UPDATED AND REVISED

THE Janet A. Brown HEALTHCARE QUALITY HANDBOOK

A PROFESSIONAL RESOURCE AND STUDY GUIDE

30TH EDITION

ORIGINAL AUTHOR
JANET A. BROWN, RN, CPHQ, FNAHQ

EDITOR
SUSAN MELLOTI, PhD, RN, CPHQ, CPPS, FNAHQ

JB4S JB QUALITY SOLUTIONS

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Please feel free to contact Josh Ivy at JB Quality Solutions, Inc. **at any time.** Josh can be reached via email at josh@jbqs.com or via phone at 626-797-3074.

THE *Janet A. Brown* HEALTHCARE QUALITY HANDBOOK

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INTRODUCTION

You are embarking on quite an adventure as you open this newly reorganized and revised 30T" Edition of **THE *Janet A. Brown HEALTHCARE* QUALITY HANDBOOK: A PROFESSIONAL RESOURCE AND STUDY GUIDE.** Along with healthcare, this book has evolved over many years. It has always been a valuable resource for those studying to take the Certified Professional in Healthcare Quality (CPHQ) examination. This newly revised edition is now also designed to be an updated general resource used by everybody in the various healthcare quality fields and settings. As a resource book, it should be available in all healthcare organizations.

Janet A. Brown and her company, JB Quality Solutions Inc., have been updating and publishing this Handbook since 1986. The Handbook is revised to incorporate the new and relevant information important for quality professionals. Following Janet's unexpected death in 2012, a new team of authors, led by Susan Mellott, took up the charge to keep the Handbook fresh and applicable, as the most comprehensive and valuable healthcare quality reference manual and study guide available . The new authors have a collective 170 years of expertise and are nationally respected professionals, consultants, and instructors in healthcare quality.

You may be planning to be certified as a healthcare quality professional, seeking general information about the field, seeking to advance in your career and scope of responsibility, or looking for up-to-date material for your current role. We wish you the very best in your particular endeavor. As a quality professional, willing to use and digest this text, you are indeed committed to providing the knowledge, expertise, and service needed to facilitate the delivery of high quality care in your setting.

The complete Content Outline for the Certified Professional in Healthcare Quality (CPHQ) Examination is included at the back of the Handbook. The beginning of each chapter also lists the specific examination Task Statements to be addressed in that chapter. The Handbook covers much more material than is required for the examination. It also incorporates the current "burning issues" in healthcare quality. The content includes information on leadership and planning, performance measurement and improvement, patient safety, continuum of care, information management, education/training, communication, external survey preparation, and the role of the healthcare quality professional.

The intent of this Handbook is for you, as a healthcare quality professional, to be your organization's known quality expert. It is not critical to know all the answers, but to be one who knows how to find

out, one who feels confident about your skills and your ability to serve as a key resource, and one who knows enough to be passionate about the role of quality in meeting your organization's strategic goals and achieving its mission and vision.

Please read the section entitled "HOW TO BEST UTILIZE THIS HANDBOOK" for helpful tips and information.

Disclaimer: It cannot be guaranteed that every examination issue is covered in *THE* Janet A. Brown *HEALTHCARE QUALITY HANDBOOK: A PROFESSIONAL RESOURCE AND STUDY GUIDE;* nor can it be guaranteed that you will pass the CPHQ Examination by reading this Handbook. The authors are not privy to the content of the examination other than what is contained on the current CPHQ Examination Content Outline. The only questions released from past examinations are in the *Candidate Handbook* and the *CPHQ Self-Assessment Practice Exam.* This Handbook is revised yearly to interpret the CPHQ Examination Content Outline in the light of what is current and pertinent in the field.

TRIBUTE

Janet A. Brown, RN, CPHQ, FNAHQ

Janet A. Brown's amazing journey in the field of healthcare quality continues with this **30'" Edition** of **THE Janet A. Brown HEALTHCARE QUALITY HANDBOOK: A PROFESSIONAL RESOURCE AND STUDY GUIDE.** After many years of battling cancer, Janet passed away on May 20, 2012 . Janet was a trailblazer and a world leader in healthcare quality. We are grateful to her for the wealth of information consolidated in this Handbook, her tireless dedication to revise and produce it annually, her wise and cheerful instruction and inspiration, her optimism and leadership in the field, and her genuine friendship. She is remembered with love and appreciation.

ABOUT THE AUTHOR

Janet A. Brown, BA, BSN, RN, CPHQ, FNAHQ, was well-known as an author, educator, and consultant in healthcare quality. She was active in the field for more than 30 years and owned her own business, now JB Quality Solutions, Inc. She passed the first offered national certification exam in 1984. Then in 1985, she designed and held a half-day teaching session for 12 colleagues who all became certified. Her passionate interest in promoting certification and professional growth grew out of that first study group and a SO-page set of handouts. She subsequently taught *over* 110 healthcare quality workshops and revised and improved The Healthcare Quality Handbook each year from 1986 to 2012 . The Handbook is a respected manual in the field and has been used throughout the world.

She also worked as a consultant for 12 years with hospitals, ambulatory care centers, surgical centers, mental health facilities, review agencies, and managed care organizations in quality management, utilization and case management, clinical risk management, information management, strategic planning, and systems development.

In addition to the Handbook, Janet was co-author of Managing Managed Care: The Mental Health Practitioner's Survival Guide (first edition, 1992), Managing Managed Care II: A Handbook for Mental Health Professionals (second edition, 1996), and Casebook for Managing Managed Care: A Self-Study Guide for Treatment Planning, Documentation, and Communication, 2000, all published by American Psychiatric Publishing, Inc.

Janet was a President (1995-1996) and Fellow of the National Association for Healthcare Quality (NAHQ) and served on NAHQ's Past Presidents' Council. She was the founding chair of NAHQ's National Healthcare Quality Foundation. She received NAHQ's Distinguished Member Award in 1991.

From 1996 to 2004, Janet served on the Technical Advisory Committee for L.A. Care Health Plan, the Medicaid managed care health plan for Los Angeles County, with more than 700,000 members. She also served many years on the National Advisory Council for Fuller Graduate School of Psychology.

JB Quality Solutions, Inc. continues to produce and distribute **THE Janet A. Brown HEALTHCARE QUALITY HANDBOOK: A PROFESSIONAL RESOURCE AND STUDY GUIDE.** The company is run by Janet's family, who work closely with Susan Mellott, PhD, RN, CPHQ, CPPS, FNAHQ, as the Editor and Course Instructor.

In Janet's Own Words:

On July 23, 1995, my life changed dramatically. I sustained a spinal cord injury and incomplete quadriplegia in a car accident. I use a wheelchair and have movement of my arms, but limited use of my hands. I consider this Handbook to be a miracle. It has continued despite disability, chronic neurogenic pain and spasticity, multiple computer crashes, and cancer.

I share my cancer story in more detail here because you are quality professionals . In 1996, I was diagnosed with breast cancer. I then experienced local recurrences in 2004 and 2006. I opted for surgery all three times, without chemotherapy (only 212.5% improved mortality) or radiation (preempted by the need to preserve my already minimal arm function).

In February 2009, I saw my eighth HMO oncologist (constant contract changes) with symptoms in my right arm. She told me the MRI and PET scan were both negative. Then in December of that year, I was diagnosed with three new tumors, with muscle involvement and nerves at risk. Surgery, radiation, and chemotherapy were not viable options.

Upon directly reviewing all 2009 test results, I learned the previous MRI and PET scans had both shown enhancement. My oncologist had missed the diagnosis months earlier. The cancer center had no electronic record or online access to test results. Their nonsystem allowed physicians to take isolated reports home to call patients, with no access to or requirement to review the medical record. She did not connect the dots between my history, my symptoms, and my test results.

In September 2011 cancer was found metastasized to several bones. In spite of circumstances, my hope and faith is in my Lord.

In my ongoing dealings with two IPAs, four different H M Os, and now M edicare, I have learned first hand -as a patient with the quality professional's eyes and ears-of our desperate need for a seamless continuum of care, care coordination and case management, electronic record and information sharing, and an effective quality strategy. Even so, I still believe that such a quality healthcare delivery system is achievable!

I cherish the history reflected in these pages, but I thrive on the growth, innovation, and, of course, improvement that represents the current environment and the future of quality in healthcare. N ow this quality passion is passed on to you, my colleague. This is a wonderful time for the healthcare quality professional . Both the organization and the public are listening. Your organization will look to your expertise as it seeks to improve . Our patients certainly do deserve-and will benefit from-al/ of our best efforts.

God bless you and best wishes in your study!

Janet

ABOUT THE EDITOR

Susan Mellott, PhD, RN, CPHQ, CPPS, FNAHQ

Over the past thirty years, Dr. Susan Mellott has focused on healthcare quality in multiple settings including hospitals, long term care centers, home health settings, clinics, and networks. She has experience with patient safety, improving patient/customer satisfaction and quality, decreasing costs, medical staff credentialing, OPPE/FPPE, and other areas while involving teams from the facility, including physicians and administrative staff. She has extensive experience with the survey process, especially with DNV and The Joint Commission on standards and surveys. Dr. Mellott has held CPHQ certification since 1991, CPPS certification since 2015 and has been a Fellow of the National Association of Healthcare Quality since 1999. Currently, Dr. Mellott is the President, CEO of Mellott & Associates, LLC in Houston, Texas, which provides educational services to healthcare facilities and groups. Dr. Mellott is an Associate Professor at Texas Women's University College of Nursing in Houston, Texas and teaches at the undergraduate and graduate levels. Dr. Mellott is a member of State of Texas Healthcare Safety Advisory Committee. Dr. Mellott has numerous publications and addresses groups around the country regarding healthcare quality, patient safety, and performance improvement, among other topics.

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Thank you especially to **Jocelyn Gomez** who kept this Handbook flowing with her formatting, corrections, and many other contributions! I could not have done this without you!

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HOW TO BEST UTILIZE THIS HANDBOOK

THE Janet A. Brown HEALTHCARE QUALITY HANDBOOK has been reorganized and has revised content to enable it to be utilized for multiple purposes. The Handbook is now designed for all quality, risk, utilization management, patient safety, performance improvement, and accreditation professionals to use as a reference for their department at work or elsewhere, as a study guide in preparation for the Certified Professional in Healthcare Quality (CPHQ) exam, and for those beginning in these fields to learn the what and why of the processes and concepts. See more information about each of these uses below.

The seven chapters begin with **Healthcare Quality Basics** (Chapter 1), focusing on those general principles that are foundational for our understanding of healthcare quality today. Chapter 2, **Organizational Leadership,** discusses the key leadership elements required in achieving a quality organization. Chapter 3, **Performance and Process Improvement,** discusses quality, risk, and utilization management and provides the structure for all the performance improvement (PI) processes with a focus on indicator development. A section of this chapter discusses the personnel involved and the concepts related to these processes. After looking at the management of quality functions and processes, **Health Data Analytics** (Chapter 4) and then **Patient Safety** (Chapter 5) are explored. Chapter 6, **Regulatory, Accreditation, and External Recognition** deals with the organization's participation in accreditation, licensure, registration, and quality awards. Chapter 7, **Legislation Initiatives** covers United States specific healthcare issues, legislation, and reform.

The Handbook is indexed, and each Chapter is detailed in the **Table of Contents** with page numbers. Each chapter begins with the listing of the applicable CPHQ Exam Content Outline items that are reflected in the chapter. The contents of the chapters in Ibexes! are those most pertinent to the CPHQ Exam Content Outline. The full Content Outline can be found at the end of this Handbook and in the ***CPHQ Candidate Handbook*** found on the National Association for Healthcare Quality's website. In addition, at the end of each chapter the reader will find a list of all references and websites cited within that chapter.

At the end of the Handbook, you will find additional information:

The **Glossary** encompasses all key terms used in the Handbook. It is very helpful for basic definitions, for those new to the field, and for CPHQ Exam study. This is followed by the list of **Acronyms** utilized within the book. The end of the book also includes the **Content Outline** for the CPHQ exam and the **Index** of topics discussed within the Handbook.

Utilizing the Handbook as a Resource

- This Handbook is a valuable reference and resource for healthcare quality and should be available in all healthcare organizatio ns.

- The flow of material moves from general concepts and principles to the more specific management and implementation activities. An outline format is used to help you focus on main points and related subpoints. Tables are presented throughout the Handbook to offer more concise information about a topic.

- The Table of Contents in the front of the Handbook provides a detailed list of the topics covered in each chapter.

- The Index at the back of the Handbook can help you find specific information.

- The Task Statements, taken from the CPHQ Exam Content Outline, are listed at the beginning of each chapter, to serve as the objectives for that chapter.

Utilizing the Handbook for Professionals New to the Quality Field

- As someone new to the healthcare quality fields, this Handbook w ill assist you with your learning and application of these concepts and principles.

- Study courses are available from JB Quality Solutions, publisher of this book, and from others throughout the United States. However, you do not need a study course to learn this information if you use this Handbook as an ongoing resource.

- The flow of material moves from general concepts and principles to the more specific management and implementation activities. An outline format is used to help you focus on main points and related subpo ints. Tables are presented throughout the Handbook to offer more concise information about a topic.

- The Table of Contents in the front of the Handbook provides a detailed list of the topics covered in each chapter.

- The Index at the back of the book can help you find s pecific information.

- The Task Statements listed at the beginning of each chapter serve as the objectives for that chapter.

Utilizing the Handbook to Study for the CPHQ Examination

- The ***CPHQ Candidate Handbook*** should be downloaded from www .nahq.org and used in conjunction with this text as you study to take the certification exam. It contains all the information you need about the exam, how to register for the exam, and what happens as you take the exam. It also includes the CPHQ Exam Content Outline, containing Task Statements on what is covered on the exam. If information/concepts are not listed in the Task Statements, then they are not on the exam . For example, case management is not listed within the Content Outline. Therefore, case management topics are not on the exam, unless aspects such as handoffs and population health are listed within a Task Statement.

- Spend the most time studying the areas with which you are ***not*** as familiar, or in which you do ***not*** currently work. Consider also the number of exam questions in each area, as you prioritize your study .

- This Handbook is intentionally somewhat organized like the CPHQ Exam Content Outline, but not all the content is found in the chapter where the Task Statements are listed. The flow of material moves from genera l concepts and principles to the more specific management and implementation activities. Tables are presented throughout the Handbook to offer more concise information about a topic .

- The complete CPHQ Exam Content Outline can be found at the back of this Handbook.

- Think of information within this Handbook as general principles of quality-most of which are applicable across all healthcare settings. For example, if leadership commitment is necessary for successful quality improvement (QI) in hospitals, then the same principle applies to Managed Care Organizations, ambulatory care, or any other setting.

- Read to understand key concepts and general principles and how one principle relates to, or integrates with, another.

- Each chapter begins w ith a table that lists the Task Statements, taken from the CPHQ Exam Content Outline, which will be discussed wilhiri Lha t chapter. You will find thcJt different chapters may have some of the same Task Statements .

- To best facilitate your studying, words and titles of sections that refer to Task Statements from the CPHQ Exam Content Outline are indicated throughout the Handbook with a lbox around! h text!. This a lerts you that you should study the information that follows and relate it to a Task Statement.

- One way to stay principle-focused and keep the information in context is to read the entire Handbook through once, before rereading and studying chapter by chapter . (It sounds overwhelming, but it is a very effective study technique) .

- You can also read each Task Statement listed in the CPHQ Exam Content Outline and determine how comfortable you fee l with that content. If you are not comfortable, go to that information in the Handbook to study.

- One important point is that some of the Task Statements have parentheses which list specific topics that shou ld be studied. However, the exam may also cover similar topics even if they are not listed in the task statement itself . For example, one task statement lists types of process tools in parentheses. Other tools, like an Affinity Diagram, are not listed, but could still be on the exam.

- Use a highlighter to prioritize for later review. Use the margins for you r notes. Avoid taking notes on a sepa ratepad.

- Create a smal l legend for later review as you read through. For example:
  "OKu or © or ¢ for information you already know and work with;
  !or ‹Ŧ or *v'* or * if you need to study further .

- You can purchase a CPHQ Self-Assessment Practice Exam from NAHQ (www.nahq.org) as a pre-test which contains questions that reflect how the questions w ill be phrased on the exam. The cost is $119 for NAHQ members, with membership number required at checkout and $149 for non-members. It contains 130 multiple-choice questions, w ith immediate feedback, divided into 2 forms (pre-test & post-test) and is available for a year from the time the order is placed. This price is subject to change by NAHQ. More information is availab le if you click on the exam name. Under "Certified Professional in Healthcare Quality", the disclaimer reads (paragraph 4):

  "The self-assessment examination should be regarded as a diagnostic tool to assess strengths and weaknesses rather than a stud y guide for the examination. A passing score on the self-assessment examination does not, in any way, guarantee a passin g score on the CPHQ certification examination. The self-assessment examination is not intended to be a substitute for studyin g for the certifica tion examination."

- It is recommended that you complete one half of the practice exam to determine your weak areas. Study those content areas, and then complete the remainder of the practice exam.

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CHAPTER 7 - LEGISLATION INITIATIVES

HEALTHCAR E QUALITY BASICS

CHAPTER 1

Susa n Mellott, Kathleen Tornow Chai

CPHQ Examination Content Outline Task Statements For This Chapter
General Overview – No specific task statements, but applies to all information.

Over many years healthcare organizations have reviewed the quality of healthcare provided. Sometimes, the individuals who did the review were physicians, and sometimes they were nurses. In the last thirty years this review has expanded from single case review, to a review of a collection of data describing the care that is given, and even more recently, to the outcomes of care. As the field of healthcare quality has progressed, the skills of the individuals overseeing the process in healthcare organizations have changed. Frequently, it takes a team of individuals, both clinical and non-clinical, statisticians and non-statisticians, coders, reviewers and those who specialize in information management and automation to develop clear, cogent, reports of findings, trends, and important issues to present to leaders and other members of the healthcare organization, so they can improve the care that is being delivered. These individuals are categorized as Healthcare Quality Professionals, a term that cuts across disciplines, skills and levels of the organization. In this chapter is information that provides the foundation for what they currently accomplish .

There are many definitions and perceptions of quality in healthcare. A greater understanding may be gained simply by reading what others say about quality and by breaking quality concepts into their parts. In this chapter, we look at quality movements and a little history; the relationship of cost, quality, and risk concepts a nd traditiona l organizational structure; the customer and quality management principles, including Total Quality Management (TQM) philosophy, and Continuous Quality Improvement (CQI) process . This chapter will also address the competenc ies of healthcare quality professionals, as well as the certification process for healthcare quality.

HISTORY OF HEALTHCARE QUALITY

Before we can move into a description of quality and performance improvement in today's environment, it is necessary to review how we got to where we are. While there were many people who contributed to our modern versions of quality and process improvement, five individuals stand out as pioneers in the field: E. Amory Codman, W. Edwards Deming, Joseph Juran, Philip Crosby, and Donald Berwick.

