A PRACTICE BASED HANDBOOK ON

HEALTHCARE QUALITY

2nd Edition

BY

Professor Assaf F. Al-Assaf MD, MPH        Professor Seval Akgun MD, PhD

2009
Preface

This handbook is a modest presentation of the concept and the techniques of quality assurance and improvement in healthcare. At least one model for the effective implementation of Healthcare Quality (HQ) is presented. Several issues are raised in order to adequately prepare for the introduction and sustainability of HQ in any country as well as internationally. The authors of this handbook are aware of the current challenges facing the healthcare industry and an attempt has also been made in this publication to address some of these challenges and lessons learned from their vast experiences in the healthcare field.

The objective of this publication is to present up to date information on HQ in a practical and concise outlet. Even though it is designed for the physician consumer, any healthcare professional may find the content and information in this publication useful. Another objective of this publication is that professionals, especially physicians, are able to provide active support to HQ and are able to participate in some of the HQ and performance improvement (PI) activities in their organization. In fact, it is the ambition of the authors that this publication is distributed as widely as possible to healthcare professionals, and is “taught” to those aspiring to become “quality professionals”. This handbook has the basic content areas that deal with - what is HQ?, why HQ?, how to organize for and implement HQ?, what will work the most?, how to achieve it? how difficult? and how long will it take to see results? The answers to these questions will become available for the reader after reading this handbook.

This handbook is divided into 11 chapters organized to follow the succession of HQ implemented in healthcare organizations around the world. It is meant to address audiences from different cultural and educational backgrounds with a leaning towards the physician as the primary target. In Chapter One you will find a general overview on HQ concepts, answering the why for improvement, the how to implement it and the supportive mechanisms to sustain it in healthcare organizations. It also contains a few definitions on HQ and what major organizations in the United States refer to quality. Chapter Two is a list and brief description of the main principles of HQ as addressed by a few of the most notable gurus in the field. The principles of manage-
ment as reported by Dr. Edward Deming is presented, similarly those of Dr. Joseph Juran and others from Dr. Philip Crosby are presented. Whether it is Deming’s 14 Management Principles, the Quality Journey or the Absolute of Quality, all are presented and briefly discussed in this publication. Chapter Three describes the ways and models of staffing and organizing for HQ in a healthcare organization. This chapter also includes a description of the quality professional, their job responsibilities, how quality departments are organized and what documentations are needed to run such a department in a healthcare organization. Performance measurements and methods for improvement are also described in this chapter. Included are several documents and forms that may prove useful to health professionals in measuring and improving performance in their organization. Chapter Four is one of the most important chapters. It is devoted to Patient Safety. With the international goals for patient safety making headlines and are major requirements for healthcare organization it is no surprise that this topic is on the top of the agenda of providers and regulators alike. This area is receiving considerable attention worldwide and is deservingly so as about 1 in 10 patients experience medical errors on the international scene. Therefore, the extent and what needs to be done about improving patient safety and how to improve patient safety is described in this chapter. This chapter also describes the process of identifying errors, reporting them and how to prevent them. It has several practical tips for healthcare providers and may find the forms attached very useful in their practice. Chapter Five presents the most common tools and techniques to collect HQ data, measure performance, display outcomes, monitor performance improvement and the ways of improvement of documentation. Chapter Six is a short synopsis on teams and teambuilding in HQ and how to organize and sustain an effective team effort to improve performance in healthcare organizations. Chapter Seven is a combination of several topics related to peer review, credentialing and privileging. These topics are somewhat new in healthcare outside the United States, but are making their way into the healthcare systems of the countries in throughout the world. They are very important from the standpoint of accreditation and accountability and their presence in healthcare facilities will increase in the near future. Therefore, mentioning them will be of importance to the target audience of this publication. Chapter Eight is a description of patient rights issues and how to protect them. It includes such topics as informed consent, confidentiality, end of life and privacy issues. It also discusses other ethical issues in patient care and how to protect patients and employees alike from abuse, over and under utilization. Chapter Nine describes utilization manage-
ment issues while Chapter Ten gives information about accreditation in general, its components, its activities, the agencies and how to prepare for and achieve it by healthcare organizations. A listing with description of the major accreditation agencies is provided. Chapter Eleven outlines the main challenges and lessons learned in implementing, sustaining and institutionalising healthcare quality in organizations. It also presents a model for system-wide organization, administration and improvement. The handbook concludes with a comprehensive listing of all of the references used or could be used in healthcare quality for this publication and beyond.

It is the desire and objectives of the authors to make this publication practical and as simple as possible. It is meant to provide the reader a quick reference to the main issues and headings related to healthcare quality and the methods on how to implement it in their organization. It is our hope that it makes an enjoyable and beneficial publication.

Seval Akgun  
A. Al-Assaf
List of Contributors

**Dr. Assaf F. Al-Assaf MD, MPH**
Professor and Associate Dean for International Health
Co-Director, Executive Healthcare Training Academy
College of Public Health
University of Oklahoma Health Sciences Center
801 NE 13th Street
Oklahoma City, OK 73104
405-271-2115 ext 1
405-271-1868 FAX
ala@ou.edu

**Dr. Seval Akgun, MD, PhD**
Professor of Public Health, Chief Quality Officer
Baskent University Hospitals Network
Baskent University School of Medicine
Director, Public Health Dept. Ankara, TURKEY
Adjunct Professor
The University of Oklahoma Health Sciences Center
College Of Public Health, LLC, Oklahoma, USA
sevalak2007@gmail.com

**Priscilla A. Pierce, RN, CHQ**
Senior Consultant
Deaconess Hospital
Oklahoma City, OK
priscilla.pierce@deaconessokc.org
Dr. Stephen L. Walston
Associate Professor and Co-Director
Executive Healthcare Training Academy
Department of Health Administration and Policy
University of Oklahoma Health Sciences Center
USA
stephen-walston@ouhsc.edu

Ali Ray Assaf, Lt JG, USN, MSC
Head, Patient Services Administration Department,
Naval Hospital, camp Pendleton, California.
Ali.r.assaf@gmail.com

Atilla Akova MD
Medical Chief Officer
Adana Numune State Hospital
Adana, Turkey
atakova@superonline.com

Diana K. Pistole, RN, MPH
Chief of Nursing
Oklahoma State Department of Health
Oklahoma City, OK
TABLE OF CONTENTS

List of Contributors
Forward
Preface
Dedication and Acknowledgements

Chapter One
Overview on Healthcare Quality
- Definitions
- Why quality?
- Perspectives and Dimensions of Quality

Chapter Two
Healthcare Quality Principles
- Edward Deming’s Principles
  - Principles of Quality Assurance and Improvement
  - Deming’s 14 Management Principles
- Joseph Juran’s Trilogy
- Universal Process for Quality Improvement
- Philip Crosby’s Absolutes
- Crosby’s Management Points
- Donald Berwick’s Principles
- Key success factors in quality improvement

Chapter Three
Building an Infrastructure for Healthcare Quality
- Quality Management Cycle
- Management Commitment
- Allocation of Resources
Increasing Awareness on Health Care Quality
Quality/PI Program Document
Re-assessment, Evaluation, Monitoring and CQI
Quality Program Evaluation
References

Chapter Four
Patient Safety
Introduction and Background
Role of Leadership
Goals and Practices
The Patient Safety Officer
Occurrence Reporting
Addressing Patient safety Issues
Regulators Role in Patient Safety

Chapter Five
Healthcare Quality Tools
Introduction
The Transformation of Data to Information
  Data versus Information
  Data Reliability
  Data Validity
  Sensitivity and Specificity
Data Collection and Display
  Tools for Identifying, Collecting and displaying data
Surveys
  Objectives
  Sample
  Sample size
✓ Brainstorming
✓ Brain-writing
✓ Logs
✓ Check sheets
✓ Pie Charts
✓ Scatter Diagram
✓ Histogram
  o Tools for Quality Improvement and Monitoring
✓ Nominal Group Technique
✓ Multiple Voting Technique
✓ Weighted Voting Technique
✓ Rank Ordering Technique
✓ Balanced Sheets or Force-Field Diagram
✓ Trend and Run Charts
✓ Flowcharts
✓ Pareto Diagram
✓ Control Charts
✓ Cause and Effect Diagram
✓ Decision-making Matrix
✓ Documentation
✓ Conclusion
✓ References

Chapter Six
Teams and Teambuilding

Chapter Seven
Credentialing, Privileging and Peer Review
✓ Credentialing
✓ Privileging
Chapter Eight

Ethical Issues Impacting HQ

- Introduction
- Patient Privacy
- Informed Consent
- Communication, Education and Cultural Needs
- Complaints and Grievances
- End of Life
- References

Chapter Nine

Utilization Management

Terminology
Methodology
Prospective Review:
Concurrent Review:
Retrospective Review
Case Management
Unit-based Case Management model
Comparative Case Studies
Measurements:
Discharge planning;
Chapter Ten

Accreditation

✓ Certification and licensure
✓ What is accreditation?
✓ Historical perspectives and trends on accreditation
✓ Why accreditation?
✓ The benefits
✓ Components of accreditation
  o Administration
  o Education and communication
  o Standards
  o Surveying
  o The core standards
✓ HEDIS
✓ Joint Commission International
✓ International Organization for Standardization (ISO)
✓ The accreditation process
✓ Conclusions
✓ References

Chapter Eleven

Challenges and Lessons Learned

✓ Lessons in Institutionalization
✓ A proposal for a change and recommendations
  o For countries
  o For international organizations
  o For short-term consultants

List of References
CHAPTER ONE
Quality Overview: Definitions, perspectives and
references

A. F. Al-Assaf, MD, MPH  Seval Akgun, MD, PhD

The definition of a quality process: The continual, pro-active effort that begins by determining your customer’s expectations and comparing them to your specifications. If they don’t match, you must do something: either adjusts the specifications to match the expectations, educate the expectations to match the specifications, or (most common) a combination. Once the expectations and specifications match, it is time to begin the cycle again.

Akgun and Al-Assaf

“Quality is the result of a carefully constructed culture; it has to be the fabric of the organization—not part of the fabric, but the actual fabric. It is not hard for a modern management team to produce quality if they are willing to learn how to change and implement.”

Philip B. Crosby

“We can’t always cure patients; we can’t always correct the problems that brought them to our doors. But we can and always should care for the whole person. Caring will be as important as curing in the overall ‘healing environment’ that will characterize the healthcare system of the future. Remarkably enough, there’s nothing at all new about this need.”

Ron J. Anderson, M.D.

So what is quality? Is it excellence? Is it the best? Is it the “Cadillac” service?

Not necessarily! Quality can be a simple measure to achieve desired objectives in the most efficient and effective manner with the emphasis on satisfying the customer or the consumer. It is not necessarily the most expensive
way to do things. On the contrary, it is a call for efficiency and cost savings. It is not necessarily luxurious items or services. It is however a product or a service that is acceptable, accessible, efficient, effective and safe that is continuously evaluated and upgraded.

Quality is often thought of as ‘goodness’ or ‘expensive’ or ‘luxurious’ and products such as a Rolls Royce, champagne or caviar as being of high quality.

A more useful definition of Quality is ‘fitness for purpose’. A Rolls Royce and Volkswagen can be both be fit for the purpose of their owners. The implication of this is that Quality is defined by the customer of the product or service, not the producer or supplier. However, every organization has to decide what it will choose to provide. And so “Quality is meeting agreed customer expectations.”

Quality is also measurable. A system is usually made up of three components; inputs, processes & outputs. Quality of inputs (structure) can be measured. This includes the quality of personnel, supplies, equipment, and physical resources. The quality process is also measurable. Diagnostic, therapeutic, and patient care procedures and protocols are all measurable and quantifiable. The same is true for system outcomes or results. They too are measurable, for example, infection rates, morbidity & mortality rates, as well as patient & employee satisfaction are all outcome measures and are all measurable variables. Therefore, the system components of inputs, processes and outcomes have certain quality characteristics that are measurable and are important in quantifying quality of a system.

Quality: Simple but Difficult

Perhaps the problem in understanding what is involved in the launching of a quality process lies in some very basic vocabulary. Consider two pairs of words:

Simple vs. Complex

and

Difficult vs. Easy
A Quality Process, correctly defined and implemented, is not complex. It is, in fact, little more than formalized common sense, some basic math, and a dash of good manners. However, it is not easy to do, particularly at the outset. There is much to be done and all pretty much at the same time. So a Quality Process is simple but difficult.

A second point that has hampered many quality efforts is the failure by senior management to trust their own employees enough to simply begin the effort at the 100% employee involvement level. The key to starting out on the right foot is to ask the right question. The well-beaten path to travel is to ask “Who can we make responsible for quality?” or “Who should we involve in this effort?”. In either case, the result is a thoroughly enjoyable assessment of every department and individual in the institute, sorting through the lists looking for those deemed worthy – or not too busy – to take part in the improvement effort. Normally, that is approximately 10-15% of the total employee base. Often, there is a vague statement about the intent to involve more employees at an as-yet-undetermined date.

Making the decision to make 100% employee involvement an integral part of a quality process is a giant step toward establishing a corporate culture in which continual improvement is the norm. Everyone knows something about the workplace that nobody else knows. By assuring every person on the payroll is enrolled in the effort to improve, the odds increase greatly that a person with an idea – big, small, or only partial – will tell someone else because the person with the idea knows as a matter of simple fact that the person to whom he or she is talking is also engaged in the continual improvement of the organization.

Also, 100% employee involvement raises the odds that groups of people with partial ideas will encounter the folks with the missing parts of their ideas. In other words, the chances of achieving a “critical mass” of knowledge are far better because some of the people may be holding their piece of the puzzle unknowingly – unaware that if their knowledge is teamed with that of one or more other employees, a major breakthrough can be defined.
100% of 100%

An aspect of quality that is not as frequently addressed is the need to not only involves 100% of the people on the payroll in the quality process but to also make every effort to involve 100% of the talents of each person on the payroll. The normal sequence is that a department in an organization defines a need for Skill A and, working with the Personnel (or Human Resources) department, locates and hires someone with Skill A. The new employee is then put to work, using Skill A. What is too often overlooked is the fact that the new employee also has Skills C, K, M, N, and W and he or she brings those skills to work every day, regardless of whether or not the skills are going to be used. One of the methods for increasing the numerator without increasing the denominator (in the outputs-divided-by-resources fraction presented earlier) is discovering what talent is already on the payroll and finding ways to use it.

Another issue related to the topic of quality involves communications and sharing of information. The world is certainly becoming smaller through the advances in communications technologies and transportation linkages. Therefore, advances and accomplishments of health care quality in one part of the country must be communicated with other parts. Sharing of ideas and learning from one another is an attribute of quality as well. Furthermore, quality in health care and services are no longer being judged solely on a local or even on a regional level, but it is becoming increasingly important for organizations to compete in these areas on a national level.

Therefore, to define quality one may refers to several definitions that present the concept most eloquently. Here is a list of some of these definitions:

“Quality is conformance to requirements or specification.”

Philip Crosby 1978

“Quality is doing the right thing right, the first time and doing it better the next.”
Al-Assaf, 1993

“Quality is the degree to which care services influence the probability of optimal patient outcomes.”

American Medical Association, 1991

“Quality is meeting the requirements of the customer; both internally and externally, for defect-free products and services.”

IBM, 1982

“Quality is providing our customers with innovative products and services that fully satisfy their requirements.”

Xerox, 1983

Quality, therefore, is a process of meeting the needs and expectations of the customers both internal and external. Quality can also be referred to a continuous process of incremental improvement.

Meeting the needs, not the wants, of the customer is emphasized. Certainly, the issue of affordability and available resources should be taken into consideration. Also, one should study the needs and expectations of both types of customers external and internal. Staff and employees are internal customers to the administration and their needs and expectations should be known and studied and every effort should be made to meet them.

Primarily the patients represent the external customers, but other entities that the organization in question deals with should also be investigated and studied to identify and meet their needs and expectations. Thus, quality has many perspectives where each customer has specific needs and expectations to be fulfilled by the provider organization.

One may conclude that quality is never an accident. It is always the result of
high intention, sincere effort, intelligent direction and skillful execution. It represents the wise choice of many alternatives.

Now, that quality has been defined, what is the difference between quality assurance (QA), quality improvement (QI), monitoring/quality control (QC), and total quality management (TQM)?

To enable comparison of health care to other enterprises it is important to use the general vocabulary of quality management produced by ISO. Quality management focuses on the customer. The patient is expecting to receive good quality care. The definition of quality (ISO 8402) is:

‘Totality of characteristics of an entity (product or service) that have an influence on its ability to satisfy stated or implicit needs’,

A quality is a characteristic. A system is a set of interrelated processes, and a requirement is an obligation. Therefore, a quality system requirement is a characteristic that a process must have.

A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, and product requirements.

**Quality management**: All activities of the overall management function that determine the quality policy, objectives and the responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

**Total quality management**: Management approach of an organization centered on quality, based on the participation of all members of an organization and aiming at long-term success through customer satisfaction and benefits to all members of the organization and to society.

**Total quality management** is a concept used to describe the totality of management techniques and strategies.
Total quality management (TOM) is a management method which emphasizes quality and is based on the participation of all the members of the organization. Its long-term objectives include success brought about by customer satisfaction, which will also result in benefit to members of the organization and to society in general (ISO 8402, EFOM).

**Quality system:** Organizational structure, procedures, processes and resources needed to implement quality management.

Other related concepts include quality assurance, quality policy, quality system, quality manual, and quality auditing. The use of uniform concepts makes it possible to use a common language and to achieve a common understanding about quality in and between organizations both nationally and internationally.

According to The Quality Management Cycle (below) each of these activities has certain steps to be followed in order to achieve the desired objectives. QA is the process of assuring compliance to specifications, requirements, or standards and implementing methods for conformance. It includes setting and communicating standards and identifying indicators for performance monitoring and compliance to standards. These standards can come in different forms, for example protocols, guidelines, specifications, etc. QA however is loosing its earlier popularity as it resolves to disciplinary means for standards compliance and therefore blames human error for non-compliance. QC on the other hand is defined by NAHQ (1994) as “a management process where actual performance is measured against expected performance, and actions are taken on the difference.” QC was originally used in the laboratory where accuracy of test results dictates certain norms and specific (and often) rigid procedures that would not allow for error and discrepancy. Thus, it makes an effort to reduce variations as much as possible. QA and QC are complimented and sometimes overwhelmed by QI efforts and processes. QI is defined as an organized, structured process that selectively identifies improvement teams to achieve improvements in products or services. Therefore, TQM or quality management in general involves all above three processes QA, QC, QI. It
involves processes related to the coordination of activities related to all or any one of the above three as well as the administration and resources allocation of these processes. Quality management becomes the umbrella under which all processes and activities related to quality falls. QM may also encompass such terms as continuous quality management, total quality management/leadership/improvement.

Why Quality?

Consider the following reasons for pursuing quality in health care organizations.

1. Requirement to define and meet patient needs and expectations.
2. Increased demands for effective and appropriate care
3. A forum for measuring performance
4. Standardization and variance control
5. Necessity for cost saving measures.
6. Benchmarking
7. Report cards on provider performance
8. Accreditation, certifications, and regulation.
9. Need for improvements in care and services.
10. Enhances positive competition
12. Ethical considerations.

Let’s discuss each of the above reasons for making quality an important process to adopt by a country and by organizations to seek.

**Patients and other customers of health care**

Health care consumers are becoming increasingly aware of the different requirements a health care organization must meet in order to be considered a “quality” organization. They are also becoming interested in learning about the status of care provided by this organization judged by their peers or professional experts. Therefore, quality processes provide just the answers and the assurances that health consumers are asking for. Quality provides for a mechanism for an objective, unbiased peer review of a health organization. It provides the consumer a set of measures they can judge health care organization in comparison with similar organizations. Quality also provides the consumer a level of comfort insuring that this health care organization has been checked and is considered a quality organization since it has passed a rigorous set of evaluation processes. Therefore, meeting the needs and expectations of the customer is a requirement for quality and it is the reason why we must have quality in health care whether private or public.

Other reasons mentioned above such as effectiveness, appropriateness, and efficiency are basic elements of a quality system and quality care (Nicholas et
You cannot provide any care without regards to available resources. It is true that we all would like to provide, and receive, the best care there is, but it is prudent to do that within the limits of current resources. Actually, if this is not taken into consideration then quality is not achieved. Quality requires efficiency in the use of health care resources and effectiveness in the delivery of care and service.

Standards are the language for what we consider quality to be. They are statements of the quality of structures, processes and the desired outcomes for health care organizations. Standards are developed to be as quantifiable as possible. These standards follow the various functions and units health care organizations perform and possess. Several standards are developed and are updated annually by a group of experts that are related directly to the process of care and to the structure of services rendered by the health care organization. These standards are therefore developed to measure the performance of the health care organization in the aspects of care and services it claims to provide. Compliance to these standards is a proxy measure of the performance of such an organization. Standardization is an effective process of not only assessing performance but also to control and predict outcome. Controlling outcomes is important in order to effectively allocating resources and to effectively budgeting for programs. Standardization therefore is important to improve efficiency and effectiveness of an organization.

Benchmarking and report card capabilities are two of the reasons why health care organizations should seek quality assurance and improvement. These are also reasons why quality should be implemented in order for organizations to be compared with one another based on the findings of assessment activities. Benchmarking is a process of identifying the best process, activity or outcome and to find ways to study them and emulate them in one’s own setting. Through quality assurance and improvement, health care organizations are encouraged to look for the best processes of other organizations in order to study these processes and learn about performing them so that they can be imported and implemented in that organization. Similarly one of the reasons for QA/I is to list on the health care organization’s report card (outcome measures) that they are a “quality” organization. A report card that
The understanding and commitment to quality improvement in health care organizations is crucial. When a report card or assessment does not have quality measures listed on it, it is not considered complete or credible. Therefore, organizations must seek, sustain, and institutionalize quality in order to market their report card.

According to the Quality Cycle shown above, steps 5 through 10 emphasize quality improvement. Improvements are based on the outcome of assessment and monitoring of compliance to certain standards. External customers respond positively to those organizations that demonstrate their experience in “closing the loop” from the identification and analyses of improvement opportunities to selection and implementation of actual improvements and then maintaining their sustainability. Therefore, quality will stimulate improvement efforts in health care organizations and will bring these organizations to a higher level of accountability.

One of the activities of quality is accreditation. Accreditation provides a mechanism for the comparison between health care organizations. Those organizations that have achieved accreditation, especially the “commendation” or “excellent” status accreditation, will have a positive image and will use that distinction to market their services accordingly. Accreditation would therefore be used in such a condition as a tool for positive marketing and as a tool that enhances positive competition between different health care organizations. Receiving accreditation is equivalent to receiving the “seal of approval” on the quality of one’s own organization. This recognition certificate is usually worthy of announcement and heavy marketing to promote it. It is both rewarding and beneficial to the organization and its employees. Attaining accreditation could also be used as the mechanism for rewarding individuals who have worked hard in order for the organization to achieve it. It is also a method of recognition among peer organizations and a proof of quality for that organization.

Competition could be based on price or could be based on non-price. Competition based on quality as exemplified by the attainment of accreditation is a form of non-price competition and is a form of positive competition. This type of competition is in contrast with the type of competition exhibited by
and between political candidates where they each try to find weaknesses in each other performance or character to attack. Positive competition on the other hand encourages benchmarking and identifying the positive attributes of your competitor in order for you to achieve even a better level of these attributes in your organization. It is a process of continuous search for excellence and a mechanism for emulating that excellence in ones own systems. Quality in general facilitates this process and encourages it.

As noted above, quality is a desired entity by all health care providers. As number 12 suggests, it is the fabric of the very existence of the health care professions. Ethics dictate that one must provide the best and most appropriate care accessible to the patient. It is the basis of the humanistic aspect of the health care field. It is our duty as health care professionals and because of that we must provide quality care and service to fulfill this ethical code.

Baseline Truths about Quality
There are certain baseline truths about quality that need to be enumerated and agreed upon in order to better position Quality management as a useful tool. These are:

Quality is not going to go away. This is not a trend or a fad that can be waited out. There has been a fundamental shift of power in the triad consisting of owners/managers, workers, and customers. Keep in mind, of course, that most people fill at least two of these roles at some point in their lives – and, often, simultaneously. For the first several thousand years of commercial operations, the owners/managers had a virtual monopoly on power in the marketplace. They decided what would be made, how well it would be made, where it would be made and sold, what employees would be paid for making it, and how much to charge for it. De facto monopolies were the norm. If workers and/or customers didn’t like the arrangement and were legally free to move, the cost of transportation, cultural habits and frequent wars combined to prevent all but the very brave from leaving their jobs and homes. In the late 19th century, workers managed to wrest some of the power away from the owners/managers thanks to efforts that resulted in everything
from labor unions to Communism. For the next several decades, the workers were junior partners in the decisions that drove the marketplace, even if they still had virtually no power as customers and, in fact, some of the changes they forced adversely impacted the customers. When the price of transportation finally dropped to the point at which Japanese companies could ship automobiles all the way across the Pacific Ocean and still sell them for less than American-made cars – and the Japanese cars didn’t require nearly as much post-purchase maintenance – the power began to shift towards the customers. Options make for powerful customers and well-informed customers have always been the most influential friends that a quality movement can have. In the past few decades, the emergence of the Internet has accelerated the power shift and made service industries subject to the same fundamental changes in relationships that manufacturing companies have been forced to struggle with. Customers now hold the power simply because they have choices. And they know it. And more and more customers each day are comfortable exercising those options. Quality is not going away because customers won’t let it. In addition, customers will punish organizations that do not measure up, both in the marketplace and in the stock market. The same situation also is also going on in health care. Today in healthcare, gone are the days of the quite and compliant patient who dared not speak, much less challenge the care providers. Today’s judgments and discriminations are about quality of care. Yesterday healthcare was a seller’s market. Today it is a buyer’s market and will continue to be so in future with the competition getting intensified. Healthcare customers easily discriminate between the way they are treated medically and treated personally.

✓ **Quality is both rational and emotional.** Attempts to treat quality as strictly rational will most likely fade as the current generation of senior managers fade away themselves. Those people who Tom Peters once dubbed WOMs (“White Older Males”) were taught while growing up that the business world was a rational place. Emotions, they came to understand, were something to use at home and, even there, they were optional. The growing consensus now is that emotions do play a role in the workplace, that organizations that wish to get ahead must deal with the fact that they have humans on their payrolls and
that humans are marvelous mixtures of rational and emotional characteristics. Jim Kouzes, co-author of *The Leadership Challenge* makes the point that “Emotional intelligence plus requisite experience has more value than IQ plus requisite experience.” Not surprisingly, it isn’t easy. Jack Welsh, legendary leader of GE, has been quoted as saying, “The hard side of quality is the soft side.” It would be easier if everyone functioned and reacted in the same identical, predictable, rational way but that simply isn’t the way the world operates. Or, at least it isn’t the way the world operates when people are free to move or to just quit whenever they choose.

✓ **Quality includes both incremental improvements and breakthrough improvements.** Done correctly, a quality process can include ISO 9000 (to fulfill a customer requirement, for instance) and reengineering (to re-think and re-design obsolete work processes) or any accreditation in health care such as JCI or CCHSA. But these efforts need to be done in context. ISO 9000, reengineering, and other sure-fire “laser focus” programs are the subsets. As mentioned at the outset, many of the “quality failures” over the last few decades came about when organizations tried to do just part of a Continuous Improvement process rather than tackle the whole thing at once. Various forms of measurement such as SPC (Statistical Process Control), Benchmarking (born from publicity following Xerox’s first Baldrige Award in 1990) and Six Sigma (born from publicity following Motorola’s 1988 Baldrige Award) plus concepts such as reengineering, thinking organizations and breakthrough thinking have each been presented at THE answer. These efforts represented attempts to convince organizations (or, at least, the folks holding the organizational purse-strings), that they didn’t have to do the whole quality thing (which would include trusting people and all that sort of threatening stuff), they had only to do the one piece – of which they could retain tight control. The disappointing results (often after some notable initial success) were predictable,

✓ **Service to external customers will only rarely exceed service to internal customers.** A blunter way of saying this is, “Nobody gives
better than they get.” It is no coincidence that every one of the Malcolm Baldrige National Quality Award winners speaks at length about the need to listen to and support their own employees. Ritz-Carlton, the luxury hotel chain whose 1999 Baldrige was its second one, has as its #1 corporate objective: “Improve the Pride and Joy and Satisfaction of All Employees.” Employees who are treated badly inside an organization should not be expected to then turn around and treat an “external” customer with grace and good will. The few people who will consistently give better service than they themselves receive are called “saints.” It is for this reason that I recommend the following as a definition of “customer”: “Anyone to whom you provide service, product or information.” No differentiation between “internal” or “external” customers; no specification if the “you” means a single person, a unit, or an entire organization.

✔ **It shouldn’t take forever to define and implement a quality process.** From the time (August 2, 1939) that Albert Einstein wrote a charmingly casual letter to President Franklin D. Roosevelt to alert him to “some recent work by E. Fermi and L. Szilard” that had the potential of being developed into “extremely powerful bombs of a new type” that could “very well destroy” a “whole port together with some of the surrounding territory” until the time a nuclear device was dropped on Hiroshima (August 6, 1945) was only six years. And that was nuclear science – with no precedents to emulate. Defining and implementing a quality process is not nuclear science and there are successful models to follow. Even if the number of models of Continuous Quality Processes is not yet high, there are numerous examples of successful instances of each of the individual components. Surely this can be done in less than one-sixth the time it took to go from Einstein’s alert to full implementation.

✔ **Every quality process will be unique.** This makes it more difficult since a process that has been successful for one organization can not
simply be superimposed on another. The principles can be adopted; the techniques must be adapted to fit a specific organization’s customer base plus its own culture and capabilities.

✓ Quality is not something that is done in addition to “real work;” it is how real work is done. In far too many organizations, quality has been introduced – or thought of – as one more task on top of all the others. Such an attitude, whether specifically introduced from the top of the corporate ladder or allowed to grow from the bottom up, cripples a quality process from the outset since it allows everyone to think of “quality” as an extracurricular activity and, thus, one that can be pushed aside. Quality must be understood to be an integral piece of how everyone’s job is done. Yes, there will be time set aside that is labeled “quality meeting time” (or some other title with the word “quality” included) but that must be presented and understood as time set aside for reflection about the job, a chance to think about how to change, to improve. Without a structured time to reflect, the chances that there will be any sort of revolution of thought diminishes significantly.

✓ Quality is best suited for a company “in the black,” a health care institute that is good and wants to be great. If a health care institute is in financial trouble, there are most likely so many issues at play that adding a quality process probably won’t help much. Oftentimes, an institute is in trouble because of a truly bloated payroll and making staff reductions is necessary for survival. That sort of obvious stuff needs to be done before the word/concept “quality” is introduced and then unfairly assumed by the employees to be the cause of their friends being fired. Once the ship has been steadied a bit – and everybody’s attention has been gotten – then quality can be carefully introduced as a way to insure that the company never gets into that sort of trouble again.

✓ More than one thing can be pursued at a time. The motivational poster declaration (under the picture of a regal-looking bald eagle)
that “If you pursue two rabbits at once, both will escape” is doubtless true for birds chasing bunnies. Humans, however, are more talented. Especially when their prey can’t hop off to the side at the last moment. The insistence by many quality approaches that only one activity can be pursued at a time, much like the too-frequent assertion that all problem-solving steps must be followed in strict sequence for every problem of any size, is counter-intuitive. In their personal lives, managers and non-managers alike always function “in multi-task mode.” If the ability to do more than one thing at a time were taken away from the human race, life would grind to a halt. To assume that humans, skilled through years of experience at keeping several things going at once, somehow lose those skills when they walk in to work in the morning is insulting.

**Perspectives and Dimensions of Quality**

Quality is a process of meeting the needs and expectation of the customer, both external and internal. Quality has many perspectives, where each customer has specific needs and expectations that should be fulfilled by the provider organization. Primarily the patients represent the external customers. The internal customers, on the other hand are the employees. Each of which has special needs and expectations and it is the obligated duty of health care organizations to identify these needs and expectations and implement mechanism for meeting them.

Health care quality has several attributes and dimensions. Data collected from several national and international surveys of consumers and providers of quality describe these dimensions as follows and in this sequence:

- Effectiveness
- Efficiency
- Technical Competence
- Safety
As seen from the above list, both effectiveness and efficiency came at the top of the list stressing the fact that quality can only be achieved if processes are performed appropriately and in a cost conscious environment (Binns, 1991; Jensen, 1991).

**Effectiveness** (*doing the right things*) - delivering agreed outputs (products and services)

**Efficiency** (*doing things right*) - managing the way that those outputs are delivered.

The overriding aim for both is to be right first time. The improvement of quality could be done by applying the principles and practices of Quality Improvement. Quality Improvement is now a mature business development strategy which is being actively pursued throughout every sector of the global economy. The common theme is to build profitable enterprises by satisfying the customer, with each seeking to do so in a unique way and thus to be different from and beat the competition.

Within this context, only appropriate and necessary care should be provided. Waste, duplication and re-work should be eliminated. Only most economical ways and most effective ways to provide care should be stressed. In a system of higher demands for quality care coupled with the reality of limited resources, prudent decisions regarding best possible combinations of effective and efficient care are required and expected.

Obviously, providing effective care in an efficient manner requires highly technical skills of health care professionals that would follow the practice of
doing the right thing right the first time and doing it better the next. In health care quality, providers and other health care professionals must be well educated and well trained to face the everyday challenges of meeting the needs and expectations of their customers, in particular their patients. Health care is a complex field and without good technical background the chance of a professional survival is weak. Quality must be associated with highly technical capabilities and competencies.

In regards to safety it is again obvious that no one should accept providing or receiving care in an environment that is unsafe or may be perceived as unsafe. From a risk management standpoint it is the duty of the health professional to secure a safe environment for his/her patient. Accidents have several consequences, all of which are negative. Unsafe conditions may lead to liability, physical and emotional injury, as well as lose of goodwill and is a detriment on the facility’s reputation in the community. Apart from that, an unsafe environment is counterproductive, as people will spend their time answering to complaints and fending lawsuits. Safety is expected and is a required dimension of quality and especially in health care.

Another important dimension of quality is accessibility. Accessible care is care that is available, acceptable, and affordable. Accessibility includes physical, financial, and intellectual accessibility. The later is extremely important in an environment where there are multiplicities of cultures, beliefs, and educational background as it is the case with the international health care community. Quality care needs to be communicated to the “users” in their own setting and under their own conditions to be truly accessible. Therefore, good communication skills are essential to providing accessible care.

Of course in a system that strives for quality other dimension must be fulfilled. Personnel interaction is important to providing quality care. Highly educated and sophistically skilled individuals provide health care, but these individuals cannot provide a holistic care to the patient without relying on teamwork. Interpersonal relationships therefore, play a tremendous role in shaping the processes of care and ensuring a positive outcome to the patient.
Think of a scenario where a highly specialized hospital with all the gadgets and whistles of technology and technical competence of its staff but without real care teams. Each provider is working on his own without regards to others in the system. No coordination of activities and no collaboration between providers. Probably total chaos! How would the care be delivered then? It would almost be impossible to deliver any care let alone quality care. Such an environment is not conducive of quality processes and this hospital is doomed to failure. Effective teamwork is a must for health care quality.

Health care quality is a process not a program. A program has a beginning and an end but a process has no end. It is continuous. Another issue in regards to quality is that care should be provided in a continuum. That is to say care should be initiated, rendered, evaluated, improved, and continuously monitored even after the patient is cured of his present illness. Care is extended to include wellness, health promotion and disease prevention. Additionally, care that is started by one provider should be continued and followed by the other provider in cases of transfer to ensure continuity of care. Fragmented care and a disjoined system are not a quality system. Health care quality may never be achieved in such a system.

Finally, it is always more pleasant to have the care provided in an esthetically acceptable environment. A facility that pays attention to the minute details of its customers’ comfort and well-being is certainly a quality facility. Whether it is cleanliness, decor, or service, health care quality can only be enhanced with such a valuable dimension.

THE SEVEN FUNDAMENTALS OF QUALITY IMPROVEMENT

The Seven Fundamentals of Quality Improvement are based on the ’Baldrige Criteria’, used widely particularly in America.

1. Leadership - Quality Improvement cannot begin unless the environment exists for changes to happen. Leadership from the top carried throughout the organization, can crate the environment or culture for
improvement within an organization.

2. Act on Facts - Quality Improvement involves the collection and analysis of data to bring about change: to act on facts, not on hunch, opinion, or guesswork.

3. Planning - Planning is a key aspect of Quality Improvement, because Quality Improvement will not happen unless it is planned at corporate level.

4. Teamwork and Empowerment of People - Quality organizations recognize that the people who are actually doing the job are best placed to know what is happening and how best to achieve the desired performance improvements. This understanding leads directly to the conclusion that all staff must have the confidence, knowledge and skills necessary to translate this potential into action. Empowerment is based on devolving authority based on knowledge, skill and training to the person best placed to deliver Quality to the customer.

5. Quality Assurance - We can plan for Quality Improvement but we need a system of procedures and controls so that everyone knows what to do and how their work relates to that of other people. These systems of procedures and controls are assessed by standards such as ISO 9000 and BS 5750.

6. Quality Results - We need to make sure that our Quality Improvement efforts deliver the results we want, so that we get a pay-off for the investment of time and money that we have made in Quality Improvement.

7. Customer Focus - The ability to provide products and services which meet the expectations of customers is based on our understanding and anticipation of their requirements. Only when everyone in the business understands what the customer wants and how they, as individuals, contribute to achieving customer satisfaction can the organization expect to attain the overall level of Quality performance demanded. The idea of internal customers and suppliers is used to emphasize that to satisfy the final customer everyone inside the business has customers they must satisfy.
REFERENCES

6. “Health Literacy” by the IOM; http://www.nap.edu/books/0309091179/html 
7. “Improving Health Professions Education”, by the IOM; http://www.nap.edu/books/0309087236/html/ 


47. Sawyer-Richards, M “Innovations and Excellence”, Journal of Nursing Quality Assurance,


CHAPTER TWO
Healthcare Quality Principles

Seval Akgun, MD, PhD   A. F. Al-Assaf, MD, MPH

The basic objective of all organizations that provide a product or service of any sort is to maximize the value of this fraction:

\[
\frac{\text{OUTPUTS}}{\text{RESOURCES}}
\]

The more outputs per unit of resources, the better.

As any child who has made it through the first few classes on fractions can attest, there are two ways to increase the value of a fraction: increase the value of the numerator (e.g., change 3/2 to 4/2) or decrease the value of the denominator (e.g., change 6/3 to 6/2).

Unfortunately, in far too many cases, when an organization decides it needs to improve, they choose the “decrease the denominator” option. Productivity programs, reengineering efforts, and various other approaches push for reducing resources, starting with people, while hoping to maintain the same level of output. The (usually unspoken, at least in public) question seems to be, “How many people can we fire and still hit our minimums?

A well-defined and well-implemented quality process takes the opposite approach by being intent on increasing the numerator. This approach consists of asking, “With these resources we have, how much more can we do? If we can find ways to take full advantage of all of the talent already in the organization, how much can we do? What is our maximum?”
It is precisely that sort of thinking – reaching for the maximum possible rather than trying to insure not falling below the minimum allowable – that is the ticket to long-term success.

Once the process was an unquestioned success and there was time to sit back and look at it, the question, “Why did that work so well?” led to thinking and theory and, in turn, made it possible to describe the process in a way that makes it a useful starting place for others.

Reasons to Pursue Quality

There are four basic reasons for taking on the expense – in time, money and energy – of initiating a quality process:

1. **It makes a lot of money or, in the case of not-for-profit or governmental agencies, conserves a lot of resources.** The growing piles of case studies in the U.S. and in every industrialized country on the connection between quality and profit are now so high that for a business person in the 21st century to not know that quality makes money requires an act of intentional stupidity. Done anywhere near well, a quality process leads quickly to the reduction of waste and, perhaps not as quickly, to an increase in sales. There is less money leaking out and more coming in. That’s called profit.

2. **It results in loyal customers.** More than surprised or delighted customers whose feelings about the organization may be very positive but temporary, loyal customers stick around. They co-produce with an organization, helping to define new products or services, for instance. They will also bring their friends around and they will forgive an organization up to a certain point. Perhaps best of all, they’ll make repeated purchases.

3. **It results in loyal employees.** A consistent trait of successful quality-driven companies is their low employee turnover rates. When the
Ames Rubber Company began their quality efforts at the urging of a major customer, Baldrige-winning Xerox, their turnover rate was 100%. A few years later, in 1993, when they won their own Baldrige, their turnover rate was 0%. Five years after Paul Revere began their quality efforts, their turnover rate was one-half the industry average – and that was without figuring in the 100 employees who had left the company to work for other employers and had then, upon discovering that they were no longer being treated as thinking, contributing adults, “came home.” A steady employee base allows the organization to spend its training dollars on advanced classes, truly enhancing the skills of its members – rather than on repeated orientation and basic skills classes. Loyal employees will work with an organization (rather than merely working “for” the company), they will contribute ideas for improvement, they will forgive the company to a certain point, and they will be marvelous ambassadors for the organization.

If none of the first three reasons is sufficient to convince a senior management team of the wisdom and/or necessity of pursuing quality, there is a fourth reason.

4. **Quality is the ethical option.** A quality process makes it possible for an organization to do what it promised its customers and employees that it would.

The Quality Cycle shows the steps of implementing quality in a Health Care Organization. This cycle is based on an adapted Juran trilogy. Dr. Juran describes quality activities to be made up of three main components and activities -- quality planning or design, quality control and quality improvement. Therefore, this cycle has three main sections; quality assurance involves steps 1-3, quality control involves steps 4 and 5, while quality improvement involves the rest steps. Additionally, quality management is considered the umbrella term for all of the steps in the cycle, which includes the coordination and facilitation processes to achieve a high level of quality in an organization.
Edward Deming’s Principles:

Principles of Quality Assurance and Improvement

Several principles come to mind when one thinks of total quality. Total quality as mentioned above involves processes of QA, QC, and QI. All of these three concepts combined produce yet another fairly new concept called TQM, quality management or Total Quality.

It was described by several experts or guru’s of quality namely, Taylor, Shewhart, Dodge, and Roemig as early as late 1800 through the 1920s. All these experts discussed the theories of “Scientific Management” where quality, as well as quantity, is taken into consideration when dealing with management issues. They all introduced new methods of statistical process control and quantifiable means in efficient management practices. Based on these principles, Dr. W. Edward Deming, a statistician, introduced new theories of management. Dr. Deming was invited by Japan after World War II to help revitalize its dying manufacturing industry. Deming based his theories on the human element and emphasized that developing human resources are the best means for achieving and improving the quality of products and services. He stresses, however, that quality efforts are successful if were led by top management. These efforts although believe in individual responsibility but must be practiced and actively supported by top management.

According to Deming (1984), the organization is made up of thousands of processes. Therefore health care quality calls for the identification and flowcharting of key processes and the early identification of opportunities for improvements in these processes in order to initiate early intervention. Deming also was very sensitive to the issue of leadership commitment. He suggests that without this commitment quality will not succeed. In health care this is partly true. Leadership commitment is still important but not a must for health care quality to succeed. Leaders can facilitate the process thus making it work faster and produce faster results. In health care, and especially on the international scene, however, leaders change more frequently and therefore
total dependence on their commitment may not prudent. Starting health care quality even at the staff level may produce positive results that will attract the attention of top leaders thus earning their support actively. This approach is what we call it the “bottom-up” approach as opposed to the “top-down” approach described by Deming. In other experiences, both approaches might be seen implemented in the same system and this may be is the most applicable

Deming has 14 Points for Management:

- Create Constancy of Purpose
- Adopt the New Philosophy
- Cease Dependence on Mass Inspection
- End the Practice of Awarding Business on Price Tag Alone
- Constantly and Forever Improve the System of Production and Service
- Institute Modern Methods of Training on the Job
- Institute Modern Methods of Leadership
- Drive Out Fear
- Break Down Barriers Between Staff Areas/Departments
- Eliminate Numerical Goals for the Work Force
- Eliminate Work Standards and Numerical Quotas
- Remove Barriers That Hinder the Hourly Worker
- Institute a Vigorous Program of Education and Self Improvement
- Create a Structure in Top Management That Will Push Every Day on the Above 13 Points. Put everyone to work to accomplish the transformation

**Create Constancy of Purpose:** Organizations and specifically leaders should aim at defining the organization’s mission and vision. These statements should be developed early in the process of improvement and should
involve participation from all levels of the organization. Ownership of the parts of this process is paramount for effective adoption and follow up of these statements.

**Adopt the New Philosophy:** Each employee in the organization should be able to recall the main components of these statements and is able to translate them into action in his/her work area towards achieving them. This is also coupled with strong management commitment. Active involvement in improvement activities, participation in performance improvement projects and providing resources and incentives for the successful implementation of improvement are all important to exhibit true commitment.

**Cease Dependence on Mass Inspection:** Quality assessment should be both individualized and just on time. Continuous and frequent unwarranted appraisal and inspection create fear, mistrust and may hinder innovation among employees in an organization. Inspection should be performed only for specific reason not routine.

**End the Practice of Awarding Business on Price Tag Alone:** Although cost is an important factor of prioritizing of projects and in the selection of companies for contracts, etc., but it should not be the only reason for that selection. Quality of the organization, its products and its process should be included in deciding on contracts and projects to award.

**Constantly and Forever Improve the System of Production and Service:** “Continuous” is the most important word here. Improvement should be continuous and consistent. It may not be ad hoc or a one-time activity. It should also include improvement of the whole system: structure, processes and outcome. You need to answer affirmatively the two questions of improvement: am I better today than I was yesterday? And will I be better tomorrow than today?
Institute Modern Methods of Training on the Job: First organizations should invest in training, as it is an investment in their infrastructure. But this training should be contemporary, modern and up to date. The methodology should take in consideration the adult learner and should be performed in relation to needed and job related areas.

Institute Modern Methods of Leadership: Quality programs require the support of leaders. In particular, quality is interested in developing and grooming leaders and to distinguish the tasks assigned to leaders vs. managers. Leadership is essential in improvement efforts as it fosters innovation, empowers followers, and is visionary. Certain skills of leadership are paramount for the success of quality activities in organizations, and it behooves these organizations to invest in preparing and sustaining leaders in their departments and units.

Drive Out Fear: One of the “deadly diseases” of management according to Deming that traditional organizations create an environment of fear for their employees, intentionally or not. It includes the fear of speaking up, the fear of being heard, the fear of participating and the fear of innovation and change. Quality organizations should avoid such environments and should create a more conducive environment to drive this fear away by making it an environment for learning not judgment.

Break Down the Barriers Between Staff Areas/Departments: Make the information flow freely between departments. Eliminate barriers that hinder passive and active communications between members of the different departments. Encourage interdisciplinary and cross-functional collaboration and cooperation.

Eliminate Numerical Goals for the Work Force: Deming does not think that numerical goals are conducive of continuous improvement and change. He believes that by putting a ceiling on the goals to be achieved then the system (including the employees and managers) will program itself to achieve just that. Once this goal is achieved, the system is at a standstill and produc-
tion may fall down again.

**Eliminate Work Standards and Numerical Quotas:** Again, Deming believes that setting a strict guideline for employees in the form of specific standards and defining work quotas are methods to hinder workers’ creativity and may stifle continuous improvement efforts. He also believes that these quotas and standards may even become disincentives for further work. He gives an example to demonstrate his point wherein he states that 2 groups were given 2 goals, one numerical and one just to improve. Then the group with the numerical standard even if they did improve their outcome but were not able to achieve that outcome will become unmotivated and disappointed while the second group even if they didn’t achieve a better outcome than the first group but still improved outcomes are better prepared to take on a new challenge and are motivated to do more.

**Remove Barriers That Hinder the Hourly Worker:** Deming believes that even the hourly worker is as important as any other worker in being a part of Q. They should be empowered and invited to participate in Q efforts and should be given the opportunity to contribute to innovation and improving performance.

**And to keep the leadership motivated to do it all over again and consistently!**

**J.M. Juran’s Principles:**

- Quality Control and Control Sequence,
- Quality Improvement and the Breakthrough Sequence, and
- Quality Planning and the Annual Quality Program
Briefly stated, the control sequence is designed primarily to attack sporadic problems, the breakthrough sequence attacks chronic problems (common causes), and the annual quality program institutionalizes managerial control and review over the quality management process.

Sporadic problems should be attacked through the quality control process. Quality control is defined as “the process through which we measure actual quality performance, compare it with standard, and act on the difference.”

Tools for attacking sporadic problems include reviews, surveys, and standard statistical process aids such as frequency distributions, histograms, and control charts. To achieve breakthroughs in quality and solve chronic problems, Juran advocates the use of a three step “Universal Process for Quality Improvement.” The steps are:

1. Study the symptoms,
2. Diagnose the causes, and
3. Apply remedies.

To institutionalize continual quality improvement, organizations should adopt this process for a vast array of quality improvement projects. Project-
by-project improvement is a cornerstone idea in the Juran quality improvement philosophy. At any point in time, hundreds or thousands of quality improvement projects, each tackled by a quality project team, should be underway throughout the organization. Projects can address issues in admissions, medical records, care processes, marketing, employee relations, customer relations, quality training, or any other area where improvement is desirable. Juran strongly advises that top managers get involved in some projects in order to display leadership and support for quality improvement and as a way to improve their understanding of quality. Projects should be nominated based on an analysis of the costs of poor quality. Project selection should be based primarily on a return-on-investment (ROI) calculation. Of course the organization should not initiate any more projects than it can support. Adequate training and sufficient resources are prerequisites for project team success.

The breakthrough sequence aids in attacking chronic quality problems. Reduction of chronic problems (i.e., long-standing adverse situations) requires a managerial breakthrough comprised of two parts: a breakthrough in attitudes, followed by a breakthrough in knowledge. Juran calls this his “breakthrough sequence.”

The annual quality program is an important vehicle for quality planning and for top management involvement in the quality management process. In Juran’s view, the strategic planning system for quality should be similar to an organization’s strategic financial planning system. Each year the quality management system, including policies, goals, accomplishments, training programs, and weaknesses, is reviewed and modified as needed. The planning process determines short-term and long-term goals, sets priorities, compares results with previous plans, and meshes its plans with other corporate strategic objectives.

Training in the quality disciplines is another cornerstone in the Juran philosophy. Accurately quantifying the benefits of training for the purposes of a return-on-investment calculation is nearly impossible. However, Juran as-
serts that the Japanese experience leaves little doubt as to the significance of the returns to quality training in terms of competitiveness in the market place, reduced failure costs, higher productivity, smaller inventories, and better care delivery performance. He observes that many Japanese companies have trained 100 percent of their employees in the quality disciplines. Few US companies provide quality training to more than 5 percent of their employees.

**Philip Crosby’s Absolutes:**

- The definition of quality is conformance to requirements
- The system for causing quality is prevention
- The performance standard is zero defects
- The measurement of quality is the price of nonconformance

The first Absolute of Quality Management is: The definition of quality is conformance to requirements. Requirements setting is the responsibility of management. Requirements are communication devices. They tell employees, vendors, and customers what to expect, and what to do in a variety of circumstances. Requirements are ironclad. All employees should perform exactly like the requirement or cause the requirement to be officially changed to what our customer and we really need.

The second Absolute of Quality Management is: The system for causing quality is prevention. The first step toward defect and error prevention is to understand the process by which the firm’s product or service is produced. Once this is done, the objective is to discover and eliminate all opportunities for error. One way to do this is by monitoring the process and learning to anticipate errors before they occur. Control charts are one example of this approach. When a defect or error does occur, the discovery and elimination of the cause becomes a top-priority item. This prevents the second and all subsequent occurrences of the problem.
The third Absolute of Quality Management is: The performance standard is zero defects. Crosby feels that this absolute is widely misunderstood; certainly it is widely resisted. He claims that most people accept zero defects as a performance standard in many aspects of their personal lives and only need to be taught and convinced that it is a reasonable and, in fact, an essential standard in their work lives. Most people cannot, and will not, live with a 2 percent acceptable quality level (AQL) with respect to the accuracy of their paychecks or the number of typographical errors in correspondence that goes out under their names. The recipients do not shrug off errors in paychecks. Rather, the source of the defect is sought out and solved. Further, whenever possible, the system is adjusted to prevent a recurrence of the error. This is the essence of the zero defect idea. Error is not inevitable and nonconformance is not inevitable. AQLs send the wrong signal to workers, suppliers, and customers; therefore, zero defects should become the personal performance standard for everyone in the firm.

The fourth Absolute of Quality Management is: The measurement of quality is the price of nonconformance. Data on the cost of poor quality is useful for three reasons:

1. To call management’s attention to the financial magnitude of the firm’s quality problems.
2. To discover and select lucrative corrective-action opportunities.
3. To track quality improvement and its financial impact over time.

Crosby places little emphasis on statistical quality control techniques in contrast to Deming and Juran. Crosby is more management and organization oriented than tool oriented.

- Management Commitment
- Quality Improvement Team
- Quality Measurement
With respect to the role of quality professionals in the organization, Crosby recommends that the quality organization exists to the degree necessary to ensure that the acceptance and performance standards for the firm’s products are met and to ensure that the costs of quality goals for each operation are achieved. Quality departments should measure and report conformance, demand corrective improvement, encourage defect prevention, teach quality improvement, and act as the conscience of the operation. However, the quality organization should not do the job for others. Crosby cautions against the quality organization becoming involved in the creation, production, marketing, or management of a firm’s product. Finally, he emphasizes that the quality organization is not responsible for quality programs; the departments that made the mistakes are.

Active top management participation is crucial to Crosby’s process. Believing that worker performance reflects the attitudes of management, he demands that all managers adopt zero defects as the personal standard of conformance.
Crosby believes that since worker performance reflects the attitudes of management, a quality improvement program should be directed first at management. However, hourly workers do play an important role in zero defects planning, corrective action, and goal setting.

**Donald Berwick’s Principles:**

- Reduce unnecessary surgery, admissions, and test
- Reduce underlying root causes of illness (e.g. smoking)
- Reduce c-sections to pre-1980 levels
- Reduce unwanted care at the end of life
- Simplify pharmaceutical use
- Increase patient participation in decision making
- Decrease waiting times
- Reducing supply inventories
- Recording useful information only once
- Consolidating and rationalizing high-tech services
- Reducing disparities

Donald Berwick is a pediatrician at Harvard University and Brigham and Women Hospital in Boston, Massachusetts, USA. He is currently the President and CE of the International Healthcare Institute in Orlando Florida an international think tank center on quality improvement in health care. He published a well-known article in the January 1989 issue of the New England Journal of Medicine where he introduced the term, CQI continuous quality improvement in health care. Also in this article he described, perhaps for the first time, the difference between quality assurance and quality improvement in health care.
The Quality principles in general:

- Leadership
- Top Management Commitment
- Customer Focus (patient oriented care)
- Process Oriented Improvement
- System-ness
- Participative Management
- Individual Responsibility
- Employee Empowerment
- Variance Control
- Proactive Intervention
- A Process not a Program
- Appraisal and Recognition
- Data Driven
- Teamwork
- Interdisciplinary collaboration
- Education and Training
- 100% Employee Involvement – with a Structure
- Communication
- Preventive Management
- Benchmarking

Key Success Factors in Quality Improvement

The following is a short list of principles that should be met in order for a system to achieve quality status. Each of these principles is considered a key success factor towards quality improvement. Leadership
The ability of the leaders of an organization to assume the role of true leaders with all of the skills associated with leadership is vital. Vision, compassion for the cause, listening skills, people skills, communication skills, empathy, charisma, persuasion, participatory management style and the like are necessary for a leader to be an effective one. Without true leadership in quality improvement, success may not be attained and maintained.

To empower people, to push power down the chain of command, is an act of leadership. Leadership is to quality as management is to productivity – which helps to explain why both leadership and quality are so difficult to actually do. Management and productivity are the rational subsets. Leadership and quality are both rational and emotional. That’s what makes them harder and far more effective and wonderfully satisfying. To move from management to leadership (and from productivity to quality), you must be both willing and able to incorporate concepts such as courage, humility, emotions, a sense of humor, a genuine concern for others and other such messy things into how you look at and go about accomplishing your work. It is virtually impossible to create, and maintain for any reasonable length of time, a quality process without good leadership at every level of the organization.

A definition of leadership that helps to fit it into the context of a quality effort is that, “Leadership is the creation of an environment in which others can self-actualize in the process of completing the job.” This definition points to one of the main connections between leadership and quality in that it addresses both emotional and rational considerations. In the same way, quality is not limited to only one dimension of the rich human spectrum of characteristics.

