revised regulations in the departments under their span of control
- c. The Assistant Administrator, Medical Administration Department (MAD) serves as PI Confidentiality Officer for the Carl T. Hayden VA Medical Center and is responsible for the day-to-day operation of the confidentiality program. All requests for the release of PI documents will be coordinated by the Assistant Administrator, MAD
- d. Department Chairs/Assistant Administrators are responsible for implementing the confidentiality law and its revised regulations within their service lines and departments.
- e. All employees who have access to confidential PI documents will not disclose these documents, or the information therein, to any person or organization, except as authorized by 38 U.S.C. 5705 and the implementing regulations either while employed by the VA or after voluntary or involuntary termination of their relationship with the VA

6. **REFERENCES:**

- a. Title 38 U.S.C. 5701
- b. 38 CFR Part 17, Confidentiality of Healthcare Quality Assurance Reviews, Final Rule. Federal Register Vol. 59, No. 204, Monday, October 24, 1994, pages 53354 - 53359c. 38 CFR Part 17, Health Services Review Organization (HSRO), Final Rule. Federal Register, July 1, 1991, pages 766-783
- d. VHA Directive 98-016, QM Activities Which Can Generate Confidential Document

NON-CONFIDENTIAL QUALITY ASSURANCE DOCUMENT

The following documents and parts of documents are not confidential under Section 5705

- a. Statistical information regarding VA health care programs or activities that do not implicitly or explicitly identify individual VA patients, employees or individuals involved in the QM process

b. Summary documents or records which only identify study topics, the period of time covered by the study, criteria, norms, and/or major overall findings, but which do not identify individual health care practitioners, even by implications. The contents of Credentialing and Privileging folders;
Those developed during or as a result of Boards of Investigations - (Note: confidential documents protected by Section 5705, such as Reports of Special Incidents, which lead to an investigation, retain their confidential status even though documents resulting from the investigations are not confidential);
Completed patient satisfaction survey questionnaires and findings;
Information concerning the number of cases treated and procedures performed by individual providers (these documents will be used during the reprivileging process and filed in the Credentialing and Privileging folders);
Those developed during or as a result of reviews performed to satisfy the requirements of a governmental body or a professional health care organization which is licensing practitioners or monitoring their professional performance (e.g., National Practitioner Data Bank (NPDB), Federation of State Medical Boards (FSMB); and National Council of State Boards of Nursing, etc.);
Office of the Medical Inspector site visit reports and documents except to the extent that the documents and reports contain information that results from activities described as confidential under Section 5705;
External reviews conducted by VA Central Office or the Network Director other than those designated as being confidential under Section 5705;
Documents and reports of Professional Standards Boards, Credentialing Committee, Executive Committee of the Medical Staff and similar bodies, insofar as the documents relate to the credentialing and privileging of practitioners;
Those developed during data validation activities;
Those developed during occupational health monitoring;
Those developed during safety monitoring not directly related to the care of specified individual patients;
Those developed during or as a result of resource management activities not directly related to the care of specified individual patients; and
Reviews conducted at the request of a third-party payer

SAMPLE POLICY MANAGEMENT OF MEDICAL RECORD FILE AREAS

1. **PURPOSE:** To establish policy and procedures for the maintenance of medical records to maximize their availability.
2. **POLICY:** It is the policy of this medical center to maintain effective control of the distribution of medical records to ensure they are readily available to users.
3. **PROCEDURES:**
 - a. **Requisitions:**
 - (1) All requests for administrative records will be phoned into the File Unit.
 - (2) Emergency requisitions (life support room, STAT requests) may be submitted by telephone or in person to the File Unit.
 - (3) Routine requisitions will be requested through the Medical Record Tracking Package. Users will input patient name, last four SSN, borrower's name and any comments needed to help expedite retrieval of medical records (ex: deceased, old volumes, employee). If you do not need the record right away, state the date you need the record in the comment section. These requests will be held in the File Room and the records will be pulled on the date requested.
 - (4) Requests for more than three records: Borrower will use the pull list menu option to create a pull list. Records should be requested 72 hours before they are needed. The list will be sorted by clinic name to show the pull list number. The comment section will contain the following information: room number, where the records will be delivered, minimum number of records required from the pull list and special instructions, if deemed necessary by the requester. Requests (pull list) that are needed in less than 72 hours or a pull list for more than 30 records, will be coordinated with the File Room supervisor to arrange the date of request, volumes and retrieval rate. After creation of the pull list, requester should print the pull list on the File Room printer named "Pull List." All pull lists will automatically default to this printer. If printer is busy, pull list should be queued to print on "Portland" printer. This procedure will allow efficient distribution of workload on a daily basis.
 - (5) For Ad Hoc pulls, all records maintained within the File Room the evening prior to your request date will be pulled. Records not available for the Ad Hoc pull list include: records on inpatients; records maintain within the Medical Record Annex (Chart Deficiency Room); records transferred to Prescott, Tucson, Northwest, Show Low and Southeast Clinics, or

Another VAMC; and records changed to another borrower. Further follow-up will not be conducted by the File Room staff unless arrangements have been made with the File Room Supervisor at extension 7119. Inpatient records must be reviewed on their respective floor. Arrangements can be made with the Annex to review records in Room 1320 by calling extension 7384.

(6) Records for scheduled clinic appointments will be printed by File Room personnel 48 hours prior to the date the records are required. An updated list will be printed and pulled the day before the scheduled appointments. A computer printout of add-on list to the clinics must be received in the File Room by noon of the day prior to the scheduled clinic appointment.

(7) Requester may also determine the status of the request utilizing VISTA options within the tracking package. Inquiries for records of patients with scheduled appointments will be directed to the expediter assigned to that clinic.

b. Availability of Records:

(1) Under normal conditions, requisitions for records for patient care services will be responded to within 15 minutes. Records for non-treatment purposes will be responded to by the date required by the requester. If the records are not available, the requester will be so notified. Requester may also determine the status of his request utilizing VISTA options within the tracking package. Request for a record shall be entered into the computer only once.

(2) Because of the need for the health care team to have access to the medical information if emergencies occur, records sent to clinics will be returned before the close of business each day. Records for purposes such as review, correspondence, etc., will be returned to the File Room within 48 hours. Records not returned to the File Room will be maintained in an area which is accessible to authorized persons but secured from unauthorized access.

(3) To ensure record availability for patients who have multiple clinic appointments the same day, the File Room will tag the records to indicate the time and location of subsequent clinic appointments. The clinic clerk will be responsible for transporting the record to the next clinic appointment.

(4) No record will be removed from the File Unit without being charged out in the computer. This rule will apply to all personnel and will be strictly enforced

(5) Each borrower will be responsible for recharging the medical records every time the record changes location. Borrowers will not recharge records that are being returned to the File Room.

c. Transportation of Records:

(1) Records will be delivered to the requester or clinic areas by the File Unit personnel. Records for subsequent appointments will be delivered by the clinic clerk having possession of the record.

(2) Records for the satellite clinics will be picked up from the staging area in Bldg. 1, Room K107. Records are transported in bins and mobile carts by van shuttle to and from satellite clinics. All bins and mobile carts will be labeled "Property of Department of Veterans Affairs; if found please return to VAMC Phoenix.

(3) Under normal conditions, patients will not hand carry records. When, due to shortage of staff, it is necessary for the patient to hand carry his/her record, clinic clerks will be responsible for recharging records to the next clinic, location, or borrower. The record will be sealed in a messenger envelope before releasing the record to the patient. Personnel will contact receiving staff in advance so that verification of receipt of record from patient is made. If not received, File Room Supervisor will be notified.

d. Safeguarding Patients Records:

(1) Only authorized personnel will be allowed access to the File Unit.

(2) During hours when File Unit personnel are not on duty, the File Unit will remain locked. Access to records may be obtained by contacting the Admitting Officer of the Day on duty for emergency requests.

e. Documents for Loose Filing:

(1) Documents intended for filing will be forwarded to the File Unit on a daily basis and will contain proper ID, including complete name and social security number. The File Room Unit will return all unidentifiable documents back to the department of origin. Documents of individuals that have never been medically seen in the VA facility and have no physical medical folders will also be returned to the originating department.

(2) Loose documents will be filed in the administrative or medical records by the originator after a patient visit when the record is in his/her possession.

(3) Only appropriate documents will be forwarded to the File Room, i.e., original documentation of a medical visit, and administrative correspondence. Documents such as routing slips, work copies, and interim reports should not be sent to the File Room as these documents are not a part of the patient's records. Electronic Computerized Patient Record System (CPRS) documents will not be filed into the patient's record by File Room personnel.

f. Retention of Medical Records:

- (1) Medical records will be transferred to the Federal Records Center after three years of inactivity and two years on all death charts.
- (2) Perpetual records will no longer be maintained at this VAMC. All perpetual records will be retired to the Federal Records Center (FRC). This will include all perpetual records created with a last episode of care prior to 1989. All records retired to the FRC with a last episode of care as of 1989 and later will not have a perpetual record created. Records will be retired in their entirety. All retired medical records and perpetual records can be retrieved from the FRC with demonstrated medical necessity or administrative authority.
4. **RESPONSIBILITY:** The Assistant Administrator, Medical Administration Department, or designee, is responsible for the management of medical record file areas.
5. **REFERENCES:** M-1, Part 1, Chapter 5, and Joint Commission Accreditation Manual for Hospitals.

SAMPLE PROTECTION OF VITAL RECORDS

1. **PURPOSE:** To establish policy and procedures for the maintenance and protection of vital records in the event of fire, disaster, civil disturbance or other hazards.
2. **POLICY:** It is the policy of this medical center to identify, maintain, protect, and safeguard all records within the medical center which are considered vital, irreplaceable, or essential to the operation of the medical center and/or to the treatment of patients.
3. **PROCEDURES:**
 - a. Administrators/Assistant Administrators/Chairs or their designees are to identify all records within their areas of responsibility which are considered vital or irreplaceable. These include, but are not limited to, patient treatment records, personnel records, payroll records, and equipment records.
 - b. Specific personnel are to be assigned within each department to move vital records if evacuation becomes necessary. They should have sufficient instructions available to act independently after receipt of a removal order. The names of these assigned employees are to be turned in to the Records Management Officer (Assistant Administrator, Medical Administration Department or designee) by memorandum annually and updated accordingly.
 - c. Depending upon the situation at the time and extent of damage or destruction of buildings or work areas, the Records Management Officer or Department Chairs/Assistant Administrators will make the decision as to whether or not records will be moved.
 - d. When notifications of a fire, disaster, civil disturbance, or other hazards are received, the following actions shall be taken:
 - (1) Close open drawers of filing equipment.
 - (2) In case of fire, place all exposed records in the filing equipment.
 - (3) Move vital or irreplaceable records to the extent possible without endangering human life.
 - e. Building 14 will serve as a temporary storage area for vital records which have to be removed from their normal area. In the event this area is not available, the Records Management Officer will work with the Assistant Administrator, Engineering Department to establish an alternate temporary storage area.
4. **RESPONSIBILITY:** The Assistant Administrator, Medical Administration Department is designated as the Records Management Officer and is responsible for the administration of this policy.
5. **REFERENCES:** M-1, Part 2, Chapter 1.

SAMPLE MEDICAL RECORD MANAGEMENT POLICY

1. **PURPOSE:**
 - a. To establish policy and procedures for timely, accurate, complete, clinically pertinent, and readily accessible patient health information which will contain sufficient recorded information to serve as a basis to plan patient care, support diagnoses, warrant treatment, support education and research, and document measurable outcomes.
 - b. Title 38 United States Code (U.S.C.) 7304(a) is the statutory authority for the Under Secretary for Health to promulgate regulations concerning the custody, use, and preservation of records and papers of the Veterans Health Administration (VHA).
2. **POLICY:**
 - a. The Consolidated Health Record (CHR) will be created and maintained for every individual assessed or treated, as well as for those receiving community or ancillary care at VA expense; veterans examined for possible exposure to

toxins, asbestos, radiation or other environmental contaminants; those undergoing Compensation and Pension examinations; and collateral or family members of veterans attending counseling.

b. The medical record is the property of the medical center and is maintained for the benefit of the patient, the medical staff, and the medical center. The medical record can be paper, computer based (electronic), or a combination of paper and electronic data. Electronic storage and capture of patient medical information will be implemented to the extent possible to enhance access to patient data by health care providers and support personnel. The electronically stored and/or printed patient information is subject to the same medical and legal requirements as the handwritten information in the CHR.

c. The most current standards of the Joint Commission will be followed, unless otherwise specifically stated by VA regulations or requirements as set forth by the Medical Staff Bylaws, Rules and Regulations.

d. Protection of confidentiality and privacy of patient information shall be ensured, including, but not limited to, compliance with Privacy Act of 1974, Freedom of Information Act (FOIA), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Information contained therein will not be accessible to, or discussed with, unauthorized persons. Authorized individuals must have an identifiable need for the record to perform their assigned duties. Please refer to Policy Memorandum Numbers FMS/136-30, Release of Information on Patients; RMS/IRM-12, Electronic Mail (E-Mail); and Veterans Health Administration Manual, M-1, Part 1, Chapter 9.

e. The borrower of a CHR paper record is responsible for its safekeeping, its availability, and its timely return to the File Room. In the event the CHR paper record is transferred to another staff member or service, the borrower must 'recharge' (i.e. transfer responsibility for) the CHR paper record so its current location may be known at all times.

f. All medical record forms (paper and electronic), the overprinting, assembly and use thereof will contain, as minimum identification, the patient's name, social security number, and facility location (VAMC, Phoenix, AZ). Refer to Appendix E.

g. Only symbols and abbreviations listed within the Stedman's Abbreviations, Acronyms and Symbols publication will be used in the patient medical record.

h. Following release of an inpatient, the medical record will be assembled and transported within 24 hours to the control of Health Information Management Department (HIMD) and remain until completion of the medical records.

i. The medical record received from an acute care admission into the Nursing Home Care Unit will remain on the NHCU floor for only one week prior to delivery to the Health Information Management Department.

j. The medical record shall be complete within 30 calendar days from the date of discharge before a record will be considered complete for filing purposes. Problem cases will be referred to the Clinical Executive Board for final disposition.

k. Records shall be kept and preserved for a period of time not less than that determined by the Records Control Schedule or when approval is received from the Federal Record Center Director.

l. In the event of a disaster, patient records will be recreated based on available computer patient record information and/or hard copy records. If hard copy records are salvageable, they will be recovered and sent out to microfilm, in accordance with requirements in RCS 10-1. All records will be afforded protection against defacement, damage, loss, destruction by fire/flood, or other hazards.

m. Medical records may be removed from the medical center's jurisdiction and safekeeping only in accordance with a court order, subpoena, or statute. Medical records, however, will be transferred to another VA Medical Center or Community Based Outpatient Clinics (CBOC) upon request for purposes of maintaining a unit record.

n. The availability of computerized patient information within the Computerized Patient Record System (CPRS) precludes having to print hard copy material until such time that the record is transferred outside VISN 18. The Health Information Management Standard Chart health summary and Medication Administration Log will be the primary sources utilized in printing out patient electronic information upon transfer. Other VA Medical Centers can access patient information using Remote Data View through CPRS.

3. DEFINITIONS:

a. Active Record: The Consolidated Health Record (CHR) of a patient who is currently receiving care, regardless of patient status or location of care being rendered.

b. Addendum: Inclusion of additional information to source document.

c. Ambulatory or Outpatient Care: Health care services provided to patients who are not classified as inpatients. For purposes of CHR maintenance, ambulatory or outpatient care refers to all categories of care such as Outpatient-Service

Connected (OPT-SC), Outpatient-Non-service Connected (OPT-NSC), Ambulatory Care; Home Based Primary Care (HBPC), etc.

d. Authentication: Approval of documentation in the patient record by means of a signature (manual or electronic), computer key or other means recognized legally. Authentication demonstrates the entry has not been altered, and affirms the validity of the author's actions(s), opinion(s) or statements. Authentication will consist of date, signature, initials or defined computer entry, time if required, and professional designation of the member of the patient care team making the entry.

e. Computer-Based Patient Record: An electronic patient record stored in Veterans Health Information System and Technology Architecture (VISTA), or other automated system using electronic storage system, e.g., optical disk, that provides easy retrievability of complete, accurate, and timely medical information.

f. Consolidated Health Record (CHR): The CHR (commonly referred to as the 'Medical Record') is the combination of the electronic and paper record. The CHR can be called the medical record, the patient record, the health record, the electronic health record and/or the computer-based patient record. The CHR contains two parts, housed in two folders:

(1) Type I, Administrative Records Folders, contains documents pertaining to a patient's demographics, eligibility, and other business-related documents.

(2) Type II, Medical Records Folder, contains health care documents related to all aspects involved in healthcare delivery. It is individually identifiable data, in any medium, collected and/or directly used in documenting health care.

g. Retired Record: A record stored off site, at a Federal Records Center (FRC), or archived to electronic storage medium. Records are retired after four years of inactivity or two years from date of death.

h. Scan/Scanning: Capture of data via imaging/pictorial technology.

4. PROCEDURES:

a. General:

(1) The primary source of documentation for all patient care activities shall be CPRS (Computerized Patient Record System). VAMC Phoenix has established the goal of a transition to a paperless electronic medical record.

Computer-generated medical record documentation does not currently eliminate the need for hard copies of specific patient medical records. The CPRS initiative is to achieve a complete electronic medical record.

(2) A concise clinical resume, progress note, or transfer summary will be included in the medical record at the time of inpatient discharge or transfer to provide important information to other caregivers and facilitates continuity of care

(3) Medical and administrative processing of records, including qualitative and quantitative analysis, final coding, and completion of deficiencies by responsible parties will be accomplished within established timeframes outlined in Appendix B, Clinician Documentation Quick Reference.

(4) Each time a patient visits the ambulatory care setting, a progress note will be recorded preferably through CPRS. Documentation should include the following: date and clinic title, chief complaint, relevant history of illness or injury, clinical observations, results of treatment, reports of tests, procedures performed, doctor's orders for medication, tests, therapy, work/activity limitations if any, diet when appropriate to clinical condition and follow-up, instructions to patient including level of understanding, signature and title of author.

(5) The problem list will be initiated and maintained by the third visit to the health care provider and shall include known significant diagnosis, conditions, procedures, drug allergies and adverse reactions. Entries other than diagnosis, if significant for the information of the health care team, may be recorded on the problem list. The health care problems listed will not be numbered and the list will be updated as necessary upon subsequent outpatient visits. Problems identified will be listed as chronic, acute or historic.

(6) The Clinical Reminder package will be used to document the assessment and counseling of chronic disease indexes and preventative health issues. Information documented on this form will also be reflected in the visit progress note. The encounter form will be used to address clinical reminders pertaining to the relevant chronic disease index and preventative health issues.

(7) Each medical record will have at least the following component parts: Discharge summary (see Attachment A for specifics), history and physical examination, progress notes, vital signs, Dr.'s Orders, a comprehensive multidisciplinary treatment plan, and nursing care documentation. When applicable, the record will include informed consent or documentation of administrative consent, operation reports, pathology reports, and autopsy findings.

- (8) Medical records will contain original and/or electronically authenticated documents. Signature, initials (where applicable), defined computer entry, professional designation, staff title and date will authenticate all entries in the record. The signature in the electronic record will be electronically timed stamped upon completion.
- (9) No edit or alteration of any documentation shall occur after manual or electronic signature has been completed. The only exception is through education of our housestaff and students, i.e. Discharge summaries and Podiatry medical student progress notes. Once the record is edited by the supervising physician, the document can no longer be edited or altered. Records will not be erased, whited-out or marked-over. In CPRS (Computerized Patient Record System) documentation can be edited on line prior to authentication with an electronic signature. After a document is signed all corrections need to be done through Privacy Act Officer or designee.
- (10) The Privacy Act of 1974 contains provisions for the amendment or correction of a medical record. In order to effect this requirement in CPRS, the Privacy Act Officer or designee will be provided a security key to access the computer-based record for purposes of amending or correcting the record.
- (11) All staff members who, by virtue of their position description, functional statement, statement of work, affiliation agreement, sharing agreement, or scope of practice when providing patient care are authorized to document care in the medical record.
- (12) Medical records must, at all times, be immediately available for patient care. Paper medical records charged out of the medical center file room must be kept in a highly visible but secure location. They will not be stored in a desk drawer or locked cabinet.
- (13) Computer screens will be turned so that a passerby may not easily read the screen. Individuals will not share computer access codes. When individuals are finished entering into the electronic record, they must make sure that they have discontinued access to VISTA (Veterans Health Information System and Technology Architecture); thus eliminating unauthorized access to patient information.
- (14) When a patient is readmitted, the paper medical record containing the most recent episode of care will be made available by the file room staff. Other records will be provided as requested. The final medical record will be maintained chronologically.
- (15) Clinicians should refrain from re-entry of previously entered or captured data, such as cut and paste in CPRS or inserting copies into paper record. Avoidance of these practices ensures conveyance of most recent data, maintains record flow in an accurate contiguous manner, and facilitates accurate and safe utilization of record by all clinicians.
- b. Downtime: When VISTA is Down, refer to Policy Memorandum Number IS/IRMD-7, AIS Contingency Planning.
- (1) Progress notes and consults may be handwritten to be filed in the paper chart.
- (2) Orders should be written on paper forms which Health Unit Coordinators and clinic support staff shall maintain supplies of for such emergent cases.
- (3) Patient data will be available from contingency health summaries that contain predetermined information.
- c. Amendment of Medical Records:
- (1) Electronic documentation (i.e., progress notes, discharge summary, etc.) may be amended at any time by the author or an expected co-signer prior to authentication.
- (2) Once a document has been authenticated, amendment is accomplished by creation of an addendum to the original document rather than a new computerized document. If a prior hard copy of the original document has been provided for placement with the paper medical record, the author should ensure the addendum is also printed and filed in the patient's paper medical record.
- (3) If a progress note is put under the wrong patient's name:
- (a) Unsigned Notes: The author should use the copy action to copy the text under the correct patient's name, then go back to the unsigned incorrect note and "delete."
- (b) Signed Notes: Copy the text to the correct patient's name. Go back to the incorrect original note and choose the "Make Addendum" command to add text-indicating note was done by author in error. Send e-mail in VISTA to G.CAC with the following information: patient's name, full SSN #, note title, date/time of note, author, and reason for error. Remember: Do not place the patient's name and SSN within the title of your e-mail but within the body of your text only. A Clinical Application Coordinator (CAC) will then change the title, so that no one will be able to view it, to "ERRONEOUS NOTE."
- (4) When a patient requests amendment of documents in his/her medical record, whether electronically generated or handwritten, the request must be referred to the Assistant Administrator, Health Information Management Department.
- (5) When original electronic documentation requires correction or amendment, the provisions of the Privacy Act of

1974, which apply to the correction or amendment of the original hard copy medical record, will be applied.

d. Medical Alert: When there is a history of allergies, adverse reactions or other conditions which, in the physician's opinion, merits special attention, the allergy and adverse reaction information will be entered in VISTA for access under the "Patient Health Summary" and "Patient Inquiry." It can also be viewed in CPRS in the top right corner of every tab in the Patient Posting box and on the Cover Sheet

e. Problem List: The problem list should contain all established diagnoses, which are relevant to the patient's health care. Entries other than diagnosis, if significant for the health care team's information, may be recorded on the problem list. In the electronic medical record, the problem list will be initiated for every ambulatory patient by the third visit by the treating clinician. An entry on the problem list is the overall responsibility of the primary care provider. As new medical diagnoses and conditions are added, resolved problems will be inactivated. A status of active or inactive will be assigned to each problem when entered or edited. Historic problems will be identified in the comment section as "Historic" and include the patient's description of the date of onset. The immediacy of each problem will be identified as "chronic" or "acute." Attempted suicide will be documented on the Problem List.

f. History and Physical Examination:

(1) A complete inpatient admission history and physical (H&P) examination will be performed within 24 hours of admission and signed by a physician on acute inpatient care units. In long term care (NHCUC), H&P will be performed within 48 hours. If the H&P is performed by a physician assistant, nurse practitioner, or house staff, an attending physician may countersign or write a separate progress note or addendum that signifies concurrence of the H&P, assessment and plan. Qualified oral surgeons may complete the history and physical examination of dental and oral surgery patients admitted to Dental Service. Podiatrists are responsible for the part of their patients' history and physical examination that relates to podiatry. Only one dictated H&P is allowed for inpatient stay.

(2) When, within a 30-day period, a patient is readmitted, the previous history and physical examination may be used, if it is professionally determined that such an examination in conjunction with the prior examination is adequate to reflect a comprehensive current physical assessment. In this case, an interval note will be written and will indicate that the previous H&P has been reviewed and will note pertinent changes or lack thereof. An interval note is not required if the H&P was conducted within seven days of admission. The initial H&P will not be moved forward, but will remain with the original period of hospitalization.

(3) When an inpatient has been hospitalized a year or longer, an annual physical exam-inaction will be required and will be completed electronically by the attending provider.

(4) As an integral part of the evaluation of all admissions, an oral examination will be completed and recorded on the oral-maxillofacial database for those patients in whom dental intervention is perceived as a necessary and an integral component of treatment.

(5) When a patient is first admitted to VA care on an ambulatory and/or outpatient care level, a relevant history of the illness or injury and physical findings will be documented in the patient record. The provider doing the exam must document the history and physical exam.

(6) If a patient is on ambulatory outpatient care status for a year, at the time of the next visit the patient will be given an annual physical or mental status examination, or as applicable, an assessment of the condition for which care is authorized. An assessment as to whether continued care on an ambulatory or outpatient basis is required, and will be documented following the diagnosis.

g. Interdisciplinary Treatment Plan:

(1) An initial treatment plan, documented by the licensed independent practitioner as part of the physical examination will be established on all patients within 48 hours of admission on acute inpatient care units. Treatment plans should specify the diagnostic and therapeutic activities that will be undertaken in regard to each of the patient problems and the specific staff members responsible for carrying out these activities, if other than the author. A discharge plan should also be a component of the treatment plan. Revisions will be undertaken as necessary.

(2) Each inpatient record will contain a nursing admission assessment within eight (8) hours of admission.

(3) Long-Term Care (NHCUC) will formulate a comprehensive assessment within 14 days of admission, which indicates a multidisciplinary approach to the patient's care. A comprehensive care plan will be formulated within seven days of completion of the comprehensive assessment.

h. Laboratory and Imaging Reports:

(1) Order entry for laboratory tests shall be completed in full; clearly identifying: patient, location, requester, test date and special handling. Only authorized individuals (as defined by their privileges or scope of practice) will enter requests for laboratory tests.

(2) Requests for tissue examination must contain the preoperative diagnosis and a brief clinical history, which

includes the reason for the examination.

(3) Requests for imaging services must be entered electronically and contain a complete reason for the exam.

(4) Signature, initials, or electronic signature must authenticate all reports.

(5) Reports of nuclear medicine tests are entered electronically. They will reflect identity, date, amount of radiopharmaceutical agents used, and specific preparation of the patient and findings.

i. Progress Notes

(1) Every episode of clinical care will be documented by the respective clinical staff as defined by their privileges or scope of practice in a progress note. The admission progress note will include the type of admission (i.e. elective, emergency), chief complaint, a brief summary of the patient's condition, references to any previous related admissions and a tentative diagnosis.

(2) Progress notes will be entered into CPRS, whenever possible, by Medical Staff, House Staff, Registered Nurses, Licensed Practical Nurses, Rehabilitative Medicine Therapists, Dietitians, Social Workers, Psychologists, Pharmacists, Clinical Technicians and other qualified members of the health care team to facilitate a multidisciplinary cooperation and approach to care. Progress notes must be dated and identified by the name and profession of the individual making the entry.

(3) Progress notes will give a pertinent chronological report of the patient's course, changes in condition, response to medications and plans for the results of treatment particularly relative to diagnostic assessment and therapeutic efforts.

(4) When a patient is transferred between specialties, an interservice transfer note will be entered in the electronic medical record which will give a concrete recapitulation of the hospital course to date, include the indications for the transfer, and be developed to assist the receiving unit. This note will be documented prior to the patient's transfer. Transfer summaries will be dictated between services (Medical, Surgical and Psychiatry) for any length of stay within that service greater than three days. Nursing transfer notes will be documented by the transferring and receiving units and shall note the patient's response to care and status.(5) Frequency of Attending Staff Progress Notes:

(a) Initial note within 24 hours.

(b) Daily for patients within an Intensive Care Unit

(c) Weekly (once every seven calendar days) for acute care hospitalization or more frequently based on patient's change in condition.

(d) Monthly (once every 30 days) for extended care hospitalization (NHCU).

(6) Any unsigned and/or un-cosigned note by a medical student, nursing student, or ancillary healthcare student will be administratively deleted by Health Information Management Department after 30 days.

j. Discharge Progress Notes/Discharge Instructions:

(1) A discharge progress note will be completed for each period of hospitalization. This note will contain date and type of discharge, diagnoses, discharge medications, recommendations relative to diet, exercise, limit of disability, condition on discharge (to include character of surgical wound, if appropriate), place of disposition, recommendations for follow up and patient education. A copy of the discharge instructions will be given to the patient and/or significant other. A formal (dictated) narrative summary does not substitute for a discharge progress note.

(2) When preprinted instructions are given to the patient or designee, the record should so indicate.

(3) In cases involving death, the time and date when the patient expired, and the events leading to the death must be recorded by the physician. Any patient leaving against medical advice will have a final progress note written by a physician indicating the reason for leaving and any special disposition arrangements. The deceased shall be pronounced dead by a physician.

k. Supervision of House Staff: There shall be sufficient evidence as documented in the medical record, to substantiate active participation in, and supervision of, the patient's care by the attending/primary care physician. The frequency of such notes shall be determined by the nature of the patient's condition, the likelihood of changes in the treatment plan, and the complexity of the care and experience of the trainee being supervised. For example, the attending/primary care physician will place appropriate documentation in the patient's medical record within 24 hours of admission, at the time of any significant change in the clinical course or therapeutic plan, or prior to any invasive procedure.

l. Consultations:

(1) Consultation requests will be entered electronically by the service requesting the consultation. The request will include a brief description of the patient's condition, reason for the consultation, other information of value (such as

medication which may affect the condition being evaluated) and the electronic signature of the requesting physician, dentist, podiatrist, or other allied healthcare professionals within their scope of practice.

(2) The consultation report will contain an electronically entered opinion by the consultant (based on examination of the patient and his/her record), date of the consult and electronic signature.

(3) Consultations should be performed as soon as possible following the request, to ensure proper treatment of the patient and to prevent prolongation of hospital stay. Emergency consultations should be requested as a “stat consultation”. These consultations should be completed as soon as possible depending on urgency. If the consult has been cancelled, it needs to be closed out in the consult tracking system.

(4) Any consultations performed by a nurse practitioner or physician assistant must be co-signed by a staff physician. Enterostomal consults do not require co-signature.

m. Behavioral Health Special Treatment Procedures: In Behavioral Health, special justification and documentation is required for the use of:

(1) Electro-convulsive and other forms of convulsive therapy.

(2) Psychosurgery or other surgical procedures to alter or intervene in an emotional, mental, or behavioral disorder.

(3) Behavior modification procedures that use aversive conditioning.

n. Anesthesia: pre-anesthesia evaluation will be completed by the Anesthesiologist or providers who administer moderate sedation, who will document pertinent information relative to choice of anesthesia (i.e., general, spinal, regional, etc.), surgical procedure anticipated, previous drug history, other anesthetic experiences and any potential anesthetic problems.

(2) A post-anesthesia note will be written by the Anesthesiologist and will include the patient’s level of consciousness on entering and leaving the recovery room, vital signs and when used, the status of infusions, surgical dressings, tubes, catheters, and drains. The medical record will document the name of the licensed practitioner responsible for the patient’s release from the recovery room or clearly document the discharge criteria used to determine release.

o. Operations:

(1) Medical records will document all aspects of a surgical patient’s preoperative, operative and postoperative care. The record will contain preoperative diagnosis, a complete description of the surgical procedure and findings, the names of all the practitioners involved in the patient’s care, the postoperative course, evidence of the patient’s readiness for discharge from the postanesthesia care, and details of the discharge.

(2) All procedures requiring anesthesia and/or conscious sedation will require a preoperative and postoperative assessment note by the staff practitioner or resident. Staff practitioners will be responsible for authorizing the performance of such procedures, and such procedures should only be performed with the explicit approval of the staff practitioner.

(3) An operative report will be fully dictated by the operating practitioner immediately after surgery before the patient is transferred to the next level of care. The report will be carefully read and signed by the supervising practitioner. It should contain the indication for the procedure, operative findings, the technical procedure used, specimens removed, estimated blood loss, postoperative diagnosis and the names of the attending surgeon, primary surgeon and assistants.

(4) Postoperative documentation will include: vital signs and level of consciousness, medications and blood and blood components, any unusual events or postoperative complications, including blood transfusion reactions, and the management of such events.

(5) Detailed reports of diagnostic and therapeutic procedures not performed in the operating room will be documented in the progress notes and will contain: name of procedure, person performing procedure, details of performance, major findings and conclusions, whether or not tissue was removed, any complications, signature, title, and date.

(6) The responsible nurse that was present during the surgery will enter the Nurse Intra-Operative Circulating Report into the computer. A hard copy will be printed and signed for the paper record. The Recovery Room nursing care will be documented on the Recovery Room record.