Dr. E. Amory Codman (1869 – 1940)

Dr. Codman was a pioneer in several fields of medicine, but in terms of healthcare, he was the first physician to look at the problem of outcomes, which he referred to as the "end results". Prior to Dr. Codman, Florence Nightingale was the only person who published similar suggestions. Dr. Cadman began publishing papers concerning this idea with some support nationally. Dr. Edward Martin agreed with Dr. Codman's ideas and together they formed the American College of Surgeons (ACS) in 1910. This led Dr. Codman to form and chair the Committee for Hospital Standardization as part of the ACS, to study hospital outcomes and determine how they could be improved. This committee is what transformed to the Joint Commission for Accreditation of Hospital Organizations (JCAHO) (Mallon, 2007).

Dr. W. Edwards Deming (1900 – 1993)

W . Edward Deming visited Japan in 1945 at the request of some Japanese companies and began working in 1950 helping to shape the Japanese auto and electronics industries into an economic world power. His strongly humanistic philosophy is based on the idea that problems in a production process are due to flaws in the processes of the system, as opposed to being rooted in the motivation or professional commitment of the workforce. Deming's approach is that variation should be identified through monitoring processes, analyzed, and sources of variation identified. Using Deming's approach, quality is maintained and improved when leaders, managers and the workforce understand and commit to constant customer sat_isfaction through continuous quality improvement . He encouraged cooperation, continual improvement, decision-making based on fact, and viewing organizations as a "system". These theories laid the groundwork of modern continuous quality improvement with Deming's 14 points. Deming and his colleague, Shewhart, promoted the PDCA cycle (Plan, Do, Check, and Act) which is still widely used today (ASQ - Deming, 2017) (Balanced Scorecard, 2015).

Joseph Juran (1904 – 2008)

Joseph Juran has been called the "father" of quality. Perhaps most importantly, he is recognized as the person who added the human dimension to quality, which broadened it from its purely statistical origins . Juran's approach was based on the idea that the quality improvement program must reflect the strong inter-dependency that existed among all of the operations within an organization's production processes.

Juran's concept of the "Vital Few and the Useful Many" helps organizations prioritize which quality improvement projects should be undertaken. In 1937 he created the Pareto Principle, or the 80 – 20 rule. In any organization, there will be a lengthy list of possible ideas for improvement. Since the resources to actually implement new ideas are limited, however, leaders must choose those vital few projects that will have the greatest impact on improving ability to meet customer needs. The criteria for selecting quality improvement (QI) projects include: potential impact on meeting customer needs, cutting waste, and gathering the necessary resources required by the project (Juran 2008).

In 1979 he founded the Juran Institute to provide research and solutions for organizations to manage quality. Juran developed his Juran Trilogy in 1986 as a standard reference for work on quality management. Quality planning is the process of understanding what the customer needs and designing all aspects of a system to meet those needs reliably. Designing a healthcare system to do anything less is wasteful because it does not meet patient needs. Once the system is put into operation, quality control is used to constantly monitor performance for compliance with the original design standards. If performance falls short of the standard, plans are put into action to deal quickly with the problem. Quality control then puts the system back into a state of "control" (i.e., the way it was designed to operate in the first place). Quality improvement occurs when new, previously unattained levels of performance, or breakthrough performance, are achieved (Juran, 2014) .

Juran developed the idea of instituting a leadership group or "Quality Council" consisting of the organization's senior executive staff. The Quality Council is typically charged with the responsibility for designing the overall strategy for quality planning, control and improvement. Senior leadership involvement is a must since QI activities are as important as other management tasks (e.g., budgeting, human resource management, purchasing and training), and leaders can integrate QI into every aspect of healthcare operations (Juran, 2014).

Philip Crosby (1926 – 2001)

Many of Philip Crosby's ideas came from his experience working on an assembly line. He focused on zero defects, not unlike the focus of the modern Six Sigma Quality methodology. In 1979, when he was a Vice President of the mega-conglomerate ITT, Philip Crosby turned his operating philosophy into the groundbreaking book *Quality Is Free* meaning that the absence or lack of quality is very costly to an organization, e .g., in money spent on doing things wrong, over, or inefficiently. Spending money to improve quality, to reduce waste, or improve efficiency, actually saves money in the long term (Crosby, 2015).

In 1979, Mr. Crosby founded his own company, Philip Crosby Associates, Inc., to educate others regarding quality management. Educating the entire workforce about quality principles, extensive measurement to document system failures, and formal programs to redesign faulty production processes was conducted in a step-by-step manner . Mr. Crosby defined quality as conform ity to certain specifications set forth by management and not some vague concept of "goodness." These specifications were not random; they were set according to what the customer needed and wanted .

Building quality into a process should occur early during the design phase. Rather than spending time and money on finding and fixing mistakes and errors, Crosby advocated for organizations to encourage their staff to do a job right the first time. Crosby challenged organizations to think of how processes can be designed or re-designed to reduce errors and defects to reach a goal of "zero defects". While "defect" is a manufacturing term, it equates to medical errors, and other such healthcare terms.

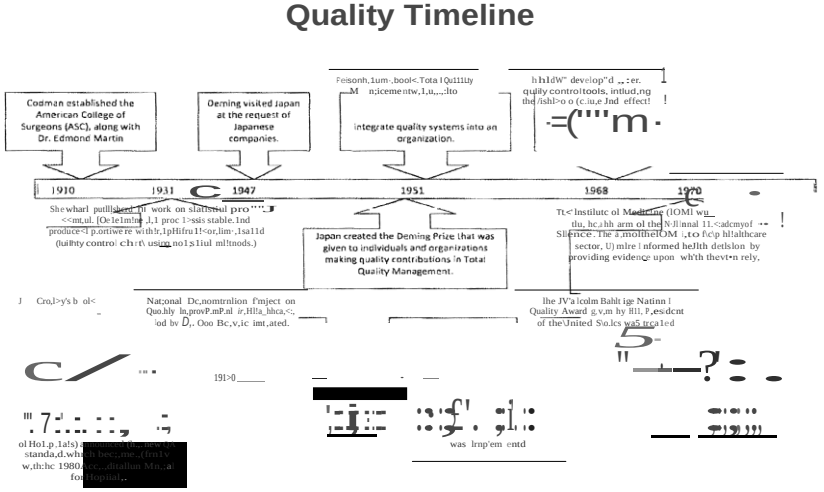
Crosby believed that leaders' policies and actions reflected their commitment to quality. If management does not create a system by which zero defects are clearly the objective, then staff members are not to blame when things go wrong and defects occur . Organizations using this approach saw dramatic dec reases in wasted resources and time.

Dr. Donald Berwick (1946 - present)

Donald M. Berwick is the cofounder of the Institute for Healthcare Improvement (IHI) and was President and CEO for 18 years. IHI is a not-for profit organization whose aim is to lead performance improvement throughout the world. Dr. Berwick left IHI in July of 2010 to become the Administrator of the Centers for Medicare & Medicaid Services (CMS), a position he held until December 2011. Dr. Berwick wa s also an elected member of the Institute of Medicine (IOM), serving two terms on the IOM's governing Council, and was a member of the IOM's Global Health Board. He served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. Dr. Berwick is currently the President Emeritus and Senior Fellow at the Institute for Healthcare Improvement (IHI) (IHI, 2017).

Dr. Berw ick has dedicated his life to transform ing the healthcare system with a focus on healthcare policy, decision analysis, technology assessment, and health care quality management. He has accelerated healthcare quality through emphasis on patient-centered care and care coordination. While at CMS, he was instrumental in the movement from fee for service medicine to treatment coordinated through accountable care organizations (Japsen, 2013).

Quality Timeline



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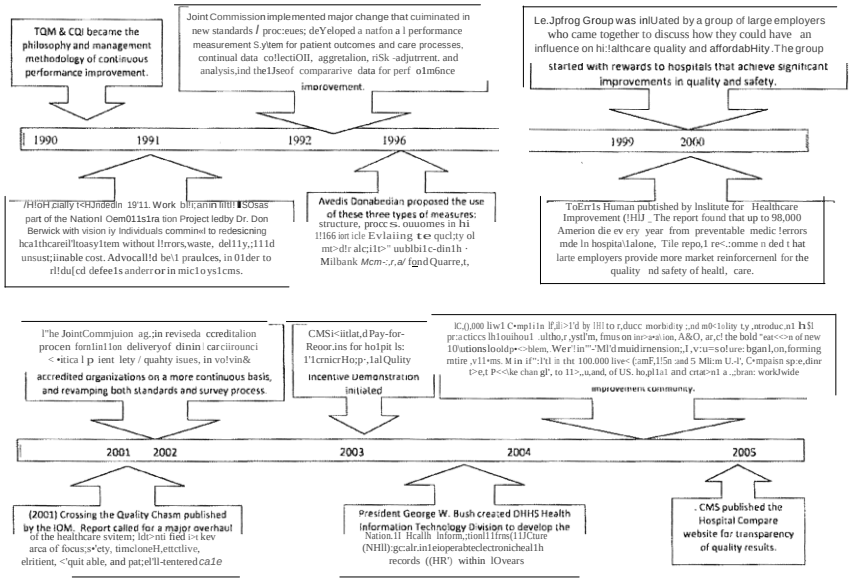

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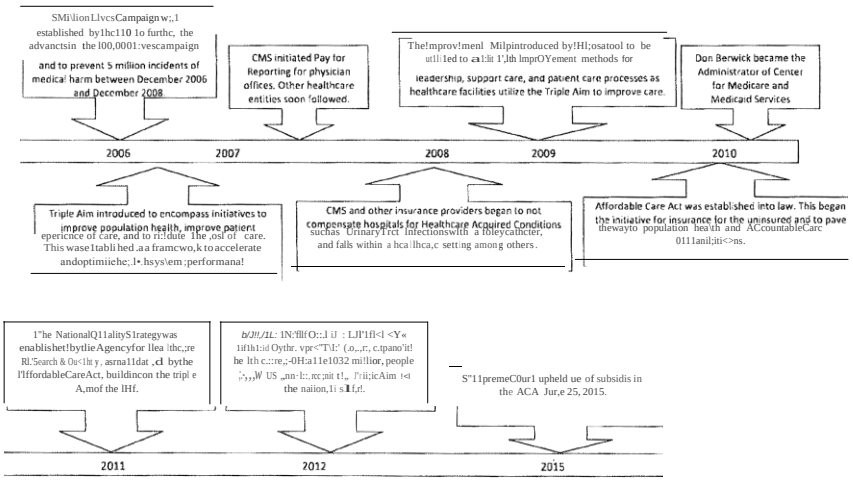

BASIC CONCEPTS OF HEALTHCARE QUALITY

Quality is best defined by the recipient of care or services. The Quality/Performance Management process is however a planned, systematic, organization wide (or network wide) approach to the monitoring, analysis, and improvement of organizational performance, thereby continually improving the quality of patient care and services provided and the likelihood of desired patient outcomes.

In today's healthcare environment, it is not possible to provide quality care without also attending to the costs and risks of care. Our evaluation of patient outcomes and the effectiveness of diagnosis and treatment must be placed within the context of appropriate use of available resources and level of care. Yet, of course, we are always monitoring for adverse outcomes-the obvious risk issues-as well as the expected positive outcomes.

The medical decision-making process taught to healthcare professionals h9s always sought to include the cost and risk consequences of one test, treatment, or procedure over another. Ultimately, the decision centers on that one with the potential for the greatest positive benefit for the patient . When the decision-making process poses a serious quality-cost-risk dilemma, we now consider it to be an ethical issue, and try to involve an appropriate team of professionals and family members to assist in making an appropriate determination.

In some ways, historically we have created confusion and have at least "unbalanced," if not biased, this decision-making process by having separate departments and/or persons monitor and administer the quality, the cost, the risk, and the continuity of care delivered to our patients. We know care should be coordinated, case-managed, measured, analyzed, and continually improved by one systematic process. We must make a concerted effort to build and formalize communication and information systems that ensure that quality, cost, and risk data and concerns are shared and used by all who participate in the delivery of patient care as described in Institute for Healthcare Improvement's (IHI) Triple Aim.

It is the business sector, particular ly the coalitions that contract with insurers, health plans and other managed care entities, independent review organizations, or directly with providers, now insisting on "value" in healthcare. Employers remain concerned about the rising costs of care, but now they are also requiring proof (positive outcomes) that the quality of care received is the best possible for dollars spent and that adverse outcomes are minimized. For many employers and consumers, the key concept is "value-added". It is a broad concept, considering clinical quality and annual cost increases. It includes issues related to access, convenience, service, relationships with physicians, safety, and innovation (Porter, 2010).

Value is difficult to define. Value should define the framework that is utilized for the quality management/improvement program of the facility. Value depends on the results not the inputs, and this should always be defined around the customer. Value is defined by the quality of care or service plus the outcome, divided by the cost (Figure 1) . The cost refers to the total costs of the full cycle of

care not the cost of individual services . Value should encompass all services or activit ies that determine the success of meeting the patient's needs (Porter, 2010). For example, if you go to a doctor's office and you have to wait 45 minutes past your appointment time to see the physician, or you do not get the chance to ask the physician all your questions, it does not matter what the cost of the visit is (free, co-pay, or other amount). The patient may not place value on the visit, particularly if the patient does not feel the practitioner listened to his/her needs.

Figure 1: Value Equation

$$\text{VALUE} = \frac{\text{QUALITY OF CARE/SERVICE + OUTCOME}}{\text{COST}}$$

There is increasing focus on a "value-based healthcare system", beyond value-based purchasing. The goal is transparency: enabling consumers to compare the quality and price of healthcare services, and make informed choices. To provide the value everyone wants, all stakeholders must agree on compatible definitions and measures of "value." "Value-based" must encompass operations, payment, purchasing, health behavior, and cooperation between all entities: providers, payers, employers, insurers, governments, and consumers.

Activities associated with improving organizational performance involve much more than the clinical aspects of care. There is increased emphasis placed on improving, in a prioritized approach, all the interrelated processes and services that impact the quality of care and affect patient outcomes: governance, managerial, and support activities, as well as clinical activities . Both the effective use of quality improvement techniques and the organization of activities around important organizational functions requires more front-line staff involvement in the process. Of course, the ultimate goal is to have everyone-in all healthcare organizations-committed to, and actively involved in, continuous improvement of the quality of patient care.

In healthcare delivery systems, the integration of cost, quality, and risk monitoring activities are happening within the context of a care coordination model across the network . There has been an increase in coordination in some "Integrated Delivery System" interdisciplinary team case management activities that are centered on the patient care process and are based upon a developed clinical path that includes preadmission and aftercare. An example is the disease management approach in managed care (for some chronic conditions such as asthma, hypertension, and chronic obstructive pulmonary disease (COPD), integrating primary care, acute care, and aftercare using validated practice guidelines.

The clinical path and/or practice guideline describes the expected process. All caregivers, and all those monitoring the care, track the patient along the path/guideline and intervene concurrently to affect a positive patient outcome. Aggregated and summary data is tracked and analyzed over time to look for system improvement opportunities (see Chapter 4 Performance and Process Improvement).

Quality Management Principles

The Basic Principles

The healthcare quality framework is based upon some "Basic Principles", utilizing Tota l Quality Management (TQM) philosophy ar;::: Continuous Quality Improvement (CQI) approaches . In 1990, Berwick, Godfrey and Roessner (1990) wrote the book, *"Curing Health Care: New Strategies for Quality Improvement"* outlining ten basic principles for Total Quality Management. These ten principles continue to apply today and they can be seen in Table 1. However, most of the literature now refers to the eight International Standard for Organizations (ISO) quality management principles. They form the basis of the ISO Quality Management System. These eight principles include aspects of Berwick's ten principles.

Table 1:Ten Basic Principles for Total Quality Management

Ten Basic Principles for Total Quality Management	
Principle	**Description**
Productive work is accomplished through processes	Each person in the organization is a part of one oi more processes. Everything we do is a process.
Sound customer-supplie r relationships are absolutely necessary for sound quality management	The c ustomer is anyone who is dependent on you as supplier. Healthcare customers include, but are not limited to: • Patients • Families and friends of patients • Physicians and other practitioners • Employees • Payers • Other healthcare providers • Reviewers/ regulators • Community
The main source of quality defects is problems in the process	The problem is more often due to a problem in the process itself than in the individual. If people do want to do the right thing, then the job of the manager/leader is more to enable their talents and energies than to monitor, control, and incentivize .
Poor quality is costly	Poor quality that results from flaws in processes, and then results in decreased customer satisfaction, costs

	in lost dollars, market share, lost time and materials, lost pride, and increased litigation.
Understanding the variability of processes is a key to improving quality	In healthcare, there are uncontrollable variations related to differences among individuals, organ systems, or diseases. Issues of patient compliance, practitioner techniques, and influences of comorbidities must be understood in order to account for them and accommodate them.
Quality control should focus on the most vital processes	Identify the most important types and components of processes that influence quality of patient care and improve those.
The modern approach to quality is thoroughly grounded in scientific and statistical thinking	Utilize scientific method/problem solving process to improve care as part of daily operational activities, like medicine does to a disease.
Total employee involvement is critical	Organizations must encourage and capture ideas from all employees. Those who know the most about process details must be empowered to improve them.
New organizational structures can help achieve quality improvement	A steering committee or "quality council" of top managers does the strategic planning for the training, technical infrastructure, procedures for problem selection, forms of recognition, and systems for evaluating and improving the overall effort itself .
Quality management employs three basic, closely interrelated activities: Quality planning, quality control, and quality improvement	This is the Juran Trilogy

The ISO eight quality management principles include customer focus, leadership, involvement of people, process approach, system approach to management, continuous improvement , factual approach to decision making, and mutually beneficial supplier relationships. These principles assist managers and others to focus on objectives, on systematic leadership, and on continual performance improvement. Table 2 lists the eight principles of quality management that the ISO quality management system is based on (ISO, 2015) (Hessen, 2015).

Table 2: ISO Principles of Quality Management System

ISO Principles of Quality Management System	
Principle	**Description**
Customer focus	Understanding current and future customer needs and expectations.
Leadership	Leaders establish and maintain an environment where employees can become fully involved in achieving the organization's objectives.
Involvement of people	People at all levels of the organization are fully involved in the organization. This will result in retaining competent employees, enabling their knowledge and skills, and leading to their empowerment.
Process approach	Processes must be managed by the leaders, and related resources provided.
System approach to management	Systems management and systems thinking leads to effectiveness and efficiency in achieving objectives.
Continuous improvement	A continuous focus on performance improvement should be a permanent objective of the organization with all personnel contributing.
Factuai approach to decision making	Analysis of data and information will lead to effective decision-making.
Mutually beneficial supplier relationships	The organization and its suppliers are interdependent and a good relationship between them creates value for all.

Distinguishing Services from Products

A key concept that distinguishes healthcare quality from other forms of quality is the difference between products and services. Healthcare is a service driven industry, while manufacturing is a product driven industry. Most of the quality basic principles and tools have originated in the manufacturing industry.

A product can be measured and counted. It is tangible and noticeable items that an organization produces. In production of a product, there is little variation from one product to the next.

A service is less concrete. It is a combination of skills and expertise, which are intangible and cannot be measured, tested, or verified in advance . A service may have high variation from provider to provider, customer to customer, and from day to day. Needs, expectations, and specifications must be communicated very clearly, and in a timely manner, or the service may be perceived unsuccessful.

Even though the associated healthcare processes may be stable, the dynamics involved in provision of a service perish once delivered. Moreover, if the service opportunity is lost, it may be that it cannot be recouped. How a delivered service is remembered by the patient and other customers, however, is not perishable-hence the value of satisfaction surveys.