This definition also resonates with the three priorities of leadership:

1) Accomplish the mission
2) Take good care of your people
3) Create more leaders

In other words, a leader must
1) Accomplish the mission if the organization is to survive today,
2) Take good care of her or his people if the organization is to grow tomorrow, and
3) Create more leaders if the organization is to survive beyond the leader’s time at the helm.
4) Leadership is a subset of love.

Aside from the theory and the idea of the rational and emotional components of leadership, perhaps the two most important and pragmatic things that can be learned are that leadership is both teachable and learnable and that leadership training should be a recurring experience throughout one’s work career.

“Natural” Leaders
Some people try to escape the role of leadership by claiming to have no “natural leadership skills.” In the same vein, others are never considered for leadership roles because they do not appear to be the magnetic, outgoing person too often thought to be a stereotypical natural leader. There is no doubt that some people are born with more leadership skills than others – as is true with any trait or ability from mathematics to dancing to basketball. What counts, however, is not what one is born with but rather what the total of their skills is at any one moment. That total is the combination of natural skills and what she or he has acquired, preferably intentionally, along the way.

Commitment
In Quality Process, active and participatory commitment is required. Leaders must show not only verbal commitment but also active and practical commitment. Leaders should get involved in the decision-making aspect of quality improvement. They should participate in quality committees and councils. They should be involved in launching teams and provide the necessary support for these teams to succeed. Under this heading the most important commitment for a successful quality program is top management commitment.
Customer focus

According to Kristen Anderson (1991), without customers, we may have to close our doors. Customers are the reason for our existence as providers. They provide the purpose for our structure. One of the main goals of quality improvement is to meet the needs and expectations of the customers, both internal and external. Therefore, for a quality improvement program to succeed it has to carefully identify its customers and learn their needs and expectations, and must find ways to meet them. Otherwise, quality improvement will have little or no impact on what matter the most.

The concept of quality management and customer (internal + external) are important in health care in relation to other enterprises. The concept of the customer is very interesting from the health care point of view, The ISO 8402 defines customer as:

‘Recipient of a product provided by the supplier’.

Another approach to the patient-customer concept is used in the European pre Standard (concepts to support continuity of care) where the patient is the Subject of Care and defined as:

“Person or defined group of persons having received, receiving, or to receive health care”

In many countries the concept of customer is not used within the health care context instead of patient. The customer is seen to be too much market oriented and that it should not be used to equal or replace the concept of the patient. Quality assurance and the general frameworks of quality management use the concept of customer. There is a need to relate the concepts to each other at least at a general level. It is important to recognize the different types of customers in health care. This will help us to understand the health care specific mechanisms for customer orientation and satisfaction. The customers can be grouped into external and internal customers. One important customer group or a supplier is the subcontractor.

External customers

High-quality operations are based on satisfying customer needs. In the health
care sector: there are many customer groups. The most important customer is the patient but purchasers are also customers. Other customers include the patient’s family and insurance companies. The prerequisites for high-quality services are to identify and fulfill the needs of the various customers. Patient needs are varied. Customer satisfaction (functional quality) covers only part of customer needs in the health care sector. In addition, patients expect to receive high-quality clinical treatment, which will improve their health (technical quality), even though they’re not able to specify the aspects of the clinical quality of their treatment.

**Internal customers**

Everything that occurs in a hospital unit depends on the staff. It is vital that people participate effectively, both as individuals and as team members, with respect to performance and rapid adaptation to change. Establishing a healthy working environment and self-direction at individual and team levels is a common ambition in modern organizations. Behind this aspiration is the concept of motivating work, which includes creativity, physical activity, and social interaction. Long-term success requires the participation of all, with each person ultimately receiving more than he or she gives.

Within social service and health care organizations it is important to identify the various internal customers and related services, such as diagnostic and support a service that is required for the realization of the care process. Large organizations often consist of many independent units, which provide services for one another. These centers purchase services from each other after negotiating and agreeing upon the price and quality of the services.

**Subcontractors**

The health care purchasers and different authorities are increasingly purchasing services from private service providers. Many support services have been transferred to other service providers, but care services are also increasingly purchased from private providers. The providers of purchased services are required to offer high-quality services and ensure quality management with regard to the provision of these services. The providers are increasingly
asked to prove the quality of their operations by means of external quality assurance.

_The Customer Supplier Chain_

Every person within our organization, whatever their job, follows the same basic work pattern. They take an input, whether it is raw material or information, they process it in some way to produce an output. Quality is providing these outputs to meet out customers’ expectations, so that they can do their job and provide Quality to their customers. One of the first steps in Quality Improvement is to identify and analyze this Customer Supplier Chain. The purposes of the Customer Supplier Chain are to help you to prepare for a dialogue with your customers and suppliers to determine your customer’s expectations, and to make sure that your expectations are clear to your suppliers. Do not assume that you know what your customer wants—use the Customer and Supplier Check Lists overleaf to help you. Negotiate an agreement to ensure that you have a common understanding and agreement about the standard of service to be provided. Talking to your customers and suppliers and taking action on your agreement is what matters.

The first time you go through the customer supplier chain, do it in this order:

- List your main work processes and their associated inputs and outputs and the suppliers and customers of them.
- Go to the people who receive your outputs and find out how closely your products and services meet their expectations. Use the Customer Expectations Check List and the section on “interviewing” to help you to prepare for these meeting.
- While you are talking to the customer, and afterwards, assess whether your processes are capable of meeting their expectations. Take action to improve your processes if necessary.
- Finally, when you have a clear, quantifiable view of your customer’s various expectations and your processes are working efficiently and effectively, re-assess your expectations of your suppliers’
inputs. Discuss these with them and help them to achieve the standards you need.

**Continuous process oriented and outcome driven improvements**

Improvements must be continuous. They must be directed at processes but should be driven by the goal of achieving the right outcome. Outcome goals should be chosen based on customer impact and organizational priorities. Without a well-developed plan for action taking into consideration these issues, quality improvement efforts may not succeed.

**Employee empowerment**

Each employee should be treated as a customer. They should be trained and continuously developed to render the best possible service to the external clients. They should be given the tools and the techniques to make decisions on their own and should be supported in their efforts of meeting the needs and expectations of their customers. A quality improvement effort that does not consider the needs and assets of the employees is doomed to failure.

The “E” Word

One of the best demonstrations of commitment to a quality process by management at any level is the empowerment of those below them on the corporate ladder. Unfortunately, “empowerment” has become a devalued concept because of the many abuses of the word introduced by motivational speakers and ill-informed executives.

Empowerment does not mean telling everyone to just do her or his own thing. Nor is it an abandonment of power or people. Empowerment simply means making sure people have authority – or power – equal to their responsibility. That’s all. Nothing more but nothing less: authority equal to responsibility. If a person or a team is responsible for a particular outcome, then he, she, or they should have the authority to change the way the outcome is reached.

Only the Self-Confident Can Lead

To empower someone else, to pass on to a subordinate power that you are
used to having, will require self-confidence: Confidence in your own capabil-
ities and confidence in the capabilities of the other person or people (based 
in part, most likely, on your belief that you have trained them well). That is 
only as it should be for only the self-confident can lead. Insecure people are 
the ones we call managers

100% Employee Involvement – with a Structure

Perhaps the most common way that quality efforts fall short of being com-
plete is their refusal to include everyone on the organizational payroll in the 
effort to get better. As mentioned above, these self-doomed efforts begin by 
asking some form of the question, “Who should we involve in this effort?” 
Such a question sets the health care organization on the path to one version or 
another of “quality control” or “quality circles” or, for the sophisticated, “six 
sigma” or “high performance teams.”

The correct question with which to begin a quality effort is, “Who can we 
afford to exclude from the effort to improve?” The only answer is, of course, 
“Nobody.” Congratulations – and welcome to 100% employee involve-
ment.

This, then, is how an organization can get to 100% employee involvement: 
Start there. That decision drives everything else. Establish the philosophy; 
the steps to be taken will fall logically into place after that. Note, however, 
that this Quality process component name includes the phrase “with a Struc-
ture.” It is not sufficient to simply announce that, “All you people should be 
involved in quality.” The rules for work are being changed throughout the 
organization. Folks need – and deserve – to know what the new rules are.

They also need to know what direction the health care organization is going 
and to have a coherent statement of that plan to refer to at any time. One 
of the best ways to provide this guidance is through the determination of a 
Strategic Plan.
Proactive improvements

Taking a proactive approach to problem solving and to identifying opportunities for improvement is key to success. Organizations should stay away from traditional “crisis management” where improvement is initiated only after a crisis or a mistake occurs. This situation will create a sense of laziness and inability to innovate.

Process-focused approach

“Right Things” and “Things Right”. There are two paths that must be traveled and the best way to get to where you want to be is to hurry down both at the same time. One path is labeled, “Are we doing the right things?”; the other is, “Are we doing things right?” As mentioned above, this idea of doing several things at the same time is, of course, a common thing when defining and implementing a quality process. Both avenues need to be pursued since it is of little worth to do the right things if they are being done badly – just as it is self-defeating to do things really well if they are the wrong things to do. The whole point of the exercise is to “do the right things right.”

Determining exactly what the right things are to do falls generally under the heading of “process analysis.” Reengineering is basically process analysis done out of context; done without the rest of this component of a quality process or virtually any other component. In context, process analysis is a powerful tool for lasting change. Done in isolation, it is disruptive and frequently causes more long-term damage than short-term gain.

Data-driven decision-making

There are, in the context of a quality process, only two reasons for taking measurements – no matter how sophisticated or powerful the particular tool used to gather the numbers is: to accumulate data that can be used as the basis of ideas for improvement and to check your progress against expectations. If your progress is not up to your expectations, then you go back to the other reason and think of more ways to improve.

Use of data is paramount in quality improvement efforts. A system of data
management should be fostered in order to adequately and correctly manipulate data and produce information necessary for appropriate decision making activities. Quality improvement is based on decision-making activities and without the necessary data these decisions become arbitrary and may not be correct.

How can you even tell if you’ve gotten better if you don’t know exactly where you were and exactly where you are now? And how can you know that without having measurement skills?

The key to this component is keeping it in context. Too often, measurement is used as a weapon or, worse yet, becomes some sort of corporate religion, complete with ceremonial garb. In the context of a quality process there are two uses for measurement: (1) to gather data that can be a source of ideas for improvement, and (2) to check progress against defined expectations. If progress is falling short, revert to the first reason.

The number of books written on measurement (and the total weight of those virtually immeasurable so there will no attempt here to spell out lengthy how-to prescriptions. Books can be found on any approach desired. Rather, what follows will be more along the line of commentary on some of the optional methods available. This is, of course, one of the components that tends to get pulled out of context and presented as the whole answer, with Benchmarking and Six Sigma being two ready examples.

Benchmarking and Six Sigma

Benchmarking is a marvelous tool. When Xerox won the Baldrige in 1990 and let it be known that using benchmarking to determine best practices was a major contributor to their success, a cottage industry of benchmarking consultants quickly sprang to life. That was fine in it but many of these newly coined experts didn’t really understand Xerox’s philosophy of identifying best practices and then adapting those practices to fit Xerox’s needs and, instead, led organizations down the path of slavish imitation.

Benchmarking is not, however, a new concept. Virtually everyone heard the
story of Sleeping Beauty while they growing up . . . the fairy tale that includ-
ed the evil Stepmother Queen asking her Magic Mirror, “Mirror, mirror on
the wall – who’s the fairest of them all?” The old queen was benchmarking.
Where she fell short was in not asking enough questions. Had she followed
up with questions like, “Who’s the fairest in the neighboring kingdoms?” or
“Who is number two and how quickly is she gaining?,” a lot of unpleasant-
ness could have been avoided.

Six Sigma – another Baldrige by-product (Motorola, 1988) – is also little
more than the formalization of well-known concepts. The exact structure
does appear to have been unique with Motorola, particularly the marriage of
large-scale employee involvement in determining what should be measured
and how to connect that with the breath-taking goals for rates of improve-
ment. What many people now overlook out of carelessness or convenience is
the length of time it took to get the process in place at Motorola, the amount
of employee involvement, and the integration of Six Sigma into the compa-
y’s other quality initiatives. Six Sigma was not all that Motorola was doing;
it was kept in context and in balance

**Interdisciplinary team-work**

If all employees work on their own without interaction with one another then
the organization may never see the fruits of the synergistic effects teamwork
can bring. One member of the team may bring one perspective and another
may build on that perspective to bring about a better perspective, and so on.
Therefore working in teams is not only to achieve collective decision-mak-
ing capabilities but also to achieve progressive and compounded capabilities
through the participation of all the team members.

The preferred approach for a Quality Management is the formation of teams,
usually called “Quality Teams.” Membership on a Quality Team is non-vol-
untary (“mandatory” seems like such an ugly, emotion-laden word), although
the actual level of active participation at any one moment will vary from
person to person.

It is true that not every person will be wildly enthusiastic about membership
on a Quality Team at the outset. So long as an organization sticks with hiring humans, that sort of variance in attitudes is to be expected. If, however, a person were allowed to “opt out,” that is, to not be on any Quality Team, this scenario could easily unfold: At some future time, when that individual figures out that being on a team is to their personal benefit because, for instance, they could initiate changes that would make their own job easier (as he or she has been watching her or his co-workers do since the beginning of the process), the first step that must be taken is to admit to being to wrong, followed by asking to be “let in.” Those two steps will be a powerful deterrent.

If, on the other hand, a person is “defined” at the outset as a member of a Quality Team and has even been included in any recognition the team has received despite not having made any noticeable contribution, when his or her personal light comes on, all the person need do is say, “Hey! I’ve got an idea.” Oftentimes, the slow-to-catch-on become quality advocates about the time early enthusiasts pause to catch their breath.

The Team Leaders will have to be trained – on how to run a meeting well and on the basics of quality – and management at all levels will have to learn to adjust to the fact that their people are gone in groups of 10-to-12 every now and then for about 30 minutes. Happily, the oft-repeated evidence is that teams quickly save far more time (usually in the course of their first few meetings) than they use in meetings.

As will be the case with individuals within the teams – even the most active of teams – teams will be active at different speeds. Some will burst out of the gate, others will spend a month or two “getting organized” before they realize how everyone else is taking advantage of the quality process to make their own jobs more satisfying and more fun.

**Communication**

Communications is made up of two components: transmission and reception. Transmission is what you think you just said. It is, in fact, what you are very sure you just said; it is what you know you just said. Reception, on the other
hand, is what someone else heard, what someone else believes you said.

The one that counts is reception. Transmission is academically interesting but it is of little practical interest. People react to what they hear, not to what is said. Making things even more difficult is the fact that different people hear things different ways. For some, one-on-one verbal communication is best while for others, getting it in writing is what counts so that they can digest it at their own speed – perhaps re-reading portions before deciding what they believe the message means to them. But always, what counts is reception: What did they hear?

Unfortunately, the communications component of Quality Process is often given short shrift by health care organizations in a hurry to get on with their efforts.

**Listen Down**

One common problem in the area of communication is that it tends to all (regardless of whether it is clear or effective or not) flow in one direction: from top to bottom. The habit in most organizations is to exhort people, explicitly and/or implicitly, to listen “up” and proclaim “down.”

In other words, everyone is expected to turn to the person(s) above them on the corporate ladder and listen up to learn from the wisdom at that level. Once informed by those above, the person at any given level can then add a few embellishments and proclaim down to those on lower rungs. It is called “passing the word” and it is designed to keep everything uniform and to benefit to a maximum degree from the increasing expertise at each ascendant level of the ladder.

A quality process, may not turn that arrangement completely on its head (after all, it is true that the senior folks in an organization do hold a large amount of very good and useful information) but it does add an additional communications channel. In this new channel, the roles are reversed: one should “listen down” and “proclaim up. It is, after all, one of the foundation beliefs
of quality process that folks at all levels of the organization know things that no one else knows but that would be of great utility if the information was made known.

It is important to understand that the people at the lower levels have not been deliberately holding back information. For one thing, many of them assumed that what seemed like a good and logical and obvious idea to them (one which they may have even raised at some point) must have been thought of by someone senior and been rejected for some very good reason – when, in fact, no one at a higher level has ever had the idea. Why make the assumption? Because they have always been taught, usually implicitly, that knowledge came with position and power and pay level. By this reasoning, everyone at each level knows everything of any value known by all the folks at every lower level. Consider all the managers/bosses who proudly (albeit erroneously) declare that they “know the jobs of all of my people.”

**Education and retraining**

Continuous development of the human resource of the organization is one of the requirements for a healthy and improving organization. Almost all experts agree that investing in your employees is highly predictive for ultimate success. Additionally, an organization that has its employees satisfied has a perfect environment for improvement and breakthroughs. When moral is high, productivity is at its best.

Training will be one of the ongoing investments needed to sustain a quality effort. Quality Team leaders will need to be trained in the mechanics of the process. Leadership training is an absolute must – at every level. Normal technical classes will continue to be needed as well as quality-specific training to insure the presence of a wide range of tools.

This component will be the most expensive over the long haul. How can that be justified? When Motorola, in the wake if having won the Baldrige in 1988, questioned themselves on the millions of dollars they were pouring into quality-specific training, they went so far as to contract with an outside agency to conduct an audit of their quality-specific training and its impact. The study concluded that the training had a positive 30-to-1 return on investment. The best response to anyone questioning a sharp increase in the invest-
ment in training by a company intent of becoming a “quality organization” is to say, “If you can find something else with a 30-to-1 ROI, we’ll do that instead.”

An example of why the organization needs to retain control over what is taught is the manner in which training companies often cover problem-solving steps. They lay out a set of logical (and more generic than they seem to realize) steps (usually seven, nine or eleven) for solving a problem and then insist that this set of steps applies to virtually every problem and all steps should always be used.

What they say about the possible application of their problem-solving steps to situations of all sizes is most likely true. What they say about the need to follow all steps each and every time is foolishness. There are, of course, problems which – because of their complexity and/or financial impact and/or cross-departmental nature – will need every step, carefully documented and followed with a near-religious fervor. There are far more problems that can be solved by saying, “We do what! Good heavens – let’s not ever do that again.” One step. Yes, Team Leaders should know all seven (or nine or eleven) steps. No, they won’t need to use every step every time.

At the same time that quality-specific training is being increased, it must be insured that technical job-specific training is not declining as a result. As mentioned above, this is the expensive one. The Training Department will doubtless grow in size. Technical training can not be left to On-the-job (OJT). It is too important for that.

Training, both technical job-specific training and quality-specific training. For the purposes of insuring long-term success, this component (in the words of George Orwell’s Animal Farm), is more equal than the other equally important components.

One point that is too often overlooked is the need to train the organization’s middle managers for their new role in the wake of the implementation of a quality process. Even if the organization “turns the organizational pyramid upside-down” so that the senior managers now “serve and support” the “front-
line troops,” the middle managers are still in the middle, trying to balance everyone’s demands and needs. Their job will most likely change from being small-time dictators (or, at least, being encouraged to be, and rewarded for being, autocratic in their managerial style) to being coaches, facilitators, resource experts and leaders. That’s a huge change and they shouldn’t be expected to move smartly to their new role without some help.

Recognition, Gratitude, & Celebration

The organization – and, specifically, the few people at the very top of the organizational pyramid – must say thank you to all deserving employees. And if it comes to a choice between taking a chance on extending a thank you to an undeserving employee in order to say thank you to a deserving one and skipping the deserving employee to make sure that no one gets any undeserved thanks, the choice is simple: say thank you. The worst thing that can happen is that the deserving employee receives what he or she has earned and the undeserving employee is reduced either to guilt or to bragging to his friends that he “put one over” on the boss.

An Act of Leadership

Saying thank you is an act of leadership. Managers understand fair payment, the exchange of agreed-upon goods for agreed-upon services or products – a neat, rational interaction. Saying thank you is, like leadership, both rational and emotional; it engages the mind but it also engages the heart. Leaders understand the emotional aspect of the gesture and prolong the moment just a bit as they take the occasion to personally connect with the deserving employee. If managers had their way, all recognition “ceremonies” would be informal affairs, conducted by the person who delivers the internal mail.

*If you want one year of prosperity grow grain*

*If you want 10 years of prosperity grow trees*

*If you want 100 years of prosperity grow people*

*Chinese Proverb*
REFERENCES


CHAPTER THREE
Quality Infrastructure: How does an organization staff quality?

Seval Akgun, MD, PhD    AF. Al-Assaf, MD
Priscilla A. Pierce, BSN, RN, C, CPHQ

Figure 1
Quality Management Cycle

According to The Quality Management Cycle above, each activity has certain steps to be followed in order to achieve the desired objectives. Quality Assurance (QA) is the process of assuring compliance to specifications, requirements, or standards and implementing methods for conformance. It includes setting and communicating standards and identifying indicators for performance monitoring and compliance to standards. These standards can come in different forms, for example protocols, guidelines, specifications, etc. QA, however, is losing its earlier popularity as it tends to lead to disciplinary measures as a means for standards compliance and, therefore, blames human error for non-compliance. Quality Control (QC) on the other hand, is defined by NAHQ (1994) as “a management process where actual perfor-
formance is measured against expected performance, and actions are taken on the difference.” QC was originally used in the laboratory where accuracy of test results dictates certain norms and specific (and often) rigid procedures that would not allow for error and discrepancy. Thus, it makes an effort to reduce variations as much as possible. Quality Improvement (QI) is defined as an organized, structured process that selectively identifies improvement teams to achieve improvements in products or services. Quality Management (QM), in general, involves all above three processes QA, QC, QI. It involves processes related to the coordination of activities related to all or any one of the above three, as well as, the administration and resources allocation of these processes. Quality management becomes the umbrella under which all processes and activities related to quality fall. QM may also encompass such terms as performance improvement (PI), continuous quality management, and total quality management/leadership/improvement.

Management Commitment

There are not enough words to describe how important management commitment is to the success of quality. Repeatedly, experts have demonstrated the value of management commitment to the quality process. Management can open doors, can facilitate interventions freely, and can coordinate resources easily. In most cases, management has the final say on activities. They make the final decision. Therefore, implementation of quality in health care can be enhanced with management being on its side, supporting its activities and encouraging professional involvement.

According to Deming (1984), if top management’s commitment is not there then the success for implementing quality in such an organization is severely jeopardized. He further tells the prospective leader, “if you can’t come, then send no one.” Commitment to a cause means being involved, being supportive, being active and being participatory in that cause. Commitment also means leading the efforts, facilitating activities, participating on tasks, and providing the necessary and adequate resources to make quality improvement a reality and a success. Commitment to a process or a program means
taking pride and joy in supporting it. It would include enthusiastic initiatives to learn more about it. It is certainly not just rhetoric and oral support, although even that is better than no support at all!

Commitment cannot be achieved without adequate understanding as to what it is you want to commit to and for what reason. Therefore, paramount to this step is increasing knowledge and awareness on the subject/field needing commitment. For health care quality, it is even more difficult to get unequivocal commitment from management without demonstrating results. Managers are usually quick to say: “show me that it works or it has worked!” Health care quality must then be based on data and should always be driven by outcomes. With adequate planning and process design, commitment will be cultivated and positive results can be achieved.

**Top Management Commitment.**

The first question to be asked – and answered – is “Who exactly is ‘Top Management’?” There are two possible definitions and both are applicable. The first is, “The CEO/President and his or her direct reports”; the second is “Anyone more than two rungs up from the bottom on the corporate ladder.” The first group is all-important and its members must accept the ideas and concepts that make up “quality.” Intellectual ascent is vital; emotional acceptance can be added in its own time. Even before they become emotionally involved, executives can do the right things because they know intellectually it will be of benefit to the organization.

In fact, senior managers most often begin with a rational commitment to a quality effort, rooted in their acceptance of the numerous examples that quality makes money. Over time, as they become more and more aware of the impact the process is having on the corporate culture, as they become active in the recognition programs or are exposed to the excitement generated by successful measurement and communications efforts, they will become emotionally committed. On the other hand, lower level employees tend to begin their involvement on the emotional level, excited because “they” are going to share power and are going to allow those below the top levels to make
decisions. With the passage of time, they will become more rational in their evaluation of the worth of the quality process, asking for more and more performance details, for instance. This is particularly true in an organization in which there is a high degree of stock ownership by the employees.

The first group must court the second group of “Top Managers” – with some help from the quality department. The commitment of this second group is necessary because, despite what some ego-driven executives might think, these lower-level managers can bring any top-down process to a halt just through inattention. The point many top-tier managers overlook is that to a non-management employee, a “senior manager” is anyone who can make their immediate boss sweat. In an institute company with more than a few hundred employees, that sweat-inducing manager may be several layers below what is traditionally thought of as “top management.”

Active, Obvious, and Informed

Top management commitment must be active, obvious and informed. The leaders of an organization must themselves improve whatever it is they do. The proper proclamation is not, “You people need to improve what you do and I’m going to tell you how;” it is, “We need to improve and I’m going to show you one way by improving what I do.” Almost as important as being active is being obvious. It may seem a little likes “blowing their own horn” but the point is that no one can follow an example unless they know about it. If the senior officers don’t find a way to politely brag to others, to make sure the word gets out about their personal contributions to the company-wide effort and their exemplary deeds, no one will know for sure exactly what the senior folks have done and, thus, will not be inspired to follow their lead. No one can follow an example that they don’t see.

Once commitment is achieved, the person in charge of the organization, usually the Chief Executive Officer needs to identify a coordinator/director of health care quality. This position is usually a full-time position which may be filled by an experienced person in the organization (or from the outside) with leadership skills, clinical background and who is given sufficient authority.
A direct link is necessary between this individual and the CEO, or his designee, in order to maintain credibility and authority. Actually, this position is such an important position that in some organizations the CEO him/herself assumes the role of chairing the Quality Council of the organization. This approach, however, has advantages and disadvantages. A prominent person like the CEO would give instant recognition and support to the quality department. He would establish commitment from day one, which sends a clear message to the rest of the organization that Quality is important and everyone must follow. The disadvantage on the other hand is that the CEO is not a permanent person, thus causing possible discontinuity of the process once he/she is changed. Regardless of whom the QA/I coordinator/director is, once identified, this individual should be trained extensively in health care quality techniques and must prepare for the organization of the quality council. Of course, the responsibilities of the quality coordinator are numerous. Among which are:

- Advocates and speaks for health care quality
- Facilitates the Quality Council
- Serves as the designated liaison with outside agencies related to quality activities
- Coordinates the strategic and operational planning for health care quality activities and the allocation of resources
- Develops and updates the Quality/PI program and plan documents
- Ensures compliance of the organization to accreditation standards
- Initiates monitoring activities of performance measures
- Serves on and coordinates most of the quality/PI committees in the organization
- Initiates process improvement teams
- Coordinates the selection of key personnel in quality
- Coordinates the health care quality, training plan
- Facilitates the intervention strategies of health care quality
The Quality Council or similar entity is formed to act as the steering body that will direct the health care quality process. It works as a coordinating committee of individuals representing the different aspects of health care and departments/units in the organization to formulate organizational policies towards health care quality. Organizing the Quality Council is not necessary but from experience, it is a necessity. Certainly, the membership of the council is important and careful selection of these individuals should rest with the top official of the organization (CEO) with advice and assistance from the quality coordinator and the consultant (if any). Again, members should be prominent individuals in the organization representing different disciplines and units of the organization. Membership may be broadened to include individuals from other units of the organization who are in lead positions and can harness some of the voices of the workers. Once members are identified a charter (or a description document) needs to be developed, with roles and responsibilities delineated. The role of the council is somewhat similar to the roles of the quality coordinator, giving a collective perspective and establishing itself as the central organizational resource in health care quality that the organization may reference when necessary. Similarly, Quality Council members need to be prepared for their roles adequately and should be exposed to the concept of health care quality and its principles early on.

Once membership has been determined, the frequency of the committee meetings should be established. Meeting at least once per month should provide ample time for review of reports, analysis of findings, and decision-making as to which direction to take. Using a minute’s template to document the committee’s findings, conclusions, recommendations, actions, and follow-up (FCRAF, See Attached Example) will prompt the recorder to document all aspects of the committee’s quality analysis process. It is important to keep an attendance record, as well, so that Administration can monitor accountability and buy-in to the program by committee members.

The meetings must be conducted in a consistent and efficient manner in order to maximize the productivity of the team. The discussion should be agenda-driven, with attention first being given to review of the previous meeting’s minutes and discussion of old business that required follow-up. New busi-
ness should include regular reports due, as well as, new opportunities for improvement or issues identified in need of the committee’s attention. There will, also, need to be some time left for members to discuss other business items that may have arisen after the agenda had been developed. *(See Attached Example Agenda)* In the interest of time, it is helpful if the previous meeting’s minutes can be sent out prior to the actual meeting for the review of committee members. The old business, new business, other business layout is representative of the organization’s continuous improvement culture.

Once formed, the first agenda item for the Quality Council should be to ratify its charter. Each member should be aware of his or her roles and responsibilities as outlined in the charter. They should get actively involved in the revision and the re-drafting of the charter to reflect actual involvement and “ownership” in the council.

Another agenda item that needs to be addressed is the development of the mission and vision statements of the organization, which should reflect the desire for health care improvements. In planning their specific journey to their distinct Quality destination, many start by articulating what the destination will look like through stating the Mission (alternatively called ‘the Vision’).

The council members should draft both statements with input from all key personnel in the organization.

These statements are important in establishing the organization’s constancy of purpose. They will serve as constant reminder of the path in which the organization is moving and a map for its future.

**What is a Mission Statement?**

It encapsulates what the organization seeks to be, to achieve. It may take some time to get there: a Mission statement acts as a constant reminder, over what may be a lengthy period, of the direction set for the journey.

This is particularly important when Quality Improvement has been selected as a business strategy, as a means of communication to all customers.
What constitutes a good Mission Statement?

There are many views on this. An approach often taken is: one which passes the ‘MARCH’ test:

- **M**emorable—thus needs to be short.
- **A**chievable—otherwise it will not be motivational.
- **R**elates to commercial realities—not abstract concepts.
- **C**ommands consensus—all need to be able to ‘buy in’ to it.
- **H**as personality—to be different and compelling.

The Mission should be a driving force for everyone, everyday. Whatever is being planned to be done or is currently being done, these should be tested against the aspirations set by the Mission. The Mission gives a framework within which to make decisions and to plan. Are plans and actions aligned with the Mission? Are they contrary to it? Are standards being met, and if not is corrective action being taken? Are groups and individuals being challenged to aim higher?

Mission and vision statements should be concise, clear, realistic, and reflect the true desire of the organization. That is why real input from other key individuals is necessary. A mission statement should answer questions such as; who are we, what our main purpose as an organization is, whom are we serving, what their needs are and how to meet those needs. Vision statements are somewhat futuristic (visionary) and should answer the question of what the organization strives to be in the future (3, 5 or 10 years). Once drafted, approved and finalized, these statements should be communicated to the rest of the organization most actively and most consistently. Actually, some organizations post the mission and vision statements in prominent places throughout the organization, even printing them at the back of personnel business cards. In this way, all improvement and other activities of the organization will be designed and targeted to achieve the vision and along the boundaries of the organization’s mission.

Allocation of Resources

It is obvious that both physical and human resources are needed to initiate change. Resources are needed for the necessary training and the acquiring
of knowledge. Resources are also needed for dissemination and increasing awareness of health professionals on the concept of health care quality. Additional resources will be required to monitor compliance to standards, to draft, test and enforce compliance to policies and procedures, to identify opportunities for improvement, initiate, and coordinate improvement projects as well as to disseminate the concept of quality and PI at the grass-root level and to the professional staff. Funds should be set aside for potential structural changes and re-designs in processes or units to fit required improvements. In some organizations, funds are, also, used to acquire reference materials and the establishment of a resource library on health care quality. Others may allocate certain funds to hire full-time or part-time individuals as reviewers and quality coordinators to be disbursed at the different units and departments of the organization, while others use additional funds to publish a newsletter on quality, and to hold organization-wide seminars on the subject. Still additional funds may be allotted to provide incentives to the quality process by offering monitory and capitol support to successful units or individuals that have demonstrated substantial improvements.

Another aspect of resource allocation for most organizations is to establish central department/unit within the organization related to health care quality and PI. This unit would be organized with a number of health professionals from within (or recruited from outside) the organization, headed by the quality director and linked directly to the CEO, or his designee. This unit would be given the mandate of setting the standards to be followed by the organization (in hospitals it is usually JCAHO’s or the Osteopathic Association but for other organizations like HMOs and Ambulatory care facilities they have a choice of an accrediting organization, each with its own distinctive standards). This unit would also be charged with the communication of these standards to the rest of the organization and, also, to disseminate information (QA/QI communication and training) related to health care quality, to monitor the quality of care delivered in the health care organization and to act on opportunities for improvements in the system. The unit must be provided with financial and political support at the CEO level and additional support from the organization’s Board, with broad authority for surveying and monitoring performance of any health care or service unit in the organization. The objective is to organize this quality unit so that it will take the responsibility
of coordinating health care quality for the whole organization, with direct input and participation of every other unit of the organization in order to institutionalize and insure sustainability of quality.

The PI Department is responsible for the following:

✔ Developing and implementing mechanisms designed to ensure the uniform performance of patient care processes throughout the organization.

✔ Developing and implementing an effective and continuous program to measure, assess, and improve performance.

✔ Continuously assessing and improving the performance of care and services provided.

✔ Adopting an approach to performance improvement that includes planning the process for improvement, setting priorities for improvement, assessing performance systematically, implementing improvement activities based on assessment, and maintaining achieved improvements.

✔ Providing education to key personnel, as needed, on the approaches and methods of performance improvement teams and activities.

✔ Assessing and prioritizing process improvement projects.

✔ Participating in cross-organizational activities to improve organizational performance as appropriate.

✔ Communicating information relevant to cross-organizational performance improvement activities to appropriate individuals.

✔ Analyzing and assessing the effectiveness of their contributions to improving performance and safety.

✔ Providing a multidisciplinary approach for analysis of risk to patient safety and the dissemination of information on identified risk for the purposes of improving patient care and reducing morbidity and mortality within the Hospital.

✔ Providing recommendations concerning identified risks and where appropriate shall request and approve plans for corrective action and evaluate the implementation of corrective actions taken.
So, what is the organizational structure of this unit on quality in a healthcare organization?

To answer this question, one should outline the main and customary functions of this unit and then decide where in the organization’s hierarchy this unit should be housed. In addition, another aspect to be considered is the support this unit should get through the committee structure of the organization.

Therefore, the list of functions of this unit may include the following:

Implement the Quality program in the organization
Initiate planning for quality initiatives

✔ Set organizational standards for quality

✔ Communicate standards to the organization’s employees
  o Organize seminars to increase awareness
  o Disseminate information on standards
  o Discuss mechanisms for compliance to standards
  o Deliver workshops and lectures on standards
  o Provide training on quality skills and methods

✔ Monitor compliance to standards
  o Identify measurable indicators for performance
  o Collect data on indicators
  o Analyze data on indicators
  o Perform periodic audits
  o Review medical records
  o Perform retrospective or concurrent reviews of care processes
  o Monitor and measure the outcomes of patient care
  o Measure satisfaction of customers; employees, patients, and providers
Collect data on patient complaints and concerns
Assist in meeting accreditation standards
Review and update of policies and procedures
Identify and draft new policies and procedures
Identify opportunities for improvement in care and services
Initiate and coordinate improvement projects
Facilitate performance and productivity measurement and improvements
Coordinate all committees related to quality and PI
Identify and acquire necessary resources for quality and PI
Develop the organization’s quality program document and annual plan
Facilitate the process for evaluation of the organization’s quality program annually
Develop the annual quality report for the organization’s Board of Directors
Coordinate all functions and activities related to the utilization of resources and encourage optimum utilization practices
Coordinate all functions and activities related to prevention, control and management of risks to organization’s customers, both internal and external
Coordinate an effective credentialing and re-credentialing system of the organization’s practitioners
Act as a liaison with all of the organization’s units to facilitate the improvement of their performance

This unit will have access to the organization’s data collected related to patient care and to all the services provided by the organization internally and externally. It will, therefore, work closely with the organization’s information technology unit.
As for the organizational structure of such a unit, there is considerable variation as to what constitutes a “typical” organizational structure of such a unit. There is variation as to what goes under this unit and to whom this unit should report. In general, this unit has traditionally been under the medical staff affairs section of the organization, although the new trends are that it is moved to a higher level where it is directly reporting to the CEO of the organization. As to who reports to this unit, again there is considerable variation. Some organizations include both administrative and clinical functions under this unit, while others narrow the scope to only the clinical functions. Other variations may include adding utilization and case management activities as part of the quality unit, as well as, the risk management and credentialing activities of the organization.

Authority and Leadership:

The method for communication of the Performance Improvement efforts is as follows:

![Organizational Chart]

Chairman
Executive Committee

Chief of Operations

Performance Improvement Department
Performance Improvement And Patient Safety Council

Hospital Departments
Hospital PI Teams

Hospital Committees
The Performance Improvement and Patient Safety Council are responsible for overseeing performance improvement activities.

Performance Improvement and Patient Safety Council

- The Performance Improvement and Patient Safety Council provide guidance and support for hospital-wide performance improvement efforts and are responsible to the Chief of Operations for its actions.

- Membership of the Performance Improvement and Patient Safety Council will include Team Leaders of all hospital-wide key functions.

- The Performance Improvement and Patient Safety Council will meet monthly to carry out its required functions.

- The Performance Improvement and Patient Safety Council is responsible for the following:

  - Fostering a culture that promotes a commitment to continually improving the quality of patient care and services.
  
  - Monitoring and evaluating the progress of Performance Improvement Teams.
  
  - Reporting performance improvement activities to Hospital Administration.
  
  - Assigning process improvement activities to the appropriate cross-functional team.
  
  - Overseeing the hospital-wide performance improvement activities.
  
  - Assessing the delivery of care through performance improvement reporting. Audits and studies will be utilized to measure and assess hospital process on an on-going basis.
  
  - Reviewing results and actions taken for performance improvement opportunities. When triggers are identified outside the determined parameters of acceptance, the process will be evaluated and redesigned to facilitate resolutions of the problem and identify opportunities to improve.
  
  - Reviewing reports on occurrences typically ranging from “no harm” frequently occurring “near misses” to sentinel events with serious adverse outcomes, claims and identified risks,
Providing recommendations concerning identified risks and where appropriate shall request and approve plans for corrective action and evaluate the implementation of corrective actions taken.

Making recommendations to the appropriate individual, committee, department or service for further action to resolve problems or to further improve care.

Hospital department heads also have some specific responsibilities regarding institute’s performance programme. Here are some responsibilities.

**Hospital Department Heads responsibilities:**

1. Coordination of all departmental team efforts.
2. Providing guidance to the team members as needed.
3. Assigning team functions as appropriate - record taking, time keeping.
4. Determining frequency and scheduling of team meetings as necessary.
5. Collecting and maintaining all policies and procedures relating to the function.
6. Reviewing and approving all policies and procedures, assist team members in other appropriate individuals or teams or committees that may need to review and approve the policy and procedure.
7. Presenting all necessary policies and procedures to the Performance Improvement and Patient Safety Council for review and approval.
8. Maintaining a record of all team activities, including minutes, performance improvement activities and performance improvement team composition, and submitting Performance Improvement reports to the PI Manager quarterly.
9. Submitting revised Departmental Team Goals to the Performance Improvement Council and PI Manager annually.
10. Reporting departmental team performance improvement mea-
sures and activities to the Performance Improvement Council and PI Department.

Performance Improvement Team is one of the employee participation methods. It implies the development of skills, capabilities, confidence and creativity of the people through cumulative process of education, training, work experience and participation. It also implies the creation of facilitative conditions and environment of work, which creates and sustains their motivation and commitment towards work excellence.

Performance Improvement Team is a small group of 6 to 12 employees doing similar work who voluntarily meet together on a regular basis to identify improvements in their respective work areas using proven techniques for analyzing and solving work related problems. It is “a way of capturing the creative and innovative power that lies within the work force. The concept of Performance Improvement Team is primarily based upon recognition of the value of the employee as a human being, as someone who willingly activists on his job, his wisdom, intelligence, experience, attitude and feelings.

**Performance Improvement Teams**

1. The Performance Improvement Committee will assign a team leader to each Performance Improvement Team.

2. The team will be responsible for the following:

3. Maintaining a current awareness of all external requirements regarding the function.

4. Establishing a complete membership representative of all necessary departments or services, with approval of the appropriate Department Manager.

5. Developing and revising the necessary policies and procedures for the function assigned.

6. Establishing priority areas for the function assigned.

7. Initiating performance improvement activities, as needed, for the function assigned.
8. Determining educational needs of staff regarding all aspects of the function, and developing a plan for in servicing, and implementing the educational activities.

9. Documenting all activities of the team, including a record of meeting minutes, performance improvement activities, performance improvement team composition, and Performance Improvement Team Goals.

10. Developing performance improvement measures for areas established as priorities by the team members.

11. Implementing actions necessary for improving performance.

There is variation as to what goes under this unit and to whom this unit should report. In general, this unit has traditionally been under the medical staff affairs section of the organization, although the new trends are that it is moved to a higher level where it is directly reporting to the CEO of the organization. As to who reports to this unit, again there is considerable variation. Some organizations include both administrative and clinical functions under this unit, while others narrow the scope to only the clinical functions. Other variations may include adding utilization and case management activities as part of the quality unit, as well as, the risk management and credentialing activities of the organization.

**Committees reporting to PI Department**

The other functions of PI Department are usually handled through the “informal” structure of the organization, i.e. the committees. Again, there is considerable variation as to which committees belong to quality and which ones belong to medical staff affairs. In general, however, such committees as the credentialing, peer review and clinical services management, utilization and case management, patient safety, risk management, infection control and medical record review are all committees that usually report to the quality unit. In addition, although not reporting to it, the organization’s Quality Council (or similar) is in direct relation with the quality unit and its staff is usually coordinating it.
Hospital Management Committee Reports:

- Short/long term/strategic plans for all hospital departments;
- Major issues, problems, opportunities, resources;
- Decisions on capital expenditures for each department;
- Departmental plans;
- Cost control activity and utilization review targets selecting the high volume/problem prone/high risk processes;
- Standard of services provided to ensure their efficiency and effectiveness;

Medical Council Committee Reports:

- Medical PI activities.
- Lessons learned: Relevant findings, conclusions, recommendations, and actions taken to improve care.

Credentialing, Privileging and Medical Staff Peer Review Committee Reports:

Credentialing and privileging is a process the hospital utilizes for obtaining, verifying and assessing the qualification of staff members at various levels of appointment in the organization. It could be performed;

- Initial (upon arrival)
- Subsequent (Supervision of existing staff)
- Temporary

Physicians under review also undergo medical staff peer review. This committee will review medical cases for:

- Appropriateness and timelines of care.
- Adequacy of documentation regarding follow-up of problems with corrective action.

The cases will be forwarded to the appropriate medical staff department head or his/her designee as appropriate; any further action will be taken based upon recommendation of the chairman of the department or committee and
reported to the Performance Improvement and Patient Safety Council.

**Mortality and Morbidity Review Committee reports:**

- All patients’ deaths occurring in association with operations or procedures performed under all clinical services from an anesthetic, pharmacological, surgical and pathological perspective,

- Identification of the deaths attributable to failure to recognize event(s), failure to take available preventive measures, or failure to act on time.

- Delivery of medical treatment to patients.

- The incidence of adverse events such as complications, readmission rates, and errors in diagnosis and/or treatment unrelated to the natural course of a disease or illness.

- The adequacy of the documentation regarding follow-up the problems with corrective action.

- Solutions for identified problems during review process priority to be given to high risk / problem prone areas.

**Pharmacy and Therapeutics and Drug Usage Committee reports:**

a. Recommendations for educational programs designed to keep professional staff updated on current knowledge on matters related to drugs and drug use.

   - Prescribing or ordering medication
   - Preparing and dispensing
   - Administering

b. Monitoring the medications’ effects on patients

c. Adverse drug reactions (All significant drug reactions undergo an intensive assessment).

**Ethics Committee Reports:**

a) Identified internal and external issues that are thought to be related to medical ethics within the laws and regulations, Medical Ethics principles, and the recommendations and the standards of the Joint Commission International;

b) Recommended courses of action regarding medical ethical is-
sues raised by management, physicians, nurses, patients and/or their immediate family members;

**Education Committee Reports:**

a. Organizational and administrative plans for hospital education program development and implementation;

b. Identified educational needs of all medical, nursing paramedical and administrative staff;

c. All new methods of management or medical techniques are reported and reviewed;

d. Continuous education programs and seminars;

**Utilization Review Committee reports:**

a. Appropriateness of admissions;

b. The clinical necessity of continued stays;

c. The appropriateness, clinical necessity and timeless of support services provided directly by the hospital or through contracts;

d. Problems with utilization of resources.

e. The following blood use processes are reported on an ongoing basis:
   - Ordering practices
   - Distributing, handling and dispensing
   - Monitoring blood and blood component effects on patients
   - Review of availability of blood and blood components
   - Review of transfusion reactions (All confirmed transfusion reactions undergo an intensive assessment)
   - Pertinent information regarding findings.

**Management of Information Committee reports:**

a. Identified information needs;
b. Transition of reporting data and information to outside sources

c. Integrating and use of hospital wide information.

d. Pertinent information regarding findings in the Medical Record Review Committee including the review of clinical pertinence and timeliness, and the approval of all new forms.

**Infection Control Committee reports:**

a. The report includes approval of policies and procedures relating to Infection Control, review and evaluation of infection statistics, focused review on infection concerns and/or issues as appropriate, review and input into the hospital’s Employee Health Program.

b. Actions taken by the Infection Control Committee or recommendations for actions.

c. Pertinent information regarding findings.

**Risk Management and Environmental Safety Committee Reports:**

a. All reported events related to patient, visitor, and staff safety including sentinel events.

b. Occurrence/Variance Reports (OVR) tracking and trending for adverse or unusual occurrences or potential problem areas, and as a means of identifying opportunities to improve care or services as deemed necessary by the Risk Manager.

c. The Environment of Care reports include the following:

- Safety hazards and management of staff activities to reduce the risk of human injury.

- Security concerns regarding patients, visitors, personnel, and property.

- Hazardous materials and waste management to reduce the risk of human injury.

- Emergency preparedness procedures in response to a vari-
ety of disasters.

- Fire safety program processes for protecting patients, personnel, visitors, and property from fire and the products of combustion.
- Equipment management program needs.
- Utility management program needs.
- Pertinent information regarding findings.
- Recommendations for action for identified problems.

### Increasing Staff Awareness of the Health Care Quality Concept

Health care quality as a concept has different facets, principles, skills, techniques and tools. In addition, there has been a vast amount of literature written about it. Therefore, an early activity of the Quality Council is for its members to participate in a seminar on health care quality. This seminar should be followed by intellectual discussions with a designated facilitator as to the application of this concept in the organization, taking into consideration the available resources, culture and structure. A similar activity should be organized to present health care quality to other key personnel in health care in order to gain further support and to increase dissemination of the concept. Certainly, the facilitator’s services could be used to present a number of short sessions with other key personnel and middle managers to discuss health care quality. These sessions, to be repeated at least annually, should be attended by at least the quality coordinator and members of the Quality Council. They can serve as focus group sessions to get feedback on quality implementation and applications in health care, as well as, an avenue to increase awareness of the concept. Information and feedback gathered at these sessions can be used in the next planning phase at the operational level and in launching improvement projects and initiatives.

Training could be conducted through 3 approaches: Hospital-wide training, Just-in-time training or a combination of both.

The curriculum includes the following elements:
a. Explanation of the need for organizational improvement and the individual and collective benefits.
b. Development and use of a common quality language.
c. Discussion of the organization’s quality goals.
d. Definition of the structure for quality/performance improvement.
e. Definition of the process for quality/performance improvement.
f. Description and clarification of responsibilities.
g. How to use the tools and techniques to participate in teams and to manage work processes.
h. Description of how change may affect the individual’s job and work relationships.
i. Training is tailored to the specific needs of each group (i.e., top management, middle management, staff). For determination of future training needs, a self-assessment will be conducted at regular intervals to identify what, when, and where additional training is needed.

**Organization wide presentation of performance improvement concepts**

The most frequent cause of failure in any quality improvement effort is uninvolved or indifferent top and middle management. It is, therefore, essential that all leadership be actively and aggressively involved from the start. Training will begin at the top and cascade down through the organization. Managers must lead the transformation effort to ensure long-lasting success. Leaders must accomplish the following:

✔ Become leaders instead of bosses, coaches instead of enforcers

✔ Change focus from blaming and controlling individuals to preventing and eliminating problems

✔ Understand Deming’s 14 points

✔ Learn new skills and approaches for stabilizing and improving processes

✔ Understand variation and know how to use data effectively

✔ The PI Department can develop a rollout plan for education throughout the organization. The following will be considered:
Educate everyone in quality improvement concepts, appropriate to their level of responsibility.

Identify specific tasks that staff at various levels can accomplish.

Define organization wide systems where employees are concentrating their quality improvement efforts.

At the leadership level, commitment will vary. In order to facilitate senior leadership buy-in to the process, their training will consist of at least the following:

- Understanding PI/PS as a strategic advantage
- The role of leadership in creating and sustaining a PI/PS focus and clear and visible quality values
- The major concepts of PI/PS: customer knowledge and satisfaction, process improvement, scientific problem solving, management by objectives, continuous improvement
- The how-to’s of integrating an hospital’s PI/PS values into day-to-day leadership
- Indicators for measuring and evaluating quality and hospital performance
- The components of a PI/PS implementation process
- Organizational tools (prioritization matrices, tree diagrams and other planning techniques, the affinity diagram, etc.)
- Basic quality improvement tools
- Role of team leaders and facilitators
- Awareness of JCIA standards

The training for the middle managers (department heads, assistant directors, nurse managers, and supervisors) is similar to that of senior management and will include the following:

1. The key concepts of Performance Improvement/Patient Safety: customer knowledge and customer satisfaction, process management, teamwork
and employee involvement, continuous improvement methods to determine customer needs, requirements and expectations

2. Principles of customer service

3. Managing process performance

4. Measurement of process performance (indicators)

5. Usage of quality improvement tools (flowcharts, check sheets, Pareto diagrams, histograms, run charts, control charts, cause and effect)

6. Measurement of variation in process
   i. Problem solving approach
   ii. Data collection and analysis
   iii. Measurement of quality outcomes
   iv. Management practices for building teamwork; involving employees in improving quality and work processes; recognizing employees for customer service, loyalty to the team, and contributions for quality
   v. Planning techniques for developing quality improvement plans
   vi. Team leadership and facilitation skills
   vii. Conflict resolution
   viii. Communication skills; listening and giving feedback
   ix. JCIA standards

Managers need on-site training to guide implementation, teams need “just-in-time” training in basic tools, and facilitators need training and pathways for career development to equip them to assist hospital to change.

**Quality improvement education- staff sequence**

Ultimately, senior management and middle management will be part of the teaching team utilized to teach quality improvement methods and tools throughout the hospital. This further exhibits their commitment to the process of continuous PI/PS hospital wide. All employees must understand their jobs
and their roles/responsibilities in the hospital and what impact they have as quality improves. This realization goes beyond manuals, operating instructions, and position description. The staff needs to understand how their responsibilities fit into the overall hospital mission and how those who precede them and those who follow influence their work. New skills must be learned for improving work.

In a quality organization, we believe everyone is constantly learning. Educating the critical mass, though, is not enough; the staff needs direction and focus. Employees will be encouraged to constantly elevate their level of technical skill and professional expertise. When they broaden their knowledge and capabilities they will achieve even greater mastery of their jobs.

Employees will receive the following training:

- PI awareness, definition of quality (i.e., orientation to the total quality management and performance improvement philosophy)
- Quality participation—fundamental training in PI/PS including process improvement tools (flowcharts, check sheets, Pareto diagrams, cause and effect) and techniques, and involvement in quality improvement efforts
- The organization’s mission, vision, performance improvement plans
- Concepts of PI: customer satisfaction, process improvement, teamwork, continuous improvement
- Ways to promote cooperation among co-workers within their department and with other departments
- Relevant standards and requirements
  - Communication skills
  - Customer service
  - Just-in-time team training as needed

New employees to the organization will receive the same training as the rest of the staff. While their training begins with their first encounter with the hospital.
Mapping Quality Improvement Intervention

In collaboration with the Quality Council and with information collected during the planning phase, the quality coordinator may identify areas in the system with an opportunity for improvement. Identified areas should be selected carefully to include simple projects that require the least amount of resources and that have the highest probability of success, yet affect a large number of beneficiaries. Examples of such projects may include:

- Improving the reception area of the organization
- Improving the esthetics of the organization
- Improving the timeliness of tests and services to the patients
- Identifying and improving patient safety such as infections, falls, complications, medication errors
- Initiating a campaign to improve reporting on sentinel events and develop strategies to address such situations
- Selecting a few areas that receive high complaints from the external customers and trying to improve customer satisfaction
- Initiation of a campaign of promoting health awareness to the public
- Leading an informational campaign on improvement initiatives, with the participation of all units

Other projects may involve the formal identification and selection of an improvement opportunity and the organization of an interdisciplinary team from the affected process to initiate improvements. Results are then organized and reported in a forum that would maximize sensitization and awareness of improvements.

It is important to develop a consistent manner for reporting quality data. This can be accomplished easily through the development of spreadsheets, which include the performance indicators, goals, and data. **(See Attached Example Spreadsheet)**
Within this context the performance improvement projects are very good tools for continuous improvement at health care organizations. The purpose of health care quality Performance Improvement Projects is to assess and improve processes, and thereby outcomes of care. In order for such projects to achieve real improvements in care, and for interested parties to have confidence in the reported improvements,

**What are Performance Improvement Projects (PIPs)?**

The performance Improvement projects are tools to:

- Implement system interventions to improve quality;
- Evaluate the effectiveness of system interventions; and
- Measure performance.

Therefore PIPs are designed to:

- Demonstrate achievement and sustainability of improvement for significant aspects of clinical care and non-clinical services; and
- Correct significant systemic issues that come to the attention of health care organization in part through:
  - Internal surveillance and service delivery monitoring;
  - Tracking and trending of complaints;
  - Incident and adverse event reporting;
  - Utilization management reviews; and
  - Patient and staff satisfaction surveys.

PIPs must be designed, conducted and reported in a methodologically sound manner.

**Procedures**

There are ten (10) steps to be undertaken when conducting PIPs:
1. Select the study topic(s). In general, a clinical or non-clinical issue selected for study should affect a significant number of patients that received health care from health care organization and have a potentially significant impact on health, functional status or satisfaction.

2. Define the study question(s). It is important to clearly state, in writing, the question(s) the study is designed to answer. Stating the question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation.

3. Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic reflecting a discrete event (e.g., an older adult has/has not received a flu shot in the last 12 months), or a status (e.g., a person’s blood pressure is/is not below a specified level) that is to be measured. Each project should have one or more quality indicators for use in tracking performance and improvement over time.

4. Use a representative and generalizable study population. Once a topic has been selected, measurement and improvement efforts must be system-wide. A decision needs to be made as to whether to review data for the entire population or use a sample of the population.

5. Use sound sampling techniques (if sampling is used). If a sample is to be used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. When conducting a study designed to estimate the rates at which certain events occur, the sample size has a large impact on the level of statistical confidence in the study estimates.

6. Reliably collect data. Procedures used to collect data for a given PIP must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. Potential sources of data include administrative data (e.g., enrollment, claims), medical records, tracking logs, results of any provider interviews and results of any recipient interviews and surveys. Data can be collected from either automated data systems? or by a manual review of records.

7. Implement intervention and improvement strategies. Real, sustained
improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Actual improvements in care depend on thorough analysis and implementation of appropriate solutions.

8. Analyze data and interpret study results. Data analysis begins with examining the performance on the selected clinical or non-clinical indicators. The analysis of the study data should include an interpretation of the extent to which the PIP was successful and what follow-up activities are planned as a result.

9. Plan for “real” improvement. When a change in performance is found, it is important to know whether the change represents “real” change or random chance. This can be assessed in several ways, but is most confidently done by calculating the degree to which an intervention is statistically significant; and

10. Achieve sustained improvement. Real change results from changes in the fundamental processes of health care delivery. Such changes should result in sustained improvements. In contrast, a one-time improvement can result from unplanned accidental occurrences or random chance. If real change has occurred, the project should be able to achieve sustained improvement.