(7) When the procedural evaluation is completed as part of an outpatient preadmission process, the staff practitioner’s pre-procedural note in the outpatient’s record, or on a preadmission form, may be regarded as valid for a period of 30 days for patients with stable diseases or conditions, or undergoing elective procedures.

p. Informed Consent: All patient records will include evidence of informed consent for any procedure, treatment, research/experimental protocol and investigational drug series for which it is appropriate. Informed consent will be obtained in accordance with M-3, Pt. 1, Ch. 9, VHA Handbook 1004.1, and current Joint Commission regulations

and VISN policies.

q. Doctors Orders:

- (1) All orders for treatment will be documented appropriately, wherever possible, utilizing the order/entry capabilities of VISTA. Medical students may write and sign orders; provided a physician/dentist immediately countersigns the orders. All orders must contain the date and time the order was written. The attending physician/dentist is responsible for any unsigned orders.
- (2) Medications must be identified as to name, strength, route of administration, frequency and the conditions under which medications shall be given. Through CPRS, the responsible physician/dentist will enter the orders.
- (3) There shall be an automatic stop order for all narcotics, antibiotics, and anticoagulants, unless the physician's/dentist's order for such a drug reflects a definitive number of doses or a specific period of time the drug is to be administered. No stop orders will be exercised without communication with the physician/dentist.
- (4) Medication orders must be reviewed and rewritten following surgical procedures, which require general anesthesia, when a patient is transferred between services/specialties or is transferred to a critical care unit.
- (5) Verbal orders must be authenticated by a physician's signature including date and time the order is signed. Nurse practitioners and physician assistants may write orders according to their particular privileges or scope of practice. Countersignature is also dictated by their privileges or scope of practice. Verbal orders may be accepted by licensed pharmacists, registered nurses, staff respiratory therapists, registered dietitians, physical therapists, and occupational therapists. The nature of the order (policy, verbal, or telephonic) must also be documented. Please refer to Policy Memorandum No. CS/118-13, Verbal/Telephonic Diagnostic and Therapeutic Orders.
- (6) An order must be written to admit, to discharge, or to transfer a patient between wards, or between services, or between Medical Staff members.
- (7) On Long Term Care programs, orders will be reviewed monthly and rewritten quarterly. The monthly review may be documented by simply writing "continue" or "renew" provided no changes are made to the orders in the paper record or CPRS.
- (8) Use of seclusion and restraint requires a time-limited order to be written by a physician. The order must be dated and timed. PRN orders must never be given for the use of restraint and seclusion.
 - (a) Restraint for Med-Surg reasons is upon physician order. If physician is not available, restraint use is initiated by a registered nurse based on an appropriate assessment of the patient. The physician is notified within 12 hours of the initiation of restraint and a verbal or written order is obtained. A written order, based on an examination of the patient by the physician, is entered into the patient's medical record within 24 hours of the initiation of restraint. Continued use of restraint requires a new order every 24 hours.
 - (b) Restraint for Behavioral Management reasons is upon physician order. If physician is not available, restraint use is initiated by a registered nurse based on an appropriate assessment of the patient. Physician must see patient within one hour of initiation of the restraint. Restraint order is limited to four hours for adults within on-going evaluation.
- (9) Medications administered in error and adverse drug reactions shall be documented and reported to the physician.
- (10) Upon physician authentication (signature) of the order, VISTA software will automatically print a copy of the Doctor's Orders on a printer reserved for medical record documents on the ward. The health unit coordinator will be responsible for filing orders.
- (11) An order must be written to admit a patient to an Observation Stay. The order must state "Admit to Observation" or "Admit to OBS." The medical necessity for the observation stay must be clearly documented.

r. Respiratory: Orders for respiratory care shall specify the type, frequency and duration of treatment, any medications, the type of diluents, oxygen concentration and the diagnosis. All administered therapy shall be recorded and include: type, date and time, effects, any adverse reactions and patient instructions. The need for long-term oxygen therapy shall be adequately documented, preferably based on arterial blood gas results.

s. Do Not Resuscitate (DNR)

- (1) The DNR order in the patient's medical record must be written by the attending physician or by the medical or surgical resident, co-signed by the attending physician. Nurses **MAY NOT** take verbal orders for DNR.
- (2) DNR orders are not subject to renewal, and are considered to be in effect indefinitely for the duration of the current admission, unless specifically revoked by the responsible physician. An accompanying progress note will include, at a minimum, diagnosis, prognosis, patient's wishes when known, family wishes, and consensual decision and recommendations of the treating team. The note should include appropriate dates and times and any applicable documentation of "informed consent" or patient's wishes for confidentiality from family. The attending physician will be the only one to enter the note in the patient's record.

t. Advance Directive: If the patient completes an advance directive, a copy will be filed in the medical record. The

paper medical record will be labeled to reflect that the advance directive is on file. The ward or clinic's staff will be responsible for placing an Alert Progress Note in the patient's electronic medical record.

u. Autopsies: Preliminary or provisional anatomical diagnoses will be documented within 72 hours. Final protocols will be completed, signed and properly filed within 30 days in routine cases, or three (3) months in complicated cases.

v. Adjudication: When requested for adjudication purposes, a 21-day certificate will be completed and will list the diagnosis responsible for the patient's inpatient stay. The discharge summary should indicate the patient's competency to handle VA funds.

w. Photographs: The medical record will document the taking of any pictures, films, etc., by written consent. All media are considered part of the medical record and therefore subject to the Privacy Act and all other confidentiality regulations. This applies to all media whether taken by Medical Media or other staff members.

x. Hospital Based Home Care:

(1) There shall be a written plan of care for all hospital based primary care patients that is updated no less than every 60 days and contains:

- (a) All pertinent diagnoses;
- (b) Prognosis including short and long-term objectives;
- (c) Type and frequency of service required;
- (d) Functional limitations of patient and activities permitted;
- (e) Required safety measures; and
- (f) Sociopsychological needs.

(2) The following additional information will be recorded:

- (a) Designation of primary care physicians;
- (b) Household composition including person assuming responsibility for care;
- (c) Suitability of residence for provision of care;
- (d) Progress Note for each visit; and
- (e) Summary.

5. **RESPONSIBILITIES:**

a. The Medical Center Director and Chief of Staff Members are responsible for ensuring that processes are in place for the use of not only the paper Consolidated Health Record (CHR) but the Computerized Patient Record System (CPRS) and that these processes are available and functional in a timely and accurate fashion. Data entry may be accomplished by various methods depending on the state of electronic evolution, finances, staffing levels, etc.

b. Health Information Management Department staff are responsible for tracking and monitoring issues as they relate to patient medical record documents, paper and electronic. HIMD staff members have continued responsibility for the amendment of documents that have been entered in error. It is the responsibility of the Health Information Management Department to ensure that medical records of patients are available for patient treatment, are properly completed, and maintained in compliance with standards established by VHA Headquarters and this medical center.

c. Clinical Informatics is responsible for ensuring that software package parameters are set up in such a way as to facilitate ease and accuracy of documentation for the end user. Clinical Application Coordinators are responsible for coordinating and assuring the necessary training is provided to all staff entering and gathering patient information.

d. All medical center staff who utilize CPRS are responsible for maintaining, improving, and advancing their electronic skill levels. Employees are responsible for ensuring that documentation gathered and entered by them is accurate, appropriate and completed in a timely fashion. They are responsible for reporting any discrepancies, identified problems, etc. All staff members are responsible for following security and confidentiality standards described by the Network/Local security and confidentiality policies.

e. It is the responsibility of the clinical staff to document evidence of the patient's medical evaluation, treatment and change in conditions during the patient's hospitalization, or during an outpatient or emergency visit to the medical center.

6. REFERENCES: M-1, Part I, Chapter 5; M-1, Part I, Chapter 9; M-3, Part 1, Chapter 9, M-2, Part 1, Chapter 30, VA Medical Center Bylaws and Rules and Regulations; RCS 10-1; Policy Memorandums No. IS/IRMD-7 and 12, FMS/136-30, and CS/118-13, Stedman's Medical Dictionary, VHA Handbook 14001, and current Joint Commission Accreditation Manual for Hospitals.

7. RESCISSIONS: Policy Memorandum Numbers FMS/136-49, Medical Record Management, dated March 1, 2000; 11-65, Computerized Patient Record System (CPRS); and FMS/136-22, Approved Abbreviations for Medical Record Documentation,

HOSPITAL SUMMARY

1. The hospital summary will be used to document a patient's discharge from the medical center.
2. The hospital summary shall be entered into the patient's record within a reasonable period of time, not to exceed thirty (30) days following discharge.
3. The attending physician will review the summary, make appropriate edits and indicate approval by signature.
4. To promote continuity of care, the physician will dictate the summary prior to transfer between the hospital and the Nursing Home Care Unit. A dictated discharge summary for any interward transfers between acute care treating specialties (Medical, Surgical, Psychiatry, and Intensive Care Units) with an average length of stay greater than three days will be required.
5. Summaries will be prepared as follows:
 - a. Diagnosis: List the principal diagnosis (i.e., that condition established after study to be chiefly responsible for the admission of the patient to the hospital for care) then, in order of clinical importance, list all other diagnoses for which treatment was given. Diagnoses will include post-operative complications or infections and drug or serum reactions. All diagnoses should include a site and etiology, when applicable, and will be stated in accordance with the latest edition of International Classifications of Diseases Coding Manual (ICD-9). Diagnoses will be stated in full without symbols/abbreviations.
 - b. Psychiatric Diagnoses: Psychiatric diagnoses will be limited to conditions under treatment or to active conditions previously diagnosed and will be included only when they directly effect the patient's condition, medical care, or length of stay. Such diagnoses will be stated in accordance with the latest edition of Diagnostic and Statistical Manual of Mental Disorders.
 - c. Observation and Examination Cases: The medical staff is responsible for observation and examination cases and will record findings adequate for both professional use and adjudication purposes. Diagnoses appearing on the Hospital Summary must reflect the condition for which the patient was observed.
9. Operations: The latest edition of ICD-9 Procedural Index will be used for recording operations and surgical procedures, which will be stated in full without symbols or abbreviations. The site involved and the procedures performed will be stated. The listing will include all operations, diagnostic and therapeutic procedures and the date performed. All procedures should be documented in the text of the summary.
10. Narrative Summary will include:
 - a. Reason for admission (Principal diagnosis – The condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital)
 - b. Pertinent past history.
 - c. Pertinent points in review of systems (including allergies or drug sensitivities).
 - d. Pertinent findings of laboratory and radiological data.
 - e. Pertinent findings of physical examination, particularly abnormalities.
 - f. Brief course in hospital stay to include treatment received and condition on discharge. Condition must be more specific than "improved" and should permit measurable comparison with condition on admission.
 - g. Condition of wound, if applicable.
 - h. Place of disposition, i.e., home, nursing home, etc.
 - i. Discharge instructions to patient or responsible other to include:
 - (1) Information regarding condition or proper home care.
 - (2) Medical follow-up, if private physician, state name if possible.
 - (3) Medications on discharge.
 - (4) Diet instructions.
 - (5) Specific date to return to work, or if retired, or to be determined at a later date, please state.
 - j. If the patient has a psychosis or an organic mental impairment, there must also be a statement regarding competency to handle VA funds. The patient's functional assessment according to GAF rating scale should also be included with diagnostic and "Axis assignment."

CLINICIAN DOCUMENTATION QUICK REFERENCE

Document	Timeliness of Completion	Documentation Components Required
Outpatient Visit	Immediately following visit	- Will include date and clinic title, vital signs, chief complaint, relevant history of illness or injury, clinical observations, results of treatment, reports of tests, procedures performed, doctors orders for medication, tests, therapy, work/activity limitations if any, diet, follow-up instructions, level of understanding and signature and title of provider.
Problem List	Initiated by third ambulatory visit. Required on all inpatient stays.	Initiated by the third visit and will contain: 1. Known significant diagnosis; 2. Procedures performed; 3. Drug Allergies; 4. Adverse Reactions.
History and Physical	Within 24 hours of admission.	Will be completed within 24 hours of admission for acute medical and 48 hours for NHCU. On patients readmitted within 30 days, an interval H&P will suffice as long as it is professionally determined that such an exam, in conjunction with the prior examination, is adequate to reflect a comprehensive current physical assessment.
Assessment Treatment Plan	Within 48 hours of admission 14 days for NHCU 21 days for NHCU care plan	Physician will establish initial treatment plan on all patients within 24 hrs as part of physical exam. Will address diagnostic and therapeutic plans for each problem, patient education, and discharge plans. - Nursing assessment within 8 hours of admission.
Laboratory and Radiology Reports	As needed.	Tissue Exams must contain the preoperative diagnosis and a brief clinical history, including reason for the exam. - Radiology request must state reason for the exam.
Nuclear Medicine	As needed	- Will reflect identity, date, amount of radiopharmaceutical agents used, and any specific preparation of the patient and findings.
Progress Notes	Immediately following ambulatory visit. Frequency of inpatient depends largely on the complexity of the patient, competency of staff, etc.	Will give pertinent chronological report of the patient's course, changes in condition, response to medications and plans for the results of treatment particularly relative to diagnostic assessment and therapeutic efforts. - Interservice transfer note will give a concrete recapitulation of the hospital course to date, including the indications for the transfer, and be developed to assist the receiving unit.
Discharge Progress Notes/ Instruction	Prior to discharge	Will contain type of discharge, diagnoses, discharge medications, recommendations relative to diet, exercise, limit of disability, condition on discharge, place of disposition, recommendations for follow up and patient education. Copy given to patient or designee. - Death cases will include time and date when patient expired, and the events leading to the death must be recorded by the physician.
Consults	Performed as soon as possible following the request.	Will include a brief description of the patient's condition, reason for the consultation, other information of value (such as medication which may affect the condition being evaluated) and signature of requesting physician. - Emergency consults will be requested as "stat" and completed as soon as possible depending on the urgency.
Anesthesia	Immediately before or after procedure.	Pre-anesthesia notes will document pertinent information relevant to the choice of anesthesia, surgical procedure anticipated, previous drug

Document	Timeliness of Completion	Documentation Components Required
		<p>history, other anesthetic experiences and any potential anesthetic problems.</p> <p>- Post-anesthesia notes will document level of consciousness on entering and leaving the recovery room, vital signs and when used, the status of infusions, surgical dressings, tubes, catheters, and drains. Also, the name of the licensed practitioner who released the patient from the recovery area or the specific criteria used to determine the release.</p>
Operative Notes and Reports	Immediately following procedure or surgical episode	<p>Will contain preoperative diagnosis, a complete description of the surgical procedure and findings, the names of all the practitioners involved in the patient's care, the postoperative course, evidence of the patient's readiness for discharge from postanesthesia care, and details of the discharge.</p> <p>An operative report will contain the indication for the procedure, operative findings, the technical procedure used, specimens removed, postoperative diagnosis and the names of the attending surgeon, primary surgeon and assistants.</p> <p>A postoperative note will include: vital signs and level of consciousness, medications and blood and blood components, any unusual events or postoperative complications, including blood transfusion reactions, and the management of such events.</p> <p>Will be entered in all cases where there is a filing or transcription delay in order to provide pertinent information for use by any practitioner who must attend the patient.</p>
Dr's Orders	As needed. Discharge order before patient is discharged.	<p>Orders for medications should include name, strength, route of administration and frequency.</p> <p>Medication orders will be reviewed and renewed following any surgical procedure requiring general anesthesia.</p> <p>Verbal orders will be authenticated by a physician's signature including date and time the order is signed.</p> <p>NHCU orders will be reviewed monthly.</p> <p>Nurse practitioners and physician assistants will write orders in accordance with their scope of practice.</p> <p>PRN orders may not be used for restraint and seclusion.</p>
DNR Order	As needed.	<p>Must be written by the attending physician.</p> <p>Nurses may not take verbal orders for DNR.</p> <p>Accompanying progress note done by physician will include diagnosis, prognosis, patient's wishes when known, family wishes, and consensual decision and recommendations of the treatment team.</p>
Autopsies	Provisional within 72 hours, final 30 days.	<p>Preliminary or provisional report within 72 hours.</p> <p>Final filed within 30 days, or 90 if complicated case.</p>

CORRECTION TO MEDICAL RECORD DOCUMENTATIO

1. PAPER RECORD:

- If an error is made and correction is necessary to an entry within the paper record, the authenticator will draw a single line through each line of the inaccurate material.
- The entry should be legible.
- The person correcting the error should date and sign the correction (first initial and last name). Add a note, in the margin if necessary, stating why the entry is being corrected.
- Enter the correct information in chronological order.
- Indicate which entry it is replacing if the re-corrected entry does not immediately follow the error.
- Record the date, time, and sign the new entry.

g. If there is any doubt as to the subsequent admissibility of the entry, it is a good practice to have a professional colleague witness the correction process. The witnessing need not be done for every minor error, but rather reserved for significant errors.

2. ELECTRONIC RECORD:

a. All clinicians should review computerized patient records before affixing their electronic signature to a document to assure information is correct. Notes are occasionally entered into VISTA by practitioners for the wrong patient, wrong clinic visits, etc. These notes should be appended immediately upon discovery with directions to the viewer to disregard their contents.

b. To further prevent the ensuing provision of patient care by other practitioners based on erroneously entered clinical information, the notes will be removed from active view but NOT DELETED from the medical record. To preserve the clinical record in full, erroneously entered notes will NOT BE DELETED from VISTA.

c. The author may copy the note into the correct patient's record or re-enter it.

d. The author will append the note with information identifying it as erroneously entered and directing the viewer to disregard its contents.

e. The author will notify the Clinical Application Coordinators by sending an e-mail message in VISTA to G.CAC. For accurate identification of the note requiring action, the message must contain:

- (1) Name of patient under whom the note was entered,
- (2) Last four of patient's SSN,
- (3) Full progress note title of the erroneously entered note,
- (4) Date and time of the erroneously entered note,
- (5) Author, if other than the message sender, and
- (6) Reason note is to be removed from view.

f. The Clinical Application Coordinators will change the title of the note to ERRONEOUS NOTE.

g. The body of the note, the author and date and time note was created will remain unchanged but will be removed from active use by VISTA users.

DEVELOPMENT OF NEW/REVISED OVERPRINTED FORMS

1. The initiating department will prepare a sample form for approval by the Chair or Assistant Administrator of that department and obtain concurrence by the Chair or Assistant Administrator of any other department involved in the completion of new form.

2. Approval/concurrence signifies the intent of the overprinted form is clear, can be implemented, does not conflict with accepted practice of their discipline, and is in keeping with the accepted standards.

3. The form, documentation of concurrence, and completed Reproduction Request (VA Form 3011), will be forwarded to the Administrator, Informatics Services (IS) for compliance review and approval in conjunction with Health Information Management Department (IS/HIMD). If this is a revision of a prior existing form, a copy of the old form must also be included.

4. The Chair or Assistant Administrator will assess form for inclusion as a computerized form in CPRS and ensure that such a form does not already exist. If appropriate, the requesting department will be contacted when the form is activated in CPRS.

5. Forms that cannot be computerized will be forwarded to Office Operations Section (RFMS/136C2) for reproduction authorization and assignment of a form number.

6. If the overprint is deemed inappropriate, or a duplication of an existing form, the individual submitting the request will be contacted by Health Information Management Department personnel for resolution.

PROTECTION OF MEDICAL RECORDS FROM WATER DAMAGE

Paper medical records may be subjected to widespread or localized damage from rising water, as in the case of flood or broken water mains, or falling water, such as from leaking or broken pipes or fire sprinkler activation. Following such an emergency, water-damaged records require special attention to restore them to their original state. Even though it is the policy of this medical center to maintain medical records in such a way as to prevent any form of water damage, this appendix details procedure to follow in the event of such an occurrence.

PROCEDURE:

a. Rising Water: Widespread damage may be caused to medical records housed on the ground level due to flooding during or following extreme rain conditions or broken water mains.

- (1) Medical records will be maintained in an area that is unlikely to flood or be subjected to damage from water.
- (2) Upon notification that it is likely that the surrounding vicinity will be subject to flooding, and the medical record file room is likely to be flooded:
 - (a) All efforts within human possibility will be made to move records to an area that is unlikely to be subjected to water damage. Personnel will not be subjected to conditions that would expose them to danger to their life or health.
 - (b) All electronic equipment will be turned off. Equipment will be moved to a dry location that is unlikely to be affected by water damage.
 - (c) To protect the confidentiality of medical records during a flooding crisis, the area will be secured and only authorized personnel will have access to the area.
 - (d) Floodwaters are often mixed with sewage, animal waste, fertilizers and/or industrial waste, and should be considered a biohazard. Employees will not be allowed to re-enter the flooded area until all freestanding water has been removed and the area is thoroughly cleaned by the Environmental Management Department.
- b. Falling Water: Widespread or localized damage may be caused to medical records due to a leaking or burst pipe or malfunctioning fire sprinkler.
 - (1) Paper medical records will be maintained in file shelving units that have a canopy top. Paper medical records will not be stored on top of filing cabinets or on the floor.
 - (2) Upon notification of a leak or malfunctioning fire sprinkler:
 - (a) Shelving units in danger will be covered with plastic. A supply of plastic sheeting will be obtained from the Engineering Department. After the threat of water damage has passed, all plastic will be removed.
 - (b) Computer equipment and any other machinery or furniture may also be covered with plastic to minimize damage, as time permits after the threat to medical records has been minimized.
 - (c) Environmental Management Department will be contacted to supply appropriate receptacles to catch water, absorbent materials to soak up water, vacuum water, and thoroughly clean and dry the affected area.
 - c. Recovery/Restoration: Should paper medical records sustain water damage, a quick response will be required to recover their contents intact. Paper records left wet for any significant length of time are at risk of unrecoverable damage due to disintegration, tearing, smearing, or mildew/mold growth. Depending on the volume of records involved, full recovery may be realized with a local effort only, or may require more extensive measures, such as a contract with a water damage restoration company.
 - (1) If a small quantity of records is wet from a clean water source, authorized personnel must respond immediately to:
 - (a) Carefully remove the records from the shelves and gently pat dry as much as possible;
 - (b) In a secure location, separate each record on a clean, dry, flat surface for the paper to thoroughly dry;
 - (c) Print any electronic documentation that may be required to reconstruct damaged pages;
 - (d) Reassemble each record in the approved filing sequence;
 - (e) Thoroughly dry the file shelves; and
 - (f) Replace the records on the shelves in the correct terminal digit order.
 - (2) If a large quantity of records is wet or if the water source may be contaminated, such as in the case of flood water:
 - (a) A water damage restoration company should be contacted immediately upon discovering the damage and an emergency purchase order be secured for their services.
 - (b) Any contract for water damage restoration services should specify the method of recovery, the time that will elapse between acquisition and return of the records, and safeguards against breaches in confidentiality.

SAMPLE POLICY RELEASE OF INFORMATION ON PATIENTS

1. **PURPOSE**: To establish policy and procedures for the release of patient health information from VA health records. The health record consists of the electronic medical record and the paper record, combined and is also known as the legal health record. A health record can be comprised of two divisions: medical record and administrative record. The privacy of patient information stored in any media shall be protected in accordance with,

but not limited to, the Privacy Act of 1974, Freedom of Information Act (FOIA), Computer Security Act of 1987, OMB Circulars A-123 and A-130, VHA Directive 6210, Health Insurance Portability and Accountability Act of 1996 (HIPAA), 38 USC, Section 5705 (Confidentiality of QM documents), and Joint Commission standards

2. **POLICY:**

- a. The health record is the property of the medical center and is maintained for the benefit of the patient and authorized personnel in the performance of their duties. Health records may be removed from the jurisdiction of the Department of Veterans Affairs only in accordance with a properly executed court order, subpoena, or statute
- b. Health records are confidential in nature. Information therein will not be accessible to, or discussed with, unauthorized persons. It is the responsibility of all personnel to safeguard the information in the medical record against loss, defacement, tampering, or use by unauthorized persons
- c. Written requests for release of information from veteran health records will be responded to by Health Information Management Department (HIMD). Written requests for release of information from employee personnel records will be responded to by Human Resource Management Service (HRMS)
- d. All patients who require a release of medical information should be referred to Release of Information, Building 1, Room E104 (front counter) or ext. 2619. The medical center staff may assist the veteran with completion of any forms or portions thereof that the patient is personally expected to complete. VA health care providers may provide statements and opinions concerning the "possible cause(s)" of an existing medical condition for disability claims purposes. The veteran patient must be informed that decisions concerning VA compensation and/or pension benefits are decided by VA regional office adjudication officials based upon the law, regulations, and the totality of medical evidence pertaining to the disability claimed, and not controlled by the physician providing the veteran's care or the medical facility furnishing treatment.
- e. An accounting of disclosed information is required for all information released from health records to any third party whether verbally, in person, or in writing. An accounting is not required when disclosure is to VA employees who have a need for the information in the performance of their official duties, when disclosure is made under the FOIA, or to the patient.
- f. When information is released in a personal or telephone contact by any member of the staff, a Report of Contact, VA Form 119, should be prepared, noting the date of disclosure, nature, and purpose of disclosure and name and address of the person or agency to whom the disclosure was made with signature of staff member making the disclosure. The form should be sent to Health Information Management, Release of Information (HIMD), for proper accounting of the disclosure. The Report of Contact will be filed in the patient's administrative record along with the appropriate signed authorization form, if applicable.
- g. Prior to the release of information, the written authorization of the patient, court-appointed legal guardian, or an individual authorized in writing by the patient (or the patient's legal guardian) to act in the patient's behalf is required. The authorization (in blue or black ink) will include the following:
 - (1) Patient's name and social security number
 - (2) Made out to the Department of Veterans Affairs
 - (3) Name and address of agency, organization or individual to whom the information is to be released
 - (4) Type and extent of information (release of information for substance abuse, sickle cell anemia, or HIV must be clearly indicated)
 - (5) Periods or dates of treatment involved, a blanket authorization is not acceptable
 - (6) Purpose for which information is to be used
 - (7) Signature of patient (or person authorized to request release)
 - (8) Date signed
 - (9) Notice that authorization is valid only for a specified period of time which may not exceed six months
 - (10) All authorizations/releases pertaining to drug, alcohol, sickle cell anemia, or HIV treatment require an expiration date, condition or event
- h. Authorization may be on VA Form 70-3288, Request for and Consent to Release of Information from Claimant's Records; or VA Form 10-5345, Request for and Consent to Release of Drug Abuse, Alcoholism or Alcohol Abuse,

HIV or Sickle Cell Anemia Information from Medical Records. These forms are not required as long as all information is included as noted above

i. Information concerning treatment which is subsequent to the date of the authorization will not be disclosed.

j. Written authorization for release of information is valid when obtained from:

- (1) An adult patient
- (2) A minor patient on active military duty
- (3) A minor who may give authorization for treatment under state law
- (4) The following when a patient is legally incompetent or unable to give his/her authorization for medical reasons:
 - (a) A legally-constituted guardian or a representative as specifically indicated in a "Power of Attorney," assigning health care decision-making powers
 - (b) Veteran's spouse or adult children;
 - (c) Parents, grandparents, or adult sibling;
 - (d) Aunts or uncles;
 - (e) Nieces or nephews; and

3. **PROCEDURES**

a. Releases that can be made upon a written or verbal request without the authorization of the patient are listed below.

(1) To personnel within the VA system having a "need to know" in connection with their duties. A verbal request is acceptable.

(2) Representatives of accredited service organizations: Notices of admission, location, transfer, and disposition of patients at this medical center. Patients cannot be identified as to participation in drug and/or alcohol rehabilitation programs or treatment.

(3) Members of Congress: When acting in their official capacity at the request of the VA beneficiary or acting as a member of a congressional committee

(4) State of Arizona County Health Departments: All diseases required by law to be reported. Letter of request/authority on file

(5) Medical Examiner: Necessary medical information when a patient or former patient has expired. A verbal request is acceptable

(6) All Branches of Military Service: Information requested on active duty personnel may be released

(7) Funeral Directors: On deceased veterans the following information, if available, may be released. A verbal request is acceptable.

- (a) Name and address of next-of-kin;
- (b) Service number, branch of service, rank or grade;
- (c) Character of discharge from military service;
- (d) Date and place of birth;
- (e) Social Security and VA claim numbers; and
- (f) VA Regional Office of jurisdiction.

(8) Information to Law Enforcement Agencies: All gunshot wounds and related conditions are to be reported immediately. Names and addresses of veterans and their dependents may be released to law enforcement agencies when VA files contain information pertinent to the enforcement activities of the agency. This does not, however, allow any disclosure from drug and alcohol treatment records. A letter of request/ authority from local agencies is on file in HIMD and Police Services. In emergency situations, information may be released with assurance that a follow-up request from the head of the agency will be sent within five (5) days for those agencies that do not have a letter of request/authority on file. Addresses of veterans may be released to law enforcement agencies and governmental agencies on the basis of a written request for the purpose of locating a parent who has deserted his/her child or children. The address will not be released for the purpose of locating a parent who has deserted his/her child or children when disclosure would be harmful to the mental or physical health of the veteran or for the purpose of enforcing child support obligations. The requesting party will be advised to write to the Federal Parent Locator Service to obtain information

(9) Information may be disclosed to the Secret Service without a written request when the President's life has been threatened and is in immediate danger. Under the provision, a notification of the disclosure must be sent to the patient's last known address. Drug, alcohol, HIV, or sickle cell anemia information can be disclosed only with written authorization or by Court Order

(10) Present status and/or location of veteran (inpatient/outpatient) - A verbal request is acceptable

(a) Inpatients - The ward number may be released but the type of program or service should not be indicated; dates Of admission and discharge may be released. The type of discharge may be released unless irregular

(b) Outpatients - Outpatient status (active or inactive) may be verified only. We cannot verify future appointments dates or type of treatment

(11) Patient's Condition - A verbal request is acceptable.

(a) General Public - A report such as condition improved, condition unchanged, etc., may be released; personal and medical information will not be released

(b) Next-of-kin (and/or the person with whom the patient has a meaningful relationship) - To the extent necessary and on a need-to-know basis in keeping with good medical/ethical practices, information relating to the patient's condition may be released. This type of release permits staff to advise them of changes in the patient's condition, to discuss the patient's medical history, which will assist in the treatment plan and provide for the patient's social, dietary, and other needs and to plan for discharge. It permits the staff to function to protect the patient's interest when the patient is comatose or otherwise incapacitated to act in his/her own behalf in instances where a guardian has not been appointed

(13) Commitment - Status of commitment and/or date of expiration can be given. A verbal request is acceptable.

All medical information required under applicable state laws incident to commitment or restoration proceedings of a patient will be furnished. A physician who gives testimony in commitment or restoration proceedings of a patient may use the patient's medical record to refresh his/her memory. When directed by the Court, copies of material contained in the record will be furnished

(14) Emergency Treatment - A verbal request is acceptable. Information can be released to non-VA practitioners and institutions for treatment under emergent conditions. Information regarding drug, alcohol, HIV, and/or sickle cell anemia may be released to medical personnel to the extent necessary to meet a bona fide medical emergency. The staff member responsible for the release of information shall enter all pertinent details of the transaction on VA Form 119, Report of Contact, or VA Form 70-5572, Accounting of Records/Information Disclosure Under Privacy Act, including at least the following:

(a) The date the information was released

(b) The person to whom the information was released

(c) The reason the information was released

(d) The reason written authorization could not be obtained

(e) The specific information released; an

(f) The signature of the person releasing the information. (HIMD will inform the patient or applicant by letter that the information was released as soon as possible after the release of the information.

(15) Treatment Authorized at VA Expense - Physicians, other health care providers, and non-VA institutions for authorized treatment at VA expense. After VA authorization is terminated, authorization of the patient is required

(16) American Red Cross (ARC) - Local ARC offices may request information about the diagnosis and prognosis of a hospitalized patient, life expectancy, and whether the presence of a close relative in the service is indicated.

Release of information to the ARC from the patient's record under other circumstances requires prior written authorization by the patient unless ARC holds power of attorney from the patient in connection with the development of a claim

b. Information pertaining to drug, alcohol, HIV, and/or sickle cell anemia may not be released unless specifically indicated. Sensitive records of a deceased individual may not be released unless the release is for the purpose of survivorship benefits. Written request is required unless otherwise indicated

c. Return to Work and Employability: An opinion of basic employability or unemployability will be made or released Information as to whether an impairment in function is temporary or permanent in nature which has been documented may be released.

d. Requests from News Media: All requests, whether written or verbal, are to be immediately referred to Public Relations. Information is not to be released unless so directed by that office

e. Photographs or Motion Pictures: Photographs or motion pictures of patients or their visiting friends and relatives are not permitted except with their written permission on VA Form 10-3203, Consent for Use of Picture and Voice.

Photographs or motion pictures which permit the identification of patients in drug and alcohol treatment programs may only be used to ensure delivery of the proper medical care

f. **Third Party Information:** Confidential information pertaining to the patient's family or a third party will not be released. Only information on the patient alone may be released.

Requests for Onsite Inspection of Medical Records (by anyone, including veterans): Requests for onsite inspection of medical records and requests for a copy or portion thereof are to be referred to HIMD (IS/HIMD). Requests for inspection of current inpatient records should be referred to Inpatient Care Services (ICS). Appropriate authorization should be obtained and review made of inspector's credentials

h. **Subpoenas/Depositions:** Any subpoenas/depositions received should have noted on them the date and time received, and monies received (if any). Subpoenas/depositions shall be referred to HIMD (IS/HIMD) for review and coordination. If a personal appearance is required, the appropriate person will be notified. No records or individuals are to go to court in response to a subpoena without coordination through HIMD. Federal laws do not always allow the VA to respond to subpoenas as issued

4. **RESPONSIBILITY:** The Assistant Administrator, Medical Administration Department serves as the facility Privacy Act Officer and Records System Manager and is responsible for implementation, coordination, and administration of any and all requests for patient-related information

Medical Staff

Medical staff members, in providing patient care and carrying out their other professional responsibilities in increasingly complex organizations, are expected to actively participate and exercise professional leadership in measuring, assessing, and improving the performance of the organizations within which they practice. Medical staff leadership and participation in assessing and improving the quality of care delivered in health care organizations occurs at the various levels within the organization, including:

- Interactions between individual staff members and patients;
- Their clinical departments; and
- Among the overall organization.

Several characteristics of the professional work of medical staff members contribute to the delivery of high-quality health care:

- Providing patient care within the parameters of their professional competence, as reflected in the scope of their clinical privileges;
- Practicing within the framework of (implicit or explicit) clinically relevant and scientifically valid standards, guidelines, and criteria;
- Participating in ongoing measurement, assessment, and improvement of both clinical and nonclinical processes and the resulting patient outcomes; and
- Leading the assessment and improvement of both clinical and nonclinical processes and the resulting patient outcomes primarily dependent on individuals with clinical privileges.

Performance Improvement

The medical staff director of each department should be responsible for the ongoing, effective operation of the department and for assessing and improving its activities. Such responsibilities include not only the internal functioning, but also the integration of each department into the overall functioning of the organization.

Fulfilling these responsibilities enables the integration of the department into the overall functioning of the organization, the coordination of its services with those of other departments, and the improvement of the services it provides.

The Credentialing Process

The medical staff is responsible for a **credentialing process**. The credentialing process includes a series of activities designed to collect relevant data that will serve as the basis for decisions regarding

appointments and reappointments to the medical staff, as well as delineation of **clinical privileges** for individual members of the medical staff. Although the specific information used to make decisions regarding appointments and reappointments is at the discretion of the individual organization, the range of information used should be explicit. In addition, within, and at the discretion of, an organization, the specific information required for appointment may differ from the information required for reappointment. The required information should include data on qualifications such as licensure and training or experience, and data on actual performance that is collected and assessed initially and in an ongoing process.

The organization should establish mechanisms for organizational-specific **appointment and reappointment** of medical staff members and for granting and renewing or revising hospital-specific clinical privileges. The governing body appoints and reappoints to the medical staff and grants initial, renewed, or revised clinical privileges, based on medical staff recommendations, in accordance with the bylaws, rules and regulations, and policies of the medical staff and of the hospital.

The processes of **appointment and reappointment** to the medical staff and of **granting and renewing or revising clinical privileges** all involve using information about an applicant to decide whether the individual will be authorized to practice within the hospital and, if so, what the individual will be authorized to do within the hospital. Because these processes consider the specific hospital's characteristics, supportive resources, and staff, the processes are designed to yield organization-specific decisions. Organization-specific decisions mean that the privileges granted to an applicant are based not only on the applicant's qualifications, but also on consideration of the procedures and types of care or services that can be performed or provided within the hospital. If an applicant's training or experience is in a specific area(s), corresponding privileges can be granted only if the hospital has adequate facilities, equipment, number and types of qualified support personnel, and any necessary support services. Specialists whose services may be contracted, such as radiologists and emergency service physicians, are also granted organization-specific privileges. Because the decisions to be made, and the data on which these decisions rely, are quite similar for appointment and reappointment and for granting, renewing, and revising clinical privileges, the sequence of steps in the processes and the sources of data often overlap and may occur in unison.

The governing body grants **medical staff membership and clinical privileges**. The governing body reviews recommendations made by the medical staff executive committee, the documentation on which recommendations are based, and records of any hearings or appeals addressing adverse decisions. The governing body's decision is based on the information submitted and is guided by legitimate patient care considerations, medical staff bylaws, and rules and regulations. The governing body is not bound by the medical staff recommendations but has the ultimate authority to render a decision, adverse or not, as long as the decision is neither arbitrary, capricious, discriminatory, nor contrary to the bylaws.

Appointment or reappointment to the medical staff is not granted solely on the basis of an applicant's membership on the medical staff of another organization. Individuals in administrative positions who are on the medical staff or who seek appointment to the medical staff are appointed or reappointed through the same procedure used for all other members of the medical staff. Likewise, individuals in administrative positions who have or who seek clinical privileges achieve and maintain their clinical privileges through the same procedure used for all other individuals with delineated clinical privileges. The applicant, medical staff, and governing body adhere to the mechanism designed for hospital-specific appointment and reappointment and for granting, renewing, and revising delineated clinical privileges.