Since healthcare is a service, we must be sensitive to these differences from quality products (goods). A particular industrial model of quality improvement may provide helpful ideas, but healthcare quality requires a balanced, integrated approach to measurement, analysis, and improvement that appreciates these unique service characteristics.

Total Quality Management

The concept of "Total Quality Management" (TQM) as advocated by management theorists and industrial engineers has been adopted by healthcare leaders. Total Quality Management is a broad management philosophy, espousing quality and leadership commitment that provides the energy and the rationale for implementation of the process of Continuous Quality Improvement (CQI) within the organization wide Quality Strategy. The principles from Berwick and from the ISO discussed above are applicable in TQM.

TQM is an organization wide management philosophy and top-level commitment to provide "value" to all customers through creating an environment of continuous improvement of people skills and processes and building excellence into every aspect of the organization . The TQM philosophy enhances and benefits the organization and all people associated with it by utilizing processes that continuously improve the quality of all products, services, and information. Utilization of TQM philosophy results in increased customer satisfaction, increased productivity, increased profits, increased market share, and decreased costs . TQM broadens the umbrella of Quality Management to encompass the entire organization with an increased top-down and bottom-up emphasis on quality, with top managers demonstrating leadership for the constant improvement of quality care, being responsive rather than directive. TQM also has a decreased emphasis on inspection, surveillance, and discipline and a focus on systems rather than individuals.

Some of the concepts espoused in TQM date back to the 1920s and 1930s. Walter J . Shewhart in 1931 wrote, *"The Economic Control of the Quality of the M anufactured Product"* (Shewhart, 1980) and argued for a major philosophical change in industrial inspection. Efforts were directed not at finding and fixing problems in products through end-point inspection, but at finding and fixing problems in work processes. W . Edwards Deming and Joseph M. Juran assisted the Japanese after W.W.11 to apply these methods in manufacturing as well as design, marketing, distribution, sales, and service delivery. However, most of the credit for what the Japanese call "Total Quality Control" and continuous improvement *(Kaizen)* goes to Taiichi Ohno and Kaoru Ishikawa.

Taiichi Ohno developed the famed Toyota production system . He created the concepts of "Just-in-

Time" production and "flexible manufacturing". He promoted the goal of total elimination of waste, formed workers together in teams with a team leader rather than a foreman, created suggestion meetings called "quality circles," developed the problem-solving system called the "Five Whys" to search for root causes, and designed the "automation" system to shut down machines automatically if they produce a defective part. Benefits to Toyota in increased productivity and equipment capacity and reduced manufacturing lead-time, costs of failure, costs of materials, inventories, and space requirements are well documented (Kaizen Institute, 2013).

Ishikawa's contributions include the focus on the customer and a very broad definition of quality. Ishikawa's fundamental message was to commit to continuous improvement throughout the entire organization. Fix the problem, not the blame. Strip down the process to find and eliminate problems. Identify the customer and satisfy customer requirements. Eliminate all waste. Instill pride in performance, encourage teamwork, and create an atmosphere of innovation. He encouraged participation by all levels of the work force (vertical integration of quality) as well as by all functions (horizontal integration of quality). He also merged the ideas of the other "gurus" with his own and developed techniques he called the "Seven Tools" to empower workers: Pareto charts, cause-and-effect diagrams, stratification, the check sheet, the histogram, the scatter diagram, and Shewhart control charts (Skymark, 2017).

Continuous Quality Improvement Process

Continuous Quality Improvement (CQI) can be used interchangeably with "Quality Improvement" (QI) to mean a management process or approach to implementing the TQM philosophy through the continuous study and improvement of the processes of providing health care services. CQI is the English translation of *Kaizen,* the Japanese word for "improvement" and a philosophy focusing on continuous improvement as a daily activity throughout one's life. In the Toyota Production System, as in other businesses post-WWII, it sought to improve standardized activities and processes and eliminate waste on a daily basis. The CQI process itself has a history similar to that of TQM, with many of the same names and instructors.

According to the National Learning Consortium (2013), the key to any CQI initiative is to utilize a structured approach, such as Plan-Do-Check-Act, to evaluate the current practice processes, and then utilize various tools to improve systems and processes to achieve the desired outcome. The tools should include strategies that enable team members to assess and improve health care delivery and services. The National Learning Consortium has developed the *Continuous Quality Improvement (CQI) Strategies to Optimize Your Practice* document to assist organizations in implementing CQI effectively in their organization. This document can be obtained through their website listed in the website list at the end of this chapter.

Continuous Quality Improvement requires top corporate and organizational commitment of mission, money, management, material, and an organizational culture that daily talks and acts like quality. An

identification of, understanding of, and focus on customers and their needs and expectations are also crucial, as is an ongoing pursuit of customer satisfaction. CQI requires a team emphasis on perfecting systems and processes in the delivery of patient care to affect good outcomes. The organization should also be one that embraces constant learning and improving. The remaining chapters of this book will expand on these concepts of continuous quality improvement .

National Quality Strategy

The National Qua lity Strategy (NQS) was established in 2011by the Agency for Healthcare Research & Quality (AHRQ), as mandated by the Affordable Care Act, building on the Triple Aim of the Institute for Healthcare Improvement (IHI). The NQS serves as a catalyst and a compass for the healthcare quality improvement efforts of the United States. It is guided by the same three goals as the IHi's Triple Aim: provide better care, healthy people/healthy communities, and affordable care (AHRQ – NQS, 2017). To achieve these aims, the National Quality Strategy focuses on six priorities that address the range of healthcare quality concerns (see Table 3).

Table 3: National Quality Strategy Six Priorities

National Quality Strategy Six Priorities
• M.:iking care safer by reducing harm caused in the delivery of care. • Ensuring that each person and family is engaged as partners in their care. • Promoting effective communication and coordination of care. • Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease. • Working with communities to promote wide use of best practices to enable healthy living. • Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

Adapted from Agency for Healthcare Research & Quality-NQS, 2017

Core business functions, resources and/or action that stakeholders can use to align their work with the NQS comprise the nine levers of the strategy (Table 4). These levers are already being used by many businesses, but they have not been associated with the NQS initiative.

Table 4: National Quality Strategy Levers

National Quality Strategy Levers	
Lever	**Description**
Measurement and feedback	Provide performance feedback to plans and providers to improve care
Public reporting	Compare treatment results, costs and patient experience for consumers

Learning and technical assistance	Foster learning environments that offer training, resources, tools, and guidance to help organizations achieve quality improvement goals
Certification, accreditation, and regulation	Adopt or adhere to approaches to meet safety and quality standards
Consumer incentives and benefit designs	Help consumers adopt healthy behaviors and make informed decisions
Payment	Reward and incentivize providers to deliver high-quality, patient-centered care
Health information technology	Improve communication, transparency, and efficiency for better coordinated health and healthcare
Innovation and diffusion	Foster innovation in health care quality improvement, and facilitate rapid adoption within and across organizations and communities
Workplace development	Investing in people to prepare the next generation of health care professionals and support lifelong learning for providers

Adapted from Agency for Healthcare Research & Quality - NQS, 2017

AHRQ is utilizing the NQS to address the many clinical quality measures that organizations are required to report to Health and Human Services (HHS) and other federal agencies . The HHS Measurement Policy Council (MPC) has been working since 2012 to align measures across HHS to establish a core set of measure definitions. The HHS agencies are expected to utilize these core set of measures whenever possible. The following nine topics are what the Council has addressed to this point: hypertension control, hospital-acquired conditions/patient safety, HCAHPs, smoking cessation, depression screening and care coordination, HIV/AIDS, perinatal, and obesity/BMI. The MPC recommends that others than just the federal government agencies adopt these measures into their quality programs (AHRQ – NQS, 2017).

The Concept of Customer

Customer satisfaction is viewed in healthcare as an essential component of success in delivering quality as well as in economic survival. A *customer* is one who receives goods or services. It is a concept utilized in Total Quality Management philosophy to identify the needs, expectations, and preferences of all who are affected by the healthcare services we provide. Customers are our "dependents"; they rely on us for a service or product. *External customers* include the patient, family, and others outside the organization receiving services from the organization or vendors. *Internal*

customers are those performing work, but dependent on others performing work, within the organization.

Healthcare customers provide a perceptive quality perspective. Both internal and external customers tend to focus on how services meet their perceived needs and whether their expected outcomes are met. Patients add to the interpretive mix their perceptions of caring associated with the service and their sense of well-being and quality of life as outcomes of the care.

Healthcare Quality and Customer Satisfaction

Annualiy, Deloitte LLP conducts a survey of healthcare consumers, and their most recent published survey results in 2013 indicated that consumers do not believe that the U.S. healthcare system is meeting their needs nor providing value. In this study, the consumers also indicated that affordability of health care concerns them (Deloitte, 2014) .

Value for the consumer includes the price of care, interpersonal interactions, and the quality of the service received. The study also indicated that the availability of the transparent information and tools to facilitate the effective navigation within the hea lthcare system is important. Three takeaways from this study directly impact healthcare quality. The first is that healthcare needs to offer a better customer experience, with more choice of products (i.e. health plan options with greater transparency of quality and cost information), in addition to convenience and customer care. Secondly, the organization should also offer websites displaying healthcare information that is easy to read and understand, as well as quality and price information about the facility. The third takeaway advises the healthcare system to look towards the future, when the Gen X and Millennial populations will want to use interactive technology to obtain this information (Deloitte, 2014) . Further information concerning customer services and satisfaction will be discussed in other chapters of this book.

The Responsibility of the Healthcare Quality Professional

It is important for healthcare quality professionals to understand the principles of both Total Qua lity Management and Continuous Quality Improvement. They must articulate to all administrative and governing body leaders how TQM philosophy, with the processes of performance measurement, analysis, and improvement; and the development of an effective Healthcare Qua lity Strategy, are necessary and compatible with the organization's financial health, and, making the Strategic Plan achievable.

In the past, many healthcare decision makers in the U.S. misunderstood what the quality process was, or was intended to be, and so "boxed it in" and confined it to meeting accreditat ion standards . They may have failed to make the critical organization wide philosophical and financial commitment to quality. Now leaders need data and information demonstrat ing the value of quality that is linked to reduced risk, reduced costs, and better patient outcomes. The quality professional's role is to

understand, teach, and guide the development and implementation of the Strategy and processes, with the effective use of data and information, to make wise improvements and effect positive change.

Integrating Quality Functions

In the current healthcare environment, systems thinking has emerged as one of the most important aspects. The different quality roles and functions cannot continue to work in isolation of the others. Silos will not work and the healthcare quality professionals must work to break down the walls between th1=se silos. C:ollc1b_or_c1tjon cmd teamw_ork are the essential requirements for quality systems management to be developed, implemented and sustained in order to have effective continuous quality improvements.

> "Interdisciplinary collaboration is commonly described using the terms problem-focused process, sharing, and working together. The elements that must be in place before interdisciplinary collaboration can be successful are interprofessional education, role awareness, interpersonal relationship skills, deliberate action and support. Consequences of interdisciplinary collaboration are beneficial for the patient, the organization, and the healthcare provider" (Petri, 2010, p. 73).

Interdisciplinary collaboration is needed to balance care decisions, incorporating quality, cost, and risk issues; to reduce duplication of effort, share appropriate information, and increase efficiency; to increase and improve communication and continuity of patient care and services; and to improve accountability through effective use of data.

Different quality management roles have much in common. They face the same obstacles within the organization, and there is an overlap of many of the quality functions. Integration seeks to coordinate or combine staff and time resources, measurement and assessment processes, responses to patient care management and service delivery issues. Integration also applies to the information systems, including .i common database, tracking over time, profiling,and reporting.

Many functions and tasks comprise the important quality roles. Quality management professionals do not need to be masters of all of them, but there should be some knowledge about the various roles and functions so as to enable collaboration. The success of the key responsibilities of Quality Manager and the effect ive use of information for organizational decision-making, are directly proportional to the degree of integration of data/information, the coordination of improvement effort, and timely effective communication. Table 5 will briefly list some of the important functions of each of the different quality roles. There are many others, but this is a beginning list.

Table 5: Important Roles and Quality Functions

Important Roles and Quality Functions	
Quality Role	**Important Functions of Role**
Quality Management (QM)	• Patient outcomes and care delivery process measurement, analysis, interpretation, and reporting • Patient safety planning, program implementation, measurement, etc.,as above • Clinical performance monitoring, including complications; appropriateness of procedures; adherence to practice guidelines, protocols, or clinical paths • Organizational systems assessment , e.g., structure; operational processes; quality controls; written policies, procedures, and protocols (looking for opportunities to improve quality and efficiency and minimize risk) • Organization performance improvement process, including training, team support, measurement and analysis support, documentation, evaluation, and reporting
Patient Safety Management (PS)	• Patient safety planning, program implementation, measurement, etc. • Patient outcomes and care delivery process measurement, analysis, interpretation, and reporting
Utilization Management (UM) (sometimes called Case Management, or Medical Management)	• Review medical necessity and appropriateness • Resource allocation: timeliness, appropriateness, efficiency, and cost • Role of Case Management/Discharge Planning in some organizations
Case Management/Discharge Planning (CM/DP) (Sometimes called Transitions of Care or Care Coordination)	• Screening and assessment • Appropriate resource/support allocation • Care coordination and aftercare planning
Risk Management (RM)	• Clinical occurrences and claims • Environmental, e.g., safety and preventive maintenance • Mitigation of the effects of negative outcomes on both the organization and the patient
Infection Control (IC)	• Surveillance, identification, isolation

	• Patterns and trends • Guidelines, policies, and procedures • Education and training
Practitioner credentialing, privileging, and competency appraisal	• All independent practitioners, specific requirements depending on the setting • Medical Staff (U.S. hospitals) at time of appointment and reappointment • To a more limited degree, all employees/contract staff who provide direct patient care, through skills/competency evaluation
Continuing medical/clinical education	• Orientation to the components of a comprehensive quality management program and the interrelationships of cost, quality, and risk issues • Knowledge of, and conformance with, performance standards, policies, procedures, and documentation standards • Knowledge of, and conformance with, professionally accepted standards of patient care and practice guidelines
Professionals performing any of the first four components (QM, UM, RM, and IC)	• Data collection, summarization, and aggregation • Information analysis, display, and presentation • Information interpretation, sharing, and use • Ongoing effectiveness oversight

communications within the organization

Today's Healthcare Quality Environment and the Healthcare Quality Professional

The only constant in healthcare today is change. This change is occurring at an ever-increasing pace and shows no signs of slowing within the next decade. New healthcare quality measurement requirements are expanding exponentially as attempts are made to change the way the United States provides healthcare. The healthcare quality professional must be able to adapt to these changes, and to assist others in their organization to change also, in their perspective and the ways that they work, to improve the quality of services provided.

It is no longer acceptable to be simply a quality improvement, utiliz.:ition management, or risk management specialist. Cross training and the adaption of new skills will be required for all positions in healthcare quality *over* the next decade . Healthcare professionals may function in a setting of inpatient or outpatient care, physician's office, portable Ready-Clinic, post-acute care, long-term care, rehabilitation, psychiatric facility, insurance company, or other setting not yet identified. The healthcare professional will require a set of skills that are transferable between settings as well as to

different levels of positions such as a corporate office, the bedside, or anywhere in between. National, state, and regional healthcare related organizations are proliferating in this environment and offering yet another set of experiences for the healthcare qua lity professional.

Many individuals view a position in healthcare quality as a 'step-up' from bedside care, or management positions. Many of these individuals may have experience of participation in healthcare quality improvement teams and other performance improvement experiences in their previous position. However, in order to function in the healthcare quality arena itself, certain competencies are required that many of these individuals do not possess at the time they are hired into these positions. Thus, they have a very steep learning curve that is constantly changing as they try to add the necessary knowledge, skills and attitudes needed to do these jobs.

Competencies of the Healthcare Quality Professional

In 2003, the Institute of Medicine (IOM) released a report entitled *Health Professional Education: A Bridge to Quality* (Greiner & K nebel, 2011). The report recommended that there be a summit of interdisciplinary healthcare leaders and other interested parties, to establish strategies on how to improve clinical health education relating to the five competency a reas identified in the *Quality Chasm* report. The five competency a reas include patient-centered care, interdisciplinary teams, evidence-based practice, quality improvement, and informatics. The Committee on Health Professional Education Summit was held in June 2002. The participants worked in small groups to generate ideas and recommendations on how to meet these competency areas. The committee completed a literature review related to these five competencies and the recommendations that were received from the participants. The resulting five core competencies were recommended to be implemented in all curriculums, regardless of discipline, to meet the needs of the current health care system and the one to be developed in the future. How the core competencies are implemented will vary between disciplines, but they remain the core competencies utilized by healthca re disciplines, such as nursing. The committee recommended that organizations move toward implementing these competencies in the curriculums of these programs.

In 20 16 IOM continued the process of developing core competencies and in a six month iterative process developed Learning Health System Researcher Core Competencies (AHRQ, 2017). Thirty three competencies were developed in seven specific domains: (1) Systems Science; (2) Research Questions and Standards of Scientific Evidence; (3) Research Methods; (4) Informatics; (5) Ethics of Research and Implementation in Health Systems; (6) Improvement and Implementation Science; and (7) Engagement, Leadership, and Research Management.

Healthcare Quality Essentials

In Spring 2015, the National Association for Healthcare Quality (NAHQ) published the first of six groups of essential abilities for healthcare qua lity professionals. Named *Q Essentials,* the s ix groups of

competencies, when completed, will involve the following areas: Health Data Analytics, Population Health and Care Transitions, Performance and Process Improvement, Regulatory and Accreditation, Quality Review and Accountability, and Patient Safety. Using a serial, rapid cycle development process, the organization is developing information on which to perform a self-assessment of one's development in the quality field. In 2017 all Six areas of competence were published: performance improvement and process improvement; population health and care transitions; health data analytics; patient safety; regulatory and accreditation; and quality review and accountability. These six areas are overlapping and interconnected because they share certain knowledge and skill requirements (NAHQ, 2017). More information can be found through their website found in the website list located at the end of this chapter.

Quality and Safety Education for Nurses (QSEN)

While the Institute of Medicine (IOM) report called for all educational programs to develop competencies, in nursing this fell to a group of nursing activists who took it upon themselves to work with Robert Wood Johnson Foundation (RWJF) and obtain a grant to develop these competencies for nursing curricula . Although these were developed for nursing, they are useful to all disciplines in healthcare. The OSEN educational competencies were developed in 2005 based on the five competencies recommended by the IOM for all health professional students. An additional competency was added for safety (Table 6). There were four phases to the development of the QSEN competencies, all of which continued with the funding of the RWJF (QSEN, 2014).

In Phase I,fifteen pilot schools were involved with the QSEN group in developing strategies and quality and safety education tools. These initial efforts grew into a network of innovative educators and practitioners with the vision of changing the basic education of nurses, in order to allow nurses to create a safer healthcare system . The competenc ies teach nursing students to focus on continual improvements in quality and safety for patient care. In Phase I, the pre-licensure education competencies for each of the six domains were established. Table 6 displays the QSEN six domains and the competencies of each domain (Kelly, Vottero, & Christie-McAuliffe, 2014).