At the completion of improvement projects, the Quality Council should analyze the lessons learned and, based upon criteria described below, prioritize services and organizational areas for further implementation of improvements in health care quality. Examples of such criteria used for the selection of services for intervention are:

- High volume
- Problem-prone
- High risk
- High impact
- High cost
On the other hand, other criteria used for selection of intervention venues and units may include:

- Availability and accessibility of necessary data
- Relatively small with a homogenous “study” population
- Simple infrastructure
- Well defined and focused intervention proposed
- Relatively stable and supportive leadership
- High need for improvement
- Intervention does not require additional resources
- Health professionals willing to participate
- Feasibility of demonstrating improvements

The Quality Council should decide on whether to allocate certain resources for the proposed intervention strategy. Using the above criteria, the Quality Council will be able to choose the area or service specific for implementation of intervention. The use of objectivity in selecting a system or an area for intervention is crucial for successful outcomes. It is often helpful to accomplish this task through the utilization of a prioritization grid. *(See Attached Example Prioritization Grid)*

**Quality/PI Program Document**

One of the most important documents the quality unit must develop is the program description document. This document is considered one of the critical documents that would be required for accreditation of the organization. Actually, an organization that lacks this document will never be accredited.

The following is a suggested outline of such a document. As is noted, this document will provide a description of the different activities of the quality unit and provide an outline of the scope of work this unit or the quality program of the organization is engaged in. It also describes the functions
of the different individuals and committees associated with the quality program. This document also serves as the basis of evaluating performance of the organization towards quality. Therefore, the outline would include the following:

Quality Program Document

✔ Purpose of document

✔ General program description and overview

✔ Statements of mission, vision and values of the organization and the quality unit

✔ Goals and objectives of the quality program

✔ Strategies for Performance Improvement

✔ Organizational structure supporting PI
  o Formal structure
  o Committee structure

✔ Roles and responsibilities of PI program
  o Board of Directors
  o CEO and Executive Team
  o Quality Council
  o Quality/PI unit
    ■ Quality Director
    ■ Quality Coordinators
    ■ Quality Reviewers/Specialists
  o Quality Committees
  o Project teams
  o Departmental, Sections and other unit Leaders responsibilities in Quality
  o Staff responsibilities and involvement in PI
✓ Scope of work and standards of care and service
✓ Authority, lines of communication and accountability
✓ Delegation of services (if any)
✓ Reporting mechanisms
✓ Criteria for setting priorities on PI projects
✓ List of indicators for monitoring PI
✓ Methods of monitoring compliance to standards and measuring performance
✓ Procedures for tackling deficiencies
✓ Mechanism/model for improvement interventions
✓ Education and awareness activities on quality/PI
✓ Rewarding results program
✓ Annual evaluation of PI program
✓ Audits and reviews
✓ Confidentiality of information
✓ Credentialing and re-credentialing
✓ Utilization Management program documentation
✓ Case Management program documentation
✓ Risk Management and Patient Safety program documentation

This document should be reviewed, re-reviewed and approved at least annually by the appropriate staff of the QA unit, as well as, the Quality Council and then forwarded to the Organization’s Board of Directors for final approval. These revisions and approvals should be documented, including approval signatures and dates.

The second document that should be in place along side the quality program document is the Quality “plan”. This document should list all of the activi-
ties/tasks related to quality that will be carried out during the coming year, along with a timeline for these activities. Actually, a better document will be to develop an action plan where the activities are listed in one column, followed by the name of the responsible person for each activity, the timeline for completion of that activity, followed by the indicator that will verify that the activity has been completed. In this way, there are both accountability and time expectations for completion of each activity. This document is very useful for monitoring the performance of the quality unit and is an important document to follow up on accomplishments.

Establishing a reporting calendar is another essential piece of the framework, which will promote consistent reporting, and accountability from all responsible departments. It is helpful if the coordinator of the committee’s activities will publish the reporting calendar and send a reminder to departments the month prior to the reports being due. This will allow time for data analysis and report development, as well as, serve as a team-building step. Encouraging participation by providing adequate support and time for reporting sets a positive tone for the program. If staff members feel harassed or are embarrassed by having missed a deadline for reporting, they are not likely to buy into the quality program. *(See Attached Reporting Calendar Example)*

**Re-assessment, Evaluation, Monitoring, and CQI**

In today’s health care arena, a number of issues are being raised that have received much attention from the health care consumers or the media. The 1990’s and moving on into the new millennium can easily be dubbed the age of “performance measurement”. Whether it is a provider, a consumer or a purchaser, each is looking for ways to satisfy one another through measuring and reporting on care outcomes. Accountability is at stake. Several third-party organizations attempted to produce certain measures to report on these care outcomes. Nationally, a number of “indicators” have been developed and are being measured by health care organizations. Report cards are assembled on the health care organizations of the nation. Benchmarking efforts are underway to identify and emulate excellence in care and services. All of these activities are being carried out in an effort to measure and improve performance in health care. On the international arena, the World Health Orga-
nization organized and facilitated a number of activities related to quality assessment, performance improvement and outcomes measurements (see work coordinated by the US Agency for Healthcare Quality and Research at http://www.qualitymeasures.ahrq.gov/). A large number of countries and institutions participated in these activities and initiatives. In addition, at the end, all agreed that there has to be an organized mechanism to account for quality and continuous measurement in order to improve performance in health care organizations (see WHO report of 2000 on health systems rankings at http://www.who.int/whr2001/2001/archives/2000/en/).

Performance Measurement includes such activities as the identification of certain indicators for performance. This is followed by the collection of data to measure those indicators and then comparing current performance with a desired performance level. Several systems of measurements and indicators have already been developed. The Health Employer Data and Information Set (HEDIS) is one example (http://www.ncqa.org/Programs/HEDIS/). This set has over 50 measures, which primarily focus on preventive health services. Organizations can compare their performance (in these measures) with their peers and trend their progress towards improvement. Other similar systems include the US Public Health Service Healthy People 2000 and 2010 list of indicators (http://www.healthypeople.gov/), the Joint Commission’s ORYX clinical indicator system for hospitals (http://www.qiproject.org/ORYX/ORYX.pdf), the Canadian Council on Health Services Accreditation (CCHSA) hospital indicators (http://www.cchsa.ca/) and the US Centers for Medicare and Medicaid Services’ (CMS) QISMC indicator system for managed care, as well as, the Scope of Work projects (www.cms.gov).

The practice of measuring pre and post improvements of every project should be encouraged. In this way, re-assessment will be much easier to accomplish. Re-assessment and evaluation may use the same method applied earlier at the assessment and planning phase through different methods of data collection and analysis.

The above text on Performance Measurement provides some highlights on
assessing performance and improvement progress. Monitoring, on the other hand, is based on specific and measured indicators related to standards. It is a process of measuring variance to standards and initiating processes for action to reduce this variance. Monitoring is a necessary step for proper selection of and consideration of quality improvement projects and studies. It can also provide the organization an indication of the status of care and services provided at any point in time. In advanced systems of health care, elaborate and comprehensive systems of monitoring have been developed that utilize the patient’s medical record for the abstraction of specific data elements. Data are then fed into a central database for analysis and monitoring. Each organization will then receive a periodic report showing aggregate data of national health care indicators compared to their specific set of data for the same indicators. Variance from the mean is then studied and acted upon using the QA/QI process mentioned above.

A few words need to be said about the issue of continuous improvement. Improvements are not one-time activities. When a team has worked on a process and improvement was accomplished, this does not mean that it should abandon this process forever and move on to the next one. Improvement is a continuous process. Monitoring should continue and improvements should be initiated every time it is needed. The other principle involves incremental improvements in the standards once compliance is achieved. If high or even perfect compliance to a specific standard has been documented, then upgrading this standard is the next prudent step to take. Otherwise, the organization will stay in the status quo without further improvements taking place.

Quality Program Evaluation

The program including its objectives, measures and activities should be assessed at least once every year to ensure its effectiveness in keeping the objectives in line with the organization’s mission and vision. This, also, serves as a mechanism to measure outcomes of the program and identify deficiencies, if any, in achieving the desired outcomes. New goals and objectives might be drafted and incorporated in the new annual plan, including any new activities introduced for the next year. Some programs develop a list of specific and quantifiable outcomes to be achieved for the coming year. This list
might include the number and type of improvement studies to be carried out, specific performance thresholds for identified outcome measures e.g. HEDIS, ORYX, etc., patient satisfaction rate goals, compliance rate for accreditation and other standards, etc.

Therefore, evaluation would include an annual review of all of the activities and evaluation as to the effectiveness of the program in meeting goals established at the beginning of the year. A summary of what has been accomplished should be developed, and a justification of deficiencies included. A plan of action for the next year will then depend on the assessment of performance of the program and may include recommendations for process revisions, enhancements or modifications in the program to ensure continuous progress in improvement.

One point that should be emphasized here is that, although evaluation of the program is a scheduled annual activity, which does not mean the program is not assessed more often. Actually, there is a difference between evaluation, which is a yearly retrospective activity, and monitoring, which is an ongoing and continuous activity where goals, progress, and accomplishments are assessed periodically, and often throughout the year. This principle should always be emphasized to program staff.

Remember, “every system is perfectly designed to meet the objectives for which it is designed” according to Deming (1984). Therefore, making sure that the quality infrastructure is designed effectively is essential and monitoring its performance regularly is even more important.
References


ORGANIZATION NAME

State Meeting Date Here
State Meeting Time Here
State Meeting Location Here

AGENDA

1.0 CALL TO ORDER
2.0 INTRODUCTION OF NEW MEMBERS OR GUESTS
3.0 REVIEW OF PREVIOUS MEETING MINUTES - Date: / /2005
4.0 OLD BUSINESS
3.1 Examples (for topics, refer to “Follow-up” column from previous meeting minutes and always identify person who will be speaking)
3.2
5.0 NEW BUSINESS
4.1 Examples (scheduled updates on previous reports or new issues to be discussed; time period for updated report – i.e. “2nd quarter, 2005”; identify person who will be reporting or speaking to the issue)
4.2
6.0 OTHER BUSINESS (topics that need to be discussed which were not known at the time the agenda was finalized)
7.0 ANNOUNCEMENTS
8.0 ADJOURNMENT
## MEETING MINUTES

**Meeting Date**

**Meeting Time**

**Meeting Location**

### MEMBERS PRESENT:
Name-Title (include name of “Recorder”)

### MEMBERS ABSENT:

### GUESTS PRESENT:
(Identify Guests Here or State) “None”

*Packet Content Attachments: Agenda, Minutes (state date here), list any other packet contents*

*Handout Attachments: state any handouts here or state “None”*

### TOPIC or AGENDA ITEM (mirrors the agenda)

<table>
<thead>
<tr>
<th>FINDINGS/CONCLUSIONS</th>
<th>RECOMMENDATIONS/ACTIONS</th>
<th>FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0 CALL TO ORDER</strong></td>
<td>The meeting was called to order at _______.</td>
<td>------------</td>
</tr>
<tr>
<td><strong>2.0 INTRODUCTION OF NEW MEMBERS OR GUESTS</strong></td>
<td>If this applies, list new members or guests. If not, delete this section and move “Approval of Minutes” to this section. Do not re-introduce members each time. It clutters agenda and minutes unnecessarily.</td>
<td>Informational Item Only. No Action Required</td>
</tr>
<tr>
<td><strong>3.0 APPROVAL OF MINUTES</strong></td>
<td>Meeting minutes for [date] were reviewed and approved as written OR “with the following corrections”:</td>
<td>Minutes were approved as written. OR “Quality Management Department will make the requested changes to the minutes. No further action required of this committee”</td>
</tr>
</tbody>
</table>
Quality Improvement Prioritization Grid

<table>
<thead>
<tr>
<th>Score Value</th>
<th>3</th>
<th>3</th>
<th>3</th>
<th>3</th>
<th>2</th>
<th>2</th>
<th>2</th>
<th>1</th>
<th>1</th>
</tr>
</thead>
</table>
| Project Name | The project scoring the highest total points is considered for highest priority.
<table>
<thead>
<tr>
<th>Department</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Care</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing – Med/Surg</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing – Obstetrics</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing – Surgical Services</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Nursing – Mental Health</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Nursing – Cardiac Services</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Nursing – Emergency and Ambulatory Services</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer Center/Radiation Therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinical Equipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housekeeping</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Facilities Management</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finance</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Medical Records</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Human Resources and Education</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Radiology</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Information Technology Services</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Laboratory</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials Management</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Nutrition Services</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Respiratory Therapy</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Rehabilitation Services</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
## PERFORMANCE INDICATOR REPORT

### 2005

**Department:**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Functions and Dimensions Key

- **ACC** = Access to Care and Continuity
- **AP** = Appropriateness
- **V** = High
- **FMS** = Facility Management and Safety
- **AV** = Availability
- **Volume**
- **SQE** = Staff Qualifications and Education
- **CO** = Continuity
- **R** = High
- **PCI** = Prevention and Control of Infection
- **EC** = Efficiency
- **Risk**
- **MOI** = Management of Information
- **EF** = Efficacy
- **P** = Problem
- **QPS** = QI and Patient Safety
- **ET** = Effectiveness
- **Prone**
- **COP** = Care of Patients
- **RC** = Respect &
- **C** = High
- **AOP** = Assessment of Patients
- **Caring**
- **Cost**
- **PFR** = Patient and Family Rights
- **SA** = Safety
- **PFE** = Patient and Family Education
- **TM** = Timeliness
- **GLD** = Governance, Leadership and Direct.
CHAPTER FOUR
Patient Safety

Seval Akgun, MD, PhD    A. F. Al-Assaf, MD, MPH
Priscilla A. Pierce, BSN, RN, C, CPHQ

Introduction and Background

Health care organizations are at a critical crossroad in the challenge to provide safe and high quality care for their patients. The achievement of quality depends on the basic principle of reducing error, which has always been a great problem in health care. Safety is the basic principle and a critical component of quality management and patient safety has become a major preoccupation in health care systems. It is often measured through rates of adverse events. Indeed the problem of adverse events in health care is not new. Studies as early as the 1950s and 1960s reported on adverse events, but the subject is neglected.

In 1999, the Institute of Medicine (IOM) published, To Err is Human: Building a Safer Health System, a very sobering pronouncement of a fragmented healthcare system that has sadly failed in its obligation to provide safe, quality care to its patients. In this treatise, the IOM reported that medical errors kill between 44,000 and 98,000 people each year in the U.S., more than the number of deaths attributed to motor vehicle accidents, breast cancer and AIDS combined. The costs associated with adverse patient events are staggering. The IOM affirmed the need to return to a system founded in the belief that it should, “Do no harm.” According to this very important report;

More people die in a given year as a result of medical errors than from motor vehicle accidents (43, 458), breast cancer (42,297), or AIDS (16,516). Medication errors alone, occurring either in or out of hospitals, are estimated to account for 7000 deaths annually. Another study, the Harvard study, which
includes 31,000 hospitalizations found that 4% of patients suffer some kind of harm in hospital; 70% of the adverse events result in short-lived disability, but 14% of the incidents lead to death. The economic costs are also huge like $17 billion in excess costs from preventable errors and $37 billion in total costs. As we all know very well the human costs are incalculable. Another study Colorado-based health data company, Health Grades, released a report stating that as many as 195,000 people a year may be dying in U.S. hospitals as a result of preventable errors and most of the current evidence on adverse events comes from hospitals. Most of the current evidence on adverse events comes from hospitals. Based on these findings, almost every tenth patient suffers from adverse effects related to care in hospitals, and those halves of these problems are preventable.

Despite growing interest in the safety of patients today, there is still widespread lack of awareness of the problem events. Capacity for reporting, analyzing and learning from experience is still seriously hampered by lack of methodological uniformity in identification and measurement, inadequate adverse event reporting schemes, weak information systems, insufficient data and fear of professional liability.

Many patients suffer increased pain, disability and psychological trauma or staff may experience shame, guilt and depression after making a mistake, with litigation and complaints imposing an additional burden. The consequences of adverse events in health-care systems are therefore huge. Several important initiatives in the past five years underline the increasing attention being paid to patient safety. However the problem is widespread that it should include nearly all health-care disciplines and actors and thus requires a comprehensive, multifaceted approach. Its improvement demands on involving a broad range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety and safe clinical practice. In addition, despite the magnitude of the problem, understanding and knowledge of the epidemiology of adverse events, frequency, causes, determinants and impact on patient outcomes, and effective methods for preventing them are limited or the existed best practices are changed from country to country, from culture to culture.
Safety is the basic principle and a critical component of quality management. Patient safety has become a major preoccupation in health care systems; it is often measured through rates of adverse events.

Carved out by the IOM is a series of strategies that should result in significant improvements in healthcare quality over the next ten years. The IOM called for:

- Establishment of a Center for Patient Safety within the Agency for Healthcare Research and Quality, developing an understanding of factors leading to medical errors, setting patient safety goals, and tracking and reporting progress on an annual basis
- Institution of a mandatory medical error reporting system that will provide the information needed in order to develop strategies which will result in positive changes in the system
- Pass legislation to extend the peer review privilege in order to encourage active participation by physicians in the investigation of medical errors

In 2001, the IOM released another publication, “Crossing the Quality Chasm: A New Health System for the 21st Century.” In this document, the IOM provided further evidence that the current healthcare delivery system is floundering in its ability to provide quality care on a consistent basis. According to the IOM, this healthcare system “frequently falls short in its ability to translate knowledge into practice, and to apply new technology safely and appropriately.” The IOM calls for the establishment of a 21st century health care system in which care is safe, effective, patient-centered, timely, efficient, and equitable.

In 2005, Joint Commission International partnered with the World Health Organization in the establishment of an international patient safety center, noting in a press release that one in ten patients worldwide are seriously harmed by medical errors. Currently, there are over 42,000,000 Internet sites devoted
to “patient safety.” It is apparent that the public has become acutely aware of the serious issues pertaining to patient safety. Many of these websites contain vital information on medical errors, benchmarking data, risk reduction strategies, and real-life examples of medical errors.

(See Attachment 1 List of Websites)

**Role of Leadership**

Even in the best of healthcare delivery systems, it has become evident that serious errors resulting in patient harm or death can, and will, happen. As the complexity of our systems increase, so does the risk of error. It has been reported in various publications that upwards to 80% of all medical errors are system-related. It is now more pressing than ever for organizations to invest the time, energy and resources necessary in order to develop an effective patient safety program. The Institute for Healthcare Improvement states that, “Leadership is the critical element in a successful patient safety program and is non-delegable.” It further states that the role of leadership is to:

- Establish the value system of the organization
- Set strategic goals
- Align organizational efforts to achieve these goals
- Provide resources for the creation of effective systems
- Remove obstacles for clinicians and staff
- Require adherence to practices which will support patient safety

Key to development of a successful patient safety program is the concept of creating a culture of safety. James Reason references a “just culture” which supports the discussion of errors so that lessons can be learned from them. The critical component of this concept is the need to encourage and support the reporting of any patient safety issue, whether it is an actual event resulting in a negative outcome, or the risk of having such an event. The overall aim of this open communication is to provide for the safety of patients and
employees. Our current healthcare system is plagued with a lack of teamwork, focus on autonomy, and poor communication, all of which have led to fragmentation. The IOM calls for a national focus on research and the development of tools to strengthen the patient safety role and focus of leadership. Through serious dedication and leadership on the part of upper management, an organization can successfully implement a culture of safety.

**Goals and Practices**

In response to patient safety concerns, the National Quality Forum (NQF) published, “30 Safe Practices for Better Health Care.” These include such strategies as adopting standardized abbreviations, utilizing intensivists to manage all general intensive care patients, implementing prophylactic treatment for deep vein thrombosis, and assessment and reassessment of patients for the risk of developing pressure ulcers. The practices identified by the NQF are grouped as follows:

- Creating a culture of safety
- Matching health care needs with service delivery capability
- Facilitating information transfer and clear communication
- Adopting strategies for specific settings or processes of care

In 2003, Joint Commission furthered its position as a leader in the field of patient safety when it developed National Patient Safety Goals that all participating hospitals are required to adopt and implement in order to meet accreditation requirements. The goals encompass a wide variety of strategies, which have been demonstrated to have a significant positive impact on patient safety efforts. These goals include:

- Improve the accuracy of patient identification by using two standard identifiers, neither of which can be the patient’s room number
- Improving the effectiveness of communication among caregivers by
implementing a verbal order “read back” process and adopting a list of prohibited abbreviations

✔ Improving the safety of using high-alert medications by removing concentrated electrolytes from patient care units, limiting the number of drug concentrations available in the organization, and providing safety precautions to prevent interchange of look alike/sound alike medications

✔ Eliminating wrong-site, wrong-patient, wrong-procedure surgeries by adopting a standardized process for marking of the operative site, and by conducting final verification of the site during a “time out” prior to the start of the procedure

✔ Improving the safety of using infusion pumps by identifying those that have potential for free-flow errors

✔ Improving the effectiveness of clinical alarm systems by implementing regular preventive maintenance and testing of alarm systems and ensuring that alarms are activated and are audible to staff

✔ Treating as a sentinel event any nosocomial infection resulting in death or permanent disability

✔ Complying with the Centers for Disease Control (CDC) hand hygiene guidelines

The Patient Safety Officer

Leadership must assess the infrastructure of the organization in order to determine if it provides the necessary structure to sustain a culture of safety. Key to this discussion is consideration being given to creating a Patient Safety Officer (PSO) position whose sole purpose is to promote patient safety. Organizationally, this position should answer directly to senior management and carry full support of Administration and the CEO. An individual with a clinical background, who has the ability to teach and mentor, in addition to possessing analytic skills, should fill the PSO position. The organization must focus efforts on development of a structured Patient Safety program. Establishment of a multidisciplinary Patient Safety Committee, chaired by a senior leader, meeting at least monthly will help sustain the ongoing activities
relative to the program. Committee members must be provided with education regarding patient safety issues, as well as, performance improvement methodologies, which will be necessary in order to implement and sustain changes in the system. Involvement of key members of the medical staff is, also, of utmost importance. Instituting what the IHI has referred to as “Patient Safety Leadership WalkRounds” during which time senior leaders are encouraged to speak informally with caregivers and line staff about safety issues should be considered. Implementation of Safety Briefings is another method to heighten staff awareness of patient safety issues. The content of these briefings should come from information gathered as part of the Patient Safety program, as well as, from the numerous resources now available for this topic.

The role of the Patient Safety Officer should include the following:

✓ Monitor for situations which place the patient and the organization at risk for a negative outcome
✓ Address such situations in a proactive manner
✓ Lead the investigation of significant occurrences such as sentinel events
✓ Aggregate, analyze, and report data obtained through the occurrence reporting system
✓ Collaborate with others on the development of risk reduction and remediation strategies
✓ Provide leadership, Administration, and the governing body with regular status reports on these activities
✓ Educate all levels of staff on the importance of the patient safety program and the occurrence reporting system and regarding initiatives undertaken based upon information received through the occurrence reporting system.

**Organization-Wide Patient Safety Program**

The organization-wide patient safety program is designed to reduce medi-
cal errors and hazardous conditions by utilizing a systematic, coordinated and continuous approach to the improvement of patient safety through the establishment of mechanisms that support effective responses to actual occurrences; ongoing proactive reduction in medical errors; and integration of patient safety priorities in the design and redesign of all relevant organizational processes, functions and services. Therefore the scope of the program could be summarized as below;

☆ Activities & functions relating to patient safety
☆ Participating sites, settings, and services
☆ Structure
☆ Management of the Program
☆ Components (safety-related committees, functions)

The main steps that of a well-designed Patient Safety programme are:
☆ Definition of terms
☆ Routine safety-related data collection and analysis
  o Incident reporting
  o Identification, reporting, and management of sentinel events
  o Medication error reporting
  o Infection surveillance
  o Facility safety surveillance
☆ Staff perceptions of, and suggestions for improving patient safety
  o Staff willingness to report errors
☆ Patient/family perceptions of, and suggestions for improving patient safety
☆ Safety improvement activities
☆ Prioritization of improvement activities
☆ Proactive risk reduction
☆ Reporting of results
  o To the Patient Safety Program
  o To organization staff
  o To executive leadership and the governing body

☆ Mechanisms for coordination
  o Among components of the Program
  o Among the departments
  o Across the organization

☆ Communicating with patients about safety
  o Patient education
  o Informing patients about their care

☆ Staff education
  o Safety-related orientation & training
  o Team training

The steps of building an organization-wide programme in a health care facility are as follows;

- Clear definition of the purpose of the program
- Involvement of the hospitals early in the measurement program efforts, preferably in the planning stages.
- Provide them an opportunity to understand the methodology including indicator definitions,
- Provide an opportunity for them to review their own data in order to identify any potential issues with coding or characteristics of their patient population that may present a measurement challenge.
- Arrangement for audits to assure accuracy and completeness of reporting,
- Evaluation of both data quality and content. Before finalizing indicator selections it is helpful, especially with new measurement programs, to begin with data explorations focusing on overall data quality and content.
- Utilize comparative benchmarks
- Include an evaluation component

However there is a need for international standardization of terminology in definition, common methods for measurement and compatible reporting of adverse events. There are some international agencies such as “National Patient Safety Foundation and “Agency for Health Care Research and Quality (AHRQ) in USA or “Quality in Australian Health Care Study” were created awareness among politicians that influenced the implementation of a comprehensive patient safety programme in Australia or in the UK. However research has not been limited to establishing the prevalence of adverse events or medical errors so AHRQ agenda now states that we need more information in topics such as;

- The epidemiology of errors, for instance the types and rates of errors in different health-care settings;
- The infrastructure to improve patient safety, for example the analytic capacity and organizational culture required;
- Information systems, for instance development of common definitions of a reporting system and how to evaluate its success
- Knowledge about which interventions should be adopted and how to encourage adoption of patient safety practices

**Building a reporting system**

Efforts must be put forth to develop efficient and effective reporting mechanisms for medical errors or high-risk situations which have been identified as posing potential to harm the patients. The actual process for reporting an occurrence or high-risk situation should be as simple as is possible. For hospital-level measurement, the following data sources are typical:

- Clinical data (e.g., medical record abstraction, laboratory data, pharmacy data, electronic medical record)
- Administrative data (refers to billing, or claims data)
- Survey data (e.g., patient satisfaction survey results, employee satisfaction)
Operational data (e.g., licensure, ownership, staffing levels, type of staff)

In order to build a healthy atmosphere for reporting, the following elements are critical:

1. Assess staff willingness to report errors.
2. Promote a non-punitive environment.
3. Develop a tool for occurrence reporting (perhaps, anonymous).
4. Educate management and staff on the rationale for reporting errors.
5. Establish a baseline on errors.
6. Involve front-line staff in corrective actions.
7. Monitor the effectiveness of changes.
8. Reward staff for reporting.
9. Implement “safety briefings.”
10. Solicit staff suggestions regarding impediments to completing their jobs in a satisfactory manner.
11. Promote safe handoffs as patients move through the continuum. (Pierce, 2006)

**Occurrence Reporting**

The most typical reporting method is through the use of an occurrence report. *(See Attachment 2 Example Occurrence Report)* While this is, perhaps, the most common-sense way to collect this information, there is much that needs to be considered in order to make the system effective. Issues to consider include:

Development of an anonymous reporting form which is simple for front line staff members to complete *(See Attachment 3, Anonymous Medication Error Reporting Form)*
- Creation of incentives for reporting
- Adoption of a non-punitive environment which encourages reporting
- Responding in a timely manner to reports and involving front line staff directly involved in the process in actions taken to remedy the situation
- Closing the loop by communicating any performance improvement activities undertaken in response to occurrence report system data

A well-developed occurrence reporting system will capture information on multiple “adverse events,” which include situations such as patient falls, which may have been out of the control of the caregivers. A comprehensive system, supported by a nonpunitive culture and commitment to patient safety will, also, garner reports on situations that were the result of medical errors. This is a broad category that encompasses a myriad of processes and handoffs in the system. Issues that have received much negative press include reports of errors or failures to meet the standard of care pertaining to the following:

- Patient misidentification
- Medication errors related to a variety of issues (i.e. look alike-sound alike drugs, concentrated electrolytes, transcription errors due to no “read back” process for verbal orders)
- Delays in treatment or reporting of critical test results
- Failure to communicate critical patient information across the continuum of care
- Nosocomial infections
- Blood administration errors
- Wrong site, wrong patient, or wrong side surgeries
- Failure to activate alarms on clinical equipment
- Inadequate staffing levels
- Inadequately trained staff
Failure to follow evidence-based medical practices

Errors related to orders that are either illegible, inappropriate, or that contain abbreviations that are frequently associated with dosing errors (i.e. trailing zeros, use of “u” in lieu of spelling out “units”)

Failure to assess patients for level of fall risks or to take appropriate interventions based upon assessed level of risk

Failure to adequately monitor patients having received sedation or anesthesia

While the information gathered via the occurrence reporting will likely cover a wide variety of issues, there are several universal high volume and/or high risk processes that require ongoing monitoring. These include the following:

Blood administration
Medication administration
Sedation and anesthesia
Invasive procedures

In addition to these clinical processes, there are numerous other organizational communication issues, and clinical equipment issues that require ongoing monitoring, as a failure can lead to a catastrophic outcome. These include:

Communication among caregivers
Clinical equipment and alarms
Patient identification
Documentation in the medical record
Assessment and reassessment of patients
Medication reconciliation
International Patient Safety Goals

The purpose of the International Patient Safety Goals is to promote specific improvements in patient safety. The goals highlight problematic areas in health care and describe evidence and expert-based consensus solutions to these problems. Recognizing that sound system design is intrinsic to the delivery of safe, high-quality health care, the goals generally focus on system-wide solutions, wherever possible. The list of the international goals is:

Goal 1 Identify Patients Correctly
Goal 2 Improve Effective Communication
Goal 3 Improve the Safety of High-Alert Medications
Goal 4 Ensure Correct-Site, Correct-Procedure, Correct-Patient Surgery
Goal 5 Reduce the Risk of Health Care–Associated Infections
Goal 6 Reduce the Risk of Patient Harm Resulting from Falls

In this part of the chapter we would like to discuss how to improve patient safety focusing on these goals.

Patient Safety Goal 1: Improve the accuracy of patient identification.

Establishing correct patient identification on admission/first contact.

1) The patient shall be positively identified on admission (for in-patients) or upon the first contact with an administrative staff member/healthcare provider (for out-patients). This step is crucial because all subsequent identification episodes will be based on the information captured in the first contact.

2) In-patients. A tamper-proof, nontransferable identification band (hereafter referred to as “armband”) shall be affixed to in-patients – preferably during the admission process. Alternately, armbands shall be sent with admission paperwork to the patient location and affixed without further delay. In this case, the person who actually applies the armband must reconfirm the patient’s identify prior to application.
3) Out-patients. With few exceptions, out-patients do not wear armbands. The exceptions (i.e. those out-patients who must wear armbands) are:
   a. Patients in Emergency Services
   b. Patients having procedures with procedural moderate sedation/analgesia or with deep sedation/general anesthesia.
   c. Chemotherapy and blood transfusion patients.

**Armbands.**

1) The armband shall be applied (in order of preference):
   a. As a “bracelet” on the patient’s wrist or ankle.
   b. With tape (appropriate to the patient’s condition/allergies) to another visible location on his/her body or clothing, if application as a “bracelet” is impossible (i.e. if patient is limbless, or is extremely agitated and harms him or herself by trying to remove the bracelet, etc.).
   c. Visibly, with tape, to the patient’s bed/crib, if neither of the above applications is possible, (i.e. if the patient has burned extremities, or is an extremely premature newborn). In these cases, it is not to be taped to monitors or other equipment or furniture.

2) If the armband is illegible, missing, or contains information that is incorrect, the test, treatment, medication, procedure, etc. will not be performed until the information is corrected and the patient is accurately identified.

3) The individual who removes an armband or who notices it is missing or illegible is responsible for reapplying it or for notifying an appropriate staff member who can reapply it. The person who reapplies the armband is responsible for reconfirming the patient’s identification.

The armbands and/or red Blood Bank bands may be intentionally and carefully removed in the OR during surgery if they obstruct access to the patient’s operative site/patient’s IV, etc. In this event replacement bands must be reapplied before the patient leaves the or the person who removed the band(s) must be witnessed when reapplying them and both individuals must reconfirm the patient’s identification. Nurses in PACU and other post-operative receiving units shall not accept patients for continued care if the correct armbands are
not securely on the patient as specified above at the time of transfer.

4) Discharge/death. The patient can remove his/her armband after discharge. In the event of death, the armband shall remain on the patient’s body.

**Required patient identifiers.**

At least two patient identifiers are required to establish positive patient identification. They are:

1) For all patients (except for newborn infants):
   a. Name (first, middle and last)

   The patient’s medical record (MR) number is not considered a primary identifier because patients are not expected to be able to state this number when asked to self identify.

   An additional identifier must be used in rare cases when all three patient identifiers are the same for more than one person (e.g. two dependent sons might have the same three names, the same badge number, and the same relationship to the employee). When SGH employees are aware of such situations they must also use the patient’s birthdate as an identifier.

   Note 3: Room and/or bed number are never used as patient identifiers.

2) For newborn infants:

   Positive patient identification:

   1) Is expected each time a healthcare provider contacts a patient.

   2) Is **required**:

       - Upon admission/first contact
       - Prior to administration and/or dispensing of all medications.
       - Prior to transfusion of blood/blood products.
Prior to performance of any surgical/invasive procedure.
Prior to collection of any bodily fluid sample, including blood.
Prior to performance of any X-ray or imaging procedure.
Prior to and upon completion of transport/transfer/discharge.
Upon death.

3) May be deferred in a true emergency when the patient’s life or health is in extreme danger, however, it must be ascertained as soon as the event permits.

The active positive identification procedure.

The steps to positively identify a patient should be undertaken in the following order (if the first is not possible, undertake the second):

1) Ask the adult competent patient to tell you their three names, employee badge number, and relationship to the employee. Ensure it matches the information on his/her armband and other record(s), as appropriate, e.g. Medication Administration Record, blood transfusion records, lab requisition form, consent form, etc.

2) If the patient is unable to provide the three identifiers verbally (e.g. if he/she has been sedated, is comatose, is cognitively impaired, has a communication/language deficit, is intubated, is sleeping, is a child who cannot respond, etc.) refer to the information on his/her armband. Ensure that information matches other record(s), as appropriate, e.g. Medication Administration Record, blood transfusion records, lab requisition form, consent form, etc.

3) If the patient is unable to provide the three identifiers and is not wearing an armband (e.g. in out-patient areas) the test, treatment, procedure, investigation should not be done and medication should not be given, until a member of the patient’s family is contacted by a nurse or a health care advocate to positively identify of the patient.

Whenever possible, children should be asked to state their own name, but
this ability alone (if they answer correctly) is not sufficient for positive identification.

Staff members should never rely exclusively on their own memories to identify patients. This method may serve to substantiate positive identification, but is not to be used as the sole source of information.

“Name Alert”. The name alert process will be initiated on the unit when two or more patients have the same name and/or two or more patients have names that look or sound very much alike. In these cases, the unit ward clerk, supervisor, or charge nurse should mark items such as the addressograph, the patient’s medical record (“chart”), and assignment sheet, etc. with the words “name alert”.

Labeling of medical records with correct patient identification. Check addressograph labels to ensure the patient information is correct before using them on medical records, test requests, prescriptions, etc.

Labeling of specimens. Label specimens in the room or in the immediate vicinity of the source patient and never in another location. Check carefully that the ID information matches the patient and the clinician’s order. Always finish labeling one patient’s specimens before collecting/labeling another set of specimens.

Numerous unit- or event-specific special precautions are described in other SGH policies and procedures.

Goal 2 Improve Effective Communication

Here are some steps to standardize and document the verbal and telephone orders given by the physicians to provide prompt service and avoid misinterpretation and inefficient documentation.
<table>
<thead>
<tr>
<th>STEP 1</th>
<th>Verbal/telephone orders shall only be given by physicians.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEP 2</td>
<td>The order shall be accepted by the appropriate personnel.</td>
</tr>
<tr>
<td>STEP 3</td>
<td>Verbal/telephone order must be read back to the ordering physician by the first person.</td>
</tr>
<tr>
<td>STEP 4</td>
<td>The order shall be written on the physician order sheet with the names of:</td>
</tr>
<tr>
<td></td>
<td>★ Ordering physician</td>
</tr>
<tr>
<td></td>
<td>★ The receivers name, signature and ID number.</td>
</tr>
<tr>
<td></td>
<td>★ The date</td>
</tr>
<tr>
<td></td>
<td>★ The time and signature by the person implementing the order.</td>
</tr>
<tr>
<td>STEP 5</td>
<td>In critical areas, the order shall be relayed by the accepting personnel to Registrar on Duty.</td>
</tr>
<tr>
<td>STEP 6</td>
<td>All telephone/verbal orders must be signed and dated by the physician within 24 hrs.</td>
</tr>
</tbody>
</table>

**Goal 3 Improve the Safety of High-Alert Medications**

**Medication Safety and Stability:**

Ordering/distribution/administration/monitoring the effects model can be used for medication administration. Specifically, one would consider the following:

- Ordering – legibility, use of abbreviations, correct dose and frequency, appropriateness of the medication
- Distribution – pharmacy placing the correct medication in the correct patient’s bin or medication drawer, medications that may be mistakenly administered in an alternate route (i.e. IV rather than via a feed-
ing tube) are clearly marked with the route

- Administration – right patient, medication, dose, time, and route
- Monitoring the effect – adverse drug reactions, food/drug or drug/drug interactions

Look Alike/Sound Alike Medication Names

There are a multitude of steps involved in the medication delivery system, any one of which can fail and lead to a medication error. Problematic issues include:

- Legibility
- Unclear dose expressions to include the use of a trailing zero (X.0) or a decimal point without a leading zero (.X), both of which can result in a medication overdose
- Dangerous abbreviations such as “QD” which may be misread as part of the medication dose, resulting in a medication overdose
- Range orders (“Demerol 25-50 mg IV every 3-4 hours prn pain), which places nurses in the position of “prescribing” the medication, in essence, as they choose which dose and which time to administer the medication

While all of the above-noted issues have a negative impact on the medication delivery system, WHO selected Look-Alike, Sound-Alike Medication Names as one of the nine problems to be addressed by Patient Safety Solutions. As medical technology increases, so does the need for new medications. In 2004, the US reported having in excess of 33,000 trademarked and 8,000 nonproprietary (generic) medication names. Both The Joint Commission and the Institute for Safe Medication Practices have posted look-alike, sound-alike (LA/SA) medication lists. Note the use of “tall man lettering” which differentiates the following medications from one another:

- humALOG versus humULIN
- epINEPHrine versus epHEDrine
- diTROPan versus diPRIVan
- novoLIN versus novoLOG
In addition to the sound-alike medications, there has been a considerable amount of attention given to “look-alike” medications which could be easily mistaken for one another. In 2006, there was a very tragic medical error which occurred in the US in which six premature infants were given Heparin Sodium Injection 10,000 units/mL rather than Hep-Lock Solution10 units/mL. It was reported that three of the infants died as a result of this error.

In spite of considerable efforts to the contrary, new medications continue to be approved with names that are similar to that of another medication. Strategies to reduce the risk of LA/SA errors include:

- Requiring that all prescriptions and medication orders include the brand name and generic name, dosage form, strength, directions, and indications
- Storing LA/SA medications in separate areas from one another and NOT using an alphabetic storing system in the Pharmacy
- Using “tall man” lettering in order to emphasize the spelling differences
- Providing regular LA/SA education to staff
- Reviewing each new medication closely in order to ascertain that it will not pose a LA/SA risk before adding it to the formulary
- Placing different colored labels or using different colored syringes for medications which can only be given one route - e.g. oral medications, so that a staff member does not inadvertently give the medication intravenously
- Printing clear alert messages for staff when dispensing medications from the Pharmacy
- Limiting the practice of accepting verbal or telephone orders to emergent situations only, as this is an area that is high risk for a sound-alike error being made in transcription
- Labeling each medication with both the brand name and generic name
- Providing patients with detailed education regarding their medications so that they are alert to the possibility of a LA/SA error
- The followings are some looks alike, sounds alike drug names that when ordering these drugs the staff should be careful.
Some interventions that could be useful to endure medication safety and stability are presented below.

**Repacking and Labeling:**

1. Repacking and labeling of medication is always carried out under the direct supervision and responsibility of a licensed pharmacist;
2. Only one medication is to be repacked at a time;
3. Medication must never be touched by bare hands or fingers during the process of repacking;
4. Unit dose dispensed medication labels must be computer generated.

<table>
<thead>
<tr>
<th>Lasix</th>
<th>Losec</th>
</tr>
</thead>
<tbody>
<tr>
<td>CİPRALex</td>
<td>CİBADRex</td>
</tr>
<tr>
<td>Sekrol</td>
<td>Ceclor</td>
</tr>
<tr>
<td>Zantac</td>
<td>Zyrtec</td>
</tr>
<tr>
<td>FLOmax</td>
<td>FOSAmax</td>
</tr>
<tr>
<td>Lamisil</td>
<td>Lacipil</td>
</tr>
<tr>
<td>Pritor</td>
<td>Lipitor</td>
</tr>
<tr>
<td>Trileptal</td>
<td>Trivastal</td>
</tr>
<tr>
<td>İnsidon</td>
<td>İncidal</td>
</tr>
<tr>
<td>Xorox</td>
<td>Zocor</td>
</tr>
<tr>
<td>DOPamin</td>
<td>DOBUTamin</td>
</tr>
<tr>
<td>HOLoxan</td>
<td>ENDoxan</td>
</tr>
</tbody>
</table>

...
and not handwritten and attached to all prepacked medications in a unit dose

5. Lot number will be written in unit dose dispensed medication if loose tablet is repacked.

6. Liquid medication expires after one month when prepacked in smaller volumes;

The Pharmacist must check and ensure the following information on all re-packaged medication labels:-

1. Correct Name of Medication Issued;
2. Strength of Medication;
3. Medication Amount;
4. Lot Number;
5. Expiry Date which is one year after repackaging unless the expiry date of the manufacturer’s expiry date is less than that.

The Pharmacist must check that the repackaged medication is sealed correctly:-

1. Re-packaged medication must be placed correctly in the designated area of the Pharmacy;
2. A logbook must be maintained as to the Pharmacist/Pharmacy Technician repacked the medication and a second Pharmacist double check.

Multidose Medication Stability;

Multiple Dose Vial:-
Once a multi-dose vial is opened, used or the seal is broken, it must be dated and refrigerated unless otherwise specified by the manufacturer and will expire at the first of the following dates:
1. The manufacturer’s expiry date;
2. The validity date specified after reconstitution.
3. A multi-dose vial must be discarded if there are any of the following:-
4. Any color change;
5. Any visible turbidity;
6. The rubber stopper integrity is compromised;
7. Leaks from the vial;
8. Deposits/sedimentations/precipitations have formed at the bottom of the vial or are suspended in the vial;

Another international patient safety goal is the improvement of high-alert medications. Within the context of medication safety policy, all high-risk medicines stocks should be removed from the emergency trolleys, bags, and floors.

**Goal 4 Ensure Correct-Site, Correct-Procedure, Correct-Patient Surgery**

The surgical verification process must be interdisciplinary. All members of the team must be involved in the final verbal verification process. All activity in the room should cease and allow for this participation. The procedure should be stated aloud, exactly as it appears on the informed consent form. Another intervention that could ensure correct-site, correct-procedure, correct-patient surgery is Universal Surgical Protocol. It is given below.

**Universal Protocol For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery**

⭐ Wrong site, wrong procedure, wrong person surgery can be prevented. This universal protocol is intended to achieve that goal. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by more than 40 professional medical associations and organizations.
In developing this protocol, consensus was reached on the following principles:

- Wrong site, wrong procedure, wrong person surgery can and must be prevented.
- A robust approach—using multiple, complementary strategies—is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the surgical team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standardized approach using a universal, consensus-based protocol will be most effective.
- The protocol should be flexible enough to allow for implementation with appropriate adaptation when required to meet specific patient needs.
- A requirement for site marking should focus on cases involving right/left distinction, multiple structures (fingers, toes), or levels (spine).
- The universal protocol should be applicable or adaptable to all operative and other invasive procedures that expose patients to harm, including procedures done in settings other than the operating room.

In concert with these principles, the following steps, taken together, comprise the Universal Protocol for eliminating wrong site, wrong procedure, wrong person surgery:

**Pre-operative verification process**

- Purpose: To ensure that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other and with the patient’s expectations and with the team’s understanding of the intended patient, procedure, site and, as applicable, any implants. Missing information or
discrepancies must be addressed before starting the procedure.

Process: An ongoing process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the “time out” just before the start of the procedure.

Marking the operative site

Purpose: To identify unambiguously the intended site of incision or insertion.

Process: For procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple levels (as in spinal procedures), the intended site must be marked such that the mark will be visible after the patient has been prepped and draped.

“Time out” immediately before starting the procedure

Purpose: To conduct a final verification of the correct patient, procedure, site and, as applicable, implants.

Process: Active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a “fail-safe” mode, i.e., the procedure is not started until any questions or concerns are resolved.

Goal 5 Reduce the Risk of Health Care–Associated Infections

Although the contribution of infection control programs to high-quality patient care has long been recognized, the importance of these programs for an increasingly complex patient population has become even more prominent. Hospital acquired or nosocomial infections pose a major threat of excess morbidity and mortality to patients hospitalized for management of other diseases. The detection of such infections, surveillance of their frequency and identification of their predisposing factors are essential prerequisites for the design and implementation of cost effective control and preventative measures.
Infections are major threats to patients and cause unexpected morbidity and mortality. The components of an infection control programs are surveillance, relevant policies and procedures, in-service training programs, hospital employee programs, and selection of the most appropriate antibiotic in order to prevent resistance, and systematic monitoring and evaluating of infections. Within these efforts, some activities of designing, measuring, assessing, and improving organizational performance in the surveillance, prevention, and control of infections should be also performed in infection control unit. Information about infection control indicators should be collected through a well-established computerized system and through the concurrent medical record review function, and then summarized and should be used for further evaluations.

The principal goal of the infection control program is the prevention of nosocomial infection in patients, personnel, and visitors. In order to provide a safe environment for patients and personnel, the health care organizations should adopt a program of infection control designed to involve and affect every member of the hospital in the surveillance, prevention and control of nosocomial infection.

The objectives of the program are:

- To objectively and systematically monitor and evaluate the quality and appropriateness of all activities as they relate to infection control for patients, staff, and visitors
- To assure that infection control policies and procedures are consistently being followed throughout the hospital
- To measure the effectiveness of procedures for patient and healthcare providers
- To monitor implementation of corrective actions taken to address identified problems
- To review and/ or update infection control policies at least every two years.
Hand Hygiene is the single most important means of preventing the spread of infection and hospital-acquired infections. The purpose of a hand hygiene program is to minimize cross-infection by the removal of transient organisms from the skin of healthcare personnel as a result of effective hand-washing and to prevent the transmission of potentially pathogenic organisms.

The hand hygiene indications are:

With the exception of urgent situations in which hand hygiene cannot be achieved, staff shall always cleanse their hands as follows:

1. On arrival for duty at the hospital, to remove microorganisms from outside.
2. On completion of duty, before leaving the hospital, to avoid taking hospital germs at home.
3. Before entering and leaving a patient’s room.
4. Before and after each personal bodily function, e.g., eating, blowing nose, urination/defecation, combining hair or scratching
5. Whenever hands are obviously soiled.
6. Before and after any physical contact with a patient.
7. After contact with a patient’s mucous membranes, blood, body fluids, secretions or excretions or other potentially infectious materials, i.e., regulated waste and cultures.
8. After touching equipment or surfaces that are likely to be contaminated with virulent or epidemiologically important microorganisms, e.g., urine measurement jugs, suction, equipment, sarinals, and bedpans.
9. Before and after wearing gloves
11. Before preparing or serving food to a patient.
12. Before and after handling patient care devices such as intravascular catheters, urinary drainage systems and respiratory equipment currently being used.
13. After leaving a contaminated area such as a soiled utility room.
14. As a general rule, when in doubt, health care workers should always wash their hands.

Hand Washing is the vigorous rubbing together of lathered hands for at least 10 to 15 seconds, followed by thorough rinsing under stream of clean water: and in a hospital setting it is achieved using antimicrobial products.

Hands must be washed before applying and following the removal of disposable gloves. Standard Precautions indicate the use of disposable gloves when in contact with:

- Blood or body fluids.
- Secretions.
- Excretions.
- Mucous membranes or non-intact skin.

**Duration Of Hand Washing**

1. Two minutes at the beginning of duty.
2. Two minutes before high-risk procedures such as IV handling, catheter care.
3. Two minutes after heavy contamination such as dressing changes.
4. Ten to fifteen seconds for other routine hand washing.
5. Five minutes scrubs are required for pre-operative hand washing.

**Products For Hand Washing**

1. **Plain Soap:** Liquid soap in sealed dispensers which shall be emptied, thoroughly cleaned and refilled by housekeeping staff with a completely new solution on a regular basis. It removes a large number of transient organisms. It is relatively infective against resident organisms.

2. **Product Containing Antimicrobials (Antiseptic)** A selection of antimicrobial hand washes approved by the Infection Control Commit-
Indications For Hand Washing With Plain Soap.
1. During routine patient care, after visiting the bathroom, or any public area.

Indications For Hand Washing With Antiseptic
1. Before invasive procedures
2. Before and after leaving isolation rooms
3. In the newborn nursery
4. In the intensive care units.
5. Before and after leaving the room of a patient with burn.

Hand Washing Facilities
1. A sink with hot and cold water (preferably with a mixer tap and temperature control devices, and foot or elbow operated taps), a liquid soap dispenser and wall mounted paper towel dispenser. Use of bar soap is discouraged unless provided in a manner that keeps the soap drained and dry between use.
2. Hand washing facilities should be located in or just outside every patient room. In non-patient care areas hand-washing facilities should be located in close proximity to work areas hand washing facilities.
3. Shall be located inside isolation rooms and in the anterooms of isolation rooms.
4. Paper towel containers, shall be refilled by the housekeeping staff daily or as often as necessary to maintain an adequate supply.

Hand Washing Technique
1. Rings and/or nail polish shall not be worn while ion duty (fingernail polish cracks provide microscopic areas for breeding bacteria).
2. Although the amount of plain soap used does not appear to influence the
result, antimicrobial products have a dose response, and 3-5 ml is recommended.

3. Wet hands with running waters.

4. Apply hand-washing agent and thoroughly distribute over hands.

5. Rub hands together vigorously for 10-15 seconds, generating friction on all surfaces of the hands and fingers.

6. Debris shall be removed from under the fingernails because the subungual area has higher microbial counts and contamination of the hands can increase when gloves provide a warm, moist environment.

7. Duration of hand washing (10-15 seconds) is important, not only for mechanical action but also to allow antimicrobial products sufficient contact time to achieve the desired effect when they are used.

   **NOTE:** Wash all surfaces thoroughly, including wrists, palms, backs of hands, fingers and under the fingernails.

8. Hands shall be thoroughly rinsed to remove residual soap, and then dried.

9. When the sink does not have foot control or an automatic shut off, a dry paper towel shall be used to shut off the faucet to avoid re-contaminating the hands.

10. Paper towels shall be dispensed from the holders that require the user to remove them one at a time. Hand-drying materials shall be placed near the sink in an area that will not become contaminated by splashed water.

11. Regular soap is adequate to wash off most bacteria and viruses.

12. Hand cleansing with an alcohol-based waterless hand antiseptic cleanser can be accomplished by applying a thumbnail sized amount of antiseptic cleanser into palm and briskly rubbing over all surfaces and under nails until dry.

**Goal 6 Reduce the Risk of Patient Harm Resulting from Falls**

*The purpose of an effective fall program in a health care organization is;*

1. To minimize the patient risk of falling;
2. To identify the risk and target the prevention of falls;
3. To educate caregivers, patients and family regarding fall precaution.

We can define the fall as;

☆ An outward event, which result in the patient coming to rest unintention-ally on the ground or other lower surface;

☆ An unintended event resulting in a person coming to rest on the ground/ floor or other lower level (witnessed) or is reported to have landed on the floor (un-witnessed) not due to any intentional movement or the extrinsic force such as stroke, fainting and seizures. The categories of the fall are;

Accidental Falls – occur when a patient fall unintentionally, for example they may slip; or fall because of failure of equipment or by environmental factors such as spilled water or urine on the floor;

Unanticipated Physiologic Falls: -

Occur when the physical cause of the falls is not reflected in the patient risk factor of falls;

This is cause by physical conditions that cannot be predicted until patient falls, for example; fall due to fainting or pathological fracture of the hip.

Anticipated Physiologic Fall – occur in patients whose score on risk assessment scale indicates that they are at risk of falling

Intrinsic Risk Factors – integral to the patient system, many of which are associated with age related changes;

Extrinsic Risk Factors – External to the system and relating to physical environment;

History of falling – the patient has fallen during present hospital admission, immediate history of physiological falls, such as seizures or impaired gait prior to admission. History of fall for the last three (3) months;
Secondary Diagnosis – more than one diagnosis listed on patient’s file upon admission and during the period of stay in the hospital;

Ambulatory Aid – patient was admitted using crutches, cane, and walker. Patient ambulates clutching onto the furniture for support. This include the usage of the device during the course of stay in the hospital;

IV Fluids/Heparin Lock – patient on intravenous fluids or a heparin lock from admission or during the course of stay in the hospital;

GAIT/Transferring: -

Normal Gait – the patient is walking with head erect, arms swinging freely at the side and striding without resistant;

Weak Gait – the patient is stopped but is able to lift the head while walking without losing balance step are short and the patient may shuffle;

Impaired Gait – the patient may have difficulty rising from the chair, attempting to get up by pushing on the arms of the chair or by bouncing (i.e. using several attempts to rise). The patient grasp onto the furniture use person as support, and walking aid for support, cannot walk without assistance.

Mental Status (oriented to own ability) – mental status is measured by checking the patient’s own self assessment of his/her own ability to ambulate. Patient reply judging his/her own ability is consistent with the doctor’s order. Unrealistic response, not consistent, patient over estimate his/her own abilities and to be forgetful of limitations.

We can list the indications of fall as;

1. Partial Paralysis
2. Loss of Limb
3. Blindness
4. Deafness
5. Impaired Mobility
6. Confusion/Disorientation
7. Sedation/Anesthesia
8. Slow Reaction Time
9. Lack of Coordination
10. History of Syncope
11. Convulsion/Seizures
12. Transient Ischemic Attack (TIA)
13. Nocturia
14. 70 years or Older
15. Recent significant blood loss
16. Previous fall
17. Other Physical Limitation or Impaired Sensorium

A health care organization needs to follow the following instruction in order to reduce the Risk of Patient Harm Resulting from Falls:

All patients admitted with the following conditions must have Morse Scale Assessment:

- History of falls;
- More than one medical diagnosis;
- Using ambulatory aids;
- Receiving IV infusion and heparin locked;
- Impaired gait, weak gait;
- Mental deterioration.

Morse Scale Assessment (MSA) must be completed within 8 hours upon patient admission;

A risk level must be completed after Morse Scale Fall (MSF) score;
A recommended action shall be initiated after the Morse Scale and Risk Level Score;

Staff awareness thru education and in-services on prevention and general safety measure on falls;

Patient and family education regarding fall preventions: -

   Refer to Patient Teaching Center (PTC) during working hours.

   Occurrence Variance Report must be initiated whenever a fall occurs.

Upon Admission: -

   The staff nurse will conduct assessment to all patients using Morse Fall Scale

Education: -

Patient and family education about the risk of falling, safety issues and their mobility limitations: -

   Teach patient to make position changes slowly;
   Orientation of patient to bed area ward facilities and how to get help;
   Refer to PTC for assistance if needed.

Environmental Issues: -

   Decrease environment risk, obstacles and clutter;
   Ensure areas have adequate lighting;
   Keep all furniture, stable beds must be locked always;
   A grab bars inside the toilet;
   Alarms and call bell in place are functioning.

Elimination: -

   Placing patients with urgency near the toilets;
   Frequent checking of patients who are receiving laxatives and diuretics;
Make a routine schedule of toileting risk patients.

Medications: -

Periodic review of prescribed medication by the physician (i.e. anti-hypertensive and anti-depressant);
Limit combination of medications when possible (i.e. sedatives, analgesia and etc.)

Mobility: -

Provide physical therapy;
Assist in ambulation high risk patient; don’t let them walk alone;
Use non-skid slippers or shoes while walking.

Mental State: -

Re-orient confused patient: -
Moving confused patient near the nurses station;
Use family member to sit with the confused patient;
Provide low bed positioning.
Orient patient to the hospital environment.

Bed Rest: -

Bed in low position;
Bed brakes are in place;
Personal items and belongings within the patient reach.