An applicant for **appointment or reappointment or clinical privileges** is informed of existing bylaws, rules and regulations, and policies regarding the application process and agrees, in writing, that he or she will be bound by them. Medical staff members and other individuals who have delineated clinical privileges are informed of any changes in existing bylaws, rules and regulations, and policies of

the medical staff and governing body. Following a positive recommendation from the Medical Staff Executive Committee on an application, the committee of the governing body reviews and evaluates the qualifications and competence of the practitioner applying for appointment, reappointment, or renewal or modification of clinical privileges and renders its decision. A positive decision by the committee results in the status or privileges requested. An applicant is usually ineligible for the expedited process if at the time of appointment, or if since the time of reappointment, any of the following has occurred:

- The applicant submits an incomplete application;
- The Medical Staff Executive Committee makes a final recommendation that is adverse or with limitation;
- There is a current challenge or a previously successful challenge to licensure or registration;
- The applicant has received an involuntary termination of medical staff membership at another organization;
- The applicant has received involuntary limitation, reduction, denial, or loss of clinical privileges; or
- There has been a final judgment adverse to the applicant in a professional liability action.

Fair Hearing and Appeal

There are mechanisms, including a fair hearing and appeal process, for addressing adverse decisions for existing medical staff members and other individuals holding clinical privileges for renewal, revocation, or revision of clinical privileges. The process for fair hearing and appeal is the same for all medical staff members. Individuals with clinical privileges who are not members of the medical staff are afforded a fair hearing and appeal process. The mechanisms for appointment or reappointment and initial granting and renewal or revision of clinical privileges are approved and implemented by the medical staff and governing body; fully documented in the medical staff bylaws, rules and regulations, and policies; and described to each applicant.

Application of Professional Criteria for Medical Staff Membership and Clinical Privileges

The mechanisms provide for professional criteria that are specified in the medical staff bylaws and uniformly applied to all applicants for medical staff membership, medical staff members, or applicants for delineated clinical privileges. These criteria constitute the basis for granting initial or continuing medical staff membership and for granting initial, renewed, or revised clinical privileges. Each clinical department makes recommendations to the medical staff regarding professional criteria for clinical privileges. The professional criteria are designed to assure the medical staff and governing body that patients will receive quality care. The professional criteria at least pertain to evidence of current licensure, relevant training or experience, current competence, and ability to perform the privileges requested.

The medical staff bylaws specify professional criteria for **medical staff membership** and for **clinical privileges**. These criteria are designed to help establish an applicant's background, current competence, and physical and mental ability to discharge patient care responsibilities. Moreover, they are designed to help assure the medical staff and governing body that patients will receive quality care. Four core criteria are essential to establishing and maintaining a qualified and competent medical staff:

- **Current licensure;**
- **Relevant training or experience;**
- **Current competence; and**
- **Ability to perform the privileges requested.**

Each **credentials file** indicates that these criteria are uniformly and individually applied. Each clinical department develops its own criteria for determining an applicant's ability to provide patient care services within the scope of clinical privileges requested. These criteria are in addition to the medical staff criteria for medical staff membership and clinical privileges. For renewing or revising clinical privileges, these criteria could include procedures performed and their outcomes and could be based on pertinent results of review of operative and other procedure(s), medication usage, blood usage, medical records,

and other performance-improvement activities, as appropriate. Additional criteria may be based on mortality rates, utilization management, meeting and committee attendance, and risk-management data. The organization may elect to add other reasonable criteria, such as the ability to provide adequate facilities and support services for the applicant and the applicant's patients; patient care needs for additional staff members with the applicant's skill and training; current evidence of adequate professional liability insurance; and the applicant's geographic location.

Appropriate documentation for each of the four core criteria includes, but is not limited to, the following:

Current licensure. There is a mechanism designed to ensure verification and documentation of current licensure for all practitioners. Licensure is verified with the primary source at the time of appointment and initial granting of clinical privileges, at reappointment or renewal or revision of clinical privileges, and at the time of expiration by a letter or computer printout obtained from the appropriate state licensing board or from any state licensing board if in a federal service. Verification of current licensure through the primary source Internet site or by telephone is also acceptable, if this verification is documented.

Relevant training or experience. At the time of appointment and initial granting of clinical privileges, the organization obtains verification of relevant training or experience from the **primary source(s)**, whenever feasible. This includes letters from professional schools (for example, medical and dental) or residency or postdoctoral programs. Information from credentials verification organizations (CVOs), such as the American Medical Association's Physician Masterfile, may also be used. Information from secondary sources, including the Federation of State Medical Boards Action Data Bank, is considered supplementary and not sufficient, by itself, to meet this condition. For applicants who have just completed training in an approved residency or postdoctoral program, a letter from the program director is sufficient. Board certification in medical specialties is confirmed by the listings in the *Official ABMS Directory of Board Certified Medical Specialists*, published by the American Board of Medical Specialists (ABMS). If the applicant or hospital uses a phrase such as "board qualified," such qualification is confirmed by a letter from the relevant ABMS specialty board.

Current competence. Current competence at the time of appointment and initial granting of clinical privileges cannot be determined on the basis of board certification or admissibility alone. Rather, it should be verified in writing by individuals personally acquainted with the applicant's professional and clinical performance, either in teaching facilities or in other organizations. The organization should obtain information directly from the primary source(s) in the form of letters from authoritative sources, which contain informed opinions on each applicant's scope and level of performance. Letters that describe the applicant's actual clinical performance in general terms, the satisfactory discharge of his or her professional obligations as a medical staff member, and his or her ethical performance are acceptable. However, ideally, letters also address at least the following two specific aspects of current competence:

For applicants in fields doing operative and other procedure(s), the types of operative procedures performed as the surgeon of record; the handling of complicated deliveries; or the skill demonstrated in performing invasive procedures, including information on appropriateness and outcomes. In the case of applicants in nonsurgical fields, the types and outcomes of medical conditions managed by the applicant as the responsible physician should be addressed.

The applicant's clinical judgment and technical skills. At the time of reappointment, current competence is determined by the results of performance-improvement activities, peer recommendations) and departmental or major clinical service recommendations.

Ability to perform privileges requested. The applicant's ability to perform privileges requested must be evaluated. This evaluation is documented in the individual's credentials file. Such documentation may include the applicant's statement that no health problems exist that could affect his or her practice; such a statement, however, must be confirmed. For an applicant for appointment or initial clinical privileges, the statement is confirmed by the director of a training program, by the chief of services or

chief of staff at another organization at which the applicant holds privileges, or by a currently licensed physician designated by the organization. For an applicant for reappointment or renewal or revision of clinical privileges, the statement is confirmed by at least a countersignature on the applicant's statement by a department director in a departmentalized organization or by the chief of staff in a nondepartmentalized organization .

For an applicant for **initial appointment** to the medical staff and for **initial granting of clinical privileges**, the organization verifies information about the applicant's licensure, specific training, experience, and current competence provided by the applicant with information from the primary source(s) whenever feasible. Action on an individual's application for appointment or initial clinical privileges is withheld until the information is available and verified. In the United States, the organization is also encouraged to consider additional information concerning the applicant from other sources, including the Federation of State Medical Boards Physician Disciplinary Data Bank. These databases and other sources may provide the hospital with information that is new or that may flag an inconsistency when compared with the individual's application.

When organizations evaluate an individual for clinical privileges, they verify the information in the application that relates to the individual's licensure, training, experience, and competence from primary sources whenever possible. The organization then evaluates the individual's credentials by comparing the information in his or her application with the information provided by the primary source to the external agency. Additional information may be required to supplement the external agency information to fully evaluate each applicant.

The "Health Care Quality Improvement Act of 1986" (Title IV of Pub. L. 99-660, as amended) requires the establishment of the National Practitioner Data Bank (NPDB), to which the following information must be reported in a timely manner by the appropriate agencies:

- Medical malpractice payments;
- Licensure disciplinary actions;
- Adverse clinical privilege actions taken by a health care entity (for example, hospitals, health maintenance organizations, group practices); and
- Adverse actions affecting professional society membership.

Adverse professional review actions taken by health care entities against health care practitioners other than physicians and dentists may also be reported. Under the act, organizations must query the NPDB at the time of initial medical staff appointments and initial granting of clinical privileges, as well as at least every two years thereafter for information on physicians, dentists, and other health care practitioners granted clinical privileges. Such queries should be performed on a timely basis to ensure that all relevant information is received by an organization before finalizing appointments and the granting of privileges.

Decisions on **reappointments** or on revocation, revision, or renewal of clinical privileges must consider criteria that are directly related to the quality of care. Such decisions are subject to a fair hearing and appeal process.

Decisions on appointments or on granting of clinical privileges must consider criteria that are directly related to the quality of care.

The determination of **initial appointment or reappointment** or of **granting, revocation, revision, or renewal of clinical privileges** is based on a variety of criteria. If criteria are used that are unrelated to the quality of care or professional competency, evidence exists that the impact of resulting decisions on the quality of care is evaluated. For medical staff members and other individuals holding clinical privileges, the decisions about the impact on the quality of care is subject to a fair hearing and appeal process (as are credentialing decisions that are based on criteria directly related to the quality of care).

Each applicant for medical staff appointment or reappointment or for initial, renewed, or revised clinical privileges provides certain information defined in the medical staff bylaws, rules and regulations, or policies. This information is intended to supplement the core criteria (current licensure, relevant training or experience, current competence, and ability to perform privileges requested).

Specifically, medical staff bylaws and rules and regulations require each applicant to provide information regarding the following, when applicable:

- Challenges to any licensure or registration, or voluntary or involuntary relinquishment of such licensure or registration; and
- Voluntary or involuntary termination of medical staff membership, or voluntary or involuntary limitation, reduction, or loss of clinical privileges.

Bylaws and rules and regulations also specify the circumstances under which an individual is to report involvement in a professional liability action. At a minimum, these circumstances include final judgments or settlements in which the medical staff member is involved. Each credentials file for medical staff members and others with clinical privileges contains information.

Appointment or reappointment to the medical staff and the initial granting and renewal or revision of clinical privileges are also based on information regarding the applicant's competence. Deliberations by the medical staff in developing recommendations for appointment to or termination from the medical staff and for the initial granting, revision, or revocation of clinical privileges include information provided by a peer(s) of the applicant.

Recommendation(s) from peers (appropriate practitioners in the same professional discipline as the applicant--for example, physician, dentist, podiatrist--who have firsthand knowledge of the applicant) are in the credentials files and reflect part of the basis for recommending appointment or reappointment and granting, renewing, or revising clinical privileges. If there are no peers on the medical staff who are knowledgeable about the applicant, a peer recommendation is obtained from outside the hospital, such as the local county or regional medical society, or a practitioner in the community or on the medical staff of another hospital. It is advisable, when possible, to include recommendations from an individual(s) in the same specialty. The peer recommendations refer, as appropriate, to relevant training or experience; current competence; fulfillment of obligations as a medical staff member; and any effects of health status on the privileges being recommended. Sources for peer recommendations may include

- an organization performance improvement committee, the majority of whose members are the applicant's peers;
- a reference letter(s) or documented telephone conversation(s) about the applicant from a peer(s) who is a member of the hospital's medical staff or who is from outside the hospital, but knowledgeable about the applicant's competence;
- a department or major clinical service chairperson who is a peer; or
- the medical staff executive committee, the majority of whose members are the applicant's peers.

A structured procedure, as defined by medical staff bylaws, rules and regulations, and medical staff policies, is used for the expeditious processing of complete applications for appointment, reappointment, and initial, renewed, or revised clinical privileges. A separate record is maintained for each individual requesting medical staff membership or clinical privileges.

A period of time is established between appointment and subsequent reappointments and between granting, renewing, or revising clinical privileges in order to review the performance of medical staff members and of other practitioners granted clinical privileges. This review can be done more often, if desired. Initial appointment is granted for a provisional period, which is specified in the medical staff bylaws and consistently applied to all applicants.

Reappraisal

Appraisal for reappointment to the medical staff or renewal or revision of clinical privileges is based on ongoing monitoring of information concerning the individual's professional performance; judgment; and clinical or technical skills. A reappraisal is conducted at the time of reappointment or renewal or revision of clinical privileges. The reappraisal includes confirmation of adherence to medical staff membership requirements stated in medical staff bylaws, rules and regulations, and policies. Relevant practitioner-specific information from organization performance improvement activities is considered and compared to aggregate information when these measurements are appropriate for comparative purposes in evaluating professional performance, judgment, and clinical or technical skills. Any results of peer review of the individual's clinical performance are also included.

The Joint Commission requires that initially requested privileges be subject to a period of focused professional practice evaluation. The granting of a renewal/reappointment is based on the information collected as a result of the organization's ongoing professional practice evaluation. This emphasis is on data drive, evidence based appointment and privileging process. This may include the process of identifying negative practice trends that may affect quality of care and patient safety. The information is used in the decision to maintain the privilege or to revisit/revoke the existing privilege.

There needs to be a clearly defined process for collecting, investigating, and addressing clinical concerns. The type of data collected is determined by the individual service and approved by the organized medical staff. The medical staff uses the information from the ongoing professional practice evaluation to decide whether to continue, limit, or revoke any existing privilege.

Credentials files contain clear evidence (for example, a signed statement by the department chairperson or service chief recommending that privileges be granted) that the full range of privileges has been included in the reappraisal, particularly privileges for performing high-risk procedures and treating high-risk conditions, and that the information is substantive and practitioner specific.

The effectiveness of the reappraisal process may be measured by objective documentation in credentials files that, within the past few years, an individual's privileges were increased, reduced, or terminated because of

1. assessments of his or her documented performance;
2. nonuse of privileges for a high-risk procedure or treatment over a period of two years; or
3. emergence of new technologies.

Because hospital practices and clinical techniques change over time, it would be unusual if clinical privileges were not to change also.

Departmental or major clinical service recommendations are part of the basis for developing recommendations for continued membership on the medical staff or for delineating individual clinical privileges.

Credentials files used for reappointment to the medical staff or granting, renewing, or revising clinical privileges contain the recommendation of the department or major clinical service to which the individual is applying. This recommendation comes through the department or major clinical service chairperson or chief of staff in a nondepartmentalized hospital. Mechanisms designed for department or major clinical service recommendations may include:

Concurrence (evidenced, at least, by the signature of the department or major clinical service chairperson) with the applicant-specific recommendations (including an applicant-specific statement of the basis thereof) of a departmental committee concerning the applicant's reappointment to the medical staff or initial granting, renewal, or revision of clinical privileges. One way to provide an applicant-specific statement is to write a narrative. Another way could consist of a document indicating that the department chairperson, chief of staff, or an appropriate committee has reviewed every item required by the Joint Commission and the hospital's medical staff bylaws, rules and regulations, and policies and made an applicant-specific judgment about each required item or

An applicant-specific statement (including the basis thereof) by the chairperson of the department or major clinical service noting that the individual is recommended for reappointment to the medical staff

or to be granted or have renewed the requested privileges. If the chairperson of the department or major clinical service is the applicant's peer, this recommendation can also fulfill the requirement.

In either case, the department or major clinical service recommendation is based on evidence of relevant training and experience; current competence (including any available relevant results of ongoing appraisals of clinical performance and practice); any effects of health status on the privileges to be recommended; and, if the level or scope of privileges was previously increased, evidence of satisfactory performance in accordance with those privileges. All individuals who are permitted by law and by the hospital to provide patient care services independently in the organization have delineated clinical privileges, whether or not they are medical staff members.

Clinical privileges may be defined several ways. For example, they may be categorized by

- practitioner specialty;
- level of training and experience;
- patient risk categories;
- lists of procedures or treatments; or
- any combination of the methods listed above--particularly a combination of patient risk categories and lists of procedures.

An acceptable model might combine patient risk categories with specific clinical areas (for example, cardiovascular diseases, endocrinology), invasive procedures (for example, cardiac catheterization, Swan-Ganz catheterization), biopsies, and interpretation of special noninvasive procedures (for example, echocardiograms). This approach to categorizing and listing procedures for recommending clinical privileges can be applied to all specialties.

The delineation of an individual's clinical privileges includes the limitations, if any, on an individual's privileges to admit and treat patients or direct the course of treatment for the conditions for which the patients were admitted. Regardless of the method used to delineate an individual's clinical privileges, the limitations on the individual's privileges to admit and treat patients or direct the course of treatment for the conditions for which the patients were admitted are specified. For example, it may be that a surgeon with privileges to perform cardiovascular procedures, including arterial grafts, is not privileged to respect abdominal aortic aneurysms until he or she has been observed while operating under supervision by an experienced cardiovascular surgeon. Likewise, it may be that a family practitioner is privileged to admit a suspected myocardial infarction case to the coronary care unit but is not privileged to manage that patient.

There is a mechanism designed to ensure that all individuals with clinical privileges only provide services within the scope of privileges granted. **Temporary clinical privileges** can be issued for a limited time, as defined by the organization. Temporary privileges are generally granted on a case-by-case basis when an important patient care need mandates an immediate authorization to practice, for a limited period of time as defined by the organization's bylaws, while the full credentials information is verified and approved. Examples include a situation in which a physician becomes ill or takes a leave of absence and an LIP would need to cover his or her practice until he or she returns, or a specific LIP has the necessary skills to provide care to a patient that an LIP currently privileged does not possess. Temporary privileges may be granted upon recommendation of either the applicable clinical department chairperson or the president of the medical staff, if:

- there is verification (which may be accomplished through a telephone call) of
- current licensure,
- relevant training or experience,
- current competence,
- ability to perform the privileges requested, and
- other criteria required by medical staff bylaws;

- the results of the National Practitioner Data Bank query have been obtained and evaluated; and
- the applicant has
- a complete application,
- no current or previously successful challenge of licensure or registration,
- not been subject to involuntary termination of medical staff membership at another organization, and
- not been subject to involuntary limitation, reduction, denial, or loss of clinical privileges.

Granting, renewal, or revision of clinical privileges is also based on the individual's demonstrated current competence. For renewal or revision of privileges, this may be determined, in part, by a review of relevant results of medical staff performance improvement activities. Specific instances of treatment outcomes and the results of other assessment and improvement activities may also be included. An evaluation of the applicant's clinical judgment and technical skills in performing procedures and in patient treatment and management is also included in an evaluation of current competence.

Peer Review

Members of the medical staff are involved in activities to measure, assess, and improve performance on an organizationwide basis. They are involved in conducting a properly designed peer review process that includes the following:

- Definition of those circumstances requiring peer review;
- Specification of the participants in the review process, including a definition of peer;
- Method for selecting peer review panels for specific circumstances;
- Time frames in which peer review activities are to be conducted and the results reported;
- Circumstances under which external peer review is required; and
- Provision for participation in the review process by the individual whose performance is being reviewed.

An effectively functioning peer review process should have the following characteristics:

- **Consistency:** Peer review is conducted according to defined procedures for all cases meeting the organization's definition of reviewable circumstances.
- **Timeliness:** The time frames specified in the peer review procedures are adhered to reasonably.
- **Defensibility:** The conclusions reached through the process are supported by a rationale that specifically addresses the issues for which the peer review was conducted, including, as appropriate, reference to the literature and relevant clinical practice guidelines.
- **Balance:** Minority opinions and views of the reviewed are considered and recorded.
- **Usefulness:** The results of peer review activities are considered in practitioner-specific credentialing and privileging decisions and, as appropriate, in the organization's performance improvement activities.
- **Tracking over time:** Peer review conclusions are tracked over time, and actions based on peer review conclusions are monitored for effectiveness.

Members of the medical staff should also be involved in

- the measurement of outcomes and of processes, and in the assessment of performance in relation to the design of processes and their expected or intended outcomes, in order to identify opportunities for improvement;
- evaluation of individuals with clinical privileges whose performance is questioned as a result of the measurement and assessment activities;
- communication to appropriate medical staff members of the findings, conclusions, recommendations, and actions taken to improve organization performance; and
- implementation of changes to improve performance.

The medical staff should assure a leadership role in the improvement of clinical processes that are dependent primarily on individuals with clinical privileges, such as surgery, physical examinations, and prescribing of medication.

Ongoing Professional Practice Evaluation Example

Required data

- Review of operative and other clinical procedures performed and their outcomes
- Blood and pharmaceutical evaluation
- Medical assessment and treatment of patients
- Use of consultants
- Appropriateness of clinical practice patterns
- Significant departures from established patterns of clinical practice
- Length of stay patterns
- Morbidity and mortality data
- Infection rates
- Cesarean section rates for OB
- Meeting attendance
- Issues identified by the peer review organization

Physician Profiles

“Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous.” Sir Cyril Chantier.

“To fix medicine we need to do two things: measure ourselves and be more open about what we are doing.” Don Berwick, MD

A program of performance profiling consists of several levels of detail focused on outcome quality measures or the end result of the care that is provided. Most organizations use risk-adjusted software for patient outcomes. Profiles are provided to each physician or provider on a regular basis, generally quarterly or every six months. Profile indicators should be based on performance (anticipating patient needs, preventing chronic disease complications and avoidable admissions, and improving quality of care). Metrics should be broadly applicable to the general population and standardized. Data needs to be timely and accurate.

Data found on profiles includes:

- Volumes
- Length of stay
- Average length of stay
- Diagnosis-related groups,
- Average cost per case
- System wide initiatives such as use of DVT/PE prophylaxis;
- Illegible records
- Unapproved abbreviations
- Severity adjusted mortality
- Severity adjusted morbidity
- Death or loss of function related to nosocomial infections
- Unexpected transfers to ICU
- Unexpected death
- Unplanned return to surgery
- Procedure complications
- Charges for the patients treated by the physician compared with those for physicians in the same specialty

- Discharges
- FTE (actual vs. budget)
- Patient falls
- Medication errors
- ASA within 24 hours of arrival
- ASA at discharge
- ACE inhibitors prescribed at discharge
- Beta blockers within 24 hours
- Smoking cessation counseling
- Patient satisfaction

A process-focused profile provides clinicians with data about the specific evidence-based care that is provided. These profiles usually include all physician data, data by specialty type, and data for individual physicians for specific diagnoses. Physicians generally receive copies of their data, and presentations of the data usually occur at routine monthly meetings. In many organizations, physician champions talk directly with medical staff about the numbers, emphasizing the involvement needed to improve the outcomes of care for the patient.

As the physicians are profiled, questions arise about data accuracy. Ensuring data validity and credibility is vital to the success of a profiling strategy. Organizations generally adopt a level of detail that identifies specific cases for each physician who didn't meet the indicators. This proactive approach makes the feedback even more timely and specific. Nonpunitive and information letters can be mailed from the chief medical officer to physicians when chart audits demonstrate lack of documentation to support compliance. The letter indicates the individual patient, discharge date, indicators not in compliance, and possible corrective actions. The letter would be generated at the time of the chart audit, so that by the time the quarterly or semi-annual profiles are distributed, the physician already knows if any of his/her cases didn't meet criteria.

“It is distressing for doctors to have to acknowledge the bell curve...in medicine, we are used to confronting failure...what we're not used to is comparing our records of success and failure with those of our peers.” Atul Gawande, MD

Performance feedback and sharing outcomes data is not commonly done. Physicians will respond to comparative data. This prepares physicians on responding to quality information requests and questions by patients. Performance feedback and benchmarking helps physicians acknowledge and accept the bell curve. It also creates a positive competitive improvement culture. Performance feedback is necessary for sustaining momentum and improvement. Key leaders must support and embrace the value of performance feedback and transparency. Dashboards should be presented to physicians compare them with other physicians in house who treat the same population and may also compare them with national benchmarks. Organizations also request department chairs to identify quality and other monitors the physicians feel are important. These become department specific monitors. Physicians need meaningful data with indicators derived from evidence based practice standards, and more clinical, outcome based data through process measures. Data should represent major service lines, patient safety issues, and include outpatient data. National targets should be agreed upon to provide comparative databases. The data need to be easily accessed and easily used. Profiles given to physicians vary according to area of practice.

Physicians generally respond well to detailed feedback. Areas in need of improvement are clear, the feedback is timely, and progress is easily seen. Data are often displayed on bulletin boards. Data are also shared at staff meetings. Physicians need to be taught how to look at data. Does the data show that you did a good job? Does the data show that you treat patients well?

If variances are identified, protocols and pathways that have been identified as critical elements in disease management have not been successfully implemented. Previously, monitoring the use of the protocols became an end in itself. This methodology focuses on providing key elements of evidence

based practice for patients, and a plan to implement that care. The three key elements of including those directly involved in the direct care of patients (participation), concurrently monitoring caregiver practice and communicating identified gaps (prompting), and providing meaningful measures of the effect of change strategies at a detailed level (profiling) can be successfully implemented to demonstrate an evidence based model for treating and continuously improving the care of patients.

Role of the Quality Professional

- Identify, collect, analyze, and report data related to quality to providers
- Seek physician leaders first, then all physicians
- Provide guidance and direction to those looking to improve
- Address barriers to practice
- Form physician teams
- Take every opportunity to tell physicians what you have done based on what they have told you; keep connecting the dots
- Focus on a few things and complete them rather than attempting everything and completing nothing
- Assess the overall quality performance
- Provide valuable data to guide organizational decisions
- Report data to external organizations charged with monitoring the quality of the organization
- Support providers
- Communicate data and action plans related to all quality improvement efforts
- Celebrate success

PROVIDER	IHD Elevated LDL	HTN BP< 140/90	HTN BP< 160/100	HTN DM BP< 140/90	HTN DM BP< 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression Screening	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Dia Retin Eye
A	67%	91%	99%	94%	100%	84%	67%	83%	92%	#DIV/0!	100%	#DIV/0!	27%	60%	
B	86%	92%	98%	96%	98%	89%	50%	80%	97%	#DIV/0!	100%	#DIV/0!	0%	63%	
C	100%	88%	99%	88%	98%	79%	70%	92%	92%	#DIV/0!	100%	#DIV/0!	80%	46%	
D	93%	98%	99%	98%	100%	88%	90%	100%	89%	#DIV/0!	99%	#DIV/0!	9%	65%	
E	#DIV/0!	0%	100%	0%	100%	100%	#DIV/0!	#DIV/0!	100%	#DIV/0!	100%	#DIV/0!	#DIV/0!	#DIV/0!	
F	79%	93%	97%	98%	98%	76%	100%	71%	90%	#DIV/0!	90%	#DIV/0!	27%	60%	
G	100%	93%	100%	91%	100%	82%	100%	100%	96%	#DIV/0!	100%	#DIV/0!	67%	50%	
WALK-IN	67%	89%	99%	94%	100%	77%	76%	85%	87%	#DIV/0!	92%	#DIV/0!	16%	46%	
**PLEASE NOTE:															
#DIV/0 = NO PATIENT DATA															

TSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Eye Exam	Diabetic Foot Exam Complete	DM Hemoglobin A1C > 9	Pap Smear	Mammogram	HEP C RISK POS BUT NO LAB TEST	Flu Vac	Pneumovax	Pain Education	Nonvested Patient	REPORT FOR TOBACCO REMINDER	FALL RISK SCREEN	Tobacco Use Cessation/Screening
100%	#DIV/0!	27%	60%	50%	78%	75%	89%	100%	91%	79%	97%	93%	100%	76%	92%	48%
100%	#DIV/0!	0%	63%	56%	92%	83%	71%	60%	93%	75%	91%	99%	99%	92%	100%	65%
100%	#DIV/0!	80%	46%	47%	79%	79%	100%	75%	94%	70%	89%	90%	100%	89%	96%	70%
99%	#DIV/0!	9%	65%	48%	94%	87%	100%	100%	96%	73%	98%	68%	98%	89%	98%	67%
100%	#DIV/0!	#DIV/0!	#DIV/0!	0%	100%	0%	#DIV/0!	#DIV/0!	#DIV/0!	0%	100%	100%	100%	100%	#DIV/0!	100%
90%	#DIV/0!	27%	60%	59%	93%	83%	100%	100%	94%	70%	93%	91%	97%	91%	83%	65%
100%	#DIV/0!	67%	50%	57%	100%	73%	89%	43%	79%	63%	91%	98%	98%	98%	100%	82%
92%	#DIV/0!	16%	46%	56%	75%	75%	86%	54%	89%	64%	89%	84%	96%	74%	90%	48%

PROVIDER	IHD Elevated LDL	HTN BP< 140/90	HTN BP< 160/100	HTN DM BP< 140/90	HTN DM BP< 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression Screening	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Exam
A	27%	86%	96%	86%	93%	89%	100%	100%	96%	#DIV/0!	99%	#DIV/0!	17%	67%	64%
B	75%	84%	96%	73%	93%	86%	38%	67%	92%	#DIV/0!	98%	#DIV/0!	9%	38%	52%
C	47%	95%	99%	95%	100%	60%	100%	88%	91%	#DIV/0!	98%	#DIV/0!	5%	50%	57%
D	36%	94%	100%	90%	100%	85%	63%	100%	91%	#DIV/0!	99%	#DIV/0!	8%	64%	60%
E	83%	93%	98%	96%	100%	80%	0%	100%	92%	#DIV/0!	100%	#DIV/0!	0%	38%	60%
F	59%	96%	100%	100%	100%	86%	42%	76%	94%	#DIV/0!	98%	#DIV/0!	0%	74%	53%
G	82%	97%	100%	94%	100%	83%	100%	86%	95%	#DIV/0!	97%	#DIV/0!	0%	65%	61%
H	91%	90%	100%	94%	100%	87%	67%	93%	91%	#DIV/0!	99%	#DIV/0!	79%	90%	87%
I	#DIV/0!	79%	100%	75%	100%	75%	#DIV/0!	100%	100%	#DIV/0!	100%	#DIV/0!	100%	50%	83%
J	50%	92%	97%	100%	100%	78%	67%	80%	93%	#DIV/0!	94%	#DIV/0!	17%	64%	67%
WALK-IN	60%	87%	98%	90%	99%	79%	68%	89%	96%	#DIV/0!	98%	#DIV/0!	13%	63%	54%
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Diabetic Retinopathy Exam	Diabetic Foot Exam Complete	DM Hemoglobin A1C > 9	Pap Smear	Mammogram	HEP C RISK POS BUT NO LAB TEST	Flu Vac	Pneumovax	Pain Education	Nonwested Patient	REPORT FOR TOBACCO REMINDER	Fall Risk Assessment	Tobacco Use Cessation/Screening
64%	86%	86%	100%	67%	88%	68%	94%	94%	100%	94%	97%	76%
52%	88%	90%	67%	50%	91%	67%	85%	91%	99%	89%	100%	67%
57%	93%	78%	33%	0%	76%	58%	88%	88%	98%	91%	91%	74%
60%	77%	68%	70%	43%	94%	75%	96%	87%	100%	70%	100%	49%
60%	58%	74%	0%	0%	71%	66%	85%	94%	100%	62%	92%	38%
53%	89%	81%	86%	40%	84%	74%	93%	90%	98%	58%	95%	40%
61%	97%	82%	100%	0%	94%	79%	96%	92%	100%	87%	100%	71%
87%	87%	89%	100%	50%	87%	70%	94%	91%	100%	90%	100%	76%
83%	89%	88%	83%	100%	95%	68%	88%	97%	100%	81%	100%	35%
67%	81%	81%	75%	0%	92%	69%	96%	91%	98%	65%	92%	45%
54%	80%	76%	79%	56%	77%	65%	90%	93%	97%	79%	99%	53%

PROVIDER	IHD Elevated LDL	HTN BP< 140/90	HTN BP< 160/100	HTN DM BP< 140/90	HTN DM BP< 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression Screen	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Exam
A	62%	92%	99%	94%	98%	91%	80%	100%	91%	#DIV/0!	99%	#DIV/0!	0%	60%	32%
B	67%	95%	100%	100%	100%	63%	100%	100%	88%	#DIV/0!	88%	#DIV/0!	0%	0%	60%
C	83%	94%	99%	94%	97%	79%	50%	100%	95%	#DIV/0!	99%	#DIV/0!	58%	81%	33%
D	80%	91%	100%	92%	100%	90%	86%	78%	93%	#DIV/0!	98%	#DIV/0!	0%	64%	50%
E	67%	92%	100%	100%	100%	88%	100%	100%	97%	#DIV/0!	99%	#DIV/0!	29%	83%	27%
F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
G	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
H	83%	95%	99%	95%	100%	92%	100%	94%	90%	#DIV/0!	97%	#DIV/0!	9%	67%	71%
I	61%	89%	99%	95%	100%	84%	50%	100%	89%	#DIV/0!	94%	#DIV/0!	0%	36%	39%
J	65%	94%	98%	95%	98%	83%	91%	92%	95%	#DIV/0!	98%	#DIV/0!	0%	45%	60%
WALK-IN	72%	88%	98%	91%	98%	80%	78%	100%	96%	#DIV/0!	96%	#DIV/0!	14%	42%	56%
FLU SHOT CLINIC	58%	93%	97%	93%	96%	84%	50%	95%	80%	#DIV/0!	84%	#DIV/0!	7%	78%	55%
**PLEASE NOTE:															
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Depression Screen	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Exam	Diabetic Foot Exam Complete	DM Hemaglobin A1C > 9	Pap Smear	Mammogram	HEP C RISK POS BUT NO LAB TEST	Flu Vac	Pneumovax	Pain Education	Nonvested Patient	REPORT FOR TOBACCO REMINDER	Fall Risk Screen
#DIV/0!	99%	#DIV/0!	0%	60%	32%	83%	83%	89%	40%	85%	76%	92%	91%	100%	78%	98%
#DIV/0!	88%	#DIV/0!	0%	0%	60%	78%	88%	50%	100%	83%	50%	65%	86%	90%	76%	100%
#DIV/0!	99%	#DIV/0!	58%	81%	33%	84%	84%	67%	#DIV/0!	97%	80%	92%	90%	98%	91%	97%
#DIV/0!	98%	#DIV/0!	0%	64%	50%	65%	81%	100%	67%	85%	67%	91%	88%	99%	81%	96%
#DIV/0!	99%	#DIV/0!	29%	83%	27%	70%	78%	86%	100%	84%	60%	76%	96%	98%	93%	100%
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
#DIV/0!	97%	#DIV/0!	9%	67%	71%	95%	74%	82%	75%	92%	67%	94%	90%	99%	94%	98%
#DIV/0!	94%	#DIV/0!	0%	36%	39%	79%	81%	83%	67%	80%	63%	88%	89%	100%	78%	96%
#DIV/0!	98%	#DIV/0!	0%	45%	68%	91%	76%	89%	100%	89%	75%	94%	94%	99%	95%	92%
#DIV/0!	96%	#DIV/0!	14%	42%	56%	78%	67%	81%	57%	80%	62%	87%	93%	93%	77%	96%
#DIV/0!	84%	#DIV/0!	7%	78%	55%	77%	80%	90%	86%	92%	99%	94%	70%	96%	75%	71%

PROVIDER	IHD Elevated LDL	HTN BP < 140/90	HTN BP < 160/100	HTN DM BP < 140/90	HTN DM BP < 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression Screening	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Dial Retin Eye
A	63%	92%	99%	90%	100%	89%	55%	53%	89%	#DIV/0!	95%	#DIV/0!	10%	55%	
B	75%	86%	99%	86%	100%	79%	83%	88%	94%	#DIV/0!	98%	#DIV/0!	63%	44%	
C	70%	98%	100%	100%	100%	88%	83%	80%	93%	#DIV/0!	98%	#DIV/0!	9%	83%	
D	100%	94%	99%	94%	100%	83%	100%	92%	93%	#DIV/0!	98%	#DIV/0!	50%	67%	
E	81%	96%	99%	95%	100%	85%	86%	89%	94%	#DIV/0!	94%	#DIV/0!	58%	28%	
F	75%	94%	97%	93%	96%	79%	67%	100%	95%	#DIV/0!	100%	#DIV/0!	75%	80%	
WALK-IN	83%	88%	95%	88%	100%	80%	#DIV/0!	67%	83%	#DIV/0!	84%	#DIV/0!	29%	63%	