For each competency, KSA's (Knowledge, Skill, and Attitude) were developed that are essent ial for mastery of each competency. There are 162 KSA's that are associated with these six competencies. Each KSA was evaluated as to what level in the prelicensure program the KSA would fit with the nursing curriculum. Three levels were defined as beginning level (first nursing education courses), intermediate level (middle of nursing education program) and advanced level (just before graduation) (Kelly et al., 2014).

Phase II occurred from 2007 to 2009 . During this phase, a Pilot School Learning Collaborative was developed.The fifteen schools were to develop different teaching strategies as to how the KSAs could be integrated into the prelicensure curriculum . In this phase, the graduate program competencies were also developed (Kelly et al., 2014).

The Phase Ill work was accomplished between 2009 and 2012. This phase focused on furthering the integration of teaching strategies into the curriculum, training faculty to uses these strategies to teach the QSEN competencies and KSAs, and creating sustainable mechanisms to continue the change throughout nursing education programs. Textbooks, accreditation and certification standards and licensure exams were created or modified to include these competencies (Kelly et al., 2014).

Phase IV began in 2012, when the Tri-Council for Nursing was established, as a two year initiative to further educate the licensed nurses in these competencies at the state and regional levels. The Tri-Council for Nursing is an alliance between the American Association of Colleges of Nursing, the American Nurses Association, the American Organization of Nurse Executives, and the National League for Nursing: The National Council of State Boards of Nursing was added to the Tri-Council in November 2014 (Kelly et al., 2014).

Learning modules for competency, developed for all undergraduate and graduate nursing education levels, are available through the American Association of Colleges of Nursing, a member of the Tri-Council. This process is continually evolving and more work is being done on graduate level competencies. More information can be found through their website found in the website list located at the end of this chapter.

Table 6: QSEN Domains & Competencies

QSEN Domains & Competencies	
Domains	**Competencies**
Quality Improvement (QI)	Use data to monitor the outcomes of care processes and use improvement methods to design and test changes to continuously improve the quality and safety of healthcare systems
Safety	Minimize risk of harm to patients and providers through both systems effectiveness and individual performance
Teamwo rk and Collaboration	Function effectively within nursing and interprofessional teams, fostering open communication, mutual respect, and shared decision-making to achieve quality patient care
Patient-centered Care	Recognize the patient and designee as the course of control and full partner in providing compassionate and coordinated care based on respect for patient's preferences, values, and needs
Evidence Based Practice (EBP)	Integrate best current evidence with clinical expertise and patient/family preferences and values for delivery of optimal health care
Informatics	Use information and technology to communicate, manage knowledge, mitigate error, and !;Upport decision making

Core Competencies for Performance Improvement Managers in Public Health

Another non-profit organization, The Public Health Foundation (PHF), strengthens the quality and performance of public health practice. Since 1970, PHF has developed effective resources, tools, information, and training for health agencies, organizations, and individuals to help improve performance and community health outcomes. PHF (2017) developed competencies in 2011, including areas such as monitoring and evaluation of programs, implementation of system-wide strategies, and evaluation of results. The use of systems thinking, analysis of data and determining cost effectiveness are also included. More information regarding these competencies can be found in the website list at the end of this chapter.

Comparison of Competencies

Core elements exist in all sets of competencies. Quality/Performance Improvement appears in all three lists. This includes the core work of the individuals involved in demonstrating and communicating quality. The Institute of Medicine and QSEN Competencies address specific areas of competence for those in healthcare disciplines. The NAHQ model is in its infancy but appears to be headed in the same direction. As stated earlier, a quality professional does not have to have a clinical background and some of the IOM and QSEN competence areas such as teamwork, collaboration, evidence-based practice and informatics do not require a clinical background. The Public Health competencies are more focused on the establishment and maintenance of a program within the public health sector. These are four approaches to looking at the competence of those involved in healthcare quality. They include the overarching expectations, but there are many basic elements of a quality professional's role that fall under each of these elements. One can expect them to expand and change as the field morphs into the expanded role in the future. There are and will continue to be different associations that will lend their expertise and outline the areas where the healthca re quality professional needs to be focused.

CERTIFICATION FOR THE HEALTHCARE PROFESSIONAL

Professional certification is a voluntary process where an individual can establish validation of a set of skills and experience based on predetermined and standardized criteria. Certification is typically granted by a non-government entity and is a time-limited recognition. Professional certification demonstrates a high level of achievement and is not earned by simply being in a position that encompasses the topics of the certification. It validates proficiency and commitment to your profession.

There is a large difference between earning a certificate and having a certification. Certificate programs typically are based on a knowledge test, but not necessarily a proficiency test. Attending an education program and receiving a certificate after the program is not professional certification. It simply is a certificate of attendance or a certificate stating that the individual has a set of knowledge. Be careful as some programs offer a certificate but advertise it as a certification . The Institute for

Credentialing Excellence (ICE, 2017) has developed a table that compares a certificate with a professional certification. Table 7 demonstrates an adaption of this information and that found in other sources.

Table 7: Certificate vs. Certification

Certificate vs. Certification	
Assessment Based Certificate Program	**Professional or Personal Certification Program**
Results from an educationa l process – Goal is for participants to acquire new knowledge, skills, competencies	Results from an assessment process of knowledge, skills and/or competencies acquired previously – Goal is to validate competency/proficiency through assessment system
Both newcomers and professionals alike	Requires a set amount of professional experience in the certification area
Awarded by Educational programs or institutions and related to program education	Awarded by a third party, or standard setting organization, independent of a learning event
Content set in a variety of ways	Content set by job analysis/role delineation that result in outline of required knowledge (Criteria based assessment)
Content is narrow in scope	Content is broad in scope
Indicated on resume detailing education, such as a master's certificate	Indicated as a designation after one's name, such as CPHQ
Requires no more education on the topic	Requires ongoing education to maintain; Holder has to demonstrate continued proficiency with the requirements

Certification Benefits for Individuals

Many individuals ask why they need to be certified in healthcare quality. There are multiple reasons to be certified. Perhaps the most important one is for yourself . Certification demonstrates to you and others that you hold advanced expertise in your field. It should be displayed proudly after your name, with the certificate displayed at your work or home. It demonstrates your commitment to your career, to your patients/customers, and to quality and safety.

Certification, especially in healthcare quality, is becoming a requirement to be able to be hired or promoted within an organization. If all else is considered equal, if one applicant is certified and one is not, chances are that the certified individual will get hired for the position.

Certification Benefits for Patients and Families

Many patients know that professional certification leads to higher competency in individuals. Patients are also aware of Magnet organizations (Magnet is a designation that the quality of nursing care is at the highest levels). They may choose to have their healthcare provided at particular facilities, knowing the nurses are held to higher standards.

Certification Benefits for Employers

Certification requires continued education and drives increased job satisfaction. When employers support certification and provide resources to obtain ...,;cl maintain that certification, employees are happier, and there is an improvement in recruiting and retention rates for that professional environment. Employers who support certification are highly valued in a highly competitive market. Some insurance providers for healthcare organizations offer discounts for certification of employees, as the employees are typically exposed to less risk and make more informed decisions.

Healthcare Quality Certifications

There are currently four healthcare quality certifications that can be obtained:Certified Professional in Healthcare Quality (CPHQ) from the National Association for Healthcare Quality (NAHQ); the Certified Health Care Quality and Management (CHCQM) certification from the American Board of Quality Assurance and Utilization Review Physicians (ABQAURP); the Certified Manager of Quallty/Organlzationai Excellence (CMQ/OEi from the American Society for Quality (ASQ) and Healthcare Accreditation Certified Professional (HACP) from the Center for Improvement in Healthcare Quaiity (CIHQ).

There are also certifications in specific areas such as Patient Safety, Credentialing, Risk Management, Health Information Management,accreditation bodies, and other parts of healthcare quality.

Certified Professional in Healthcare Quality (CPHQ) Certification

The CPHQ certification was developed by the National Association for Healthcare Quality (NAHQ) and is designed for individuals who have experience in the healthcare quality field. Any person with experience in healthcare quality may sit for the exam. While not required, a minimum of two years of experience in this field is suggested. However, depending on where and what that experience was, an individual may not be prepared to take the exam after the 2 years. The exam is designed for the experienced professional who can demonstrate the competencies of the topics on the Content Outline. In order to sit for the exam, the individual does not have to be a member of NAHQ. The key subject areas for the exam are listed in Table 8 and a more detailed content outline can be found at the end of this book or obtained from the website (CPHQ, 2017).

As of 2016, there were 9,687 CPHQ certified professionals, of which approximately 1,940 were newly certified that yea r. The United States pass rate of the exam for 2016 was 73%, with an average U.S.

pass rate of 76% over the previous 4 years. The exam may be taken any day during the year, except for some holidays, at a designated testing site in an area near where the candidate lives. The exam is three hours long, and has 125 questions, plus 25 additiona l preliminary questions being tested for their reliability and validity. The questions in the exam will come from the four domains (Table 8) and they will be 23% recall, 57% application, and 20% analysis. The results are known by the candidate at the end of the exam. If the candidate passes the exam, the letters CPHQ may be utilized immediately. The cost of the exam will vary based on NAHQ membership. CPHQ certified individua ls are required to maintain their certificat ion with 30 hours of continuing education every 2 years, based on the current content of the exam (CPHQ, 2017).

Table 8: CPHQ Core Content in Exam Content Outline (2018)

CPHQ Core Content in Exam Content Outline (2018)	
Domain	**Categories Within the Domain**
Organizational Leadership (35 items)	Structure & Integration
	Regulatory, Accreditation, & External Recognition
Health Data Analysis (30 items)	Design & Data Management
	Measurement & Analysis
Performance and Process Improvement (40 items)	Identifying Opportunities for Improvement
	Implementation & Eva luation
Patient Safety (20 items)	Assessment & Planning
	Implementation & Evaluation

Health Care Quality and Management (CHCQM) Certification

The HCQM certification was developed by the American Board of Quality Assurance and Utilization Review Physicians, whic h was established in 1977. The certification exam is open to physicians, nurses, and other healthcare workers. The key concepts of the exam are listed in Table 9 (CHCQM, 2017).

In order to sit for the exam, the individual does not have to be a member of ABQAURP . However, they must hold a current non-restricted license in each state in which licensed. They must also have 20 hours of ABQAURP approved continuing education in at least one of the main exam categories, provide 2 colleague or supervisor letters of recommendation/references, and have a professional working knowledge of the English language.

The exam is held once per year during an exam window which for 2018 is from August 15th to October 15th. The exam will be taken at a testing site on a date within the testing window . The exam is four hours long, has 175 multiple choice questions, and the results will be known to the candidate at the

end of the exam period (i.e.: in 2018 – after October 15th). If the candidate passes the exam, the letters CHCQM may be utilized immediately. The cost of the exam will vary based on membership and other factors. Recertification time frame begins January 1st following the passing of the certification exam. Diplomats are required to maintain their certification with a minimum of 8 hours of continuing education as relevant to fields of health care quality and management every 2 years.

ABQAURP also provides several sub-specialty Certifications in Physician Advisor (physicians only), Transitions of Care, Managed Care, Patient Safety/Risk Management, Case Management, and Workers Compensation. In order to sit for these sub-specialty certification exams, the candidate must be a Diplomat in the organization, which indicates current HCQM certification prior to sitting for the sub-specialty certification exam(s), along with several other requirements.

Table 9: HCQAURP Exam Core Body of Knowledge (CBK) Concepts

HCQAURP Exam Core Body of Knowledge (CBK) Concepts
• Patient Safety
• Transitions of Care
• Accreditation Organizations
• Insurance and Managed Care
• Workers Compensation
• Case Management
• Clinical Resource Management
• Credentialing and Privileging
• Quality Improvement, Quality Management, and Quality Assurance
• Risk Management
• Regulatory Environment

American Society for Quality (ASQ) Certification

There is one other certification in quality and organizational excellence that many people are aware of. However, this certification is not designed especially for the healthcare quality professional, but rather for quality professionals in any industry. The American Society for Quality (ASQ)'s Certified Manager of Quality/Organizational Excellence (CMQ/OE) requires ten years of on-the-job experience in one or more areas of the body of knowledge for this certification. A minimum of five years must be in a decision-making position with the authority to define, execute, or control projects/processes and be responsible for the outcome. However, a process to waive some of the required years of experience possible based on the degree you have achieved from a school whose accreditation is accepted by ASQ. This exam is a two-part process consisting of 150 multiple choice questions and 2 essay

questions. Table 10 displays the body of knowledge areas that are covered on this exam (CMQ/OE, n.d.).

Table 10: Certified Manager of Quality/Organizat ional Excellence Body of Knowledge Concepts

Certified Manager of Quality/Organizational Excellence Body of Knowledge Concepts
• Leadership • Strategic Plan Development and Deployment • Management Elements and Methods • Quality Management Tools • Customer-Focused Organizations • Supply Chain Management • Training and Development

Related Certifications

Many other healthcare certifications are related to the healthcare quality certifications. In the recent past certifications in the fields of patient safety, compliance, quality in other industries, and so on, has been developed. In addition to these, each healthcare profession has multiple certifications that are applicable to their profession. The ANCC Certification Center, as we!! as the Accreditation Board for Specialty Nursing Certification has information about the various nursing certifications that are available. A list of many of the other healthcare certifications can be found on the internet using the search words healthcare certification and other related terms .

Certificate Programs

There are certificate educational programs that can be taken to advance one's knowledge in the healthcare quality fields . Some are complete programs and some are simply modules from which that the learner can pick and choose.

The *Institute for Healthcare Improvement* established in 2008 is an "Open School" where individuals can take online certificate courses. The courses are free for students, residents, and faculty, but an annual fee is required for other individuals and organizations . Currently there are 30 online courses in six modules: Patient Safety, Improvement Capability, Leadership, Person-and-Family-Centered Care, the Triple Aim for Populations, and Graduate Medical Education. The courses were all updated in August 2016. These courses are approved by NAHQ to provide CPHQ Continuing Education (CE) credit. As of December 2017, over 115,600 basic certificates were earned, and over 486,440 students have completed at least 1course. There are over 611,460 students and professionals taking these courses and over 1,000 healthcare organizations utilize these courses to train their staff (Open, 2017). There are over 880 chapters of interprofessional individuals in 89 countries. For more information bout the Open School, go to the IHI website found in the website list located at the end of this chapter.

George Washington University offers both a master's degree and a graduate certificate in Health Care Quality. The master's degree requires 36 credit hours and the graduate certificate requires 18 credit hours, which can later be applied toward the master's degree.The program is web-based for distance learning and it is offered in a flexible asynchronous format. Students are expected to have at least 2 years of professional experience working in a health care setting, which does not have to be clinical experience (GWU, 2017). More information on this program can be found in the website links at the end of this chapter.

Other organizations have programs such as those discussed above and these may be found by searching the internet and other sources .

This chapter has laid out the basic information that will serve as the foundation for your journey through the rest of this book. As leaders in our profession we all need to be sure and teach others at least this basic information found here in this chapter.

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WEBSITES

HEALTHCARE QUALITY BASICS

American Board for Specialty Nursing Certification	http://www.nursingcertification.org
American Society of Quality	http://www.asq .org
ANCC Certification Center	http://www .nursecredentia ling.org/certification. asp x
Certified Manager of Quality/Organizational Excellence Certification (CMQ/OE)	https://asq.org/cert/man ager-of-quality
CHCQM Certification	http://www.abqaurp.org/
Deloitte 2013 Consumer Healthcare Survey	http://www 2 .deloitte.com/content/dam/Deloitte/ u s/Docu ments/1ife-scie nces-hea lth-care/us-chs-quest-for-va1ue-in-the-hea lth-care-102414.pdf
Donald Berwick	http://www.ihi.org/education/ihiopenschool/resou r ces/pages/ profilesinleadershipdonberwick.as px
Edward Deming	https://asq .org/about-asq/honorary-members/deming
George Washington University	https://healthsciencesprograms.online.gwu.edu/ma sters-hea lthcare-quality
Health Care Quality and Management Certification (HCQM)	http://abqaurp .org/ABQMain/Certification .aspx
IHI Open School	http://www.ihi.org/education/ihiopenschool/Pages/ default.aspx
Institute for Credentialing Excellence	http://www.credentialingexcellence.org .
Joseph Juran	http://www.juran.com/
Kaoru Ishikawa	http://www .skymark .com/ resources/leaders/ishika wa.asp
National Learning Consortium	https://www.healthit.gov/sites/default/files/nlc_co ntinuousqualityimprovementprimer.pdf
National Quality Strategy	http://www.ahrq.gov/workingforquality/
Pay For Performance	http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment - lnstruments/QualityInitiativesGenlnfo/downloads/v bproadmap_oea _ -16_508.pdf
Phillip Crosby	http://www.philipcrosby.com
Public Health Core Competencies or Performance Improvement Managers	http://www.phf.org/resourcestools/Pages/PI Ms_co mpetencies.aspx

Quality and Safety Education for Nurses (QSEN)	http://www.qsen.org
Tri-Council for Nursing	http://tricouncilforn ursing.org

ORGANIZATIONAL LEADERSHIP

CHAPTER 2

Kathleen Tornow Chai, Betty Brown

CPHQ Examination Content Outline Task Statements For This Chapter	
Organizational Leadership	
I.A.1	Support organizational commitment to quality
I.A.2	Participate in organization-wide strategic planning related to quality
I.A.3	Align quality and safety activities with strategic goals
I.A.4	Engage stakeholders to promote quality and safety (e.g., emergency preparedness, corporate compliance, infection prevention, case management, patient experience, provider network, vendors)
I.5	Provide consultative support to the governing body and clinical staff regarding their roles and responsibilities (e.g., credentialing, privileging, quality oversight, risk management)
I.A.6	Facilitate development of the quality structure (e.g., councils and committees)
I.A.7	Assist in evaluating or developing data management systems (e.g., data bases, registries)
I.A.8	Evaluate and integrate external best practices (e.g., resources from AHRQ, IHI, NQF, WHO, HEDIS, outcome measures)
I.A.9	Participate in activities to identify and evaluate innovative solutions and practices
1.A.10	Lead and facilitate change (e.g., change theories, diffusion, spread)
I.A.11	Participate in population health promotion and continuum of care activities (e.g., handoffs, transitions of care, episode of care, outcomes, healthcare utilization)
I.A.12	Communicate resource needs to leadership to improve quality (e.g., staffing, equipment, technology)
I.A.13	Recognize quality initiatives impacting reimbursement (e.g., pay for performance, value-based contracts)
I.B.5	Facilitate communication with accrediting and regulatory bodies
I.C.5	Disseminate performance, process, and quality improvement information within the organization
Performance and Process Improvement	
3.A.1	Facilitate discussion about quality improvement opportunities

Words and titles of sections that refer to task statements from the CPHQ Exam Content Outline are indicated throughout the Handbook with a lbox around the tex.

THE IMPORTANCE OF LEADERSHIP IN AN ORGANIZATION

"Without the Affordable Care Act, it is doubtful that much of the progress made so far would have happened. Yet, continued reliance on the ACA alone is wholly insufficient to accelerate delivery system reform to the level needed. Laws, regulations, and payment changes cannot alone create health systems that realize the full promise of the Triple Aim. **Leaders** involved in health care **must be actively and directly involved** in catalyzing change needed to achieve the Triple Aim" (Berwick, Feeley, and Loehrer, 2015, p. 1707) .