Wheelchairs and chairs: -

Use safety straps on seat belts;
Use of geriatric chairs;
Select suitable chairs with arm rest with appropriate height for rising and sitting.
Staffing Concern: -

- Use fall precaution sign outside the patient door;
- Adjust allocation to observe fall precaution;
- Demonstrate the use of call bell to patients and ensuring it is within reach;
- Involve the family in care;
- Communicate the patients “at risk” status during shift report.

When to conduct Risk Assessment and Re-assessment: -

- Upon admission;
- Changes in patient status;
- Whenever a fall occurs;
- Periodically during hospital stay when transported or transferred to other units.

Documentation: -

- Morse Fall Scale;
- Occurrence Variance report;
- Nurses Notes.
Morse scale is given below

<table>
<thead>
<tr>
<th>History of falling</th>
<th>No</th>
<th>Yes</th>
<th>0</th>
<th>25</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary diagnosis</td>
<td>No</td>
<td>Yes</td>
<td>0</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Ambulatory aid</td>
<td>none/bed rest/nurse assist</td>
<td>crutches/cane/walker furniture</td>
<td>0</td>
<td>15</td>
<td>30</td>
</tr>
<tr>
<td>Intravenous therapy/ heparin lock</td>
<td>No</td>
<td>Yes</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Gait</td>
<td>normal/bed rest/wheelchair weak impaired</td>
<td></td>
<td>0</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Mental status</td>
<td>oriented to own ability overestimates / forgets limitations</td>
<td></td>
<td>0</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

Definition of Variables for the Morse Scale

History of falling
Yes (scored 25) if a previous fall is recorded during the present admission or if there is immediate history of physiological falls (i.e., from seizures, impaired gait) prior to admission.

Secondary diagnosis
Yes (15) if more than one medical diagnosis is listed on the patient chart.

Ambulatory aids
Scored 0 if patient walks without a walking aid even if assisted by a nurse or is on bed rest.
Scored 15 if ambulatory with crutches, cane, or walker.
Scored 20 if clutches for support.
**Intravenous therapy**

Scored 20 if has an IV apparatus or heparin lock.

**Gait**

Normal gait scored 0 if patient is able to walk with head erect, arms swinging freely at the side, & strides unhesitantly.

Weak gait scored 10 if patient is stooped but able to lift head while walking. Furniture support may be sought but is of feather-weight touch, almost for reassurance. Steps are short, and the patient may shuffle.

Impaired gait scored 20 if patient is stooped, may have difficulty rising from the chair, and attempts to rise by pushing on the arms of the chair and/or by “bouncing”. The patient’s head is down, and because balance is poor the patient grasps the furniture, a person, or walking aid for support and cannot walk without assistance. Steps are short and patient shuffles. If patient is wheelchair-bound, the patient is scored according to the gait used when transferring from the wheelchair to the bed.

**Mental Status**

The patient is asked if s/he is able to go to the bathroom alone or if she/he is permitted up. If the patient’s response is consistent with the ambulatory orders on the Kardex, the score is 0.

If the response is not consistent with the orders or if the patient’s assessment is unrealistic, score is 15. Each institution can determine its own cut-off for high risk or address each targeted (greater than 0) risk factor.

**Addressing Patient safety Issues**

Addressing the high volume/high risk processes of the hospital is an enormous undertaking. It is important to build in a system that has multiple safety-checks. Even the best of systems can still result in what James Reason describes as a “latent failure.” His well-known diagram of the “Swiss cheese” model of complex systems failure has been widely used in discussions pertaining to medical errors (*See Attachment 4, Diagram of Model*). Reason’s theory is grounded in the belief that medical errors are the result of systems failure and not solely based upon the actions of an individual. He theorizes that serious medical errors are the result of the combination of latent...
and active failures. Latent failures are weaknesses built into a system due to poor design or decisions and which weaken the system’s defenses. Active failures are actual errors made by individuals providing the service or care. If these two forms of failure align, the result can be a catastrophic incident resulting in patient injury or death. Reason’s “Swiss cheese” diagram depicts the process of failures at successive levels of defense by aligning the holes in the cheese to demonstrate the vulnerability in the system, which results in the disaster. This model can be transposed upon the complex healthcare delivery system in which there are multiple opportunities built in to catch an error but which, even in the best of organizations, can fail.

Given the inordinate complexity of the healthcare delivery system, it is critical to be able to analyze each step on an individual process. For example, when evaluating the blood administration process the following aspects of care must be evaluated:

- Ordering
- Distribution
- Administration
- Monitoring the effects

The monitoring of this high-risk process starts with the physician’s order. The medical staff may have already established criteria for blood administration. Therefore, before a physician orders blood, he needs to determine whether or not the patient’s hemoglobin and hematocrit are low enough to warrant administration of blood. The administration of blood is a high-risk process, which can result in patient injury or death if the patient suffers a transfusion reaction. In addition, blood products are scarce in most parts of the world and are quite expensive to process. Thus, there is a need to monitor the ordering component of this process.

The process for distributing the blood is multi-phasic. The nursing unit must communicate to the lab that the physician has ordered the blood. The lab
must, in turn, draw specimens for the type and crossmatch. The lab technician may place a special armband on the patient at this time, which will be used to verify that the correct patient is receiving the blood once it has been released from the lab. The lab must make certain that they are crossmatching blood for the correct patient with the correct blood specimen. When the blood is released from the lab to the nursing unit, the nurses must check to be certain they are receiving the correct unit of blood for the patient. As is demonstrated by this discussion, there are multiple components to the distribution aspect of blood administration.

Once the nurse goes to the patient’s room to hang the blood, he or she must first verify that the correct unit of blood is being hung for the correct patient. Once that has been verified, the transfusion begins. As the development of a transfusion reaction is a significant event, the nurse must monitor the patient closely while the unit is running. The patient’s vital signs will be monitored for any sign of a reaction. It is, also, important that the nurse run the transfusion in over an appropriate amount of time. If the unit hangs for too long, the blood begins to break down, which poses a risk to the patient. All of these issues are a clear indication of the need for monitoring the administration of blood, as well as, to monitor the effects of the transfusion.

As is evidenced by the previous discussion, just in the blood administration process alone, there are numerous steps involved in the process. There is the possibility for an error to be made at any of the steps. Blood administration, in particular, has the potential to result in permanent injury or death should a patient inadvertently receive the wrong unit of blood.

**Facts about Speak Up Initiatives**

In March 2002, The Joint Commission, together with the Centers for Medicare and Medicaid Services, launched a national campaign to urge patients to take a role in preventing health care errors by becoming active, involved and informed participants on the health care team. The program features brochures, posters and buttons on a variety of patient safety topics. Speak Up encourages the public to:
Speak up if you have questions or concerns, and if you don’t understand, ask again. It’s your body and you have a right to know.

Pay attention to the care you are receiving. Make sure you’re getting the right treatments and medications by the right health care professionals. Don’t assume anything.

Educate yourself about your diagnosis, the medical tests you are undergoing, and your treatment plan.

Ask a trusted family member or friend to be your advocate.

Know what medications you take and why you take them. Medication errors are the most common health care mistakes.

Use a hospital, clinic, surgery center, or other type of health care organization that has undergone a rigorous on-site evaluation against established state-of-the-art quality and safety standards, such as that provided by The Joint Commission.

Participate in all decisions about your treatment. You are the center of the health care team.

**Speak Up initiatives**

- Help prevent errors in your care
- Help avoid mistakes in your surgery
- Information for living organ donors
- Five things you can do to prevent infection
- Help avoid mistakes with your medicines
- What you should know about research studies
- Planning your follow-up care
- Help prevent medical test mistakes
- Know your rights
- Understanding your doctors and other caregivers

Health care organizations have reported printing Speak Up materials for patient rooms; sponsoring local public service announcements using their own physicians and nurses; including the brochure content in patient informa-
tion materials, websites and community newsletters; distributing material at health fairs; sharing it on closed-circuit patient education television; using it for staff education and orientation; and distributing it on bedside tent cards.

Joint Commission (JCAHO) accreditation standards require that organizations complete a root cause analysis any time a sentinel event occurs or the risk thereof is identified. JCAHO defines a sentinel event as one in which “the event 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.” Such events include:

- Infant abduction or discharge to the wrong family
- Unanticipated death of full term infant
- Rape of a patient
- Hemolytic blood transfusion reactions involving major blood group incompatibilities
- Patient suicide in a setting where round the clock care is provided
- Surgery on the wrong patient or wrong body part

In addition to the above-noted events, Joint Commission encourages inclusion of “near misses” as sentinel events, as well.

**Root Cause Analysis**

*Root cause analysis* (RCA) is a methodology for finding and correcting the most important reasons for performance problems.

RCA is a process analysis method, which can be used to identify the factors that cause adverse events. The RCA process is a critical feature of any safety management system because it enables answers to be found to the questions posed by high risk, high impact events—notably, what happened, why it occurred, and what can be done to prevent it from happening again.

Risk managers and other health care personnel use RCA analytical methods to investigate (‘drill down’ into) serious incidents (including near misses) to
identify the underlying causes and to guide solutions to address safety system failures.

What the RCA analysis therefore provides is a retrospective, inquisitive investigation into the web of factors that may have contributed to the observed outcome. Thus, RCA rarely answers the question of what the root cause was; rather, it provides the investigators with a number of new paths to follow in order to understand performance better. The second challenge lies in the expectation that an RCA can go to the very root of the issue. However, at its best, the technique is capable of identifying the correlates, the enablers and the facilitating factors that precipitate an event.

RCA is a very useful approach, both as a tool and as a promoter of a mindset for understanding performance. By looking back systematically when ‘un-toward’ outcomes are lead to a certain practice style or to a distinct outcome. It is therefore possible to use RCA, not necessarily as a methodology that always enables the identification of the reasons for the observed outcome, but also as an educational tool. In addition to being an educational tool, RCA may also contribute to the consideration of evidence based practices.

The goals of a root cause analysis are to determine:

✓ what happened;
✓ why it happened; and
✓ what can be done to reduce the likelihood of a recurrence.

To be thorough, a root analysis must involve:

1. An understanding of how humans interact with their environment;
2. Identification of potential problems related to 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 to the event;
5. Development of actions aimed at improving processes and systems;
6. Measurement and evaluation of implementation of these actions; and
7. Documentation of all steps (from the point of identification to the process of evaluation).
When should RCA be undertaken?

RCA is normally only performed on high risk, high impact events, such as sentinel events. In 2004–05, the Department of Human Services included the requirement for health services to report ‘near miss’ sentinel events as part of the reporting requirements for the sentinel event program. In this program, a reportable near miss sentinel event is managed using the same processes as an actual event.

The RCA process forces an organization to complete analysis of the following factors in response to the investigation of an event:

- Human factors, to include:
  - Staff competency
  - Staff education
  - Staff training
  - Staffing levels
  - Use of contract staff, if applicable
  - Staff communication

- Information management issues (information availability, communication among caregivers)

- Environmental issues (equipment-related, appropriateness of the environment to carry out the processes associated with the event, effectiveness of failure-mode responses)

- Leadership issues (culture of safety, clear communication of priorities, culture conducive to risk identification)

- Uncontrollable factors which may have contributed to the event

What are the timelines for RCA?

The RCA processes should be instigated as soon as practical after an incident. The more time elapsed, the less reliable the account of events by people involved and important information might no longer be available.

- A RCA team should be convened within two working days of the in-
Al-Assaf and Akgun (Eds.)

An incident occurring.

✓ The RCA report should be signed off within 2 calendar months of commencing the investigation.

RCA investigation principles

The main principles of a RCA investigation are to:

✓ focus on systems and processes, not individual performance
✓ be fair, thorough and efficient
✓ focus on problem solving
✓ use recognized analytical methods
✓ use a scale of effectiveness to develop recommendations.

Attributes of a RCA investigation

The four major attributes of a RCA investigation are:

1. thoroughness: a complete review of all possible causes is required
2. fairness: in terms of involvement of all staff associated with the incident
3. efficiency: the time taken to undertake the investigation should be consistent with the significance of the problem being investigated
4. independence: including independent team members will reduce the impact of bias and overcome the fear of having to present information others might not want to hear.

Major steps in a RCA investigation

The major steps in a RCA investigation are:

1. Verify the incident and define the problem
2. Commission the RCA investigation
3. Map a timeline (event and causal factor chart)
4. Identify critical events
5. Analyze the critical events (cause and effect chart)
6. Identify root causes
7. Support each root cause with evidence
8. Identify and select the best solutions
9. Develop recommendations
10. Write and present the report.

**Forming the RCA team**

A small group of staff, which has expertise either in RCA methodology or in an area relevant to the incident, conducts the RCA investigation. Organizations should try to keep the size of the team manageable: between three and six members is ideal.

**A RCA facilitator** is responsible for facilitating the RCA investigation. This includes forming the team, mapping the event, ensuring the team meetings occur and follow the agreed process, and facilitating team meetings. This person might also be the RCA coordinator.

**A RCA team leader** is usually the head of a clinical unit or another staff member with a recognized leadership role. Their role involves ensuring clinical participation, supporting the team facilitator at meetings, and ensuring the clinical content is relevant and appropriate.

**RCA team members** are these staff who participate in the team meetings and assist with data gathering. They provide relevant expertise and should be able to provide impartial input.

Organizations should only involve staff who were directly involved with the incident if their ability to remain objective is not compromised.

Team members do not need to be clinical staff. Organizations should involve staff who are familiar with work practices and systems (for example, biomedical engineering, security, consumer liaison, and administrative staff.

Therefore the three main steps to perform a root cause analysis are:

1. Investigation
   - Data Collection
   - Causal Factor Charting
2. Analysis
3. Recommendations and Implementation

- Display of Results
- Plan of Action

The process encourages repeated questions as to “why” the event occurred. If the organization is able to get down to no more than three causative factors, it has likely completed a thorough analysis of the event. Investigation of a sentinel event and completion of the root cause analysis is, at best, a stressful and challenging undertaking. Staff involved in the event may be defensive and uncomfortable with the RCA process. It is important to involve legal counsel in order to protect the investigation of the event. Staff must be educated on identification of sentinel events, as well as, the need for immediate reporting of such events. The most critical factor in the sentinel event process is the focus on system issues, rather than blaming individuals for the error or event. As Dr. Reason’s Swiss cheese model of latent system failures depicts, a series of failures in the system, when aligned, can result in a catastrophic situation. A sentinel event must not ever be attributed to failure on the part of one individual’s performance.

In RCA investigation; Do NOT answer:

☆ What should have happened?
☆ What didn’t happen?

Answer:

☆ What did happen?
☆ How did it happen?

Be objective! And avoid: should, not, error, must, inapprop., etc.

During analysis of the roots;

1. Answer, “WHY it happened?”
2. Compare with “what should have happened?”
3. Answer, “why it did Not happen?”
4. Do NOT answer “how Can I fix it?”
5. Think of the environment as well!
6. Subjectivity is OK!
7. Apply different tools

**Root cause statements-The five rules of causation**

1. Causal statements must clearly show the ‘cause and effect’ relationship. When describing why an event has occurred, show the link between the root cause and the undesirable outcome.

2. Negative descriptors are not used in causal statements. To force clear cause and effect descriptions (and avoid inflammatory statements) do not use negative descriptors.

3. Each action cause must have a corresponding conditional cause. For every human error in the causal chain, there must be a corresponding condition cause that combined to contribute to the undesired effect.

4. Each procedural deviation must have a preceding cause. Identify the cause of a procedural violation, not the violation.

5. Failure to act is only causal when there was a pre-existing duty to act. The duty to perform might arise from standards and guidelines for practice or other duties to provide patient care.

We can use the following RCA tools during our analysis;

1. 5 Whys
2. Barrier Analysis
3. Change Analysis
4. Causal Factor Tree Analysis
5. Failure mode and effects analysis
6. Fish-Bone Diagram or Ishikawa diagram
7. Pareto Analysis
8. Fault Tree Analysis
9. Surveys
10. Histograms (Frequency Charts)
11. Flowcharts
12. RC Map
13. Prioritization Grid
14. RC Summary Table
15. Trend Charts

JCAHO requires organizations to complete a thorough and credible root cause analysis (RCA) in response to a sentinel event. (See Attachment 6, Root Cause Analysis Worksheet)

Joint Commission has pushed for mandatory reporting of sentinel events, which has received much resistance from healthcare organizations. Whether or not an organization chooses to report an event to JCAHO, it is still required to complete a thorough and credible root cause analysis, which includes adoption of risk reduction strategies that must be implemented in a timely manner. The effectiveness of these strategies must be evaluated by the organization. Healthcare providers and patients both reap significant benefit from the RCA process, which should prevent future recurrence of the event.

In an effort to heighten awareness that the patients must be active participants in their own healthcare, Joint Commission developed the “Speak Up” program. Patients are encouraged to be alert, questioning caregivers, sharing information, taking an active role in learning about their medications, and in decisions pertaining to their healthcare needs. Joint Commission has made it possible for organizations to download “Speak Up” brochures from their website free of charge. The brochure may then be given to each patient upon admission. This is a strategy for organizations to undertake which will demonstrate the commitment to patient safety efforts. Such good faith actions will go far in fostering a trusting and therapeutic relationship with the patients.

Failure Mode Effect Analysis
FMEA, was developed outside of health care and is now being used in health care to assess risk of failure and harm in processes and to identify the most important areas for process improvements.

Failure mode and effects analysis is an analytical method that has been used for decades in engineering to identify and reduce hazards. (9) This technique examines the individual components of a system to determine the variety of ways each component could fail and the effect of a particular failure on the stability of the entire system. There are two distinct types of FMEA risk analyses: design FMEA and process FMEA. It is common to find both types of FMEA analyses being used in manufacturing, aviation, computer software design, and other industries to evaluate system safety.

The need to address process issues in a proactive manner, before an actual error occurs is obviously crucial to the well-being of the patients. The Veteran’s Administration has taken the lead in the realm of patient safety as is evidenced by their development of a Healthcare Failure Mode and Effect Analysis (HFMEA) tool. *(See Attachment 5)* The FMEA process has been utilized for over 40 years by the aerospace industry, but has only recently been adopted by healthcare. It utilizes several innovative strategies in order to identify weak links by:

- Convening a multidisciplinary team that includes line level staff involved in the process
- Flowcharting the process under analysis
- Identifying key steps in the process that are potential weak links and which could result in a medical error
- Completing a hazard analysis, listing all potential failures for each subprocess
- Determining the severity of a failure at each point
- Determining the likelihood that the error will be detected
- Calculating a score for each of these steps
- Selecting those steps that fall out as the highest risk points and developing risk reduction strategies to prevent these from occurring
Providing education to all pertinent staff members and disciplines
Implementing system changes
Monitoring the effectiveness of the changes in the overall process

Healthcare Failure Modes and Effects Analysis (HFMEA) has been designed by the VA National Center for Patient Safety (NCPS) specifically for healthcare. Since then FMEA, has been used by hundreds of hospitals in a variety of institute for healthcare improvement programs, including:
- Idealized Design of Medication Systems (IDMS),
- Patient Safety Collaboratives, and
- Patient Safety Summits.

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.

STEP 2 Assemble the Team
Be sure to include everyone who is involved at any point in the process. Some people may not need to be part of team throughout the entire analysis, but they should certainly be included in discussions of those steps in the process in which they are involved. The team is to be multidisciplinary including Subject Matter Expert(s) and an advisor.

STEP 3 Graphically Describe the Process
Have the team meet together to list all of the steps in 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
Number every step of the process, and be as specific as possible.
Flowcharting can be a helpful tool for outlining the step.
Team should agree that the steps enumerated in the FMEA accurately describe the process

STEP 4 Conduct a Hazard Analysis

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)

Have the team list failure modes and causes
A. List all possible/potential failure modes under the sub-processes identified in HFMEA. For each step in the process, list all possible “failure modes” – that is anything that could go wrong, including minor and rare problems.
B. Determine the Severity and Probability of the potential failure. Look up the Hazard Score on the Hazard Score Matrix and record this number.
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”.
D. List all of the failure mode causes for each failure mode where the decision is to “Proceed” Then, for each failure mode listed, identify all possible causes

STEP 5 Evaluate the results
A. To calculate the Risk Priority Number (RPN) for each failure mode, multiply the three scores obtained (the 1 to 10 score for each of likelihood of occurrence, detection, and severity).
B. For example; the failure mode “Wrong medication selected” has a 3 for likelihood of occurrence, a 5 for likelihood of detection, and a 5 for severity, for an overall RPN of 75.
C. To calculate the RPN for the entire process, simply add up all of the individual RPNs for each failure mode. (See attachment 7)
STEP 6 Actions and Outcome Measures

A. Identify outcome measures that will be used to analyze and test the redesigned process.

B. Identify a single, responsible individual by title to complete the recommended action.

C. 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.

Occurrence scale “scoring”

☆ Remote (1): no known occurrence; or happens<10 % of the time

☆ Low (3): possible, but no known data; or happens 10-30 % of the time

☆ Moderate (5): documented and frequent; or happens 40-60 % of the time

☆ High (7): documented and frequent; or happens 70-80 % of the time

☆ Very high (10): documented, almost certain; or happens 90-100 % of the time

Severity scale “scoring”

☆ No effect (1)
★ Slight annoyance (2): may affect the system
★ Moderate system problem (3): may affect the patient
★ Major system problem (5): may affect the patient
★ Minor injury (7): temporary patient harm
★ Major injury (9): permanent lessening of body function, surgical intervention required, disfigurement.
★ Terminal injury or death (10):

Detection scale “scoring”
★ Very high (1): error almost always detected; or we’ll catch it 9 out of 10 times
★ High (3): error likely to be detected; or we’ll catch it 7 out of 10 times
★ Moderate (5): moderate likelihood of detection; or we’ll catch it 5 out of 10 times
★ Low (8): Low likelihood of detection; or we’ll catch it 2 out of 10 times
★ Remote (10): detection not possible at any point; or we’ll never catch it! (0 out of 10)

As a summary HFMEA is;
✔ Multidisciplinary approach
✔ Tracks the medication process from start to finish
✔ Identify the stages at which errors can occur
✔ Predict the effects of the failure on the remainder of the process
✔ Rank the estimated likelihood of occurrence (O)
✔ Rank the severity of harm resulting from the error (S)
✔ Rank the likelihood that the error will be detected (D)
✔ Calculate the criticality index (O x S x D)
✔ The higher the criticality index the higher the risk
Identify an intervention to lower the criticality index
Reassess the risk with the intervention in place

Organizations with a sincere commitment to adopting a culture of safety must adopt a proactive versus reactive mentality in order to protect patients against medical errors. Reliance solely on a reactive response to an error puts patients at undue and unnecessary risk for catastrophic events and outcomes. Joint Commission has levied an accreditation requirement that all hospitals must complete at least one FMEA annually. While the FMEA process itself can be somewhat cumbersome, the cost/benefit analysis of preventing a medical error clearly supports the meaningful nature of this strategy.

Regulators Role in Patient Safety

Unfortunately, even in the best of organizations medical errors are made which have devastating consequences. There have been numerous media reports related to such events. One event that received national attention involved a reporter for the Boston Globe who received massive chemotherapy overdoses over a period of time that resulted in her death. Another involves an eight-year-old boy who died during a routine tympanic surgery as the result of his eardrum having been infiltrated with atropine instead of lidocaine, resulting in his death. In both of these situations, the hospitals involved publicly acknowledged the events and the subsequent steps taken to prevent the chance of recurrence.
References


Attachment 1

Patient Safety-Related Websites

(Page 1 of 2)

Agency for Healthcare Research and Quality
   http://www.ahrq.gov

Australian Council for Safety and Quality in Health Care
   http://www.safetyandquality.org

Centers for Medicare and Medicaid Services
   http://www.cms.hhs.gov

ECRI (formerly the Emergency Care Research Institution)
   http://www.ecri.org

Food and Drug Administration
   http://www.accessdata.fda.gov

Health and Safety Executive
   http://www.hse.gov.uk

Institute for Healthcare Improvement
   http://www.ihi.org

Institute for Safe Medication Practices
   http://www.ismp.org

Institute of Medicine of the National Academies
   http://www.iom.edu

Joint Commission International Center for Patient Safety
Joint Commission on Accreditation of Healthcare Organizations
http://www.jcaho.org

Leapfrog Group
http://www.leapfroggroup.org

Massachusetts Coalition for the Prevention of Medical Errors
http://www.macoalition.org

Medical Device Safety Reports
http://www.mdst.ecri.org

MedWatch
http://www.fda.gov/medwatch

National Patient Safety Agency
http://www.npsa.nhs.uk

National Patient Safety Foundation
http://www.npsf.org

National Quality Forum
http://www.qualityforum.org

Partnership for Patient Safety
http://www.p4ps.org

U.S. Pharmacopeia Center for Advancement of Patient Safety (CAPS)
http://www.usp.org/patientSafety

VA National Center for Patient Safety
http://www.patientsafety.gov
# ATTACHMENT 2

## Medication Error Report Form

**CONFIDENTIAL: Do not photocopy. This information is used for evaluating the quality of patient care, made for the purposes of reducing morbidity or mortality, and as such is privileged pursuant to the Oklahoma Statute Title 63, Section 1-709. COMPLETE ALL INFORMATION REQUESTED IN BLUE AND FORWARD TO SUPERVISOR. PRINT ALL INFORMATION.**

**Date of error:**
**Time (military) of error:**
**Location where initial error was made:**

### Medication(s) Involved in Error:

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Brief Description of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra Dose</td>
<td>Incorrect medication activation</td>
</tr>
<tr>
<td>Wrong drug</td>
<td>Preprinted medication order form</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>Knowledge deficit</td>
</tr>
<tr>
<td>Wrong Preparation</td>
<td>Procedure/protocol not followed</td>
</tr>
<tr>
<td>Wrong route</td>
<td>Pump, failure/ malfunction</td>
</tr>
<tr>
<td>Wrong time</td>
<td></td>
</tr>
<tr>
<td>Prescribing</td>
<td></td>
</tr>
<tr>
<td>Wrong administration technique</td>
<td></td>
</tr>
<tr>
<td>Omission</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
</tr>
<tr>
<td>Improper dose/quantity-Dose ordered:</td>
<td>Handwriting illegible/unclear</td>
</tr>
<tr>
<td>Dose given:</td>
<td></td>
</tr>
<tr>
<td>Wrong dosage form-Med ordered:</td>
<td></td>
</tr>
<tr>
<td>Med given:</td>
<td></td>
</tr>
<tr>
<td>Node (Where in the medication process did the initial error occur?):</td>
<td></td>
</tr>
<tr>
<td>Prescribing</td>
<td></td>
</tr>
<tr>
<td>Administering</td>
<td></td>
</tr>
<tr>
<td>Monitoring</td>
<td></td>
</tr>
<tr>
<td>Documenting</td>
<td></td>
</tr>
<tr>
<td>Dispensing</td>
<td></td>
</tr>
</tbody>
</table>

### Level of Staff that made initial error:

<table>
<thead>
<tr>
<th>RN</th>
<th>LPN</th>
<th>HUC</th>
<th>Pharmacist</th>
<th>CRNA</th>
<th>Pharmac tech</th>
<th>Physician</th>
<th>PA</th>
<th>RT</th>
<th>Other:</th>
</tr>
</thead>
</table>

### Recommendations to avoid similar error:

- **Possible cause(s) of error (check all that apply):**
  - Abbreviation
  - Decimal point
  - Calculation
  - Diluent wrong
  - Communication
  - Documentation
  - Computer entry (Pharmacy)
  - Inaccurate/lacking
  - Contraindicated-drug allergy
  - Drug distribution system/Pysis
  - Contraindicated-drug/drug
  - Drug names look/sound alike
  - Contraindicated-drug/food
  - Drug Shortage
  - Contrainindicated-disease process
  - Fax error
  - Handwriting illegible/unclear
  - Incorrect medication activation
  - Preprinted medication order form
  - Knowledge deficit
  - Procedure/protocol not followed
  - Pump, failure/malfunction
  - Computer software modified/obtained
  - Labeling (facility/manufacturer)
  - Informational staff who made the initial error
  - Labeling (facility design)
  - Informational staff who made the initial error
  - Leading/trailing zero missing
  - Informational staff who made the initial error
  - Monitoring inadequate/lacking
  - Workflow disruption
  - Packaging/container design
  - Verbal order
  - Patient ID failure
  - Written order
  - Patient ID transfer
  - Confusing/incomplete/misunderstood
  - Physican notified
  - Confusing/incomplete/misunderstood

### Supervisor and physician must be notified of all errors that reach the patient:

<table>
<thead>
<tr>
<th>Supervisor notified:</th>
<th>Date:</th>
<th>Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physician notified:</th>
<th>Date:</th>
<th>Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**To be completed by Manager. Forward to Risk Manager within 72 hours.**

### Result of the Error:

<table>
<thead>
<tr>
<th>Category</th>
<th>Circumstances or events that have the capacity to cause error</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>B</td>
<td>Antibiotic administration</td>
</tr>
<tr>
<td>C</td>
<td>Antidote administered</td>
</tr>
<tr>
<td>D</td>
<td>Antidote administered</td>
</tr>
<tr>
<td>E</td>
<td>CPR administered</td>
</tr>
<tr>
<td>F</td>
<td>Drug therapy started/change</td>
</tr>
<tr>
<td>G</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>H</td>
<td>Hospitalization, 1-5 days</td>
</tr>
<tr>
<td>I</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
</tbody>
</table>

### Severity Level/Outcome-Risk Management to complete:

<table>
<thead>
<tr>
<th>Category</th>
<th>Circumstances or events that have the capacity to cause error</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>B</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>C</td>
<td>Hospitalization, 1-5 days</td>
</tr>
<tr>
<td>D</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>E</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>F</td>
<td>Hospitalization, 1-5 days</td>
</tr>
<tr>
<td>G</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>H</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>I</td>
<td>Hospitalization, 1-5 days</td>
</tr>
</tbody>
</table>

### Actions taken to avoid similar error:

<table>
<thead>
<tr>
<th>Category</th>
<th>Circumstances or events that have the capacity to cause error</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>B</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>C</td>
<td>Hospitalization, 1-5 days</td>
</tr>
<tr>
<td>D</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>E</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>F</td>
<td>Hospitalization, 1-5 days</td>
</tr>
<tr>
<td>G</td>
<td>Hospitalization, &gt;10 days</td>
</tr>
<tr>
<td>H</td>
<td>Hospitalization, initial</td>
</tr>
<tr>
<td>I</td>
<td>Hospitalization, 1-5 days</td>
</tr>
</tbody>
</table>

### Product Information (Pharmacy to complete):

<table>
<thead>
<tr>
<th>Generic Name</th>
</tr>
</thead>
</table>
| Dosage form (e.g. cream, tablet, etc.):
| Intended route of administration:
| Strength/concentration:

### Signature of Pharmacy Coordinator:

Date reviewed:

---

**Physician follow-up:**

**Date:**
**Time:**

**Signature of Unit Manager:**

**Date:**
**Time:**

**Signature of Risk Manager:**

**Date:**
**Time:**

---

**PLACE PATIENT LABEL HERE**

**Deaconess Hospital**

**MEDICATION ERROR & SUSPECTED ADVERSE DRUG REACTION FORM**

**Page 1 of 2**

**Not a Chart Form**

---

**Chapter Four: Patient Safety**

---

**Form # PIR-0040 (rev 06/22/05)**
ATTACHMENT 3

SUSPECTED ADVERSE DRUG REACTION FORM

Protected BY O.S. Title 63, 1-1709

An adverse drug reaction is defined as a detrimental response to a medication that is undesired, unintended and unexpected in doses recognized in accepted medical practice. The medication is discontinued, (and/or) A medication is ordered to treat the reaction, (and/or) The patient's hospital stay is prolonged.

Admitting Diagnosis: ___________________________ Allergies stated before reaction: ___________________________

Drug(s) suspected of causing reaction: ___________________________ Date/Time of reaction: ___________________________

Detailed description of reaction: ___________________________

Treatment and action taken: ___________________________

CHECK ALL THAT APPLY:

Allergic

[ ] Anaphylaxis
[ ] Fever
[ ] Angioedema
[ ] Urticaria

Cardiovascular

[ ] Angina
[ ] Hypertension
[ ] Hypotension
[ ] Tachycardia
[ ] Bradycardia
[ ] Syncope
[ ] Dyssrhythmia/palpitations
[ ] Qtc prolongation
[ ] Asystole

ENT

[ ] Hearing loss
[ ] Tinnitus
[ ] Visual disturbance
[ ] Swallowing difficulty

Gastrointestinal

[ ] Diarrhea
[ ] Constipation
[ ] Nausea
[ ] Vomiting
[ ] Ulceration/bleeding
[ ] Gastritis

Hepatic/renal

[ ] Elevated liver enzymes
[ ] PT/INR (inc. or dec.)
[ ] BUN/creatine

Metabolic balance

[ ] Hypokalemia
[ ] Hyperkalemia
[ ] Hypoglycemia
[ ] Hyperglycemia

Respiratory

[ ] Wheezing
[ ] Dec. respirations
[ ] Inc. respirations
[ ] Cough
[ ] Bronchospasm
[ ] Respiratory distress

Psychiatric

[ ] Depression
[ ] Confusion
[ ] Hallucinations
[ ] Psychosis
[ ] Agitation
[ ] Coma

Other (describe): ___________________________

Skin

[ ] Pruritus
[ ] Rash edema phlebitis
[ ] Flushing
[ ] Red man syndrome
[ ] Sweating

Hematologic

[ ] Bleeding
[ ] Thrombocytopenia
[ ] Leukopenia
[ ] Thrombosis

Status of patient at time of report: Pt. Recovered [ ] Yes [ ] No [ ] Recovering, but not fully recovered

Physician notified: ___________________________ M.D. ___________________________ Date: ___________________________ Time: ___________________________

Pharmacist notified: ___________________________ R.Ph./Pharm.D. ___________________________ Date: ___________________________ Time: ___________________________ Signature: ___________________________

Supervisor/Manager notified: ___________________________ Date: ___________________________ Time: ___________________________ Signature: ___________________________

Monitor and treat the patient and report the suspected reaction to the responsible physician. Document the suspected reaction in the patient's medical record if confirmed by the physician. This form is not a permanent part of the patient's medical record.

Forward to Risk Manager for review.

Pharmacy follow-up

[ ] Mild ADR: A reaction that is self-limiting and requires no treatment and/or does not prolong hospital stay.
[ ] Moderate ADR: A reaction that requires treatment and/or prolongs hospital stay.
[ ] Severe ADR: A reaction that 1) is life-threatening or contributes to the death of the patient; 2) is permanently disabling; 3) requires intensive medical care; 4) takes longer than 15 days for recovery to occur.

Current medications

Pertinent labs:

Chart Review:

Drug Adjustment: [ ] Dose decreased [ ] Drug Discontinued [ ] Extra Treatment Required [ ] Yes [ ] No

Prolonged hospital stay: [ ] Yes [ ] No

Drug reaction relationship: [ ] Certain [ ] Probable [ ] Possible [ ] Unlikely

Pharmacy and Therapeutic Committee review

P & T review: ___________________________

[ ] Report forwarded to the FDA

P & T physician: ___________________________ Date: ___________________________

PLACE PATIENT LABEL HERE

Deaconess Hospital

Chapter Four: Patient Safety

Not a Chart Form

Page 2 of 2

Form # P080040 (rev 06/22/05)
ATTACHMENT 4

“Swiss Cheese” Model of Latent System Failures Resulting in a Medication Error

Non-Employee Occurrence Report

Confidential: DO NOT photocopy. Forward to your Manager. DO NOT place in the patient record. This information is used for evaluating the quality of patient care, made for the purposes of reducing morbidity or mortality, and as such privileged pursuant to the Oklahoma Statute Title 63, Section 1-1709/1709.1

ALL BLUE SECTIONS MUST BE COMPLETED ON ALL OCCURRENCES

PRINT ALL INFORMATION

Date of occurrence: Time of occurrence: Location (dept, unit, room #):

Person involved (use patient ID sticker below, or name-last, first):

Status:  Patient  Visitor  Volunteer  Medical Staff  Student  Agency  Equipment  Other

Address:

FOR PATIENT OCCURRENCES ONLY: Admitting Dx:

DESCRIPTION OF THE OCCURRENCE:

Patient Assessment after event:

Area event occurred:

Hospital grounds (outside)  Corridor  Stairway/elevator  Patient's Home  Public area (inside)  Physician's office

Mental Status PRIOR to event: Alert  Confused/disoriented  Sedated  Unconscious  Other

NATURE OF OCCURRENCE: (CHECK ALL THAT APPLY)

Fails

Bed position: High  Low  NA  On  Off

Bed Alarm: On  Off  NA

Side rails: Up  Down  NA

Restrains: Yes  No  NA

Type: High Risk Fall?  Yes  No  NA

Notify Family of all falls.

Nature of Fall:

<table>
<thead>
<tr>
<th>Slip/Trip</th>
<th>Found on floor</th>
<th>From bed</th>
<th>From Chair/wheelchair/commode</th>
<th>Assisted to floor</th>
<th>While standing</th>
<th>Patient self reported, not witnessed</th>
<th>Other (specify)</th>
</tr>
</thead>
</table>

Equipment:

- Unavailable
- Expired date
- Malfunction/breakage/defective
- Incorrect Count
- Improper utilization
- Puncture by used sharp
- Puncture by sterile clean sharp
- Other:

Treatment/Procedures:

- Incorrect procedure
- Improper performance/technique
- Wrong patient
- Omitted/missed treatment
- Improper prep
- Undesired result/adverse reaction
- Other:

Miscellaneous:

- Assault
- Burn
- Damage to facility
- Left AMA
- Consent  Missing  Not obtained
- Suicide attempt
- Unanticipated or unexplained death
- Self inflicted injury
- Elopement
- Refusal of Medical Treatment
- Altercation
- Infectious disease exposure
- Toxic/Hazardous material exposure
- Other:

Damaged/missing property:

Notify Security

Safe Medical Device Act (SMDA) Criteria:

Medical use/misuse contributed to patient injury: Name of equipment: ID #:

Complete the following steps: 1. secure patient; 2. contain equipment, parts, packaging; 3. contact Risk Management or Clinical Equipment immediately; 4. forward to Risk Manager; 5. notify supervisor.

Name of Family notified:

Name of Supervisor notified:

Name of Physician notified (for all patient events):

Exam/treatment ordered?  YES  NO  N/A  REFUSED

Exam/other nature of exam/test/treatment:

Name(s) & title(s) of person(s) involved: Employee (y/n) Witness name(s), address(es), phone number (if not employee):

Person completing form (print):

Person completing form (signature):

Title

Date/Time

FORWARD TO SUPERVISOR

PLACE PATIENT LABEL HERE

Deaconess Hospital
COMPLETED REPORT FORWARDED TO RISK MANAGEMENT
NON-Employee OCCURRENCE REPORT

Page 1 of 2

Form # RMG5077 (rev 02/24/05)
### VA HFMEA Tools

**This Side to be completed by Supervisor:**

**Page 2**

**ATTACHMENT 5**

**Nature of Injury**
- No apparent injury
- Anaphylactic reaction
- Asphyxia
- Burn/Scald
- Chemical Burn
- Concussion
- Fracture/Dislocation
- Infectious Exposure
- IV Infiltration
- Laceration/Abrasion/Skin Tear
- Sprain/Strain/Contusion
- Unknown at this time
- N/A- property occurrence

**Other:**

<table>
<thead>
<tr>
<th>Policies, Procedures</th>
<th>Target/complete date</th>
<th>Initials</th>
<th>Equipment/supplies/facility</th>
<th>Target/complete date</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation</td>
<td></td>
<td></td>
<td>Evaluation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommend Revision/change</td>
<td></td>
<td></td>
<td>Recommend</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop</td>
<td></td>
<td></td>
<td>Revision/change/immediately</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enforce</td>
<td></td>
<td></td>
<td>Tagged/Secure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor/Instructions</td>
<td></td>
<td></td>
<td>Recommend additional/purchase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QI Monitor/Initiate</td>
<td></td>
<td></td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-service Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual Counseling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competency demo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proctor assignment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective action plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supervisor/Manager:** Name/Signature: ________________________ Date: ________ Time: ________

**Comments:**

__________________________

**Physician Follow-up:**

Name: ______________________ Method: (person, phone, letter) __________________ By: __________________

Name: ______________________ Method: (person, phone, letter) __________________ By: __________________

Review completed by: __________________ Title: __________________ Date: __________

Review completed by: __________________ Title: __________________ Date: __________

**Risk Management:** Signature ___________________________

Date received: __________________ Date reviewed: __________________ Date entered: __________________

**Patient follow-up (optional):** __________________

**Comments/follow-up:** __________________

__________________________

**PLACE PATIENT LABEL HERE**

Chapter Four: Patient Safety

Deaconess Hospital

COMPLETED REPORT forwarded to Risk Management

NON-EMPLOYEE OCCURRENCE REPORT

Page 2 of 2

Form # RMM5077 (rev 02/24/05)
ATTACHMENT 6
Root Cause Analysis Worksheet

Date Analysis Initiated: _________________________
Date Completed: _______________

Principal Investigator: ______________________________

Team Members:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

What Happened?

Provide a detailed description of the event, when it occurred, where it occurred, and who was involved.

What happened?
When did it occur (date, time, shift)?
What was going on just prior to event?
Where did it occur (department, unit, or other exact location)?
Who was directly involved in the event?
Who witnessed the event?
How was the event reported?
What departments or disciplines were affected?
### Root Cause Analysis Worksheet - continued

#### Why Did It Happen?

- What human factors contributed?
  - Training, education, or competence issues?
  - Supervision issues?
  - Compliance issues?
  - Communication issues?
  - Staffing issues?
  - Contract staff involved?

- What process issues contributed?
  - Steps involved?
  - Failure in one of the steps?
  - What is being done to prevent a bad outcome if there is a failure at this step?

- Were there information management issues?
  - Necessary information available?
  - Communication adequate?

- Were there environmental issues?
  - Physical plant appropriate for activities being carried out?
  - Equipment issues?
  - Systems in place to identify environmental risks?
  - Emergency and failure-mode responses tested?

- Were there Leadership issues?
  - Corporate culture supportive of effective communication?
  - Clear communication of priorities?
  - Appropriate policies in place?

- Were there any factors that are uncontrollable?

#### Risk Reduction Strategies
What strategies will be implemented in order to prevent this from happening again?

How will these strategies be measured?

When will all strategies be fully implemented?

How will the effectiveness of these strategies be monitored?

Prepared by: ______________________________________________
Date: ____________________________________________________

Reviewed and Approved by: _________________________________
Date: ____________________________________________________
CHAPTER FIVE
Quality Improvement: Tools And Methods

Seval Akgun, MD, PhD  A. F. Al-Assaf, MD, MPH

As discussed earlier, when completing the cycle of healthcare quality implementation, improvement initiatives are the next tasks after monitoring and assessment. And as discussed in the previous chapter, the purpose of monitoring is to measure variance from a “norm” or a threshold in order for the organization to study causes for that variance and to set in motion a process or processes to decrease this variance. The process(s) of decreasing variance is quality improvement.

According to the Quality Cycle developed by the USAID Quality Assurance Project, the following steps have to be in place (or at least some of them) before improvement intervention processes can begin:

1. Planning for Quality,
2. Setting of Standards (and indicator)
3. Communicating of Standards
4. Monitoring (against thresholds)
5. Identification and prioritization of improvement opportunities (IOs)
6. Defining the key IO
7. Organize a team
8. Analyze and study the IO for root causes
9. Develop solutions and actions for improvement
10. Implement and Evaluate Improvement efforts...then re-start the cycle again.

Items (steps) 5 thru 10 are all related to improvement processes. Each has a number of activities and tasks. This chapter will not address each of these
items in details as some of them are self-explanatory and the others have been discussed in other publication in much more details. This chapter however will concentrate on introducing the quantitative aspects and the tools commonly used in improvement interventions in general. The background presented here is to form an understanding of the need for and the comprehension of data management and statistical thinking in addressing quality improvement options.

Introduction

Quality is an amalgam of many management philosophies presented with a unique list of principles that are primarily customer oriented. Customer satisfaction means not merely reacting to and addressing complaints but also the methodical approach to researching the origin if problems and the magnitude of their occurrence and impact. Therefore, quality seeks an aggressive proactive customer oriented approach to problem identification and solution.

Two approaches can be used to evaluate the service provided by the organization to its customers: a qualitative approach and a quantitative approach. A qualitative approach is used to satisfy the internal evaluation process. This approach focuses primarily on the “do it right the first time” processes. The external evaluation process is best evaluated using the quantitative approach, which determines the extent of customer satisfaction. This approach includes collecting and analyzing data on the nature and scope of the problems or potential problems that may face customers. Data should be collected on needs and expectations, as well as trending of occurrences and measuring levels of customers’ dissatisfaction segmented by specific categories and experiences.

This chapter will present three main issues in quantitative approaches to quality. The first is the concept of transforming data to information. The second is data collection and display, while the third issue is data analysis techniques. In each of the above areas several tools and methods will be presented and illustrated. However, before we dive into these issues, let’s go back to the QA cycle steps presented earlier. Step 5 suggests the identification and prioritization of opportunities for improvement. How is this done?
As we presented in the last chapter, the purpose of monitoring is to identify gaps or variance in compliance to communicated standards. Therefore the next step is to evaluate these gaps or improvement opportunities (IOs) and select those that are most important for the organization to address. This process of selecting the most important IO is a process of prioritization. Several tools are presented later in this chapter to assist in this process of selection. In general, one may use specific criteria to compare the different IO with one another and therefore selecting the one(s) that best fit more criteria than the rest or fit the most vital criteria more. For example, one may use such criteria as feasibility for implementation, impact on patients, cost, political environment, probability for success, etc. One may use nominal group technique to choose the most suitable IO or use multiple voting techniques to do the same (these techniques are described later in the chapter).

Once an IO (or a group of IOs) has been selected then the next step in the cycle is to define the IO in a more “operational” terms i.e. what are the parameters of the IO? In doing so, the following questions need to be answered before a statement is developed for the IO:

- What is the IO?
- What is not functioning?
- What is our desire?
- What will the desired outcome look like?
- How do we know it is an IO?
- How do we know when it is fixed?
- What data do we need to learn more about this IO?
- What effects does this IO have on quality?
- How long has this IO been in existence?
- How frequent does it occur?
- What are the boundaries of the IO? Identify a beginning and an end.
Additionally, one should state the IO in a statement that is clear and in simple terms to be easily followed by the assigned team members. Other conditions defining the IO are that the operational statement should not contain a proposed solution, nor identify a cause, and should not assign blame.

Therefore, once the IO statement is developed, then a team should be organized to study the IO and identify causes and solution for improvement. Selecting team members should be based however on the identification of those individuals knowledgeable on the processes related to the IO and are interested in serving on such a team. Voluntary involvement should be one of the criteria for organizing the team. You do not want team members who are not interested in serving on that team. They will produce mediocre results at best.

Once team members are selected, convene the team. Assign responsibilities of team members; leader, scribe, and identify an external facilitator to ensure group dynamics and provide a background training in quality improvement tools. The addition of a facilitator, sometimes called a coach, is a major advantage for teams to function most effectively. The facilitator could be functioning as a “full-time” member of the team and has voting rights, but it is preferable that a facilitator be a part-time member and not part of the team. This individual should be well trained in quality improvement skills and tools and is ready to train others on how to use these skills and techniques when needed. The facilitator’s job should also include providing advice to the leader in team dynamics and ensuring that the team develop its mission early in the process and encourage members to focus on that mission.

Now the process is at a stage where the improvement opportunity needs further clarification and studying. In this step, the team members should discuss data management issues related to this IO and identify steps for the transformation of data into information in order to implement improvement.
Measurement techniques

The unit and the organization use information that is systematically collected to evaluate the quality of their own activities and to identify potential areas of improvement. Collecting data helps the organization assess outcomes or determine the performance of a function or process. Before collecting data, the organization develops specific questions to be answered by the collected data. The organization collects only useful and necessary data. When data collection is systematic, the data can be used to:

- Establish a baseline when a process is implemented or redesigned;
- Describe process performance or stability;
- Describe the dimensions of performance relevant to functions, processes and outcomes;
- Identify areas for improvement; and
- Determine whether changes in a process have met objectives.

The detail and frequency of all data collection have been determined and are appropriate to the activity or process being measured. The organization collects data about important processes and outcomes on a continuous basis. Repeated measurements, over time, enable the organization to judge a particular process’s stability or a particular outcome’s predictability. These data can then be transformed into information to identify areas for intensive or more detailed measurement. The organization collects data about patients’ and families’ needs.

The organization collects data about staff points of view on current performance and opportunities for improvement. Patients, families, and staff members can provide information to give the organization insight about process design and functioning. Other sources of information are surrogate decision makers and payers.

There are many methods for measuring quality, factually and perceptively, including surveys, logs, check sheets, time charts, histograms, and more.

- Focus on standards and customer expectation and engage staff, peers, and/or experts in a creative discussion of how you might monitor performance.
To monitor customers’ perception, surveys and face-to-face or telephone interviews work well.

To monitor facts about timeliness or accuracy, rework, or other attributes of the work process, simple check sheets and logs work well.

The monitoring and assessment of practical activities are not the same as the scientific study of efficiency; they consist mainly of a systematic evaluation of the respective activities of the unit. The unit must decide what information to collect and use. Possible information includes changes in the patient’s health (for example, measured using an appropriate health indicator or based on a medical examination), the realization/non-realization of treatments according to the agreed practice, the evaluation of the smooth progress of care, the patients’ assessment of the clinical quality of care, and the assessments by the units’ own specialists of the clinical quality of care.

The analysis of the results requires the application of statistical methods. Statistical tools and methods are helpful in both assessing variation and studying a process to determine where the improvement needs to occur. By understanding the type and cause of variation and using statistical tools and methods, the organization can focus its attention and resources on the processes and outcomes that would benefit from this intensive assessment.

The transformation of Data to Information

Regardless of the particular research being done, investigators collect observations and generally want to transform them into tables or graphs or to present summary numbers, such as percentages or means. From a statistical perspective, it does not matter whether the observations are on people, animals, inanimate objects, or events. What matters is the kind of observations and the scale on which they are measured. These features determine the statistics used to summarize the data, called descriptive statistics, and the types of tables or graphs that best display and communicate the observations.

Data versus Information

The definition of data can be simplified as all the raw numbers, figures and in-
dividual responses collected from a sample or a population. Data are unprocessed facts. Data alone are meaningless and are worthless. Information, on the other hand, are meaningful, interpreted or processed data. Whenever one set of data is analyzed and used in specific relationship with other data set, the end product is information. For example the number 18 is without a meaning by itself, but it becomes meaningful if it relates to the number of diagnosis coding errors per month in a hospital. Therefore only information can be used to make judgment on a hypothesis or answer a research question.

Scales Of Measurement

The scale for measuring a characteristic has implications for the way information is displayed and summarized. The scale of measurement—the precision with which a characteristic is measured—also determines the statistical methods for analyzing the data. The three scales of measurement that occur most often in medicine are nominal, ordinal, and numerical.

Nominal variables

Nominal scales are used for the simplest level of measurement when data values fit into categories. Although we talk about nominal data as being on the measurement scale, we do not actually measure nominal data; instead, we count the number of observations with or without the attribute of interest.

Nominal measurement consists of assigning items to groups or categories. No quantitative information is conveyed and no ordering of the items is implied. Nominal scales are therefore qualitative rather than quantitative. Religious preference, race, and sex are all examples of nominal scales. Frequency distributions are usually used to analyze data measured on a nominal scale. The main statistic computed is the mode. Variables measured on a nominal scale are often referred to as categorical or qualitative variables.

Many classifications in medical research are evaluated on a nominal scale. Outcomes of a medical treatment or surgical procedure, as well as the presence of possible risk factors, are often described as either occurring or not occurring. Outcomes may also be described with more than two categories, such as the classification of anemias as microcytic (including iron deficiency), microcytic or megaloblastic (including vitamin B12 deficiency), and normocytic (often associated with chronic disease).
Data evaluated on a nominal scale are sometimes called qualitative observations, because they describe a quality of the person or thing studied, or categorical observations, because the values fit into categories. Nominal or qualitative data are generally described in terms of percentages or proportions, such as “the fact that 38% of the patients in the study of patients with acquired hemophilia (Bossi et al, 1998) developed hematuria.” Contingency tables and bar charts are most often used to display this type of information.

Nominal scales simply classify persons or objects into two or more categories where members of a category have at least one common characteristic. Nominal variables include gender (female, male); employment status (full-time, part-time, unemployed); marital status (married, divorced, single); and type of school (public, private, charter). For identification purposes, nominal variables are often represented by numbers. For example, the category “male” may be represented by number 1 and “female” by the number 2. It is critically important to understand that such numbering of nominal variables does not indicate that one category is higher or better than another. The numbers are only labels for the groups.

### Ordinal Scales

Ordinal variables, like nominal variables, classify persons or objects but also rank them in terms of the degree to which they possess a characteristic of interest. In other words, ordinal variables put persons or objects in order from highest to lowest or from most to least.

However, ordinal variables do not indicate how much higher or how much better one person performed compared to another. In other words, intervals between ranks are not equal; the difference between rank 1 and rank 2 is not necessarily the same as the difference between rank 2 and rank 3. For example, consider the ranking of these four heights:

<table>
<thead>
<tr>
<th>RANK</th>
<th>HEIGHT</th>
<th>INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6 ft, 5 in</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6 ft, 0 in.</td>
<td>5 inches</td>
</tr>
<tr>
<td>3</td>
<td>5 ft, 11 in.</td>
<td>1 inch</td>
</tr>
<tr>
<td>4</td>
<td>5 ft, 4 in.</td>
<td>7 inches</td>
</tr>
</tbody>
</table>
Measurements with ordinal scales are ordered in the sense that higher numbers represent higher values. However, the intervals between the numbers are not necessarily equal. For example, on a five-point rating scale measuring attitudes toward gun control, the difference between a rating of 2 and a rating of 3 may not represent the same difference as the difference between a rating of 4 and a rating of 5. There is no “true” zero point for ordinal scales since the zero point is chosen arbitrarily. The lowest point on the rating scale in the example was arbitrarily chosen to be 1. It could just as well have been 0 or -5.

When an inherent order occurs among the categories, the observations are said to be measured on an ordinal scale. Observations are still classified, as with nominal scales, but some observations have more or are greater than other observations. Clinicians often use ordinal scales to determine a patient’s amount of risk or the appropriate type of therapy. Tumors, for example, are staged according to their degree of development. The international classification for staging of carcinoma of the cervix is an ordinal scale from 0 to 4, in which stage 0 represents carcinoma in situ and stage 4 represents carcinoma extending beyond the pelvis or involving the mucosa of the bladder and rectum. The inherent order in this ordinal scale is, of course, that the prognosis for stage 4 is worse than that for stage 0.

Classifications based on the extent of disease are sometimes related to a patient’s activity level. For example, rheumatoid arthritis is classified, according to the severity of disease, into four classes ranging from normal activity (class 1) to wheelchair-bound (class 4). To illustrate, Apgar scores, which describe the maturity of newborn infants, range from 0 to 10, with lower scores indicating depression of cardio respiratory and neurological functioning and higher scores indicating good functioning. The difference between scores of 8 and 9 probably does not have the same clinical implications as the difference between scores of 0 and 1.

Some scales consist of scores for multiple factors that are then added to get an overall index. An index frequently used to estimate the cardiac risk in non-cardiac surgical procedures was developed by Goldman and his colleagues (1977, 1995). This index assigns points to a variety of risk factors, such as age over 70 years, history of an MI in the past 6 months, specific electrocardiogram abnormalities, and general physical status. The points are added to get an overall score from 0 to 53, which is used to indicate the risk of compli-
cations or death for different score levels.

A special type of ordered scale is a rank-order scale, in which observations are ranked from highest to lowest (or vice versa). For example, health providers could direct their education efforts aimed at the obstetric patient based on ranking the causes of low birth weight in infants, such as malnutrition, drug abuse, and inadequate prenatal care, from most common to least common. The duration of surgical procedures might be converted to a rank scale to obtain one measure of the difficulty of the procedure.

As with nominal scales, percentages and proportions are often used with ordinal scales. The entire set of data measured on an ordinal scale may be summarized by the median value, and we will describe how to find the median and what it means. Ordinal scales having a large number of values are sometimes treated as if they are numerical. The same types of tables and graphs used to display nominal data may also be used with ordinal data.