PROVIDER	HD Elevated LDL	HTN BP< 140/90	HTN BP< 160/100	HTN DM BP< 140/90	HTN DM BP< 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression Screening	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Dial Retin Eye
A	63%	92%	99%	90%	100%	89%	55%	53%	89%	#DIV/0!	95%	#DIV/0!	10%	55%	
B	75%	86%	99%	86%	100%	79%	83%	88%	94%	#DIV/0!	98%	#DIV/0!	63%	44%	
C	70%	98%	100%	100%	100%	88%	83%	80%	93%	#DIV/0!	98%	#DIV/0!	9%	83%	
D	100%	94%	99%	94%	100%	83%	100%	92%	93%	#DIV/0!	98%	#DIV/0!	50%	67%	
E	81%	96%	99%	95%	100%	85%	86%	89%	94%	#DIV/0!	94%	#DIV/0!	58%	28%	
F	75%	94%	97%	93%	96%	79%	67%	100%	95%	#DIV/0!	100%	#DIV/0!	75%	80%	
WALK-IN	83%	88%	95%	88%	100%	80%	#DIV/0!	67%	83%	#DIV/0!	84%	#DIV/0!	29%	63%	

Depression Screening	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Eye Exam	Diabetic Foot Exam Complete	DM Hemoglobin A1C >9	Pap Smear	Mammo-gram	HEP C RISK POS BUT NO LAB	Flu Vac	Pneumovax	Pain Education	Nonvested Patient	REPORT FOR TOBACCO REMINDER	FALL RISK SCREEN
#DIV/0!	95%	#DIV/0!	10%	55%	45%	66%	90%	75%	50%	86%	70%	91%	60%	99%	57%	96%
#DIV/0!	98%	#DIV/0!	63%	44%	79%	72%	66%	100%	100%	85%	79%	91%	90%	94%	94%	96%
#DIV/0!	98%	#DIV/0!	9%	83%	67%	88%	80%	100%	75%	95%	88%	97%	88%	99%	60%	98%
#DIV/0!	98%	#DIV/0!	50%	67%	46%	88%	58%	100%	50%	97%	76%	98%	67%	100%	91%	96%
#DIV/0!	94%	#DIV/0!	58%	28%	48%	92%	76%	100%	50%	95%	71%	92%	76%	99%	89%	91%
#DIV/0!	100%	#DIV/0!	75%	80%	43%	96%	56%	100%	100%	95%	80%	93%	93%	100%	98%	97%
#DIV/0!	84%	#DIV/0!	29%	63%	75%	81%	81%	#DIV/0!	100%	89%	67%	90%	73%	93%	77%	90%

PROVIDER	IHD Elevated LDL	HTN BP< 140/90	HTN BP< 160/100	HTN DM BP< 140/90	HTN DM BP< 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression Screening	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Eye Exam
	63%	92%	99%	98%	100%	81%	80%	90%	91%	#DIV/0!	97%	#DIV/0!	0%	32%	45%
	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	73%	93%	98%	94%	98%	69%	88%	100%	91%	#DIV/0!	98%	#DIV/0!	0%	81%	68%
	78%	95%	98%	97%	100%	84%	56%	80%	91%	#DIV/0!	97%	#DIV/0!	70%	71%	67%
	80%	91%	99%	88%	96%	81%	75%	90%	94%	#DIV/0!	100%	#DIV/0!	0%	85%	54%
	57%	90%	100%	85%	100%	87%	63%	100%	93%	#DIV/0!	100%	#DIV/0!	0%	50%	28%
	69%	88%	96%	89%	92%	71%	#DIV/0!	100%	94%	#DIV/0!	100%	#DIV/0!	25%	40%	52%
	70%	88%	97%	97%	100%	86%	75%	100%	92%	#DIV/0!	99%	#DIV/0!	57%	75%	53%
	100%	88%	100%	100%	100%	82%	75%	100%	94%	#DIV/0!	99%	#DIV/0!	90%	46%	77%
ALK-IN	66%	87%	97%	89%	97%	67%	74%	84%	91%	#DIV/0!	94%	#DIV/0!	21%	38%	47%
*PLEASE NOTE:															
#DIV/0 = NO PATIENT DATA															

SD	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Eye Exam	Diabetic Foot Exam Complete	DM Hemoglobin A1C > 9	Pap Smear	Mammo-gram	HEP C RISK BUT NO LAB TEST	Flu Vac	Pneumovax	Nonvested Patient	Pain Education	REPORT FOR TOBACCO REMINDER	FALL RISK SCREEN	
	97%	#DIV/0!	0%	32%	45%	93%	71%	63%	75%	93%	69%	86%	57%	98%	92%	93%
	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	98%	#DIV/0!	0%	81%	68%	93%	85%	100%	75%	95%	72%	91%	75%	100%	89%	94%
	97%	#DIV/0!	70%	71%	67%	92%	89%	100%	83%	94%	80%	96%	94%	100%	90%	95%
	100%	#DIV/0!	0%	85%	54%	81%	72%	75%	33%	88%	58%	86%	67%	100%	85%	100%
	100%	#DIV/0!	0%	50%	28%	85%	90%	#DIV/0!	#DIV/0!	100%	72%	100%	88%	100%	93%	100%
	100%	#DIV/0!	25%	40%	52%	94%	81%	80%	100%	86%	64%	91%	94%	100%	94%	100%
	99%	#DIV/0!	57%	75%	53%	81%	83%	100%	50%	98%	63%	88%	86%	100%	93%	100%
	99%	#DIV/0!	90%	46%	77%	84%	88%	60%	67%	97%	66%	87%	86%	100%	97%	94%
	94%	#DIV/0!	21%	38%	47%	71%	76%	61%	63%	84%	60%	86%	73%	96%	79%	83%

PROVIDER	IHD Elevated LDL	HTN BP< 140/90	HTN BP< 160/100	HTN DM BP< 140/90	HTN DM BP< 160/100	Colorec Cancer Screen	CHF NOT on ACE and/or ARB	CHF Weight Education	AUDIT C	Depression	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Eye Exam
A	63%	91%	98%	93%	98%	86%	50%	73%	92%	#DIV/0!	91%	#DIV/0!	0%	47%	53%
B	90%	98%	100%	98%	100%	95%	91%	93%	93%	#DIV/0!	98%	#DIV/0!	60%	89%	55%
C	75%	94%	99%	93%	97%	80%	89%	95%	92%	#DIV/0!	90%	#DIV/0!	29%	42%	71%
D	89%	98%	99%	98%	100%	86%	83%	71%	97%	#DIV/0!	99%	#DIV/0!	94%	85%	53%
E	91%	92%	98%	96%	100%	87%	73%	76%	92%	#DIV/0!	98%	#DIV/0!	9%	76%	73%
F	79%	94%	99%	97%	100%	73%	63%	58%	84%	#DIV/0!	89%	#DIV/0!	6%	16%	50%
G	56%	94%	98%	98%	100%	85%	90%	100%	95%	#DIV/0!	99%	#DIV/0!	18%	44%	63%
H	63%	97%	99%	99%	100%	75%	63%	70%	87%	#DIV/0!	87%	#DIV/0!	0%	40%	55%
WALKIN	54%	88%	95%	96%	96%	78%	52%	68%	78%	#DIV/0!	78%	#DIV/0!	23%	50%	52%
*PLEASE NOTE:															
#DIV/0 = NO PATIENT DATA															

Depression	PTSD Screen	Iraq & Afghan Screen	Diabetic Elevated LDL	Diabetic Eye Exam	Diabetic Retinopathy Eye Exam	Diabetic Foot Exam Complete	DM Hemoglobin A1C > 9	Pap Smear	Mammogram	HEP C RISK POS BUT NO LAB TEST	Flu Vac	Pneumovax	Pain Education	Nonvested Patient	REPORT FOR TOBACCO REMINDER	FALL RISK SCREEN
#DIV/0!	91%	#DIV/0!	0%	47%	53%	51%	71%	100%	100%	91%	78%	84%	80%	99%	69%	89%
#DIV/0!	98%	#DIV/0!	60%	89%	55%	94%	83%	94%	92%	85%	74%	93%	94%	99%	87%	97%
#DIV/0!	90%	#DIV/0!	29%	42%	71%	73%	87%	83%	67%	83%	81%	83%	69%	95%	55%	83%
#DIV/0!	99%	#DIV/0!	94%	85%	53%	100%	90%	100%	78%	100%	82%	93%	96%	100%	98%	98%
#DIV/0!	98%	#DIV/0!	9%	76%	73%	91%	79%	80%	33%	93%	81%	87%	91%	100%	89%	99%
#DIV/0!	89%	#DIV/0!	6%	16%	50%	72%	88%	0%	0%	84%	78%	72%	78%	99%	54%	85%
#DIV/0!	99%	#DIV/0!	18%	44%	63%	85%	78%	67%	40%	91%	81%	88%	78%	96%	88%	97%
#DIV/0!	87%	#DIV/0!	0%	40%	55%	74%	90%	75%	50%	72%	77%	81%	65%	100%	74%	79%
#DIV/0!	78%	#DIV/0!	23%	50%	52%	62%	78%	81%	69%	90%	56%	79%	71%	97%	74%	71%

Massachusetts Health Care Quality and Cost Information
 FY2005 Surgeon Volume, by Hospital
 Bariatric Surgery, Laparoscopic Gastric Banding

Baystate Medical Center		
Total number of procedures done at this hospital: 114		
Surgeon Name:	Number of procedures surgeon did at this hospital	Total number of procedures surgeon did in Massachusetts
Fiallo, Viriato Manuel	42	45
Haag, Burritt L	66	68
Beth Israel Deaconess Medical Center		
Total number of procedures done at this hospital: 55		
Surgeon Name:	Number of procedures surgeon did at this hospital	Total number of procedures surgeon did in Massachusetts
Jones, Daniel B	31	31
Schneider, Benjamin E	22	22
Boston Medical Center		
Total number of procedures done at this hospital: 4		
Surgeon Name:	Number of procedures surgeon did at this hospital	Total number of procedures surgeon did in Massachusetts
No surgeons performed 10 or more procedures statewide	n/a	n/a
Mercy Medical Center		
Total number of procedures done at this hospital: 7		
Surgeon Name:	Number of procedures surgeon did at this hospital	Total number of procedures surgeon did in Massachusetts
Fiallo, Viriato Manuel	3	45
Haag, Burritt L	2	68

The Society of Hospital Medicine has identified the following ten metrics as a starting point for hospitalist practices to develop a comprehensive performance measurement and reporting process.

1. Volume data
2. Case mix
3. Patient satisfaction
4. Length of stay
5. Hospital cost and ancillary utilization
6. Productivity measures
7. Provider satisfaction
8. Mortality
9. Readmission rates
10. Joint Commission core measures

PROFESSIONAL STANDARDS BOARD

1. **PURPOSE:** To establish medical center policy and procedures on the Professional Standards Board (PSB) functions and responsibilities

2. **POLICY:** The Professional Standards Board is a subcommittee of the Clinical Executive Board (CEB) with responsibility for accomplishing the following functions regarding appointments and performance reviews of Physicians, Dentists and Podiatrists. The board is also responsible for reviewing scopes of practice for Physician Assistants, Nurse Anesthetists, Audiologists, Speech Pathologists, Clinical Dietitians, Nurse Practitioners, Clinical Pharmacists, Physical Therapists, Occupational Therapists, Kinesiotherapists, Psychologists, and Social Workers. The Professional Standards Board also:

- a. Reviews and acts on all applications for appointment and determines whether the applicants meet the necessary requirements.
- b. Recommends grades and rates of pay of applicants to the Medical Center Director through the CEB.
- c. Reviews individual qualifications for advancement.
- d. Conducts probationary reviews.
- e. Serves as the Medical Staff Committee authorized to review and recommend clinical privilege delineations and scopes of practice to the Medical Center Director through the CEB.

3. **RESPONSIBILITY:**

- a. The Chief of Staff is responsible for recommending the composition of the Professional Standards Board from among the most capable, experienced and responsible medical personnel.
- b. The Medical Center Director is responsible for approving the membership of the Professional Standards Board and for taking action, within delegated authority, on PSB recommendations.
- c. The Professional Standards Board is responsible for reviewing and acting on applications for appointment, reviewing and acting upon qualifications for advancement, approving changes in tours of duty from full-time to part-time or vice versa for Physicians, Dentists, Podiatrists, Physician Assistants and Nurse Anesthetists.
- d. The Human Resources Management Specialist is responsible for serving as a technical advisor at PSB meetings and assuring that all legal and administrative requirements are met before board actions are recommended.
- e. The Medical Staff Coordinator of the Human Resources Management Department or designee is responsible for:
 - (1) Administrative processing of applications for employment through the PSB;
 - (2) Requests for advancement; and
 - (3) Recording the PSB minutes for approval by the CEB.
- f. The Professional Standards Board functions as a review body to assign the appropriate level of clinical privileges to the medical staff initially and biennially.
- g. The Professional Standards Board is responsible for considering and recommending action on requests to establish, modify, or abolish clinical privileges.

4. **PROCEDURES:**

- a. Membership:
- b. Dental Professional Standards Board will consist of two Dentists and the Chief of Staff as chairperson.
- c. Appointments and advancements for Podiatrists will be coordinated with the VHA Director of Podiatry Service and the national Podiatry Professional Standards Board
- d. Requests for Professional Standards Board review and action will be submitted by Department Chairs to the Medical Staff Coordinator through the chairperson of the Professional Standards Board. Recommendations of the board will be forwarded to the CEB, which will submit its recommendations to the Medical Center Director for approval.

e. The PSB will meet the fourth Thursday of each month, at 2:30 p.m., or at the call of the chairperson. The attendance of the chairperson and two members or alternates is required to conduct official business of the board.

SCOPE OF PRACTICE FOR ALLIED HEALTH PROFESSIONALS¹. PURPOSE: To establish policy and procedures related to the delineation of Scopes of Practice for staff providing allied health services. An allied health professional (AHP) is an individual, other than a licensed Physician, Dentist, or Podiatrist, who exercises judgment within the areas of his/her professional competence and the limits established by the Governing Body, the Medical Staff, and the applicable State Practice Acts, who is qualified to render direct or indirect medical, dental, or podiatric care under the supervision or direction of a Medical Staff member possessing privileges to provide such care in the medical center, and who may be eligible to exercise privileges and prerogatives in conformity with the rules adopted by the Governing Body, the Bylaws, and the Rules and Regulations. AHPs function under their individual Scope of Practice. They are not eligible for Medical Staff membership

2. **POLICY**

a. Each service line, department, or section will have a process regarding specific details on practice guidelines and competencies, performance monitoring, and other requirements consistent with their profession. Scope of Practice Statements will vary in the level of independence permitted based upon the professional standards of practice, level of competency, and the assigned duties and responsibilities of the individual

b. An individualized Scope of Practice will be prepared for each Advanced Practice Nurse (Nurse Practitioners and Clinical Nurse Specialists), Clinical Pharmacy Specialist, Clinical Pharmacist, Physician Assistant, Certified Registered Nurse Anesthetist, and Psychologist. Other allied health professionals who provide expanded services will also develop Scope of Practice Statements within the guidelines of this policy. This may include Audiologist, Speech Pathologist, Clinical Dietitian, Social Worker, Physical Therapist, Occupational Therapist, and Kinesiotherapist. The Scope of Practice Statement will identify routine, non-routine, and emergency professional duties, patient care responsibilities, therapies, procedures, and prescriptive authority, when appropriate. The Scope of Practice Statement must be specific to the individual and must specify the type and level of patient care

3. **PROCEDURES:**

a. An individualized Scope of Practice Statement will be developed for each employee as identified above within 45 days of employment. The Scope of Practice will be prepared in the standard format as reflected in Appendix A (Initial Packet used for new employee) and Appendix B (Renewal Packet). The Scope of Practice will be developed utilizing a collaborative process involving the supervising/collaborating Physician or the Department Chair, as appropriate. Scopes will address such functions as diagnostic studies, assessments, disease management, medications, etc. Scopes of Practice (initials and renewals) must be signed by the individual employee and collaborating Physician and/or Department Chair, whichever is appropriate

b. **Initial Appointment:** All new applicants will be required to certify a declaration of appropriate health status. This declaration must be confirmed by a physician designated by or acceptable to the facility, such as the Employee Health Physician or Physician Supervisor from the individual's previous employment. Confirmation, at a minimum, should be in the form of a countersignature by the confirming Physician. NOTE: Additional information may be sought from appropriate source(s), if warranted.

c. Three to four references will be solicited as to the applicant's physical and mental capability to fulfill the requirement of the Scope of Practice being sought. (Note: One reference should be from most recent employer.)

d. The following documentation is to be completed in an **Initial Appointment Packet**

- (1) Application for Initial Scope of Practice for Allied Health Professionals
- (2) Scope of Practice (departments to insert Scope of Practice specific to their department)
- (3) Declaration of Health Form
- (4) Continuing Education Activities Form
- (5) Copies of current Licensure(s) or Certification/Registration(s)

e. When Initial Packet is returned by the AHP, the department will complete the following:

Obtain four References

f. Renewals: The supervising/collaborating Physician and/or Department Chair will assess the allied health professional to evaluate his/her professional credentials and clinical competence for the purposes of recommending renewal of Scope of Practice. In addition, the AHP will also obtain names of three peers for recommendation. (Note: Peers listed cannot include collaborating Physician or Department Chair).

g. The following documentation is to be completed in the Renewal Packet:

- (1) Application for Renewal of Scope of Practice for Allied Health Professionals
- (2) Scope of Practice (departments to insert scope of practice specific to their department)
- (3) Declaration of Health Form
- (4) Continuing Education Activities Form
- (5) Copies of current Licensure(s) or Certification/Registration(s)

h. When Renewal Packet is returned by the AHP, the department will complete the following:

- (1) Obtain two Peer Appraisals (cannot be Department Chair or Supervisor);
- (2) Assessment by collaborating Physician or Department Chair for Renewal of Scope of Practice;
- (3) Allied health professionals – Quality Review; and
- (4) Include copy of current Proficiency Report or Performance Appraisal

i. Scopes of Practice (Initials and Renewals) will be routed for review and approval as follows

- (1) Supervising/collaborating Physician or Department Chair;
- (2) Nursing Professional Standards Board, or Departmental Review Group;
- (3) Medical Staff Coordinator;
- (4) Chief of Staff (Professional Standards Board and Clinical Executive); and
- (5) Medical Center Director

J. The Scope of Practice and related protocols will be maintained on file in the appropriate department/clinical area with the original copy filed in the Medical Staff Office. Provider signature cards will be kept on file in the Pharmacy Department.

k. Scopes of Practice must be renewed every two years. Renewal forms will be forwarded to the AHP 4 months prior to the expiration date of the current scope. The renewal packet forms should be returned within 10 days to the department/service line for processing. If any existing scopes are deleted during the renewal process, the AHP must provide a statement as to why he/she is requesting any deletions. Requests to increase scopes will be fully explained in an accompanying memorandum with appropriate documentation supporting the AHPs assertion of competence, i.e., advanced educational or clinical practice program information, references, etc.

l. Medication Prescribing Authority: The Scope of Practice must clearly identify the medication prescribing authority for those AHPs which have been approved to do so. At this medical center, this authority may apply to Nurse Practitioners, Certified Registered Nurse Anesthetists, Physician Assistants, Clinical Pharmacy Specialists, and Clinical Pharmacists. Only credentialed and privileged Physicians, Dentists, or Podiatrists may give verbal and/or telephone orders. Prescribing authority for controlled substances must only be granted to those AHPs who are authorized to do so by their state of licensure or registration and only in compliance with any limitations and restrictions on that authority as well as, approval within this VA Medical Center. All inpatient pharmaceutical orders and outpatient prescriptions which are not specifically identified in the individual Scopes of Practice must be cosigned by a Physician in accordance with the respective Scope of Practice. To be granted prescriptive authority

- (1) Nurse Practitioners (NP) must have a current licensure as a Registered Nurse in any state that authorizes subscribing and dispensing of medication; current American Nursing Association or other nationally-recognized

certification as an NP and have completed an approved upper division or continuing education courses in pharmacology

(2) Physician Assistants must be graduates of a Physician Assistant training program accredited by the Committee of Allied Health Education and Accreditation and be certified by the National Commission on Certification of Physician Assistants

(3) Clinical Pharmacy Specialists and Clinical Pharmacists must possess a current state license and a Pharm.D. or M.S. degree or equivalent. Examples of equivalent qualifications include, but are not limited to, completion of an American Society of Health System Pharmacists accredited residency program, specialty board certification, or two years of applicable clinical experience.

(4) Certified Registered Nurse Anesthetists must possess a current state license, be certified by the Council on Certification of Nurse Anesthetists, have six months training in anesthesiology or the successful completion of a program approved by the AANA Council on Accreditation of Nurse Anesthesia Education Programs. To be a CRNA one must graduate from a Nurse Anesthesia educational program accredited by the Council on Accreditation (COA) of Nurse Anesthesia Education Programs or its predecessor and pass the certification examination administered by the Council on Certification on Nurse Anesthetists or its predecessor. Each graduate of a Nurse Anesthesia program must pass the national certification examination before he/she can be certified as a CRNA

4. RESPONSIBILITIES

a. The Medical Center Director is the approving official for each Scope of Practice authorized under this policy and is ultimately responsible for the Scope of Practice program

b. The Chief of Staff is responsible for the oversight of the Professional Standards Board (PSB) and the Clinical Executive Board (CEB) through which each initial Scope of Practice and each biennial renewal will be submitted for review and recommendation of approval or disapproval. The PSB also functions as the official review board for reviewing Scopes of Practice for Physician Assistants (PA) and Certified Registered Nurse Anesthetists (CRNA).

c. The Associate Chiefs of Staff and/or Service Line Administrators are responsible for ensuring that departments within their service lines develop and implement the internal review process required by this policy, including appointment of individuals to serve in applicable Department Review Groups

d. The Department Chair is responsible for ensuring appropriate credentials are presented, for review of performance, assessment of current competence, and utilization of peer review, quality assurance/performance improvement/risk management information in the recommendation of awarding, removing, and restoring Scopes of Practice, and initiation of the renewal request every two years.

e. The Departmental Review Groups and/or the Nurse Professional Standards Board will be responsible for the review of initial and renewed Scopes of Practice and verification of credentials for all allied health professionals, except CRNAs and Physician Assistants

f. For those AHPs who require supervision by a Physician, the name and signature of the supervising/collaborating Physician, (a designated staff Physician) will be identified on the signature page of the individual's Scope of Practice Statement, if applicable. In this circumstance, the supervising/collaborating Physician is ultimately accountable when an employee performs functions under approved protocols that overlap the practice of medicine.

g. Individual employees are responsible for maintaining current clinical knowledge and skill, continuing education appropriate to the Scope of Practice, and for providing complete and current documents to the applicable reviewing body in a timely manner

h. The Medical Staff Coordinator is responsible for reviewing all submissions to ensure forms are properly completed and any added or deleted Scopes of Practice are fully explained. This review will be accomplished prior to forwarding initial Scopes of Practice, renewals, or additions to Scopes of Practice to the PSB and CEB for review

QUESTIONS	YES	NO	
1. Have you had any problems with your health status, which might affect your ability to carry out your scope of practice at this medical center?			
2. Have you received any type of sanction or are you currently under investigation by a hospital, state licensing agency, or other health care organization?			
3. Have you allowed a license, registration, and/or certification to expire?			
4. Have you had any license, registration, and/or certification revoked, suspended, denied, restricted, limited, voluntarily or involuntarily relinquished, or issued/placed in a probational status?			
5. Has your license ever been limited, suspended, or revoked?			
6. Have you had previously successful or currently pending challenges to any licensure or registration or the voluntary/involuntary relinquishment of any licensure, registration, or certification?			
7. Have you received any additional license(s)?			
8. Have you had any felony criminal charges?			

E. Request for Approval of Scope of Practice.

I request approval for Initial Scope of Practice as indicated on the attached form.

Signature of Applicant

Date

Collaborating Physician

After careful review and consideration of the applicant's scope of practice, clinical competence information, references, and health status, I:

- _____ Recommend approval as requested.
 _____ Recommend approval with the following deletions or modifications:
 Deletions: _____
 Modifications: _____
 _____ Recommend Disapproval. Reason: _____

Signature of Department Chair

OR

Signature of Collaborating Physician

Date:

Date:

G. Departmental Review Board (if applicable)

- _____ Recommend approval of Collaborating Physician and/or Department Chair recommendation.
 _____ Recommend disapproval of Collaborating Physician and/or Department Chair recommendation.

Signature of Chair, Department Review Board (if applicable)

Date

Signature of Coordinator (if applicable)

Date

H. Professional Standards Board

- _____ Approve Collaborating Physician and/or Department Chair recommendation.
 _____ Disapprove Collaborating Physician and/or Department Chair recommendation.

Signature of Chairperson, Professional Standards Board

Date

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_____ Approve scope of practice as recommended by the Professional Standards Board.
 _____ Disapprove scope of practice as recommended by the Professional Standards Board.

Signature of Chairperson, Clinical Executive Board Date

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_____ Approve scope of practice as recommended by the Clinical Executive Board.
 _____ Disapprove scope of practice as recommended by the Clinical Executive Board.

Signature of Medical Center Director Date

Application for Scope of Practice	
Title: (CRNA, PA, NP, RN, etc.)	LINE”
Carl T. Hayden VAMC – Phoenix, AZ	<i>Department:</i>
	<i>Section:</i>

Applicant:
Effective Dates: From: _____ To: _____

I hereby request nurse practitioner core scope of practice as follows: upon demonstration of satisfactory training, certification, and experience, and after approval by the hospital board or designated individual, provide patient care independently within approved Scope of Practice and in collaboration with a physician(s) with appropriate privileges. Initial and ongoing assessment of patients’ medical, physical and psychosocial status, including:

Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
<i>GENERAL</i>					
Admit outpatients to the inpatient service and collaborate with the physician when indicated.					
Conduct and interpret diagnostic tests.					
Conduct preventive screening procedures based on age and history.					
Determine the effectiveness of the plan of care through documentation of client care outcomes.					
Develop a client education plan.					
Formulate the appropriate differential diagnosis based on the history, physical examination, and clinical findings.					
Give local anesthesia for wound infiltration and suturing of minor lacerations not involving nerve, tendon, or vessels.					
Identify appropriate pharmacologic agents.					
Identify medical and health risks and needs.					
Identify needs of the individual, family or community as a result of the evaluation of collected data.					

Identify nonpharmacologic interventions.					
Incise and drain minor abscesses.					
Make appropriate referrals to other health professionals and community agencies.					
Obtain a relevant health and medical history.					

Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
Order appropriate diagnostic tests.					
Participate in quality assurance review on a periodic basis, including systematic review of records and treatment plans.					
Perform a physical examination based on age and history.					
Perform CPR when necessary.					
Perform gynecological and breast cancer screening care.					
Prescribe controlled substances.*					
Prescribe nonpharmacologic therapies					
Prescribe pharmacologic agents.*					
Provide relevant patient education.					
Reassess and modify the plan as necessary to achieve medical and health goals.					
Treatment of minor gynecological problems and venereal diseases.					
Triage patients with life-threatening problems.					
Update and record changes in health status.					
Write prescriptions for needed medication and/or home supplies.*					
GERIATRICS & EXTENDED CARE					
Active participant of NHCU interdisciplinary care planning team.					
Acts as a consultant in management of geriatric/rehabilitation/palliative patient.					
Consults independently with other health care professionals					
In collaboration with physician, primary care provider writes admission and discharge orders, and completes patient discharge summary.					
In collaboration with physician, transfers patients for acute hospitalization.					
Manage specialized groups of patients including subacute, rehabilitation, palliative and spinal cord.					
Performs treatment modalities mutually agreed upon by nurse practitioner and medical/surgical staff to include suture removal and debridement.					
Prescribes Class II medications for patient pass or discharge.*					
Provides leadership at patient/family conferences to deal with complex health maintenance and discharge planning issues.					
Utilizes research findings to support management and specialized care of geriatric/rehabilitation/palliative patients.					
Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
SPINAL CORD INJURY					
Education and treatment of pressure sores which may include various combinations of medical treatment, equipment recommendations, and mechanical and/or enzymatic debridement.					
Evaluates and treats autonomic dysreflexia including nifedipine use.					
Evaluates, recommends, and educates appropriate management of the neurogenic bowel and bladder.					

Orders appropriate medications and equipment for the management of neurogenic bowel and bladder.					
Provide patient and staff education regarding recognition of autonomic dysreflexia.					

*Contingent upon yearly certification by the Arizona State Board of Nursing for prescription writing privileges as well as approval within this VA Medical Center. I request approval for the above scope of practice.

Signature of Applicant **Date**

Signature of Collaborating Physician **Date**
CARL T. HAYDEN VA MEDICAL CENTER
Phoenix, Arizona

Name:		
(Last)	(First)	(Middle)
Department/Section:		
Specialty:		

EDUCATION ACTIVITIES

Course Title	Location	Date	

CARL T. HAYDEN VA MEDICAL CENTER
Phoenix, Arizona

DECLARATION OF HEALTH FOR ALLIED HEALTH PROFESSIONALS

I, _____, hereby declare that, to the best of my knowledge, I do not have a physical or mental health condition that would adversely affect my ability to carry out the scope of practice which I have requested from the VA Medical Center, Phoenix, Arizona.

Signature of Applicant **Date**

 (TO BE SIGNED BY VA MEDICAL DEPARTMENT CHAIR PHYSICIAN OR VA MEDICAL CENTER EMPLOYEE HEALTH PHYSICIAN.)

To the best of my knowledge, I concur with the Declaration of Health presented by

 (Name of Applicant)

Physician Signature

Printed Name of Physician

RENEWAL PACKET

CONTENTS:

- (a) Application for Renewal of Scope of Practice for Allied Health Professionals
- (b) Scope of Practice - Department Specific (sample format)
- (c) Declaration of Health for Allied Health Professionals
- (d) Continuing Education Activities
- (e) Assessment by Collaborating Physician or Department Chair for Renewal of Scope of Practice
- (f) Peer Appraisal for Renewal of Scope of Practice
- (g) Allied Health Professionals – QA Review/Scope of Practice Renewals

Include:

- (a) Copies of current licensure(s), registration(s), and/or certifications

- (b) Copy of current Proficiency or Performance Appraisal **Effective Date: From: To:**

CARL T. HAYDEN VA MEDICAL CENTER
Phoenix, Arizona

APPLICATION FOR RENEWAL OF SCOPE OF PRACTICE FOR ALLIED HEALTH PROFESSIONALS

Name: _____
(Last) (First) (Middle)

Department/Section: _____

Specialty: _____

The following information is offered in support of the request for renewal of scope of practice. Please answer each question as it applies to the period of time since your initial appointment or renewal.

A. Licensure/Registration: List all current and past licenses and registrations, even if expired. (If expired, please explain on a separate sheet of paper and attach to this application why it was not renewed.)

State	Expiration Date	Current	
		Yes	No

B. Certification: (Name and Date): _____
If not certified, then formal post-graduate training: _____

C. Membership in Professional Organizations: (Local, State, Professional Society):

D. Continuing Education (Educational meetings, seminars, course, etc., attended during the last 24 months.) Attach TEMPO listing.

Name: _____

Please list **three peers** familiar with your clinical skills. (Note: Peers listed cannot include your Department Chair.)

Name Position Complete Address Telephone #

Name: _____

For any questions answered "YES," provide complete information on a separate sheet of paper and attach to this application.

Since your initial appointment or renewal of scope of practice:

QUESTIONS	YES	NO	
1. Have you had any problems with your health status, which might affect your ability to carry out your scope of practice at this medical center?			
2. Have you received any type of sanction or are you currently under investigation by a hospital, state licensing agency, or other health care organization?			
3. Have you allowed a license, registration, and/or certification to expire?			
4. Have you had any license, registration, and/or certification revoked, suspended, denied, restricted, limited, voluntarily or involuntarily relinquished, or issued/placed in a probational status?			
5. Has your license ever been limited, suspended, or revoked?			
6. Have you had previously successful or currently pending challenges to any licensure or registration or the voluntary/involuntary relinquishment of any licensure, registration, or certification?			
7. Have you received any additional license(s)?			
8. Have you had any felony criminal charges?			

E. Request for Approval of Scope of Practice.

I request approval for Renewal of Scope of Practice as indicated on the attached form.

Signature of Applicant

Date

Collaborating Physician

On the basis of the information on this application, a review of patient care activities, professional staff and committee participation, and my knowledge through my own personal observation and peer review of the applicant's current professional competency and clinical judgment, I:

_____ Recommend approval as requested.

_____ Recommend approval with the following deletions or modifications:

Deletions: _____

Modifications: _____

_____ Recommend Disapproval. Reason: _____

Signature of Department Chair

OR

Signature of Collaborating Physician

Date:

Date:

Name: _____

G. Departmental Review Board (if applicable)

_____ Recommend approval of Collaborating Physician and/or Department Chair recommendation.

_____ Recommend disapproval of Collaborating Physician and/or Department Chair recommendation.

Signature of Chair, Department Review Board (if applicable)

Date

Signature of Coordinator (if applicable)

Date

H. Professional Standards Board

_____ Approve Collaborating Physician and/or Department Chair recommendation.

_____ Disapprove Collaborating Physician and/or Department Chair recommendation.

Signature of Chairperson, Professional Standards Board

Date

Empty signature box for Professional Standards Board chairperson.

- Approve scope of practice as recommended by the Professional Standards Board.
- Disapprove scope of practice as recommended by the Professional Standards Board.

Signature of Chairperson, Clinical Executive Board

Date

Empty signature box for Clinical Executive Board chairperson.

- Approve scope of practice as recommended by the Clinical Executive Board.
- Disapprove scope of practice as recommended by the Clinical Executive Board.

Signature of Medical Center Director

Date

Application for Scope of Practice Title: (CRNA, PA, NP, RN, etc.)	LINE”
Carl T. Hayden VAMC – Phoenix, AZ	<i>Department:</i>
	<i>Section:</i>

Applicant:

Effective Dates: From: _____ To: _____

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Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
<i>GENERAL</i>					
Admit outpatients to the inpatient service and collaborate with the physician when indicated.					
Conduct and interpret diagnostic tests.					
Conduct preventive screening procedures based on age and history.					
Determine the effectiveness of the plan of care through documentation of client care outcomes.					
Develop a client education plan.					
Formulate the appropriate differential diagnosis based on the history, physical examination, and clinical findings.					
Give local anesthesia for wound infiltration and suturing of minor lacerations not involving nerve, tendon, or vessels.					
Identify appropriate pharmacologic agents.					
Identify medical and health risks and needs.					

Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
Identify needs of the individual, family or community as a result of the evaluation of collected data.					
Identify nonpharmacologic interventions.					
Incise and drain minor abscesses.					
Make appropriate referrals to other health professionals and community agencies.					

Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
Obtain a relevant health and medical history.					
Order appropriate diagnostic tests.					
Participate in quality assurance review on a periodic basis, including systematic review of records and treatment plans.					
Perform a physical examination based on age and history.					
Perform CPR when necessary.					
Perform gynecological and breast cancer screening care.					
Prescribe controlled substances.*					
Prescribe nonpharmacologic therapies					
Prescribe pharmacologic agents.*					
Provide relevant patient education.					
Reassess and modify the plan as necessary to achieve medical and health goals.					
Treatment of minor gynecological problems and venereal diseases.					
Triage patients with life-threatening problems.					
Update and record changes in health status.					
Write prescriptions for needed medication and/or home supplies.*					
GERIATRICS & EXTENDED CARE					
Active participant of NHCU interdisciplinary care planning team.					
Acts as a consultant in management of geriatric/rehabilitation/palliative patient.					
Consults independently with other health care professionals					
In collaboration with physician, primary care provider writes admission and discharge orders, and completes patient discharge summary.					
In collaboration with physician, transfers patients for acute hospitalization.					
Manage specialized groups of patients including subacute, rehabilitation, palliative and spinal cord.					
Performs treatment modalities mutually agreed upon by nurse practitioner and medical/surgical staff to include suture removal and debridement.					
Prescribes Class II medications for patient pass or discharge.*					
Provides leadership at patient/family conferences to deal with complex health maintenance and discharge planning issues.					
Utilizes research findings to support management and specialized care of geriatric/rehabilitation/palliative patients.					
SPINAL CORD INJURY					
Education and treatment of pressure sores which may include various combinations of medical treatment, equipment recommendations, and mechanical and/or enzymatic debridement.					
Evaluates and treats autonomic dysreflexia including nifedipine use.					

Scope of Practice	Requested	Not Requested	Granted	Modified	Denied
Evaluates, recommends, and educates appropriate management of the neurogenic bowel and bladder.					
Orders appropriate medications and equipment for the management of neurogenic bowel and bladder.					
Provide patient and staff education regarding recognition of autonomic dysreflexia.					

*Contingent upon yearly certification by the Arizona State Board of Nursing for prescription writing privileges as well as approval within this VA Medical Center. request approval for the above scope of practice.

Signature of Applicant

Date

Signature of Collaborating Physician

Date

CARL T. HAYDEN VA MEDICAL CENTER

Phoenix, Arizona

Name:

(Last)

(First)

(Middle)

Department/Section:

Specialty:

Education Activities

Course Title	Location	Date	

Declaration of Health for Allied Health Professionals, _____, hereby declare that, to the best of my knowledge, I do not have a physical or mental health condition that would adversely affect my ability to carry out the scope of practice which I have requested from the VA Medical Center, Phoenix, Arizona.

Signature of Applicant

Date

(TO BE SIGNED BY VA MEDICAL DEPARTMENT CHAIR PHYSICIAN OR VA MEDICAL CENTER EMPLOYEE HEALTH PHYSICIAN)To the best of my knowledge, I concur with the Declaration of Health presented by

(Name of Applicant)

Physician Signature

Printed Name of Physician

ASSESSMENT BY COLLABORATING PHYSICIAN or DEPARTMENT CHAIR FOR RENEWAL OF SCOPE OF PRACTICE

Name: _____

Department: _____

Period Covered: _____

Additional information is required of "NO" answers.

	YES	NO	N/A
1. Does individual have a current, valid, and unrestricted license?			
2. Is the individual free of physical or mental disability or changes in health status which would impact professional functioning?			
3. Has quality of care information been utilized in the evaluation of the individual's scope of practice?			
4. Are peer comments positive?			
5. Has the individual's clinical and/or technical skills been observed and evaluated?			
6. Does the individual exercise appropriate professional judgment and performance?			
7. Does the individual complete medical records on a timely basis, if applicable?			
8. Does the individual show positive evidence of contributions to patient care and quality assurance?			
9. Does the individual have an acceptable attitude towards patients, medical center staff, residents, students, and other members of the medical staff?			
10. Does the individual actively participate in medical staff affairs including peer review and committee assignments?			
11. Should the individual's requested scope of practice be approved?			
12. COMMENTS:			

Signature of Collaborating Physician OR Department Chair

Date

Application for Renewal of Scope of Practice

Using the items listed below as guidelines, please provide your evaluation of _____'s clinical practice at this medical center.

Questions			N/A
1. Has exercised good medical judgment in the care of patients in this medical center? Comments: _____			
2. Individual is free of physical or mental disability or changes in health status which would impact professional functioning? Comments: _____			
3. Has complied with medical center policies? Comments: _____			
4. Participates actively in medical staff affairs including peer review and committee assignments? Comments: _____			
5. Has an acceptable attitude toward patients, medical center staff, and other members			

of the Medical Center? Comments: _____			
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6. Please provide a narrative assessment of the individual's clinical practice abilities. (Attach a separate sheet if necessary.)

The above information is true and accurate to the best of my knowledge. Please consider this my recommendation in support of their requested scope of practice.

Signature

**ALLIED HEALTH PROFESSIONALS - QUALITY ASSURANCE REVIEW
SCOPE OF PRACTICE RENEWALS***

Name of Allied Health Professional: _____

Department/Section: _____

Specialty: _____

Period Covered:

From: _____

To: _____

1. Risk Management Issues/Cases: Occurrence Screens/Peer Review: _____ Tort Claims: _____ Patient Complaints: _____ Incident Reports: _____	2. Quality Assurance/Quality Control Issues:
3. Invasive Procedures Review: Variances: _____ None: _____	4. Laboratory Patterns: Variances: _____ None: _____
5. Mandatory Training: Safety: _____ BLS: _____ ACLS: _____ Infection control: _____ Information management: _____	6. Medication & Clinical Nutrition Management Review: Special ordering patterns: _____ Variances: _____ None: _____
7. Current Proficiency/Performance Appraisal: Date Last Completed: _____	8. Other: Medical record suspensions Number of admissions Number of ICU admissions Number of surgeries Number of transfusions Number of central line infiltrations Number of ventilator related pneumonias Number of nosocomial MRSA's Mortality rates Morbidity rates Readmission rates Average length of stay Peer review issues Malpractice suits

***Fill in boxes as appropriate.**

Signature – Department Chair/Date

OR

Signature – Collaborating Physician/Date

(Printed Name)
Peer Review

(Printed Name)

Objective: Implement mechanisms to ensure that objective measurable data is used consistently to re-evaluate Allied Health Professionals at the time of reappointment

Policy: Quality Improvement (QI) data will be utilized in the scope of practice process as part of the overall quality improvement program. In order to assist in that process, an Allied Health Professionals - Quality Review form will be completed for each Allied Health Professional immediately prior to the renewal process, using data that is available through various quality improvement mechanisms. The data-reporting period will be the same as the annual evaluation period. It is the responsibility of each collaborative physician and/or Department Chair to utilize QI data in the renewal process. Each collaborative physician and/or department chair shall consider QI data collected at the department level, medical center committees as well as data the Department Chair may have received from the Quality Management Department related to peer reviews, incident reports, etc.

PEER REVIEW PROCESS

1. **PURPOSE:** To outline the policy and procedure requirements of the Peer Review Program and related processes. These processes focus on Medical Staff peer review. However, the process may also be utilized in relation to other allied health personnel.
2. **POLICY:** As part of the medical center wide quality reviews, Medical Staff functions, Utilization Management, Morbidity and Mortality reviews, Patient Safety and other related items, each clinical department will participate in the peer review process as outlined. The scope of this policy includes review of adverse events identified in the Patient Incident Review, and other cases that fall out or are referred for further review. This information is confidential in accordance with Title 28 U.S.C 5705
3. **PROCEDURES:** a. **Clinical Review:**
 - (1) The initial review of records identified by the screening process (Appendix A - Flow Chart of Peer Review process) will be performed by a registered nurse who will verify that the case meets the appropriate criteria:
Criteria: Return to the O.R. in same admission (this is tracked by National Surgical Quality Improvement Program [NSQIP] nurse - Justified exceptions include:
 - (a) Two operations separated by more than 7 days;
 - (b) Second procedure unrelated to first;
 - (c) Planned multiple stage procedure documented prior to first surgery (when the case is scheduled prior to the first surgery being done);
 - (d) Planned multiple stage procedure documented prior to the first surgery (when the case is not scheduled prior to the first surgery being done); and (e) Second operation in response to findings from first procedure.

Death: (see Appendix B for criteria) - Justified exceptions NONE:

Other Reviews: (See Appendix C for criteria)-(2) For each of the aforementioned cases a data retrieval sheet will be completed and a determination made on whether a) the case needs to be examined by a peer reviewer and b) the case should be referred to a committee or service for review of possible management, system or equipment problems.

(3) If the care is identified as less than optimal because of practitioner-related issues, the case is then referred to a peer reviewer.

b. **Peer Review:**(1) The peer reviewer will examine cases as referred and will evaluate the quality of practitioner care and the severity of any injury or disability resulting from sub-optimal care using the Peer Review Form (Appendix D) and the Severity of Injury/ Practitioner Quality of Care Scale (Appendix E) as follows:

- (a) Level 1 - Most experienced, competent practitioners would have handled the case in all of the respects listed below (peer reviewer lists them on the form).
- (b) Level 2 - Most experienced, competent practitioners might have handled the case differently in one or more of the respects listed below (peer reviewer lists them on the form).
- (c) Level 3 - Most experienced, competent practitioners would have handled the case differently in one or more of the respects listed below:
 1. Choice of diagnostic tests;
 2. Timely performing of diagnostic tests;
 3. Addressing abnormal results of diagnostic tests;
 4. Timeliness of diagnosis;
 5. Appropriateness of diagnosis to evidence;
 6. Timing of treatment initiation;
 7. Appropriateness of treatment to condition;
 8. Adequacy of technique during procedure;

9. Recognition and communication of critical clues to patient's condition during period of clinical deterioration;

10. Timely initiation of appropriate actions during period of clinical deterioration; and

11. Other relevant aspects of care.

(2) When peer reviewers determine that Level 2 or 3 practitioner care occurred, they will indicate the involved practitioners on the data retrieval form. Housestaff, consultants, members of support services and non-physicians as well as attending physicians should be designated when appropriate. The attending physician will be considered the responsible physician on the case. Physicians will not act as peer reviewers on cases where they are identified as the attending physician.

(3) If the peer reviewer identifies possible non-practitioner problems that were not noted by the clinical reviewer, those should be documented on the data retrieval form. The Risk Manager of the Quality Management Department will refer these cases to the appropriate service or committee for review and recommendations.

(4) The peer reviewer will have the option of withdrawing from a case when the specialized knowledge required exceeds their expertise or when they feel uncomfortable about judging the care provided by a particular colleague.

(5) After review by the Chief of Staff, cases in which practitioner care is evaluated as Level 2 or 3 will be referred by the Risk Manager, Quality Management Department to the Department Chair for determination of appropriate corrective action. The actions chosen by the Department Chair will be communicated in writing to the Chief of Staff and the Chair, Quality Management Department.

(6) If the Department Chair was identified by the peer reviewer as an involved practitioner, the case will be referred to the Chief of Staff for the development of corrective action.

(7) Practitioners whose care is under review will be given an opportunity to comment on issues raised during the review process and to provide additional information not available in the chart. This should occur either at the time of peer review, committee review (if applicable) or Department Chair review and can either be in writing or through face-to-face discussion.

(8) If an appropriate peer reviewer for a case cannot be identified within the medical center's staff, the assistance of a practitioner from another VA Medical Center or from a facility outside DM&S will be requested.

(9) All physician staff and Quality Management Department staff will comply with the medical center's policy that defines Confidentiality of HSRO/QA Documents.

4. RESPONSIBILITY: a. The Chief of Staff is responsible to:

(1) Ensure that there is a peer review procedure established. Peer reviewers, comprised of representatives of the clinical services, will be appointed by the Chief of Staff/ designee. The peer reviewers will be responsible for those cases in their bed section/ specialty requiring peer review. The Chief of Staff is responsible for reviewing those cases in which the Department Chair was identified as an involved practitioner and will determine and report corrective actions. If an appropriate peer reviewer cannot be identified within the facility's staff, the Chief of Staff will seek the assistance of another VAMC or will request the assistance of a practitioner or facility outside of the VHA Department of Medicine and Surgery.

(2) Ensure that appropriate action is taken and that appropriate recommendations resulting from that action are implemented.

b. ACOS's/Administrators/Department Chairs and Assistant Administrators are responsible to

(1) Assure that the process described herein is in place in all their departments.

(2) Assure timely reporting of patient deaths, adverse incidents, near misses, utilization management issues and other events.

(3) Take follow-up actions as needed to "close the loop."

(4) Share information such as risk management reports with staff as appropriate.

c. Department Chairs are responsible to:(1) Select peer reviewers within their department and will ensure that a back-up individual is selected to review cases involving the peer reviewer in his or her absence.

(2) Respond to and act upon recommendations made by the peer reviewers including: determining and implementing corrective actions concerning practitioners in a given case, communicating actions to the Chief of Staff and the individual or the committee and coordinating the Peer Review/Occurrence Screening Program.

(3) Complete the department provider form related to QI activities for each individual prior to their semiannual credentialing and re-privileging process.

(4) Implement corrective plans of action as needed.

d. Peer Reviewers are responsible to:

(1) Review cases referred from the Chief of Staff or Risk Management/Quality Management. This includes, but is not limited to death reviews, utilization reviews, unplanned clinical occurrences, adverse patient events (patient incident reporting program) and "near misses."

(2) Review ad hoc cases from department chairs or the Chief of Staff.

(3) Meet the primary pre-requisite of having the clinical expertise necessary to make judgments about issues involved in the case.

(4) Should have no direct involvement with the episode of care in question.

(5) Complete and “sign off” the required documents, including findings, discussion, conclusions as to the level of care, and recommendations for preventative or corrective action.

e. Risk Management/Patient Safety Section of the Quality Management Department will:

(1) Coordinate and oversee all activities related to peer review including, but not limited to: data collection, review, follow-up on recommendations, tracking of implementation of corrective action and reporting of aggregate data and individual-specific information as appropriate.

(2) Ensure compliance with VA and other regulatory mandates.

(3) Maintain the official files of all peer review/peer review cases, adverse events-related reviews, sentinel events, close calls and investigations.

(4) Coordinate with the Chief of Staff and Department Chairs to facilitate the follow-up activities and communication of findings/recommendations of relevant events to appropriate individuals and groups.

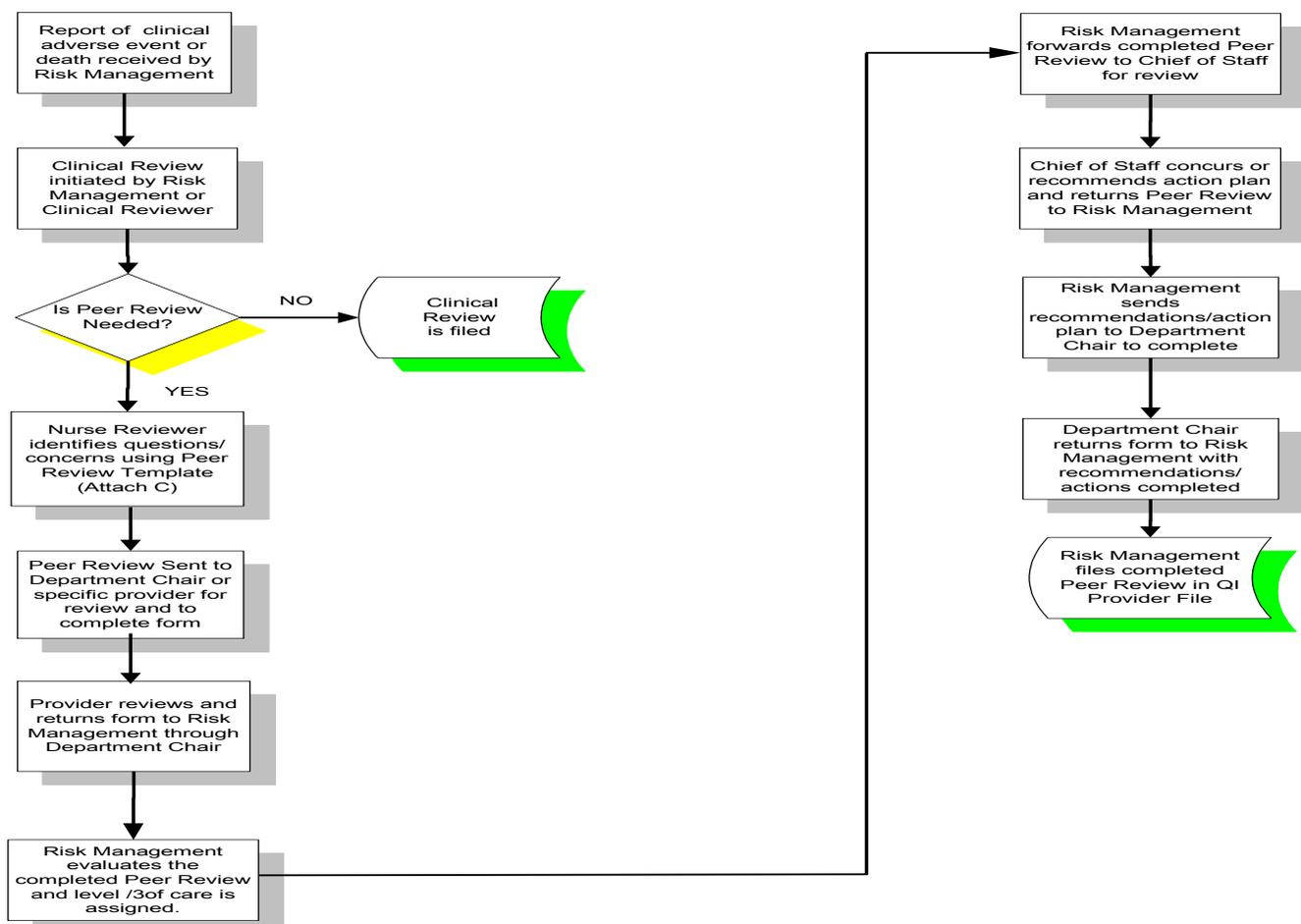
(5) Track the status of follow-up actions on recommendations.

(6) Provide a quarterly report of aggregated data to the Clinical Executive Board (Starting with FY 2003).

(7) Provide supporting literature review as needed when Sentinel Events and outside peer reviews occur.

5. REFERENCES: Code of Federal Regulations, Death Reviews; Occurrence Screening Circular 10-88-71, and all corresponding supplements.

Peer Review Process Flow Chart



Clinical Review Worksheet

Death Review

This information is confidential in accordance with Title 28 U.S.C 5705.

PATIENT NAME:	SSN:
LOCATION OF DEATH:	TREATING SPECIALTY:
ATTENDING:	RESIDENT/PROVIDER:
CLINICAL REVIEWER:	DATE OF DEATH:
DIAGNOSIS OR CAUSE OF DEATH:	

Instructions: Review the medical record and answer the following by circling the appropriate ‘Y’ or ‘N’. Record any comments at the end of the worksheet.

1	Y	N	There is a lack of documentation of patient’s deterioration during the 48 hours preceding death.
2	Y	N	Change in Patient’s condition with no action taken during 48 hours preceding death.
3	Y	N	If there was a cardiac or pulmonary arrest could it have been avoided.
4	Y	N	There was a lack of concordance between patient’s premortem and postmortem diagnosis.
5	Y	N	It appears there were signs of patient’s deteriorating condition that should have been noted and/or communicated to M.D. but were not
6	Y	N	Death appears to be related to failure to carry out orders.
7	Y	N	There is a lack of documentation indicating explanation for the death.
8	Y	N	There is a lack of documentation indicating patient’s death was expected.
9	Y	N	Death was within 24 hours of admission.
10	Y	N	Death was within 72 hours of transfer out of special care unit (unless transfer made because death was expected.)
11	Y	N	Death during or within 72 hours of elective procedure.
12	Y	N	Death appears to be related to complication of elective procedure.
13	Y	N	Death appears to be related to medication error or choice of medication.
14	Y	N	Death appears to be related to equipment malfunction.
15	Y	N	There is reason to think death may have been preventable.
16	Y	N	Other
17	Y	N	Was autopsy requested?

	1. DNR order
	2. Admitted to palliative (terminal) care
	3. Death did not occur anywhere in the medical center.

This information is confidential in accordance with Title 28 U.S.C 5705.

	1. Usual, customary and reasonable.
	2. Peer Review Needed
	3. Exception to criteria
	4. Equipment issues
	5. System Issues

ACTION(S):

	1. No further action
	2. No further action (investigation or RCA)
	3. Refer for Peer Review. (Please state questions for peer review below.)

Comments/Questions for Peer Review:

Clinical Review Worksheet (General)

This information is confidential in accordance with Title 28 U.S.C 5705.

PATIENT NAME:	SSN:
SERVICE/WARD:	TREATING SPECIALTY:
ATTENDING:	RESIDENT/PROVIDER:
CLINICAL REVIEWER:	DATE OF ADMISSION:
DIAGNOSIS and PROCEDURES:	

Instructions: Review the medical record and answer the following by circling the appropriate ‘Y’ or ‘N’. Record any comments at the end of the worksheet.

1	Y	N	There is a lack of documentation of patient’s deterioration/complications during the length of stay. Comments:
2	Y	N	Change in patient’s condition with no action taken during the last 24 hours. Comments:
3	Y	N	If there was a cardiac or pulmonary arrest could it have been avoided. Comments:
4	Y	N	There was a lack of concordance between patient’s admission diagnosis and length of stay. Comments:
5	Y	N	It appears there were signs of patient’s deteriorating condition that should have been noted and/or communicated to M.D. but were not. Comments:
6	Y	N	Length of stay appears to be related to failure to carry out orders. Comments:
7	Y	N	There is a lack of documentation indicating explanation for the length of stay. Comments:
8	Y	N	There is a lack of documentation indicating patient’s length of stay was expected. Comments:
9	Y	N	Complications were within 24 hours of admission or post-procedure. Comments:
10	Y	N	Complications were within 24 hours of transfer out of special care unit. Comments:
11	Y	N	Complications were during or within 24 hours of elective procedure. Comments:
12	Y	N	Length of stay appears to be related to complication of elective procedure. Comments:
13	Y	N	Length of stay appears to be related to medication error or choice of medication. Comments:
14	Y	N	Were consults and other procedures requested in a timely manner and completed in a timely manner? Comments:

	1. Usual, customary and reasonable.
	2. Peer review needed
	3. Exception to criteria
	4. Equipment issues
	5. System issues

ACTION(S):

	1. No further action
	2. Further action (investigation)
	3. Refer for peer review. (Please state questions for peer review below.)

COMMENTS/QUESTIONS FOR PEER REVIEW:

Peer Review Results Sheet

Items A-C to be completed by Nurse Reviewer

A. Sources and type of Review:

Incident Report	Individual Peer Review
Quality Indicator	Concurrent Peer Review
Team conference, M&M, Psych. Autopsy	Nursing Review
Occurrence Screen (death)	

B. Patient identification and information:

Patient Name	
Social Security No.	
Date of Occurrence	
Service/Ward	
Diagnosis	
Attending MD	
DNR	Yes No Unknown

C. Dear Reviewer:

These issues were found to be of concern to the Clinical Reviewer:

a.
b.
c.

PHYSICIAN/ REVIEWER: *Please review this patient record and check the statement, which fits the case in your opinion.*

1. According to the Practitioner Quality of Care Scale, I rate this case:

Level 1 – Most practitioners would handle the case similarly
Level 2 – Most practitioners might handle the case differently
Level 3 – Most practitioners would handle the case differently

2. Please identify the type of problem (check all that apply)

Choice of diagnostic tests
Timely performing of diagnostic tests
Addressing abnormal results of diagnostic tests
Timeliness of treatment initiation
Appropriateness of diagnosis to evidence
Timing of treatment initiation
Appropriateness of treatment to condition
Adequacy of technique during procedure
Recognition and communication of critical clues to patient’s condition during period of clinical deterioration
Timely initiation of appropriate actions during period of clinical deterioration
Other relevant aspects of care

3. Have actions been implemented as a result of the practitioner care provided? Yes _____ No _____
Please check appropriate response(s).

Practitioner counseled
Practitioner education (case presented at conferences/M&M, etc.)
Case discussed for practitioner education in literature, periodicals, newsletters, etc.

	No Action
	Other/ or Unknown:

4. In retrospect, are there any areas, (care, processes, or systems) where patient care could have been improved? If yes, please check type of problem and explain: If more room is needed, feel free to write on back of page.

_____ Practitioner _____ Management _____ Equipment _____ System

Please Sign and Print Name Below:

Signature	Date
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Printed name	
--------------	--

Concur/Do Not Concur
 CHIEF OF STAFF
 Quality Management Assessment and Follow-up

Refer To:
Regarding:
a.
b.
c.
d.

SEVERITY OF INJURY LEVELS

- Level 0: No injury or disability
- Level 1: Minor or Moderate injury:

Injuries are minor or moderate in nature and if they do require any medical intervention, it does not extend the patient’s hospital stay or outpatient treatments, except for observation or to obtain laboratory/ radiology results. Examples: Fractures of fingers, bruises, abrasions, small lacerations requiring sutures, choking, bites, burns (those less than 1% of the body surface and 3rd degree smaller than ½ by ½”)

- Level 2: Major

Injuries that require medical or surgical intervention, increased hospital stay or are disabling/disfiguring to a degree that the patient will have any degree of permanent dysfunction are sentinel event. Examples: Laceration requiring extensive suturing, vital structure damage fractures of major bones, significant burns, organ loss, etc.

- Level 3: Catastrophic - Death

Sample Medical Education Policy

Medical staff members should participate in a program of continuing medical education designed to keep them informed of significant new developments, current technology, and skills in medicine.

Medical staff education will include hospital-based programs, planned and scheduled in advance and held on a continuing basis. Educational programs also include any educational opportunities held within or outside of the hospital sponsored by educational institutions, societies, or organizations approved for continuing medical education (CME).

Documentation of these activities will be recorded and maintained in order to evaluate scope, effectiveness, attendance, and the amount of time at such effort.

Medical staff members are required to complete 50% of the minimum requirements of their continuing education units in the area of their specialty.

This continuing education must be documented in the medical staff member's file. Departmental meetings at which continuing education is conducted may be used, but they must be documented, and approved for CME credit. Individual program certificates are requested not to be submitted for inclusion in the practitioner's credential file, rather documentation of CME shall consist of :

A copy of the information submitted to the state licensing board of medicine with the practitioner's renewal application or

Completion of the medical staff CME credit program document that is available from the medical staff office which includes an attestation statement, completed and signed by the practitioner that lists all CME programs attended and attests to the practitioner's attendance at the programs.

Sample CME Record

Practitioner Name: _____ Medical Staff Number: _____

License Number: _____ DEA Number: _____

Dates: (time frame for appointment or reappointment period)

Completion Date	Provider Number	Course Name	Contact Hours

Attestation Statement

<p>I have successfully completed the hours of continuing education as stated during the period of time indicated on this form. I declare under penalty of perjury under the laws of the state of _____ that the foregoing is true and correct. I agree to provide proof of attendance and program content upon request.</p>	
<p>Signature: _____</p>	<p>Date: _____</p>

Communication

Communication is a process that remains incomplete until the message reaches its destination as undiluted or unchanged as possible. Proper encoding, clear transmitting and receiving, and accurate decoding are all involved. The main concern in proper communication is that the most accurate method of selecting a message, transmitting it without interference, and reproducing it at the receiving or destination end is used. In addition, the proper selection of the channel and use of media are critical to the effectiveness of even the most carefully prepared message.

However, whether spoken, written, graphic, or nonverbal, the message simply cannot be more effective than the quality of its preparation. A poor message will always be poor regardless of how well its transmission was effected. As long as human beings are involved in the process of communication, semantics, behavioral patterns, motivation, and attitudes enter the communication process. Difficulties in communication lie not so much with what people say or write but with what goes on in the minds of those sending and receiving the messages. Bridging the gap between one mind and another primarily by the use of words is the task of communication.

Communication in Organizations

Communication in the large formal organization is actually an extension of person to person and group communication, because the organization is made up of interdependent and often overlapping

groups. The organization exists because it can accomplish more than groups and individuals by themselves. As an entity, the organization develops when task complexity and size require increased specialization and, thus, greater interdependence of units. A formalized hierarchy is usually designed to assist in the coordination of organizational activities.

Organizations will change; only the form they will take is unknown. The communication processes will not change fundamentally. People will still send messages to be received and decoded by others. These messages will consist primarily of spoken and written (including electronic) words and the nonverbal aids that accompany them. Speaking, writing, listening, and reading will continue to be the elements of human communication. In a sense, then, the person best prepared to cope with today's world may also be the person best prepared to adapt to the changes of tomorrow.

Reflecting on the state of the art of organizational communication, scholars and researchers have long studied the organization and what makes it function. But few universal principles or findings have emerged, perhaps because organizations have already begun the accelerated change that inevitably accompanies rapid changes in technology, governmental relationships, and increased understanding of human elements. In other words, organizations generally don't stand still long enough to provide static subjects for analysis.

Two systems of organizational communication simultaneously influence human behavior. The **external system** is typified by the formal organizational chart, which is created by management to control individual and group behavior and to achieve organization goals. Essentially, the external system is dictated by the technical, political, and economic environment of the organization. Within this external system, people are required to behave in certain ways simply to get the work done. Because it is dictated by environmental forces existing outside the needs of the individuals in the organization, the system is called external.

The **internal system** develops as people interact within the formal, external system and certain behavior patterns emerge, patterns, which accommodate social and psychological needs. The external system, then, requires certain behaviors to get the work done, nothing more. The internal system develops from emergent behaviors and assists in achieving maintenance goals. These two systems operate concurrently in all organizations but to varying degrees, and management must recognize and work with both. The two systems together represent the organizational culture.

When participants rely almost entirely on the formalized external system as a guide to behavior, the system might be identified as a bureaucracy. Procedure manuals, job descriptions, organization charts, and other written materials dictate the required behavior. Communication channels are followed strictly, and red tape is abundant. Procedures are generally followed exactly; terms such as rules and policy serve as sufficient reasons for actions. But even the most formal of organizations cannot function long without an internal system emerging. As people operate within the external system, they must interact on a person to person basis and create an environment conducive to satisfying their personal emotions, prejudices, likes, and dislikes.

The internal system may emerge and overlap the external system. These behaviors become norms for the organization. People who do not engage in the internal system may be ostracized or cut out of communication by others. Obviously, the informality of the internal system is good for people because it helps satisfy maintenance goals. At the same time, it affects communication. The grapevine is perhaps the best-known informal communication system. It is actually a component of the internal system. As people talk casually during coffee breaks and lunch periods, the focus usually shifts from topic to topic. Even though the external system calls for very definite communication channels, the grapevine tends to develop and to operate within an organization.

Directional Communication

Within the external system, communication may flow downward, upward, or horizontally.

Downward communication is that from superior to subordinate, and from policy makers to operating personnel.

One study has identified five elements in downward communication:

1. **Job instruction:** Teaching new or current employees how to do particular tasks.
2. **Rationale:** The justification for the organization and its goals, how a particular task or function fits into the total organization.
3. **Information:** Orientation to the company, its rules, practices, procedures, and history.
4. **Feedback about job performance:** Supervisor's evaluation or appraisal of employee performance.
5. **Ideology:** The effort to convey to and instill in employees a degree of enthusiasm, loyalty, or support for the organization.

Downward communication flow is, of course, related to the hierarchical structure of the organization. Messages seem to get larger as they move down through successive levels of the organization. A simple instruction given at the top of the hierarchy, for example, may become a formal plan for operation at lower levels. Much of this growth of messages is also related to the relative knowledge of the total organization and its goals possessed by those at each level. An objective established by people at the policy level, the board of directors or executive officers would result in detailed plans at a lower level.

Horizontal or lateral communication is often used to describe exchanges between organizational units on the same hierarchical level. This description is one of the major shortcomings of organizational charts. Charts really don't leave much room for horizontal communication when they picture authority relationships by placing one box higher than another and define role functions by placing titles in those boxes. But horizontal communication is the primary means of achieving coordination. In fact, horizontal communication would probably exist as part of the internal system even though it was not defined by the formal chart. Workers at the same level tend to talk with one another about their work, their superiors, and their working conditions. They also talk with one another about various personal, non-work problems. As a result, horizontal communication can contribute to self-maintenance goals as well as to task goals.

Types of Organizations

All organizations are different, and no single set of guiding principles can apply to all of them. Some organizations are static and predictable. For example, governmental organizations tend to be bureaucratic. The day to day work is routine. Procedures and systems are fixed and are perhaps only revised infrequently. Many health systems organizations fall into this category. On the other hand, some organizations are dynamic and unpredictable. Within both extremes of organizations, static to dynamic, some units will vary from the definition.

The **static organization** relies heavily on the external system. This means that rules and procedures are fixed, little interpersonal communication of an informal nature is necessary, and individual and group maintenance activities are quite separate from task activities. This kind of system relies on commands, and directs people to perform tasks. It uses a formal communication method, which places a small communication load on the organization. It also tends to have a well-defined difference between task and maintenance goals. Nothing is wrong with this type of organization. It developed because of the nature of the tasks involved and happens to be the most effective type of organization for accomplishing those tasks. Although this could not be a universal distinction, the mechanistic nature of the organization requires little informal communication related to work.

The **dynamic organization** also developed as the most effective way to accomplish its tasks, relying heavily on the internal system. Rapid changes in technology and in market demands for improved products necessitate a reliance on the internal system. It involves participation, as problem solving requires personal exchange and input from various units of the organization. Because formalized rules and procedures may be outdated shortly after having been developed, it relies heavily on informal communication. The communication load in the organization is extremely heavy because individuals and units must be constantly informed quickly and accurately about changes. It tends toward greater integration of task and maintenance goals. In a sense, individuals in the dynamic organization achieve individual and group maintenance goals through activities that seem primarily task goal oriented.

Effective Communication

Communication can be viewed as three challenges:

1. **Knowledge challenge:** The intended recipients of the message need to be able to understand the information.
2. **Process challenge:** The intended recipients of the message need to feel involved in the process.
3. **Communications skills challenge:** The intended recipients of the message and those who are communicating need to be able to communicate effectively.

Those who are communicating must meet each of these challenges for communication efforts to succeed. The implication for those who are communicating is that both those who are communicating and the intended recipients of the message must have excellent communication skills. If the recipient's skills are lacking, those who are communicating will probably have to compensate with techniques designed to increase comprehensibility.

To meet the knowledge challenge, information should be presented in a variety of ways, such as in print (graphics such as simple diagrams, pie charts, conceptual drawings), orally (presentations with projected graphics and handouts), visually (advertisements and displays), and through interactions (small group discussions with facilitators who are knowledgeable). To meet the process challenge, the intended recipients of the message will have to be included. They can be involved in helping to select methods or measures, developing the way decisions will be made, making decisions by working within groups to develop consensus, or implementing decisions by developing policies and procedures. To meet the communications skills challenge, those who are communicating may need to interview the message recipients to help them focus their thoughts or meet with them in smaller groups so that they can help each other communicate.

A number of factors can constrain communicating in a way that makes it understandable to an audience. Those who are communicating need to be aware of constraints so that they can recognize and overcome the problems to increase their chances of communicating effectively.

Organizations put the following roadblocks in the way of communication:

- Inadequate resources,
- Difficult procedures,
- Conflicting organizational requirements, and/or
- Insufficient information to adequately plan and set schedules.

Methods of Communication

Once the organization has the information, it can be used to tailor communication messages to meet specific audience and situational needs. The information can tell an organization what media to use, how much audience interaction is needed, and what concerns must be addressed. Once an organization knows what it's trying to communicate and why and to whom it will be presenting the information, the

next decision is how best to communicate the message. Which media, which avenues of communication, will best meet both purpose, objectives, and needs of the people receiving the information. Usually, no one medium will meet the needs of every segment of an organization. The basic categories to choose from are **written messages, oral messages, visual messages, audience interaction, and computer based applications.**

Written messages are those that people will need to read. While these messages may have pictures and other graphical elements, they differ from visual presentations in being generally longer and carrying more complex messages. Newsletters, fact sheets, brochures, booklets, pamphlets, newspaper articles, trade journal articles, popular press articles, and reports are examples of written messages. Written messages have the advantage of being able to include a wealth of information. They can be expanded or condensed to meet audience needs. Written messages are relatively inexpensive to produce, as opposed to a video.