The Institute for Healthcare Improvement's (IHI) Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHi's belief that new designs must be developed to simultaneously pursue three dimensions, which we call the 'ıTriple Aim": Improving the patient experience of care (including quality and satisfact ion); Improving the health of populations; and Reducing the per capita cost of health care (Stiefel & Nolan, 2012). What is needed in all entities is strong leadership.

Systems Perspective

Looking at the healthcare system, it is evident that it consists of a number of parts. When these parts work in unison, things go well. When they do not, less than optimal results are primed to occur . This chapter will describe some of the basic elements of leadership and how they contribute to the success of an organization.

Systems Theorv

Systems theory is a way of looking at an organization holistically and breaking it down into a series of individual elements that interact with each other. Originally described by biologist Ludwig von Bertalanffy in 1968, Systems theory allows the user to recognize the synergy between the multiple parts, as well as the interdependence and connection needed. Not only can we analyze the organization and its multiple parts, but we also need to recognize that the organization and each element are impacted by the environment. Systems theory also provides a framework by which to evaluate organizational behavior.

Peter Senge simplifies the concept of looking at systems by using the illustration that we are all part of a family (Senge, 2012). Sometimes in a family, people act in a way or have experiences that one would not expect to happen. Why do they happen? When the individuals within the family begin to tell their stories, it becomes clear that the interdependent structure in which they are part (syslem) contributes to the outcome. Taking that analogy, Senge discusses that the best way to come to a solution is to analyze issues or concerns by taking multiple perspectives on the same problem and coming to a conclusion about what might be the best way to solve it (Systems Thinking).

!Systems Thinking!

Senge describes three characteristics of systems thinking:

- A very deep and persistent commitment to 'real learning'.
- Be prepared to be wrong. If it was pretty obvious, what we ought to be doing, then we would be already doing it. I could be part of the problem. My own way of seeing things, and my own sense of where there's leverage, is probably part of the problem . This is the domain we have always called 'mental models.' If I am not prepared to challenge my own mental models, then the likelihood of finding non-obvious areas of leverage is very low.
- There is a need to triangu late. You need to get different people, from different points of view, who are seeing different parts of the system to come together to collectively see something that individually none of them see (Senge, 2012).

With systems theory at the base of analysis, one understands that not only finding solutions, but also identifying problems and challenges, must be done in ways that utilize multiple individuals and perspectives. In order to work together, there must be shared vision and a commitment to achieving the stated outcome.

Frequently when a problem is identified, a quick fix is employed. Leaders and managers want to address the problem quickly and get it out of the way . Unfortunately, many of these fixes do not last. Why is that? One of the main reasons is that the individuals fixing the problem are unaware of the different systems and processes that are involved in the current problem. A ll of these processes are related in some way to one another . Without understanding the impact of how one process affects another, there is danger that another part may break down due to unforeseen outcomes of the changed process (Senge, 2012).

Systems thinking is the study of structures and behavior which are facilitated through the use of tools and techniques that have been developed over the last fifty years (Senge, Cambron-McCabe, Lucas, Smith, & Dutton, 2012). A Root Cause Analysis is an excellent example of a tool that has been developed to facilitate systems thinking. In a root cause analysis, the specifics of the incident are initially reviewed, but the cause is not determined until an analysis of the systems and processes involved in the event are reviewed to see if there are contribut ing factors (see Chapter 5 Patient Safety).

Using an example of a medication team, let us say that the team determines that the data shows there were six medication-related sentinel events in the last year that had been reviewed individually. Each had identified a root cause and developed an action plan. However, no one had taken the results of the six root cause analyses and put the findings related to the system deficits together . The task of the

team was to review each analysis and see if common themes were identified among the six. In doing so, they were using the thinking of individuals in the six previously deployed teams as their starting point and taking the learning to a new level.

!strategic Leadership!

Leaders come in many styles, having many different attributes. Later in this chapter, we will discuss different leadership styles and the benefits and challenges of each. An organization needs a strong leader, however what does that mean? Today's leadership responsibilities are a rapidly changing menu of challenges, and the skills needed to accomplish leading have been described in many journals. Schoemaker described six skills that underscore the capabilities of a strategic leader based in the research done at Wharton School of Business (Schoemaker, Krupp, & Howland, 2013).

Anticipate: Where would you be today if you thought five years ago that the government would pay no attention to healthcare acquired pressure ulcers? In those organizations that began 10 years ago or more to work on preventing these events, leadership anticipated the response and were prepared when the government began to fine hospitals for these events . Ascension Health was one of those organizations and their journey which began in 2004 is described in the literature (Gibbons, Shanks, Kleinhelter, & Jones, 2006). In order to anticipate what the future may hold, a leader must be vigilant in scanning the horizon to not only see what's ahead but also to know what is not working well within the organization. This involves not only reading the appropriate journa ls and reports but also networking with others in the field and seeing what they are doing to prepare for what might be coming.

Challenge: Do you as a ieader challenge the assumptions of others? Does your leader challenge the reports you present? If so, that demonstrates an aspect of leadership that elevates one from ordinary leadership to strategic leadership. However, it is not a comfortab le process, and we frequently are not particularly fond of having people who challenge as part of the team. Those individuals should be encouraged. Doing so takes the team from simple acceptance to understanding the rationale or basis for the information. The challenging is similar to the process within a root cause analysis. Using the "five whys" until you get to the root cause, the effort allows you to focus on the issue as opposed to the symptoms of the issue.

Interpret: A strategic leader takes time to understand the information. To do that, the individual must look at the information being presented from a number of perspectives, even inviting those with diverging perspectives to participate in the analysis of the information. The leader must have all the facts and be able to look at things from both a micro-perspective, close up, and from a distant perspective. Take a look at the data from a longer time period. Understand the data trends by analysis of the reasons the data changed . Look for pieces of information that might be missing from the analysis. When possible, use quantitative data to support the conclusion. Finally, after coming to a conc lusion, take a time out and return to the information after a break. See if it still makes sense.

Decide: Strategic leaders make carefully thought out decisions . In most cases, they prepare a number of optional decisions before they decide and consider the pros and cons of each one, all in an attempt to avoid yes or no decisions. This does not mean that in an emergent situation they cannot make quick decisions, but those situations are not the norm or should not be. In decision-making, strategic leaders consider the options and anticipate the consequences of each option. They consider and seek counsel of those who may be impacted by the decision or have a divergent view . They determine whether this is a long term or a short-term decision and then support the decision once it is made.

Align: When a strategic leader makes a decision, those around that leader and those impacted by that decision understand why the decision has been made, even if they do not agree with it. That is due to the fact that the leader has taken the time to communicate with the team and those impacted by the decision before the decision is made. It is not a surprise to those involved. People know why the decision has been made. In order to do this, the leader must have identified and communicated w ith the key individuals who are involved or impacted by the change. The leader will have answered negative perceptions before the decision is put in place and have made sure there is a clear understanding of not only the decisions but also reasons it is being initiated. Finally, a strategic leader will recognize those who support the decision and continue to work in a way that aligns them to the purpose.

Learn: Strategic leaders foster and support a learning organization. They learn from decisions they have made a s well as decisions others have made. They welcome open dialogue and inquiry and support those who engage in these efforts. In addition, when a project does not accomplish what was intended, they support those who initiated the project and help them discover what may have impeded progress. This takes an organizational culture that is open and rewards progress as well as attempts to make progress. The opposite of this would be a culture that punishes those who attempt to make changes. A negative reaction to those who take risk in improvements frequently leads to organizations in which no one is willing to try.

The literature suggests that all six of these traits must work together, as a deficit in one will not make up for the strength of another. To do a short assessment of your strategic leadership skills, see the strategic leadership skills assessment in the website links at the end of this chapter and determine where you stand.

TYPES OF ORGANIZATIONS

Organizations can be cha racterized in a number of ways . In this section, a brief description of traditional United States organizational infrastructure will be discussed . Then three types of specialized organiza tions, as described in the literature, will be highlighted.

lunited States Healthcare Organizational Infrastructure

Historically, elements of the healthcare system including hospitals, home care agencies, health clinics, long-term care agencies and others have been structured as stand-alone entities, with little sharing of information between them. Each organization maintains its own data and measures its own level of quality, and while they may share within an organization, little information is shared outside of the specific corporation or entity. One might say that the healthcare system was organizationally focused and not patient/client focused. Over the last 20 years, that structure of parallel systems has been breaking down to look at all areas that impact the healthcare of the population (Health System Infrastructure, 2013).

There are organizations that were not set up as a stand-alone entity, usually because they care for a particular population of individuals that spans either a geographic area or the entire country. Examples of this are managed care organizations or the national Veterans Administration. In these organizations, it became imperative that to manage the care of the population, all facets of healthcare from acute to primary care, from medication management to specialized services, needed to be shared to optimize the ongoing care and wellness of the individual or population. These organ izations were the first to recognize the value of automation of information and to begin using tools such as the automated medical record to facilitate care and communicat ion. In one reference, the Institute of Medicine identified three structural elements that support and affect the ability to improve care:

- Information systems for data collection, quality improvement analysis, and clinical communication support
- Adequate and well-distributed workforce
- Organizational capacity to support emerging models of care, cultural competence services, and ongoing improvement efforts (Health System Infrastructure, 2013)

lchallengesl

Researchers have difficulty describing and comparing healthcare organizations as there is little or no common taxonomy used to compare (Pif\a et al., 2015). In 1999, the Agency for Healthcare Research and Quality (AHRQ) developed a taxonomy characterized by three shared structural and strategic elements: differentiation, integration, and centralization.The taxonomy was updated in 2004 using the same three basic elements, with an updated definition of centralization as organizations were continuing to evolve. And again in 2006, as organizations continued to morph and transform, definitions were widened to capture interrelationships and systems as opposed to individual entities (Pif\a et al.,2015).

During the process of attempting to categorize healthcare organizations, the study principals identified six key areas to evaluate as shown in Table 1(Pif\a et al., 2015).Using elements of this assessment may

allow an organization and its leaders to compare itself with other organizations and identify differences and challenges.

Table 1:Key Areas to Evaluate and Categorize Healthcare Organizations

Key Areas to Evaluate and Categorize Healthcare Organizations	
Areas to Evaluate	**Description**
Capacity	This section of the analysis defines not only the size of the organization but its capital and physical assets, the number and type of individuals supporting the healthcare delivery system, and the specific population of clients it is meant to serve.
Organizational Structure	This section identifies the formal and informal methods employed to manage the organization. What is the organizational structure? Who has the authority to do what? How are the leadership and governance of the organization structured? How does communication occur? How do resources and other information flow within the system? How do research, innovation and education occur?
Finances	This includes funding areas such as payment, other funding sources, and the ways the organization manages its financial obligations and opportunities. It should also include financial status.
Patients	This analysis includes the types of patients served including the patient demographics and other characteristics that are important to the healthcare delivery system .
Care Processes and Infrastructure	This portion of analysis includes aggregate patient outcomes and accreditation information as well as systems used within the organization to provide care and support. Integration, standardization, public reporting, health information systems, decision support and care coordination are included.
Culture	Implicit shared values, beliefs, and long held assumptions of the organization, contribute to the picture of the healthcare delivery system. Collaboration, competition, competence and the working climate is included.

Another challenge to the traditional healthcare system organization is the payment models that are evolving (Edmondson, 2015). As stated earlier in this section, one of the three Triple Aims in healthcare is to reduce costs. Healthcare organizations traditionally are set up to pay for the healthcare that was consumed, more payment for sickness than wellness. Over the last 25 years that has been changing. More and more both nationally and in particular states,the movement has been to compensate not for the healthcare that is provided,but to give one payment per individual, no matter

ORGANIZATIONAL LEADERSHIP

How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?
Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?
What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board 1·eceive reports about the quality improvement efforts?
How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk assessment and corrective action plans?
What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems? What guidelines exist for reporting quality and patient safety concerns to the board?
Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinica l quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?
Do the organization's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
How are "adverse patient events" and medical errors identified, analyzed, reported, and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

Skills, knowledge and traits of Board members are important. Many organizations evaluate their Board members in areas that they believe are important to the organization (Lockee, 2009). For instance, when financial challenges and innovations are a priority, the Board often seeks members who can bring experience and guidance to the role. Another example may be a healthcare organization in which there is a desire to expand services or types of care delivery. Someone who is well versed in potential new models may be a valuable new Board member.

In changing times, healthcare organizations have used different ways to approach and deal with transformations that are occurring. In the next section, a brief description of some of the approaches organizations have taken will be discussed.

- Deference to expertise. Recognize that those closest to the frontline are the experts and understand the reasons behind issues that arise. Frontline staff members can more easily determine how to make the environment safer.

!Learning Organizations!

Senge has identified learning organizations, and what it is that makes them special (Senge et al., 2012). He states several basic concepts: 1) Every organization is a product of how its members think and act; 2) Learning is the connection to change; and 3) Learning is driven by vision. Senge discusses five concepts or disciplines that are the underpinnings of a learning organization. They are:

- Personal Mastery
- Shared Vision
- Mental Models
- Team Learning
- Systems Thinking

Personal Mastery

Developing personal mastery is a process. First, you need to realize what your own vision is. For example, you have been given the charge of leading the medication error team. The team has been in place for a few years but according to administration, it has not been successful. Your first task in taking on that challenge will be to identify what you see as the vision for the team. What are your goals for the team? How strongly do you feel about those goals? Are your goals the same as the goals of organizational leaders? The next step is to compare those goals to the reality of the situation. This will produce creative tension as you think you know where you need to go, however, there may be considerable distance between the current reality, and where you want to go.

Creative tension is necessary to reach your goals, but finding a way to work through the process successfully involves a number steps. It is important to add context and breadth to your vision. When this team is functioning successfully, what will be the relationship between team members? How will the work of the team get done, as individuals or as groups? What products will this team produce? Remember to go back to your analysis of the current situation to determine what might need to happen for success.

Shared Vision

The shared vision is the next step in the process and involves coming together as a team to make sure you are all on the same wavelength. Other members of the medication error team have their own vision of what their role and purpose is on the team. They may be part of the team for very different

Emergency physician, expands the perspective and allows for consultat ion with other members of the team. Consultation both inside and outside the team may be necessary.

Finally, once the different perspectives are presented, it is time to *re-establish as a team*. To review, the vision of the leader has been told, sold, tested and members have had an opportunity to provide consultation on the team. Now is the time for the team to work together and develop its shared vision of the process that needs to take place.

Mental Models

One challenge, and an opportunity we face in healthcare, comes from the fact that many of the players in healthcare quality come from a clinical background. Therefore, we often assume that we share the same perspective on things from patient satisfaction to the best way to wash hands. Unfortunately, we do not always validate our shared assumptions until we realize somewhere down the line that we are not all going in the same direction. Much of that has to do with our different perspectives. Chimamanda Adichie, a Nigerian novelist, describes the way we tend to view things as a single story. In her 2009 TEDTalk, she explains the direction a single story will lead, and how that direction may inhibit team members from developing mental models that are consistent and understood by all (Adichie, 2009). Chimamanda Adichie's TEDTalk can be found in the website list at the end of this chapter.

One of the basic tasks of group development is to bring some of the assumptions that members have to the surface and explore whether or not they are all coming from the same understanding of the projects at hand. There are two steps to getting to mental models in a group. The first step is reflection and the second is inquiry (Senge et al., 2012). Going back to the example of Medication Team as previously stated, it would be better to have multiple disciplines on the team, but even if the team consisted of all nurses, it cannot be assumed that all share a common perspective on the issue. Each member comes to the team with his own nurse specialty, life experiences and set of values. All of that information comes into play as the team proceeds to complete its task. It might be wise to start this team with a discussion of medication errors and why they occur. The importance of this is expressed in Simon Sinek's work (2011) *Start with Why*. Different perspectives may lead the team to focus on a particular way to tackle the problem. Talking about medication errors brings a sense of unity to the group, allowing shared common understanding. As the team progresses, it may be useful to go back to this understanding to validate that all are still working with the same mental model.

Team Learning

The fourth step in Senge's model involves team learning. This does not mean people always agree, but they are aligned having understood as a group what they need to do and how to get there. It calls for dialogue, which is different from discussion. Team learning involves successful implementation of all of the previously stated elements (personal mastery, shared vision, and mental models) and supporting the team to come up with new ideas and solutions to the challenges they face. Together, the team is

High Performance Organizations

"Reliability in healthcare translates into using valid rate-based measures" (Pronovost et a l., 2006, p. 1599). Therefore, high performance organizations are able to demonstrate the quality of their care using the data they collect. This can be clinical data, safety data and satisfaction data. Measurement is done by any one of a number of organizations and fed back to the healthcare organization to identify strengths and weaknesses.

A Studer report identified that there are six basic characteristics of high performing organizations (Dunn, 2012):

1) The organization does not tolerate low performers
2) There is consistency at senior levels of the organization
3) Leaders within the organization receive adequate leadership training
4) Leaders within the organization are evaluated effectively
5) Consistency in leadership is valued; high turnover is avoided
6) Organizations seek to standardize practices; consistency and uniformity is prized

Having this information, an organization may wish to begin reviewing itself using these objectives and determine if the appropriate characteristics are already in place to move toward high reliability. If not, the journey will be much more difficult.

LEADERSHIP STYLES

The American idiom, "It takes all kinds to make a world" applies to leadership. There are many types of leadership and all of them may work, but some are better suited to different times or situations than others. For instance, a direct, autocratic, top down type of leadership seems to work in the military or during emergency situations, but it may not be the best style to use to convince a team to work together . The purpose of this section is to introduce a number of different styles of leadership that may be appropriate for use in healthcare organizations. It may be useful to inventory the types of leadership seen in the organization and validate if this is producing the expected or desired results. It might also open opportunities to evaluate why certain things work and others do not.

Autocratic leadership, also known as authoritarian leadership, is a leadership style characterized by individual control over all decisions and little input from group members. Autocratic leaders typically make choices based on their own ideas and judgments and rarely accept advice from followers. Autocratic leadership involves absolute, authoritarian control over a group (Cherry, 2015).

member is allowed to contribute as long as he wishes, takes time. Unless someone or the group makes a decision to go a particular direction, the process can be endless and nothing is accomplished. Situational leadership supports the fact that there may be no single way to approach each situation and having an array of approaches will support an effective leader when used judiciously.

Participative leadership is employee involvement. Stakeholders at all levels participate in analysis of problems, development of strategies and implementation of solutions. Employees have a share in the organizationa l decision-making. Leaders treat the ideas of employees with consideration and respect.

The Laissez-faire management style allows employees to let their own ideas and creativity flourish in their respective areas. The manager is looked upon as more of a mentor than a leader. This leadership style leads to the lowest productivity among group members according to researchers (Cherry, 2017).

There are many other leadership styles described in the literature. Collins coined the phrase "Level 5 Leader" in describing the leader who inspires with vision and values by getting things done in a diffuse power structure (Collins, 2005). Level 5 Leaders use various methods found in the types noted previously to achieve goals. What is your leadership style? There are tests that can be taken to assess one's leadership and management style. The point is to use this information to identify the types of leadership in your organization, including your own leadership style, and plan your approach in implementing the quality program to best accommodate the various styles within your organization.