**Numerical Scales**

Observations for which the differences between numbers have meaning on a numerical scale are sometimes called quantitative observations because they measure the quantity of something. There are two types of numerical scales: continuous (interval) and discrete scales. A continuous scale has values on a continuum (e.g., age); a discrete scale has values equal to integers (e.g., number of fractures).

**Discrete data** refer to facts that are explained by yes or no, female or male, success and failure, etc. For example, the number of coding errors, the number of personnel in the nursing department, the number of discharged patients from a hospital per month, etc.

**Continuous data** refer to those facts that are variable in quantity and can be explained by answering the questions of how old, how tall, how much, etc. For example, the average length of stay in a hospital, the cost of nursing services for a patient, the response time to an emergency call, etc.

If data need not be very precise, continuous data may be reported to the closest integer. Theoretically, however, more precise measurement is possible.
Age is a continuous measure, and age recorded to the nearest year will generally suffice in studies of adults; however, for young children, age to the nearest month may be preferable. Other examples of continuous data include height, weight, length of time of survival, range of joint motion, and many laboratory values.

When a numerical observation can take on only integer values, scale of measurement is discrete. For example, counts of things—number of pregnancies, number of previous operations, number of risk factors—are discrete measures.

On interval measurement scales, one unit on the scale represents the same magnitude on the trait or characteristic being measured across the whole range of the scale. For example, if anxiety were measured on an interval scale, then a difference between a score of 10 and a score of 11 would represent the same difference in anxiety, as would a difference between a score of 50 and a score of 51. Interval scales do not have a “true” zero point, however, and therefore it is not possible to make statements about how many times higher one score is than another. For the anxiety scale, it would not be valid to say that a person with a score of 30 was twice as anxious as a person with a score of 15. True interval measurement is somewhere between rare and nonexistent in the behavioral sciences. No interval-level scale of anxiety such as the one described in the example actually exists. A good example of an interval scale is the Fahrenheit scale for temperature. Equal differences on this scale represent equal differences in temperature, but a temperature of 30 degrees is not twice as warm as one of 15 degrees.

Characteristics measured on a numerical scale are frequently displayed in a variety of tables and graphs. Means and standard deviations are generally used to summarize the values of numerical measures. We next examine ways to summarize and display numerical data and then return to the subject of ordinal and nominal data.

Data Reliability

According to Longo and Bohr (1991), measure’s reliability is the extent of its reproducibility. This means that if the measure is applied repeatedly (even by
A different researcher) it will produce the same results over and over again. A tape measure is a reliable measure of the length of a sofa. Similarly, the number of medication errors is a reliable measure since the same measure can be used by another researcher at any other time and get the same result given the same definition of medication errors is applied. Reliability of a measure is important to ensure the collection of accurate data. Accurate and reliable data are dependent on the level of training and understanding of the data collectors and data processors. Incorrect or missing entries in a data set may render that set of data unreliable thus any judgment based on this data set may become inaccurate and not representative of the true facts.

Data Validity

To ensure the accuracy of the data collected one must not relay only on reliability measures. The validity of the measure is equally important. It is the ability of the measure to actually measure what it really meant or what you really want it to measure. In our earlier example, using the measuring tape to measure the length of the sofa is valid since the result indicates the desired information. Measuring medication errors in a hospital is valid if the result answers our beginning question that a number of medication errors did occur. However, this same measure may not be valid if our intent with this measure is to measure the quality of services rendered. To what extent does the occurrence or absence of medication errors indicate that an unexpected adverse condition did or did not occur? Therefore to measure the validity of a measure one must know the predictive value of a measure. This can be further understood by explaining the concepts of sensitivity and specificity.

Sensitivity and Specificity

Accuracy of a measure or a test is estimated by the calculation of its sensitivity and its specificity. Sensitivity is the proportion of times that the measure or the test is positive when the adverse condition or the disease is present. Specificity is the proportion of times that the measure or test is negative when the adverse condition or the disease is absent. This is to say that the accuracy of a test or a measure is dependent on the minimum occurrence of false posi-
itives and false negatives. The number of false positives and/or negatives should be very low to make the test accurate. To illustrate these points, let’s examine the following two-by-two table for measuring the accuracy of a test in detecting the presence of a disease in a population:

**Figure 1: Measuring Test Validity**

<table>
<thead>
<tr>
<th>TEST</th>
<th>DISEASE</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Present</td>
<td>Absent</td>
</tr>
<tr>
<td>Positive</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>Negative</td>
<td>c</td>
<td>d</td>
</tr>
<tr>
<td>Total</td>
<td>a+c</td>
<td>b+d</td>
</tr>
</tbody>
</table>

a = the number of cases with disease that the test detected
b = the number of cases the test falsely detected as diseased
c = the number of cases with disease that the test missed
d = the number of cases the test truly labeled as not diseased

Sensitivity = a/(a+c)
Specificity = d/(b+d)
Predictive Value = a/(a+b)

Using the principles in Figure 1 one can relate the measure in our earlier example, the number of medication error, to the quality of care as follows:

**Figure 2: Relating a Measure to Quality of Care**

<table>
<thead>
<tr>
<th>Medication Errors</th>
<th>Unexpected Adverse</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>81</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>88</td>
</tr>
</tbody>
</table>
Sensitivity = \( \frac{10}{12} = 0.83 \)
Specificity = \( \frac{81}{88} = 0.92 \)
Predictive value = \( \frac{10}{17} = 0.59 \)

We can then conclude that the number of medication errors as a measure did predict 10 true adverse conditions out a total of 17 detected adverse conditions, i.e. a predictive value of 59%.

From the above it is obvious that for the data collected to be transformed to information, data must be defined in details and their measures must be accurate. Accuracy of a measure is dependent on whether it is reproducible (sensitivity of a measure), on whether it measures what we want it to measure (specificity of a measure), and on whether it predicts true occurrences of what we want it to measure (predictive value).

**Data Collection and Display**

One of the main principles of Total Quality Management is statistical thinking (Deming, 1985). Using statistical methods in data collection and analyses increase the credibility and accuracy of the information obtained. Statistics is a science based on the quantitative measures of data and their elements. It is therefore not surprising to see that quality emphasizes the use of statistics to accurately interpret data and produce meaningful information to understand, improve and monitor processes in an organization.

This section will introduce several tools and techniques utilized in TQM through its quest for continuous process improvement. Leebov and Ersoz (1991) suggest several tools for use in quality improvement. We further categorized these tools in two separate categories reflecting their usual cited use as follows:

- Tools for identifying, collecting and displaying data
- Tools for quality improvement
Let’s describe and present some of the most common tools in each of these categories.

**Tools for Identifying, Collecting and Displaying Data**
- Surveys
- Brainstorming
- Bain writing
- Focus group
- Logs
- Check Sheets
- Pie Charts
- Scatter Diagram
- Histograms

**Tools for Quality Improvement and Monitoring**
- Nominal Group Technique
- Multiple Voting Technique
- Weighted Voting Technique
- Rank Ordering Technique
- Balance Sheets
- Trend and Run Charts
- Flowcharts
- Pareto Diagram
- Control Charts
- Cause and Effect Diagram
- Decision-making Matrices
Tools for Identifying, collecting and displaying data

It is imperative to understand that the process of collecting data has several preceding processes. The objective of collecting data is to collect adequate, comprehensive, accurate and representative data elements. Then, data collection processes should be preceded with the identification and listing of all of the limits and biases the data might encounter through the collection process or during the analysis phase. One must also take into consideration the different sources of data both the internal and the external sources. Caution should always be applied when collecting and interpreting data from different sources. Data collection sources may be heavily biased from one source against another. Also the list of data sources should be exhaustive and every effort should be made to make sure data is collected from all actual and potential sources. If however, exploring all sources of data is not feasible due to certain barriers (resource, logistics, etc.) then a statement to this fact should be provided with the report on data collection and analysis. Therefore data collection barriers should be identified as early as possible and attempts should be made to overcome these barriers as much as possible. Accurate and useful information depend heavily on data integrity, validity and applicability.

Surveys

One of the most widely used techniques in collecting data has been survey. Collecting data from a target population through surveys is considered a simple and a fairly accurate measure of the target population. Surveys are written questionnaires used to collect quantitative data. Surveys are quantitative devices for collecting feedback to enlighten decision-making. They are useful for soliciting perceptions of customers when you want to identify reliable trends and patterns for large number of people.

There are, however, several questions that must be applied when conducting surveys to ensure adequate and true representation of the population under study. These questions may include: What is our objective(s)? Is there a need for selecting a sample of the population? Which method should be used in surveying the population? What questions should be asked?
Objective(s):

Each survey must have an objective or a set of objectives that the survey is set to achieve. The objective(s) have to be realistic, measurable, and applicable to the target population. For example, an objective of a survey could be to find out the percentage of discharged patients that have utilized our “hot line on patient education” during the three months after their discharge from our hospital during a specific year. Objectives are excellent measuring items useful in the evaluation of surveys before, during and after data collection.

Surveys can be used:

- To identify customer or staff expectations and needs
- To monitor customer satisfaction with the attributes of your service
- To identify the gap or discrepancy between real and desired performance in order to target problems or improvement opportunities
- To measure the effects of an improvement in order to see whether customer and staff perceptions improved as a result
- To elicit reactions to hypothetical improvement alternatives
- To tune staff to their customers
- To show your customers or staff that you care about their input

The initial objective in setting out to design a study is the preparation of a written document, called a research protocol that describes the proposed study in detail. Many points (the following questions) need to be addressed in a logical fashion:

- What is the problem?
- What are the general aims and the precise questions to be answered?
- What will the study contribute the knowledge?
- What is already known about the problem?
- What study design will be used?
- What are the advantages and disadvantages of this design?
Will an intervention be required?
What population will be studied?
Will a sample be necessary?
How will it be chosen? What are the criteria for entry to the study?
What data are to be collected?
What are the variables of most interest?
What are the potential confounding variables?
How are the data to be collected?
Are the proposed methods reliable and valid?
Are appropriate quality assurance methods available?
Who will collect the data?
How will the data be recorded?
What training will the observers need?
How will the data be processed and analyzed?
Is computerization necessary?
How will the data be entered?
What analyses are planned?
Who will analyze the data?
What tables and figures will be required?
Is the study ethical?
Which ethical committee will consider the protocol?
What information is required for the participants?
How will informed consent be obtained?
Will any of the participants need referral?
How will this be arranged?
What follow-up will be required?
How long should the pilot study last?

Will the participants in the pilot study enter the main study?

How much will the study cost?

What resources, apart from money, are required?

Will a report and papers be written?

How will the participants obtain feedback?

How will the results be applied?

Sample:

The population sample is defined according to the type and the size of the target population. First, one must define and identify the target population. The next step is to see if this population is accessible, if data already exists, and if the size is too large (based on resources available, and logistics) that will require the need for selecting a sample (smaller in size) of this population.

If we decided to survey the total target population as in our earlier example, all the discharged patients from our hospital during a specific calendar year, then this type of sample is called a census sample. This sample is obviously the least biased sample. If, on the other hand, we decided to survey a smaller number of individuals in a population then we would need to determine two major elements: sampling method and sample size.

Sampling methods will select either a probability or a non-probability sample of the population. A Probability sample could be a simple random sample, a stratified random sample or a systematic sample. A non-probability sample could be a convenience sample, a purposive sample or a quota sample. The following is a brief explanation of each of these sampling methods:

**Simple Random Sampling** is a process where the required sample size is selected randomly from the total population under study through the use of randomly generated number tables, random number generating computer programs, or a lottery. This type of sampling methodology produces a simple but unbiased sample.
**Stratified Random Sampling** requires the determination of a sample based on one or a set of categories, usually demographics. In our earlier example we would select a random sample from the population by deciles age categories or another by income level categories, etc.

**Systematic Sampling** utilizes generating one random number and then selecting a constant interval. Thereafter every case that falls at that interval will then be selected. For example if our random number was nine and the constant interval was six, we will then select the ninth discharged patient and then every sixth discharged patient thereafter i.e. 15th, 21st, 27th, etc. Here of course we are assuming that those patients were not discharged using any systematic interval.

The other type of sampling method is the non-probability sampling method. Three different sampling techniques are discussed below using this method. For the following non-probability sampling techniques one must keep in mind that samples of these categories may not be representative of the target population. Therefore inferences should be strictly related to the sample of the study while projections on the total population from sample studies alone should be accepted with the caution of potential non-representation.

**Convenience Sampling** is performed to select readily available data. For example we would select those discharged patients from the surgery unit during the month of March of a given year only. This sampling method is considered to be the weakest to withstand the test of sample representation of the population or bias.

**Purposive Sampling** is a technique used to select a sample for a specific purpose. For example following a 30-day probationary period to re-accredit a hospital, the accrediting agency will only look at the hospital activities during the probationary period.

**Quota Sampling** is usually chosen to select a sample based on an arbitrary
quota. For example we may select only 5% of the target population to be included in our sample.

Sample Size

Calculating the sample size is the second element concerning sampling in general. To determine sample size one would require the availability of several preliminary data elements. One method of determining sample size utilizes the following equation:

\[ N = \frac{(z/e)^2 \times p(1-p)}{} \]

Where,

- \( N \) is the sample size
- \( z \) is the level of confidence determined by the z score
- \( e \) is the error rate
- \( p \) is the proportion of the target population in the total

Once we have determined the sample size and selected a sampling technique, the individual “member” of the sample can then be identified. To proceed in our survey, one must then determine the method by which to survey this sample population. Selection of any method is dependent on availability of resources (human and physical), time, accuracy, bias, and convenience.

There are at least three main methods of surveying a population. Surveys can be conducted through a mail survey, a telephone survey, or through an interview. All of which require a predetermined and pre-tested questionnaire.

In a mail survey you will be able to reach larger number of individuals with the least amount of expenditures and human resources. This method also provides you with honest (especially if the respondents’ identity is anonymous) and least biased answers. The major problem however with this type
of survey is the response rate which if it is too low, renders the responses non-representative of the total population. Of course misinterpretation of the survey questions or not completing all the questions may cause a problem in accurately analyzing the results. Also mail surveys require at least three to four weeks to complete and analyze.

A telephone survey is a very accurate survey but answers could be biased or are in response to leading questions. Since a human element is involved in actually collecting the data over the phone, specific training and coaching is required to accurately record and extract data from the respondents. Telephone surveys have the advantage of receiving a 100% response rate and can be completed within a relatively short period of time especially if collecting the responses were performed electronically.

The face-to-face interview is the most accurate but again could be biased since the identity of respondents albeit protected is not anonymous. Again, data collectors (interviewers) should be adequately trained in interviewing techniques and should be instructed to avoid leading questions to minimize bias of responses. Interview surveys usually enjoy a much higher response rate than other types of surveys, but are considered the most expensive and the most inconvenient type of surveys due to scheduling of interviews and respondents’ availability.

It must be noted here that the integrity of the data collected through any of the above types of surveys depends on the content and the quality of the survey questionnaire. A questionnaire should be designed to provide information that can answer the survey objective(s) adequately. Each of the questions included should be composed and designed in relations to the sample population. Therefore questions must be clear, simple to understand, and should require the minimum of effort (and time) for the respondents to answer. It is suggested that closed-ended questions are easier to answer and are certainly easier to analyze. In other questions where the opinion of the respondents is needed to be captured and quantified, one may design the questions in the form of statements. Each statement is succeeded with a choice of several answers (on a numeric scale) based on the level of agreement or disagreement to that statement, e.g. strongly agree, agree, disagree and strongly disagree.
Once the questionnaire is designed and the questions are constructed, one must proceed to administer the questionnaire to a small number of individuals that share the same characteristics of the sample population. This process is called “pre-testing” and will mimic the survey process in terms of survey process and methodology. Pre-testing is important since it gives the researcher the ability to predict the behavior of the sample population. It also provides the researcher with feedback regarding the design, the quality, and the efficiency of the survey instrument. Pre-testing of the questionnaire will provide the researcher the chance to modify it for clarity making it simpler to understand and easier to answer.

**Brainstorming**

Although Brainstorming is listed here under tools for identifying, collecting and displaying data it is a quick, simple and very useful tool that is equally important in making quality improvement decisions. This technique is usually group-oriented, whereby a group of individuals meet to generate an exhaustive list of ideas regarding an area or a topic at hand. It is a process that stimulates and encourages creative thinking and independency of thinking. The concept of creative and independent thinking is facilitated by one of the rules of Brainstorming that will allow individuals to list any idea they choose without being criticized. The generated list can either be used to answer a question or trigger other questions in problem identification and solving. Brainstorming is performed to generate the information needed to proceed for other steps in the quality improvement process. This technique becomes especially useful when all members of the group are participating and no boundaries of thought are adopted. The following is a description of the Brainstorming technique:

- Members of a group are gathered to discuss an issue, e.g. the causes of high patient waiting time in the emergency department. After few minutes of thinking about the issue, a group facilitator is selected and is asked to record the listing of all of the ideas generated from the group on a board or a flip chart to be easily seen by everyone in the group. Each member will then be given a turn to voice any one of his/her ideas on that issue. This is done by using either a freewheeling
Brainstorming is a good tool for:

- To establish a common method for a team to creatively and efficiently generate a high volume of ideas on any topic by creating a process that is free of criticism and judgment.

- This technique is usually group-oriented, whereby a group of individuals meet to generate an exhaustive list of ideas regarding an area or topic at hand. Brainstorming:

- Encourages open thinking when a team is stuck in the same old way of thinking

- Gets all team members involved and enthusiastic so that a few people don’t dominate the whole group
Allow team members to build on each other’s creativity while staying focused on their joint mission.

**Brain-writing**

This technique is similar to brainstorming where members of a group gather to generate a list of ideas on a topic. Unlike brainstorming, the ideas generated are evaluated and utilized aggressively by other members in the group to expand their list of ideas. Brain-writing is performed with each group member asked to write his/her list of ideas on a piece of paper. All of the papers are then left at the center of the table or the room for all the members to view and choose from to either add to or modify ideas in the lists. Another method is that each member is given 20 to 30 minutes to generate ideas and record them on separate flip charts that are then posted around the room. Each member is then asked to read those ideas recorded by others and go back to their sheets to continue listing more ideas that were stimulated by others’ ideas. Brain-writing has the advantage over brainstorming in occasions where some members of the group are dominating the idea generating process. It will also provide all members equal opportunity to participate and that it will eliminate less thought-out ideas. I can also be designed to be anonymous. Brain-writing can have the same uses as brainstorming in collecting and displaying data as well as in quality improvement efforts.

**Focus group**

The focus group is a powerful information-gathering technique that uses small-group discussions to identify the views of people in the group about a certain subject. A facilitator leads the discussion using a question guide. Focus groups work best when questions are open-ended and the facilitator encourages substantial discussion of each question.

**Logs**

This is a tool that is both simple to construct and easy to use. It is useful to keep track of the sequence of events or the time occurrence of certain data for charting trends or frequency analyses. Logs are constructed by identifying
and organizing the data elements into a table. For example one may want to keep a log of all the medical charts reviewed by the chart reviewers by date, by time, and by finding. Figure 3 below shows a log sheet for the reviewed medical charts. It is important to keep in mind that logs are constructed to be simple in design and is user-friendly. Logs are usually drawn as rows and columns with the summary statistics at the bottom of the log sheet. Recorders should be given a brief orientation session on the log’s use and are encouraged to only record the raw data requested and not to try to identify or elicit a trend of that data.

**Figure 3: Log**

<table>
<thead>
<tr>
<th>Medical Record</th>
<th>Reviewer</th>
<th>Date</th>
<th>Time</th>
<th>Finding(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234567</td>
<td>Smith</td>
<td>8/31/98</td>
<td>8:30 am</td>
<td>no lab results</td>
</tr>
<tr>
<td>4567890</td>
<td>Jackson</td>
<td>9/1</td>
<td>9:30</td>
<td>no signature</td>
</tr>
<tr>
<td>3256701</td>
<td>Phillips</td>
<td>8/30</td>
<td>10:00</td>
<td>no referral form</td>
</tr>
<tr>
<td>4100056</td>
<td>Bradford</td>
<td>8/31</td>
<td>11:00</td>
<td>missing H&amp;P</td>
</tr>
<tr>
<td>3255671</td>
<td>Sharp</td>
<td>9/1</td>
<td>9:00</td>
<td>incomplete ID</td>
</tr>
</tbody>
</table>

**Check sheets**

We use check sheets because they allow a team to systematically record and compile data from historical sources, or observations as they happen, so that patterns and trends can be clearly detected and shown. Check sheets are also useful tool for data collection in order to answer questions regarding resources allocation, analyze a current problem or identify potential problem areas.

To answer the questions “what do you want to know?” and “What is the most reliable way to collect the data?” one must construct a check sheet. To construct one, check sheets can be either drawn in the form of a table or a diagram. The recorder will make a check mark or enter the appropriate data across from the item in the sheet once the observation occurred or the event happened. Figure 4 below illustrates the use of an example of an event on a check sheet.
Figure 4: Check Sheet

Lab Technician Present (x) or Absent (o)

<table>
<thead>
<tr>
<th>Days</th>
<th>Jones</th>
<th>James</th>
<th>Lee</th>
<th>Dean A</th>
<th>Li</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday</td>
<td>x</td>
<td>o</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Tuesday</td>
<td>x</td>
<td>x</td>
<td>o</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Wednesday</td>
<td>o</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Thursday</td>
<td>x</td>
<td>x</td>
<td>o</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Friday</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>o</td>
</tr>
<tr>
<td>Saturday</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Sunday</td>
<td>x</td>
<td>x</td>
<td>o</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Total (x)</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td>6</td>
</tr>
</tbody>
</table>

Check sheets are useful to collect data to answer questions regarding resources allocation, analyze a current problem or identify potential problem areas.

Pie Charts

Pie charts are powerful tools for clear and simple presentation of data. A pie chart is a form of graphic presentation of data elements that are part of a whole. This tool is useful for visualizing the differences between different parts compared to the whole.

For efficient and impressionable presentation of data, pie charts will provide a powerful toll to accomplish that. A pie chart is a form of graphic presentation of data elements that are part of a whole. This tool is useful to visualize the differences between the several parts of a whole. Pie charts can be used in place of bar graphs.

Pie charts construction however, has few rules to follow:

- Pie charts segments must add up to 100% of the whole.
The number of segments in a pie chart should not exceed more than six segments to avoid “cluttering” of information.

Each segment should indicate the percentage amount compared to the whole to enhance comparability.

If there are one or more categories that have a zero value, then pie charts should not be used.

**Scatter Diagram**

This technique is useful in displaying data from two variables that may have a relationship (but not necessarily an impact) with each other. The data collected for each variable is then plotted on a graph with one variable on the X-axis and the other on the Y-axis. If a pattern is noticed then a positive or a negative relationship may be concluded. This technique is considered the easiest way of recording correlation analysis without actually quantifying of the strength or the significance of the relation between the variables. It is however simple to construct and is useful in showing patterns of data and providing supportive data for cause and effect diagram construction (described later in this chapter). Although scatter diagrams are sometimes used to plot pairs

---

**Weekly Outpatients Visits**

![Weekly Outpatients Visits Diagram](image)
An example of scatter diagram

Histograms

This tool is a modified bar graph, where the data on the X-axis are continuous data thus the bars are adjacent to one another. Histograms are useful to present a pictorial view of the data elements and to show data patterns. Histograms are constructed primarily to display data. For example, the X-axis shows the time spent (in intervals) for routine outpatient visits while the Y-axis shows the number of routine patients visits completed within each of the time interval.

A histogram is constructed in steps. In the above example, we collect data by constructing a table of patient visits column by time spent (in minutes) in the outpatient department. We would then arrange the time into equal intervals depending on the range of the times in minutes. The next step is to construct a check sheet with a number of patient visits that each fell in one of the identified time intervals. A histogram will then be constructed using the above information by plotting the number of patient visits on the Y-axis while plotting the time intervals on the X-axis. Each time interval will represent the width of the bar while the number of patient visits will determine the height of the bar.
Tools for Quality Improvement and Monitoring

Once data are collected and other tools are constructed to display data, analysis of data begins and several tools can be used to aid in this process. Quality improvement tools are important for decision making and for evaluating the progress and the success or failure of the decision made to improve a process. There are several process improvement tools and I will attempt to present and explain most of them.

Nominal Group Technique

This technique is a continuation of the brainstorming and the brain-writing techniques for the purpose of ranking or prioritizing. Once a list of ideas is generated then a process of prioritizing or ranking of ideas begins with all the group members. Ranking is done by one of three popular methods (as described below): multiple voting, weighted voting, or rank ordering techniques. A second list will then be generated with the ideas ranked accordingly and presented for its intended use of implementation and process improvement. This technique is especially helpful to decrease the number of ideas to a shorter list of manageable number of “best” ideas.

Multiple Voting Techniques

To complement brainstorming and brain-writing techniques, multiple voting is another technique that is intended to shorten, evaluate, critique and rank a long list of ideas. The members of the group that generated the list of ideas perform multiple voting. The group will decide on a number of votes each member may have (usually 1.5 times the number of ideas present). Each member will then cast his/her votes on the set number of ideas. Members can spread their votes any which way they desire on the list of ideas. Therefore, one member may cast half of his votes on ideas number 1 and the other half on idea number 3 but none on any other idea and so on. All members post all those ideas voted on by group member on a flip chart to be visible. Discussions will then follow to determine which ideas received the most number of votes and whether these ideas are adequate to describe the group choices. Further consideration of other ideas may be required if the group decides that
more ideas are needed on the final list. The new and final list of ideas is then presented for ideas to be implemented by the processes involved.

**Weighted Voting Technique**

Again, this technique as with multiple voting techniques is useful in determining a final and best list of ideas to be implemented by a group of individuals. As with multiple voting each member is able to cast their vote on the full list of ideas or only on a short list of ideas. In these techniques, group members are asked to provide their individual ranking for each idea based on set criteria; for example feasibility, cost, impact, politics, etc. If the idea is most feasible to implement then it could receive a maximum of 5 points and so on for cost, impact, politics or other criteria present. Each idea is therefore evaluated individually using these criteria by each member. The total points received for each idea is added from all the members. Ideas are then ranked according to the number of points each received.

Example: (Al-Assaf and Shouman, 1998)

- Each solution to be measured according to different criteria that is supposed to be of importance to the organization such as Impact, Cost, Feasibility, Politics, Reputation, Relevance, etc.

- The solutions that get the highest score will be adopted for implementation.

- The score range from 3-1 with 3 means high score for better solution.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Name A</th>
<th>Name B</th>
<th>Name C</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Form Team</td>
<td>I C F P R R</td>
<td>I C F P R R</td>
<td>I C F P R R</td>
<td></td>
</tr>
<tr>
<td>2 Establish Plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Set Standards</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Measure Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Calculate Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Example: I- Impact P- Politics C-Cost R-Relevant F- Feasibility RP- Reputation
Rank Ordering Technique

In conjunction with brainstorming and brain-writing this technique is used to rank ideas for further consideration and/or implementation. Rank ordering technique requires working on a short list of ideas (ideally less than ten ideas) by the ideas generating group. If the number of ideas is too large then use the principle of “one half plus one”. If the number of ideas is 20, then one half is 10 plus one equals 11. Therefore use only 11 ideas and may apply the same principle again for the rest of the ideas. Once the number of ideas is agreed upon, each group member is asked to rank these ideas starting with one as most important and ending with the least important idea. The recorder of the group will post the list of ideas on flip chart and on columns record the ranking given by each member to each idea. After recording all the rankings for each idea, these are then added together to get the total ranking score given to each idea. Since a score of one is given to the most important idea, the idea that receives the least numbers is therefore the most important and so no for the rest of the ideas.

Example:

<table>
<thead>
<tr>
<th>Idea</th>
<th>Jack</th>
<th>Jill</th>
<th>Jasmin</th>
<th>Ahmed</th>
<th>Susan</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>8</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>7</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>C</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>D</td>
<td>7</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>23</td>
</tr>
<tr>
<td>E</td>
<td>3</td>
<td>4</td>
<td>6</td>
<td>6</td>
<td>8</td>
<td>27</td>
</tr>
<tr>
<td>F</td>
<td>6</td>
<td>7</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>25</td>
</tr>
<tr>
<td>G</td>
<td>5</td>
<td>1</td>
<td>8</td>
<td>8</td>
<td>5</td>
<td>27</td>
</tr>
<tr>
<td>H</td>
<td>8</td>
<td>6</td>
<td>7</td>
<td>5</td>
<td>1</td>
<td>27</td>
</tr>
</tbody>
</table>
Balance Sheets or Force-Field Diagrams

This technique is used to help a group of individuals select a shorter list of ideas, options, decisions, etc. All of the ideas under consideration are listed on a two column table. One column will be noted as the positives/the advantages/the strengths/the driving forces column. The other column will be the opposite descriptors column. Each idea is then discussed and the group members regarding its positives and the negatives produce a listing. After considering all the ideas on the list, the group “balances” the positives with the negatives i.e. the forces for it and those against it, and then determine if some of these ideas might be eliminated. This technique is again very useful in determining the best ideas for further consideration and implementation. It is therefore another important technique in the process of quality improvement.

Trend and Run Charts

A trend or a run chart is a line graph that visualizes a pattern of behavior of certain data over time. It is therefore a pictorial indicator of the extent of fluctuation of performance of a data element during a period of time. Trend charts are very useful in displaying and monitoring the behavior of data as well as a predictor of the future performance of that data. For example one might chart number of medication errors on the Y-axis against the months on the X-axis over a year to look for trends.

Interpreting patterns (see figure below for examples): all these patterns suggest a non-random event (special cause, a process not in control).

- More than 7 consecutive points above or below the mean suggest a pattern of change
- 6 points consistently increasing or decreasing suggest a trend (2)
- more than 7 points in a zigzag pattern suggest a cyclical event (3)
Flowcharts

Flowcharts are a step-by-step sequence of processes and sub-processes that pictorially includes events, reaction(s) or a decision(s). This tool provides a detailed list in a form of a sequenced diagram outlining all the action and steps required for each and every process in an organization. It also provides a common language to be used by teams when discussing the different elements of a process. For example one could flowchart any process in a hospital from patient registration to patient admissions and discharges. Each of the steps in the process is denoted by a symbol indicating the nature of the action or the reaction.

Flowcharts can be one of several types; detailed (with loops of rework), top-down (only outline of the major steps in the process), or a workflow type chart based on the actual steps occurring related to a specific work process. Team members should be collectively involved in flowcharting a process. Teams should start by defining the process in consideration, and then a determination of a beginning and an end of the process is made. The team will then start to write the steps of the process in the sequence they occur. Certain members of the team or with the aid of action teams will be responsible for flowcharting the technical steps in the process. Once a flowchart is produced of the process the team will revise it again for completeness and correct any errors. The final version of the flowchart is then transferred on a sheet of paper denoting the steps of the process in symbols and is put in use by the organization. The following is a list of some of the more common symbols used in flowcharting processes:
Although many symbols are used in flow charts, the most common ones are:

- **Start / Stop**
- **Cloudy, or uncertain step**
- **Step or activity**
- **Connector to another page**
- **Decision point**

Flowcharts are important tools both for displaying a process and for understanding the process steps. It supports the principle that if you understand your processes and how they work, then you will be able to identify process requirements and its “bottlenecks”. Therefore to analyze the process using OTS flowchart, the team might begin by asking such questions as; Is there any delay? Are there any bottlenecks? Are there any steps that are missing? Any that is redundant? Are there opportunities for improving process flow?, etc. Flowcharts are management tools that will support the quality improvement efforts of an organization. For example: (Reinke, 1998)
Pareto Diagram

According to Omachonu (1991), an Italian economist called Alfredo Pareto (1897) and an American economist, M. C. Lorenz (1907) developed a concept that suggested only a few of the population share the most of the total income of the population. The quality expert J. Juran applied this principle to problems of quality dividing them into the vital few and the trivial many, i.e. most of the problems are linked to only few of the causes. The procedure that classifies these problems is thus called the Pareto Analysis.

The Pareto concept is further known as the rule of the 80-20. In healthcare this can be applied, for example, as saying that 80% of documentation errors
are caused by 20% of staff. Another example is that 80% of medication errors are caused by 20% of nursing staff and so on. One can further analyze data utilizing this principle by the use of bar and line graphs. To do this there are few steps that need to be followed to display the data on a graph according to this principle:

1. Identify a quality problem to be studied e.g. patient complaints of dietary services.
2. Determine and carry out a data collection method e.g. mail survey.
3. Categorize the complaints cited by respondents according to type e.g. temperature, taste, promptness of service, esthetics, etc.
4. Calculate the frequency of complaints by category e.g. temperature 74 complaints, taste 43, etc.
5. Plot the frequencies of each complaint categories on a bar graph and arrange the categories in order of descending frequencies from left to right on the horizontal axis (x-axis). Two vertical axes must be designed, the left axis (y-axis) will be divided in equal intervals into the number of highest category frequency (74 in our example), while the right vertical axis is divided into percentages from 0% to 100%.
6. Add the percentage values of the bars and calculate the cumulative total over each bar. Plot these totals on the same graph but as a line graph.

Pareto diagrams are important not only to display the causes of a quality problem, but also to provide the quality team a diagnostic and monitoring device that can be used to identify and monitor progress in the quality improvement measures being tried. Its importance becomes evident when Pareto diagrams are used as incentives for achieving an eventual flattening of those bar graphs.

☆ Can be used to focus attention on the “vital few” instead of the “trivial many” problems or processes needing attention

☆ Can be used to decide which problem to pursue

☆ Can be used to identify the more influential causes of your problem
☆ Can be used to show changes in performance over time
☆ Progress is measured in a highly visible format that provides incentive to push on for more improvement
Control Charts

Control charts are tools designed to monitor a process over a period of time to study its trend and variation. It is constructed to display process stability around a historical (acceptable) trend with the capability of measuring small changes in the process. A control chart provides an analysis of a process behavior and indicates when certain factors had an impact on process trend. It is a useful tool in process improvement efforts in that it identifies the times when process is “out of control” i.e. outside the calculated control limits. It is therefore useful in identifying improvement opportunities of a process. It is also used to determine whether process variation from the norms (averages) is due to “special” or “common” causes. Special causes have the tendency to occur sporadically and acutely and will therefore need to be attended to by the management team. Common causes on the other hand are long-term causes that have no capability of destabilizing a process but can produce slight impact on process variation away from the norm. Common causes of a process variation are the result of interaction of several causes over a period of time. Common causes need to be studied by appropriate quality improvement teams of the organization. Control charts are useful in controlling variation at an acceptable level of measurement.

Control charts are basically a run chart with three additional horizontal lines. One line represents the mean value (average) is drawn in between an upper control limit (the mean plus 2 standard deviations) and a lower control limit (the mean minus 2 standard deviations) lines. A process is said to be in control if the trend line lies within the upper and lower control limits around the average. In this case variation is caused by common causes and therefore an intervention by quality teams is necessary. If however, the trend line falls outside those lines then the process is said to out of control. Here the causes of making the process to fall outside the control limits are considered to be special causes and therefore it is management responsibility to resolve it. There is however one additional element to this concept. The process is again considered to be out of control if at least three consecutive points on the process trend line fall below or at least three consecutive points fall above the average line even-though the process trend line is still between the upper and lower control limits. Here again special causes are attributed to this type of trend. Few other rules apply to the concept of process control and the
reader is instructed to consult the reference listing at the end of this chapter. An important point need to be communicated here is that control limits are not thresholds or standards. They are measures that describe the behavior or the nature of a process. Therefore a process that is in control does not necessarily means a good process and so is a process that is out of control is not necessarily a bad process.

To construct a control chart one needs to calculate the averages of a process/quality problem over time, for example the number of medication errors per week over a five-month period. It is recommended that twenty data points are needed to construct a control chart. An overall mean (average), $x$ is calculated which will represent the middle horizontal line on the chart. The standard deviation of the mean, $S$ is then calculated, using the following formula:

$$S^2 = \frac{1}{n(n-1)} \left[n\overline{x}^2 - (\overline{x})^2\right]$$

The upper control limit is then calculated and is equal to 2 standard deviations above (plus) the mean while the lower control limit is equal to 2 standard deviations below (minus) the mean. A line graph of the data points is plotted with the number of the weeks at the X-axis and the average number of errors per week at the Y-axis. The graph is then examined to determine whether the trend of medication errors is in control or if it is out of control. The process is attended to accordingly as was mentioned above.

It should be noted here that the above described control chart is only one type of control charts. This type however is considered the most useful in healthcare data. Other less common types of control charts are available and their use and selection depends on the type of data to be analyzed. The references at the end of this chapter are selected to provide the reader with additional information on control charts.

**Cause and Effect Diagrams**

Sometimes called the Fishbone diagram or the Ishikawa’s diagram is a tool useful in the identification of problem causes and “sub” causes. A cause and
effect diagram, as what the name refers to, is a diagram that displays root causes of a problem of a situation in several related categories of causes. Each of these categories further displays several subcategories and each of which is either further branches of into more subcategories of displays a number of causes related to it. Fishbone diagrams utilize few other quality improvement tools to construct, such as brainstorming, surveys, etc.

The Cause & Effect diagram was developed to represent the relationship between some « effect » and all possible « causes » influencing it.

- The effect or problem is stated on the right side of the chart and major influences or “causes” are listed to the left.

- Cause & Effect diagrams are drawn to clearly illustrate the various causes affecting a process by sorting out and relating causes.

- For every effect there are likely to have several major categories: People, Machine, Methods, and materials.

Cause and effect diagrams are constructed by the quality improvement team in a few steps. Once a problem is selected for study, the causes of this problem are then listed. The list is further refined to reflect realistic and traceable causes for further study. The list of the causes is then classified into categories (and subcategories) and these are then displayed on the diagram with arrows directed towards the main problem. Categories are either selected randomly by the team or selected from the standardized list of possible causes of variation by category. A separate list of causes may be generated for each of the following categories; people, materials, machines, methods and measurements.
Decision-making Matrices

A matrix that can be used for decision-making is composed of a table of rows and columns. The rows will display the list of alternative decisions or solutions for improving a quality problem, while the columns represent the criteria of judging between those decisions. Criteria can be given different weights by the team to indicate importance of certain criteria over the others. Examples of criteria are cost, politics, staff support, impact, simplicity of implementation, administration, etc.

Decision matrices are very useful in making rational and democratic decisions to solve a problem or improve a process. The alternative decisions are listed in the left-hand column, while the evaluation/selection criteria are listed across the top row. Also notice that each criterion is further weighted according to its importance and feasibility.

The quality improvement team in a few steps should construct a decision-making matrix. After identifying and listing the causes of a problem (prioritized), the team will then decide to study the most important solutions to this problem. Once alternative solutions are selected, the team should then identify the selection or evaluation criteria for the alternative solutions. This step is considered very important and a consensus should be reached on the list of criteria. A weight may be assigned to each criterion denoting the importance of one criterion over the other, e.g. one may give cost a 3 multiplier units while impact a 2 multiplier units, etc. A scale of rating each decision is selected, e.g. 1=low rating while 5=high rating. Each team member is then asked to rate each decision by criterion from 1-5 and list the score in the related cells under each criterion. If however there is a weight on a criterion then the multiplier factor is multiplied by the rating score and entered in the cell. Each member will add the total scores for each decision (total of scores in each row). The totals for each decision from each member are added up to get a team total for each decision. Those decisions that get the highest number are those that are rated highly by the team for further study and possible implementation.
Decision-making matrices are helpful in selecting an acceptable decision. It shifts the burden of responsibility of decision-making to an interdisciplinary group of individuals and away from bureaucracies. It instills confidence and pride in team member as it provides them a sense of responsibility and assures them a role in the decision-making process of an organization.

<table>
<thead>
<tr>
<th>Options</th>
<th>Criteria (rating 1-10); 1 low</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c # 1</td>
<td>c # 2</td>
</tr>
<tr>
<td>Option 1</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Option 2</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Option 3</td>
<td>10</td>
<td>9</td>
</tr>
</tbody>
</table>

Decision Matrix

More demanding statistical methods are used in scientific health care studies to make multivariate analyses possible. These are also necessary for the analysis of health care processes as part of normal activity. In practice, it is simpler to use less complicated statistical methods at first hand to identify the variation for which more complicated statistical methods might then be used. Many of the care process processes have not been evaluated for different reasons: (1) the benefit for the patient is self-evident; (2) the speed of the development of health care technology and care methods has been so rapid that systematic evaluations are just being carried out; (3) health care has functions that cannot be evaluated through a strict statistical approach; and (4) the need for support, information and caring for the person has always been essential parts of health care in practice. However, all of the care activities can be evaluated. Most of the activities carried out by a health care expert or an organization can be evaluated using statistical methods or other quality techniques.

**Statistical methods**

**Systems theory and SPC - Statistical Process Control**

The scientific quality approach is mainly based on a systems theory. The starting point is that all work is a process and part of a system. A system is a group of parts that interact to accomplish something. According to the
systems theory, when the aim is to optimize activity it is essential to understand how the parts of the system interact. Systems aim at stability (minimization of variation). The development of quality is based on the management of stability and, after that, on conscious deviation from stability.

Techniques have been developed based on systems theory to manage and analyze the variation of processes (the system). One commonly used technique is the SPC (statistical process control), in which the aim is to identify variations in the process variables and the specific and random factors which cause such variations. A control chart is often used to identify variations, which makes it possible to identify the normal variations of the variable, which is being examined (random factors) and the measurement results outside the normal variations (specific factors). For the purposes of the development of quality, attention should be focused on the measurement results that are detected outside the normal variations. There is plenty of literature and training available concerning systems theory and SPC.

Other statistical techniques

More developed tools are also available for health care organizations as well as other enterprises. These methods like Taguchi, Six Sigma or the Quality Function Deployment (QFD) enable the health care organization to analyze its performance, the properties of its products etc. in a much more systematic way than we have been accustomed to so far. In general, these methods have been used very little by health care organizations so far. Lack of resources has forced health care organizations to improve their performance. The existing variation is also a challenge to be met. The experiences from other enterprises suggest that the use of these methods could also save resources thus helping health care personnel to manage the growing workload. The health care expert needs to be trained for these methods if they are to use them in their everyday practice.

The quality techniques

Competitive companies routinely analyze the properties of the product. In health care there has been customer satisfaction surveys carried out by many of the quality focused organizations. Customer expectations can
never be fully met by health care organizations due to resources limitation. Industrialized countries have means of regulating the health care market in an attempt to use the available resources in the best way possible. This attempt is increasingly challenged by the citizens (patients) who consume health care products subjectively perceiving the outcome. The properties of these products can and should be analyzed both from the consumer and the provider perspective. There are numerous quality techniques available for these analyses that would help increase the transparency of health care products and resolve the debate between patients and health care experts.

Process development techniques are often based on problem solving. When the problem is being specified, the aim should be to generate factual information with the heir/use of appropriate indicators and measurements. Problems can be analyzed with different techniques, such as the scatter diagram, the Pareto chart, the histogram, the fishbone technique and the check sheet. Useful ways of trying out alternative solutions to problems include piloting, simulation, and looking for good practices. The results must be assessed to make sure that the solution works. The new action plan can then be introduced as part of a continuous quality management system.

**DOCUMENTATION**

Appropriate and complete documentation is an important part of all the quality management systems. The motto is, *“Document what you do, do what you document.”*

**Write what you do**

The documentation of our activities is necessary for different reasons. You need to document your activities (products) to inform your clients (patients as well as purchasers).

Our staff needs a description of the activities being planned and instructions to ensure that their work is carried out as required. The documentation should use an evidence’ based approach and this has actually been the aim in the clinical guidelines and protocols produced by different health care experts.
Do as you write

The idea behind a documented quality system is that work is carried out according to the quality manual and protocols that have been developed. In health care this raises an interesting challenge. We have a long tradition of producing guidelines and protocols to define good practice for care as well as prevention. There is very little research and evidence to demonstrate how well these guidelines have been implemented in every day practice. Many of the guidelines have been criticized as being too scientific and impossible to implement in real life.

With this in mind, the hospitals functions should be documented in detail. In order to clarify responsibility transfer, hospitals should document job descriptions, function flow, procedures, and various indicators at the departmental level. The first step should be to draw flowcharts and record procedures in detail. The flowcharts are used to define the stages in our process, and the responsibilities involved in executing these. The documentation for each procedure will describe us who did what, the sequence of tasks involved, and the responsibilities associated with those tasks.

GENERAL GUIDELINES FOR PROPER DOCUMENTATION

A. Accuracy
B. Brevity
C. Clarity
D. Date and maybe time
E. Errorless
F. Final must include signature/co-signature
J. Justification (investigation, procedures)

Health care providers should only document factual and objective information from their own treatment and/or observation of the patient. When documenting information derived from other sources, for example, other health care providers, other medical records, or entries in the same medical record, are sure to reference the source of that information. Subjective documenta-
Barriers to Proper Documentation

- Time Management
  - Too busy,
  - No administrative time,
  - Overload

- Incomplete Understanding of Requirements

- Do not understand the importance of
  - Medical, legal, financial

- Attitude
  
  “I am here to provide patient care”

Accurate concise documentation is paramount in communicating the past, present, and expected future of a patient’s progress. So what does this have to do with Compliance – quite a bit? The Medical Record should not just reflect what has occurred with the patient during their stay (Inpatient or Outpatient), but through the History and Physical through to and including discharge plans, the continuum of care is recognized.

(Showered -2000)

It has been shown that as many as 1/3 of all hospitalized patients experience some iatrogenic event while in hospital. Few, however, make a claim. The Harvard Medical Practice Study demonstrated that most injuries, which are the result of negligence on the part of a physician, do not result in claims. Despite the current “malpractice epidemic”, these figures suggest that malpractice claims could increase even more.

Frank, m. Lewis 1999 Harvard Medical School.

It is from the Medical Record that the provider is able to properly apply CPT (procedure) and ICD-9-CM (diagnosis) codes to the medical record, which directly identifies the condition of the patient and the care delivered. The ability to code the medical record correctly is totally dependent on proper documentation, and through correct coding; the provider is able to submit correct
billing for the services rendered. This becomes problematic and a compliance issue when the coding isn’t supported by the documentation and ultimately the inability to bill or submit correct billing.

The medical record serves many purposes but its primary function is to plan for patient care and to provide for continuity in information about the patient’s medical treatment. As a permanent record, the patient’s medical record informs other health care providers both inside and outside the hospital about the medical history of the patient. In addition, the medical record:

- **Provides** information which serves as the basis for financial reimbursement to hospitals, health care providers and patients;
- **Serves** as a legal document for use by an injured patient against other parties or for use in other legal proceedings;
- **Is used** by hospital quality assurance and peer review committees, licensing agencies, and other entities in accessing the quality of patient care by hospitals and health care providers; can be used in clinical research (via retrospective review)
- **Is a key** portion of accreditation processes such as that of the JCI?

**What Is Documentation And Why Is It Important?**

Documentation is the recording of pertinent facts and observations about an individual’s health history including past and present illnesses, tests, treatments, and outcomes. The medical record chronologically documents the care of the patient in order to:

- Enable the physician and other health care professionals to plan and evaluate the patient’s treatment
- Enhance communications and promote continuity of care between physicians and other health care professionals involved in the patient’s care
- Facilitate claims review and payment
- Assist in utilization review and quality of care evaluations
- Provide clinical data for research and education; and
Serve as a legal document to verify the care provided (e.g., in defense of alleged professional liability claims)

** Corrections to the Medical Record**

The following guidelines should assist you in making proper medical record corrections:

- Never add or clarify an entry after you have received a subpoena for record
- Never make entries in pencil or erasable ink, and never attempt a correction by erasing.
- Never obliterate an entry or use correction fluid like “white out”.

When a correction becomes necessary, merely draw a single line through the entry so that the original entry is still readable.

- Make a notation explaining the correction, or directing the reader to the appropriate addendum.
- Date and sign the correction.
- If using an addendum, place it in sequence or chronological order.

The record should be kept in chronological order. If there are areas of blank space at the end of a page, cross them out before starting a new page.

** Omitted Information**

In the event information is omitted from the medical record, it is considered acceptable to amend the record. “Late entries” are also acceptable however should be used infrequently. Acceptable methods for recording “amendments”, “addendum” and “late entries” are:

- Create a new entry for the additional information. Do not annotate in the margins to add information.
- Keep all entries chronological and in record sequence.
Title or head the entry or note as “Addendum”, “Amendment” or “Late Entry”.

Use the actual date of the addendum, amendment or late entry.

Reference the original entry or document by indicating the date of the service. It is helpful to provide a brief explanation regarding the necessity for the additional documentation.

always sign the additional entry or document

The Harvard Medical School study – April 2000

Each medical record contains at least the following Patient information and authorized representative;

- Legal status, for mental health services;
- Emergency care prior to arrival;
- Record and findings of the patient assessment;
- Conclusion/impressions from history and physical;
- Diagnosis or diagnostic impression;
- Reason(s) for admission or treatment;
- Goals of treatment and treatment plan;
- Evidence of informed consent if required;
- Diagnostic and therapeutic procedures/tests performed and results; All operative and other invasive procedures performed;
- All progress notes;
- All reassessments;
- Clinical observations;
- Response to care provided;
- Consultation reports;
- Every medication ordered/prescribed for inpatients;
- Each medication dispensed/prescribed for ambulatory patient or inpatient on discharge;
- Every dose of medication administered and any adverse drug reaction;
- All relevant diagnoses;
- Any referrals/communications to external/internal care providers and community agencies;
- Conclusions at termination of hospitalization;
- Discharge instructions to the patient and family; and
- Clinical resumes and discharge summaries, a final progress note, or transfer summary.

“The discharge summary contains the following information”
- Reason for hospitalization;
- Significant findings;
- Procedures performed and treatment rendered;
- Condition on discharge; and
- Specific instructions.

Substitutions include:
- Final progress note for patients with minor problem and interventions (defined by the medical staff) with <48 hours LOS and normal newborns/uncomplicated obstetrics deliveries.

☑ Transfer summary note for patients transferred to a different level of hospitalization or residential care within the organization.

☑ “Medical record data and information are managed in a timely manner”

☑ “For patients receiving continuing ambulatory care services, the medical record contains a summary list of known significant diagnoses, conditions, procedures, drug allergies, and medications.”

☑ “Verbal orders of authorized individuals are accepted and transcribed by
qualified personnel who are identified by title or category in the medical staff rules and regulations

✔ Dated and identified by names of individuals giving, receiving, and implementing the orders;
  - Authenticated by the prescribing practitioner within the specified time period when required by state or federal law or regulation.

✔ “Every medical record entry is dated, its author identified, and, when necessary, authenticated

✔ Entries made only by authorized individuals;
  - Entries authenticated only by the author to verify they are complete, accurate, and final [serves as a definition of “authentication”];
  - Entries authenticated by written signature or initials, rubber stamp, or computer “signatures” or codes, faxed signatures;
  - Entries requiring authentication identified in policy, including at least H & P, operative reports, consultation, and discharge summaries.

✔ The [organization] can quickly assemble and have access to all relevant information from components of a patient’s record, when the patient is admitted or is seen for ambulatory or emergency care.” “The medical record, computer system, or organization policy indicates when part of the record has been filed elsewhere

The Medical Record Documentation

Documentation is also the recording of pertinent facts and observations about an individual’s health history including past and present illnesses, tests, treatments, and outcomes. The medical record chronologically documents the care of the patient in order to

☆ Enable the physician and other health care professionals to plan and evaluate the patient’s treatment
☆ Enhance communications and promote continuity of care between physicians and other health care professionals involved in the patient’s care

☆ Facilitate claims review and payment

☆ Assist in utilization review and quality of care evaluations

☆ Provide clinical data for research and education; and

☆ Serve as a legal document to verify the care provided (e.g., in defense of alleged professional liability claims)

Medical College of Wisconsin-2000

General Principles of Medical Record Documentation

The principles of documentation listed below apply to all types of medical and surgical services in all settings.

✔ All entries must be completed in preferably black ink, do not photocopy or fax well

✔ All entries must be legible

✔ Each entry should be titled or labeled for accurate service identification, including ancillary entries

✔ Entries such as progress notes must be completed at the time of the encounter or immediately after

✔ All entries must contain a date and time

✔ All entries must be authenticated

✔ Entries should be listed in chronological order and should contain no blank spaces

✔ Use only hospital approved abbreviations and acronyms

✔ When appropriate, the use of illustrations with descriptions and measurements is considered extremely valuable for complete documentation
Proper patient identification must appear on every document, and both sides if necessary.

The documentation of each patient encounter must include the following:

- Reason for the encounter and relevant history, physical examination findings and prior diagnostic test results
- Assessment, clinical impression and diagnosis

**Plan for care**

- If not documented, the rationale for ordering diagnostic and other ancillary services must be easily inferred
- Past and present diagnoses must be accessible to the treating and/or consulting physician
- Appropriate health risk factors must be identified
- The patient’s progress, response to and changes in treatment, and revision of diagnosis must be documented
- The written plan for care should include:
  - Treatments and medications
  - Specific frequency and dosage
  - Any referrals and consultation requests
  - Patient/family education and counseling Specific instructions for follow-up

The documentation should support the intensity of the patient evaluation and/or treatment, including thought processes and the complexity of medical decision making.

**Conclusion**

This chapter presented an overview of the more common tools and techniques used by quality improvement teams to manipulate data and transform that data into meaningful information. The list of tools that can be used to
meet this objective is even longer than what was presented above. The tools presented above however, are the most widely used tools but the reader is encouraged to seek more information on the subject. The objective of quality improvement tools is to support organizations achieve improvement in the most rational and cost effective way possible. Use of statistical thinking according to Deming (1986) will identify causes of process variations and will lead us to ways to reduce variation. Statistics in quality management tells us that the results of a process is not necessarily equal to the summation of all of the factors composing it but it is the result of the synergistic interaction of these factors with each other. Applying statistical principles to process improvement will eventually decrease waste, eliminate rework and reduce duplication.

Documentation is the other common tools to ensure quality in health care organization so some tips and practical issues in proper documentation are also shared with the readers in this chapter.
References


CHAPTER SIX
Teambuilding in Healthcare Quality

Stephen L. Walston, F.A.C.H.E., Ph.D.

Why Teambuilding?
Healthcare professionals work in teams all of the time. Nurses team with respiratory therapists, housekeepers, nursing aides, and physicians to provide care. However, at times quality improvement requires people from different areas and specialties that do not generally work together to join forces. These may be called focus or charter teams. Focus teams and task forces may address multi-faceted problems that extend across departmental lines, develop new ideas, and foster greater cooperation. Working in effective focus teams also allows greater acceptance of the outcomes and a higher implementation rate. However, bringing together different people involves substantial risks and rewards. Left alone some teams flounder and may produce only anger and cynicism. Teambuilding, efforts to improve the function and quality of team performance, is essential today to ensure proper team performance. If done correctly teambuilding can quickly allow people from diverse settings to come together and produce impressive results.

Forming Teams
Teams can be organized and created through a number of different means. For those organizations that have a Quality Council, teams may be chartered. This may involve a formal process involving a written request to the council, followed by a preliminary investigation of the issue prior to chartering the team. Requests may range for issues as small as the efficient placement of supplies to as large as the admission system for the whole hospital. For example, nurses working on weekends at one hospital voiced concerns about the delays in admitting patients from the Emergency Department (E.D.). Chronically, patients would be held in the E.D. for up to six hours prior to admission on weekends. This would cause overcrowding in the E.D. and make other patients wait longer than needed for lack of rooms. The Quality Council upon
investigation found that the laboratory and radiology departments also contributed to the E.D. delays. A team was chartered to address this problem and included representatives from the E.D., laboratory, radiology, nursing, and administration. On the other hand, often enlightened managers may realize that a team is necessary to address problems that cross departmental boundaries and take the initiative to work directly with the other departments to solve problems. Whatever the approach, there are certain things that can be done when forming a team that will improve their outcomes. These are:

1) Have a clearly defined purpose or task. Teams need to understand clearly what they are trying to accomplish and for what purpose. The purpose should be linked to larger organizational goals and/or mission and be seen to add value to patients, staff, and/or the organization as a whole.

2) Keep the purpose to a workable scope. Establish attainable goals for the team. Do not seek to design a plan to achieve world peace. If the overall needs are too large, break the tasks into separate components that could be given to the team in phases or given to multiple teams.

3) Do preliminary research to outline resources and constraints. It is helpful for teams to be given a list of resources, and constraints. Resources may include internal or external experts who may be called upon for input, available budget, suggested literature, and potentially helpful organizations. Constraints may be ending dates, resource limitations, scope of decisions, and forbidden zones, areas that should not be explored.

4) Involve those that may best contribute. Choose those that have knowledge and ability to contribute. It is not necessary to have equal representation by area or hierarchical level. Although people directly involved with the issue or problem should be selected, sometimes inviting someone outside may provide a fresh and unique perspective. For example, including a former patient or university faculty on a team can give extra insight.