Oral messages are those in which someone speaks directly to people. Usually there isn't an opportunity to interact with the speaker, except to ask questions. Examples include one to one discussions, presentations, talks in educational settings. Oral messages have the advantages of having an identifiable human representative of the organization or another credible person presenting the information and personalizing it. Oral messages also offer the opportunity of immediate feedback, if not through questions, then through people's visible reaction to statements. Presentations can be individually tailored, based on analysis information. Specific groups can be targeted to receive a specific message. Oral messages can be presented in the language of the people. If the objectives are to present information in a forum that allows immediate feedback and to target specific groups, oral presentations may be best choice.

Visual messages are those that use graphical elements and relatively little text to carry simple messages. Examples include posters, displays, direct advertising, tours, demonstrations, videotapes, and television. They have the advantage of being memorable. The use of graphical elements like color, shape, and imagery along with compelling language can bring simple messages to life with stunning clarity. Visuals may be culture specific. However, because they contain very little written information, they can usually be more easily translated into another language than written messages. They can be placed where people work, such as posters in cafeterias, and on bulletin boards. So, if the purpose of the communication is to raise awareness, visual messages may be the best choice.

Audience interaction involves the audience in some way in the discussion, analysis, or management of the situation. Examples include committees and focus groups. The advantage of audience interaction is that the audience can see for themselves what is known, how it will be managed, and how decisions are reached. Because they can participate in the decision, it is likely to be more acceptable and lasting. Audience interaction can be structured to accommodate a variety of audiences, including those that are hostile or have difficulty understanding other forms of communication. So, if one of the objectives is to increase the chances that a decision will be the one that meets the needs of the audience, audience interaction may be the best choice.

A relatively new way to communicate, **computer based applications**, allow people to query and receive a variety of information. Computer based applications have the advantage of being able to disseminate an incredible amount of information, which each person can tailor to individual needs. They appeal especially to the technophiles, those who always have to have the latest toys and gadgets technology has to offer. Once developed, computer based applications can be updated and revised more easily than any of the other media, depending on hardware and software, so that they are always current, a plus in the area of communications, which can change hourly.

Electronic Communication

Building and maintaining a good electronic communication network within an organization requires substantial resources, money, time, and personnel. It is not a short term project, but a long term commitment to changing the way in which employees work. Nothing will kill an organization faster than building a communication network and then suddenly pulling support from it and letting it waste away. Resources for building and maintaining an electronic communication network must be stable. Open communication and the sharing of goals and resources, which are elements of a positive communication plan, are what make the eventual success of the organization even more certain.

Evaluating communication.

How can you tell whether communication has been successful? An evaluation of the communication process can assist an organization to determine whether communication was effective. Why is the organization conducting an evaluation of communication efforts? Possible reasons include determining how the current efforts are going so it can be revised, determining what to improve in future efforts, demonstrating to management the results of programs, and proving compliance.

Education and Training

There has to be an organized and integrated approach to the management of quality training. Some key components include:

- A delineation of responsibilities for who contributes and in what ways
- A strong and unswerving focus on the customer, internal and external
- A plan established with clear strategies and tactics for quality training
- A budget to fund the plan

Training for quality, and the TQM system the training supports, can succeed only if there is accountability and responsibility for its implementation and effectiveness. This accountability and responsibility lies with the same group that it does in any other key competitive or developmental strategy, with the leadership team. It is their responsibility to agree on a strategy and assure that it will support other operational, cultural, and financial corporate strategy. They are not responsible for the planning, design, and execution of the quality strategy; this responsibility generally lies with a component of the human resources function, with technical support provided by key quality professionals.

Executive leadership is responsible for creating a quality culture in the organization. A quality culture is a product of behaviors, skills, tools, and methods as they are applied to the work. These changes don't come about without showing people how to implement and sustain this culture. Therefore, executive leadership must become educated in quality and stimulate their professional development team to offer options for training for quality. On the basis of these options, executive leadership will then develop and approve a strategy and strategic goals for the quality training effort.

Human resources or education staff are responsible for implementing the quality training strategy. The implementation activities include the selection of subject matter, training design and delivery, and establishing an evaluation process. This is integrated into other corporate training activities and follows the same implementation process. The subject matter may be internally sourced, or may be outsourced to external quality training providers. There is a strong trend to seamlessly integrate the quality training into the professional development curriculum and to include a high degree of customization to reflect the organization's culture.

Quality professionals bear the responsibility to collaborate with the human resource/education professionals to share their technical expertise on quality.

An underlying principle of quality is to have an unswerving focus on the customer. Training for quality demands the same. A clear understanding of who the customers are, what their needs are, and what the features should be of a training strategy and the subsequent training subject matter that responds to those needs are critical components in training for quality. A contemporary and integrated training system for quality requires an organization to design the system using a process that incorporates all of the basics of quality planning.

Developing the strategic training plan for quality is critical to the success of any TQM implementation. A strategic training plan addresses these key areas: quality awareness, executive education, management training, technical training, resources, budgeting and staffing.

Principles of Adult Learning

Malcolm Knowles introduced the term andragogy, defining it as the art and science of helping adults learn. Andragogy is based on five assumptions about how adults learn and their attitude towards and motivation for learning. These assumptions are:

- Adults are independent and self directing
- They have accumulated a great deal of experience, which is a rich resource for learning
- They value learning that integrates with the demands of their everyday life
- They are more interested in immediate, problem centered approaches than in subject centered ones
- They are more motivated to learn by internal drives than by external ones

Knowles later derived seven principles of andragogy, which are guidelines on how to teach learners who tend to be at least somewhat independent and self directed.

- Establish an effective learning climate, where learners feel safe and comfortable expressing themselves
- Involve learners in mutual planning of relevant methods and curricular content
- Involve learners in diagnosing their own needs; this will help to trigger internal motivation
- Encourage learners to formulate their own learning objectives; this gives them more control of their learning
- Encourage learners to identify resources and devise strategies for using the resources to achieve their objectives

Self directed learning

- Organizing teaching and learning so that learning is within the learners' control
- A goal toward which learners strive so that they become able to accept responsibility for their own learning

Self efficacy

- Modeling or demonstration
- Setting a clear goal or image of the desired outcome
- Providing basic knowledge and skills needed as the foundation for the task
- Providing guided practice with corrective feedback
- Giving students the opportunity to reflect on their learning

Constructivism

- Teacher is viewed as a guide who facilitates learning
- Learning is based on prior knowledge, so teachers should provide learning experiences that expose inconsistencies between students' current understandings and their new experiences
- Engage students in learning in active ways

Reflective Practice

- Unexpected events or surprises trigger reflection in action
- Ability to learn & develop continually by creatively applying current & past experiences to unfamiliar events while they are occurring

- Process of thinking back on what happened in a past situation & how this situation may affect future practice

Adult Learning Theory

Adult learning principles are approaches to adults as learners based on recognition of the individual's autonomy and self-direction, life-experiences, readiness to learn, and problem orientation to learning. Approaches include mutual, respectful collaboration between the educator and the learners in the assessment, planning, implementation, and evaluation of educational activities. Adult learners require recognition of autonomy and self-direction, and need to feel they have control over their learning. Designing education programs for adult learners requires recognition of readiness to learn, as well as utilization of previous experience in the learning because adult learners have a need to share experiences during the learning process. Adults also respond well to use of problem-oriented approaches and inquiry focused activity. It's important to recognize that adult learners have different learning styles, so that learning strategies for adults need to be flexible. Experimental learning activities are often successful, because adult learners need to participate in the learning experience, and are seeking immediacy of application of knowledge. Adult learners need to participate in developing the plan for learning, as well as the evaluation. Adult learning principles are reflected in the teaching methods used throughout educational activities developed for nurses.

The Assure Model (analyze, state, utilize, require, and evaluate) is a procedural guide for planning and conducting instruction. It allows for flexibility and revision and is especially useful in developing programs for adults.

Analyze the learners: Analyze the participants in regard to general characteristics, entry competencies (knowledge, skills, and attitudes), and learning styles. It is important that the activity is developed for the target audience. The educators must develop content on a level suitable for the capabilities of the lowest learner expected to attend. Knowledge of the target audience is crucial to successful program planning.

State the objectives: Objectives must be stated as specifically as possible. They should be stated in behavioral terms and express exactly what the participant will be able to do as a result of attending the activity. An objective is not a statement of what the instructor will teach, but rather of what the learner should get from the class. Action verbs should be used in writing class objectives.

Utilize media and materials: Once selections and modifications have been made, the faculty must plan how these teaching aids can best be utilized. Planning and previewing the use along with the presentation is vital. It is unwise to use media and material without a practice session so that a smooth, relaxed delivery will not be interrupted by a breakdown of technology.

Require learner participation: Adult education requires that learners are directly involved in the learning process. The participants should be allowed time to practice what is to be learned and they should also be allowed time to respond and receive feedback. There should be no surprises.

Evaluate and revise: After instruction, time should be allowed for discussion and evaluation. Were the learner's objectives met? Could all participants use the materials supplied? Did the participants learn what the faculty intended? Were there other issues to be resolved prior to the next presentation?

Another method for program evaluation is to consider what an ideal competency orientation program might look like, and comparing actual outcomes to ideal outcomes. The following characteristics should be evident.

- There will be an adequate grasp of a definite set of skills by the newly trained staff member.
- The level of achievement is guaranteed.
- The learner will have a thorough knowledge which makes sense of the skills, enabling him/her to be applied flexibly and creatively, and assisting the growth of new skills.
- There will be a perfect match between skills and knowledge acquired by the learner, and the demands of the job.
- The skills and knowledge will be transferable from one context to the next.

- The newly trained staff members will be aware of the place of their own work in the overall scheme of the organization of health care.
- These capabilities can be assessed in a way which is reliable and valid.
- The tools of assessment can be applied both to those who have reached the end of a formal course and to people who have learned in other ways.

Implementation of Quality Training

There are two steps:

1. **Implementation planning and preparation:** The assessment, selection, and deployment of delivery media, mechanisms, and facilities; the establishment of physical infrastructure and information technology support; assignment of support staff and other resources.
2. **Delivery:** Transfer of the training content (subject matter) to the students, in an individual or group setting.

Instructional techniques: Before selecting delivery media, decided what instructional techniques will be most appropriate for delivering the training. Training will be most effective when:

- Program material is easily available to the student
- Training is measurable on the basis of acquired competency
- Facilitation is provided if group setting
- Materials possess high graphic clarity
- There is interactive content
- There is a high degree of learner control over the pace and receipt of training
- Training includes performance based testing and scoring
- Training materials are reusable and revisable
- Training is supported by practice and exercise

Delivery Systems, Media, and Devices

- Live lecture
- Audience response system
- Workbooks and case studies
- Audiotape
- Live video (TV, Satellite)
- Recorded video (tape, CD ROM, DVD)
- Multimedia computer
- Internet

Instructor led programs are appropriate when the training request requires quick response and the design calls for frequent interaction. Computer based training is more efficient for a large audience to defray the costs and requires adequate development time. Multimedia approaches are best when the training program includes multiple activities (information presentation, exercises, case studies, laboratory or practice sessions).

Training Methods

- On the job training
- Independent study
- Self directed learning
- Group learning
- Computer supported learning
- Computer assisted instruction
- Distance learning

Challenges

- How to replicate successes across the organization

- How to measure the effectiveness of training
- How to keep training, and work materials up to date and relevant
- How to reduce the costs of training and teamwork
- How to ensure the correct application of new skills and tools
- How to provide just in time training

Measuring Training

Teaching all employees how to eliminate the cost of poor quality in their daily work is essential to performance improvement.

Very few healthcare professionals have a combination of analytical and people skills. Educational programs with skill building opportunities are essential to help people develop and combine these skills.

Organizational capacity and capability are enhanced by a strong educational curriculum. The curriculum must include time for appropriate skill building and a chance to practice these skills in a safe environment. As the process expands, the structure must expand as well. As the institutional knowledge base grows, new tools, techniques, and methods will be required to ascend to the next learning plateau.

A complete educational program must be tailored to the organization's needs. Learning needs assessments should be completed periodically to adjust the educational process. It's helpful to survey by category, such as mid level, or senior level management; and by role in the quality process, such as team leader or team member. The key to success is to accelerate organizational learning, to reach a new series of plateaus, and to compete more effectively.

Successful implementation of a quality program depends on a strong educational program designed to increase sensitivity, knowledge, and skills to meet and exceed customer requirements. A quality educational program should address several **components** which are listed below.

Reason for change. One of the first and most important issues to address is why change is needed. People won't change unless they see a clear need for change. The need for change has to be clearly described, with examples related to the organization and to individuals.

Successful implementation of a quality effort depends on strong, customer-responsive quality education and training programs. Without an appropriate quality curriculum, the required change doesn't happen. Long term commitment to new learning and new philosophy is required of any organization that seeks to change. Without education, organizations can't continue to meet their improvement goals. Quality/performance improvement education shouldn't be viewed or communicated as separate from other elements of the organization. Education should be described in relation to previous programs and management practices. To be effective, quality/performance improvement education must become part of your organizational and personal culture, which requires an understanding of those characteristics that are the same as and different from previous practices.

Determining the requirements for educational and training programs is difficult. Asking management and staff may be helpful, but may miss some issues. People don't always know what they need to know about performance improvement and quality. There also has to be a perceived need to change or a perceived benefit. If people don't see any need for change, they won't identify any related training needs. In addition, many people are unwilling to admit that they don't know anything. The organization should evaluate input from several sources to determine educational needs. In general, educational requirements may include:

Quality Philosophy: The principles of W. Edwards Deming, Joseph Juran, Philip Crosby, and Donald Berwick underlie quality and need to be presented. There are differences in how each presents the quality paradigm, and organization should use those principles that best fit with the organization. Successful educational programs will include customer oriented skills, continuous improvement philosophy, analytical skills, and people skills. Successful examples help to convince people that quality works and should be included in educational programs. To have the greatest impact, each participant

must see that quality is relevant to his/her job. Many people initially resist quality because they believe that its additional work, or that the methodology is unproven. Examples can help demonstrate that customer satisfaction, quality, cost effectiveness, and working environment can all be improved at the same time. Most people believe that quality always costs more and that increases in productivity always decrease quality. Logical and practical examples help convince them that this is not true.

Quality/Performance Improvement Process: Using a single problem solving process for quality/performance improvement projects is very important. A common process establishes a common language, approach, review process, and timeliness to assure smooth implementation. All managers and staff will need education related to this common process. Which quality/performance improvement process is selected is less important than the fact that a single process is used throughout the organization.

Analytical Tools, Techniques, & Skills: Several analytical tools are used to analyze and improve processes. Examples include flowcharts, checksheets, Pareto charts, run charts, control charts, cause & effect diagrams, stratification and scatter diagrams. Educational programs should include explanation and exercises using these tools and techniques. Case studies allow practice sessions to learn the tools and techniques and to develop the skills necessary to utilize the tools within quality/performance improvement teams and daily work. Many people have an initial fear related to analytical methods, feeling that they require advanced mathematical knowledge. Educational programs should focus on the concepts and simple graphical examples to overcome this fear. For most people, graphs are much easier to understand and use than numerical tables and analyses. If the organization has chosen one method of analysis, for example, control charts, this should be the focus of the program.

People Skills: In order to provide complex healthcare services for patients and other customers, extensive coordination of the efforts of many is required. Successful daily work and quality/performance improvements are possible only when people work together effectively. Teaching your people to work in teams and to break down barriers is the key to success. Techniques to improve the involvement and contribution of employees include brainstorming, affinity diagrams, nominal group techniques, tree diagrams, interrelationship diagrams, and tailored reward and recognition programs. It's best to focus on the concepts, simple examples, and practical case studies to avoid fear and develop skills related to the methods.

Knowledge and skills to perform the job: The most immediate requirements are those needed to perform the basic job functions of each person's current job. Although these requirements clearly vary widely among staff, they should be identified along with the job description. Both analytical and people skills should be included. Each person should receive education to meet these requirements. These are generally provided by the department.

Survey of requirements perceived by employees: Employees should be asked what knowledge and skills they would like to develop and what education might help them achieve the knowledge and skills to improve job performance.

Quality/performance improvement requirements: The organization needs to identify the knowledge and skills required to plan for quality/performance improvement, participate in quality/performance improvement teams and projects, and continuously improve quality in daily work.

Basic management knowledge and skills: The organization should identify basic management knowledge and skills that all new managers should have.

External customer expectations: External customers should be asked what behaviors, knowledge, and skills they expect of different people within a healthcare organization.

Knowledge and skills assessment: After the required behaviors, knowledge, and skills are known, different types of assessments can provide information about current performance compared to those requirements.

Customer Requirements: The focus of a quality educational program should also include increasing the sensitivity, knowledge, and skills to meet and exceed customer requirements. The customers are employees, managers, physicians, others within the organization, and external suppliers and customers. Courses have to be based on learner’s needs.

Sample Quality Management Training

Topic	Executive Leadership/Board	Management	Staff
TQM Overview	X	X	X
Developing strategic measures & goals	X		
Role of leadership	X		
Deploying the strategic quality plan		X	
Quality Processes— improvement, planning, control		X	X
Measuring & evaluating organizational performance	X	X	
Quality Tools		X	X
Facilitation skills		X	
Data collection and analysis		X	X
Benchmarking		X	X
Communication skills		X	X
Reward and Recognition	X	X	
Statistical methods		X	X
Quality culture	X	X	
Empowered employees		X	
Customer focus	X	X	X
Quality team roles and responsibilities			X
Conflict resolution		X	
Collaboration			X

Faculty

Carefully selection of faculty is a key indicator of success for quality/performance improvement programs. The faculty must be knowledgeable about the curriculum content, and also have the people skills to relax the participants and communicate the information well. Suggested skills and characteristics for faculty include the following:

Knowledge and experience: Quality/performance improvement is a complex process including diverse subject material. Faculty members should be able to illustrate different concepts with specific examples and stories. Different faculty may be needed to teach philosophy, analytical and statistical tools

and techniques, and people skills and techniques. It takes substantial training and experience to be qualified to teach all of these subjects in an easy to understand manner.

Credibility: The faculty must be credible to earn the respect of participants. Internal faculty often face specific barriers related to credibility. In many cases, the senior administrative and clinical leaders don't attend educational programs in their own institutions. Managers may feel that training and development programs are for entry level staff. In some organizations, the education and training staff lack credibility with senior and middle managers. If these issues exist, they must be addressed. Senior staff must first learn and then personally participate in quality/performance improvement programs to show their commitment to quality, followed by middle management before staff can fully accept these programs.

Strong interpersonal and teaching skills: Managers, physicians, and other staff may be threatened by ideas that vary substantially from their current practice. New ideas that can change work habits are best presented by faculty who can relax the participants, communicate the reasons and methods for change in a simple manner, and excite participants to try the strategies and techniques on their daily jobs. Faculty should be able to present fun exercises to illustrate the concepts and methods.

Senior management participation: As mentioned previously, there is nothing more critical to communication of the quality/performance improvement process than senior leadership and administrative support as faculty for programs. Obviously, this requires that those senior managers learn the material before presenting it. They must believe in the process to be credible. Another important role for senior managers to demonstrate commitment is to answer questions from program participants.

Successful educational programs include a use component. Teaching staff the theory and use of quality/performance tools and techniques won't help the organization unless those tools and techniques are regularly used by management and staff in daily work processes, as well as in improvement projects. The information has to be regularly enforced by management actions. Management must "walk the talk" if education or any other change is to be effective.

Educational program principles

The following principles are useful to guide the development and presentation of quality/performance improvement programs.

1. **Managers before employees:** A key education strategy is that every manager should be trained before the employees who work for that manager. A manager or supervisor does not want to feel uninformed when an employee asks about a topic. If the managers are not trained before or concurrently with their employees, the managers are likely to disregard or discredit, consciously or not, the educational program and the knowledge gained from it. The strategy for rollout of educational programs begins with board, management, and clinical leadership. The next step may depend on the size of the organization and the level of educational effort that the organization is willing to undertake. For a small organization, or one willing to mount a major educational effort, the strategy is to educate next all middle managers, then all employees, physicians, and others. However, for a larger organization, or one with very limited educational resources, a stepwise approach may be the most useful. All supervisors and people serving on quality/performance improvement teams should be trained. To keep everybody informed, the strategy chosen and plan should be widely communicated.
2. **Comfortable environment:** The environment should be comfortable for participants both physically and emotionally. There should be comfortable seating, and the room should be at a comfortable temperature. Everyone should be able to see the speaker and any displayed materials easily. The environment should avoid stress and conflicts.

3. **Minimal disturbances:** As much as possible, eliminate interruptions and disturbances to the educational sessions. People will get called away, leave on break, or not return in a timely manner.
4. **Concepts and theory:** The principles, concepts, and theory should be explained to establish the basis for the education. This should be quickly followed by practical examples and experience.
5. **Participation:** Try to get everyone involved to participate in the discussion and experiences of the program. People learn best by active participation, which enhances their understanding and sense of belonging to the group. Allow time for questions and answers, and provide evaluation forms so participants can provide feedback.
6. **Sequence of deployment:** There are five general audiences: leadership, including the board, administration, and clinical leaders; managers, physicians and staff; customers; and suppliers. For effective education and implementation of quality/performance improvement, each audience should address the why issues first. Each audience must be convinced there is a need to change first, then the organization has to explain why quality/performance improvement is important in that organization. Management and staff have to have a culture or context in which to apply what will be done. Additionally, line managers also have to be personally and visibly involved in the quality/performance improvement effort to communicate personal and organizational commitment to the staff. Then, address what will be done, followed by how, the approaches, tools, and techniques. It's important not to do the how before the organization has done the why. Finally, discuss actual implementation and practice. It's critical that the leaders go through the education first, to review the mission, visions, values, goals, and management expectations. If the leaders don't understand the quality/performance improvement effort, they won't be able to lead that effort and create the right culture. In addition, they communicate a strong message to the rest of the staff that quality/performance improvement wasn't important enough for them to get involved.

Evaluation

Evaluation is critical to effective training for quality. Evaluation is not just an afterthought but a necessary and systematic part of an effective training process for quality. Good training begins with an accurate assessment of training needs, and then proceeds through needs analysis, instructional design, and content development of training events, ending with more effective on the job and organizational performance of those trained. The classic approach to training is based on assessing:

- Trainees' reactions
- Trainees' learning
- Whether and how trainees are using what they learned
- Whether and how the use of learning has enhanced job performance

The function of evaluation for quality training is broader than simply checking to see whether a particular training event has achieved learning results. The purpose of quality related training is to enhance the value of the products and services of the organization through the systematic improvement of the skills and knowledge of trainees who contribute to those products and services. Ultimately, the purpose of training for quality is to enhance customer satisfaction and loyalty. In designing an approach for quality related training, the evaluation must fit the strategic context of improving product and service quality. The implications for evaluation design are:

Objectives of training for quality should be derived from the organization's quality strategy, established through strategic quality planning.

Training for quality should be conducted only after the organization receiving training has deployed its quality measurement system.

Training for quality should be delivered on a prioritized basis such that those employees with direct effect on customer satisfaction receive training first. Trainees should be ready for the training and

have the prerequisite knowledge and preparation. Examples during training should include references to product and service quality; training sessions should also allow students to practice quality management skills, including appropriate tools. Students should leave training committed to the application of their newly acquired knowledge. Once back on the jobs, students need accurate and timely feedback on their impact on organizational performance, especially regarding customer satisfaction.

In designing evaluation of training for quality, the key question is how much and what sort of evaluation should be carried out. Evaluation design is a continuing process, since evaluation also must be continuously improved and adapted to changing needs. Evaluation will always work best when it has been part of the overall training strategy and training design. As with any reasonably complex process, managing the evaluation process should include the use of project management concepts, tools, and techniques, as well as professional quality management expertise as appropriate.

Evaluation should be employed throughout the training process, not just during and after the training event itself. A good evaluation of quality will help assess:

- Are the goals of the training for quality linked to major business goals, and is the quality related training strategy driven by critical business needs?
- Do training plans deliver the required amount of learning at the right time and in the most effective and efficient ways?
- Are training outcomes (e.g., learning, retention, and application on the job to enhance organizational performance and customer satisfaction) being achieved?

Why Training Fails

Training for quality can fail for a variety of reasons, including:

- Failure of training materials
- Failure of leaders,
- Lack of budgets
- Lack of prior participation by line managers
- Too narrow a base
- Failure to change behavior

Management has a role to play in heading off failures of training programs. That role consists of laying down the necessary policies and guidelines, which include the need for a strategic plan to training for quality and the requirement that trainees should apply their new learning to their job.

In any organization, the prime role of training is to develop work related skills, knowledge, and expertise. Training for quality occupies a special position in the spectrum of training activities, as it supplies quality management expertise that can have a major impact on the organization's relationship with its customers. Quality management practices encompass the entire spectrum of organizational performance. In the industrialized society, training for quality traditionally addressed levels of performance related to operations and troubleshooting, primarily through training in quality control. After World War II, and in particular as a result of the research and practical work of such experts as Deming, Ishikawa, and Juran, quality management began to shift its focus of to quality improvement and planning for quality, with a corresponding shift in the focus of training for quality. Another more recent development has been the extension of training for quality to include training in teamwork, team building, meeting management, and team facilitation, as necessary methods and techniques supporting the implementation of quality management through the empowerment of teams and individual employees.

Coordinating Surveys

An accreditation process evaluates a health care organization's performance, including the processes of patient care, functions that most affect patient care outcomes, and in some cases, patient outcomes. The accreditation process is voluntary and begins when the organization applies for a survey.

Information from the initial application is used to schedule a survey. The length of the survey, the composition of the survey team, and the fee charged are generally based on the volume, type, and complexity of services, and where services are located. Accreditation surveys are conducted by highly skilled surveyors who have generally worked in the type of organizations being surveyed by a given accreditation program. If there are multiple person teams, there is usually one person designated as a team leader who is responsible for coordinating on site activities and communicating with the organization's staff about survey issues. During the survey itself, the surveyors will usually:

- Conduct interviews with organization leaders, department directors, caregivers, and others who provide technical or other support.
- Tour the settings where services are provided (as applicable to the organization being surveyed)
- Talk to patients or other individuals served by the organization and observe care being provided
- Review documentation such as minutes, reports, logs, plans, policies and procedures
- Provide educational services to help the organization improve its compliance with the standards

At the conclusion of the survey, the surveyors may or may not report preliminary findings during a meeting with leaders of the organization. A preliminary written report of the survey findings will follow. The organization may have to provide responses to the written report. Then, a final accreditation decision will be awarded. There is generally a type of appeal process for the organization to follow

Survey Readiness Coordinator Job Functions

1. Ensures organizational knowledge of the accreditation and regulatory standards and associated interpretative guidelines
 - a) Maintains current knowledge of the accreditation and regulatory standards and associated interpretative guidelines and clarifications through newsletters and bulletins, electronic communications, and attendance of audio conferences and workshops.
 - b) Transfers knowledge of current standards and interpretations to the Function Lead Team Leaders (FLT Leaders).
 - c) Serves as liaison between the FLT Leaders and the accrediting organizations to seek needed clarification of the standards.
2. Ensures a state of survey readiness through continuous assessment and resolution of opportunities for improvement
 - a) Works in collaboration with the respective team leaders to coordinate and facilitate the individual patient and system tracer activities focused on assessing compliance of problematic or key focus areas.
 - b) Aggregates the information learned from tracer activity to generate a summary of opportunities for improvement.
 - c) Serves as administrator, educator, and coach for the software selected for compliance assessment/management.
 - d) Assists the Function Lead Teams in planning appropriate compliance assessment activities and aggregation and presentation of results.
 - e) Plans and coordinates the Continuous Survey Readiness Committee meetings to ensure reporting of compliance status and discussion and resolution of opportunities for improvement.
3. Coordinates the accrediting organization annual Periodic Performance Review
 - a) Coordinates the annual Periodic Performance Review process ensuring the good-faith assessment of compliance and development of appropriate corrective action plans and related performance monitors for standards deemed not fully compliant.
 - b) Ensures the Periodic Performance Review is submitted accurately and timely and revises corrective action plans according to the feedback from Standards Interpretation Group.
4. Plans for and coordinates unannounced surveys

- a) Coordinates the onsite unannounced surveys facilitating the surveyors' ability to accurately assess compliance and assisting with the exchange of communication and information between the organization and the survey team.
 - b) Develops and executes an unannounced survey response plan ensuring the timely notification and call to action of key positions/duties and availability of requisite documents and information.
5. Ensures implementation of a robust communication and education program related to readiness activities including:
- a) survey methods and processes
 - b) results of compliance assessment activities
 - c) methods of compliance for problematic and high-priority requirements.

Ideally, organizations would never have to prepare for accreditation surveys because everything would be in place, and organizations would be functionally optimally all the time. Some regulatory agencies perform unannounced surveys. Organizations need to be ready any time. For those types of surveys, information that surveyors would need (profile of the organization, key leaders, mission, etc.) should be updated and readily available. The organization should have a process in place to assemble key leaders quickly in the event of a survey team's arrival.

For those that still announce surveys, survey preparation is an important part of a healthcare quality professional's job. The intent of accreditation processes is to see that organizations have the mechanisms in place to perform important processes and functions, measure outcomes of those processes and functions if they are doing them well, and continuously try to improve those outcomes by improving their performance of those important processes and functions. In order to do this, it is essential that the organization attain and maintain consistent compliance with the standards of accrediting organizations. During the survey process, surveyors look at the structure of the organization, the processes that are in place, and the outcomes.

Both healthcare and accrediting organizations are in a period of constant change. The first step in coordinating survey processes is to become familiar with the standards of the accrediting organization. Compliance with the standards is necessary for achieving accreditation. Disseminate specific standards to staff in the organization who are responsible for those specific standards. Then, it's important for organizations to measure and assess current compliance with the standards of accrediting organizations. Following this process, it may be necessary to develop action plans to achieve the standards. These action plans should be an integral part of the organization's strategic quality planning. Surveyors will look for sustained compliance in specified time frames for standards that are not new. The time frame may vary from 12 months to 3 years, depending on the accrediting organization.

Measurement and assessment of current compliance with the standards and planning for future improvement is essential to assure successful surveys. Coordinating the survey process begins with planning for compliance with the standards.

1. The leadership of the organization should establish that compliance with the accrediting organization's standards is a priority for the organization.
2. The responsibility for measuring and assessing compliance may be assigned to individuals and/or team. These individuals or teams should be responsible for planning, designing or redesigning systems and processes, and improvement activities related to the standards.
3. Leadership of the organization should oversee the process of standards compliance in order to assure coordination, communication, and collaboration among individuals and teams. The assigned individuals and/or teams need to have expert knowledge of the standards and expected outcomes for the standards.
4. Knowledge of standards is also a requirement for all individuals and/or teams that are responsible for measuring and assessing compliance.
5. It's important to review previous survey results to ensure current compliance and assess weaknesses in the organization.
6. Establish appropriate disciplines and/or departments to be responsible for appropriate standards.
7. Begin education of all staff regarding the standards.

8. The individuals and/or teams will require education regarding the standards and the survey process. An assessment of educational needs should be conducted prior to developing an educational program. In addition to information on the required standards, individuals and/or teams should be given resources, including methods of achieving compliance with the standards.
9. Identified key individuals and/or teams should have regular meetings to monitor progress.
10. Individuals and/or teams should review all standards. The next step is to make a log of specified requirements, such as policies, mechanisms, time frames, plans, elements of minutes and/other documentation to be included. Identify where this documentation is currently. Begin the log so that if changes occur, they can be tracked and recorded in order to prepare a final log of materials with supporting documentation that can be compiled prior to the survey. Be aware of linkages with other standards so there isn't any need for duplicative work.
11. Individuals and/or teams should then measure and assess compliance with all the standards. The standards in the accreditation manual should be used as the framework.
12. Identify required data sources and location. Collect data and assess compliance.
13. Identify ideas for improvement.
14. Establish priorities, based on the strategic quality plan, considering mission, vision, and values, staff and other customer input, mandatory requirements, required resources, and any other criteria established by the organization.
15. Plan improvement activities based on priorities, including objectives, related tasks, accountabilities, responsibilities, required resources (including people, time, finances, support systems), and completion dates. In determining expected dates of completion, establish realistic time frames, allowing time for testing improvement strategies, approval processes, and consideration of compliance time frames if specified in the standards.
16. Implement changes. Collect data to ensure that changes have been effective.
17. Identify and involve staff in the change process.
18. Identify any resistance to change.
19. Address areas of resistance to change and compliance with standards.
20. Manage change within the organization.
21. Provide ongoing education to the organization's staff regarding:
 - Standards
 - Survey process
 - Role of surveyors
 - Conferences and interviews
 - When changes are made, what the change is and why it was made.
22. Identify key individuals who will be assigned to each surveyor at all times. These individuals should be knowledgeable of the standards and evidence of compliance required, and the survey process itself.

For announced surveys:

Six to three months prior to the survey

1. Begin organizing; don't expect the surveyors to do the organization and synthesis for you.
2. Begin collecting and organizing master copies of all written evidence that demonstrates compliance with standards. Begin a master log to identify by standards the required compliance and where it's located.
3. Documents should be organized by function in a notebook and either flagging or highlighting pertinent information necessary for compliance with standard numbers.
4. Minutes of meetings are a frequent source of compliance with standards. Identify appropriate minutes and highlight important information for easy retrieval.
5. Staff need to practice answering questions and presenting data for surveys. Begin conducting mock surveys of units/departments/services, including staff interviews and document reviews, to

assure that staff feel comfortable with the terminology of the accrediting body and responding to questions. Included in mock surveys should be tours of units looking at compliance with environmental issues appropriate to the accreditation standards. Be objective in the evaluation.

6. Do mock survey interviews with individuals who will be involved in the survey interviews.

Three months to one month prior to survey

1. During this period, you should receive a tentative survey agenda. You should review this agenda, and request any changes that may be needed due to organizational conflicts.
2. Share the tentative agenda with staff.
3. Identify a key individual in the organization to consistently communicate with the accrediting body. This person will be responsible for relaying information to other staff in the organization as appropriate.
4. Gather data within the organization that will assist you in tailoring the agenda, if possible. Know when certain key individuals will be available.
5. Know activity levels in departments and avoid peak work load hours and intense activity. The survey process should never interfere with patient care.
6. To the extent possible, staff should be relaxed and comfortable and the environment should support this comfort level.
7. Complete the log of location of written evidence of standard compliance.
8. Collect required documents, organize them, and have them in one place. The information should be easily reviewed, clearly marked, flagged, and highlighted.

One month prior to survey

1. Meet with staff and review survey dates and schedule.
2. Share information on the survey process and reinforce education previously provided.
3. Remind staff never to become defensive or argue with surveyors, but to present objective information.
4. Handle any disagreements politely and professionally.
5. Staff members should answer questions but not give additional information unless it is requested.
6. Educate staff regarding:
 - Listening to the question asked
 - Requesting clarification if they don't understand the question
 - Where to retrieve needed documents
 - Stating they don't know if they don't know an answer to a question, but offering where to get the information or who to ask
 - Responding to questions in own words rather than reciting policy
 - Not becoming defensive
 - Turning uncomfortable situations into positive ones
 - Taking advantage of the surveyor's role as an educator
 - Avoiding words like never and always (in most cases; they may be appropriate in limited situations)
 - Adding to answers from other disciplines when appropriate
 - Giving a real life example to illustrate processes or functions
7. Identify required attendance by staff at meetings, etc.
8. Be sure to include security and reception staff about the survey.
9. Check staffing schedules for the dates of the survey. You may prefer to have additional staff available who can cover for staff and management who will be attending interviews and conferences.