!Qualities of a Successful Leader!

Not every successful leader is a good manager and not every good manager is a leader. There are basic elements to each position that distinguish between the two, and there may be some overlap. Review Table 3 below and then apply the information to your own style. Are you more of a leader or a manager?

Table 3: Successful Leader and Manager Attributes

Successful Leader and Manager Attributes	
Successful Leader	**Successful Manager**
Establishes vision and direction Focuses on the future (Toor, 2011)	Focuses on the present (Toor, 2011)
Maintains holistic view Clarifies organizational vision and values Aware of changing internal and external demands (Larsson & Vinberg,2010)	Executes plans Aware of immediate environment (Lunenburg, 2011)
Communicates effectively across the organization (Yoder-Wise, 2014)	Communicates to maintain effective and positive work environment for employees
Interprets the environment and improvises	Directs, controls and evaluates others as they

but many do not report what positive impact the process improvement (or what negative impact the adverse drug events) had on costs and savings to the organization. This is an important function of the quality professional. At the same time, organizations are seeking ways to limit costs by purchasing products as part of a larger entity and thereby getting a better price. This is known as value based purchasing and often feeds into the quality management process.

The cost of quality refers to the costs to prevent non-conformance from happening and the costs incurred when non-conformance in products and services occurs (cost of poor quality). The cost of poor qualiy is also known as the cost of doing things wrong when providing a poor quality product or service . In healthcare, this generally refers to both medical errors and to the provision of services that could be improved to provide a better outcome for the patient. Identifying and reporting the Cost of Quality (COQ) and Cost of Poor Quality (COPQ) activities of the quality program are important, not only to justify expenditures, but also to support the organization's commitment to quality with clear financial data. A quality program typically starts out spending most of its costs on failure activities, a smaller amount on appraisal, and very little on prevention. As improvements occur and failure costs decrease, resources should shift to prevention and appraisal (ASQ-COQ, 2012).

There are four categories: "internal failure costs (costs associated with defects found before the customer receives the product or service), external failure costs (costs associated with defects found after the customer receives the product or service), appraisal costs (costs incurred to determine the degree of conformance to quality requirements) and prevention costs (costs incurred to keep failure and appraisal costs to a minimum)" (ASQ, 2013). The Prevention costs refer to the cost to prevent poor quality in products and services. In healthcare, this can be equated to making improvements in the delivery of healthcare and the processes utilized to produce the patient outcomes. Appraisal costs refer to the measuring, auditing and evaluating of products or services to assure that they are being completed with compliance to the established policies, procedures, pathways, and/or guidelines. Internal failure costs are the costs that occur prior to the customer receiving the product or services. An internal failure cost would be a medication error that is identified prior to the patient receiving the medication. External failure costs occur after the product or service has reached the customer. The wrong medication being administered to a patient is an example of this type of failure.

fSTRATEGIC PLANNING!

Strategic Planning is a process by which an organization indicates the way it plans to progress from the current state to the desired future state. Zuckerman (2014) describes strategic planning as a valid and useful tool that guides an organization to achieve goals. The process is systematic and rational, and integrates the short, medium, and long-term goals allowing the healthcare organization to focus on relevant and lasting transformation for the future .

The healthcare organization that first understands the quality of the service produced has reached new heights in care delivery . The leader who considers quality as a method of reducing cost, creating

- Helps prioritize complex and unclear issues
- Provides a quick and easy method for evaluating
- Takes some of the emotion out
- Quantifies decision with numeric rankings
- Is adaptable for many priority setting needs
- Facilitates the leaders reaching agreement on key issues

Predictive Analytics – Winters-Miner et al. (2014, p. 969) states, "Predictive analytics uses technology and statistical methods to search through massive amounts of information analyzing it to predict outcomes for individual patients". In the new health models, predictive analytics:

- Increases accuracy
- Assists in preventive health
- Provides answers for individual patients
- Predicts insurance product costs
- Predicts models for smaller populations over time
- Can be used by pharmaceuticals to meet public needs for medications, and
- Provides potential for better outcomes for patients

Healthcare quality leaders will do well to use techniques, tools, and methods to ensure strategies are executed for optimal progress toward the most effective healthcare delivery system. With the consistent mission and vision for the future, the person seeking health and wellness and quality of life will benefit.

!strategic Planning Process!

Utilizing forecasting, prioritization, and predictive analytics, there are five steps during the actual strategic planning process. The frequency with which the strategic planning process is utilized is determined by every organization .

Step 1consists of the examination and analys is of what is occurring on the national, regional, state, and local levels. The development of new laws and regulations, the incentives provided by the government and others, as well as many other factors must be considered. For example, the reimbursement for healthcare is in a constant state of flux with CMS adding and deleting what is to be measured and reported for reimbursement purposes, as well as the bundles (codes tnat are placed together for payment purposes) that are being created. The organization must examine what is coming

organization that will build this into the process. It also needs to be connected to operations. Frequently operations are disconnected from the quality plan and when that happens, it becomes difficult to stay focused and make progress (Zuckerman, 2012).

Step 5 consists of the development of the goals and objectives to support the strategic plan just developed. Once the goal is developed, the objectives are determined to identify the actions that must be taken to meet the goals. These goals and objectives should then be reviewed throughout the year to determine if the organization is successfully progressing towards meeting the goals . The organizational goals and objectives should also be shared throughout the organization so that all other plans and programs that are developed or revised can set their goals and objectives that complement those of tiie organization.

Instead of handing the measurements to staff to perform, consider moving from strategic planning to strategic management. Strategic planning is criticized for its detachment from day-to-day operations and its inability to produce real, sustainable change in organizations. Many organizations use strategic management approaches to integrate core management (Zuckerman, 2012).

In addition to the goals and objectives, the organization should determine strategic initiatives that support the goals. Patient Safety is one strategic initiative that should be developed in every organization. Refer to Chapter 5 Patient Safety. These same 5 steps should be utilized when developing any program or plan, such as the quality, risk, utilization, and patient safety plans.

\LEADERSHIP IN QUALIT

!Goal of Leadership!

The commitment to quality must be supported by senior leadership. When leadership is involved from the top, quality activities are sustained and outcomes accomplished. A recent Veterans Administration study identified that when senior leadership (Director, Associate Director for Patient Care, Associate Director for Operations, and Chief of Staff) were aligned with inpatient medical services, more quality improvement activities were performed, resulting in improvements in care (Restuccia, Mohr, Meterko, Stolzmann, & Kaboli, 2014). The authors suggested that the leaders' ability to communicate goals led to improvements in and sustainment of quality for the organization.

In another study, the authors concluded that "leaders in high performing hospitals appear to be more effective at creating a vision of quality care and creating a culture that supports an expectation that staff and leadership will work across traditional boundaries to improve quality" (Vaughn et al., 2014, p. 111). The study conducted a survey, with the belief that the major organizational drivers of quality and safety are 1) commitment of governing boards and C-suites to foster continuous improvement, 2) a vision of exemplary quality, 3) a culture supportive of change, 4) designated and accountable leadership, 5) appropriate organizational structures (e.g.,committees, education, clinical management

Facilitation between leaders, and those who have the data and information to identify the organization's outcomes, is needed, so all levels understand the organization's strengths and weaknesses and are aware of activities being undertaken to improve them. Dissemination of quality improvement information throughout the organization is critical.

Other areas of the organization also need to be addressed . This includes the support of key stakeholders in the process in areas such as corporate compliance, patient advocacy, management of outside sources and vendors, emergency preparedness, infection control and how patient transition is managed within the system.

For example, the organization is responsible to provide oversight of all the medical staff within the organization. That looks different at the levels of the governing body, leadership, medical staff leadership, and department levels. At the level of the governing body, they should be made aware that there is a system in place to assure credentialing, privileging, and monitoring quality outcomes, and that each member of the medical staff has passed through the process in a timely and effective manner. They fulfill this function by receiving adequate information and then appointing or reappointing and privileging the members of the medical staff.

At the senior leadership level, the executive team, in conjunction with the Medical Staff Executive Committee, makes sure that all members of the medical staff have met credentialing and privileging requirements. They may both be involved if any activities do not meet standards and action is needed.

The organizat ion has most likely tasked one or more departments to get the data together to support this process and each of these departments or services collaborate to provide adequate information for the process to go through approval as outlined in the organization's bylaws and policies. More information for these processes for leadership can be found in Chapter 3 Performance and Process Improvement.

!standards, Regulations, Guidelines for Leadership Involvement)

There are a variety of organizations requiring senior leadership be involved and responsible for the quality process. The fact that senior leaders are singled out provides emphasis to that requirement. That will be determined by each organization's regulators, accreditors and oversight entities. The leaders must be aware of the key rules, regulations, and standards that pertain to that type of organization . Examples of this requirement are listed below and discussed throughout this book. Leaders need to facilitate communication with these regulatory and accreditation bodies. However, everything required cannot be covered in this book, so leadership must obtain an understanding from this book and other sources.

Table 4: Examples of CMS's Conditions of Participations Outlining Leadership Responsibilities for Quality

Examples of CMS's Conditions of Participations Outlining Leadership Responsibilities for Quality	
CoP	**Description**
§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program (QAPI)	The hospital must develop, implement, and maintain an effective, ongoing, hospital wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS
§482.21(c) Standard: Program Activities	Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
§482.21(e) Standard: Executive Responsibilities	The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that clear expectations for safety are established.

More information about CMS is available in Chapter 6 Regulatory, Accreditation, and External Recognition & Chapter 7 Legislation Initiatives.

§ccrediting Bodies!

Multiple agencies accredit healthcare organizations throughout the United States. The organizations include hospitals, managed care organizations, physician practices, ambulatory care services, rehabilitations centers, home health, psychiatric care, and more. Many organizations accredit with more than one type of agency. Each agency has established standards or guidelines by which it measures the adequacy of the organization. All accreditors have identified specific leadership responsibilities. Chapter 6 Regulatory, Accreditation, and External Recognition, discusses several of these accrediting bodies. Please refer to the appropriate accrediting body for your organization and review leadership standards.

Financial/Operations Officer or Chief Nurse Executive. In other organizations, senior leaders are classified by President, Vice President and so forth. In smaller organizations, the top leader may be the Administrator, Assistant Administrator and other management titles. Whatever the top level is called, those leaders are the ones in the organization that have power ascribed to the position they hold. As discussed previously, there are many leadership styles and each of these leaders may exhibit one or two of the styles described. The layer below senior leadership is usually referred to as middle management. These are the Directors and Managers of areas or departments. There may or may not be other layers of management depending on the size and complexity of the organization.

It is important for the individual(s) who oversees Quality, Utilization Management (UM), Patient Safety (PS), accreditation and Risk Management (RM) within the organization to know in which level or leadership position they sit . In some organizations, the Chief of Quality is at the highest organizational level, reporting directly to the CEO. As might be expected, this level of leadership comes with a great deal of power within the organization. However, this level of leadership is frequently not the home of the manager of quality. Sometimes, the Manager of Quality/UM/RM/PS/Accreditation reports to one of the senior leaders and thus has a direct pathway to senior leadership. Commonly, the individual overseeing the collection, aggregat ion, analysis and display of data is at the middle management level. Implications include lack of accessibility to senior leaders and/or confusion related to senior leadership goals and objectives . This may also result in a difficult reporting relationship from the top level through the manager and back.

I1nfluential Leadership/Importance!

There are many leaders within an organization and not all of them have positional power. As a leader in Quality/UM/RM/PS/Accreditation, one wants to have the power to influence decisions on important aspects of the quality improvement processes. This is done through expert power and influence.

Influence is the ability to compel people to do something without having power over them (Lucas & Baxter, 2012) . It is based on having the respect and trust of others. One of the ways to build a network of influence is to initiate and maintain relationships throughout the organization . These positive relationships expand the individual's network within and without the organization and allow the individual to gather a team of like-minded colleagues to work together. The sphere of influence then spreads past the individual to a wider group. This builds on social capital which is defined as the network of social connections that enable and encourage collaborative social interaction (Social Capital, n.d.). In order to maintain the trust and confidence of these individuals, one must be careful to do what one promises and say what one means.

!Roles and Responsibilities of Quality Leadersl

Depending on the specific organization, responsibilities for the Quality/UM/RM/PS/accreditation in an ambulatory surgery center or critical access hospital, all of the tasks will be the responsibility of one

- **Communicating :** While coaching includes communication, there are many other ways for leaders to positively impact the success of change. When a leader strongly communicates to the organization the risks of maintaining status quo and the benefits of changing the current status, it motivates others to move toward the change. However, if the leader does not communicate this to team members, change may languish. This may be because the leader has less than positive thoughts about the change or simply does not communicate in a way that inspires others to move the project forward. Frequent, enthusiastic communication with the ability to curb unrealistic expectations supports the change.
- **Involving others:** Allowing members of the organization that will be impacted by the change to be part of it, supports successful change. By being part of the ongoing process, employees or team members feel that they have been involved in making the decisions and are much more likely to support the change. Even if it is not possible to involve all the stakeholders in the process, eliciting feedback periodically throughout the change engenders good will, and those asked to participate will be less likely to resist the change.
- **Motivating:** Motivation can be either positive or negative. Allowing employees to reach a higher level of goal accomplishment is positive motivation. The satisfaction of being part of successful change can reinforce the employees' motivation to be involved in changes as they continue to occur. Meeting goals, whether they are financial or intrinsic, motivates employees to succeed . A study of creative professionals identified that if they were managed in a way to allow optimal freedom, flexibil ity and resources, they were motivated to continue improving processes (Hebda, Vojak, Griffin, & Price, 2007).
- **Rewarding:** Finding the right reward to motivate others can be challenging, but it is often surp rising how little is needed to incentivize others to support the change process. Rewards often range from very small, such as a treat for all who participate in a meeting, to a coffee card for completing a task . The process of rewarding those who are involved engenders good will and commitment to the project. Sometimes something as simple as letting team members out of a team meeting half an hour early is reward enough for those with full schedules.
- **Promoting Teamwork:** For many individuals, the synergistic energy from working with others motivates them to continue participating in the change process. Time seems to go by more quickly when everyone is doing the "heavy lifting" to accomplish the goals of the team. The effort on any one person is reduced and as all members participate, accomplishments are made. Those involved are able to use their strengths and others help them build their talents in other areas.

shift hours or an upcoming raise). A leader uses this method when it is essential that all staff members are aware (e.g. information about benefits).

- Spread – Propagation of information from person-to-person to achieve communication on a topic disseminated across the organization. A leader, who is well versed in how to accomplish spread, even when the topic is not on the surface essential to some staff members, is inspirational.

Processes

The basic communication processes are oral and written.

Oral processes are an interpersonal method of conveying information; to talk directly to others. Be aware that just because a person speaks directly to others, it does not mean the person or group spoken to is listening actively, or that they understand. Only a small percentage of information gathered through oral means is actually remembered and put into action.

Written processes provide a paper trail to ensure you can track what was stated, and when.

- *Reports* – Routine reports can be provided to staff, groups, the entire organization, or external stakeholders. Providing the reports at routine times creates an expectation for communication.
- *Emails* – E-mail is a good method of written communication. The issue with e-mail is that the recipient has to open and read the information and then take action. There are programs that will allow you to see if an e-mail was received and opened and if the person took any action with the e-mail.
- *Paper versus electronic* – Although one can argue the pros and cons of paper versus electronic information flow, it is best to decide which method works best for the information you need to share. It is most likely that using both is needed. There may be circumstances in which for one or the other is the most beneficial.

This chapter presented an overview of leadership responsibilities as well as perspectives on leadership from experts and through research. Leadership involvement is key in quality improvement, and organizations without strong, committed leaders often find themselves missing something in the programs and processes. As a Quality/UM/RM/PS/accreditation manager you are also a leader, and while you may not have positional power, you have expertise and influence that is key to your organization's success.

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WEBSITES

ORGANIZATIONAL LEADERSHIP

AHRQ Prioritization Tool	https://archive.ahrq.gov/professionals/systems/hospital/qitoolkit/qiroadmap.html
American College of Surgeons National Surgical Quality Improvement Program® {ACS NSQIP®)	https://www.facs.org/quality-programs/acs-nsqip
Chimamanda Adichie's TED talk about developing mental models	http://www.ted.com/talks/chimamanda_adichie_the_danger_of_a_single_story?language=en
CMS Conditions of Participation	http://www.ems.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospitals.html
Communication Matrix	www.doh.wa.gov/Portals/1/Documents/Mtgs/2011/20110824-PR-PMC-MOD-08-24-11H3ExProjectMgmtPlans.doc
Examples of CMS's Conditions of Participations Outlining Leadership Responsibilities for Quality	https://www.ems.gov/Regulations-and-Guidanee/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf
Leadership Style Assessment	http://www.gpslifeplan.org/century/leadership/index.php?link=who-know-yourself
NAHQ Six Domains of Leadership Competency	http://www.nahq.erg/uploads/Healthcare_ Quality_ Competency_Article _2011.pdf
MS Dept. of Health Prioritization Matrix	http://www.hea lth.state. mn.us/divs/opi/qi/toolbox/prioritizationmatrix. html
Peter Senge - Systems Thinking	http://www.mutualresponsibility.org/science/what-is-systems-thinking-peter-senge-explains-systems-thinking-approach -and-principies
Physician Compare Data	https://data. medicare.gov/data/physician -compare
Physician Quality Reporting System (Physician Quality Reporting or PQRS)	http://www.cms.gov/Medicare/Quality-1nitiatives-Patient-Assessment-1nstruments/PQRS/
Strategic Leadership Skills Assessment	https://hbr.org/2013/01/strategic-1eadership-the-esssential-skills
The Society for Cardiovascular Angiography and Interventions (ACC, AHA, SCA!)	http://www.scai .org/Press/detail.aspx?cid=deeea906-4f6a-463f-9d01 -78fd3a2242ac#. VWzNW89Vi ko
The Society of Thoracic Surgeons STS National Database	http://www .sts.org/national-data base
Writing Executive Summaries	https://www.umuc.edu/writingcenter/writingresources/exec summaries .cfm

PERFORMANCE AND PROCESS IMPROVEMENT

CHAPTER 3

Susan Mellott, Sarah Yelton, Kathleen Tornow Chai

CPHQ Examination Content Outline Task Statements For This Chapter	
Organizational Leadership	
I.A.1	Support organizational commitment to quality
I.A.3	Align quality and safety activities with strategic goals
I.A.4	Engage stakeholders to promote quality and safety (e.g., emergency preparedness, corporate compliance, infection prevention, case management, patient experience, provider network, vendors)
1.A.5	Provide consultative support to the governing body and clinical staff regarding their roles and responsibilities (e.g., credentialing, privileging, quality oversight, risk management)
I.A.6	Facilitate development of the quality structure (e.g., councils and committees)
I.A.8	Evaluate and integrate external best practices (e.g., resources from AHRQ, IHI, NQF, HEDIS, outcome measures)
I.A.11	Participate in population health promotion and continuum of care activities (e.g., handoffs, transitions of care, episode of care, outcomes, healthcare utilization)
I.B.4	Participate in the process for evaluating compliance with internal and external requirements for: a. clinical practice guidelines and pathways (e.g., medication use, infection prevention) b. service quality c. documentation d. practitioner performance evaluation (e.g., peer review, credentialing, privileging) e. gaps in patient experience outcomes (e.g., surveys, focus groups, teams, grievance, complaints) f. identification of reportable events for accreditation and regulatory bodies
I.C.1	Design performance, process, and quality improvement training
I.C.2	Provide education and training on performance, process, and quality improvement, (e.g. Including improvement methods, culture change, project and meeting management)
I.C.3	Evaluate effectiveness of performance/quality improvement training
l.C.5	Disseminate performance, process and quality improvement information within the organization

PERFORMANCE IMPROVEM ENT PROG RAM STR UCTU RE

The organizational structure of any organization's performance improvement/risk/util ization/patient safety/accreditation programs will be different based on the organization's mission and vision, structure, organization important functions, and many other aspects. The information presented in this portion of the chapter will discuss the general information that must be considered and utilized as appropriate when your organization establishes its own program. The information in this chapter is also useful in organizations, which already have programs and plans in place.This information can then be utilized to analyze what is currently in place to assess adequacy of the program and plans. It must be remembered that all concepts discussed in this chapter pertain to both clinical and non-clinical (operational and service) quality. The actual performance improvement plans will be discussed in the next section of this chapter.