5) Limit membership generally to 5 to 7. Generally, numbers greater than this can quickly become dysfunctional. Rather than expand the com-
mittee, bring in outside experts when their expertise is needed.

6) Have a sponsor or champion within the organization. The purpose of the team should dictate the level and power of the sponsor or champion. Critical teams with organization-wide responsibilities should have a champion at the executive level. Teams that are unit based may suffice with a unit leader as the champion. The correct champion will be positioned to facilitate implementation of the team’s recommendations. For instance, in one hospital the chief operating officer, who had a great interest in quality improvement, was informally the champion for quality teams. This was widely known in the organization that if there were any barriers or problems, he was the one to resolve them. If there is not a clear informal champion, then the Quality Council should consider to appoint someone with the interest and ability to support and facilitate teams’ efforts.

7) Create a start, interim reporting, and end date or time limit for the team. Team members should know what the extent of their commitment will be. Interim and end dates will also encourage more timely action.

8) Establish team roles. Often a team leader, quality advisor/coach, and recorderscribe will be chosen. The team leader is frequently a senior person who is responsible to the sponsor. He or she should be one of the most skilled on the team. The team leader will have responsibility to plan meetings, set agendas, and coordinate the team’s efforts with the Quality Council and other departments. The team leader should have excellent interpersonal relation skills and the ability to teach and train the team members. The quality advisor/coach should help the leader monitor the process and be a resource to train the team. The quality advisor/coach should be one who is respected by the team and has the ability to facilitate change. He or she needs to be able to understand group process and recognize problems. He or she then works with the team leader to devise means to resolve problems through interventions including training. The recorderscribe records the minutes and progress of the team. This person needs the ability to summarize complex discussions and, as shown below, develop action minutes. He or she works with the team leader to circulate the minutes prior to
meetings and follow-up with those working on assignments to assure timely completion.

**Team building**

High functioning teams are the results of a healthy organizational culture and team building efforts given to new and established teams. Not all new teams will need intensive team building efforts. However, more team building should be planned when a greater diversity of team participants, problems with the organizational culture, longer chartered time for the committee, and higher importance of the anticipated results exist. Team building can allow teams to produce results more quickly and achieve more openness, participation, and creativity.

Team building can be accomplished in three separate areas: operational processes, quality improvement skills, and group processes. Since chartered and focused teams bring together members from diverse departmental and educational backgrounds, some of the team members may lack knowledge of key areas that may be discussed. Training may need to be provided to educate members regarding the operational processes, technology, and organizational interface of the problem or issue under evaluation. For example, if pharmacy distribution system is under evaluation members of the team may be from materials management, nursing, information technology, administration, and pharmacy. Initially, these team members may not understand the operation and function of the pharmacy. Education may need to be provided regarding the process and function of the hospital’s formulary, purchase contracts, existing distribution system, among other things. This common knowledge is essential to communicate and improve the existing systems.

Likewise, quality improvement skills should be taught as needed. The team, after understanding the nature and scope of the charter, should determine which skills are most likely needed and then ascertain if training for the team is necessary. Skills could include work-flow diagrams and flowcharts, Pareto charts, trend plots, cause-and-effect diagrams, scatter plots, etc. Team leaders should not just assume that members know quality improvement skills, but
should be proactive in evaluating skill levels and scheduling needed training. One option is to teach and/or review one skill at the beginning of each meeting. Providing adequate training in quality improvement skills will allow the team to better perform.

Team dynamics and group processes can dramatically affect team performance. Teams often underestimate the need for team development. When people form into teams, undercurrents of conflicting emotions and loyalties always seem to get in the way of efficient progress. If left unattended these undercurrents can impede effective team performance. Teams must spend time on dynamics and feelings not directly related to the task. Teams do not automatically function at high levels of performance. Team building in team group processes is critically important.

High performance is the result of attention paid to the interaction and processes within the group. These fall into three general categories personal identify to the team, relationships among team members, and identity with the organization.

1) Personal identify in the team. Team members should feel included and part of the team. Team members should also feel free to contribute and trust other members.

2) Relationships among team members. Proper interaction among team members is critical to performance. However, conflicts will arise and should be promptly and clearly resolved.

3) Identity with the organization. Team members usually strongly identify with their own departments and will need to know how team membership will affect their department roles and responsibilities. The team should actively interface with the organization and allow team members to balance team and departmental responsibilities.

Meeting coordination and the successful use of healthy conflict also need to be appropriately managed. Meeting coordination includes the careful preparation and organization of meetings. Work should be completed outside of
meetings, as required. Agendas should be distributed prior to meetings with background materials needed to prepare for the upcoming meeting. Meetings should start and end on time. Keep only action related minutes.

1) Complete work prior to meetings. Many often delay completion of tasks until a deadline approaches. The team leader or recorder should remind members of their assigned tasks and, as needed, may ask to meet with them to review their work prior to the next meeting. This encourages task completion and allows the leader to better prepare for the next meeting.

2) Establish agendas. Agendas should include the purpose of the meeting, along with each topic to be addressed. Common items in each agenda should be

☆ Attendance
☆ Agenda review
☆ Follow-up on past assignments
☆ New Discussion/topics with presenter, time estimate, and desired outcome
☆ Time for next meeting
☆ Meeting evaluation

The person who will introduce the topic should be identified and a time estimate for this discussion listed. The desired outcome for each topic should also be indicated. These may be background, discussion, or decision actions. Members, thus, will know the purpose of each topic and direct the meeting to these ends. Agendas should be distributed to members early enough for them to take any action needed prior to the team meeting.

What about decision making process and how to reach consensus and using participative management skills or democratic process to do that?

3) Keep action related minutes. Do not create unnecessary long, detailed minutes. However, retaining key discussion points along with their re-
spective outcomes and action items is important for follow-up.

4) Include evaluation and improvement of your meetings. Meetings should be evaluated and improved like any other process. The evaluation should include what worked well and what will be done to improve the next meeting. Some questions that can be used are:

☆ What went right in this meeting? Wrong?
☆ Were items handled in a reasonable sequence? Did the meeting get stuck somewhere?
☆ How well did we stay on topic?
☆ How well did we discuss the information? How clearly? How accurately?
☆ How well did we respond to each other’s questions?
☆ What might we do differently? What should we do more of? Less of? Not at all?

Teams have been suggested to progress through four predictable stages. These have been conceptualized as Forming, Storming, Norming, and Performing. Effective results occur in the last stage and, therefore, the ability to move efficiently through the first three stages is important. Forming occurs when a team comes together. Members are usually excited and this becomes a stage of transition from individual to member status. Storming may be the most difficult stage for any team. Members may realize that the task is more difficult than they realized and may begin to resist collaboration with other team members. Members may become defensive and argue over non-critical issues. Teambuilding is especially critical in this stage. Next comes Norming that involves establishing group rules for the team. Harmony begins to replace conflict and a sense of team cohesion and common goals develop. Finally, at the Performing stage relationships and expectations are settled. Team members have accepted each other’s strengths and weaknesses and learned their roles. Members can prevent or work through group problems and begin to function as a cohesive, efficient team
How can you tell if your team is effective? Here are some questions under eight categories that may help you determine the level of underlying team effectiveness:

1) Participate leadership.  
Does your team have a leader that is approachable and listens?  
Is discussion shared during team meeting or dominated?

2) Responsive  
a. Are tasks completed as assigned?  
b. Do members willingly volunteer when asked?

3) Aligned on purpose  
a. Do members share common goals for the team?

4) Communicative  
a. Do team members communicate freely and openly?  
b. Is proper feedback provided?  
c. Do members use good listening skills?

5) Task focused  
a. Does the team focus on the given task and not pursue other agendas?  
b. Do personal differences not interfere with the task?

6) Problem solving  
a. Are proper problem solving tools being used?  
b. When problems are addressed are acceptable solutions quickly found?

7) Shared responsibility  
a. Do all members take responsibility for team decisions?  
b. Do all members have responsibilities to communicate the outcomes of the team to outside parties?

8) Innovative.  
a. Does the team suggest innovative, new ways to attempt to solve problems?
Conflict can also be positive or negative for any team. Whenever people work together conflict is probable. Many people associate conflict with tension and anger, but it can actually be of value to a team’s function. Conflict, if managed, can increase the team’s energy level, provide greater creativity, and lead to more effective solutions. Managed conflict minimizes the potential of “groupthink” where everyone goes along with a proposal or idea even when they may have reservations about it. Conflict is natural and can be valuable to better understanding. Conflict can be positive if a team performs teambuilding and establishes mutual trust and respect. Team leaders need to be aware of group dynamics and respond to unresolved conflict. Some guidelines include:

1) Do not overreact or under-react to conflict. Some behaviors are minor issues and may just provide a needed break in team activity. Other behaviors, however, are disruptive and may hurt the team’s progress toward its goals. The team leader should respond appropriately to the nature of the problem, ignore minor disruptions, but confront chronic or serious disruptions directly.

2) Try to praise in public and criticize in private. Leaders should address serious conflicts and problems in private. Public admonitions and criticism tend to only create more problems. Trained leaders can explore the nature of the problem and conflict and develop an informal “contract” regarding agreed-upon changes in behavior. For example, “I now understand that you feel that Joe did not follow-up on the assignment the two of you last had and I will do everything I can to avoid pairing you up on assignments. For your part I want you to stop being critical of him during team meetings.”

3) Use appropriate humor to diffuse tense situations. Sometimes the use of humor can have a profound effect on a group. Tension can be resolved and energy redirected toward the task at hand.

4) Focus on group process and not individual problems. Negative conflict often occurs when an individual feels that they are being personally attacked. Individuals should feel secure that they are safe and not personally being blamed. Teams should focus on how the group functions and how to improve this.
Overall, team building is an exciting, dynamic process. Proper attention can bring wonderful benefits to your organization.

What are you looking for here? Something simple like “2 Truths and a Lie” or more complex that is in your team book?

**Teambuilding Beginning Exercises:**

Team members enter their team roles with many distractions. Prior to beginning the serious matters at hand beginning exercises can allow a team to leave behind concerns, become better acquainted, and function better. A few different beginning exercises follow:

1) **Two truths and a lie:** Each team member is asked to tell three stories about themselves. Two of which are true stories and one a lie. After each member tells his or her three stories, all other members vote to see which the lie was.

2) **First jobs:** Go around the group and have each member tell about their first job. Have them answer the following three questions-

    - What parts of the job did not make sense then?
    - What impression did you have of the owners and managers? What did you learn from them?
    - What did you learn most about that job?

3) **Superlatives:** Have each of the team members answer a list of questions and then compare to see who the extreme in each is. Sample questions could be-

    - How old are you?
    - How many children do you have?
    - How many homes have you lived in?
    - How many years have you attended school?
    - How old was your father?
    - How many brothers and sisters did you have?
4) Conversation starters: Prior to the meeting make a list of incomplete sentences and post them so they can be seen. Go around the table and have one member start a conversation on one topic, focusing on what this person has experienced. Then have the whole team discuss the idea. When that conversation is done, the next person can select a new topic. Some of the sentences could be-

★ Anybody will work hard if….
★ People who run things should be….
★ I would like to be….
★ One thing I like about myself is….
★ Nothing is so frustrating as….
★ The teacher I liked best was a person who….
★ Ten years from now, I….
★ Every winning team needs….
★ I take pride in….
★ If you want to see me get mad….
★ A rewarding job is one that….

5) If I were still at my job: Have members say what they would be doing if they were not in the team meeting. Allow them to go into detail. Let members probe for more detail. Once everyone has spoken, suggest that members now forget about the usual job responsibilities until the meeting ends.
CHAPTER SEVEN

Credentialing, Privileging And Peer Review

Priscilla Pierce, BSN, RN, C, CPHQ

Credentialing

As the Hippocratic Oath affirms, it is critical that the physician is competent to render the patient’s care. A healthcare organization makes this determination through the credentialing process, which is initiated at the time the physician requests appointment to the medical staff. Through this process, an organization reviews the applicant’s educational, licensure, certification, references, and professional affiliation information. Joint Commission International (JCI) defines credentialing as “the process of obtaining, verifying, and assessing the qualifications of a healthcare practitioner. The process determines if an individual can provide patient care services in or for a healthcare organization or network.”

Credentialing is a two-step process in which a physician is evaluated for membership to the medical staff, as well as, to be granted clinical privileges to practice. The privileging process determines the type and scope of services a physician is approved to perform. Once the information has been verified and evaluated, the organization makes the determination as to whether or not the physician is qualified to provide services and/or patient care for the organization. The credentialing process begins once the practitioner has completed an application to join the medical staff. (See Attached Example 1).

Credentialing involves multiple steps. Each organization must develop a process that meets its specific needs. The organization does this by developing a structure that is driven by policies, procedures, rules and regulations, and/or bylaws. (See Attached Flowchart, Example 2) In all cases, the criteria used in making the credentialing decisions must be based upon objective factors such as education, experience and clinical competence. This should ensure that all staff members are treated in a consistent, uniform and non-discrimina-
Having a clear delineation of the steps required to complete the process and of the criteria used will ensure that all applicants are given equitable treatment. Should an adverse determination be made and an applicant is denied membership on the medical staff, having a well-defined and consistent process will minimize any potential legal liabilities of the organization.

A solid credentialing process is critical to the organization’s successfully setting the standard for high quality medical care. There were once clearly defined national and international boundaries that were seldom crossed by professionals desiring to practice medicine or other healthcare specialty. In recent years, the barriers to international travel and practice have dissolved, resulting in a surge of technology-sharing and development which will serve to benefit patients world-wide. However, these open borders have, also, resulted in the increased incidence of identity fraud. There have been numerous cases of individuals posing with false credentials and being granted privileges to practice medicine, nursing, or other allied healthcare profession.

This explosion in the use of false credentials has resulted in the critical need for primary source verification in which an organization has direct contact with the listed source of the credentials (i.e. medical licensure board, university, certification board). The source agency will indicate whether or not the credential reported by the individual is valid. By going directly to the source of the information, there is no chance that an individual’s appointment to the medical staff was based upon forged documents. Under no conditions should an organization accept copies of certificates, licenses, diplomas, or other documents provided by the individual requesting medical staff membership. An organization may opt to manage the process for primary source verification internally or may contract with a Credentials Verification Organization (CVO). Should an organization use a CVO for this process, the organization must have oversight in order to ensure that the CVO’s process is consistent and timely and that the information being collected is accurate.

Requests for verification of credentials may be handled verbally by telephone. While this can be the most expeditious way to obtain information, the
organization may incur additional expenses in long distance phone charges. Verification is most often accomplished by mailing a request to the organization. *(See Attached Example 3)* Online verification is another route increasingly available. Whichever verification route is chosen, time is of the essence. All matters pertaining to the credentialing process must be handled in a time-sensitive manner. Individuals responsible for completing the process must have a tracking system in order to assure that information is received within the timeframe established by the organization, as well as, to meet regulatory and accreditation requirements. While activities related to the credentialing process are generally completed by clerical staff, there must be clear oversight and active involvement on the part of medical staff leadership and hospital administration.

The numerous elements included in the verification process include:

- Education – undergraduate, medical school and/or other postgraduate school
- Training – internship and residency
- Fellowship
- Board certification
- Licensure and any sanctions or limitations on licensure
- Continuing medical education
- Professional liability insurance
- Malpractice claims, adverse awards, and settlements
- Peer references and recommendations
- Work history
- History of loss of privileges or disciplinary actions
- Healthcare organization affiliations (i.e. current status, changes to scope of practice, adverse determinations)
- Work history
- Clinical competence
- Health history
As part of the application process, the practitioner signs a release which permits the organization to contact peer references, employers, academic institutions, insurance carriers, licensing agencies, certification boards, etc. In addition, each applicant must sign an acknowledgement that they were made aware of the organization’s provisions relative to the credentialing and privileging process. This document, also, includes a list of obligations to which the applicant agrees in order to be considered for membership and privileges. *(See Attached Example 4, Authorization and Consent)*

The need to establish a centralized repository of information pertaining to the credentials of all physicians, dentists, and other healthcare professionals was identified several years ago in the United States. This resulted in the creation of the National Practitioner Databank (NPDB). This centralized repository contains data pertaining to:

- Licensure
- Professional memberships
- Medical malpractice history, to include settlements and jury awards against practitioners
- Clinical privileges, to include any loss or reduction of same

The NPDB enables state licensing boards, hospitals, and other health care entities to conduct investigations into a practitioner’s history. Accessing the databank is a key part of the credentialing and privileging processes.

Organizations are required to report to the NPDB any adverse decisions pertaining to a practitioner’s clinical privileges which affect the privileges for a period of more than 30 days. Professional organizations are required to report any adverse actions taken in response to issues regarding professional competence or conduct, based upon concerns that such behaviors or practices may negatively impact a patient’s wellbeing.

The process for approving a practitioner’s request to join the medical staff includes the assignment to a category of membership, which is determined by
the individual’s anticipated volume of cases, as well as, interest in assuming other responsibilities in regards to medical staff activities. These categories can be as follows:

✔ Active Voting – regularly admit patients; actively participate in medical staff quality activities; providing emergency care coverage, as needed; attending medical staff meetings; voting on matters presented at medical staff meetings, Services, and committees to which he is an appointee; participating in the processes for election of medical staff officers; and performing other duties as may be required based upon Bylaws or Rules and Regulations

✔ Active Staff – regularly admit patients, actively participate in medical staff quality activities; attending medical staff meetings; voting on matters presented at medical Service meetings and committees to which he is assigned; and performing other duties as may be required based upon Bylaws or Rules and Regulations

✔ Provisional Staff – assigned for a period of not less than six months at which time advancement to full membership will be considered; providing emergency call coverage, as needed

✔ Courtesy Staff – occasionally admit patients; attending meetings of medical staff meetings and Services, if appointed; providing emergency call coverage, as needed; performing other duties as may be required based upon Bylaws and Rules and Regulations

✔ Consulting Staff – do not admit patients, but may consult with medical staff members regarding patient care management when requested to do so

✔ Associate Staff – provide call coverage for other physicians who have privileges to admit patients; may attend, but may not vote at medical staff Service meetings and committees

✔ Honorary Staff – retired from active practice; may not admit patients; may attend medical staff and Service committee meetings, but may not vote
Each facility must have a Credentialing Plan that clearly defines the steps associated with the initial appointment, reappointment, and privileging processes. The documents governing this plan include the bylaws, rules and regulations, policies and procedures. Strict adherence to these documents should curtail any legal challenges, based upon allegations that the process was, in some way, discriminatory. The governing body has oversight of the credentialing and privileging process and makes the final determinations regarding the granting or refusal to grant membership on the medical staff or clinical privileges. An individual must apply for reappointment to the medical staff every two or three years, depending on the timeframe adopted by the organization. The process for reappointment to the medical staff is very similar to the initial appointment process.

**Privileging**

Privileging is the process in which a practitioner receives authorization from a health care organization to perform clearly defined patient care services, based upon the individual’s credentials and performance. The impetus behind the privileging process is the need to ensure that qualified, competent individuals are providing patient care services. The granting of clinical privileges is based upon criteria established by the medical staff.

The department chairperson plays a key role in the privileging process by developing the criteria specific to his/her department/specialty. The criteria set includes required licensure, training, and experience. Technical skills, performance, and judgment are incorporated, as well. Criteria for privileges need to be clearly defined and provided to the applicant at the time they receive the privilege list. All recommendations pertaining to the credentialing and privileging processes must receive final approval from the governing body.

The process for selection of criteria for privileges can be accomplished by a variety of methods to include:

- ✔ Categories or levels
“Laundry” lists

Core privileges

Combination of the above

In the category/level method, the degree of complexity or level of training or experience determines the level of the privilege. Examples of this process include the following:

- Category 1 – Must have completed at least one-year internship in general medicine and may care for patients using skills acquired during this training. Board certification is not required. Consultation required for critically ill patients or in order to admit to the critical care unit.

- Category 2 – May care for patients with medical conditions, which pose a serious threat to life. Board certification in internal medicine or completion of residency program and Board-eligibility required. May act as consultant to others but should obtain consultation, as needed, for assistance in choosing an appropriate course of treatment or making a diagnosis.

- Category 3 – May care for patients who require the expertise of a subspecialist. Board certification in subspecialty required or completion of residency program and Board-eligibility required. Acts as a consultant in his/her field, but obtains consults as needed.

The “laundry” list process for privileging relies on a list of procedures or skills for a designated clinical area without specifying training or educational requirements. The individual requesting privileges simply checks which procedures he/she wishes to be granted privileges to perform. An organization may adopt guidelines which will guide the process for determining actual competence to perform these procedures.

Core privileges refer to the grouping of privileges that require similar education, training, and skills. This method is an efficient way to cover the enor-
mous list of procedures learned during residency training. The list includes procedures and diagnoses that are high volume for the organization, but will not be all-inclusive. Specialties, in turn, adopt core privileges.

If the core privileging methodology is adopted, it is important that hospital staff members are educated regarding the need to obtain clarification if uncertain whether or not the physician has privileges for a procedure that is not included on the core procedure list. Organizations must update the privilege lists on a regular basis in order to stay current as new technologies arise.

For procedures that typically require additional or special training and experience, an organization may require that a practitioner provide documentation that he/she has completed a required (predetermined by the organization) number of the procedures. Once privileges are granted, the organization may require that a new member to the medical staff is assigned a proctor who must be present in order to observe the physician performing either a required number of procedures or for a defined period of time. Once it has been established that the physician is competent to perform the procedure(s), full privileges are granted.

The issue of privileging becomes especially challenging when dealing with individuals requesting reappointment to the medical staff who have had a very low volume of cases at the facility. When this situation occurs, the organization may require that the physician provide documentation of cases performed at other facilities.

On rare occasion, an organization may decide to grant temporary privileges for a limited amount of time pending review of an applicant’s file or as a one-time approval so that an individual can care for a patient with very specialized needs. These special exceptions must be addressed in the bylaws.

A physician may be granted locum tenens privileges if covering a physician’s practice on a temporary basis. Privileges are granted for a specified period
of time, with the possibility of extension being granted. The locum tenens process must be addressed in the bylaws.

An organization may have rare occasion to grant emergency privileges if a patient develops an unanticipated condition necessitating immediate treatment and there is no person on the medical staff qualified to treat this condition.

Regardless of whether an applicant is granted privileges as part of the normal processes associated with joining the medical staff or due to unusual situations necessitating special approval of privileges, the organization is obligated to provide for the safety of its patients by ensuring that qualified and competent individuals are rendering the care.

**Peer Review**

Once an individual is approved for medical staff membership, it is paramount that there is an effective, on-going peer review process in place in order to ensure that the quality of the health care services being provided meets the standards established by the organization, as well as, accrediting and regulatory bodies. Peer review is the process for review of the performance of individual practitioners using a set of well-defined criteria and indicators. Individuals having the same or comparable credentials typically complete the review.

Peer review can be accomplished through formal or informal mechanisms. Informal peer review may be accomplished on an on-going basis by a department such as radiology where the physicians routinely perform over-reads of one another’s film reviews. A more formal structure for peer review can be accomplished through the activities of the various medical staff services and committees. Organizations may establish separate Morbidity and Mortality or Peer Review Committees to accomplish these reviews or may choose to complete the reviews during the normal course of a committee’s meeting activities.
Cases are generally reviewed on a retrospective basis due to the need for the chart to be complete before it can be fully analyzed for quality indicators. However, peer review can be performed on a concurrent basis, particularly if there has been an adverse outcome to care resulting in patient harm or death.

An effective peer review program includes the following attributes:

- Clear criteria for case review
- Definition of “peer”
- Uniform methodology for “rating” the findings of the reviewer
- Established levels of review (i.e. general medical staff committee, Medical Executive Committee)
- Timely completion of reviews
- Specific stipulations for dealing with special situations in which there has been either a serious breach in the standard of care or of several records for the same practitioner which failed to meet quality standards (i.e. suspension of privileges, pending investigation)
- Guidelines for convening an ad hoc committee, a panel, or for obtaining external reviews
- Communication with the practitioner regarding the review process, with opportunity for him/her to respond

The medical staff must formally adopt quality indicators. *(See Attached Example 5)* Documentation of this selection process via committee minutes is vital in order to validate that the process for chart reviews was not arbitrary but, rather, driven by predetermined indicators. If review of a practitioner’s cases results in an adverse determination regarding his/her clinical privileges or membership on the medical staff, it is quite possible that the organization’s peer review process may be the focus of litigation. Having the documentation in place to support the unbiased process for review of records and rating the results of the review will limit the organization’s legal exposure and risk.
Medical staff leadership must monitor information gained through this peer review process in order to determine if there is an unacceptable variation in the outcomes of a specific practitioner. It is most meaningful to monitor a sufficient amount of data over a period of time in order to evaluate for trends, although there may be times when a negative occurrence requires immediate review and action.

As previously stated, the process for peer review must be consistent and fair. It is important to have a standard method for rating the reviewer’s findings and for referral to a higher level of review. Levels of review will typically start with a general medical staff committee, on to a Service committee, with final review being completed by Medical Executive Committee. An example rating system *(See Attached Example 6)* is as follows:

1. standard of care met, no quality of care concerns identified
2. standard of care met, although minor concerns noted
3. standard of care met, although unexpected features in the aspects of care were noted. Response may be required from the physician.
4. failure to meet the standard of care, unexpected and/or unacceptable features identified. Response required from physician.

Once an unfavorable outcome or trend has been identified, the medical staff must pursue the next step in the process. This may require that the physician under review meet with a group of his peers in order to discuss the case(s). The outcome of such discussion could result in the physician being proctored by a peer for a specified period of time, or undergoing 100% review of his or her charts. If there are not a sufficient number of peers in the specialty under discussion to support the proctoring or intensive review process, the organization may opt to request that the case(s) be reviewed by an external reviewer who will typically do so on a contracted basis for a fee.

In any case, the responsibility for making a decision based upon the results of this additional review rests upon the medical staff and, ultimately, the governing body of the organization. The process for any disciplinary action
must be clearly documented in the hospital’s policies, procedures, rules and regulations, and/or bylaws. All aspects of the peer review process must be handled with the utmost discretion. Should the organization fail to establish and follow a well-defined credentialing and privileging process that includes primary source verification or fails to take action when it has become apparent that a practitioner’s clinical practice is substandard, the organization is at risk for litigation due to negligent credentialing. Legally, the organization is at risk for having failed in its obligation to provide the patients with appropriate and high quality care.

The peer review process may reveal that there is a more generalized, versus practitioner-specific, issue that warrants a more broad evaluation using an established performance improvement process such as PDSA (Plan, Do, Study, Act). A vital component of this peer review/medical staff quality review process is the need to identify medical staff educational needs. This is true, as well, as new technologies and procedures are developed. This ongoing focus on performance improvement and medical staff education will help ensure that high quality medical care is being rendered.

If the care delivery to patients with a specific diagnosis appears to have an unacceptable degree of variation involving multiple practitioners, the medical staff may opt to pursue the development of a critical pathway or disease management program.

Impaired Practitioners

Unfortunately, the medical staff may, at times, be required to deal with the issue of an impaired practitioner. By definition, this would encompass any physical, psychiatric, emotional or behavioral disorder that interferes with a practitioner’s ability to engage safely in professional activities. These include:

- Mental or physical deterioration or loss of motor skills due to disease or aging process
- Apparent intoxication when reporting for duty
- Verified reports of excessive drug or alcohol use
- Inappropriate use of prescription drugs
- Psychiatric illness

The organization must have clearly written policies or stipulations in the governing documents for the medical staff that address any situations pertaining to the impaired physician. It is critical that employees be educated on the process for reporting suspicions, concerns, or actual observations of any of the above-noted scenarios. The safety of the patients is at risk if the organization fails to immediately address any situation in which a physician may be unable or unwilling to render appropriate medical care.

The investigation of the practitioner may begin on an informal basis by having the appropriate representative from hospital Administration or medical staff leadership meet with the physician in order to provide him/her the opportunity to explain. If it is apparent that the physician is impaired, the Chief of Staff may then meet with the practitioner, inform him/her of the findings of the investigation, and afford the practitioner the opportunity to seek treatment. In addition, the Medical Executive Committee may levy any of the following requirements in order for the individual to remain a member of the medical staff:

- Require that the physician enter a rehabilitation or treatment program
- Impose restrictions on privileges
- Stipulate what must be undertaken and completed in order to remain a member of the medical staff
- Require proctoring for services or procedures
- Suspend privileges immediately on either a temporary or permanent basis
- Request that the practitioner resign from the medical staff
- Take other actions as may be required by law or as required by accrediting or regulatory agencies
Should a physician meet all of the requirements in order to be reinstated to the medical staff with or without restrictions, the organization must closely monitor the individual’s performance for an appropriate length of time in order to verify that the medical care being provided is adequate. All activities pertaining to each step taken in addressing an impaired practitioner must be clearly documented.

**Disruptive Practitioners**

The medical staff may, also, be faced with the challenge of dealing with a disruptive practitioner. By definition, this would include any behavior which disturbs the normal operations of the facility, affects the ability of staff to perform their duties, interferes with the practitioner’s ability to practice in a competent manner, or adversely affects the community’s confidence in the facility’s ability to provide quality healthcare. Examples of disruptive behavior include:

- Inappropriate physical contact with another
- Inappropriate physical behavior such as throwing objects or breaking equipment
- Verbal attacks on patients, visitors, employees, or peers
- Use of profanity or language with sexual or discriminatory overtones
- Intimidating behavior, either physical or verbal
- Inappropriate or inflammatory documentation in the medical record
- Derogatory comments about the organization or staff members

Dealing with issues surrounding a disruptive practitioner may be handled in the same or similar manner as when dealing with an impaired practitioner. As noted in the previous discussion regarding the impaired practitioner, the organization must have clearly written documents that detail the manner in which these situations will be addressed, documentation of the process must clear, and employees and medical staff members must be made aware of how to report instances of any disruptive behavior on the part of a practitioner.
Given the intricacy of today’s healthcare systems, with rapidly emerging sophisticated technology and treatments, as well as, a burgeoning population world-wide, the need for effective medical staff leadership is critical. Patient safety issues are now gaining international attention. An organization’s commitment to providing care that is of the highest quality to its patients is evidenced by efforts taken in order to develop a strong foundation for ongoing evaluation of the care and services being delivered. Such is the obligation that we have to our patients.
References


**Attachment 1**

**Sample Medical Staff Application**

***PLEASE PRINT ALL ENTRIES***

**Section 1: DEMOGRAPHIC INFORMATION**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
<th>Suffix</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other name by which you have been known</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other name by which you have been known</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Social Security Number</th>
<th>Birthdate</th>
<th>Place of birth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nationality</th>
<th>Visa type</th>
<th>Visa number</th>
<th>Expiration date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mailing address</th>
<th>City/State</th>
<th>ZIP code</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Phone #
Section 2: PROFESSIONAL INFORMATION

Primary specialty
Subspecialty

Secondary specialty
Subspecialty

Are you part of a physician group? £ Yes £ No

If “yes”,

please specify:_____________________________________________________

Are you accepting new patients?
£ Yes £ No

Section 3: EDUCATIONAL INFORMATION

Please list all institutions, whether or not you completed the degree or program.
<table>
<thead>
<tr>
<th>Institution #1</th>
<th>Degree awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dates attended (MM/DD/YYYY) to date</td>
<td>(MM/DD/YYYY)</td>
</tr>
<tr>
<td>Graduation date</td>
<td></td>
</tr>
<tr>
<td>Mailing address</td>
<td>City/state</td>
</tr>
<tr>
<td>Phone #</td>
<td>ZIP code</td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Institution #2</th>
<th>Degree awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dates attended (MM/DD/YYYY) to date</td>
<td>(MM/DD/YYYY)</td>
</tr>
<tr>
<td>Graduation date</td>
<td></td>
</tr>
<tr>
<td>Mailing address</td>
<td>City/state</td>
</tr>
<tr>
<td>Phone #</td>
<td>ZIP code</td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Institution #3</th>
<th>Degree awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dates attended (MM/DD/YYYY) to date</td>
<td>(MM/DD/YYYY)</td>
</tr>
<tr>
<td>Graduation date</td>
<td></td>
</tr>
<tr>
<td>Mailing address</td>
<td>City/state</td>
</tr>
<tr>
<td>Phone #</td>
<td>ZIP code</td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
</tbody>
</table>
### Section 4: TRAINING INFORMATION

*Please list all institutions, whether or not you completed the program.*

**Type of program:**

- [ ] Internship  
- [ ] Residency  
- [ ] Fellowship  
- [ ] Preceptorship  
- [ ] Other: ____________

<table>
<thead>
<tr>
<th>Mailing address</th>
<th>City/state</th>
<th>ZIP code</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone #</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Institution #1</th>
<th>Specialty</th>
<th>Program Director</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Dates attended (MM/DD/YYYY) to (MM/DD/YYYY) Successfully completed (Y/N)

Type of program:

£ Internship £ Residency £ Fellowship £ Preceptorship £ Other:

Institution #2  Specialty  Program Director

Address  City/state  ZIP code  Country Phone #

Dates attended (MM/DD/YYYY) to (MM/DD/YYYY) Successfully completed (Y/N)

Type of program:

£ Internship £ Residency £ Fellowship £ Preceptorship £ Other:

Institution #3  Specialty  Program Director

Address  City/state  ZIP code  Country Phone #
Section 5: HEALTHCARE ORGANIZATION AFFILIATION INFORMATION

Please list, in chronological order, all hospitals or other healthcare organizations where you have been employed, practiced, associated or held privileges for the purpose of providing patient care. Indicate which of these is your current primary and secondary admitting facility.

£ primary £ secondary Facility name #1

Mailing address City/state ZIP code Country Phone #

Dates of appointment (MM/DD/YYYY) to (MM/DD/YYYY) Staff category

Reason for discontinuance Department or Service

£ primary £ secondary Facility name #2

Mailing address City/state ZIP code Country Phone #
Section 6: OTHER PROFESSIONAL WORK HISTORY

Please list chronically, all professional work history (i.e. partnerships, clinics, solo or group practices, employment. Include military or public health service. Please account for all time gaps of 30 days or more.

Name of entity #1 Nature of affiliation
<table>
<thead>
<tr>
<th>Mailing address</th>
<th>City/state</th>
<th>ZIP code</th>
<th>Country</th>
<th>Phone #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dates of affiliation (MM/DD/YYYY) to (MM/DD/YYYY)</td>
<td>Reason for discontinuance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of entity #2</td>
<td>Nature of affiliation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mailing address</td>
<td>City/state</td>
<td>ZIP code</td>
<td>Country</td>
<td>Phone #</td>
</tr>
<tr>
<td>Dates of affiliation (MM/DD/YYYY) to (MM/DD/YYYY)</td>
<td>Reason for discontinuance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of entity #3</td>
<td>Nature of affiliation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mailing address</td>
<td>City/state</td>
<td>ZIP code</td>
<td>Country</td>
<td>Phone #</td>
</tr>
<tr>
<td>Dates of affiliation (MM/DD/YYYY) to (MM/DD/YYYY)</td>
<td>Reason for discontinuance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of entity #4</td>
<td>Nature of affiliation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mailing address</th>
<th>City/state</th>
<th>ZIP code</th>
<th>Country</th>
<th>Phone #</th>
</tr>
</thead>
</table>

Dates of affiliation (MM/DD/YYYY) to (MM/DD/YYYY) Reason for discontinuance

### Section 7: LICENSURE INFORMATION

*Please list all pending, current, and past professional licenses, registrations, and certifications to practice in your field, including all states or countries where you applied to practice.*

<table>
<thead>
<tr>
<th>State or Country Type</th>
<th>License #</th>
<th>Initial date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration date</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Country Type</th>
<th>License #</th>
<th>Initial date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration date</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Country Type</th>
<th>License #</th>
<th>Initial date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration date</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Section 8: CERTIFICATIONS AND REGISTRATIONS

*Please list all other current certifications and registrations (i.e. DEA – Drug Enforcement Administration, CDS – Controlled Dangerous Substances).*

<table>
<thead>
<tr>
<th>State or Country</th>
<th>Type</th>
<th>DEA</th>
<th>License #</th>
<th>Initial date of issue</th>
<th>Expiration date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Country</th>
<th>DEA</th>
<th>License #</th>
<th>Initial date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Country</th>
<th>Type</th>
<th>License #</th>
<th>Initial date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Country</th>
<th>Type</th>
<th>License #</th>
<th>Initial date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Board Certifications

Are you board certified?  £ Yes  £ No

Name of Board: _______________________________________________

Initial certification date               Most recent recertification date               Ex-  piration date
(MM/DD/YYYY)                   (MM/DD/YYYY)                   (MM/DD/YYYY)

Have you ever been examined by any specialty board, but failed to pass?  £ Yes  £ No

If yes, please provide details: _______________________________________________

Subspecialty Board Certification and Added Qualifications

Subspecialty or added qualification               Name of Board

Initial certification date               Most recent recertification date
Expiration date               (MM/DD/YYYY)                   (MM/DD/YYYY)
(MM/DD/YYYY)                   (MM/DD/YYYY)
Subspecialty or added qualification                  Name of Board

Initial certification date                  Most recent recertification date
Expiration date  (MM/DD/YYYY)
(MM/DD/YYYY)                  (MM/DD/YYYY)

Board Qualification

If you are not certified, are you qualified to sit for the exam in a primary or subspecialty board or added qualification?

£ Yes    £ No

Are you planning to take the exam? £ Yes    £ No

Are you scheduled to take the exam? £ Yes    £ No

£ Written (date)________________________
£ Oral (date)________________________
£ Other (date)________________________

Note: If yes, attach confirmation letter

Subspecialty or added qualification                  Name of Board

Date qualified (MM/DD/YYYY)                  Date qualification expires (MM/DD/YYYY)
Other Certifications

Are you certified in CPR?  £ Yes  £ No  £ Expiration date _________

Classifications:
£ Basic Life Support (BLS), expires on date ___________
£ Advanced Cardiac Life Support (ACLS), expires on date
£ Advanced Trauma Life Support (ATLS), expires on date
£ Neonatal Advanced Life Support (NALS), expires on date
£ Pediatric Advanced Life Support (PALS), expires on date
£ Other ______________ expires on date _________

Section 9: OFFICE INFORMATION

Primary Office

Group Name % of time spent at this location

Type of practice:  £ Solo  £ Partnership
£ Single-specialty group £ Other: £ Multi-specialty group

Physical address City/state ZIP code Country

Mailing address City/state ZIP code Country
<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency or pager #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Answering service #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>__________________________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of office manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of office nurse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group tax identification #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group federal provider #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>__________________________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Office billing address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City/state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZIP code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is this a claims billing service?</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Does this office have laboratory services?</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Reference lab?</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>On site?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLIA ID#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLIA Waiver #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>__________________________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does this office have the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EKG</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Radiology</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Audiology</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Treadmill</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Sigmoidoscopy</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Wheelchair or handicapped access?  £ Yes  £ No

Other services for the disabled?  £ Yes  £ No

Does this office meet local and federal fire, safety, and sanitation requirements?  £ Yes  £ No

Do you or any of your office staff members speak a foreign language fluently?

You, language(s) spoken: _________________________________
Your staff, language(s) spoken: _________________________________

Please list all independent licensed non-physicians working in this office.

<table>
<thead>
<tr>
<th>Name</th>
<th>Provider Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>License Number</td>
<td>_________________________________</td>
</tr>
<tr>
<td></td>
<td>_________________________________</td>
</tr>
<tr>
<td></td>
<td>_________________________________</td>
</tr>
<tr>
<td></td>
<td>_________________________________</td>
</tr>
</tbody>
</table>

Office hours:  Monday  Tuesday  Wednesday  Thursday  Friday  Saturday  Sunday

From:  _____  _____  _____  _____  _____  _____

To:  _____  _____  _____  _____  _____  _____
Do you provide 24-hour, seven day a week coverage? £ Yes £ No

List name, specialty, and phone number of physicians covering your practice in your absence.

*Note: These practitioners must be affiliated with this organization.*

Name_________________________ Specialty __________________
Phone # ______________

Name_________________________ Specialty __________________
Phone # ______________

Name_________________________ Specialty __________________
Phone # ______________

Name_________________________ Specialty __________________
Phone # ______________

Do you or your business own, operate, manage or participate in any medical enterprise or business?

£ Yes £ No

*If yes, please explain on a separate attachment.*

**Secondary Office**

____________________________________________________________
Group Name                          % of time spent at this location

Type of practice: £ Solo £ Partnership
£ Single-specialty group £ Other:
£ Multi-specialty group

Physical address  City/state  ZIP code  Country

Mailing address  City/state  ZIP code  Country

Telephone #  Fax #

Emergency or pager #  Answering service #

Name of office manager  Name of office nurse

Group tax identification #  Group federal provider #

Office billing address  City/state  ZIP code  Country

Is this a claims billing service?  £ Yes  £ No

Does this office have laboratory services?  £ Yes  £ No

Reference lab?  £ Yes  £ No

On site?  £ Yes  £ No

CLIA ID#  ______________  CLIA Waiver #  ________________________

Does this office have the following:
<table>
<thead>
<tr>
<th>Service</th>
<th>£ Yes</th>
<th>£ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audiology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treadmill</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sigmoidoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Wheelchair or handicapped access?  £ Yes £ No
Other services for the disabled?  £ Yes £ No
Does this office meet local and federal fire, safety, and sanitation requirements?  £ Yes £ No

Do you or any of your office staff members speak a foreign language fluently?

You, language(s) spoken: ________________________________

Your staff, language(s) spoken: ________________________________

Please list all independent licensed non-physicians working in this office.

<table>
<thead>
<tr>
<th>Name</th>
<th>Provider Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>License Number</td>
<td></td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
<tr>
<td>__________________________</td>
<td>________________</td>
</tr>
</tbody>
</table>


Office hours: Monday Tuesday Wednesday Thursday Friday Saturday Sunday
From: ______ ______ ______ ______ ______ ______ ______
To: ______ ______ ______ ______ ______ ______ ______

Do you provide 24-hour, seven day a week coverage? £ Yes £ No

List name, specialty, and phone number of physicians covering your practice in your absence.

Note: These practitioners must be affiliated with this organization.

Name ________________________ Specialty ________________________
Phone # ______________

Name ________________________ Specialty ________________________
Phone # ______________

Name ________________________ Specialty ________________________
Phone # ______________

Name ________________________ Specialty ________________________
Phone # ______________

Do you or your business own, operate, manage or participate in any medical enterprise or business?
£ Yes  £ No
If yes, please explain on a separate attachment.

Section 10: OTHER REQUIRED DOCUMENTATION

Practitioner should check off items that are being attached to this application:
£ Curriculum vitae
£ Emergency care training certificates (CPR, ACLS, etc)
£ Tax identification information forms
£ Photo identification
£ Current federal DEA registration certificate
£ Current Bureau of Narcotics and Dangerous Drugs Registration (BNDD)
£ ECFMG and/or Visa, if applicable
£ Professional Liability Certificate of Insurance
£ Other: __________________________________
£ Other: __________________________________

Section 11: ADDITIONAL INFORMATION

This section is furnished for your convenience in completing questions or providing additional information. As appropriate, please note section number and question that you are answering.

_____________________________________________________________
_____________________________________________________________
_____________________________________________________________
_____________________________________________________________
_____________________________________________________________
_____________________________________________________________
Section 12: ATTESTATION

All information and documentation submitted by me is true, correct and complete to the best of my knowledge. I further acknowledge that any material misstatements in or omissions from this information or documentation may constitute cause for denial of my application for staff membership, privileges, or participation.

Printed Name

Signature          Date
Section 13: PROFESSIONAL REFERENCES

Please list three (3) peers who have personal knowledge of your current clinical abilities, ethical character, and ability to work cooperatively with others. These should be individuals who will provide specific written comments on these matters upon request. The named individuals must have acquired the requisite knowledge through observation of your professional practice over a reasonable period of time.

Examples of professional references are other practitioners in the same field and/or other practitioners in your specialty. None of your references should be relatives or current professional associates.

If your training was completed within the past three (3) years, you may list your Program Director(s) as professional reference(s). If you have been out of training for more than three (3) years, it is important to name individuals who have not been listed previously in your Initial Application.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>(Sub)specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address City/State</td>
<td>ZIP code</td>
<td>fax #</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>(Sub)specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address City/State</td>
<td>ZIP code</td>
<td>fax #</td>
</tr>
</tbody>
</table>
## Section 14: DISCLOSURE INFORMATION

1. Have any of the following ever been, or are any currently in process or pending, either on voluntary or involuntary basis: denied, revoked, suspended, reduced, limited, cancelled, sanctioned, placed on probation, not renewed, or relinquished for any disciplinary reasons? *All “yes” answers require full explanation on a separate page.*

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Medical license in any other state or country</td>
<td>Yes ___</td>
</tr>
<tr>
<td>b.</td>
<td>Other professional registration or license</td>
<td>Yes ___</td>
</tr>
<tr>
<td>c.</td>
<td>DEA registration</td>
<td>Yes ___</td>
</tr>
<tr>
<td>d.</td>
<td>BNDD registration</td>
<td>Yes ___</td>
</tr>
<tr>
<td>e.</td>
<td>Academic appointment</td>
<td>Yes ___</td>
</tr>
<tr>
<td>f.</td>
<td>Membership on any hospital or healthcare facility medical staff</td>
<td>Yes ___</td>
</tr>
<tr>
<td>g.</td>
<td>Clinical privileges, prerogatives, or rights on any medical staff</td>
<td>Yes ___</td>
</tr>
<tr>
<td>h.</td>
<td>Membership in other healthcare organizations or facilities</td>
<td>Yes ___</td>
</tr>
<tr>
<td>i.</td>
<td>Professional society membership or fellowship</td>
<td>Yes ___</td>
</tr>
<tr>
<td>j.</td>
<td>Any other type of professional reprimand or sanction</td>
<td>Yes ___</td>
</tr>
<tr>
<td>k.</td>
<td>Board certification</td>
<td>Yes ___</td>
</tr>
<tr>
<td>l.</td>
<td>ECFMG certification</td>
<td>Yes ___</td>
</tr>
<tr>
<td>m.</td>
<td>Participation in any governmental healthcare benefits program</td>
<td>Yes ___</td>
</tr>
</tbody>
</table>
2. Has your employment at a healthcare organization ever been terminated?  Yes ___  No ___

3. Have you ever been charged or convicted of a crime other than a minor traffic offense?  Yes ___  No ___

4. Are there any felony charges pending against you?  Yes ___  No ___

5. Have you ever withdrawn your application for appointment, reappointment, and/or clinical privileges or resigned from the medical staff or surrendered your clinical privileges while under investigation or before a recommendation or decision by a hospital’s or healthcare facility’s medical executive or governing board was rendered?  Yes ___  No ___

6. Has any information about you been reported to the National Practitioner Data Bank?  Yes ___  No ___

* A voluntary relinquishment or voluntary non-renewal is for disciplinary reasons when the relinquishment or non-renewal is done to avoid an adverse action, preclude an investigation, or is done while the provider is under investigation related to professional conduct.

Are you able to perform the procedures and the essential functions of the position for which you have applied or requested privileges, with or without reasonable accommodation, according to accepted standards of professional performance and without posing a direct threat to patients?

*If no, please explain on a separate sheet.*
Are you currently engaged in the illegal use of drugs?  Yes ___  No ___

Have you ever been denied professional liability insurance or has your coverage ever
Yes ___  No ___
been cancelled or terminated?
If yes, please explain on a separate sheet.

Have there ever been, or are there currently pending, any malpractice claims,
Yes ___  No ___
settlements, judgments, or arbitration proceedings involving your professional
practice?
If yes, in your explanation, include a list and status (settled, dropped, pending), and
explain the nature of the allegation(s).

Has your present professional liability insurance carrier excluded any specific
Yes ___  No ___
procedures or imposed other restrictions on your coverage?
If yes, list the procedures which have been excluded and provide a full explanation.

**Present Carrier**

<table>
<thead>
<tr>
<th>present carrier</th>
<th>agent name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>address</th>
<th>city/state</th>
<th>ZIP code</th>
<th>phone #</th>
</tr>
</thead>
</table>

name in which the policy is issued policy #
All prior carriers within the past five years

<table>
<thead>
<tr>
<th>prior carrier #1</th>
<th>agent name</th>
</tr>
</thead>
<tbody>
<tr>
<td>address</td>
<td>city/state</td>
</tr>
<tr>
<td>name in which the policy is issued</td>
<td>policy #</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>prior carrier #2</th>
<th>agent name</th>
</tr>
</thead>
<tbody>
<tr>
<td>address</td>
<td>city/state</td>
</tr>
<tr>
<td>name in which the policy is issued</td>
<td>policy #</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>prior carrier #3</th>
<th>agent name</th>
</tr>
</thead>
<tbody>
<tr>
<td>address</td>
<td>city/state</td>
</tr>
<tr>
<td>name in which the policy is issued</td>
<td>policy #</td>
</tr>
</tbody>
</table>
Office of the Dean
Name of Medical School
Address

Re: Applicant’s Name

Dear ____________________,

Dr ___________________ has applied to ______________________________ Hospital for appointment to the medical staff with a request for clinical privileges. The applicant has indicated that he/she received a _______________ degree from your medical school in (month/year).

We would appreciate your assistance with verifying this information by completing the section below. Thank you for your assistance with this matter. Your timely return of this form in the enclosed stamped and self-addressed envelope will be greatly appreciated.

Yours truly,

Vice President, Medical Affairs

Degree                Date Awarded
ATTACHMENT 3
Credentialing Process Flowchart

1. Practitioner contacts organization and requests application for membership and privileges
   - Medical Staff Office of the hospital sends the practitioner an application
2. Practitioner completes and returns the application
3. Application is complete
   - Information reviewed by the Medical Staff Office
4. Primary source verification completed by the Medical Staff Office
5. Information provided by the applicant was accurate
   - Credentials Committee reviews application and recommends membership and privileges as requested
     - Yes
     - Medical Executive Committee reviews and approves membership and privileges as requested
       - Yes
       - Governing Board reviews and approves privileges as requested
         - Yes
         - Applicant is notified of approval
     - No
     - Practitioner notified that application was denied
   - No
   - Application returned to practitioner for completion or correction

Signature   Date
ATTACHMENT 4
Sample Authorization for Release of Information

By requesting appointment to the medical staff of _____________________ Hospital, I hereby:

Authorize the hospital, its medical staff and their representatives to consult with prior and current associates and others who may have information bearing on my professional competence, character, health status, ethical qualifications, ability to work cooperatively with others, and qualifications for membership and the clinical privileges I request;

Consent to the inspection by the hospital, its medical staff and their representatives of all documents that may be material to an evaluation of my qualifications and competence;

Consent to the release of such information and documents;

Release from liability all representatives of the hospital and its staff for their acts performed and statements made, in substantial good faith and without malice, concerning my professional competence, ethics, character and other qualifications for staff reappointment and clinical privileges;

A photostatic copy of this original authorization constitutes my written authorization and request to release any and all supportive documentation regarding this application. Said photostatic copy shall have the same force and effect as the signed original.

I hereby confirm that all information submitted by me in this application for reappointment is true and complete to the best of my knowledge and belief.

________________________________________
Signature Date Printed name
Sample Consent

By this request for appointment to the Medical Staff of
______________________ Hospital, I agree and consent to the following:

I have read and agree to abide by the provisions of the Medical Staff Bylaws, including specifically those relating to privileges and immunities, as well as the Credentialing Plan, the Fair Hearing Plan, and the Rules and Regulations, and I release from any and all liability those persons to whom such privileges and immunities provisions of the Medical Staff Bylaws are intended to benefit;

I agree to appear for interviews in regard to my request for appointment to the Medical Staff and I authorize the Hospital and its medical staff and representatives to consult with representatives and the medical staff of other hospitals and health care facilities who may have information bearing on my competence, professional conduct, ethics and character;

I authorize the Hospital, its medical staff and their representatives to inspect all documents that may be material to an evaluation of my competence, professional conduct, ethics and character;

I release from liability all representatives of the Hospital and its Medical Staff for their acts performed in good faith and without malice in connection with evaluating me and my credentials and I also release from liability all individuals and organizations who provide information to the Hospital in good faith and without malice concerning my competence, professional conduct, ethics and character, including otherwise privileged or confidential information;

I agree that if an adverse ruling is made concerning my appointment, Medical Staff status or clinical privileges, I will exhaust all remedies
afforded by the Medical Staff Bylaws, Credentialing Plan, and the Fair Hearing Plan before resorting to formal legal action or commencing legal proceedings;

If granted an appointment to the medical Staff of ______________________ Hospital, I will provide continuous care to patients, comply with all legal and ethical standards of my profession, discharge my responsibilities as a medical staff member, and work cooperatively with others;

I currently have and will continuously maintain professional liability insurance covering acts and occurrences involving professional activities during the period Medical Staff membership and clinical privileges are granted in an amount approved by the Board, with coverage for all clinical privileges granted;

I will report final judgments or settlements involving professional liability claims or proceedings to the Hospital within five (5) business days after entered or made;

I will immediately notify the Hospital upon receipt of a sanction or notice of intent to sanction from any peer review or professional review body, and any sanction or notice of intent to sanction or to revoke, suspend or modify this license from any licensing or regulatory authority;

I will immediately notify the Hospital of any adverse action involving my medical staff membership or clinical privileges at any other hospital or health care facility, including any voluntary or involuntary relinquishment of such medical staff membership or clinical privileges; and

I hereby authorize and consent to the release of information by the Hospital, its Medical Staff and their representatives to other hospitals,
health care facilities, medical associations, and other interested persons of
any information the Hospital may have concerning my qualifications and
competence so long as it is done in good faith and without malice and I
release from the liability the Hospital, its Medical Staff and their representa-
tives for doing so.

____________________________
Signature   Date                        Printed name

ATTACHMENT 5
Sample Medical Staff Quality Indicators by Specialty
(Page 1 of 3)

Anesthesia:
✓ Difficult intubation
✓ Reintubation
✓ Unscheduled transfer to critical care
✓ Patient injury during intubation
✓ Cardiac or respiratory arrest
✓ Aspiration pneumonia after anesthesia
✓ Adverse reaction to anesthesia
✓ Sedation complication requiring the use of a reversal agent
✓ Neurologic deficit not present prior to anesthesia

Cardiology:
✓ Unexpected mortality
Complication during or post an invasive cardiology procedure (hematoma, perforation, dissection, myocardial infarction, stroke)

Unsuccessful PTCA

Hemorrhagic complication after the administration of a thrombolytic agent

Sedation complication

Failure to assess and treat left ventricular systolic dysfunction (i.e. ACE inhibitor or Angiotensin receptor blocker)

Failure to administer Aspirin for acute myocardial infarction

Adverse drug reaction

Transfer to a higher level of care

History and physical on the chart within 24 hours of care

Emergency Medicine (ED):

Unscheduled return to the Emergency Department for same or related condition within 72 hours

Discovery of an injury or condition not detected in previous visit

ED x-ray discrepancies resulting in the need for additional treatment (i.e. missed fracture, bowel perforation or obstruction)

Unplanned return to the Emergency Department, resulting in the need for hospitalization

Cardiac arrest in the ED or within 24 hours of ED admission

Patients who left against medical advice

Adverse drug reaction

Family Medicine:

Readmission to the hospital within 30 days for same or related condition

Unexpected mortality
Complication post procedure
Adverse drug reaction
Transfer to a higher level of care
History and physical on the chart within 24 hours of care

Obstetrics and Gynecology:
Maternal death
Death of an infant greater than 24 weeks gestation
Decision to incision time for emergency C-section exceeding 30 minutes
Maternal length of stay greater than three days post vaginal delivery
Delivery of an infant following induction of labor weighing less than 2500 grams or requiring admission to the Neonatal Intensive Care Unit
Transfer of the mother to the Critical Care Unit
Cardiac or respiratory arrest
Complication post delivery (hemorrhage greater than 500 cc, uterine rupture or perforation, infection)
Unscheduled return to the delivery room
Unscheduled return to the operating room
Retained foreign body
Sedation complication
Adverse drug reaction
Readmission within 30 days related to previous delivery or surgical procedure
History and physical on the chart prior to a procedure (may include prenatal records, if physician updates the findings)
Pediatrics:
- Unplanned admission or readmission to the hospital
- Missed diagnosis resulting in hospitalization
- Cardiac or respiratory arrest
- Adverse drug reaction
- Transfer to another institution or higher level of care
- History and physical on the chart within 24 hours of admission

Surgical Services:
- Unplanned return to the operating room
- Normal tissue or tissue discrepancy
- Discrepancy between preoperative and postoperative diagnosis
- Unplanned removal of an organ
- Excessive blood loss greater than 500 cc
- Postoperative infection
- Accidental laceration or perforation of an organ
- Retained foreign body
- Unexpected mortality
- Unscheduled readmission to the hospital within 30 days for same or related diagnosis
- Unscheduled transfer to the Critical Care Unit
- Adverse drug reaction
- Postoperative pneumonia
- Failure to administer appropriate antibiotic prophylaxis prior to a procedure
- Prolonged procedure, greater than six hours
- Transfer to a higher level of care
- No History and physical on the chart prior to the start of procedure
ATTACHMENT 6

Physician Case Review Form

Physician Case Review

SERVICE/SPECIALTY: MEDICINE  SURGERY  OB/GYN
FAMILY PRACTICE  OTHER:__________________________

CONFIDENTIAL: This information is used for evaluating the quality of patient care and/or peer review, to be used for the purposes of reducing Morbidity and Mortality and is, therefore, considered to be privileged information.