Last minute readiness assessment

- Do a quick sweep before the survey. Ask questions of staff to prepare for the real survey. Staff become more comfortable with practice.
- Review records closely prior to survey. Remind caregivers of the importance of documentation and that surveyors will be conducting open record reviews during their visit. Encourage everyone to document completely, legibly, and with acceptable abbreviations.
- Have your documents ready. Having documents like QI storyboards and patient safety posters will be helpful reminders for staff. Check out your bulletin boards to see what's posted. Communication is always a hot topic.
- Be on time. The survey team has a tight schedule and can't wait for people to assemble.
- Dress the part. Clean clothing, hygiene, shined shoes present a professional appearance. Wear your picture ID.
- Be positive and frame answers in a positive way. For example, "Yes we do that; let me tell you our approach." You may know your shortcomings but focus on how you meet the standards, not what you haven't done or what you might be doing in the future. This is not the time to vent or complain.
- 3-second rule: Someone should answer the question in 3 seconds, even if they don't know the answer. There are 3 ways to answer: 1) Repeat the question; 2) Ask for clarification if you don't understand the question; and 3) Redirect to someone who can answer the question. Be honest with the surveyor. You might say, "I don't know, but it's in our policy manual and I can find that for you, or I'll ask my manager."
- Answer only the question being asked. Approach surveyor questioning as if you were in a courtroom. Don't elaborate or provide extraneous details about a process or procedure unless a surveyor asks. The surveyor will ask a follow up question if he needs to know more. The more practice everyone has, the more comfortable each person will be answering questions.
- Everyone should participate in the practice. Help each other to respond to questions.
- During interviews, share best practices. If the surveyor is teaching, listen patient and thank him for the information.
- Use plain English and be polite. Speak in clear, simple language. Don't interrupt the surveyor or others. Describe what you actually do by giving examples. Don't argue with the surveyor. If the surveyor seems to be requiring something beyond the standards, just explain that you don't understand what is required, and ask for the standard he is referencing.
- Be prepared to answer questions multiple times a day or not at all. Repeat visits by surveyors can be stressful for staff and managers. Be constantly ready while maintaining daily, operational, patient-activities.
- Remain calm and friendly. Surveyors may visit each unit several times. Being constantly ready may be stressful.
- Focus on the excellent care and service you provide. The surveyors will be observing staff. Don't worry about performing for the surveyors, rather concentrate on the excellent job you do every day.
- If there's a problem, buy a little time. Explain to the surveyor that you will look into it and get some information. Provide it to the surveyor no later than the next morning.

For unannounced surveys:

Unannounced surveys prepare organizations to take care of the next patient rather than the next survey. The organization shifts to operational processes and patient care processes rather than preparing for the next survey. Accreditation is viewed as a validation of an organization's continuous systems

improvement efforts rather than a standards compliance exercise. This survey will provide a more accurate picture of an organization's day-to-day performance, enhancing the accreditation process by ensuring that surveyors observe organization performance under normal circumstances. Unannounced surveys will also reduce the unnecessary costs that health care organizations incur to prepare for surveys. These surveys will present an accurate reflection of the quality and safety of care in the organization, assisting health care organizations to focus on providing safe, high quality care at all times instead of just when preparing for survey. Unannounced organizations are seen as more credible with outside organizations and the public because they affirm the expectation of continuous standards compliance both by the organization and the accrediting body.

In the continuous systems improvement model, standards can be thought of as indicators of the types of systems that can be built into the health care organization's daily processes. Organizations continually develop and monitor processes that will produce and maintain safe, high-quality systems of care, treatment, and services. Processes are monitored through a series of data loops; data are collected, analyzed, and then used to further improve the processes.

Many systems and processes are developed using standards as a guide. Through the careful attention and action related to the analysis of data, the organization maintains continuous compliance. Organizational leaders should set this system in place by building in data indicators or measures as part of the processes. The data will indicate the extent that the process has been implemented, showing that staff are following the procedures. The data will also show the extent to which the organization is achieving desired results. If the data indicators show that the desired results are not yet being achieved, the organization should make further improvements to its processes. This process, implementing a procedure, examining the data from the procedure, making changes to the procedure as indicated by the data, followed by reexamining the data from the improved procedure, continues until desired results are achieved.

Quality improvement and continuous systems improvement start with the leadership of the health care organization. When organization leaders adopt the continuous systems improvement model, leaders acknowledge that safe and high quality care can be maintained only through constant attention to the systems within the organization that are responsible for the production of these elements. Leaders should empower staff to develop, maintain, and monitor the processes within each of the systems that are responsible for the elements of safety and high quality care.

A core skill in systems thinking is the ability to see the organization from a different viewpoint. Systems thinking tries to see the systems and processes within an organization in terms of their relationships to each other and to the whole, seeking to figure out how the relationships between systems contribute to the processes. For example, the relationships between departments will affect the delivery of services.

One of the best ways to be continually prepared for a survey is to walk-through the organization with a particular patient problem selected and review the processes, scheduling appointments, etc.; following the path that a patient would have taken related to the concern. This will help you see the organization from the eyes of the patient, noting processes involved in each step encountered. You should also note how the various organizational systems are involved, and how they are related to each other, particularly focusing on delays or bottlenecks. These are areas that can be improved.

Think from a systems focus rather than an individual focus. Processes and systems can be mapped from the walk through. This formal approach is the first step in a systems analysis. Another method is to outline the processes and steps discovered in the walk through. With a systems approach, systems can always be improved; the emphasis is on continuous improvement. There are always processes within systems that are working well that can be used as models for improvement. Carefully examine the systems and processes that are not working well. Talk to staff members. What processes or steps are occurring in departments that are working well that can be used in those areas that are having problems? All organizations are composed of systems and processes. Other organizations can also be a source of continuous learning and continuous improvement. Through systems thinking, organizations can

learn from other organizations. Continuous systems improvement methods typically use some form of formal planning methodology.

For unannounced surveys, the surveyors will show up unannounced and will usually bring a standard survey agenda. Organizations should keep a binder with current information about the organization (e.g., organization chart, key leadership positions and phone numbers, medical staff bylaws, key policies) available at all times. They should also develop an emergency cascade or call back system to announce the arrival of a survey team to the entire organization, as well as to assemble top leadership. Organizations should have a plan for a quality “command center” to operate during the survey, with a central area for all communication. In addition, organizations should have a plan for implementing all of the items listed above in the last minute readiness assessment.

During the survey

1. Be alert and prepared for anything that might happen. Remind staff that they are knowledgeable about the standards and their supporting documentation, and will be able to demonstrate compliance.
2. Double check all computers and other equipment available for surveyors to make sure everything is working appropriately.
3. Allow the surveyors to set the pace of the survey. Don't attempt to rush or slow down the process.
4. Use large enough rooms for large groups of people or documents.
5. Relax and maintain a positive attitude. Open, honest communication will go along way during the survey.
6. Ensure the designated staff members are always available and able to assist the surveyors with questions or request for information.
7. Take advantage of the surveyors as educators and consultants.
8. Ask questions or seek clarification if you don't understand what the surveyor is asking.
9. Never leave the surveyors alone during the survey process.
10. Make sure surveyors are escorted from one location to the next.
11. When questions arise during the survey process about standards compliance, always speak to the standards and why you believe you have met them. Use examples from minutes if available.

Tips for Successful Surveys

1. Make the standards available to all staff.
2. Read all parts of the standards.
3. Turn the standards manual into a scrapbook of ideas, strategies, questions, and answers. Insert extra pages for notes if possible. Keep a record of calls to the accrediting agency.
4. Focus on the concepts describe and the points made in the standards. Gather examples of implementation and examples of evidence of performance. Concentrate on incorporating the standards' framework and concepts into your day to day work, rather than viewing the concepts as rules to be followed for surveys.
5. Further your understanding of the standards by seeking out additional information on standards related topics from other sources.
6. Talk with colleagues whose organizations were recently surveyed.
7. Conduct mock surveys to identify areas of partial or noncompliance and develop a strategy to improve your compliance in those areas.
8. Prepare staff for surveyor questions by roaming the units and asking unit specific questions, while pretending to be unfamiliar with the day to day operations of the unit as the surveyor would be.
9. Act on strategy to correct areas of partial or no compliance and raise the level of your compliance.
10. Develop a systematic process for addressing weak areas in your compliance with the standards, whether weaknesses are identified through your own self assessment or through official surveys.

11. Keep up with standards changes occur until waiting until time close to the survey.
12. Read all you can about the accrediting agency's standards and changes.
13. Evaluate your performance throughout the year by conducting internal surveys of selected standards.
14. Keep a track record of evidence of implementation.
15. If you choose an innovative approach to comply with standards, plan from the beginning to gather evidence that will be provided to a surveyor to demonstrate compliance.
16. Develop a team responsible for creating innovative ways to achieve and maintain standards compliance such as:
 - Question of the week or month
 - Standards related posters
 - Column in staff newsletters
 - Mock surveys
17. Meet with staff immediately before the survey to state expectations and allay presurvey apprehensions.

Additional Survey Preparation Tips

1. Reserve enough rooms.
2. Provide meals for surveyors.
3. Provide a locked room for surveyor personal items.
4. Have ideal number of documents for document review.
5. Assign one person to each surveyor.
6. Make sure everyone attends all meetings on time.
7. Have critical staff available for questions.
8. Inform leadership group and medical staff of exactly where and when to be.
9. Rehearse, rehearse, rehearse.
10. Double check medical records.
11. Double check data and statistics.
12. Plan for crises.

Types of Surveys

Centers for Medicare & Medicaid Services (CMS) www.cms.org

- Largest health insurer/payer in United States
- Administers Medicare
- Works with states to administer Medicaid & State Children's Health Insurance Program
- Social insurance program financed by payroll taxes, premium payments, general revenues
- Works to improve outcomes of care

Individual State Departments of Health Services

- Licensing & certification programs
- Required quality improvement activities

Federal Certification Requirements

- Clinical Laboratory Improvement Amendments (CLIA)
- Accreditation provides external seal of approval

National Committee for Quality Assurance www.ncqa.org

- Evaluates quality of care and services provided by healthcare organizations
- Healthcare Effectiveness and Data Information Set (HEDIS)
- Accredits managed care organizations, managed behavioral healthcare organizations, preferred provider organizations, disease management, new health plans

The Joint Commission www.jointcommission.org

- Improve safety of care using accreditation & certification as risk reduction activities
- Accredits hospitals, healthcare networks, home healthcare, nursing homes, long term care facilities, behavioral health, assisted living, ambulatory care, clinical laboratories, disease-specific care
- National Patient Safety Goals
- SPEAK UP Campaign

Utilization Review Accreditation Commission www.urac.org

- URAC, American Accreditation Healthcare Commission
- Accreditation programs: case management, claims processing, consumer-directed health, core accreditation, credentials verification organization, disease management, health call center, health network, health plan, health provider credentialing, health utilization management, HIPAA privacy, HIPAA security, workers' compensation utilization management

Healthcare Facilities Accreditation Program www.osteopathic.org

- American Osteopathic Association's HFAP accredits acute care hospitals, hospital laboratories, ambulatory care/surgery, mental health, substance abuse, physical rehabilitation medicine facilities
- Commission on Accreditation of Rehabilitation Facilities www.carf.org
- Promote quality, value, & optimal outcomes of services through consultative accreditation

College of American Pathologists www.cap.org

- General laboratory accreditation, specialty programs for reproductive laboratories and forensic urine drug-testing programs
- Commission of Office Laboratory Accreditation www.cola.org
- Private alternative to help laboratories stay in compliance with CLIA
- Accredits physician office laboratories in compliance with CLIA, hospitals, and independent laboratories

CIHQ Center for Improvement in Healthcare Quality www.cihq.org

- Member-based organization comprised of hospitals & other healthcare entities throughout the United States
- Hospital accreditation program approved by CMS
- Committed to helping hospitals improve quality of care by providing tools and support in a collegial, respectful, educational, and cost-effective manner

DNV (Det Norske Veritas) independent foundation

- www.dnv.com and www.dnvusa.com
- Purpose to safeguard life, property, and the environment
- Established in Norway in 1864 to inspect and evaluate the technical condition of Norwegian merchant vessels
- Hospital accreditation program approved by CMS
- Annual deemed status surveys and quality improvement using ISO 9001 Standards

ISO 9001

Although the ISO 9001 standard was first published in 1987, the United States did not recognize the use of the document as a tool for improvement until the 1990's. At this time, the big three (Ford, General Motors, and Chrysler) developed a standard called QS9000 that included ISO9001 as the foundation. As the big three introduced this new standard to their suppliers, it came with a mandate

which was become certified to the new QS9000 standard or cease to do business with the big three. This created a flurry which included the movement of many ISO certification bodies from around the world to the United States. The certification body movement to the United States was needed to support the thousands of suppliers faced with this new certification. The influx of these certification bodies followed interpretive differences which extended to the thousands of consultants and auditors. Eventually two different groups of ISO9001 emerged, compliance and performance. The compliance group focused on adherence to guidelines and structure. The performance group focused on achievement of performance as embraced by leadership of the supplier and aligned with the culture of the organization.

While it may appear to be a new phenomenon, a few hospitals in the United States have been certified since the mid-1990's. The vast majority of hospitals that have been ISO9001 certified fall in the compliance group. Compliance ensures that they meet the requirements as set forth by regulations and conditions of participation. Performance based systems include key aspects, such as building a system beyond the walls of quality, performance improvement or accreditation. Performance requires alignment of the ISO9001 system with leadership initiatives resulting in positive impacts for healthcare outcomes. The compliance approach to ISO9001 focuses on checking the box to ensure compliance. The performance approach focuses on a clear understanding of the ISO9001 standards as well as a system that will have a positive impact on patient care outcomes.

Magnet Recognition Program www.nursecredentialing.org/magnet.asp

- Recognizes healthcare organizations for quality patient care, nursing excellence, and innovations in professional nursing practice
- Ultimate credential for high quality nursing
- Developed by the American Nurses Association's American Nurses Credentialing Center (ANCC)
- Leading source of successful nursing practices and strategies worldwide.

Sample Unannounced Survey Readiness Plan

I. Introduction

The purpose of this Plan is to prepare the organization for an unannounced survey. The Plan is to provide direction and to facilitate the optimal performance of the organization during the survey process.

II. Public Notice

A public notice is posted on the organization's website to inform the public of the process for addressing patient complaints/concerns and for their ability to contact the accrediting organization should they want to set up an interview with a representative. The Survey Team will notify hospital leadership during the opening conference if an interview to discuss a complaint/concern with a patient/patient's family has been scheduled during the survey.

III. Accrediting Organization Website Review

Selected personnel will be named responsible for checking the accrediting organization website each weekday morning to determine if a survey team has been named to visit the organization that day. In the event that survey team information is posted on the website, the operator will be called (dial "0") and the operator will be asked to implement the "Code Survey" page system. The message, "Accrediting Organization Survey Today" will be entered as the message.

IV. The Arrival of the Survey Team

The Information Desk or Administration will be the most likely point of arrival for the Survey Team. The hospital staff member who first greets the Survey Team members should escort the Team members to the assigned conference room. Under no circumstances should the Survey Team members be allowed to walk unaccompanied in the facility.

Upon notification of the surveyor's arrival, a member of the Executive Team will formally welcome the surveyors and proceed with the identification check. This check will include verification of the accrediting organization identification badges against the information posted on the website.

To alert the staff of the arrival of the Survey Team, the operator will be asked to make the following overhead announcement, "Sample Hospital welcomes the Survey Team from Accrediting Organization". An email announcement will also be sent from the Performance Improvement Department's Command Center that states the following:

"This message is notification that an accrediting organization Survey Team has arrived in the building to begin our unannounced survey process. Please take every opportunity to show your pride in the work that you do each day. Be aware that the Survey Team may visit your areas once or several times during the survey process. Further information regarding the location of the Survey Team will be coming out from the Command Center during the day".

V. The Command Center

The Performance Improvement Department will be responsible for immediately establishing the Command Center. The Command Center will be responsible for communicating the following:

- § The current location of each member of the Survey Team
- § The schedule for table-top review sessions (Infection Control, EOC, Medical Staff, Medication)
- § Any schedule revisions
- § Identified focus areas and key findings that require additional attention by Directors/ Managers.

The primary mechanism for communication from the Command Center will be email and telephone.

The telephone numbers to the Command Center are as follows: (list phone numbers)

VI. The Surveyor Conference Room Set-U

The Surveyor Conference Room will be used as the central meeting place for the members of the Survey Team. On the morning of arrival, the schedule for the room will be cleared for the duration of the survey. Additionally, Nutrition Services will be contacted to make the necessary arrangements for meals and beverages.

Once the Survey Team is escorted to the Conference Room, the staff of the Performance Improvement Department will make the following information available to the Survey Team:

- § Priority Focus Process Data (to be printed from the website)
- § Periodic Performance Review (PPR) Report and the Response (to be printed from the Joint Commission website)
- § All Measure of Success data for any standard/element of performance that required a plan of action from the PPR
- § The Evidence of Compliance Report and Measure of Success Report with supporting data from the most recent on-site survey. (The Evidence of Compliance and Measure of Success Reports are to be printed from the website)
- § Performance Improvement data
- § Staffing Effectiveness data
- § Medical Record Statistics Form (to be completed and signed by the Director, HIM)
- § Top ten procedures and diagnoses from the previous calendar year
- § Minutes from the Medical Executive Committee
- § Minutes from the Infection Control Committee
- § Minutes from the EOC/Safety Committee
- § Core Measure Data (to be printed from the website)
- § EOC Plans and Evaluations
- § Statement of Condition/updated Plans for Improvement
- § Organization Chart
- § Listing of Departments/Department Directors
- § Key Contract Person with telephone/pager information
- § Medical Staff Bylaws/Rules & Regulations
- § Medical Staff Roster
- § HR Listing of Employees

Additionally, a current census report and the day's surgery schedule will be brought to the Conference Room. A census report and a surgery schedule are to be brought to the Conference Room each morning of the survey.

VII. Other Materials for the Survey

Department Directors and Managers must respond promptly to requests for personnel files, medical record forms/documents, and department-specific policies and procedures. It is important to make sure that these items are accessible in the event that the Director or Manager is not present during the survey.

VIII. The Opening Conference

Upon escorting the Survey Team to the Conference Room, they will be asked for an estimated time for the Opening Conference. The leadership of the organization will be contacted and notified of the need to gather in the Board Room for the Opening Conference at the stated time. The CEO will present the prepared opening presentation to the Survey Team. The leadership will also address any initial questions from the Survey Team.

IX. Key Roles During the Survey

Escort: The Escort accompanies the surveyor through his/her tour of the organization. An important role of the Escort is to identify and communicate any key issue to the Command Center.

Scribe: The Scribe documents the questions from the surveyors during the survey. This includes both table-top sessions and tracer activities. The Scribe must also document each medical record used by the surveyor during unit and Department visits. To facilitate the documentation of the medical record used, a patient ID sticker may be placed on the notepad. The Scribe may assist in summarizing key information that must be communicated during the daily briefing.

Runner: The Runner accompanies the surveyor and Escort and obtains any documents/materials requested by the surveyor. Additionally, the Runner alerts the next Department or unit of the surveyor's anticipated arrival either by going to the Department/unit or by contacting the Command Center.

X. The Survey Schedule

Please refer to the survey templates located in the red folder. It is important to note that the schedules may be revised by the Survey Team and that the most current information related to the schedule will be communicated by the Command Center.

XI. The Daily Briefing

A daily briefing will be held each day of the survey. Upon the daily departure of the Survey Team, Department Directors, Managers, and other key staff members will gather in the following locations: (list locations)

Sample Survey Readiness Guide

Joint Commission Readiness for All Employees

Introduction

This informational booklet provides employee's assistance in answering a variety of questions for the Surveyors. This survey provides us an opportunity to demonstrate processes and procedures that produce quality patient care.

The Facts

- Joint Commission on Accreditation of Healthcare Organizations (TJC) is an independent, not-for-profit, national organization that develops standards for health care facilities.
- Accreditation is offered on a voluntary basis.
- TJC representatives (surveyors), determine accreditation status.
- Surveyors may request to talk to any employee and tour any area providing patient care or support services.
- Accreditation surveys occur every three (3) years.
- Our survey will occur some time in 2006.
- UHS requests TJC representatives conduct the survey to help us evaluate ourselves and improve our services.

- Through participation in the survey, UHS is better positioned to receive reimbursement and to improve services.
- The survey team consists of a physician, a nurse, an administrator, and a life Safety Specialist
- The surveyors work independently, and as a group, making visits throughout the hospital.
- They will visit with UHS physicians, administrators, nurses and employees.
- They may also conduct brief interviews with patients.
- The UHS CEO, hospital leaders, and staff are ALL key participants in the survey process.

Mission: The mission of UHS is to promote the good health of the community by providing the highest quality care to both inpatients and outpatients; by teaching the next generations of health professionals; and by supporting research, thereby advancing medical knowledge and improving the delivery of patient care.

Vision: We will continuously improve the health and well-being of the people of Bexar Country, South Texas, and beyond.

Values: Our patients come first; We work as a team; We work for the community; We do everything with respect, dignity, sensitivity, and trust; We are experts at our jobs; Education and research are important to excellent patient care.

Standards of Conduct

Employees communicate the real spirit of a health care facility. We are expected to be responsible for our attitudes and actions at all times, consistent with the standard and behaviors contained in *Guest Relations*, UHS Policy 4.11, individual job descriptions, department guidelines, performance evaluations, and *4 For the Customer*.

Manuals

You should be familiar with the following Manuals and their location.

- Department Procedure Manual (on units or in department)
- Policy and Procedure Manual (UHS Intranet)
- MSDS (Material Safety Data Sheets) Department Specific Chemical List (on units or in departments) Fax-on-Demand for MSDS Sheets.
- Quality and Performance Improvement Notebook (on units or in departments)

Points to Remember and verbalize

TJC Surveyors will evaluate how we fulfill our Mission Statement through the UHS Spirit. Our customer skills are what matter to our patients, families, co-workers, and visitors.

Our “4 for the customer” program includes:

- Take care: Showing respect, understand differences, show empathy, protect privacy & confidentiality
- Take initiative: Giving information, anticipating customer needs.
- Take responsibility: Assume ownership, initiate service recovery (doing what you can to make customers happy, sharing successes and mistakes so others can learn), solving problems (identifying improvement opportunities) and staying informed (asking questions & sharing information).
- Taking pride in yourself, your environment, your team, and in our health system (Demonstrating teamwork, speaking with pride about the hospital, showing an attitude of caring in what we say and do!: Creating great first impressions when greeting customers, assisting in public areas, helping lost customers, answering phones, and entering patient rooms.

Emergency Codes

Do you know the meaning of the following codes?

Code name	Meaning
Code Red	Fire/smoke
Code Blue	Cardiopulmonary arrest
Code Pink	Infant Abduction
Code Black	Bomb threat

Code Orange Bio-terrorism Emergency
Code Skywarn Inclement Weather, Tornado warning
Operation Lifeline Activation of the UHS disaster plan

Understand and be able to describe your role during each code.

Review the Fire Safety and Emergency Management Plans located on the UHS Intranet.

Q: What are the steps in responding to a fire or smoke emergency in your work area?

A: RACE Rescue, Alarm, Contain, Extinguish (Evacuate if necessary)

Q: What steps are taken if the fire or smoke emergency is in another area of the building?

A: Check all rooms, close doors, ensure all staff are advised, advise patients and visitors, review evacuation procedures, and await further instruction.

Q: What are the steps used to operate a fire extinguisher?

A: PASS Pull pin, Aim at base of flames, Squeeze handle, Sweep discharging agent at the base of the flames.

Quality & Performance Improvement

Q: What is your role in delivering quality service?

A: Always perform your job in a caring, safe competent and cost aware manner looking for ways improve service to all customers.

Q: Who are your customers?

A: Be able to state three key customers of your department (Examples: Patients, Physicians, other employees or Volunteers).

Q: What is the System's approach for designing a new process & performance measurement, assessment & improvement?

A: DMAIC

- D - Define
- M – Measure the process
- A – Analyze the process
- I – Improve the process
- C – Control the new process

B: Six Sigma, Failure Mode Effects Analysis (FMEA)

Q: What is a Rapid Cycle Test and has this been conducted on your unit?

A: A quick, rapid way to test new IDEAS.

Q: What orientation did you receive for your job?

A: Every employee is required to go through new employee orientation. In addition, employees receive unit/department specific orientation even if they have transferred from another department within the hospital or system. Nurses also receive a nursing orientation in addition to their unit orientation.

Q: How often are you given a Performance Evaluation?

A: At least one time per year.

Q: Have you attended any in-service education this year that will improve patient care or customer service?

A: Yes. Examples: Telephone Etiquette, TB Update, Standard Precautions Update, New equipment inservice, and Client Relations Programs, Weapons of Mass Destruction Training, HEICS, EOC, HIPAA, Core Measures etc.

Q: What kind of continuing education have you had?

A: Each person should be specific regarding: What is mandatory for their position.

Q: Where are employee education records kept?

A: In the Education/In-service Database, that is maintained by Learning Resources. Computer courses in Health Stream, and outside seminars and in-services are kept in the department in the individual's competency folder.

Sentinel Event:

The definition of a Sentinel Event is: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The phrase “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called sentinel because they signal the need for immediate investigation and response.

Examples:

Wrong site surgery; Delay in treatment; Transfusion error; Patient death/injury in restraints

Infection related event; Medication error; Patient Abduction including infant abduction.

UHS performs a thorough Root Cause Analysis (RCA) following any Sentinel Event. The analysis focuses on process and system factors and incorporates the DMAIC model to develop a risk reduction plan.

Q: How do we prevent a Sentinel Event?

A: We review new Sentinel Event Alerts for risks and recommendations. We also look at high volume, problem prone or high risk areas and perform root cause analysis (RCA) on critical incidences. We also identify potential problems before they occur using the FMEA (Failure Mode Effects Analysis) tool.

Q: Give an example of an RCA or FMEA for your facility.

A: RCA:

-“Medical error at Duke University Health System”. A transplant was performed with type A donor heart and lungs to a girl with type O positive blood leading to a unanticipated outcome or death.

-A sign was not posted after the floor was waxed and a patient fell in the hallway.

Q: Name one of the TJC current patient safety goals. Be able to elaborate on one way this is being done on your unit.

A: They are:

- Improve the accuracy of patient identification
- Improve the effectiveness of communication among caregivers
- Improve the safety of using medications
- Accurately and completely reconcile medications across the continuum of care
- Improve the effectiveness of clinical alarms systems
- Reduce the risk of health care-acquired infections
- Reduce the risk of patient harm resulting from falls

Patient Rights and Ethics

Q: How do we inform patients of their rights and responsibilities?

A: Signs are posted throughout the facility informing patients, and each patient receives a copy of the patient handbook that contains a copy of their rights and responsibilities.

Q: Is there any method in place at your hospital to provide extra security for nursery/pediatric patients?

A: Yes, individuals working in the Maternal Newborn and Pediatric units are identified with a special security photo I.D. badge. Parents are made aware of the “special” red badge and are taught the importance of identifying anyone approaching or caring for their child. A special alert, “Code Pink,” requires the participation of all employees in the case of an actual or suspected abduction or during a drill. Staff members on all Maternal-Child and Pediatric units have identified risk areas on their units and strategies to reduce those risks.

Q: How do you keep patient information confidential on your unit?

A: Examples:

- Limited information on wipe boards
- Computer screens turned away from traffic areas
- Use of computer privacy screens in high traffic areas
- OR Schedules not posted in traffic areas
- Attempt to provide privacy in high traffic or public access areas
- Proper handling of documents with patient names or identification
- Staff expected to wear UHS badges at all times
- Charts not left open or in public areas

- No patient identifiers (i.e. name, social security number, etc.) in the open

Q: What is HIPAA?

A: The Health Insurance Portability and Accountability Act – passed in 1996, and revised in 2002.

Q: What were the HIPAA Privacy Rules designed to do?

A: Provide the patient with more control over his medical information and protection from unwanted disclosure of information.

Q: How do we protect patient privacy?

A: Hard Copy: Name 2 ways

- Do not leave patient information on counters, chairs, tables
- Verify recipient of faxed information
- Do not share my ID and password with anyone
- Log off computer terminal when I leave
- Share only the “minimum necessary” information to co-workers with a need to know
- Do not talk about patients or patient conditions in public access areas

Q: What are ways to demonstrate respect of a patient’s privacy?

A: Draw curtains, close doors, position patient away from door opening (as much as possible), provide care in private areas (not public access areas such as hallways), keep patient covered especially during any procedure or transport. Provide private area to discuss financial matters. Turn off cameras when treatments are being provided.

Q: Describe your hospital-wide no smoking policy.

A: UHS is a smoke free hospital system, with designated smoking areas located outside each facility.

Q: What does the MSDS tell you? Where are they located?

A: Material Safety Data Sheets give you information needed to protect yourself when working with hazardous chemicals. The MSDS sheets include important information about spills, clean up procedures, health risks, personal protective equipment, etc.

Q: What Environment of Care and Infection Control training have you had?

A: Examples:

- Electrical Safety
- Fire Safety (Life Safety)
- Back Safety
- Security & Workplace Violence
- Environment of Care Competency
- Standard Precautions: Blood & Body Fluids
- Emergency Preparedness
- Transmission Precautions: Contact & Droplet

Q: What should you do if you have a hazardous chemical spill or release in your area?

A: Contain (as trained), notify employees in immediate area and evacuate if necessary, notify appropriate supervisor, and consult your Department Specific Chemical Inventory List and MSDS to determine precautions. In the event of a large quantity hazardous spill, contact your supervisor, Safety department, Environmental Services, Protective Services and report type of spill.

Q: Where is the closest evacuation route from your area?

A: Employees should know at least two evacuation routes from their work area and know where the evacuation maps are located.

Q: Where would you evacuate a patient or staff member in case of fire or smoke?

A: First horizontally beyond specified fire/smoke doors, then vertically down stairs. Use of elevators during a fire or smoke emergency can only be accomplished when authorized by the Fire Department.

Q: Who can authorize a patient evacuation?

A: Because fire and other internal disasters sometimes necessitate that decisions be made immediately, the patient care manager, supervisor, or designee is authorized to issue the order for a partial facility

evacuation. The manager or designee may issue an order to initiate a downward or upward evacuation, only in areas of the Hospital where there are no areas of refuge on the same floor.

Q: Who is authorized to turn off patient room medical gas zone valves (oxygen, medical air)?

A: Turning off medical gases during a fire emergency may impact patient safety. The supervisory staff member in charge will assess patient care and direct the closing of medical gas valves, stopping the flow of oxygen and/or medical air to one or multiple patient rooms.

Q: What is the frequency of fire drills conducted in your work area?

A: Fire drills are held quarterly, one drill per shift per quarter. The frequency of fire drills may be increased if building Life Safety (fire safety) conditions are altered or changed as a function of construction, renovation or repair.

Q: How would you know if the main electrical supply was off?

A: Reduced light levels would be observed in corridors. Some areas would have no lights. Only red emergency power outlets would work in patient care areas. Critical care areas should have emergency power available. Not all areas have emergency power available.

Q: Who should you direct your questions to regarding the Environment of Care (safety, security, hazardous materials and waste, emergency management, fire safety, medical equipment and utility programs)?

A: You may contact your Department Safety Representative or the Safety Director.

Q: Who is your facility Safety Director?

A: David Guerrero (office 358-2461, pager 756-5544).

Q: What patient room(s) in your department have negative air pressure to aid in the control of infection and exposure?

A: Be able to identify isolation rooms in your area, the types of isolation and what you do if a patient requires isolation.

Q: What are some ways to determine an isolation room's negative pressure is functioning properly?

A: Examples:

- Call Plant Engineering to verify
- Tissue test
- Smoke test

Q: What are the seven (7) Environment of Care (EOC) Management Plans?

A: All employees working at UHS share responsibility for these programs:

- Safety Management Plan
- Security Management Plan
- Hazardous Material & Waste Management Plan
- Emergency Management Plan
- Fire Safety Management Plan
- Medical Equipment Management Plan
- Utility Management Plan

Everyday Actions That Contribute to Patient Safety

- Wear name identification badges at all times
- Use wet floor signs
- Keep corridors clear and unobstructed
- All employees must participate in Fire drills
- Know your role in system-wide Code Pink drills
- Fall precautions
- Safety zone in surgery
- Separate medical gases
- Locking up valuables

Infection Control

Q: Who is responsible for Infection Control?

A: We are all responsible. The Infection Control Department oversees our program.

Q: What are Standard Precautions?

A: Treating all patients as if they are potentially infectious, is a method of protecting patients, healthcare workers and customers. Consider body secretions from all patients as a source of potential infection, regardless if you see blood.

Q: What is the single, most effective way in preventing infections:

A: Hand washing.

Q: What should you do if you see an isolation sign on a patient's door?

A: Read the sign and follow directions, or ask the nurse before entering the room.

Q: What is personal protective equipment (PPE) and when do you use it?

A:

- Gloves – when in contact with blood/body fluids
- Goggles/Face Shield – when a splash to the face is possible
- Gowns or aprons –if a splash to your clothing is possible
- Respirators for airborne exposure protection

Q: What patient rooms are designated as isolation rooms in your department and how do you improvise for an isolation/negative pressure room, if you need one?

A: Two rooms on each floor have been designated for isolation room. The 2 rooms on my floor are _____ or/_____.

Q: To prevent airborne infections in ambulatory settings everyone needs to practice good cough etiquette? True or False

A: True

Q: How do you dispose of isolation gowns, PPE or any trash from an isolation room?

A: UHS Infection Control (IC) policy IC 5.12 recommends disposing of contaminated isolation gowns, PPE or any trash from an isolation room in red bags. The IC Manual is available online via the intranet, by going to the corporate web page and clicking on Departments. From there a drop down menu will appear, click on Infection Control, and then click on Infection Control Manual from the menu on the left. Any unit/department that does not have access to computers must have an updated IC manual available to all staff.

Q: Does UHS autoclave or incinerate red bag trash?

A: Autoclave

Q: What is the Exposure Control plan?

A: A plan which provides measures to eliminate or minimize employee exposure to blood or other potentially infectious material and directs the employee what to do in the event of an exposure.

Information Management

Security:

Q: List three (3) types of confidential information in the UHS.

A: Examples:

- Clinical
- Financial
- Human Resources

Q: What are ways computer access is controlled?

A: Examples:

- IS Security Access Request and Agreement Form
- Confidentiality and Security Access Agreement Form
- Computer lockdown

Privacy:

Q: What are three (3) ways patient health information is moved around within the UHS?

A: Examples:

- Verbally Electronically

- Hard copy

Q: What is PHI relative to patient privacy?

A: Protected Health Information.

Q: List at least three (3) ways that you protect the privacy of patient health information.

A: Examples:

- Log off or lockdown computer terminal when I leave
- Do not share my ID and password with anyone
- Do not leave patient information on counters, chairs, or tables Share only the “minimum necessary” information when working with others
- Do not talk about patients in public access areas

Q: List five (5) of the 18 identifiers that are considered to be protected health information.