To build an effective performance improvement program structure, there are many things to consider. Table 1lists a succession of tasks that should be completed to develop the program. This portion of the chapter will flow through this structure as a means to identify the framework of the structure for a healthcare organization to utilize. Of course, the structure that is best for your improvement program will depend on the type of healthcare organization, organization structure, size and location of the organization. Regardless, this table can be effective to assure that all the components have been addressed.

Table 1: Building an Effective Quality Improvement Program Structure

Building an Effective Quality Improvement Program Structure
• Definition of the term quality for the organization
• Clarify leadership roles
• Create an accountability structure
• Determine what the name of your program will be i.e., quality, patient safety or performance improvement
• Identify the important functions of the organization
• Identify approaches to process improvement framework
• Develop an information flow chart
• Establish reporting routines
• Integrate quality principles into organization's policies and procedures
• Identify educational needs

It seems reasonable to assume that successful, effective quality systems in healthcare, as in any other type of organization, are achieved by committed to the "passionate pursuit" of quality as a

Table 2: Organizational Influences for Program Effectiveness

Organizational Influences for Program Effectiveness
• Organizational culture, ethics, priorities and degree of leadership commitment to mission, vision, and values
• Governing body support and involvement
• Administrative and management leadership support and involvement
• Medical/professional staff or medical group/ IPA support and involvement, as applicable
• Organizational ,team, and committee structures
• Scope of services and programs
• Important organization wide functions
• Strategic quality initiatives
• Care and service delivery functions, systems, and processes
• Information system resources
• Financial budget and resources
• Political environment

Preparation for Quality Management/Performance Improvement

Determine the Definition of Quality for the Organization

Every healthcare organization must define how they view quality for their organization. This definition will be impacted by: the type of organization, whether it is for profit or not for profit, the mission, vision, and values of the organization, patient population, type of services offered, type of practitioners utilized, geographic and environmental factors, in addition to many other components.

!clarify Leadership Roles!

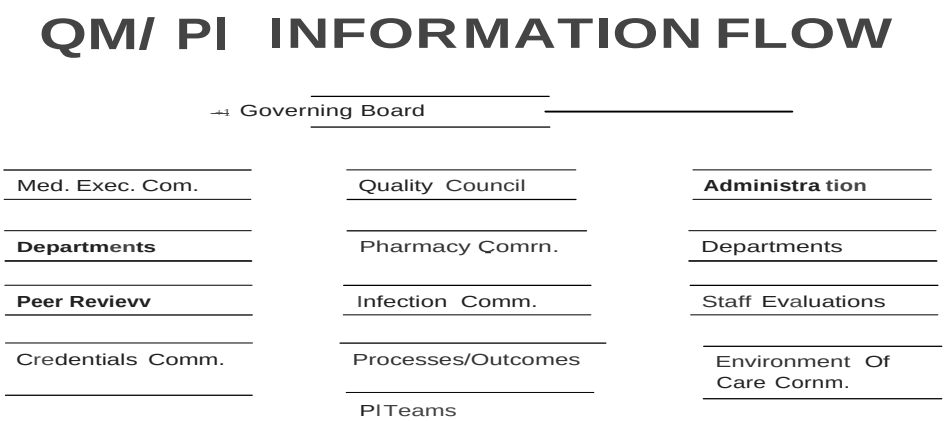
It is important that all the leaders of the organization know and meet the expectations regarding their role in the quality strategy of the organization. There must be evidence of cohesiveness and integration among the leaders. If the leaders are not all working together toward a common quality strategy, the organization will not have an effective quality program. There should be active participation by senior leaders, if not on the Quality Council, and or at least one high level committee that reviews quality management information. The most knowledgeable senior leader should lead the Quality Council. The roles and responsibilities of the key leaders should be delineated in writing, perhaps within the quality plan itself .

If the organization has a medical staff, the Quality Council is usually identified in the medical staff bylaws as a committee of the medical staff, which is chaired by a physician. This provides increased protection of clinical quality information, but the amount of protection will vary state by state (see Chapter 4 Health Data Analytics). In some organizations, the Quality Council is a subcommittee of the governing board, and thus has at least one governing board member on the council. If there is not a medical staff, such as in Home Health, the leaders of the organization establish this council and determine who will be the chair.

The frequency of the Quality Council meetings is determined by the organization, e.g. monthly or quarterly. If the Quality Council is established in the medical staff bylaws, the meeting expectations should be stated in a manner that does not violate the bylaws should a meeting not occur as stated in the bylaws. For example, if the bylaws state that the Quality Council meets monthly, then it must meet once a month, and cannot, for example, not meet in the month of December.

The Quality Council reports directly to the Governing Board through minutes, but also shares quality information with the medical staff and the administration of the organization. Figure 1is one format for the reporting of the information that flows through the Quality Council. The solid line between two entities shows direct communication and reporting. The dotted lines indicate both communication and reporting based on the information and where it should be reported. As mentioned previously any information regarding an individual (i.e. : peer review or employee evaluations) goes directly to the Governing Board and is not communicated to the Quality Council. If there are process and/or outcome issues identified following the peer review or staff evaluation, then that should be communicated to the Quality Council, but no individuals should be identified.

Figure 1: QM/PI Information Flow



can then flow back down the chain of command. All this must be established up front with the agreement of all involved before this process will become an effective technique.

Determine the Quality Language

It is important to determine the quality language that the organization will utilize for their quality program. Just as there must be an organization wide commitment and strategy, there must be a common quality language with well-defined terminology. This is very important for communication within the organization since there are many different terms that mean the same thing in relation to quality.

Will the organization speak of the quality strategy as Quality Management (QM), Quality Improvement (QI), Quality Assessment and Improvement (QA&I), Continuous Quality Improvement (CQI), Quality Resource Management (QRM), Performance Improvement (PI), Quality and Patient Safety (QPS), or some other combination?

A common quality language facilitates leaders' ability to articulate clearly the corporate passion for quality and to be consistent and organized in the development and rollout of the selected quality strategy. The language of the organization communicates the culture. Once the language is selected, it should be consistently utilized in all written documents; team, council, and/or committee names; the name of the quality department, service, or resource center; certain job titles; corporate bylaws; medical staff bylaws, rules and regulations; and if applicable, all relevant policies and procedures, and education and training materials.

The staff must also know what the common terms are so that when talking with others, they can be talking about the same things. In a surgery center, a surveyor asked the staff about their performance improvement activities and the staff could not answer her so they almost got a citation during the survey. However, the quality staff informed the surveyor that the words they used were quality improvement. The staff thought that performance improvement was related to their evaluations and their individual performance. The same principle applies to other terms utilized in the program, such as near miss, and so on.

Identify the Organizational Important Functions

In the determination of what should be measured and then improved if needed, there are many things to consider. It is well known that the organization cannot measure and improve everything at the same time due to the lack of resources available. Nevertheless, the organization needs to focus their improvement efforts on the issues that provide the most value to the organization and its patients/clients.

appropriate . The balanced scorecard is then what the focus of organizational quality should be directed towards for these groups (see Balanced Scorecard later in this chapter) .

Initiatives and Collaboration

Part of the Quality Council's prioritization and development of the strategic quality plan is to determine if there are external collaboratives and/or quality initiatives that the organization would benefit from participating with them. A collaborative involves individuals working with others to do a task and to achieve shared goals and to cooperate with an agency or instrumentality with which one is not immediately connected . An initiative is the power or opportunity to do something before others do; it is a plan or program, which is intended to solve a problem.

Initiatives are formed when stakeholders come together to solve dilemmas. The concept of "initiatives" is a means of proposing or confirming changes in current status. These can be applied to healthcare, education, politics and manufacturing. The focus of this diversity of initiatives is specific to a need or shortcoming of the system . There are numerous initiatives in healthcare that organizations can participate in. Table 3 lists several national initiatives.

Table 3 : Healthcare Initiatives and Collaboration Opportunities

Healthcare Initiatives and Collaboration Opportunities		
Initiative Organization	**Initiatives**	**Website**
Institute for Healthcare Improvement (IHI)	100 Million Healthier Lives IHI Leadership Alliance IHI Triple Aim	www.ihi.org
World Health Organization (WHO)	Targeted at specific diseases Roll Back Malaria Stop TB Global Alliance for Vaccines and Immunizations	www.who .int
Agency for Healthcare Research and Quality (AHRQ)	Accelerating Change & Transformation in Organizations & Networks Ill (ACTION Ill) Child Health Insurance Research Initiative (CHIRI) Primary Care Practice-Based Research Networks (PBRN)	www.ahrq.gov
National Quality Forum (NQF)	Healthcare Quality 2.0 Identify strategies for increasing the quantity and quality of data for systematic improvements in health and healthcare	www.qualityforum .org
National Patient Safety Foundation	Patient Safety Immersion Initiative Integrates membership and education programs	www.npsf.site-ym .com

involved (Network for Regiona l Healthcare Improvement, n.d.). In 2010, there were more than 40 Regional Health Collaboratives in the United States, with some being in existence for 10-15 years or longer. More information on Regiona l Healthcare Improvement Collaboratives can be found in the website list at the end of this chapter.

The Center for Medicare and Medicaid Services (CMS) has published a brief on the use of a collaborative care model in Medicaid Health Homes to integrate physical and mental healthcare (CMS – Medicaid Health Home, 2013). This program integrates primary care providers, care managers, and psychiatric consultants to provide care and monitor the patients' progress. This program, utilized with a variety of mental health conditions and settings, was able to be both clinically effective and cost-effective. This is but one example of how effective collaborative can be in the current healthcare arena.

The Agency for Healthcare R esearch and Quality (AHRQ) offers tools for community healthcare quality collaboratives. These include a leaders' guide to engage consumer advocates, as well as tools on measures, data and reports on quality and efficiency, tools for public and private reporting, tools for incentives for quality (including financial incentives), and tools to improve preventative services. All of this information is available on the AHRQ website at Community Quality Collaboratives .

The Organization's Approach(es) to Performance Improvemen

Several methodologies can be used to establish an organization wide approach for Quality/Performance Improvement (Q/PI) activities. These possible approaches/models focus on process improvements and are generally designed for use by cross-functional, interdisciplinary teams. Leadership and planning are essential for integrating existing and new improvement activities and for gaining consensus across the organization or system.

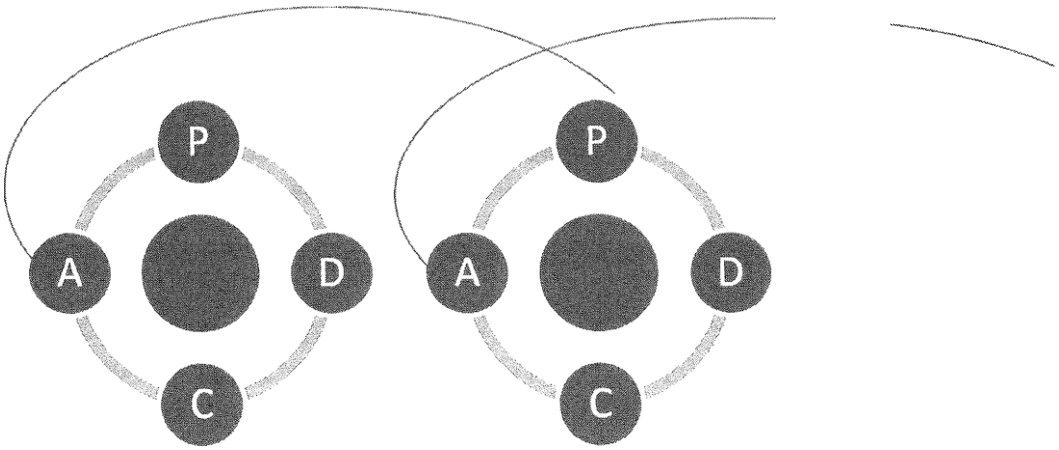
In recent years, some organizations have adopted multiple approaches to QM/PI, particularly with the rise of Six Sigma® and Lean as a strategic model, along with PDCA, for example, as the ongoing (original) operational team approach . Review the many different approaches available and select a framework that is acceptable to the entire organization, including physicians, all departments/serv ices/settings, affiliated healthcare organizations . Document the approach in the Plan document.

All approaches/models should embody continuous improvement concepts and should be planned, systematic, organization wide, and collaborative . Common characteristics of all approaches/models include identifying/focusing on prioritized areas in the organization, developing measures and collecting data, assessing performance, taking action for improvement, assessing improvement, effective team development and interaction, and use of statistical, analytical, and consensus tools at all steps. All of the character istics will be discussed in several models here, but other information about how to actually do the improvement activities can be found later in this chapter. The use of quality tools and statistics can be found in Chapter 4 Health Data Analytics.

or if not what your next steps might be. Based on this analysis, you will either repeat the same behavior at another time, or determine that you would do something else the next time you close this book (ACT).

One PDC/SA cycle can easily lead to another. In fact, a POCA cycle can identify other issues that need to be addressed in order to reach the goals one is trying to achieve. Many times, these identified issues can relate to the culture of the organization, and other organizational issues. Until these issues are addressed and overcome one may not be able to reach their desired goal of change (Reed & Card, 2016). Figure 2 demonstrates how this continuous improvement occurs. If you conduct a PDCA cycle and you do not get the results you wanted, you will move into another PDCA cycle and identify what to do next. When that cycle is complete, and you have the desired results, you will have identified another part of this process or other processes and move into a POCA cycle there. One of the aspects to be remembered is that once your POCA is complete with the desired results, you must have some plan to sustain the gain. If the facility begins to slip back into old practice habits, it needs to be identified early and another PDCA cycle completed to bring the process back under control.

Figure 2: POCA Continuous Cycle



the demand. The goa l is to match the supply with the demand exactly. Waste is defined as "any activity or resource that destroys value or consumes resources without creating value for the patient or the healthcare It involves reducing waste, variation, and overburden within processes (Delisle & Freiberg, 2014). There are eight forms of waste: defects, oversupply, waiting, not fully utilizing people's abilities, transportation, inventory, motion, and excess processing.

Several components are required for successful implementation of Lean management. The scientific method is utilized to solve problems. There must be a manager who is a facilitator, mentor, and coach. The frontline workers are the ones who identify and solve the problems. The quality manager must move the organization toward reducing the risk of adverse events and assisting staff and practitioners in the redesign of processes that improve the quality of the services provided (Mannon, 2014). This includes standardization of the process as much as possible. One of the first things that must be done is to begin to change the organization culture to one of focusing on the process and not blaming the individual.

There are multiple tools that are utilized in Lean management and several of them can be found in more detail in Chapter 4 Health Data Analytics. One essential tool is that of Visual management. In healthcare, bed boards, patient tracking systems, surgery flow boards, strategy deployment boards, and daily huddle basics are typical visual management tools. These tools communicate important information, keep all involved moving in the same direction, create transparency , increase trust, and create common information sharing for decision making, and shares and spreads improvements (Fausz, 2015). Every department that is involved in lean management should have a board in a designated area where the department metrics can be displayed, along with the quality goals of the unit.

Another tool that is extremely important to the lean methodology is the SS tool. This tool utilizes a systematic approach that is effective and simple to use model for process design and improvement. There are five phases in this tool: Sort, Store, Shine ,Standardize, and Sustain (Delise & Frieberg,2014) . The currrent state process map is drawn first to display how the process currently functions prior to any improvements and to determine the overall processing time. The Sort phase then evaluates what is needed and what non-value added items/steps can be deleted. Store consists of examining the effectiveness of the order of steps in the process, and reorganized to increase efficiency and productivity . Shine consists of streamlining the process to eliminate additional processing time. Standardize work phase is when the process steps are standardized. At this point in the Sustain phase, the process can be monitored and refined in order to maintain the new processing time. The key to the sustainment of this and other processes is the hardwiring of a performance monitoring and feedback loop to the staff. This is where the visualization board can really help.

- ANALYZE : root or potential causes of current or anticipated defects, respectively; confirm them with data; and discover nonvalue-added process steps, translating both into cost of poor quality.
- IMPROVE: Create possible solutions for root causes and select solutions, develop plans; pilot each plan, then implement; measure results. For each different proposed process improvement scenario, determine unit cost savings as well as all other benefits to customers/stakeholders.
- CONTROL: Standardize the work processes; develop the monitoring system, e.g., performance measures linked to balanced scorecard (see also Chapter 2 Organizational Leadership and later in this Chapter), both to sustain the improvement gains and control the process; create process for updating procedures; summarize and communicate learnings; recommend future improvement plans.

There are five levels of expertise in Six Sigma methodology, designated by a color-belt system. The color-belts are described in Table 5. There are two additional positions that provide organizational support to the team. The Champions are upper management who are concerned about the overall Six Sigma implementation and work with mentoring lower-level Six Sigma practitioners, identifying resources and removing roadblocks. They translate the company's mission, vision, goals and measures that will identify individual projects and determine a project deployment plan. Executive leadership is the highest level and includes the CEO and senior managers. The executives determine the overall strategy for Six Sigma implementation and establish the strategic focus for the program (ASQ – Six Sigma, n.d.).

Table 5: Six Sigma Belt Colors

Six Sigma Belt Colors	
White Belts	Work on local problem-solving teams but not part of Six Sigma teams Have an awareness of Six Sigma aspects
Yellow Belts	Participate as project team member Reviews process improvements that support the project
Green Belts	Lcuds Green belt projects and teams Assist with the data collection and analysis for Black Belt projects Integrate Six Sigma implementation into their primary jobs
Black Belts	Leads problem-solving projects Trains & coaches project teams Dedicate all their professional efforts to Six Sigma
Master Black Belts	Concentrates on Six Sigma implementation Trains and coaches Black and Green Belts

improved, the improvements/changes need to be changed in the policy and procedures, as appropriate.

Identify Educational Needs

The educational needs in regard to quality/performance improvement, risk management, patient safety, accreditation, and utilization management will vary in each type of healthcare organization. It is up to the quality management leaders to determine who requires what education and to determine the best methodology to deliver that education. Specific educational goals should be developed along with ways to measure the effectiveness of the teaching. The effectiveness should be measured at the conclusion of the educational event, but also later in time to assure that information learned is applied as appropriate in the organization. Educational methods, etc., are further described later in this chapter.