LEVEL I: NON-PHYSICIAN REVIEW

<table>
<thead>
<tr>
<th>ADMIT DATE:<strong>/</strong>/___</th>
<th>DISCHARGE DATE:<strong>/</strong>/___</th>
<th>MR #:____________</th>
<th>PHYSICIAN CODE:____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>READMIT DATE:<strong>/</strong>/___</td>
<td>DISCHARGE DATE:<strong>/</strong>/___</td>
<td>PHYSICIAN CODE:____________</td>
<td></td>
</tr>
<tr>
<td>INDICATOR(S):__________________________</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SIGNATURE OF REVIEWER  DATE

LEVEL II: SERVICE COMMITTEE REVIEW

PHYSICIAN PEER REVIEW COMMENTS: This area must be completed by Physician Reviewer, noting concerns or questions related to the quality of care and documenting evidence of its presence in the medical record.

_________________________________________________________________________________________________________
_________________________________________________________________________________________________________
_________________________________________________________________________________________________________
CONCLUSION: 1 2 3 4

1 – Case reviewed and found to be within community standard of care. No quality of care concerns noted. No follow up required with physician.

2 – Case reviewed and found to be within community standard of care, although there are minor concerns noted. Includes illegible documentation. Follow up with the physician may be indicated.

3 – Case reviewed and found to be within community standard of care, although unexpected features in the aspects of care were noted. Response may be required from the physician.

4 – Case reviewed and found to be below the community standard of care, with unexpected and/or unacceptable features in an aspect of care. Response required from physician.

Referral to Level III: (Circle One) YES NO

_________________________________________

SIGNATURE OF REVIEWER DATE
CHAPTER EIGHT
Patients’ Rights and Ethical Issues Impacting Health Care

Seval Akgun, MD, PhD  Priscilla A. Pierce, BSN, RN, C, CPHQ

The Hippocratic Oath (circa 4th century BC) set forth a list of standards intended to guide the practice of medicine. Key to the oath is the assertion that the physician must practice within the scope of his or her expertise, preserving life, abiding by a code of ethical and moral behavior when interacting with patients, and maintaining confidentiality at all costs. The core principles of this oath established the moral foundation on which our modern health care delivery system rests. The care and services provided by all health care facilities should be driven by an internal code of ethics, which provides the guiding principles that encompass the values, and responsibilities of the organization to its patients and customers. It has become standard practice in many regions for patients to be given a copy of a “Patient Bill of Rights” at the time of admission (See Attached Example 1).

Clearly communicating with the patient at time of their initial contact with the facility regarding steps that have been taken to ensure that their rights will be protected helps foster the development of positive expectations. It is critical that all staff members are educated on the need to provide care to the patients in a caring, compassionate and empathetic manner. Development of a relationship with patients that fosters confidence that they are receiving quality care will support positive patient outcomes and decrease the risk of litigation for the facility.

Patients’ rights

The goal of the patient rights and organization ethics function is to help improve patient outcomes by respecting each patient’s rights and conducting business relationships with patients and the public in an ethical manner.

Patients have a fundamental right to considerate care that safeguards their
personal dignity and respects their cultural, psychosocial, and spiritual values. These values often influence patients’ perception of care and illness. Understanding and respecting these values guide the provider in meeting the patients’ care needs and preferences.

Usually the hospital is committed to ensuring that the individual rights of all patients are respected during their hospital stay. Most importantly, all patients have the right to expect to be treated with dignity and respect. It is important for all health care providers to be familiar with patients’ rights under state law and hospital policy and observe them at all times. Patients afforded these basic considerations are usually more satisfied with their hospital experience, and from a risk management perspective, it makes them less likely to make a complaint, which could ultimately result in a claim or lawsuit.

The hospital is obligated to provide appropriate assistance, including the use of an interpreter, to ensure that patients understand their rights. All individuals are entitled to receive emergency care and/or treatment without discrimination due to race, color, religion, sex, national origin, disability, sexual orientation, or source of payment. Patients are entitled to be informed of the identity and role of all physicians and support staff involved in their care, and have the right to refuse treatment or examination by them. Patients have the right to privacy while in the hospital and to expect all information and records regarding their care will be kept confidential.

Patients must be given all the information they need to give informed consent regarding treatment and refusal of treatment. Under most circumstances patients are entitled to review, and should they so desire, obtain a copy of their medical records (after discharge if the record is a hospital record). A patient may refuse to take part in research and should be able, without fear of reprisals; to complain about the care and services they have received.

Patients, or appropriate family members, should be informed about unexpected and/or negative outcomes promptly. This should include the nature and cause of the event, if known, as well as the manner in which the event will affect the patient’s prognosis and treatment plan. Failing to disclose, or disclosing only partial information regarding such occurrences, is perhaps the most common cause of patient dissatisfaction. Often, this dissatisfaction results in malpractice claims and lawsuits. Regardless of how difficult it may be for patients, it is legally unwise to speculate on the cause of an untoward
Patients should also be made aware that in order for the health care team to render good care and patients have certain responsibilities. The most important of these is to provide, to the best of their knowledge, accurate and complete information about their present complaints, past illnesses, hospitalizations, medications and other matters relating to their health. Patients are responsible both for following the treatment plan recommended by the members of the health care team, and for the consequences should they refuse treatment or not follow recommended instructions.

Patient’s have a right to:-

- Treatment with kindness and respect regardless of race, age, religion, gender, national origin physical or mental disability;
- Respect of personal values and beliefs. Should the patient face an end-of-life situation, patient’s need for comfort and dignity will be respected;
- Proper access to care by qualified care givers, medical and social personnel;
- Receive as much information about any proposed treatment or procedure necessary to give informed consent;
- Receive complete understandable current information regarding his/her illness, prognosis, course of treatment and continuing health care needs following discharge;
- Receive privacy regarding medical treatment plan;
- Receive confidential treatment of all communications and records;
- Be able to express opinions/complaints and receive resolution in a timely, accurate and confidential manner;
.receive information regarding which hospital rules and policies apply to his/her conduct as a patient;

Notify a family member or representative promptly upon admission.

During the last few years France and the Netherlands have been innovative in their civil law and ‘bioethical legislation’. In countries like Finland, Sweden, Denmark, and recently in Belgium, legal initiatives were taken to define specific patients’ rights, in the UK the publication of a Patients’ Charter was undertaken. However, in too many countries and in too many domains of health and healthcare the (national) legal situation is intolerably obscure for the patient. The citizen is in the first place barely protected by the law in his body and person in comparison with the mass of legislation on assets, property transactions, and on the obligations once again concerning primarily assets. This legal insecurity on the most basic questions concerning the patient-care relationship (person or institution) should be removed.

It concerns questions on explicit consent given before-, hand or not, on who should consent if the patient is incapable of doing so. This concerns the rights of spouses and the rights of parents over their children, on the right to truth, on the right to protection of one’s private life and on health and death. This is even more so for certain categories of patients - the elderly, the mentally ill, those with chronic problems who are, moreover, often absent from the debates. Ethics have a very important role here but they cannot replace law, which should also intervene in the health field, not only in case of catastrophes (trials of responsibility), but also, and above all, in prevention through clear general rules.

Hospitals are very complex institutions (enterprises), where the quality of care depends on a lot of possible tensions created through the degree of autonomy of the many professionals, doctors, nurses etc. and the necessary organization of the institutions. The associations (also the European and international ones) both of professionals and institutions have an important role to play in finding the right balance in present and future relations within hospitals. The status of doctors in some countries creates a challenge from this respect because of a quasi-independent status of doctors in hospitals (the Netherlands, Belgium, Luxembourg, Germany, Switzerland, U.S.A., Canada, and partially France). In some countries doctors are an integral part of the
hospital and employed by it. Even in those hospitals medical doctors often take an independent consultants role. In this role they work with the patient and demand all the technical resources possible for the care despite the local circumstances and the resources of the hospital. This creates a risk for a legally split not-integrated hospital.

Therefore the hospitals should define (also legally) and organize their relations with the healthcare professionals in such a way that they can truly guarantee and assume their own institutional responsibility for the promotion of health of their patients in the most literal and realistic way. In practice before health education and promotion will be able to contain a clear subsection empowering patients through correct information on patients’ rights a lot of very basic legalistic work will have to be done nationally and/or internationally. Therefore establishment of an effective physician-patient relationship requires that the physician strives to do the following:

- Treat the patient with honesty and respect
- Maintain strict confidentiality of all healthcare information
- Acknowledge the patient’s right to participate in healthcare decisions
- Allow time for the patient to ask questions or share concerns
- Operate within one’s scope of practice, privileges, and capabilities

Patients, also, have obligations to healthcare providers. These include:

- Report any changes in their medical condition or symptomatology
- Adhere to the treatment regimen
- Ask questions and share concerns
- Keep appointments with the physician
- Make wishes known regarding end-of-life care and life supporting or life sustaining treatment
The physician’s skills at maintaining an interpersonal, but professional, relationship with the patient may be as valuable and important as his or her technical abilities. The development of a healthy therapeutic relationship with the patient will open the door for the patient to communicate healthcare information which may be critical to arriving at an accurate diagnosis or the selection of an appropriate treatment regimen.

**Patient Privacy**

It is crucial for all staff members of the facility to have a thorough understanding of the organization’s policies and procedures governing the protection of any information collected or generated during the course of treating patients. This would include financial and research-related activities, as well as, those associated with arrangements the facility may have with educational institutions which utilize the facility for training purposes. At the time a patient first presents at a facility for any sort of medical care or treatment, he/she should be provided with information regarding the facility’s privacy practices.

Healthcare providers have an irrefutable obligation to protect a patient’s healthcare information. As the complexity of today’s healthcare delivery system increases due to new technology, so do issues pertaining to patient confidentiality. Until recent times, one primary care physician met most or all of a patient’s healthcare needs. With the ever-increasing number of medical specialties and specialized treatment centers, a person’s medical information may now be housed in multiple locations. What was once a single, handwritten record is evolving into a document that is comprised of a combination of handwritten notes, dictated reports, and lab and radiology results originating from different locations. This increases the possibilities for a patient’s medical information to be viewed by others.

In such a complex system, stringent measures must be put into place in order to assure that patient privacy is protected. Policies and procedures must be developed and enforced, along with provision of ongoing staff education pertaining to patient privacy issues. Safeguards must be put into place at multiple levels in order for the organization to meet the obligation to protect
the patient’s privacy. These include:

- Limiting access to the patient’s medical record on a “need to know” basis only
- Storing patient medical records away from high traffic, high visibility areas
- Discussing patient information in privacy, away from other patients or visitors
- Providing staff with regular education on issues pertaining to patient confidentiality
- Using patient initials, rather than full names, on dry erase boards which are often used in such areas as the emergency room or surgery
- Obtaining permission from the patient before releasing any medical information
- Verifying the identity of the individual or organization requesting access to, or a copy of, a patient’s healthcare information
- Building multiple security measures into computer systems:
  - assigning passwords which are changed on a regular basis in order to limit unauthorized access to patient records
  - positioning computer screens so that they cannot be viewed by other patients or visitors
  - setting up an automatic “logoff” in the computer system which is triggered by a specific inactivity threshold (i.e. “PC not used for 30”)
  - encrypting files containing patient information in order to ensure that the data are secured and controlled
  - developing an ongoing security awareness and training program for staff
  - requiring verification that any third party sources for data transmission or reporting have the appropriate security measures built into their system
  - establishing a contingency plan in order to address system failures,
as well as, emergencies, disasters, theft, or other occurrences that involve the information system

- periodically performing a risk assessment in order to evaluate the effectiveness of the system
- enforcing all of the above-mentioned policies and taking disciplinary action when there has been unauthorized access or release of confidential information

✓ Completing a thorough investigation of any patient complaint regarding unauthorized access or release of information

✓ Coding patient-specific information that may be contained in reports, committee minutes, reports, or correspondence

Should a patient authorize release of their medical information to an individual or entity outside of the hospital, they must sign a release of information consent form. This document should become a permanent part of the patient’s medical record. (See Attached Example 2) At a minimum, the form should contain:

✓ Patient name
✓ Name of individual or entity to whom the information is to be released
✓ Reason for the request
✓ List of what sections of the record are to be released
✓ Dated signature of patient or legal representative

**Informed Consent**

Honoring the patient’s right to participate in healthcare decision-making is a critical issue today, particularly given the numerous treatment options now available. In order to be able to give true informed consent a patient must have been provided with information on the risks, benefits, and alternatives to a procedure or treatment. The physician need not overwhelm the patient with technical jargon in order to provide the information pertaining to the proposed treatment. Rather, it may be more helpful to the patient if non-technical terminology is used, along with a basic explanation of the requisite risks,
benefits, and alternatives. The process of informed consent should always be documented in the medical record. While a signed consent form is the most common means of documenting this process, the physician may opt to document this information in a progress or procedure note.

Consent – is a core clinical activity and is fundamental to patient care, best practice and clinical governance which can be informed or implied. Patients have a fundamental legal and ethical right to determine what happen to their own bodies, therefore valid consent to treatment is central in all forms of health care from providing personal care to major surgery;

Informed Consent – is a communication process, and a document authorizing the treating Medical Team to provide the patient treatment or procedure;

Implied Consent – in emergent condition when the conditions require alleviation of severe pain or immediate diagnosis and treatment of unforeseeable medical condition, which if not immediately treated, would lead to serious disability or death. The consent is only for the time frame of the emergency. This also include but not limited to physical examination, radiographs, simple laboratory tests, dental prophylaxis or minor procedures, venipuncture, IV therapy etc.;

*The informed consent process is the opportunity to share information with the patient, to take time to listen to the concerns of the patient, to respect the patient as a decision maker.*

At all times, the patient has the right to be aware of the any developments in their care. This includes the right to be made aware of an adverse event or unanticipated outcome that has occurred during their course of treatment. This is a most sensitive issue and is fraught with many legal implications. However, it is hard to ignore the critical importance of open, honest communication on the part of healthcare providers and the patient’s right to same. Organizations should have a policy in place in regards to how they will address such situations should they arise. It is most typical to designate that the patient’s attending physician, accompanied by a member of the hospital administration, will be the one to discuss the incident.
Informed consent is the process by which a fully informed patient can participate in choices about his or her health care. It originates from the legal and ethical right the patient has to direct what happens to his or her body and from the ethical duty of the physician to involve the patient in his or her health care.

✔ Informed consent as a process includes the following three elements:

1. Discussion with the patient
2. Documentation of the discussion
3. Decision-making by the patient

A complete informed consent process includes the following components:

✔ Description of the proposed treatment or procedures
✔ Risks, benefits or side effects
✔ Alternatives to the treatment or procedure and associated risks, benefits, or side effects of same
✔ Likelihood of achieving the goals of the treatment
✔ Possible impact of opting against the treatment

In order for consent to be truly “informed,” the physician should discuss with the patient:

1. The nature of the proposed treatment or procedure.
2. A description of any reasonably foreseeable material risks or discomforts. “Reasonably foreseeable” means published in the medical literature, widely known, capable of being deduced, present in the labeling.
3. A description of the anticipated benefits.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous
5. Special instructions regarding food, drink, or lifestyles
Elements of informed Consent

When discussing this with the patient/patient’s representative, the clinician must disclose in a reasonable manner, using layman’s language to enhance the patient’s understanding, all significant medical information that he/she believes is relevant and material to making an informed decision by the patient in deciding whether or not to undergo the procedure or treatment.

Elements of Informed Consent - is performing an invasive procedure or administering anesthesia for any urgent or other non-emergent condition, specialized treatment or procedure, the patient’s treating physician and anesthesiologist, if appropriate, shall inform the patient or the patient’s representative, clearly, and in lay terms, and in a language the patient or representative can understand, of material information and discussion regarding:

  o The patient’s condition, assessment of patient understanding;
  o The type of anesthesia proposed;
  o A description of the proposed treatment or procedure and acceptance of the intervention by the patient;
  o The potential benefits of the proposed treatment or procedure and anesthesia;
  o The potential drawbacks of the proposed treatment or procedure and anesthesia;
  o Complications discomforts, disability or disfiguring aspects that reasonably might occur;
  o Risk arising from the proposed procedure and anesthesia;
  o The potential for death or serious harm;
  o The risk arising from the patient’s condition;
  o Possible problems related to recovery from the procedure and the anesthesia;
  o Possible results of non-treatment or procedure including the risks, benefits, and complications;
  o The possible results of the patient declining the recommended
treatment or procedure and recommended anesthesia plan;

- The likelihood of success from the proposed treatment or procedure;

- Reasonable alternative including additional consultation to the proposed treatment or procedure and anesthesia, and the dangers inherently and potentially involved in each;

- Such additional information as a skilled practitioner in good standing would provide under similar circumstances;

- The identity of the physician or other practitioner responsible for the treatment or procedure and the administration of anesthesia if this is to be done by the same physician;

- The identity of the physician or other practitioner who is authorized to perform the treatment or procedure;

- Existence of financial interest in recommending a particular course of treatment, or the extent to which the treatment options are covered by health insurance;

- The identity of the anesthesiologist responsible for administering anesthesia. It is the anesthetist responsibility and not the surgeon to gain consent for anesthesia.

**Indications for Informed Consent**

Obtain the patient’s informed consent before procedures and under conditions as follows:

1) Major or minor surgical procedures which involve entry into the body, either through incision or through one of the natural body openings

2) Procedures in which anesthesia or IV conscious sedation is used, regardless of whether entry into the body is involved

3) Non-surgical procedures which include more than a slight risk of harm to the patient or involve the risk of change in the body structure (for example, diagnostic procedures such as lumbar puncture, myelograms, pyelograms, arteriograms, and cardiac stress tests)

4) The administration of blood products in other than an emergency
5) Procedures involving the use of cobalt and radiation therapy
6) Electroshock therapy
7) Experimental procedures
8) Situations in which the patient is to be photographed or videotaped.
   Administration of chemotherapeutic agents
9) Administration of psychotropic medications (when possible)
10) Administration of medications with potentially serious side-effects
   (for example, long-term high-dose steroids, and, in pediatric patients, Ritalin)
11) For obtaining informed consent in any situation in which there is a question about whether it is needed.

**Documentation of the consent** following the discussion, and the patient or patient’s legal guardian understands the discussion and is capable of giving consent, the treating physician and, where applicable, the anesthesiologist obtaining the consent obtains the signature of the patient or the patient’s guardian, obtain the signature of two (2) witnesses, execute the form, and place the form to be placed in the patient’s medical record. It is also important to document any questions asked by the patient and the answers given in the progress notes. If the physician obtains consent but without sufficient information for an informed consent, then there is basically no consent and we may contravene patient’s rights. It is important to write the relationship of the person signing the consent for the patient;

A description of the procedure and the type of anesthesia shall be written on the form by the treating physician or attending anesthesiologist, in terms that the patient or the patient’s guardian can understand, rather than using technical jargon, and no abbreviations should be used;

A translator may be used to convey the message to the patient. If a translator is used, he or she should sign the consent form(s) as a witness to the patient’s signature. List of translators is available and can be availed thru telephone operator;
Validity – the date and time at which consent forms are executed shall be noted in the patient’s medical record. The consent shall be valid for 30 days from execution, until revoked, or until discharge, whichever is first. If the procedure is not commenced within 30 days of signing, the patient must again give his informed consent. For Hemodialysis patients it is valid for one (1) year. If circumstances have changed, it is prudent to review and obtain a new informed consent. Information should be reviewed with the patient. The patient shall not be under sedation effects when signing, it may affect patient’s judgment;

The witnesses (2 RNs or other health professionals) must be present throughout the explanation and shall sign the consent form as witnesses to the patient’s signature;

Therefore during documentation;

✔ Do not delegate responsibility for obtaining informed consent.

✔ Document all discussions with the patient about informed consent and refusal. Include in the documentation a statement about the patient’s questions, concerns, and response(s).

✔ Take particular care to document the patient’s inability to give consent in the event of an emergency.

✔ Document the statement made by an individual who presents him/herself as the legal guardian of a patient.

✔ Be especially meticulous with documentation if the patient is or you suspect him/her to be resistant to complying with a suggested therapy.

Revocation or Refusal of Treatment: -

1) If at anytime the patient or legal guardian refuse to give consent, it is presumed that the patient or legal guardian is competent to refuse consent. Notify physician and document accordingly in the form Refusal of Treatment Procedures;

2) If a patient revokes consent before a procedure, it should be docu-
mented in the patient’s medical record;

3) If a patient revokes consent out of fear and/or misunderstanding, it is appropriate to counsel and instruct them, it is not appropriate to use coercion;

4) In case the patient is in a life-saving situation, critical and is conscious but refuses to sign the consent form and surgical or invasive procedure is necessary: -

5) Call and ask the opinion of the family, legal guardian or sponsor and if still refuses, request patient to sign the Refusal Form witnessed by the family and attending physician, a full medical report should be documented in the patient’s medical record indicating the patient’s refusal and patient’s condition, potential complications, death or serious harm.

Modification of Treatment – if there is a change in patients condition which needs alteration or modification of operation form procedure, the physician has to inform and explain to patient or legal guardian and another consent form must be obtain.

SPECIAL POINTS

✔ Consents are valid for the duration of patient’s hospitalization.

✔ The consent shall be valid for a period not to exceed thirty days from the date of signing should the procedure need to be postponed.

✔ Some surgeons include a clause in their consent forms that covers unanticipated conditions discovered during surgery. This authorizes them to extend an operation to address the condition so the patient can avoid the risks of a second surgery. However, the courts are less willing to permit surgeons to rely on the unanticipated condition exception if a procedure involves removing an organ, affects reproductive capability, or significantly increases the risks of the operation. And no condition would be considered unanticipated if the patient indicated beforehand that he doesn’t want it treated if discovered.

✔ If the patient refuses to sign consent for release against medical ad-
vice, a note should be written in the chart documenting this fact, and signed by the nurse in charge.

✓ Refrain from telling the patient that a proposed procedure/treatment/therapy is “simple” or “routine.” It is not likely to be simple or routine for the patient and may invite a claim or suit in the event of unforeseen complications.

✓ Signature of two physicians (one is a specialist – pediatrician or obstetrician) attesting to the fact that continuation of pregnancy will be harmful for either mother or fetus or both. The patient and her husband should sign the consent and if they are unable to sign, then the natural guardian of the unborn child must sign the consent.

✓ Emancipation is the event of becoming legally competent to act and decide for oneself without consent of a parent or guardian. Emancipation is normally presumed to occur when an individual attains the age of 18 but may occur earlier when facts and circumstances, most commonly marriage or employment by the Company, indicate a minor has attained a requisite level of responsibility and maturity to act in his or her own behalf.

✓ Emergency situation is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, severe psychosis and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual in serious jeopardy, serious impairment of bodily functions, or serious dysfunction of a bodily organ. All patients (adult, minor, incompetent, walk-in, in- or out-patient, EMS, etc.) shall be treated.

✓ Consent is implied and may proceed without obtaining written consent. The clinician must document the nature of the emergency and the treatment given in the patient’s medical record.

✓ Entitlement to make informed decisions.

1) Adult patients (males or females who are 18 years of age or older,
or otherwise emancipated) have a moral, ethical and legal entitlement to make decisions regarding their treatment, and to be provided sufficient information in order to make informed decisions regarding their healthcare.

2) Extraordinary circumstances: In the case of a competent adult or competent emancipated minor who is mentally capable of understanding the nature of a procedure and its associated risks and is able to give consent orally (or in any other way in which consent can unmistakably be determined to have been given) but:

- Is physically incapable of giving written consent: The patient’s parent, spouse, or other relative, or, if no family member is able to be present, two responsible employees will sign the consent form, on which it has been noted that the patient is physically unable to sign for himself/herself.

- Is willing to cede authority to grant consent to a “guardian”: The patient will be asked “Would you prefer for the details of your medical condition to be discussed with your (specific) relative and for that person to have the power to make decisions related to your medical care?” If so, details of the guardianship authorized by the patient shall be documented in the medical record so as to be accessible by all caregivers.

3) Minors’ (patients who are under the age of 18 years) or incompetent adults’ rights regarding informed consent will be exercised through their parents or other representative.

Informed Consent in the Clinical Setting

Case 1

A 39-year old woman scheduled for surgical removal of a pelvic mass gave written informed consent for laparoscopy and laparotomy. She also had an unwritten “understanding” with the surgeon that a hysterectomy would be performed if malignancy is found. The laparoscopy revealed severe endometriosis but no malignancy. The surgeon proposed performing a hysterec-
tomy and bilateral Salpingo-oophorectomy. Before proceeding, the surgeon asked the patient’s primary care physician, a personal friend of the patient’s who was in attendance in the operating room, to obtain the consent of the patient’s husband, who was waiting outside. Upon hearing that the husband had given verbal consent; the surgeon proceeded with the hysterectomy.

After surgery, when the patient realized what had happened, she became irate, her husband denied ever having given consent, and the physician was sued for negligence. This case closed with a payment of almost $2 million.

**Question 1:**
The most important risk management issue in this case was:

a. Performance of the hysterectomy without formal written consent
b. Performance of the hysterectomy without the patient’s consent
c. Reliance upon the primary care physician to obtain informed consent

**Question 2:**
When the surgeon found the endometriosis, his best approach, from a risk management perspective, would have been to:

a. Proceed with the hysterectomy, recognizing it as the most effective treatment for severe endometriosis
b. Plan a hysterectomy for a later time when the proper consent had been obtained
c. Terminate surgery and plan a course of drug therapy
d. Terminate surgery and discuss alternatives with the patient at a later time

**Case 2**
A 33-year old male went to his internist complaining of cluster headaches of such piercing intensity they had him writhing on the floor and screaming in pain. The physician treated the patient with Prednisone 5 mg. t.i.d. with a 26-day taper. Over the next 18 months, this regimen and another similar to it were prescribed and refilled until the patient had consumed a total of 955
tablets or almost six grams of Prednisone. When the patient subsequently develops osteonecrosis of hips, shoulders, and knees, he filed a claim against the physician. The claim alleged that although the physician had obtained the patient’s written informed consent before beginning steroid therapy, he had not told the patient that avascular necrosis could be one of the side effects of long-term use of Prednisone.

This claim closed with a total payment of almost $1 million.

**Question 1:**
The physician stated that he did not inform the patient of the risk of avascular necrosis because he didn’t want to frighten the patient to such an extent that the Prednisone would be refused.

This might be considered an example of:

a. Paternalism

b. Thoughtfulness

c. Uninformed consent

d. Informed refusal

**Question 2:**
When the risk for a side effect, for example, avascular necrosis, is considered remote, it should not be included in the informed consent discussion.

a. True

b. False

**Meeting the Patient’s Communication, Educational and Cultural Needs**

Another basic right of the patient is to be provided with effective communication. This includes the need to provide translator services for those patients with a primary language that differs from that of the institution. While family members or friends may be a ready source, caution needs to be used, as they may be unable to accurately translate medical terms and discussions regarding treatment plans. It is often best to use a translator service, or “language bank” for this purpose.
Accommodations must be made for those patients with a sensory impairment. In order to meet the needs of patients who are hearing impaired, the hospital may need to enlist the services of someone able to communicate with the patient using sign language. For those patients with impaired vision or blindness, it may be necessary to provide information translated into Braille.

All education provided to the patient should be provided in a learning style appropriate to the patient’s cognitive, developmental, and emotional capacities. An entry should be made in the medical record, indicating the topic discussed, the patient’s preferred learning modality, the manner in which the was presented (i.e. verbally, written, video), how the patient received the information, and how the effectiveness of the education was evaluated (i.e. return demonstration of process for self-injection).

At discharge, the patient should be provided with written instructions that contain, at a minimum, the following information:

- ✔ Diagnosis
- ✔ Medications, to include dose, frequency, and special instructions (i.e. food/drug interactions)
- ✔ Diet
- ✔ Activity level
- ✔ What to do if symptoms worsen
- ✔ Follow-up appointment

Provision of appropriate, ongoing patient education will support positive patient outcomes. It has, also, been shown to result in higher patient satisfaction and fewer instances of litigious situations. It behooves the physician and benefits the patient if adequate time is spent in this activity. It is possible to utilize technology in the development of standardized educational materials or preprinted forms that include checkboxes for the key elements of the educational process. However, the education itself must be tailored to meet the individual needs of the patient.
Protecting the patient’s dignity is critical at all phases of the healthcare delivery process. This requires attention to such issues as:

- Keeping the patient draped and covered as is feasible, when administering care or treatments
- Addressing the patient by his or her proper name
- Closing the door to the patient’s room when completing an examination or attending to the patient’s personal needs

The healthcare team must, also, be respectful of the patient’s cultural beliefs and customs and make accommodations to meet these needs, as is feasible. Such accommodations could include:

- Preparing special meals in order to meet culturally dictated dietary requirements
- Flexing visitation regulations to allow for extended family to stay with the patient
- Allowing the patient’s religious leader to come and perform a healing or prayer ritual
- Respecting the patient’s wishes as pertains to end-of-life issues and burial practices

It is important that hospital staff receive regular education on cultural sensitivity issues pertaining to health care. This can be accomplished through in-service educational offerings, continuing medical education, or staff educational fairs.

Complaints and Grievances

Another basic right of the patient is to file complaints or grievances. Patients should be apprised of this right at the time they are admitted. This can be accomplished by providing a preprinted Patient Rights booklet or brochure.
It is critical that staff is educated regarding how to handle a complaint or grievance once received from the patient. Generally, most complaints can be addressed immediately. An example of this would include a complaint about the dinner entrée or meal temperature, which is easily remedied by offering the patient a different meal. Encouraging a service-oriented culture benefits both the patients and the organization. Physiologically, patients who are in a better frame of mind tend to experience better outcomes than those patients who remain angry over unresolved complaints or concerns. On a pragmatic note, happy patients are far less likely to sue over care issues or unacceptable outcomes.

Many organizations seek to address patient complaints in a proactive manner by having a position designated as the patient advocate. This can lead to high patient satisfaction, as patient complaints and concerns are addressed in a consistent and thorough manner. It helps for the patients to be able to put a face with a position and most see the patient advocate as just that, an individual dedicated to making sure that their stay is as pleasant as is possible.

Many complaints are received after a patient is discharged. These should be handled in as thorough and timely manner as those which are received while the patient is still in the hospital. It is desirable for a follow-up letter, written in response to the complaint, to include as much specific information as is possible in order to assure the patient that the issue has been resolved. This would include whether or not the complaint was validated, steps taken to remedy the situation if a problem was identified, along with a point of contact should the patient need additional clarification.

Results of patient satisfaction scores, as well as, complaints should be tracked and trended in order to identify areas most in need of improvement. Primary consideration should be given to any issue that may impact patient safety. At a minimum, a report containing a summary of all complaints received during a designated period of time should be reviewed by hospital Administration. It is often quite beneficial to task the Quality Council with the responsibility of reviewing reports on patient satisfaction and patient complaints on a regular
basis in order to identify any trends, positive or negative. The Council can then make decisions as to what areas to target for improvement and enlist the involvement of appropriate departments and individuals in this endeavor.

**End of Life Issues**

The patient’s right to participate in treatment decisions, also, includes decisions regarding cessation of treatment in the face of medical futility. Discussions regarding the right to refuse further treatment or the withdrawal of life support are often times quite difficult for the patient and family, as well as, members of the treatment team. Given the emotional and psychosocial issues that may be encountered, it is often wise to involve social workers or therapists in such discussions. Once the decision is made to cease aggressive treatment or to abstain from such interventions as cardiopulmonary resuscitation, it is critical that all members of the healthcare team are advised so that the patient’s wishes are honored. Given the technical advances available today, the issues surrounding decisions to cease life sustaining/supporting are occurring with greater frequency. This has heightened the need for further emphasis and education on the emerging field of medical ethics.

- The unit of care is the patient and their family, who have the right to make choices and decisions based on an understanding of their illness and to have those decisions respected;
- Medical services staff shall strive to provide quality care and to support the patient and family in coping with the dying process and in making care decisions that agree with their values and sensibilities;
- Supportive and holistic care (the care of the whole patient) should be provided at time of diagnosis, so that the improved quality of life from initial treatment can be maintained as far as possible until death;
- Teaching healthcare professionals how to provide better symptom control, psychological support, and a delivery of services to the patients;
- Every effort will be made to: -
- Promote coordinated multidisciplinary care;
Reduce patient’s transfers, especially when patients are near death;
Recognizing special needs, such as facilitating: -
A designating family member/watcher to stay with the patient, ample space and time for the family (including children) to be with their beloved family members (this may include adapted visiting hours);
Food and comfort measures to be brought in by the family;
Support of the family (physical, psychologically and spiritually);
Ensure that family members or care givers are provided with respite needs during their care of terminally ill patients by arranging with family, someone to be responsible during that specific interval;
Support of end-of-life concerns, hopes, fears and expectations in an open, honest, and culturally sensitive manner, considering that special wishes of the patients and family are supported whenever possible;
Pain management, comfort measures, and treatment of primary and secondary symptoms related to the disease process or to curative treatments will be offered and explained to the patient and his family;
Patients and families (to the extent desired by the patient) shall be given sufficient information needed to participate in decisions about care;
Details of the guardianship authorized by the patient shall be specifically and prominently documented in the medical record so as to be accessible by all caregivers.

Spiritual Care: -

Patients/families who so desire may arrange for their spiritual representative to visit with the patient and offer prayers. The social worker and or nursing shift supervisor on duty can facilitate such visits upon request.
The social worker should be consulted when the patient is near the end of life to make an assessment and plan for delivery of supportive care
to the patient and family;

✔ In the event of sudden or unexplained death, staff members should contact the social worker in duty or their appropriate personnel to assess the family’s needs and provide the necessary support;

✔ Care of deceased patients body is addressed with full respect of patient and family spiritual concerns or beliefs.

It is obvious that there are a myriad of issues surrounding the issue of patient rights. Joint Commission has put considerable efforts into the “Speak Up” program which, as the title denotes, encourages patients to be actively involved in their healthcare. If such a philosophy is adopted by healthcare facilities, it will benefit the patients, as well as, the healthcare providers.
References


ATTACHMENT 1

Patients’ Bill of Rights

1. Patient has the right to quality health care regardless of race, creed, color, sex, educational level, religion, national origin, or ability to pay
2. Patient has the right to respectful and considerate care
3. Patient has the right to receive care which includes efforts put forth to address the patient’s personal values, beliefs and spiritual and cultural needs
4. Patient has the right to be involved in decisions pertaining to all aspects of care
5. Patient has the right to refuse treatment, to the extent permitted by law
6. Patient has the right to have all matters concerning their health care handled in a confidential and private manner
7. Patient has the right to participate in discussions regarding ethical issues that may arise during the course of treatment to include those pertaining to conflict resolution, withholding of resuscitative services, forgoing or withdrawing life-sustaining treatment, and end of life issues
8. Patient has the right to be informed as to any proposed investigational studies and clinical research trials, as well as, the right to refuse to participate
9. Patient has the right to receive an itemized statement for all charges incurred during the course of treatment
10. Patient has the right to be informed in advance of customary charges for the anticipated course of treatment
11. Patient has the right to be informed of hospital policies, procedures, and processes in a manner that can be understood
12. Patient has the right to file a complaint or grievance
13. Patient has the right to be informed of other healthcare providers that may
be able to meet the patient’s health care needs

14. Patient has the right to have personal belongings safeguarded and returned upon discharge

15. Patient has the right to be informed of continuing health care needs following discharge from the hospital, as well as, assistance with making arrangements to meet these needs

16. Patient has the right to be fully informed as to the nature, purpose, expected outcomes, risks, benefits, and alternative treatments which may be available in regards to a proposed invasive or technical treatment

17. Patient has the right, at his or her own expense, to consult with a specialist.

18. Patient has the right to know the identity of all persons providing care or service

19. Patient has the right to open communication with those responsible for his/her care, to receive information regarding the nature and extent of condition in need of treatment, planned course of treatment and prognosis

20. Patient has the right to comprehensive and compassionate pain management through individualized treatment of total pain, including physical, psychological, social, and spiritual components
ATTACHMENT 2

Consent for Release of Health Information

Patient Name: _____________________________
ID Number: ______________________________

Date of Birth: ____________________________
Medical Record Number: ___________________

I am requesting that ________________________________
Hospital disclose information in my medical record to: ____________________________
__________________________________________________
at this address: _______________________________________
for the purpose of: _______________________________________
____________________________________________________________

I am specifically authorizing the release of the following information:

£ History & Physical
£ Radiology Reports
£ EKG/Echocardiogram
£ Pathology Report
£ Lab Results
£ Physicians’ Progress Notes

£ Nurses’ Notes
£ Physicians’ Orders
£ Consultation notes
£ Discharge Summary
£ Operative Report
£ Other: ___________

Dates of treatment, if known: ________________________________
_____________________________________________________________

I understand:

1. ____________________________ Hospital will not condition treatment on
my providing this authorization for use or disclosure of my medical information. If I refuse to sign this authorization, I will still be eligible to receive medical services from this hospital.

2. I have the right to revoke this authorization at any time by sending a letter or completing a revocation form which gives my name, the date I signed this authorization, and states that I revoke the authorization to use my medical information.

3. ____________________ Hospital may disclose my information to a recipient who could possibly later use or disclose the information without my authorization.

4. I may inspect or copy the information from my medical records that will be used by __________________ Hospital for the purposes set forth in this authorization.

5. I have the right to refuse to sign this authorization and if I refuse, my medical information will be not used by this hospital for the purposes indicated on this form. I will receive a copy of this form.

6. ____________________ Hospital will not receive compensation for the use or disclosure of information in my medical record.

I understand that my medical information may indicate that I have a communicable or venereal disease which may include, but is not limited to, diseases such as hepatitis, syphilis, gonorrhea, or human immunodeficiency virus, also known as Acquired Immune Deficiency Syndrome (AIDS). I further understand that my medical information may indicate that I have or have been treated for psychological or psychiatric conditions or substance abuse.

______________________________
Signature of patient or patient’s representative Date Printed Name

Description of representative’s authority:
£ parent of minor  £ durable power of attorney
£ legal guardian  £ other:
CHAPTER NINE
Utilization Management

Ali Ray Assaf, MPH, CHQ  Diana K. Pistole, RN, PH
Atilla Akova, MD

Introduction

As providers, Healthcare Organizations strive to provide the highest quality care to the greatest possible number of individuals in the most efficient manner possible. Meeting this objective assumes that the appropriate care is given at the right time and in the proper setting. With the rising costs of healthcare in the United States, efficiency is a major concern for all provider organizations. Efficiency often translates into employing the most effective cost saving strategies while striving to maintain the highest standards in the delivery of healthcare. The development of health maintenance organizations, HMOs, in the 1970s evolved in part from the industry driven goal of meeting the objective of efficiency in healthcare (3,4). Decades later changes in healthcare are apparent; an older and sicker patient population; increased consumer expectations; increased competition within the market; and vastly intensified government regulations have all led to an evolution of managed care. Changes in managed care can most commonly be seen in physician practice groups, health plans, and hospitals (4,7).

Thus, the physician-hospital relationship has become increasingly important (5,6). Various strategies have been employed within the market. Managed care brought capitation contracts which aim to align financial incentives and shift risk to the provider. This risk shifting means the provider will also pay when efficiency is not achieved or maintained. Efficiency has therefore been at the forefront in healthcare reform. Healthcare organizations have sought more physician-hospital cooperation to improve the efficiency of care delivery (5). Within this context utilization management is an important issue.

Utilization Management is a process performed in health care institutions to ensure that patients are hospitalized appropriately for the severity of their illness and the intensity of service (resources) needed for the management of their care.
Managing the utilization of care is of utmost importance in any managed health care organization, and one cannot discuss the subject of managed health care without also recognizing the role of utilization review or management. The provision of medical services consumes more of the premium dollar in a health maintenance organization (HMO), or health care organization, than any other activity in which it engages. Therefore, close attention to this function can provide the organization with a successful financial return, while still providing appropriate and quality care for its members.

The term “utilization review” is often used interchangeably with “utilization management,” and “utilization improvement.” Whichever term is used by any particular organization, the function of this process can be divided into three distinct activities: prospective review, concurrent review and retrospective review. The objective of these activities is to control cost, while also reviewing for appropriateness of care, medical necessity and quality of care. Historically, most utilization review programs have focused predominantly on cost, but increasingly the focus is shifting to appropriateness. Registered nurses, under the direction of a licensed physician, usually provide these activities using recognized scientific review criteria. In selected circumstances, all or some of the criteria may be locally developed and approved by the health care organization.

The major components, which form the structure of the utilization review process, are:

A. The Utilization Management Plan

B. Screening criteria:
   1) ISD-A Review System.
   2) Hospital Reason Acute Code List.
   3) Barrier Screens.

C. The review process:
   1) Admission Review.
   2) Continued Stay Review.
   3) Discharge Review.
   4) Focused Review
The definitions of the major components of utilization management are;

**Admission Review** is the process by which a case is reviewed within 24 hours of admission to ensure that the criteria for admission to the hospital have been met.

**Continued Stay Review** is the process by which a case is evaluated throughout a patient’s hospitalization to determine the medical necessity of the patient’s need for continued treatment at a hospital level of care.

**Discharge Review** is the process by which a case is evaluated against pre-established criteria to determine indication of patient stability prior to discharge.

**Focused Review** is the concentration of review activities on those diagnoses, problems, procedures and/or practitioners with identified or suspected utilization-related problems. This may include review of medical necessity of support services as well as delays in the provision of support services.

**ISD-A Review System** is the process of screening cases by using intensity of service, severity of illness, and discharge criteria.

In this part of the chapter, we would like to discuss some techniques in detail that are used in utilization management

**Prospective Review:**

Prospective review refers to an assessment of the services before it is delivered. It is most often seen in the form of a preadmission certification for a planned hospital admission. Using appropriate criteria, the reviewer assesses the requested service to assure that it is medically necessary, and delivered at the most clinically appropriate and cost effective level. Also at this time, some organizations will match the requested service to the benefits to which the patient is entitled. It is at this point of entry into the health care system that significant attention must be paid to the appropriateness of the level of care requested. Inpatient admissions are costly and often unnecessary, especially now that there are many other options available to deliver the same quality of services at significant savings. These options include, but are not limited to: outpatient surgery, home infusions services, home health nurs-
ing, and outpatient rehabilitation services. If the information provided to the
review nurse satisfies the criteria for admission, a certification or “precert”
number is issued to the hospital, along with an assigned length of stay.

For example, if a patient is scheduled to have an elective procedure, the at-
tending physician would place a call into the utilization review department.
At this point, a nurse would obtain information regarding the proposed proce-
dure and any clinical information relevant to the case. If the clinical informa-
tion provided satisfies the required criteria for that procedure, authorization
is granted. If information is lacking, the nurse may elect to place the request
in a “pend” or “hold” status, until the relevant information is obtained. The
nurse may also elect to refer the case to the organization’s medical director
for review. The medical director may approve or deny the request.

In the event that the admission was not planned, such as an emergency admis-
sion, the admission is then reviewed, retrospectively, for appropriateness and
is referred to as an admission certification. The process is the same as the
precertification, except that the admission has already taken place.

Concurrent Review:

Concurrent review refers to gathering information about the patient
and making an assessment of the continuation of services for an inpatient
stay that has already been certified by the health care organization. Licensed
medical professionals who understand disease processes, estimation of length
of stay and discharge planning, should perform this. The concurrent review
nurse receives information through fax or telephone from a designated person
within the hospital facility regarding the patient’s condition and the level of
services that are currently provided. Recognized criteria and organizational
guidelines are applied to the case and reviewed before approval of a con-
tinuation of stay is granted. Often, managed care organizations elect to have
concurrent review performed on-site at the facility by licensed nurses. This
gives the health care organization an advantage of actually reviewing the
patient’s entire chart and actively participating in discharge planning. This
consists of communication between the review nurse, the patient and fam-
ily, the hospital nurses, and with the attending physician to discuss the care
plan, expected outcomes and possible alternatives to continued hospitaliza-
tion. On-site review also makes it possible for the review nurse to identify
obstacles early in the case and consult with the health plan’s medical director. Although this is sometimes negatively perceived by the physician as interference by the health care organization in the clinical treatment of the patient, if it is approached sensitively by addressing both quality and medical necessity of the care provided, and not just the financial interests of the health plan, both the physician and the patient will be more receptive to alternatives to the inpatient stay and personalized the service that the plan provides to its members.

It is during the concurrent review process that the utilization review nurse identifies the need for the possible involvement of the case manager and refers the case in a timely manner. A case manager is most often a registered nurse who acts as a patient advocate or facilitator of care for complex and expensive medical cases. While many cases referred to the case manager are recognized at the time of admission, based on diagnostic red flags or trigger lists, others can be identified during the concurrent review process, particularly if an unusually extended length of stay is anticipated. This is not to say that all lengthy inpatient admissions are candidates for case management; however, this presents an excellent opportunity for the case manager, in consultation with the health organization’s medical director, to explore more creative avenues to have the patient discharged to an alternative care setting, or even home. Health organizations often give case managers the authority to trade out designated benefits to provide the most cost effective and appropriate level of care for the patient. Case management functions will be further addressed later in this chapter.

**Retrospective Review:**

The third level of utilization review is retrospective review. This level of review takes place after the service has been rendered to the patient. The medical records of the case are requested and reviewed for medical necessity and appropriateness. Treatment patterns are also monitored and trended for procedures that are expensive or tend to be over-utilized. This information can be used to provide feedback to the physician, and also when initiating recredentialing activities for the involved providers.
Most managed care plans also provide second opinion review, as part of their utilization management plan. It can be mandatory for selected procedures, but most often it is used selectively by the health care organization. A second opinion review can be required for both surgical and complex medical cases. An independent specialist who is usually board-certified by their college or is known to have demonstrated expertise in the area that is involved reviews the case. In surgical cases, the independent physician must have specialized knowledge of the procedure in question. This is most often used when the medical director for the health care organization is in disagreement about the plan of treatment with the attending physician. The goal of a second opinion is to reduce unnecessary or inappropriate treatment for the patient. This not only benefits the patient from a clinical standpoint, but helps control expenses.

**Case Management:**

Case management is an integral part of the utilization management program used by managed care plans, especially the HMOs. Case management began to evolve in the 1970s from a coordination of care effort from discharge planners in the hospital setting. In 1990, an international professional society of case managers was founded, the Case Management Society of America (CMSA). CMSA defines case management as “a collaborative process which assesses, plans, implements, coordinates, monitors and evaluates options and services to meet an individual’s health needs through communication and available resources to promote quality, cost-effective outcomes.”

Case management cases are often complex, catastrophic cases, identified during the preadmission review or concurrent review process, and referred to the case manager to begin the process of coordination of medical and social needs of the patient. Each health care organization develops their own criteria for what is deemed to be catastrophic. This can be measured by length of stay or billed charges, or both. For example, criteria for a catastrophic case could be defined as any hospital admission that results in a length of stay greater than ten days, or billed charges of $30,000 or more. Diagnoses that are almost always considered catastrophic include HIV, hemophilia, multi-system trauma, and organ transplants. The medical profes-
sionals, social workers, community agencies, and the family are all a part of this coordination effort. The case management process has the potential to significantly reduce the average length of stay (ALOS) while still providing the patient with necessary services by a quality provider and ensuring the continuity of medically necessary care.

Decisions made regarding the plan of treatment include the physician, the patient and his family, and the hospital utilization/discharge nurse, the case manager and the health care organization’s medical director. This requires frequent communication between the involved parties if the health plan is to be successful in managing cost-effective utilization of limited resources.

Although the past trend to identify case management cases was similar to episodic crisis management, today’s trend is to identify individuals at-risk for complex medical conditions. This identification process can be accomplished with health risk assessments, which are health surveys developed by the health plan or professional survey vendors, or with retrospective utilization reports which identify their members with certain chronic diseases. The case manager is then involved, with the assistance of disease management programs, to help reduce the occurrence of an acute exacerbation that may result in a hospitalization.

**Unit-based Case Management model**

In this part, we would like to explain the unit-based management model with a case study. Our case is a particular local healthcare center in Oklahoma City, OK.

As previously mentioned above, managed care aims to provide the most efficient care possible. Efficiency in managed care requires limited hospital stays and intensified scrutiny over decisions concerning patient care and admission. Therefore it is not surprising that high payor denial rates are often directly related to long(er) ALOS. Clearly from a financial perspective limiting the number of patient stays is of chief concern to cost containment strategies. Hospitals also find long patient stays to be particularly disruptive to their missions and objectives as well. The longer a patient is housed within a hospital,
the longer the liability is extended to the provider organization. Therefore, long ALOS are likely a risk management issue as studies have not shown hospitals to be safe and healthy for the sick. To the contrary, studies have shown hospitals to be harbors of infection and risk of medical errors. This statement is supported by the number of medical errors experienced within US hospitals annually. It is therefore in the patient’s best interest for providers to deliver care and process discharge within the shortest time frame allowed. Aside from the risk of insurance denials for excessive hospital stays, hospitals incur daily costs in patient upkeep. Both managed care organizations and hospitals share similar desires to limit the length of inpatient stays, of course without compromising the quality of care given. Hospitals intending to lower ALOS without compromising quality of care must examine the control measures they have in place and determine the method of reform needed to accomplish this effort. Case management is the commonly used system for the determination of patient stays within US hospitals. Typically case management involves the cooperation of RNs, social workers, and physicians in determining proper discharge planning and necessary initiatives in the process of inpatient care across the continuum. Case management exists in a variety of models exemplified in different hospital settings. Of the multitude of categorizations described for case management, the models are best divided into three main groups: unit based, product lined, and physician-aligned. Most simply it is daily oversight, evaluation and management of patients in the hospital by individuals aligned with the provider and payor.

This need has been most recently translated in cost saving efforts and lowered patient denial rates, and more specifically in lowering the average length of stay. Average length of stay, ("ALOS") is an indicator described as the number of patient days divided by the number of discharges per month. This indicator is influenced greatly by the disease related groups, ("DRGs") which represents those patients with more acute needs who require more inpatient care (3,8). Consequently, it is difficult to determine an average as the ALOS is often calculated per department, patient group, or DRGs. It is also a challenge to compare hospitals based on this indicator as independent hospital characteristics such as size and capability can influence this statistic. (1) However, it has been shown that the lowering of the ALOS, for whatever descriptive measure of interest, can translate directly in terms of cost savings for that particular healthcare organization.
This study included the shadowing of particular administrators within the quality resources management office as well as case managers and physicians within the medical-surgical unit. This included a presentation of a current problem the healthcare center was experiencing in the area of utilization review/quality management. A solution was sought and a mechanism for its implementation. Literature review was conducted and comparative analysis led to the proposed solution presented herein. The objectives of unit based case management encompassed the following:

- To become familiar with quality measures in a healthcare setting;
- To understand the processes included in utilization review, quality resource management, and more specifically in case management as a tool for cost containment and quality assurance;
- To gain a better understanding of the roles and responsibilities of a healthcare administrator as it relates to case management;
- To gain awareness of the challenges facing contemporary healthcare administrators and the basis for policy development in this area.

**Limitations**

Confidentiality within the healthcare market is of great concern. During this experience data analysis was almost totally prevented by control measures in place to protect the proprietary information of the hospital. Also, limitations were placed on the ability to identify and associate the healthcare center among its competitors. Given the time period available and information available the following paper aims to describe ALOS as a cost containment issue and the options available to the subject hospital to solve this problem, with quality control and performance improvement in mind.

Unit based case management divides case management responsibilities by hospital unit such as the ICU, telemetry unit, and medical-surgical unit. The administration of this model is typically through the case management department, which is often housed within the quality resources management office. This administrative office consolidates the roles of utilization review, discharge planning, and social services within one department. Due to the framework of the unit based model, case management is administered principally at the nursing level. A RN and often times a social worker are responsible for utilization and review of patient care per department to ensure timely
discharge planning. Records are kept concerning the acute criteria associated with a patient’s admission, procedures of care employed, and criteria associated with discharge. The Effectiveness of this model is in its making a quality initial assessment and discharge plan. The fundamental shortcoming of this model is that often times a patients’ condition worsens and care needs intensify. Documentation on a per case basis becomes increasingly important as patients get moved to different hospital units, depending on their care needs. When a patient is moved from on unit to another, a new set of case managers becomes responsible for utilization review and discharge planning. Considerable rework and duplication can be seen within this model as a patient and physician transcends across the systems’ units.

Product lined case management is often described as the organ system model. In product lined case management, groups providers and case managers that are working in relation to body’s organ systems. Renal care would therefore group nephrologists, urologists, and endocrinologists with one particular case management team. The organ system model came about when hospitals began to reorganize their structures to try and find a more efficient means to deliver care. A number of hospitals in the US demonstrate units divided according to organ system and thus necessitate need for the development of the product lined case management model. The organ system model compensates for patient movement across the continuum assuming that the patient’s care needs do not extend beyond a particular organ system Clearly, multi-system patients compromise the efficiency of this model as overlapping exists concerning the discharge plans developed and scrutinized by the case management team.

Physician-aligned case management is the newest effort to approach inpatient stays and as its name suggests, it aligns individual physicians with a case manager or team. In this model physicians play the most important role in case management. The case management process is adapted to suit each individual physician’s style of practice concerning inpatient discharge plan and care procedures. The physician’s relationship with the case manager is very important as they assume the most accountability for whatever decisions are made during a patient’s stay. Hospitals have demonstrated success in the employment of this model in terms of lowering ALOS and payor denials. However, intensified scrutiny over medical decision making from the physician can put additional strain on the hospital-physician relationship. Within this
model case management teams can better identify whether exceptionally long hospital stays are the result of unresponsive treatment practices or physicians who are particularly negligent in following up on their patient’s discharge plans. The physician aligned model serves a parallel purpose in creating a motivation for physicians to create and implement successful discharge plans as to streamline payment for performance initiatives.

**Which is best?**

Much debate exists within the realm of quality management for which particular case management model is best in improving the efficiency of care delivered within a hospital. With utilization management in mind, a healthcare organization finds most success in employing a case management model that can be implemented without hiring more staff, while still allowing for the most quality control. Quality management departments across the country deal with the question of which model is best employed within their hospital to satisfy their missions’ of delivering quality care in the most efficient manner possible. There are many factors to consider when making the assertion of which particular model to introduce. Size and location of the hospital are important factors to include, as well as patient demographic and health care capabilities. A large urban hospital that serves a particularly diverse patient population across many DRGs may not have the resources or staff to accommodate a physician-aligned model which individualizes the case management more than the other two models. Conversely a small suburban hospital with limited care capabilities may find it easier to implement case management on a more confined level rather than dividing the responsibilities among departments or across departments like in the product lined model. Clearly the decision must consider all factors when determining the most efficient way to examine and manage inpatient stays.

**Comparative Case Studies**

The article entitled “Using a Physician-aligned Case Management Model to Influence Hospital Length of Stay and Payer Denials,” by Susan Jaques, describes a particular hospital in Southern California serving an urban population which demonstrated cost savings in the implementation of a new physician aligned case management model. Much like the Hospital that is the subject of this study, the Hospital is approximately the same size, serving a similar population demographic. The article centers on San Antonio Hos-
pital in San Bernardino California, which is a 310 bed full service hospital experiencing inflated inpatient stays and costs resulting from payer denials and high ALOS. Since Medicare or acute care patients represented the bulk of inpatient stays at SAH, pressure from managed care intensified the search for a solution to the ALOS problem within the hospital. The quality resource management department sought analysis from a consulting firm regarding the effectiveness of their unit based case management model finding that a new focus was needed. Findings suggested that the focus of case management should be to follow the patient from admission to discharge, thus reducing the amount of duplication and rework existing within the current system, and providing less reliance on making a quality and comprehensive initial assessment and discharge plan. For this focus to be realized, the implementation of a physician aligned model was recommended and a post-implementation study was initiated. A fundamental aspect of the new physician-centered approach was to align case managers, typically RNs, of particular clinical backgrounds with physicians sharing such specialties. The relationship between case managers and physicians was stressed and case management teams were influenced to adapt their communication strategies, availabilities, and post-acute preferences concerning patient care to align with the physicians with whom they are paired. The study found that although ALOS remained virtually the same through the study period, payor denial rates decreased by approximately a third and although direct dollar amounts in cost savings were not extrapolated it was assumed that healthcare delivery was overall more efficient and cost saving was apparent.