A: Examples

- Patient name
- Account numbers
- Telephone numbers
- Social security numbers
- Medical record number
- Health plan numbers
- All elements of dates related to patient (DOB, Admission, Discharge, and death)
- Device identifiers
- Full face photographs
- Internet address
- Fax numbers URLs
- Certificate/license numbers
- Vehicle identification numbers
- Any identifying characteristics
- All geographic subdivisions smaller than State

Survey Readiness for Clinical Employees

Manuals

You should be familiar with the following Manuals and their location.

- Nursing Procedure (Perry & Potter)
- Infection Control (on units and department)

Quality & Performance Improvement

Q: Where is the written UHS Quality Management Plan?

A: In your department’s Quality & Performance Improvement Notebook, and on the UHS Intranet Policies and Procedures (Policy 5.01).

Q: Describe a Performance Improvement (PI) project in which your unit is currently involved.

Be prepared to dialogue about your own unit specific PI projects.

Q: What is the goal of your Performance Improvement project?

Q: How do you measure improvement?

Q: Are you measuring improvement in this project?

Q: Are there separate standards of care for inpatients and outpatients?

A: No, a consistent performance of the patient care process is delivered to all patients.

Q: How do we ensure that the same level of care is consistently given all UHS patients with the same need and that they receive a comparable level of care throughout the System?

A: We follow the Patient Bill of Rights and Responsibilities, Medical Staff Bylaws, established UHS Policies and Procedures and the guidelines of our Quality Management Plan, which establishes a method of collaborating, sharing and reporting Performance Improvement information among representatives from like clinical and administrative services throughout the system. In addition,

clinical leaders and staff from similar areas throughout the System work together to develop policies and procedures for their specialty (Example: Surgical Services, Women's Health Services, Med-Surg. Critical Care).

Sentinel Event:

The definition of a Sentinel Event is: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called sentinel because they signal the need for immediate investigation and response.

Examples:

Wrong site surgery

Delay in treatment

Transfusion error

Patient death/injury in restraints

Infection related event

Medication error

UHS performs a thorough Root Cause Analysis following any Sentinel Event. The analysis focuses on process and system factors and incorporates the DMAIC model to develop a risk reduction plan.

Q: How do we prevent a Sentinel Event?

A: We review new Sentinel Event Alerts for risks and recommendations. We also look at high volume, problem prone or high risk areas and perform root cause analysis (RCA) on critical incidences. We also identify potential problems before they occur using the FMEA (Failure Mode Effects Analysis) tool.

Q: Give an example of an RCA or FMEA for your facility.

A: RCA:

-"Medical error at Duke University Health System". A transplant was performed with type A donor heart and lungs to a girl with type O positive blood leading to a unanticipated outcome or death.

-A sign was not posted after the floor was waxed and a patient fell in the hallway.

Q: What are Core Measures?

A: These are defined sets of measures monitored and analyzed for Performance Improvement in certain patient groups.

Q: What are the Core Measures?

A: Heart Failure (CHF), Acute Myocardial Infarction (AMI), Pneumonia, Surgical Infection Prevention (SIP), and pregnancy related conditions.

Q: What are some of the nurse sensitive indicators to measure the quality of patient care.

A: Staff turnover, staff overtime, falls, medication errors, and pressure sore development.

Patient Rights and Ethics

Q: How are patients informed of their rights regarding Advance Directives?

A: Upon admission, Nursing personnel ask patients if they have an advance directive. If, the patient has a directive it is received and placed in the chart. If not, nurses ask if they would like more information or assistance in formulating an advance directive. If, patients want more information or assistance, nursing and Pastoral Care will assist them. If, the patient already has an advance directive, but did not bring it with him/her, the nurse asks that a copy be provided and documents the intent of the patient to provide a copy and be included in the patients medical record. The physician is responsible for documenting the content of the directive until a copy is provided by the patient.

Q: What procedure is followed if a patient has a concern or complaint?

A: The first step is that the employee should listen and try to resolve the problem. Whether it is resolved or not, the immediate supervisor should be made aware of the concern. If the complaint cannot be resolved the patient may speak to the manager or an administrative representative. Complaints are reported by contacting the Patient Satisfaction/Customer Service Department.

Q: What have you done to accommodate culturally diverse patients and visitors?

A: The Telephone Language Line providing interpreters for most languages, in-house interpreters speaking several languages, and patient education materials written in a 5th grade reading level are all available. Additionally, the patient handbook that is given to all patients upon admission is available in English and Spanish. Many forms and materials are available in English and Spanish.

Q: What do you do if you have an ethical concern regarding patient care?

A: Anyone can initiate a biomedical ethics consult by contacting the Legal Services Department M-F 0900 to 1700 or by contacting the house supervisor during other hours.

Q: How is staffing determined to be adequate?

A: Staffing is based on standards developed by the Director who takes into account the patient acuity, the skill mix and competencies of the staff available, the distribution of workload per shift, and special needs of the unit.

Q: Are restraints the first choice for use on an agitated, confused patient?

A: No. Less restrictive alternatives are attempted and documented before restraints are used. (e.g.: reality orientation, bed check alarm, family members at the bedside. etc.).

Q: If you have to apply patient restraints, how soon do you obtain the physician's order?

A: Within four (4) hours.

Q: What UHS policy covers restraints?

A: UHS policy 9.13, Restraints and Seclusion.

Q: What is the maximum amount of time that an order for restraints can be written?

A: 24 hours.

Q: What are ways patients and families can participate in their care?

A: Examples:

- Discussion about the diagnosis and plan for treatment
- Offering choices
- Encourage patients and families to ask questions
- Education
- Providing written literature

Q: In what ways do you keep patients and families informed of care issues and progress?

A: Examples:

- Discussion
- Phone calls
- Providing written literature
- Explain procedures
- Encourage patients and families to ask questions

** Interactions with patients and families is documented on the Interdisciplinary Patient and Family Education Record or and Family Education Record or Multidisciplinary Progress Notes.

Q: In what ways do we get feedback from patients and families?

A: Examples:

- Satisfaction surveys
- Phone Calls
- Complaints (verbal and written)
- Feedback on unit during the patient's stay

Q: T or F: Only those individuals who have a "business need" may use or disclose patient information?

A: True

Assessment and Care of Patients

Q: How soon after admission must the initial RN nursing assessment be completed?

A: Within 24 hours of admission or sooner if the patient's condition warrants.

Q: What age patient must have their immunization history documented?

A: All patients 18 years and younger.

Q: List four (4) potential barriers to patient learning.

A: Examples

- Cultural and religious beliefs
- Emotional, physical and cognitive factors
- Language
- Socioeconomic/Education level

Q: When administering medications to achieve conscious sedation, what parameters are monitored during the intra-procedural phase?

A: Examples:

- Pulse
- Respiratory Rate
- Blood Pressure
- Pain Scale
- Oxygen Saturation
- Aldrete Score (activity, respiratory effort, oxygenation/color)
- Any adverse effects of medications

Q: Do all patients need to have a cardiac monitor during moderate sedation?

A: No, Cardiac rhythm is monitored when ordered based on underlying patient condition or procedure, or when deep sedation is planned or occurs unexpectedly. We monitor respirations, pulse, blood pressure, oxygen saturation and level of consciousness. However, monitoring devices often record a cardiac rhythm at the same time.

Q: How often are the assessment parameters documented in the intra-procedural phase?

A: At least every 15 minutes for moderate sedation, and at least every 5 minutes for deep sedation.

Q: Why is medication reconciliation important for the patient and providers?

A: Medication reconciliation is the process of communication between the patient and provider and from provider to provider about the medication the patient is taking. This helps both the patient and provider maintain a current list of patient medications, provided information to the next caregiver and avoids medication errors.

Q: What are the requirements for monitoring and documenting the patient's response to a medication?

A: Whether it is the first time for the patient to receive a medication or the last in a series of doses the patient should be monitored for the effectiveness of the medication, allergic reaction and adverse drug reaction. The patient perception of the effectiveness of the medication should also be included.

Q: What do you do in the event of an Adverse Drug Reaction?

A: Examples:

- Assess and treat the patient
- Notify the physician
- Report on the Risk Assessment form

Q: Where are replacement locks for the crash carts?

A: Pharmacy-Pyxis

Q: When are patients assessed and reassessed for pain?

A: Patients must be assessed on admission, and reassessed following interventions or as condition worsens, and at least every eight (8) hours.

Q: What patient reported level of pain must Unlicensed Assistance Personnel (UAPs), or LVNs report to the RN.

A: Level three (4) or greater, and implement comfort measure under RN supervision.

Q: What is a patient hand-off?

A: A patient hand-off occurs anytime a patient's care is transfer over to another staff member, provider, service or unit. A safe patient hand-off includes enough and appropriate information about the patient to support the next teams care of the patient.

Q: When do we initiate planning for discharge?

A: On admission for all patients. High risk discharges require collaboration with Care Coordination/Social Worker.

Q: Where would you find evidence of participation of all disciplines in the medical record?

A: Examples:

- Plan of Care: Interdisciplinary Patient Problem List & Goals
- Interdisciplinary Patient/Family Education Record
- Multidisciplinary Progress Notes
- Physician Progress Notes

Q: What screening assessments are completed on our patients on admission?

A: Examples:

- Pain with pain scale rating
- Fall Risk
- Skin
- Nutritional
- Functional
- Physical
- Abuse
- Pharmaceutical
- Pressure Ulcer/Wound Ostomy
- Continence
- Diabetic
- Spiritual/Cultural
- Psychosocial/Economic

Q: How do you report a medical equipment malfunction?

A: Place a tag on the equipment noting it is “out of order”, date and a brief description of the problem. Remove the equipment from the work area if possible. Notify Bio-Med who will assign a technician to the malfunctioning equipment

Q: How do you report a medical equipment malfunction that involves an injury to the patient or staff member?

A: Remove the equipment and all necessary devices and accessories (i.e. an IV pump & IV tubing) and secure it in a safe place. Notify your supervisor and complete a Risk Assessment form (BCHD # 37).

Available online UHS intranet

Q: How often do we assess safety risks and hazards?

A: Hazard Surveillance surveys are conducted in patient care areas two times a year and once a year in non-clinical areas.

Q: Where are UHS Environment of Care issues reported and discussed?

A: The Environment of Care Committee is a multi-disciplinary committee and sub committees that meets to review issues regarding safety, security, hazardous materials and waste, emergency management, fire safety, medical equipment and utilities.

Q: List three (3) ways to ensure patient safety in your work area.

- A:
1. Be sure medical equipment alarms are operating properly and can be heard in your work area.
 2. Report equipment that has malfunctioned.
 3. Be sure to perform hand washing between patient contact and each time gloves are put on and removed.

Everyday Actions That Contribute to Patient Safety

- Two patient identifiers
- Read-back process
- Wear name identification badges at all times

- Use wet floor signs
- Keep corridors clear and unobstructed
- Only use the appropriate patient status codes when asked for information about a patient.
- Verify Security locks
- All employees must participate in Fire drills
- Know your role in system-wide Code Pink drills
- Fall precautions
- Blood loc system
- Infant I.D bands
- Proactive Risk Assessments
- Keep sharps locked up
- Safety zone in surgery
- Site verification process
- Informed consent
- Separate medical gases
- Removal of concentrated electrolytes from floors
- Locking up valuables
- Not storing medications in alphabetical order
- Medication Safety Protocol Steps
- UHS prohibited abbreviations

Infection Control

Q: Does UHS recap needles?

A: No.

Q: What is the proper way to dispose of sharp objects?

A: In sharps containers located in patient rooms and designated areas. *Please note they should be no more than $\frac{3}{4}$ full*

Q: What should you do if you see an isolation sign on a patient's door?

A: Read the sign and follow directions, or ask the nurse before entering the room.

Q: What type of mask is used for a suspect TB patient and who wears it?

A: N95 respirator mask. Health care workers, staff and visitors wear the mask...NEVER the patient.

Patient and Family Education

Q: Who is responsible for the patient's education?

A: All clinicians involved in the patient's care.

Q: Where is patient education documented?

A: On the Interdisciplinary Patient/Family Education Record (Pink Sheet) located under the Multidisciplinary Progress Record Tab of the Medical Record. Additional comments related to the patient's response to teaching can be made on the Multidisciplinary Progress Record.

Q: How do you determine your patient's/family's readiness to learn?

A: An RN assesses their current knowledge/understanding of his/her condition/disorder, at the time of admission. In addition, level of coping and anxiety are assessed.

Q: How do you decide what to teach?

A: Through the assessment of learning needs, and RN determines what the patient/family knows, and then plan the teaching to provide the information still needed. Nursing will also refer to other clinicians as needed to coordinate the appropriate specialty education. The patient's plan of care reflects the goals of education.

Q: How is teaching done? Are special learning needs considered?

A: Nursing teaches through group and one-to-one methods. If special learning needs are identified, (such as blindness), nursing may use videos and audiotapes. Clinicians will also inquire from the patient and family how the patient learns best.

Q: What teaching material resources are available for patient education?

A: The teaching materials might include pamphlets from American Heart Association, Krames, Krames on Demand (KOD), patient education videos, or BHS developed materials. Selected teaching materials are chosen at a reading level 4th – 7th grade. Many of the teaching materials are available in English and Spanish. Health Educators at UCCH are available for referrals.

Q: What disciplines are included in patient/family education?

A: Disciplines such as; PT, OT, RT Dietary, and Nursing are included according to the medical condition and assessed deficiencies. All disciplines document teaching on the Interdisciplinary Patient/Family Education Record.

If you have questions or uncertain of the most appropriate response please contact your supervisor. The staff of Quality and Process Improvement is available to answer any questions or direct you to the appropriate source.

Important Terms and Abbreviations

Accreditation: Determination by the Joint Commission's accrediting body that an eligible health care organization complies with applicable Joint Commission standards.

Accreditation Cycle: A period of accreditation at the conclusion of which, accreditation expires unless a full survey is performed.

Accreditation Decisions: Categories of accreditation that an organization can achieve based on Joint Commission survey. These decision categories are: Accredited, Provisional Accreditation, Conditional Accreditation, Preliminary Denial of Accreditation and Denial of Accreditation. (See definitions)

Accredited: The organization is in compliance with all standards at the time of the on-site survey or has successfully addressed all requirements for improvement in and Evidence of Standards Compliance (see definition) within 45 days following the survey.

ADE (Adverse Drug Event): A patient injury resulting from a medication, either because of a reaction to a normal dose, or because of a preventable adverse reaction to a drug resulting from an error.

ADR (Adverse Drug Reaction): Unintended, undesirable, or unexpected effects of prescribed medications or of medication errors that require discontinuing a medication or modifying the dose; require initial or prolonged hospitalization; result in disability; require treatment with a prescription medication; result in cognitive deterioration or impairment; are life threatening; result in death; or result in congenital anomalies.

APR (Accreditation Participant Requirement): A set of TJC standards that speak to the basic requirement for participation in the TJC process. These include the National Patient Safety Goals.

Best practices: Clinical, scientific, or professional practices that are recognized by a majority of professionals in a particular field, typically evidence based and consensus-driven.

CLIA '88: The Clinical Laboratory Improvement Amendments of 1988. This amendment sets the rule for all laboratory services.

Conditional Accreditation: The organization is not in substantial compliance with the standards, as usually evidenced by a count of the number of standards identified as not compliant at the time of survey which is between two and three standard deviations above the mean number of noncompliant standards for organizations in that accreditation program. The organization must remedy identified problem areas through reparation and submission of an ESC and subsequently undergo an on-site follow-up survey.

Continuum of Care: Matching the individual's ongoing needs with the appropriate level and type of care, treatment, and service within an organization or across multiple organizations.

CMS (Centers for Medicare and Medicaid Services): Self explanatory.

CSG (Clinical Service Group): Groups of patients in distinct, clinical populations for which data are collected. Tracer patients are selected according to clinical service groups.

Denial of Accreditation: The organization has been denied accreditation. All review and appeal opportunities have been exhausted.

e-App (Electronic Application for Accreditation): The electronic version of an organization's application for accreditation.

e-SOC (Electronic Statement of Conditions): A living electronic document describing the organization's improvement plans for the hospital facility.

EP (Elements of Performance): The specific performance expectations and/or structures or processes that must be in place in order for an organization to provide safe, high-quality care, treatment, and services.

ESC (Evidence of Standards Compliance): A report submitted by a surveyed organization within 45 days of its survey, which details the action(s) that it took to bring itself into compliance with a standard or clarifies why the organization believes that was in compliance with the standard for which it received a recommendation.

Evidence-based guidelines: Guidelines that have been scientifically developed based on current literature and are consensus driven. These are also referred to as National Guidelines or Professional Guidelines. (see Best Practice also)

FMEA (Failure modes and effect analysis): An assessment that examines a process in detail including sequencing of events; assesses actual and potential risk, failure, or points of vulnerability; and through a logical process, prioritizes areas for improvement based on the actual or potential patient care impact.

HVA (Hazard Vulnerability Analysis): The identification of potential emergencies and the direct and indirect effects these emergencies may have on the health care organization's operations.

LSC (Life Safety Code): A set of standards for the construction and operation of buildings, intended to provide a reasonable degree of safety to life during fires; prepared, published, and periodically revised by the National Fire Protection Association and adopted by the Joint Commission to evaluate health care organization under its life-safety management program.

Medication Reconciliation: The process an organization uses to collect current patient medication at the time of admission and with each patient hand-off. Applicable to both the inpatient and outpatient setting.

MOS (Measure of Success): A numerical or quantifiable measure usually related to an audit that determines if an action was effective and sustained due four months after Evidence of Standards Compliance approval.

MedPar Data: (Medicare Provider Analysis and Review): Data which are collected by the Centers for Medicare and Medicaid Services (CMS) from hospitals in order for hospitals to receive reimbursement for performed services and procedures.

Near Miss: Used to describe any process variation which did not affect an outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. Falls within the scope of a sentinel event but outside the scope of those sentinel events that would be reviewed by Joint Commission.

NQF (National Quality Forum): The Joint Commission on Accreditation of Healthcare Organizations hosts a national quality forum every year in an effort to share new information about Joint Commission and quality.

NPSG (National Patient Safety Goal): Goals that highlight problematic areas in health care and describe evidence and expert-based consensus to solutions to these problems. The goals generally focus on system wide solutions whenever possible. The purpose of the goals is to promote specific improvements in patient safety.

Organizations Strengths: Areas in which an organization's performance is exemplary, as evidenced by the implementation of innovative approaches to meeting Joint Commission standards. An organization will not be cited for having a strength if the organization has a related non-compliant standard and/or partially compliant element of performance (EP).

ORYX: Joint Commission quality performance measurement initiative. Not an acronym.

Patient Tracer: The process of evaluating a patient's total care experience with a health care organization.

Performance Measurement System: An entity consisting of an automated database(s), that facilitates performance improvement in health care organizations through the collection and dissemination of process and/or outcome measures of performance. Measurement systems must be able to generate internal comparisons of organization performance over time and external comparisons of performance among participating organizations at comparable times.

PFA (Priority Focus Area): Processes, systems, or structures in a health care organization that significantly impacts the quality and safety of care. The priority focus areas are:

Assessment and Care/Services	Organizational Structure
Communication	Orientation and Training
Credentialed Practitioners	Patient Safety
Equipment Use	Physical Environment
Infection Control	Quality Improvement Expertise and Activity
Information Management	Rights and Ethics
Medication Management	Staffing

- *Primary Priority Focus Area:* Every standard is linked to one or more priority focus areas. When a surveyor has findings under a standard, he/she determines which of the linked priority focus areas is most related to the specific finding and this becomes the primary priority focus area. For example, a finding under standard HR.1.10 may be assigned a primary priority focus area of Staffing. The organization's accreditation report is organized by priority focus area.
- *Secondary Priority Focus Area:* The additional priority focus areas that are also related to a specific finding, in addition to the primary priority focus area. For example, a finding under standard HR.1.10 may be assigned a secondary priority focus area of Orientation and Training. The organization's accreditation report also lists the secondary priority focus area(s).

PFI (Plan for Improvement): An organization's written statement that details the procedures to be taken and time frames to correct existing Life Safety Code deficiencies.

PFP (Priority Focus Process): The process for standardizing the priorities for sampling during an organization's survey based on information collected about the organization prior to survey. The process also helps to focus the survey on areas that are critical to that organization's patient safety and quality of care processes. Examples of such information may include, but not be limited to, data from the organization's e-App (see def); the organization's plan of action prepared as part of PPR (see def) process; complaint and sentinel event information; data collected from external sources, such as Med-Par (see def) data; performance measurement data; and previous survey results.

PFT (Priority Focus Tool): An automated tool that supports the priority focus process through the use of algorithms, or sets of rules, to transform a health care organization's data into information that guides the survey process.

PI (Improving Organization Performance): The continuous study and adaptation of a health care organization's functions and processes to increase the probability of achieving desired outcomes and to better meet the needs of individuals and other users of services. It involves measuring the functioning of important processes, and services, and, when indicated, identifying changes that enhance performance. These changes are incorporated into new or existing work processes, products or services, and performance is monitored to ensure that the improvements are sustained. It focuses on outcomes of care, treatment, and services as well as effectively reducing factors that contribute to unanticipated adverse events and/or outcomes.

POA (Plan of Action): A detailed plan of action the organization will take in order to come into compliance with a Joint Commission standard. The plan must be completed for each EP associated with a non-compliant standard and the MOS must also be included.

Point-of-care testing: Analytical testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to individuals. Testing may range from simple waived procedures, such as fecal occult blood, to more sophisticated chemical analyzers. The testing may be under the control of the main laboratory the direction of another specialized laboratory (such as for arterial blood gas), or under the nursing service. Testing may be categorized as waived, moderate, or high complexity under CLIA '88. Also called alternate site testing, decentralized laboratory testing, and distributed site testing.

PPR (Periodic Performance Review): An additional requirement of the accreditation process in which an organization reviews its compliance with all TJC standards then submits a plan of action to TJC for any standard not in compliance, including the identification of a measure of success (MOS). This encourages

organizations to remain in continuous compliance with TJC standards. At the time of the next survey, the surveyors will validate that the MOS(s) were implemented and effective.

Practice Guidelines: Tools that describe processes found by clinical trials or by consensus opinion of experts to be the most effective in evaluating and/or treating a patient who has a specific symptom, condition, or diagnosis, or describe a specific procedure. Synonyms include practice parameter, protocol, preferred practice pattern, and guideline.

Preliminary Denial of Accreditation: There is a preliminary finding of justification to deny accreditation to the organization as usually evidenced by a count of the number of noncompliant standards at the time of survey which is at least three standard deviations above the mean number of standards identified as not compliant for organizations in that accreditation program. The decision is subject to review and appeal prior to the determination of a final denial of accreditation.

Provisional Accreditation: The organization fails to successfully address all requirements for improvement in an ESC within 45 days following the survey or does not pass their first MOS.

Range Orders: Orders in which the dose or dosing interval varies over a prescribed range, depending on the situation or individual's status.

RCA (Root Cause Analysis): A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

RFI (Requirement for Improvement): A recommendation that is required to be addressed in an organization's Evidence of Standards Compliance (see def ESC), and needs to be addressed in order for the organization to retain its accreditation decision. Failure to adequately address a requirement improvement after two opportunities will result in a recommendation to place the organization in Conditional Accreditation.

SE (Sentinel Event): An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

SOC (Statement of Conditions): A proactive document that helps an organization to do a critical self-assessment of its current level of compliance and describe how to resolve any Life Safety Code (LSC) deficiencies. The SOC was created to be a "living, ongoing," management tool that should be used in a management process that continually identifies, assesses, and resolves LSC deficiencies.

System Tracer: A session during the on-site survey devoted to evaluating high-priority safety and quality of care issues on a systemwide basis throughout the organization. Examples of such issues may include infection control, medication management, staffing effectiveness and the use of data.

Tracer Methodology: A process surveyors use during the on-site survey to analyze an organization's systems, with particular attention to identified priority focus areas, by following individual patients through the organization's health care process in the sequence experienced by the patients. Depending on the health care setting, this may require surveyors to visit multiple care units, departments or areas within an organization or a single care unit to "trace" the care rendered to a patient.

Waived Testing: Tests that meet Clinical Laboratory Improvement of 1988 (CLIA '88) requirements for waived tests; are cleared by the Food and Drug Administration for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no risk of harm to the patient if the test is performed incorrectly.

Survey Last Minute Checklist

What are the FIRST FIVE things you would do if you heard Joint Commission was in the building now?

1. Make sure everyone is wearing a badge that is visible and above the waist

2. Declutter hallways; boxes off floor; linen off chairs; refrigerator/eyewash/crash cart logs up to date; no doors propped open		
3. Make sure there is no PPI information visible; monitors are at sign-on screen if not in use		
4. Close all Medication Room doors; no expired meds, open/unattended med carts; unlabeled vials or syringes		
5. Assess the types of patients on your unit, decide which record(s) a surveyor might want to review, and which staff member might be interviewed. Allow staffer time to review the chart so they are familiar with pt's history & current status, they know where key information is documented in the chart, and they can read it.		
What are the most important things you should look for when doing an open chart review?		
Issue	Where to Look	What should be There
Advance Directives	Nursing database "Advance Directives" section	*Checkoff boxes complete; DNR sticker on Face Sheet *Documents on chart [or portal] match those noted on database *Follow-through for all "No" or "Pt/Family will bring in" statements
H&P	H&P Short Form (Pink) H&P Dictated Initial Progress note	*Handwritten or dictated & typed within 24 hours of admission *Signed if patient went to the OR *Signed and dated if handwritten *All checkoff boxes complete on short form
Core Measures [MI, HF, PN, SCIP]	Core Measures Worksheet (yellow)	*Date completed, location of information, and if element not done/ not documented the reason why is clearly stated
Legibility	Everywhere; Primarily prog notes and orders	*Everyone should be able to read another staff member's handwriting
Postoperative Note	Progress Notes	*Date/time and "time out" section completed *All elements of Brief Postop Note completed; dated, timed, & signed
Medication Orders	Physician Orders	*No dangerous abbreviations *Read back for all verbal and telephone orders *All elements of an appropriate order: drug, dose, route, frequency *Indication for all PRN orders
Medication Reconciliation	MRR (blue)	*RN lists meds, indicates "Yes" ordered, or "No" not ordered on admission *MD addresses all "No's"; signs and dates form
Nursing Care Plan	NCP	*Individualized for THAT patient *Up to date
Restraints	Restraint orders (beige)	*Indication *Date, time, & signature every 24 hours
Pain Management	Pain Flow Sheet ER Triage & Pain	*Assessment includes interventions taken *Reassessment following intervention

What are the most important things staff should be able to verbalize to a surveyor?

Issue	Question	Surveyor Expectation
National Patient Safety Goals	Patient Identification	*Use two patient identifiers (name, DOB) *Ask "What is your name and DOB" not "You're Harry Smith?"
	Handoff Communications	*At a minimum information about the patient's current status, pending labs/other results, and recommendations regarding the next caregiver's plan of care are provided including an opportunity to ask/respond to questions
	Handwashing	*Before and after every patient contact *Infection control monitors compliance via observational studies
Fire Procedure	RACE PASS (extinguisher)	*Rescue, Activate, Confine, Extinguish *Pull, Aim, Squeeze, Sweep
HIPAA	Opt-out	*Know patient wishes re: presence on list as being hospitalized *Know patient wishes re: disclosure of health status
Documents at bedside	How are they managed?	*Removed when patient discharged *Manilla folders discarded; if plastic covers are used, they are washed between patients
Performance Improvement	1. What does your unit monitor/report on? 2: How have YOU used Perf Imp data/outcomes to change YOUR practice	1: Core Measures; Handwashing; Falls; Restraints; ADEs and Near Miss; Patient Satisfaction; Pressure Injuries; Pain; Unit-Specific...? 2: Everyone should develop an answer of their own: Think about which PI measure is most closely related to your daily routine? How did the results impact the WAY that you perform your daily routine?

REMEMBER: Hospitalists are available to assist in obtaining restraint orders, medication reconciliation, H&Ps, and completing other "open" issues if necessary

Consultants

Advantages of using consultants

- Take advantage of experience
- Extra pair of eyes
- Need a heavy
- Want new ideas
- Need horsepower

Disadvantages of using consultants

- Too expensive
- Leadership doesn't allow
- Don't know what to do with the person
- Don't know how to use the information

Consultants are often utilized to acquire expertise the organization needs but cannot provide for itself. Consultants may be utilized to assist with selection and implementation of a new information system. Consultants are also used to provide unbiased opinions on performance and improvement opportunities. When a consultant is used by an organization, one person should be identified as a liaison with the consultant. This will assist in the elimination of confusion regarding what is expected from the consultant. It's important to have a letter of understanding, or contract, specifying the services that will be provided by the consultant. This contract should contain:

- Scope of services that will be provided by the consultant, including departments or areas covered in the work, type of services to be provided
- Objectives that should be accomplished by the consultant
- Approaches to be used by the consultant, e.g., facilitation of meetings, interviews with staff, medical record reviews
- Deliverables or output of the consultant's work, including recommendations, a written report
- Time frame in which the work is to be accomplished
- Fee, including how billing will be done, for specific services, type of services such as travel, copying of materials, etc., hours worked, products delivered, and when the fees are due, i.e. monthly, or on completion of the project

If this information isn't clearly documented in the contract, it should be requested from the consultant prior to the beginning of the project. Check references provided by the consultant, and ask for a sample of the consultant's completed deliverables prior to signing the contract.

Once the contract has been signed, the organization liaison should work with the consultant to determine a schedule of meetings and activities that need to occur. If the project is going to continue over time, the organization liaison should meet regularly with the consultant to determine if the objectives are being met in a timely manner. The liaison should ensure that organization staff are available as needed and the at the project is continuing as planned and on schedule. If there are delays, or increased costs are encountered during the process, the liaison should work with the consultant and the organization administration to address these items as they occur so that they can be effectively managed. When the consultant has delivered the agreed on product, the liaison should ensure that the contract has been completely fulfilled, taking whatever steps are necessary to complete the terms of the contract, and determine any follow up needed by the organization.

Contracts

1. Identify all contracted services
 - a. Patient care
 - b. Patient support
 - c. Non patient care
 - d. All services provided by organization but portions supplemented by contract
 - e. Supplemental staff
 - f. Shared services between two organizations
 - g. Services provided by corporate entities that oversee the organization
2. Evaluate for
 - a. How is orientation of staff accomplished
 - b. Who is responsible?
 - c. Do the objectives and content meet specifications?
 - d. How is orientation evaluated?
 - e. How is documentation of orientation achieved?
 - f. Where is the documentation located?
 - g. What is the job description for each provider?
 - h. Where is it located?

- i. Does it meet the expectations?
- j. How is initial competence assessed?
- k. How often is it reevaluated?
- l. What criteria are used?
- m. Who performs the evaluation?
- n. Where is the documentation of the process?
- o. Is health information required?
- p. What information is it?
- q. Who is responsible to see that it's collected?
- r. Where is written evidence of compliance?
- s. Is quality control required?
- t. If so, who is responsible?
- u. How is the information fed into our existing quality process?
- v. How has this contract been approved by the medical staff?
- w. Where is this documented?
- x. How often is the contract reviewed?
- y. Renewed?
- z. What data is used in the evaluation?

Contract Service Performance Improvement Review

Department	Volume Indicators	Risk Indicators	Timeliness Indicators	Patient Satisfaction	Other	Comments

Healthcare organizations enter into contractual relationships for many services, including reimbursement, physician services, acute care services, alternative care services, medical equipment and supplies, and staff. All of these contracts impact the organization and daily functioning of an organization's healthcare quality programs. Healthcare quality professionals should be involved in contract negotiation to ensure consistency with goals of the quality program, and adherence to appropriate standards and regulations.

Members of the negotiating team vary, depending on the type of contract, but would generally include:

- Healthcare quality professionals
- Leadership
- Finance
- Utilization
- Legal
- Health information management
- Specific department/service representatives as appropriate

Members of the negotiating team should review the contract closely, considering the impact of the contract and offering suggestions for necessary changes. Contracts also should be reviewed by impacted departments, services, and individuals responsible for implementing the contract. The team members need enough time to adequately review the contract and address concerns and issues. Input should be sought and obtained from all affected parties. The following should be considered in contract negotiations:

- Timeframes, including effective date, length of contract, and annual review requirement
- Terms of payment, including payment method, deductibles, co-payments, required authorization, collection procedures, outlier payment, and nonpayment appeal procedures
- Confidentiality procedures
- Establishment of ongoing communication, including arbitration and negotiation

- For utilization issues, consider any requirements for review, including approval requirements before service, concurrent review, and retrospective review
- Specific criteria to be used in the review of utilization of services, including definition of appropriate regional norms for length of stay or access to specific level of care as appropriate
- Procedures involved in denial of services as well as appeal rights for the organization and the patient or member
- Requirements for medical peer review of denials during appeals
- Definition of any quality information reporting requirements
- Requirements for quality review protection of quality information that has been reported
- Clarification of intended use of quality information

Organizations want to achieve contractual relationships that are compatible with their work processes and minimize organizational impact. Effective contract review and negotiation are essential to promoting proper reimbursement, timely payment, appropriate use of resources, and customer satisfaction. Each organization should establish and work to continually improve processes for contract review

Internet Resources

Online statistical resources

<http://www.stattrek.com/> online tool; can calculate a variety of statistical procedures, including t-tests, Poisson distributions, and other calculations; includes user-friendly guide
<http://www.statsoft.com/textbook/stathome.html> StatSoft's Electronic Statistics Textbook
<http://www.robertniles.com/stats/> Statistics Every Writer Should Know
<http://www.vassarstats.net/textbook/> Concepts & Applications of Inferential Statistics
<http://www.graphpad.com/www.Book/Choose.htm> Intuitive Biostatistics: Choosing Statistical Tests
<http://www.randomizer.org/> Randomizer (generates random numbers)
<http://www.physics.csbsju.edu/stats/> Statistics to Use

Quality Web Sites

<http://www.patientsafety.va.gov/>
<http://www.cqaimh.org>
<http://www.ahrq.gov>
<http://www.qualitymeasures.ahrq.gov>
<http://www.leapfroggroup.org>
<http://www.brownspace.com>
<http://www.hcahponline.org>
<http://www.nahq.org>
<http://www.nchpad.org/>
<http://webmm.ahrq.gov>
http://www.wrgh.org/egpb_exec.asp
<http://www.vhct.org>
http://www.jointcommission.org/core_measure_sets.aspx

Electronic Medical Databases

<http://www.nci.nih.gov>
<http://hivinsite.ucsf.edu>
<http://www.thebody.com/index.shtml>
<http://docguide.com/dgc.nsf/ge/Unregistered.User.545434?OpenDocument>
<http://www.healthleaders.com>
<http://www.cardiosource.com>
<http://www.acg.gi.org>

<http://ndei.org/website>
<http://www.cdc.gov/DiseasesConditions/>
<http://www.arthritis.org>
<http://www.medscape.com/surgeryhome>
<http://www.quackwatch.org>

Health Related Internet Sites

- <http://adam.com>
- <http://www.ahd.com>
- <http://www.ama-assn.org>
- <http://www.cnn.com/health>
- <http://www.healthcentral.com/>
- <http://familydoctor.org>
- <http://www.healthfinder.gov>
- <http://healthgrades.com>
- <http://hippo.findlaw.com/hippohome.html>
- <http://www.healthleaders.com>
- <http://www.thehealthpages.com/index.html>
- <http://www.hhnmag.com>
- <http://www.ICD10Data.com>
- <http://www.intelihealth.com>
- <http://www.managedcaremag.com>
- <http://www.mayohealth.org>
- <http://www.medscape.com>
- <http://www.modernhealthcare.com>
- <http://www.onhealth.com>
- <http://www.reutershealth.com>
- <http://www.webmd.com>
- <http://www.wellnessjunction.com>

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