An article entitled “Hospital cuts overall length of stay by 1.3 days,” by Pat Eason RN, evaluates a large multispecialty teaching hospital in the New York city metropolitan area which found success in reforming the current unit based system of case management by employing a more multi-disciplinary approach. The article describes the Hackensack University Medical Center (HUMC), which is a 683 bed university affiliated hospital running on 92.5% occupancy. HUMC had experienced high payor denial rates and ALOS numbers across DRGs. The administrators within the hospital formed an in-house consulting team to develop strategies to integrate performance improvement with LOS and resource management procedures and programs. The consulting team had as its goal the objective to provide the most cost effective quality of care with a focus on influencing better coordination of patient care across
disciplines and services. Without undertaking the daunting task of implanting a new case management model within this large hospital, the consulting team instead introduced new policies aimed at reorganizing and reforming the current unit based model. To influence multidisciplinary care coordination HUMC created a multidisciplinary team including but not limited to physicians, case managers, social work professionals, nurse managers, advanced practice nurses, staff nurses, pharmacists, nutritionists, physical therapists and others. HUMC began requiring daily physician-led multidisciplinary rounds across all departments to account for case management extending across the continuum. In addition, new policies of individual case manager visits to patients within 24 hours of admission; personal visits by case management services team members to patients who have been discharged to other facilities; and direct conversations with insurance companies (instead of faxing information or leaving voicemail messages) were implemented. The focus behind such measures was not only to facilitate a better line of communication between consumers, providers, and payors, but also to foster better cooperation between case managers and care givers without compromising their individual roles. The direct link between the case manager and the patient, as well as between the case manager and the physician, achieved both goals of improving patient satisfaction and physician satisfaction within the organization. By establishing a more direct dialogue with insurance companies the hospital saw significant reduction in their payor denials and cost savings were also attributed to the policy changes. The work of the administrators in reforming their unit based case management model at HUMC demonstrated that the essential utilization of resources and increased efficiency translated into the lowering of ALOS by 1.3 days, for certain DRGs, and overall lowered costs. Although, it is likely that such measures employed by HUMC increased the administrative burden on inpatient stays on the organization, the organizations’ efforts to deliver quality care at the lowest costs were realized and have demonstrated justifiable results.

A similar situation exists within a particular local community hospital in the Midwest. This hospital is a 313-bed full service facility with over 600 medical staff members serving a large metropolitan city. The subject hospital is currently dealing with rising medical costs stemming in part from a higher than “normal” ALOS and payer denials. The quality resources management department of the hospital is examining the unit based case management sys-
tem in place to explore various methods, which could offer solutions of lowering costs while maintaining existing quality measures. Also, the hospital is in the process of expanding their payment for performance (P4P) initiative organization wide. The hospital feels that alignment with case management practices would facilitate this project. Prior attempts to reconcile the ALOS problem resulted in the creation of the “ALOS team,” a multidisciplinary board meeting bi-weekly to discuss particularly problematic cases within the organization to determine how to facilitate discharges and better develop future discharge plans for new inpatients. The ALOS team effectively documents ALOS records and charts trends in relation to previous attempts to solve the ALOS problem. The problem however of long inpatient visits persists and the rising costs coupled with payor denials have led the hospital to more actively seek a timely and effective solution.

As previously discussed, ALOS data is difficult to compare across healthcare centers due to demographics and varying extenuating circumstances. Therefore, the most effective utilization of ALOS data is to trend the LOS, over time, by a particular department, DRG, physician or specialty, depending on the particular case management model. The subject hospital’s ALOS team has identified the current trend of escalating ALOS to be problematic. They have seen marginal success which they have attributed to past administrative efforts to control long inpatient stays and cost containment. Reform within the organization’s case management system is a necessary undertaking if the increasing ALOS trend is to be disrupted positively. With costs savings in mind, current data analyzed by the ALOS team has suggested that the subject hospital look towards implementation of a new case management model as a solution to the ALOS problem.

In reviewing comparative literature, in particular the examples described above, the subject hospital would be wise to incorporate some of the successful strategies that similar healthcare organizations have successfully employed to deal with their own problems in addressing ALOS and rising costs.

A plan for dealing with ALOS can be developed and implemented at the subject Hospital through the employment of the following measures:

Keeping P4P objectives in mind, the subject hospital should reorganize its’ case management to fit the physician aligned model. Intensified scrutiny over
medical decisions and discharge plans would motivate more cooperation between case managers and care givers. Additionally, the alignment of administrative goals would be more appropriate and would be in accordance with the P4P measures currently being expanded. The subject hospital should form a multidisciplinary team to account for cases transitioning across the various departments and units within the hospital system and limit the duplicative efforts of individual unit’s case management. The subject hospital should revise its’ policies to ensure patients are visited by case managers within the first 24 hours following admission and discharge, requiring individual consultation of patients by case managers to better communicate care efforts. Also, the organization should implement a policy requiring direct contact with insurance companies to improve communication channels in hopes of limiting the number payor denials thus increasing payments. These initiatives would likely translate into cost savings across the board, although a reduction in ALOS would remain to be seen.

As a conclusion of this case study average length of stay is a vital measure of efficiency within a particular healthcare organization. Although using this indicator alone would be difficult to gauge the effectiveness of one hospital over another. Reducing the number of ALOS remains a chief concern of quality departments within healthcare organizations across the United States. A number of healthcare organizations have found that reform within the case management system can lead to effective cost savings measures. It is apparent that reforms must be individualized according to the particular needs of the respective hospitals. Depending on a variety of factors, some healthcare organizations find success in certain case management initiatives, while others do not. Furthermore, some examples mentioned above resulted in cost savings, while keeping ALOS relatively constant. With lowering ALOS as the motivation for change, the question remains as to what the ultimate goal is for the healthcare organization. Pat Eason, in describing the mission of HUMC, explains that “We are dedicated to providing health care services of the highest quality, providing the patient with the right care at the right time and the right setting.”. Even when inserting the goal of providing the most cost effective means of care while maintaining such values, ALOS may not be the chief concern for a provider organization. If certain policy initiatives can be successfully implemented with patient and physician satisfaction improvements apparent, as long as cost savings are demonstrated, ALOS can be
shown to be a negligible indicator. If the subject hospital is able to effectively implement the suggested measures, one can assume that the accomplishments of cost saving, while maintaining quality standards, regardless of what any effect on ALOS, would be the ultimate objective. Comparative analysis of a medical center with a similar patient demographic and size, although in a different region, suggests that a physician-centered case management model would be best suited for the subject hospital. This hospital would also find success in implementing some of the successful strategies exemplified by the HUMC in incorporating multidisciplinary cooperation and improved communication with payors as well as consumers.

**Measurements:**

It is common for health care organizations to measure and trend the utilization of health care services. This allows the organization to apply the measurement to the budget and more accurately accrue for expenses. Most commonly, this is measured in the number of bed days per 1,000 members per year and the number of admissions per 1,000 members per year. Each organization must decide for itself what they need to measure and define that measurement. A bed day might be counted only for a hospital admission resulting in over 24 hours. However, another organization may include skilled nursing facility (SNF) admissions and rehabilitation facility admissions as bed days. Most organizations will not count outpatient surgery as a bed day, but will report that under a separate heading. They will also track average length of stay by facility. However, when looking at this, one must remember that different facilities may handle patients of very different acuity levels.

A typical method of reporting inpatient utilization is to identify admissions by bed-type: Medical, Surgical, Maternity, Skilled Nursing/Rehabilitation, and Psychiatric. Also, it is helpful to identify the catastrophic cases within these groups. All of this information can be tracked, on a daily basis, by the utilization review nurses.
Discharge planning;  

**Discharge Planning** - is the process of activities that involve the client and a team of individuals from various disciplines working together to facilitate the transition of that client from one environment to another. It includes a systematic process of assessing the assets and limitations of the client during hospitalization, planning for continuity in his/her health care upon discharge from the hospital, and coordinating needed individual, family, hospital and community resources to implement the discharge plan.

The purposes of a discharge planning are;

- To define standards for collaborative planning which prepares the patient and his/her family for discharge from hospital and care at home.
- To identify patients for whom discharge planning is critical.
- To reduce unplanned re-admissions due to incomplete course of treatment or recourse gaps and prevent unnecessary admissions.
- To plan for better quality of life and health outcomes.
- To promote integration and continuity of care.

---

**Example:**

**Membership** = 38,073

<table>
<thead>
<tr>
<th>Admission Type</th>
<th>Number of Admissions (A)</th>
<th>Number of Days (B)</th>
<th>Length of Stay (B/A)</th>
<th>Admission Rate (A/C x 12000)</th>
<th>Days per 1000 (B/C x 12000)</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>96 4</td>
<td>14 4</td>
<td>.3 3</td>
<td>0.3</td>
<td>130.5</td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td>9</td>
<td>113</td>
<td>2.9</td>
<td>12.3 3</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td>Maternity</td>
<td>45 1</td>
<td>01 2</td>
<td>.2 1</td>
<td>4.2</td>
<td>31.8</td>
<td></td>
</tr>
<tr>
<td>subtotal</td>
<td>80 6</td>
<td>28 3</td>
<td>.5 5</td>
<td>6.7</td>
<td>197.9</td>
<td></td>
</tr>
<tr>
<td>SNF/Rehab</td>
<td>1</td>
<td>11 1</td>
<td>1.0</td>
<td>0.3</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>181</td>
<td>639</td>
<td>3.5</td>
<td>57.0 2</td>
<td>01.4</td>
<td></td>
</tr>
</tbody>
</table>
Discharge planning should start prior to admission (for planned admissions), or at the time of admission (for unplanned admissions). The patient and his/her family shall be included in identifying realistic goals and all efforts shall be directed towards helping the patient to achieve these goals. The plan for discharge shall be reassessed at appropriate intervals and shall be documented and updated in the client’s medical record. Discharge planning is critical when patient or his/her significant others are assessed to have knowledge deficit regarding the condition, prognosis, and treatment needs. Conditions may include:

- Patients having deviations in growth pattern.
- Child with special needs.
- Patients who have undergone surgical interventions.
- Patients undergoing organ transplantation.
- Psychiatric conditions.

Discharge planning shall be a multi-disciplinary and inter-disciplinary team function. The plan shall be a part of the patient’s medical record and shall be updated as changes, due to the patient’s condition, as indicated. The process includes mechanics to foster continuity of medical and/or dental aftercare to meet patient’s needs and to initiate discharge planning on a timely basis. The discharge of clients should be based on the client needs for continuity of care wherein the family needs to be involved in the discharge planning process as appropriate to the client needs. The client and the family are provided with clear follow up instructions at discharge including when to obtain urgent care.

The responsibilities of the health personnel in discharge planning process are summarized below;

**Nursing Unit staff:**

- Determine the discharge needs of the client as part of the admission assessment using the Patient Discharge Planning Assessment Tool.
- Determine if the client is high risk for discharge, and then initiate a
Social Worker

- Consultation to evaluate patient’s home situation and the available support services.
- Plan for client and family education and ensure that they are able to assume responsibility for self-care prior to discharge.
- Obtain or coordinate necessary supplies/equipment that the client may need at home to do self-care.
- Plans for patient and family education in preparation for discharge.

Attending Physician:

- Conducts ward rounds to review client records.
- Checks on discharge plans and appropriate attention to actual and potential discharge problems.
- Discuss with client sponsor or family the discharge plan.
- Write order for either discharge home or transfer to other facilities.
- A comprehensive discharge summary should be made that include the following:
  - Reason for admission
  - Significant findings
  - Diagnosis
  - Procedure performed
  - Medications and other treatments
  - Client condition on discharge
  - Discharge medication and follow up instructions

Social Worker:

- Interview the client/family to evaluate the home situation in preparation for discharge and communicate with rehabilitation services, as necessary, for information regarding the patient’s functional status and equipment recommendations.
- Counsel the family and prepare them to accept the patient upon returning home.
- Assist in making appropriate education of discharge instruction for the family with the help of the healthcare team.
- Complete the social work service intervention in the interdisciplinary form.

Dietitian:
- Make nutritional assessment using the nutritional scoring system and report on client’s nutritional status, form of feeding, method of feeding, nutritional intake, nutritional requirements and any problem with feeding.
- Instruct and educate the client and/or family in therapeutic dietary needs ordered by the clinician.
- Assists the client in planning for his/her diet so that cultural and religious customs can be maintained.
- Interprets how and when the client can substitute cultural foods in therapeutic diets.
- Documents in the client’s file and diet instructions given to the client on the order of the attending clinician.
- Anticipate and recommend what diet and tests will be needed after discharge/transfer as part of the follow up nutrition reassessment plan.

Nursing Administration:

Ensures that discharge planning is a part of everyday care given by nursing staff.

Physical Therapist:
- Evaluate client’s needs for rehabilitation related special medical item such as wheelchairs, splints, pressure garments or adaptive equipment
in order to maximize client function.

- Teach client and their families the exercise / activities of daily living and skills needed to function effectively and independently within the limitations of their disability.

REFERENCES


2. Eason, Pat R.N., “Hospital Cuts Overall Length of Stay by 1.3 Days.” Hospital Case Management 2005, 13(8):119-121


5. Lawrence, Thomas P. MD MBA et. al. “Physician buy-in helps PI team reduce LOS: data credibility, physician champion key elements” Healthcare Benchmarks and Quality Improvement 2004, 3(1):54-56


CHAPTER TEN
Certification, licensure and accreditation

A. F. Al-Assaf, MD

In today’s health care arena, a number of issues are being raised that have received more attention either from the health care consumers or the media. The 1990s can easily be dubbed the period of “performance measurement”. Whether as a provider, a consumer or a purchaser, each was looking for ways to satisfy the other through measuring and reporting on care outcomes. Accountability was at stake in that period. Several third-party organizations attempted to produce certain measure to report on these care outcomes. In the United States, a number of “indicators” were developed and measured and “report cards” were assembled on the health care organization of the nation. All of these activities were done in the effort to measure performance. In the international arena, WHO organized and facilitated a number of activities related to quality assessment, performance improvement and outcome measurement. A large number of countries and institutions participated in these activities and initiatives. And at the end, all agreed there had to be an organized mechanism to account for quality, continuous measurement and improved performance in health care organizations. In order to do this a mechanism for certification, licensure or accreditation should be put in place.

It is not the scope of this chapter however to discuss all of these three mechanisms (licensure, certification and accreditation) in details. In this chapter only accreditation will be explored in more details. A definition of certification and licensure will be presented, and a modest comparison between the three mechanisms will be attempted. A detailed exploration of accreditation will take the majority of discussion of this chapter. The process and the methodology of accreditation will be discussed and a system for its implementation is presented.

Certification and licensure

It is very easy for a layperson to get confused with the terms and mechanisms
of certification, licensure and accreditation. In general, certification, licensure
and accreditation are all methods of evaluation and are also methods of as-
sessing and rewarding organizations (and individuals) for quality. Accredi-
tation is the only method however that requires a health care organization to
follow a rigorous set of performance standards and be subject to a compre-
hensive process of self-assessment in addition to external evaluation. Both
licensure and certification follow the same principle of assessment whereby
an organization must demonstrate to the granting agency its capability and
proof that it has met the standards prescribed by that granting agency. The
difference between the three is therefore based on the rigour of the assess-
ment process and whether the evaluation is comprehensive to all aspects of
the organization. It is believed that in the case of accreditation, the process
and the standards are more rigorous and more comprehensive in nature.

Therefore, certification can be defined as a process of assessing the degree
by which a facility, product, unit or professional attains minimum standards.
It is specific to the nature of the assessment, and the entity is “certified” as a
special agency for the purpose of providing a specific service or activity. For
example, an organization may be certified as a provider of care to a special
population or as a training facility. Similarly, an individual may be able to pass
a certain examination and become certified. Certification for an individual
could be certification to be an auditor or an accountant or a trainer. Therefore
certification is established for a specific purpose and is organized in order for
the certified entity to engage in that specific activity on a prospective basis.
Certification is an “add on” to the roles and responsibilities of an entity. For
example, an organization that is certified as a sports medicine centre would
still be able to provide services in other areas if it chose to do so and as long
as the other services did not require additional certification or licensure. Also,
certification may not give the entity the permission to practice a certain activ-
ity or provide a certain service, especially if that activity or service requires
a licence. Therefore in most cases, certification is not governed by law and
is usually voluntary. It is used primarily as an added credential to an entity’s
qualifications and portfolio. Of course, certification has a set of minimum
guidelines that must be met by the entity to be certified. It is also governed by
a granting agency similar to accreditation and lasts a set time before renewal
is necessary. Renewal however is usually automatic as long as the organiza-
tion is paying its dues and is in good standing. Certification would seldom be revoked or withdrawn, and an entity would in most instances have to provide documentation that it still met the standards of the certifying agency. Unlike accreditation, a recertification on-site survey may not be necessary.

Licensure is somewhat more like certification than accreditation. Again it is targeted at all entities, individuals, organizations or groups. Licensure can therefore be similarly defined as the process of assessing the extent that a facility, organization, or professional has attained minimum requirements. Again, licensure is a prospective process. The licensed entity is given such a privilege in order to be able to engage in a certain activity. Unlike certification, however, without a license, an entity is prohibited from practising the activity for which a licence is needed. Failure to license renders an entity in violation of the law. Therefore licensure is usually a government-sponsored activity that is put in place to control the practice of a profession or an act that has the potential of risk to the recipient or the beneficiary. For example, if an organization is licensed as a mental health centre then it may function only as a mental health centre unless it has another licence that specifies otherwise. Licensure is also limited by time and is usually renewable annually and may only require the payment of dues and maintenance of good standing in the community. Licensure, however, is closely monitored for potential violations. It can be revoked or suspended if a violation is committed by an entity and can only be reinstated by the same governing agency (which is usually composed of peers). Although licensure can be voluntary, without it an entity cannot perform the specific activity for which licensure is mandatory. An obvious example would be a physician without a valid licence, who may not see patients. Therefore technically speaking, qualified physicians are not obliged to get a license unless they intend to practice their profession.

What is accreditation?

Accreditation is applied primarily to organizations rather than individuals, departments or units. Accreditation is a rigorous and comprehensive evaluation process through which an external accrediting body assesses the quality of the key systems and processes that make up a health care organization. Accreditation also includes an assessment of the care and service health care organizations are delivering in important areas such as preventive services
and client satisfaction. Accreditation was developed in response to the need for standardized, objective information about the quality of health care organizations. Almost all accreditation programs are voluntary. Organizations seek accreditation for different reasons but most do so in an effort to increase market share and to win customer satisfaction and professional reputation. In all cases accreditation is voluntary.

The International Society of Quality in Health Care (1998) defines accreditation as:

[A] self-assessment and external peer review process used by health care organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health care system. Quality standards and the external peer review process are directed by nationally recognized autonomous, independent accrediting agencies with a commitment to improve the quality of health care for the public.

The Canadian Council on Health Services Accreditation (CCHSA) describes accreditation as one of the few and most effective measures that health service organizations can use to accurately assess their level of performance. It is a peer review and a self-assessment process that focuses on ways to continuously improve the health care system.

Each health service organization’s performance is assessed against a set of national standards set by the accrediting organization in collaboration with key players in the health care system and related stakeholders. The assessment is designed to address processes; outcomes and structures, with the focus on continuous improvement within the health service delivery system.

The value of accreditation is in the internal self-assessment that an organization undergoes in preparation for the survey visit and in the consultative peer review process which is part of the on-site survey visit. The principle of self-assessment is the fundamental basis of accreditation. It serves as the mechanism by which an organization can assess its own performance, on an ongoing basis, against a set of nationally developed standards.
The on-site survey represents an opportunity for the health service organization to receive advice and have its performance validated by external reviewers. The survey is planned in partnership with the health care organization and recognizes areas of excellence as well as areas for improvement. (CCHSA, 1998)

There are a number of accrediting organizations that have been established on the international scene. Some of these organizations are sponsored by the government of a specific country whiles others are primarily private not-for-profit organizations that have the support of national governments and key health care players in that system. In the US, there are four major accrediting agencies; each is independent and each has a specific emphasis. For example, hospitals in the US are accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) while ambulatory care organizations are accredited by either the Accrediting Association for Ambulatory Health Care (AAAHC), or by Utilization Review Accrediting Commission (URAC) or yet by the JCAHO. Managed care organizations are accredited by such organizations as the National Committee on Quality Assurance (NCQA) or by any of the other three agencies, JCAHO, AAAHC or URAC.

On the international scene, accreditation is handled primarily by a government agency or a quasi-government agency such as the Canadian Council on Health Services Accreditation (CCHSA) or its Australian, Japanese, Indonesian, Austrian or Argentine counterparts. In all cases however, these accrediting organizations are governed by a board of both experts and independent agencies that represent other sectors in the health care system such as the private sector and academia.

According to AAAHC (1999), the certificate of accreditation is the most visible result of the assessment process. The ultimate value of accreditation, however, lies in the ongoing self-analysis, peer review and consultation the health care organization gains as it continues its participation in the programme. Organizations that seek accreditation first perform an internal (self) evaluation of all of their services and activities. Standards obtained from the
desired accrediting organization are used to perform this internal assessment. Depending on the results of this assessment the organization may feel ready to invite the accrediting organization for the on-site external evaluation. During the survey, a team of senior health care professionals experienced in both clinical and administrative aspects, representing the accrediting organization, evaluates each and every aspect of the health care organization’s care and service activities and units. The team then scores each standard according to the result of its on-site evaluation. When they have completed their survey, the team of surveyors makes an accreditation recommendation which is then reviewed by the accrediting organization’s board of directors, which makes the final decision. Accreditation may be awarded for six months, one year, two years or three years depending on the level of compliance with the standards.

As per URAC (1999), accredited organizations must continue to remain in compliance with the applicable standards throughout the accreditation cycle. Accreditation status may be rescinded if an accredited company is unable to comply with the accrediting organization’s standards. There are periodic and unannounced on-site visits scheduled by the accrediting organization throughout the accreditation cycle. The purpose of these visits is to make sure that the accredited organization is continuing its compliance with the accreditation standards.

Of course each accrediting organization has a different system for accreditation and a different set of accreditation decisions. JCAHO for example, has seven levels of accreditation, namely:

- Accredited with commendation or with excellence
- Accredited with recommendations for improvement
- Accredited without recommendations for improvement (accredited)
- Provisional accreditation
- Conditional accreditation
- Preliminary non-accreditation
- Adverse decision in appeal.
NCQA (1999) on the other hand has the following five levels for accreditation of managed care organizations:

- Excellent
- Remarkable
- Accredited
- Provisional
- Denied.

Historical perspectives and trends on accreditation

Accreditation was originated in the US as a mechanism to ensure compliance to a set of standards in order for professionals to expect a certain level of quality in a health care organization. During the early 1900s a new awareness of quality in medical education was brought to the US government’s attention through a report published by a notable physician, Abraham Flexner. According to this report, US medical schools at that time were functioning without any real guidelines or any specific standards that they had to meet. Therefore, the standards of medical education were extremely variable from the very good to those that were barely considered adequate. It was at this same era that a group of US surgeons represented by the American College of Surgeons put together a list of minimum standards for hospital operating rooms. The purpose was to have these hospital operating rooms comply with these standards in order to be “certified” by this group as an acceptable operating room. This programme was known as the hospital standardization programme. The programme was established as a reactive measure against the wide variations that existed then between the different hospital operating rooms. Its purpose was, of course, to minimize this variation and to ensure a certain level of quality in order for these rooms to host surgical operations. This programme is considered the precursor of the accreditation system that US hospitals currently have.

Following this initiative by the American College of Surgeons and still leading the efforts of standardization, the same organization got together with a group of other professional organizations to form the then called Joint Com-
mission on Accreditation of Hospitals (JCAH) in 1951. JCAH published its first standards for hospital accreditation in 1952 and rapidly became the hallmark for quality in US (and Canadian) hospitals. Of course this list of standards has grown considerably over the years and now the accreditation manual for hospitals boasts hundreds of standards and over 300 pages.

Accreditation standards not only grew in quantity but also in focus, setting and quality. When first developed, these standards were primarily structure standards—standards related to either the physical structure of a hospital or to its human resources. More process-oriented standards were introduced to manual and later outcome-related standards were also added. The current list includes more process standards than structure and has over the years included such areas as patients’ rights and responsibilities, leadership and ethics, therefore moving away from distinct “departments” to functions. The focus of accreditation has also changed over the years. Hospitals were the first to be accredited but now, ambulatory care facilities, nursing homes, rehabilitation facilities, mental health facilities and home health organizations as well as managed care organizations are also surveyed for accreditation. Another change in accreditation is that not only the Joint Commission is responsible for all accreditation activities but other agencies started forming for the same purpose and not only in the USA but also in other countries as well.

In late 1987, the Joint Commission changed its name to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). They explained that the change of name was a reflection of their current involvement since their services has expanded considerably to include other health care organizations. Also, and because of pressure indirectly exerted by the US government and consumer demands, accreditation criteria started to emphasize not only compliance with a certain set of standards but also on mechanisms for continuous improvement of performance. So, a health care organization may have met the structure and process accreditation standards but it must also demonstrate a proven path and experience in the continuous pursuit of improvement. Moreover, certain accrediting organizations such as the National Committee on Quality Assurance (NCQA), the premier accrediting organization for managed care plans in the US and most probably the world, are push-
ing their constituents to “close the loop” on improvements. These organizations, in order to receive accreditation, must demonstrate their capabilities and experience in improving certain patient outcomes and that they are able to maintain and continuously improve such outcome through frequent monitoring and re-measurement. Therefore, accreditation as we see it now is not only a quality assurance activity but also a quality improvement effort.

More and more organizations and countries are becoming interested in accreditation. The International Society of Quality in Health Care has organized a group of international representatives, and this group has met at least annually since 1996 in order to design a system for international accreditation. This group has also received the attention of major health care organizations around the world including accrediting organizations from the US, Canada, UK and Australia. Similarly, WHO began its efforts to increase awareness of different countries in the six WHO regions on accreditation. In 1998 WHO’s South-East Asia Region held an intercountry meeting on accreditation in Indonesia with representatives from the countries of that Region. The East Mediterranean Region organized a similar activity in 1999 in Limasol, Cyprus. Again, almost all of the countries of that region sent their representatives to that meeting. The outcome of the meeting included a number of recommendations for member countries to organize specific activities towards introducing accreditation in these countries. The WHO Regional Office for the Eastern Mediterranean is working with those countries that showed interest in accreditation to design a system and a mechanism for implementing such a programme in their health care systems.

Why accreditation?

For more than four decades, accreditation has been the highest form of public recognition a health care organization could receive for the quality of care it provides. Accreditation offers quantitative as well as intangible benefits to a health care organization besides public recognition. Accreditation can actually enhance the organization’s strategic management decision-making process (AAAHC, 1999).

The purpose of accreditation can be summarized into the following categories:
- Demand of the customer
- A forum for measuring performance
- Standardization and variance control
- Benchmarking
- Report cards
- Quality improvement
- Positive competition
- Reward and recognition
- Efficiency.

Effectiveness

Let us discuss each of the above reasons for making accreditation an important process to adopt by a country and by organizations to seek:

Health care consumers are becoming increasingly aware of the different requirements a health care organization must meet in order to be considered a quality organization. They are also becoming interested in learning about the status of care provided by an organization judged by its peers or professional experts. Accreditation provides just the answers and the assurances that health consumers are asking for. Accreditation provides for a mechanism for an objective unbiased peer review of a health organization. It provides the consumer a set of measures by which they can judge a health care organization in comparison with similar organizations. With the seal of approval, accreditation also provides the consumer a level of comfort ensuring that a health care organization has been checked and is considered a quality organization since it has passed a rigorous set of evaluation processes. In essence, accreditation could be defined as the process of assessing the quality of an organization for the purpose of providing comparative information to the customer.

Accreditation standards are developed to be as quantifiable as possible. These standards follow the various functions and units health care organizations
perform and possess. Standards are developed and are updated annually by a group of experts that are related directly to the process of care and to the structure of services rendered by the health care organization. These standards are therefore developed to measure the performance of the health care organization in the aspects of care and services it claims to provide. Compliance with these standards is a proxy measure of the performance of such an organization. Of course compliance may have to be substantial for the health care organization to receive the seal of approval from the accrediting organization. In this way accreditation can work as a measure of the performance of the organization, especially in such areas as structure and process.

One of the main activities of accreditation is to set standards that a health care organization must meet. Experts usually rigorously develop these standards. It is with these standards that the accreditation agency is able to measure the quality of the health care organization they want to evaluate for accreditation. Therefore, these standards soon become the yardsticks by which performance is measured and accreditation is achieved. Standardization is important in order that objectivity can be assured in the evaluation process. It is also a mechanism for controlling outcomes and comparing performances. Meeting certain standards will render the health care organization “accreditable” and will decrease variation between its current performance and the desired one. Standardization is also useful in controlling cost by controlling expectations, predicting outcomes and facilitating effective budgeting.

Benchmarking and report card capabilities are two of the reasons why health care organizations should seek accreditation. These are also reasons why accreditation should be developed in order for companies to be compared with one another based on the findings of accreditation. Benchmarking is a process of identifying the best process, activity or outcome and to find ways to study them and emulate them in one own setting. Through the process of accreditation, health care organizations are encouraged to look for the best processes of other organizations in order to study these processes and learn about performing them so that they can be imported and implemented in that organization. Benchmarking is usually enhanced by the fact that most quality organizations are accredited. Similarly one of the reasons for accredi-
tation is to list on the health care organization’s report card (outcome measures) that they are accredited. A report card that does not have accreditation listed on it is not a complete and certainly not a credible report card. Therefore, organizations must seek accreditation and attain in order for them to list it on their report card.

According to the quality improvement cycle shown below, accreditation is involved in all of the steps of the cycle, including quality improvement. The process of accreditation emphasizes assessment but it also encourages improvement based on the outcome of such assessment. It also encourages organizations to initiate improvement projects. Most of the new accreditation standards call for health care organizations to demonstrate their capabilities of identifying improvement opportunities and initiating processes for improvement and development. Accreditation agencies respond positively to those organizations that demonstrate their experience in “closing the loop” from the identification and analyses of improvement opportunities to selection and implementation of actual improvements and then maintaining their sustainability. Therefore, accreditation will stimulate improvement efforts in health care organizations and will bring these organizations to a higher level of accountability.

Accreditation provides a mechanism for comparison between health care organizations. Those organizations that have achieved accreditation, especially “commendation” or “excellent” status, will have a positive image and will use that distinction to market their services accordingly. Accreditation can therefore be used as a tool for positive marketing and as a tool that enhances positive competition between health care organizations. Competition can be based on price or other factors. Competition based on quality as exemplified by the attainment of accreditation is a form of non-price competition and is a form of positive competition. This type of accreditation is in contrast with the type of competition exhibited by and between political candidates where they each try to find weaknesses in each other performance or character to attack. Positive competition on the other hand encourages benchmarking and identifying the positive attributes of your competitor in order for you to achieve even a better level of these attributes in your organi-
zation. It is a process of continuous search for excellence and a mechanism for emulating that excellence in one's own systems. Accreditation facilitates this process and encourages it.

As stated earlier, receiving accreditation is equivalent to receiving the seal of approval on the quality of one's own organization. This recognition certificate is usually worthy of announcement and heavy marketing to promote it. It is both rewarding and beneficial to an organization and its employees. Accreditation can also be used as the mechanism for rewarding individuals who have worked hard in order for the organization to achieve it. It is also a method of recognition among peer organizations and proof of quality.

Quality has many dimensions. Two of these dimensions are related to the ability of an organization to attain its objectives in a timely and cost-beneficial manner. Therefore the ability of an organization to use its resources in the optimum way is one of the important dimensions of quality. Similarly, an organization that can demonstrate its ability to achieve its goals and objectives in a timely manner is considered an effective organization and therefore has met another dimension of quality. Accreditation is somewhat similar to what quality is all about. Accreditation requires an organization to be effective and to use its resources most efficiently. In order for the health care organization to achieve accreditation it has to demonstrate its effectiveness and its efficiency through completed projects related to their mission, their objectives and their goals. Efficiency and effectiveness must be practised and proof must be documented in order for an organization to receive accreditation.

The benefits

Here are some of the benefits of accreditation according to JCAHO (1999), NCQA (1999) and AAAHC (1999):

- Enhances community confidence
- Provides a report card for the public
- Offers an objective evaluation of the organization’s performance
- Stimulates the organization’s quality improvement efforts
- Aids in professional staff recruitment
- Provides a staff education tool
- May be used to meet certain government certification requirements
- Expedites third-party (insurance) payment
- Often fulfils licensure requirements
- May favourably influence liability insurance premiums
- Favourably influences managed care contract decisions
- Finds new ways to improve the care and services they offer
- Increases the organization’s efficiency and reduce costs
- Develops better risk management programs
- Motivates staff and instils pride and loyalty
- Strengthens public relations and marketing efforts
- Recruits and retains qualified professional staff members
- Develops alliances with other provider groups and health care organizations.

Components of accreditation

A typical system of accreditation (as seen below) is organized around four different components: administration, standards, communication and education, and surveying.

Administration

Of course such a system must have credibility, and this is usually attained through an upper management structure such as a board of directors or a governing board. The board most probably will consist of representatives of all of the major players in the health care system. For example, representatives from both the government and the private sector would be represented on the board. Professional organizations and societies may also be included on such a board. Certainly, this board would act as the top decision-making entity in the system of accreditation. It is responsible for evaluating survey reports for
health care facilities and would render the final decision regarding eligibility for accreditation. Therefore this board is responsible for:

- Evaluation of surveyors’ recommendations
- Verification of information
- The accreditation decision
- The appeal process
- Re-evaluation and periodic surveys
- Re-accreditation
- Accreditation violations/abrogation.

The accrediting organization will have an administration. This component will have a number of activities and functions that are supportive and somewhat facilitative in nature. This component is usually responsible for providing leadership and administrative to the accreditation process. Specific functions include:

- Facilitating the application process
- Collecting of the application and survey fees
- Scheduling of the on-site survey
- Identification and contact of surveyors
- Travel arrangements of surveyors
- Secretarial and clerical support.
- Help desk/customer service, etc.

**Education and communication**

The second component of the accrediting organization is education and communication. This component is primarily responsible for increasing awareness of the target organizations and their employees of the process and the standards of accreditation. Specifically, this component is responsible for:
Seminars/workshops
Conferences
Consultations and advice
Newsletters
Web-site
Direct mailings
News releases
Marketing.

Standards
The third component is related to the setting and continuous updating of the accreditation standards and the scoring guidelines for measuring compliance to the standards. Specifically, this component will be responsible for:

- Organizing the domains (see below)/sections for the standards manual
- Developing and setting the accreditation standards and sub-standards
- Identifying the documentation requirements for evaluating compliance
- Establishing scoring guidelines
- Organizing and updating the standards manuals.

Surveying
The forth and last component of the accreditation organization is probably the most important: where the actual assessment of the health care organization is handled. This particular component is usually called the surveying component. Professionals working for this component will be responsible for:

- Selection of surveyors
- Training of surveyors
- Scheduling of surveyors/facilities
- The organizing of the site visit
The survey report and the score card

The surveyors’ recommendations.

**The core standards**

Depending on the accrediting organization’s emphasis, the areas for the development of standards may be different from one another. Also, the type of facility to be accredited has an effect on the type and the “domains” of standards to be developed by the accrediting organization. For example, the Accreditation Association for Ambulatory Health Care (AAAHC) developed standards in the following domains: rights of patients, governance, administration, quality of care, quality management and improvement, clinical records, professional improvement, and facilities and environment.

For the National Committee on Quality Assurance (NCQA) there is a different focus. During an accreditation survey, managed care plans are reviewed against more than 60 different standards. Plans must also report their Health Employer and Data Information Set (HEDIS) results on 10 different measures and at least one member satisfaction survey. These standards and performance measures fall into five broad categories.

**Access and service**

Do health plan members have access to the care and service they need? For example, are doctors in the health plan free to discuss all treatment options available? Do patients report problems getting needed care? How well does the health plan follow up on grievances?

**Qualified providers**

Does the health plan assess each doctor’s qualifications and what health plan members say about their providers? For example, does the health plan regularly check the licences and training of physicians? How do health plan members rate their personal doctors and nurses?

**Staying healthy**

Does the health plan help people maintain good health and avoid illness? Does it give its doctors guidelines about how to provide appropriate preven-
tive health services? Are members receiving tests and screenings as appropriate?

**Getting better**

How well does the health plan care for people when they become sick? How does the health plan evaluate new medical procedures, drugs and devices to ensure that patients have access to safe and effective care?

**Living with illness**

How well does the health plan care for people with chronic conditions? Does the plan have programmes in place to assist patients in managing chronic conditions like asthma? Do diabetics, who are at risk for blindness, receive eye exams as needed?

**HEDIS**

NCQA (1999) is also the leader in the field of health plan performance measurement. NCQA manages the evolution of the principal performance measurement tool for managed care, the Health Plan Employer Data and Information Set (HEDIS), a set of standardized measures used to compare health plans. Today, through employer initiatives, national magazines and local newspapers, many consumers receive HEDIS data in the form of health plan report cards.

HEDIS sets the standard in assessing how effectively health plans care for acute and chronic illnesses, and includes measures that address many of the nation’s most pressing health problems, such as cancer, heart disease, smoking and diabetes.

Internationally, healthcare facilities have several options to explore should the decision be made to seek accreditation. While some countries have an internal, governmental survey process, many are still in the formative stages of the accreditation process. There are currently two external accreditation survey options that are being utilized with increased frequency.
Joint Commission International

The US-based Joint Commission on Accreditation of Healthcare Organizations (JCAHO) launched Joint Commission International (JCI) in 1999. JCI standards were developed with input from numerous international healthcare professionals and are based upon international consensus standards. JCI’s stated mission is to improve the safety and quality of health care in the international community. There are currently four JCI accreditation programs:

- International Standards for Hospitals
- International Clinical Lab Standards
- International Standards for the Care Continuum
- International Standards for Medical Transport Organizations

The JCI hospital survey team will include a physician and a nurse, with the addition of an administrator surveyor, at times. In addition to the evaluation of patient care services and patient safety issues, the surveyors will assess the overall effectiveness of communication throughout the organization, the processes related to management of information, the adequacy of the physical facility, the processes for ensuring competency of staff, and the preparedness of the facility to address disasters.

Survey activities include the following:

- Interview with Leadership
- Review of policies, procedures, plans, bylaws, and other required documentation
- Tour of the facility
- Visit to clinical areas, including patient care areas, Pharmacy, Emergency Services, Laboratory, Rehabilitation Services, Radiology, as well as, areas where anaesthesia and sedation are administered
Interview of the infection control practitioner(s) and evaluation of the infection control program

Review of staff qualifications and education

Evaluation of the quality improvement and patient safety programs

Assessment of the organization’s information management program, to include review of documentation components in medical records

Given the overall focus on healthcare quality, JCI has adopted several required clinical, managerial, and other general quality monitors that are evaluated during the survey process. The required clinical monitors include:

- Patient assessment
- Antibiotic and other medication use
- Medication errors
- Blood and blood products administration
- Surgical procedures
- Radiology and Laboratory quality control programs
- Anaesthesia use
- Infection Control surveillance and reporting
- Medical records – availability, content and use of same
- Clinical research

Required managerial monitors include:

- Processes related to procurement of supplies and medications
- Risk management
- Utilization management
- Patient, family, and staff satisfaction
Financial management

Patient, family and staff safety-related risk reduction strategies and surveillance

Reporting of those activities required by law and/or regulation

Patient demographics and diagnoses

Required general measures monitors include:

- Use of data collection to identify areas in need of study and improvement

- Evaluation of implemented improvements through data collection and analysis

**International Organization for Standardization (ISO)**

Another option for accreditation is the International Organization for Standardization (ISO) system. ISO was founded in 1946 in order “to facilitate the international coordination and unification of industrial standards.” While ISO was originally oriented toward the electrotechnical industry, it has since broadened to encompass numerous other industries, to include healthcare.

The premise under which ISO was developed is that development of common standards provides a framework, which facilitates information and technology sharing and trade. Having uniform standards eliminates, on an international level, the technical barriers that would normally be in place due to differing regional practices, standards, cultural and language issues.

Participation in the ISO program is voluntary. The standards are developed by member consensus and market requirements. ISO standardization pertains to such issues as terminology, symbols, performance and safety requirements, protocols for computers, quantities and units. ISO standards are specific to a particular process or product.
ISO includes standards that encompass how an organization addresses customer satisfaction, regulatory requirements, and works to continually improve its performance. While ISO accreditation may not necessarily serve as a substitute for JCI accreditation, it will likely result in a less costly and more structured survey preparation process. Through the adoption of the ISO quality standards, an organization can anticipate improved compliance with record-keeping, documentation, and utilization of the overall quality program. ISO provides the structure for ongoing quality improvement throughout the organization.

The ISO paradigm differs from that of JCI in that its guiding principle is that the organization develops and defines its own unique quality program. Using the Quality Performance Wheel concept, an organization addresses program cost, performance measurement, and customer satisfaction in order to develop an effective quality program. Once the organization has developed a quality program that will meet financial, customer satisfaction and process and outcome goals, a system must be put into place to continuously monitor the effectiveness of the program.

ISO has received increased attention from the healthcare industry in recent years due, in large part, to concerns over rising healthcare costs coupled with serious concerns about patient safety. Advances in medical technology have leveraged organizations to balance the cost of being able to provide higher technical care with the resultant cost of recruiting and retaining staff competent to provide this increasingly complex healthcare. The need to develop a structured environment to support the processes related to the delivery of safe, high quality care is now an international imperative. Seeking and maintaining accreditation is a viable means to achieve this goal.

The Accreditation Process

The accreditation process consists of a “desktop review” of the application and a site visit. Through this process, applicant organizations submit evidence of compliance with accreditation standards, which is then verified by an accreditation reviewer.
Once the desktop review is complete, the organization may be asked to submit additional information and/or revisions to the application. After receipt and review of the additional documentation, an on-site visit will be scheduled. Applicants refer to a specific interpretation guide to prepare for the on-site verification. The processing time for an application, that is the time an application is received at an accrediting organization until the time the accreditation is granted, is approximately four to six months. The actual time frame will vary according to the type of accreditation applied for, the number of standards that are met versus not met upon desktop and on-site review, the number of applicant sites, and the number of applicants in the queue for accreditation, among other factors.

During the on-site visit, a team of surveyors meets with many representative groups from various parts of the health care organization to discuss the processes of care and support function within the organization, as well as, the quality improvement initiatives related to them. The survey team meets with the health care facility’s board of directors, senior administration, care teams and other supporting teams, such as human resources, environment and information management. Most important, the surveyors meet with clients and their families, who are interviewed about their understanding of the care received, their feelings about the quality of care/service, and their level of understanding of their role in the care and treatment process.

In addition, the survey team reviews documentation (for example, policies and procedures, minutes, care plans and clinical records) and visits key work areas to support their observations. In summary, the survey team is invited by the organization to review the quality of care and services provided against nationally developed standards.

After the survey team completes its verification process a report including the accreditation recommendation is prepared and submitted to the accrediting organization for decision-making. The accrediting organization in turn analyses the report and discusses the recommendation, thus making its final decision regarding accreditation. The decision is verified by the accreditation organization’s governing board and is provided to the health care facility. If the decision is a denial for accreditation or any adverse decision, then the
facility has the right to appeal that decision.

Conclusions

Accreditation has played a major role in the monitoring of health service organizations for over 40 years. The success of accreditation rests with the recognition of it as a voluntary, objective peer review process with self-assessment at its core. Its success also rests with the on-going participation of the multitude of professional groups who all work collectively and collaboratively to ensure that accreditation reflects the common goal of delivery of consistent, high quality care.

It is a process that has the potential of insuring continuous improvement, and institutionalisation of quality. Sustaining quality activities are enhanced with certain incentives and accreditation is an example of such incentives. In this era of performance measurements and accountability, a mechanism that encourages compliance to standards such as accreditation is exactly what this era needs. It is no wonder that countries around the world are becoming increasingly and seriously interested in such an activity.
References


CHAPTER ELEVEN
Challenges, Opportunities and Lessons Learned for Sustaining Healthcare Quality

A. F. Al-Assaf, MD  Seval Akgun MD, PhD

After the full implementation of health care quality in an organization, a community or a country, the next expected milestone is to establish a “quality culture”. Total health care quality coupled with a quality culture is a status of institutionalization of health care quality. In a system where there is planning for quality, QA, monitoring, QI, and QM, institutionalization is eminent. Therefore, institutionalization is achieved when appropriate health care quality activities are carried out effectively, efficiently, and on routine basis throughout a system, organization, district or country (Brown, 1996). It is a state of achievement whereby health care quality is practiced and maintained without additional outside resources. In such a state expertise are available within and commitment is fully integrated and maintained.

A quality environment or culture is achieved when quality activities become day-to-day type activities. Such activities are not separate from the normal activities that are carried out daily by the system and its personnel. It is a state where each employee is aware of the quality concept, believes in it, practices its principles and makes it part of his/her responsibility and not the responsibility of a department or another individual. In such a culture each individual is responsible for his/her task’s own quality structure, process and outcome. Employees are making every effort at that level to make sure that the processes of QA are maintained, i.e. planning, standard setting, and monitoring. In such a culture, employees are also practicing QI, i.e. they identify opportunities for improvements and set the motion individually or in collaboration with others to make improvements. It is also a situation in which employees are empowered to achieve their goals, which are in turn aligned with the organization’s mission and vision statements.
Lessons in Institutionalization

- **Planning** for quality should be done systematically and thoroughly. Delineation of responsibility, identification of scope of involvement, the allocation of resources, and the anticipation for the change should be completed before activities in QA or QI begin.

- Securing *commitment* from management, and hopefully from the minister, is helpful and can make the process of implementation move rapidly. The involvement of these top managers in the early activities of planning is essential.

- Develop a policy for quality at the national level as early and as solidly as possible. A policy that is well prepared and developed in collaboration by senior staff will have a much better chance of survival even with the expected high turnover of managers and staff.

- Identification of a *leader* or *champions* (local cadre) to lead this movement is highly recommended. A local person with authority, credibility, enthusiasm and interest can be an asset to the acceleration of health care quality implementation. This individual can act as facilitator and cheerleader for health care quality initiatives.

- Organization of a steering committee or *council* of national representatives would give the health care quality process credibility, sustainability and momentum.

- Forming the *structure* for health care quality should be gradual and cautious based on progress and understanding of the concept and the practice. Organizing large structures of committees and councils early on may shift the focus on organization and away from the actual mission of health care quality, which is improvement. Staff at the beginning of implementation should be concentrating more on learning and understanding the concept and practice it daily to achieve positive results. Too many committees with too many meeting and too many tasks distract from focusing on expected goals.

- Always have an *alternative plan* in case one is slowed down due to the anticipated and frequent staff changes. Make a habit of not relying on one single individual is helpful when trying to implement health care quality effectively. Train a number of individuals and prepare several qualified staff
simultaneously. This practice will allow for wider selections of coordinators, and will enhance sustainability efforts.

✔ Keep quality activities closely related to MOH activities and its mission without unnecessary change in organizational structure and the allocation of additional resources. At least at the beginning of its implementation, health care quality activities may be delegated to an existing staff or an existing department as part of their normal responsibility.

✔ Prepare yourself to answer questions related to incentives for staff to participate. As long as health care quality activities are not required as integral parts of their jobs, employees will question their role in participation. A system of employee rewards and recognition based on health care quality achievements is necessary.

✔ Document improvements by measuring pre and post status. Always have quantitative data available for comparisons and measurements of effectiveness. It is also useful if cost savings are calculated to measure efficiency. Providing measurable parameters gives credibility and sustainability to the process of health care quality.

✔ Actively disseminate achievements and health care quality awareness information to as many individuals in the system as possible. Make sure that participation is voluntary and is open to anyone and everyone as opportunities for improvement are identified. Do not make it a “private club”! Keep everybody informed and involved as much as possible.

✔ Resist the temptation of expansion to other regions or sectors early. Building an effective process in one area is more important that starting several incomplete processes in different locations and areas. Keep the implementation process focused.

✔ Always keep adequate funding available for the development of new projects and activities not originally planned for. This will also give you the flexibility of shifting additional funds in needed areas where improvements are taking place more effectively. Adequate funds will increase the likelihood of sustainability.

✔ Finally, encourage and foster an environment of learning not judgment. In particular, rely on data and facts in making judgments. Avoid the antiquated disciplinary method of management.
A Proposal for a Change and Recommendations

For Countries

Three themes are emerging as the guiding themes for institutionalizing quality in the different countries. One is that quality must be measured proactively. Second is that with quality, performance can be measured and both organizations and individuals can be objectively assessed. Third is that quality has a direct relationship with health care costs.

Therefore, the following strategies could be formulated in support of the above three themes:

Proposed Strategy Statement #1: Provide a proactive approach on quality in health care by requiring member countries to perform the following:

1.1 It behooves member countries to establish a cohesive Structure (a QA Plan authority, human and physical resources) on quality measurement in health care.

1.2 Identify and develop a cadre of local professionals trained as trainers in quality issues.

1.3 Based on assessment studies, standards for important areas of care and service should be developed, documented and communicated to the right users.

1.4 A system of data management related to the measurement of compliance (monitoring) to these standards should be developed.

1.5 Opportunities for improvement are identified on a regular and periodic basis for action.

1.6 Report on improvement activities on a periodic basis through such avenues as newsletters, seminars, conferences and national meetings.

Proposed Strategy Statement #2: Measurement of performance on health care facilities and professionals should be started and results are reported and shared with member countries on a regular basis.
2.1 A list of at least 5 national key health care performance indicators should be developed.

2.2 Using the health care monitoring system, performance against these indicators is measured on a regular basis.

2.3 Reports are assembled and disseminated to users and regional office for comparative purpose and actions for improvement.

2.4 Improvement opportunities based on these indicators are identified and national projects are launched for action.

2.5 Documented improvements are disseminated and expanded.

2.6 Develop a system for accreditation, certification and licensure of health care organizations.

2.7 Develop a system for credentialing, peer management and licensure of health care professionals.

Proposed Strategy Statement #3: The relationship between quality improvement activities and cost savings should be measured and success in that direction should be encouraged and recognized.

3.1 Develop a system for utilization management of health care resources. High cost health care and service areas should be identified and prioritized.

3.2 Projects related to improvement of care and services on the top 5-10 indicators are identified and launched.

3.3 In at least these projects, cost savings should be one of the main driving reasons for initiating improvements.

3.4 Cost savings are measured, documented, and results are disseminated to the proper audience.

3.5 Teams achieving success in cost savings should be appropriately rewarded and recognized.

3.6 Develop a system for risk management (including infection control) in order to minimize and document the cost of failure of care.
For International Organizations

The following is a short list of the types of roles and involvement an international organization can play in introducing health care quality to a country or a system:

- Organize and sponsor a comprehensive regional situational analysis on the state of QA/I in health care in the member countries.
- Organize and coordinate inter-country meetings to share experiences and formulate regional policies on quality.
- Organize national meetings on health care quality strategic planning.
- Provide technical assistance to Member Countries to strengthen QA/I in their health care systems and to establish strategic plan of action.
- Assist country officials in drafting strategies of health care quality implementation and interventions.
- Introduce the concept of performance management and measuring accountability through such mechanisms as accreditation, certification, credentialing, continuing education and licensure.
- Provide resource materials (including technical assistance) regarding QA/I and Accreditation and standardize quality assurance terminology.
- Establish a regional panel of experts or advisor on QA/I and Accreditation.
- Facilitate the delivery of national or regional seminars on the health care quality.
- Identify and fund international consultants, long-term and short-term with specific expertise in the subject, to assist countries in gaining local expertise in any of the processes towards successful implementation of health care quality.
- Assist countries with project-specific or goal oriented financial support towards achieving common objectives.
- Coordinate “benchmarking” visits of key personnel between regional countries for exchange of ideas and expertise.
- Provide assistance, financial and technical, in organizing study tours of
key personnel from regional countries to other regions or other countries for benchmarking.

✔ Provide expertise in developing national/regional standards and performance indicators. This activity may include the development of a regional or national accreditation system.

✔ Assist countries through planning, training and the development of local expertise in gaining sustainability of processes and reaching health care quality institutionalization.

For Short term Consultants;

1. Complete a pre-assessment activity to measure and establish baseline data on health status indicators, performance outputs and resources availability.

2. Develop a strategic plan on QA for the country in question. This plan should include information on strengths, weaknesses, threats and opportunities for improvement. A mission and strategy(s) for improvement should also be developed.

3. Identify and train a cadre of health care individual as trainers on quality.


5. Organize a preliminary system of data collection, reporting and analysis to measure compliance to these indicators.

6. Assist in the identification of QI projects that will have both monitor and political impact.

7. Assist in the recognition of improvement successes.

8. Assist in the coordination of a system for performance measurement. This system could be in the path of accreditation, certification and/or licensure.


10. Prepare answers to questions on rationale and outcome e.g. the “so what?” question.
Prof. Dr. Seval Akgün MD, PhD

Seval Akgün is a Physician, Public Health Specialist who has worked as a researcher and lecturer/trainer as well as being involved in Quality in Health Care and Public Health in the field. The variety of research topics she has addressed with collaboration of several international technical supports demonstrates the wide scope of her interests in quality in health care, public health and her commitment to a comprehensive and holistic approach to health issues. She has trained, motivated and supported many young researchers with interest of public health and quality of health care. Currently, she is working as a professor of Public Health, Baskent University School of Medicine, Ankara, Turkey and Adjunct professor of University of Oklahoma Health Sciences Center. She is also coordinating the continuous quality improvement (CQI) activities of all the hospitals and schools attached to the university. She has involved many national and international projects on CQI in hospitals and primary health care for more than fifteen years. She has 3 books, 12 book chapters and more than 250 papers to her credit and working as a consultant and giving lectures at national and international level on building quality and accreditation systems, patient safety and total quality management issues.

Besides lecturing on continuous quality improvement principles, models and techniques, accreditation in health care, public health, epidemiology, research methodology and community nutrition for students and professionals., Dr. Akgün is also an experienced in; quantitative research design, implementation and analysis, burden of disease methodology, need assessment studies, evaluation of EU projects, methodology of patient and employee satisfaction, quality of care and utilization surveys, process and outcome management surveys, problem solving techniques etc. for health personnel and monitoring and evaluation specialist on health related projects and training programmes. She is certified as health organization surveyor, Trainer on different topics of total quality management issues such as implementation of CQI models in health care facilities like ISO 9001; 2000 version, EFQM module and JCI accreditation standards, Expert on ISO 14001 Environmental Management System, HACCP, ISO 22000 Food safety management systems, OHSAS 18001 Occupational Health and Safety, and also Hospital surveyor on accreditation standards.

Prof. Dr. A.F Al-Assaf

Dr. Al-Assaf is a physician and a consultant in preventive medicine and quality management with emphasis on accreditation and system performance.

Dr. Al-Assaf is serving the University of Oklahoma Health Sciences Center as the distinguished Regents’ Professor and the Associate Dean for International Health and Professor of Health Administration and Policy at the College of Public Health. He also holds adjunct and Clinical appointment as Professor in Medicine, Nutrition, Nursing and Liberal Studies at the University of Oklahoma. He is frequent consultant for the U.S. Air Force, U.S. Veterans Affairs Health System, US Agency for International Development (USAID), Hospital Corporation of America, Selected Professional Associations, World Bank, UNDP, UNICEF, World Health Organization (WHO), and the American Association for World Health. He has provided advice on healthcare quality and preventive medicine to a number of organizations in countries in the Mid-East, North America, North Africa, South East and Central Asia and Eastern Europe. Dr. Al-Assaf is a recipient of 50 awards and recognitions.

As a researcher and public speaker, Dr. Al-Assaf has published ten books, five book chapters, and over 120 scientific and professional publications in national and international journals, and presented lectures, seminars, or workshops to over 250 groups and organizations both nationally and internationally. He is the recipient of many awards and honors including Who’s Who in America and the World.