QUALITY, RISK, UTILIZATION, AND PATIENT SAFETY PLANS

Written plans generally describe quality management/improvement, utilization review/management, risk management, patient safety functions, and govern their operations. The plans may be separate or integrated. All plans should align with the organization's vision and strategic goals, as well as sound and look like they came from the same organization. This demonstrates the collaboration between the different areas. The plans for quality, risk, and utilization management will be discussed separately here. While there are many elements of similarity between the plans, there are also unique differences. The Patient Safety Plan will be described in Chapter 5 Patient Safety.

All organization wide plans related to the provision of patient care and services must be approved by administration, the governing body, and, in hospitals, by the medical/professional staff. In managed care, such plans are approved by a plan performance or quality committee involving a key physician and the governing body. Individual provider plans are approved as part of the contracting process.

In the U.S., written plans for quality and utilization management functions are required by most states for licensure, by federal agencies for participation in funded programs, and by most contracting health plans (managed care). A written plan generally is not required for risk management, except as specified by liability insurers, but is highly recommended. A written plan for patient safety is not required either, but some accreditation standards require a patient safety program, which should have a plan to increase effectiveness of the program.

CMS requires both a performance improvement plan and a utilization management plan. The National Committee for Quality Assurance (NCQA), which accredits managed care organizations, requires a "written description" of the QI program structure and content and the UM program structure and accountability, but not risk management.

2. Use of data and measurable outcomes in the progress towards evidence-based benchmarks.
3. Focuses on linkages, efficiencies, and provider and client expectations when improving outcomes.
4. Continuous process that adapts to change within the organization's quality improvement arena.
5. Data collected is utilized to assure that the goals of the program are accomplished and they are concurrent with the improved outcomes.

Table 6 lists the basic elements that must be in a Quality/Performance Improvement Plan. The contents of the elements will be different based on the type of organization and patients served.

Table 6: Elements of a Quality/Performance Improvement Plan

Elements of a Quality/Performance Improvement Pln	
I.	Purpose
II.	Organizational mission, vision and scope of service
III.	Goals and Objectives for this year's plan
	a . Clinical goals
	b. Operational goals
	c. Strategic Initiatives
IV.	Overview and Planning
	a. Identify customers
	b. Organizational important functions
	c. Prioritization of performance opportunities
V.	Structure and Design - Program infrastructure
	a. Quality Council
	b. Roles and Responsibilities
	c. Pl Teams
VI.	Approach and Methodology
VII.	Documentation and Communication
VIII.	Confidentiality and Conflict of Interest
IX.	Program Evaluation
X.	Appendices
XI.	Approval Signatures

Risk Management Plan

Risk management in healthcare involves improving patient safety, investigating potentially litigious situations, preventing harm, minimizing losses and the impact they may have, and protecting organizational resources. The Risk Management department seeks to identify potential risks and then

organized, system-wide approach to ensure effective and efficient utilization of hospital facilities and services and includes a performance improvement component.

Many U.S. State Departments of Health Services require Utilization Management Plan as a condition of licensure. A solid plan forms the foundation for a meaningful, action-oriented initiative that drives improvement and change. The overarching principle outlined in the plan is to ensure that the hospital provides medically necessary, reimbursement-eligible services at the appropriate level of care while optimizing quality outcomes and financial performance. The purpose (scope), goals and objectives of the UM plan serve to set the direction and tone for the utilization review committee, physician leadership, administration and staff charged with overseeing and/or carrying out the plan in the best interests of the hospita i, healthcare team and patients. The utilization plan is an organized, system-wide approach designed to take a broad view of the care provided and resource management while maintaining quality of services and adhering to professionally recognized standards.

Utilization Management generally is described in writing because it is an organization-wide process with many component steps. UM has potential to impact greatly patient outcomes, particularly through decisions made about setting, visits/revisits, level of care, admission/continued stay, resource use, and associated access to care. All healthcare organizations have cost containment and other financial goals stated in strategic plans, annual objectives, or acted out in operational practice. UM is the one management activity with potential to assess the impact of such goals, objectives, and operational practices on the patient. It is understood that underutilization, overutilization, or otherwise inappropriate utilization of healthcare resources can have a direct impact on both the quality and clinical risks associated with care delivery.

In a nutshell, utilization management is all about doing the right thing for every patient, every time. That includes the continuum of care from before admission for services, through the discharge from care, and services provided post discharge. Care is taken to ensure effective and efficient utilization of healthcare facilities and services with performance improvement achieved through a concurrent, collaborative process of utilization review and management of all healthcare admission for care, continued stay reviews and retrospective reviews, using firm criteria. The length of stay and other indicators are tracked and trended, issues with avoidable days are examined, and questionable use of resources is explored. Any patterns of under-utilization, over-utilization, and inefficient use of resources are investigated. The appropric1lene!>!> o f treatment settings is also reviewed.

Because the services, data, and resources are different at each organization, the purpose (scope), goals, and objectives will be specific to the entity. One of the issues to address is the relationship between utilization management activities and other equally important functions and processes of the organization and across the delivery system. The basic elements of a comprehensive hospital utilization management plan are provided in Table 8. Spec ific aspects to any organizational Utilization

The Role of the Quality/Utilization/Patient Safety/ Accreditation/Risk Professiona l in Organizational Preparation for Quality Management/Performance Improvement

The following list of prerequisites for *implementin g* a new or redesigned organization-wide Quality/Risk/Utilization/Patient Safety/Accreditation management strategy is not necessarily chronological. The organization must be sensitized to these issues, and preparations should be in process before the actual organization-wide plan document(s) is developed or redesigned so that the information flows well between the facility structures. It is assumed that the Quality/Utilization/Risk/Patient Safety/accreditation professional facilitates the coordination and fulfillment of these basic tasks:

1. *Secure the approval, support, and commitment of* ***all*** *key players,* which at a minimum includes the governing body, administration leaders, medical staff leaders, medical directors, nursing leaders and other clinical and support service directors/managers. Leaders each must make a personal commitment and be willing to participate in Quality/Risk/Utilization/Patient Safety/accreditation management strategy development and implementation. All others in the organization must see leadership develop a passion for Quality/Risk/Utilization/Patient Safety/accreditation management. The healthcare quality professional must have the leadership skills and passion 1) to maximize the commitment of other key players and 2) to identify those leaders and others who are willing to be the Quality/Risk/Utilizat ion/Patient Safety/accreditation champions for the cascade of activities throughout the organization .

2. *Establish effective rap port and relationships* . Leaders should not **demand** participation, but must build effective, trustworthy relationships, based on an obvious personal commitment, a willingness to share information and expertise, and proven credibility. If the leader is demanding, the staff may react negatively and be less willing to engage.

3. *Perform assessment and identif y existing organizational strengths, weaknesses, and needed changes* through quality planning and prioritizing, in conjunction with strategic planning, considering:

- Structure and environment, including climate for change
- The extent and type of support, including the knowledge and involvement of members of the governing body, medical/professional staff or Licensed Independent Practitioner (LIP) leadership, administration, and management
- Results from previous regulatory and accreditation survey reports
- The extent and type of resistance, both real and anticipated

4. *Develop a written report and Action Plan for* Quality/Risk/Utilization/Patient Safety/accreditation management *system and process development* . The Action Plan is not the same type of plan as the written organization w ide Quality/Risk Management/Ut ilization/Pat ient Safety/Accreditation Plan(s)

MEASU REMENT/PERFORMANCE IMPROVEM ENT PROCESS

The measurement/performance improvement process overview leads off this section of the chapter. Following the overview, the information in the overa ll process will be discussed in more depth. This will be followed by different types of measurements that need to be done w ithin different types of healthcare organizations.

Once the performance improvement program structure is determined and the improvement plan written, it is time to implement the program and the plan. If you are not starting from scratch, and most of you are not, then this section should be utilized as an evaluation process for your existing Quality/Risk/Utilization/Patient Safety/accreditation measures and processes to determine if there are opportunities for improvement there.

Measuring performance (data collection) is the basis of all quality management/improvement activities. Measurement is the systematic collection of quantifiable data about both processes and outcomes over time or at a single point in time. Quantifiable process and outcome indicators are used to monitor performance to be measured. Since quality improvement has strong affiliations with business and manufacturing, it is no wonder that a form of measurement in these processes needed to be quantifiable. There are many ways these data can be measured. However, many individuals in healthcare are not used to measuring outcomes. Alternatively, based on previous data collection that was mainly focused on negative data, they focus on what's wrong but not what's right and how to make it better. Data must be collected about the current, existing level of performance. Once interpreted (aggregated and analyzed), the data becomes valuable information for decision-making. Collecting data about current performance enables the organization to identify opportunities to improve or the need to redesign existing processes as well as to determine whether improved/redesigned processes meet objectives/expectations. Remember, data should not be only from the clinical areas processes, but also from non-clinical areas. A combination of clinical and financial data is often useful.

Data collection is used at any point, and at multiple points, in the Quality Management Cycle to provide the necessary information (once data is properly interpreted) for decision-making (Figure 3). The frequency of measurement depends on the specific process or outcome, as well as the purpose. It can occur at one point in time or it can be repeated over time. For some processes, data collection is continuous and results in a database about current performance over time (trend reports): For example, door-to-door time in the emergency department, or encounter time in a clinic or doctor's office, and so forth. In other cases, data collection provides a baseline and then periodic measurement to examine and/or prioritize processes for improvement at points in time, for example, safety checks of the environment.

The measurement process includes an ongoing prioritization of measurement efforts based on strategic goals, data already collected, and available resources. There must be validation that selected

Once the measurement process is completed and the data analyzed, there must be a determination of whether there needs to be any improvements to the process/outcome. This decision-making can be done at a variety of levels and the decision should be made based on the evidence. There should be documentation of what the organization considers good enough. You do not want someone to decide that the improvements are good enough simply because someone does not want to deal with that issue any longer. If it is determined that 85% or 90% is good enough, remember that means that 1or 1.5 patients per 1,000 were not satisfied or cared for correctly . If that one patient were your grandmother, how would that impact her and your family? Let's look at an example. Adult patients are admitted through the emergency department with the diagnosis of pneumonia. Data is collected to determine how quickly the antibiotics are started. It is found that they are started within 45 minutes 80% of the time. If this is not good enough, something i1eeds to be done to improve the process.

If improvements need to be made, then a Pl Team, or other process designated by the organization, is formed to make the necessary improvements. Utilizing the PDCA, or other improvement model, the team develops an action plan and implements it on a pilot, or small basis if using rapid cycle improvement.

Continuing with the pneumonia example, the team determines that the antibiotics need to be ordered right away and the antibiotic infusion begun within the 45 minutes allotted. When implemented, any changes or refinement are completed and re-measured . If acceptable, the action plan is then expanded to the entire organization as appropriate. Data is again collected and analyzed, with actions taken as appropriate if the results are not where desired . If the results are acceptable, then methods must be put in place to sustain the gains. Once this has been established, then the changes and important aspects of the process are documented in policies and procedures. The results of the improvement process are documented and then communicated through the Quality Council and to other departments and areas that can benefit from the results of these improvements . For example, the improvements that were made in the care of adults admitted with pneumonia should be communicated to pediatric practitioners for them to utilize in improving the care of pediatric patients admitted with pneumonia, as applicable .

!concept of Performance Measuremenij

The measurement of performance was always the **intent** in using "indicators" of care in past monitoring and evaluation activities. The focus in analysis of those indicators was on **negative variance** from an acceptable clinical standard or threshold . Also, for the most part, clinical variance was assigned to the appropriate responsib le direct care provider: physician, nurse, physical therapist, etc. Healthcare has come a long way in now having both the information technology and the understanding to use performance measures to provide information about how well processes are working to deliver patient care in the organization.

than creating new indicators, etc. to be utilized in data collection. Items such as the core measures, infection control/prevention measures, CMS required indicators, and so on should be found here also.

Performance Measures/ Indicators/Metrics are gauges or points of reference for evaluating the organization's actual performance and comparing that performance with a targeted objective or a standard. Well-defined and constructed performance measures are predictors of the organizat ion's ability to achieve strategic goals. They are not considered to be direct measures of quality, however, but rather indicators of performance. They are measurement tools to assess the degree to which the appropriate and expected course of action **(process)** is being followed, and the degree to which the expected **outcome** is being met, for clinical, resource and service functions. Standards and guidelines may facilitate the development of indicators . I ndicator data may assist in the development or refinement of standards and guidelines.

!structure, Process, & Outcome Measure

In 1996, Avedis Donabedian proposed the use of these three types of measures: structure, process, and outcome. Structure is defined as, "conditions under which care is provided" (Donabedian, 1981,p. 46) . Structure measures are the things that must be present to do the work. This would include the right equipment and supplies, as well as healthcare professionals with appropriate licenses, certifications, or registration as required. Process is defined as "the activities that constitute health care" (Donabedian, 1981, p. 46). Processes are how the healthcare is carried out, the policies and procedures, the techniques utilized, and so on. Of note here is that some individua Is consider policy as structure rather than processes. Outcome is defined as "changes (desirable or undesirable) in individua ls and populations that can be attributed to health care" (Donabedian, 1981 p. 46). The outcomes are the results that come from completing the processes.

lstructurel measures are necessary to assure that there is compliance with the structure elements that must be in place to provide the health care. These are measured during quality control measurement and not necessarily with quality/performance measures. Structure is the arrangement of parts or elements of a care system that facil itate care; the care "environment"; evidence of the organization's capacity to provide care to patients. Several other examples include: the ability of a hospital to provide cardiac catheterization lab services for a patient presenting with an ST segment elevation myocardial infarction (STEM!); the ambulatory clinic w ith adequate doses of flu vaccine ; or in the home health areas, having enough working blood pressure cuffs and scales for the patient load.

!Proces refers to the procedures, methods, means, or sequence of steps for providing or delivering care and producing outcomes. In industrial terms, processes are activities that act on an "input" from a "supplier" to produce an "output" for a "customer" . The more complex the process, the more difficult it is to manage the quality and the greater the opportunities for deficiencies. In healthcare, we have the greatest control over the processes. Clinical processes are what practitioners do for patients and

lKey Points in Indicator Selection/Developmen

The detemination of specific indicators to utilize is often driven by many different needs of the organization. What needs to be measured and what indicators to utilize can derive from regulations, accreditation standards, governing boards and other leader determinations, the organizational strategic plan, current data or by identification of weak areas within the organization . Whatever is driving the need to utilize indicators, it is extremely important that the process or outcomes to be measured has been defined as to specifically what is to be examined. If someone determines that patient flow needs to be measured, and no other information is obtained, then the organization may measure one aspect of patient flow, but it may not be the actual desired portion of patient flow meant to be measured . This is just one of the many considerations that have to be examined before any indicators can be selected or developed.

There is a definite skill set needed to write a 'good' indicator. As in writing behavioral objectives, there are different degrees to which the writer needs to be aware. If the indicator can be one that comes from the organization's performance database, data inventory, or from one that has been developed by others to decrease the variation in indicator definitons, then this will assist the organization to acquire good indicators. There are several national measure inventories that can be utilized for this purpose. These national measures already developed should be investigated and utilized, if appropriate, prior to making the decision to develop them independent ly.

The first national measure inventory is the **!National Quality Forum (NQF)l** a not-for-profit, membership-based organization (NQF, 2010). Measures endorsed by NQF are intended for quality improvement, accountability, and public reporting in the U.S. NQF reviews, endorses, and recommends use of standardized health care performance measures. The national government and other organizations use NQF-endorsed measures because of the rigor and consensus process used to develop them.

The second national measure inventory is the **!National Quality Measures Clearinghouse (NQMC)l** a public resource for evidence-based quality measures and measure sets. NQMC is an initiative of the Agency for Healthcare Research and Quality (AHRQ) (NQMC, 2017). "The NQMC mission is to provide an accessible mechanism for obtaining detailed information on quality measures, and to further their dissemination, implementation, and use in order to inform health care decisions" (pg. 1). It is a database for information on evidence- based health care quality measures and measure sets . The measures in NQMC are grouped into two main categories: measures related to health care delivery and measures related to population health. Measures in NQMC may be used for quality improvement as well as for accreditation, certification, and decision-making. NQMC does not endorse measures, and it includes measures developed by organizations in other countries.

Table 9: Possible Focus Areas for Indicators

Possible Focus Areas for Indicators
• Accessibility, appropriateness, timeliness, efficiency, and continuity of delivery
• Safety and acceptability of care and service
• Patient outcomes
• Service outcomes
• Expected clinicaljudgments and competencies
• Technical skills and performance
• Organizational skills and performance

Once the focus of the indicator is determined, the develper must then determine if the indicator is to be rate-based or a sentinel event indicator (Table 10). The rate-based indicator consists of a numerator and a denominator. A rate-based indicator assesses either for an event for which a certain proportion (subset of the population) of the events that occur in a specified time period represent expected care, or service, or which assesses for the degree to which an event/outcome occurs with a different denominator. Sentinel event indicators (100% analysis or 0% acceptability) assess serious or signif icant events that require further investigation for each occurrence. This type of indicator does not have both a numerator and a denominator, but when it happens, an investigation must begin immediately (see Chapter 5 Patient Safety for RCA information).

Table 10: Indicator Types with Examples

Indicator Types with Examples	
Indicator Type	**Example**
Rate-based Indicator: Proportion (Used with nominal & ordinal data)	# of falls with injury this month Total # Falls this month
	# ets who brought their medications to clinic Total # patient seen in the clinic
Rate-based Indicator: Different definitions (Used with interval and ratio data)	# of eatients with falls this month Total # of patients seen this month
Sentinel Event	# of falls resulting in a head injury

The indicator must also possess importance, be feasible and have reliability and validity. The same definition must be utilized by everyone who is measuring the process or outcome. Reliability is the

!ggers!

A trigger can be defined as a stimulus that sparks or activates an action. Performance analysis should include comparison of actual performance data with a benchmark, previous validated data, an aggregated rate over time, or another equally significant "signal." Comparison will assist in answering the question, "Based on this data, should we initiate more intensive analysis of this process?" Therefore, each measure selected to assess the level of performance needs a mechanism to determine when to look further or when to prioritize for improvement.

!characteristics of Triggers!

Triggers are generally stated as incidence rates (numerator over denominato r), >0 for sentinel event indicators, standard deviations (>2 or >3 SDs above or below the mean), and upper and/or lower control limits (stated as SDs or the top or bottom of a range) . Table 12 displays several possible triggers that can be utilized.

Investment of organization resources for in-depth analysis must be weighed against potential for quality improvement and improved patient satisfaction. Three questions should be answered before intensive, in-depth analysis isbegun:

1. Is there or is there not a problem?
2. Should action be taken now to prevent a problem later?
3. Is there still an opportunity to improve care or service, though no special problem has been identified?

In performance improvement, dipping above or below outcome control limits can serve as triggers that alert the observer that something intentional needs to be done quickly to get the process back into control or stable. When outcomes are consistently jumping in and out of control limits it indicates that there is a great deal of variabi lity in the process. On a run chart, upper and lower control limits, are triggers in and of themselves to alert observers to institute intervention activities (see Chapter 4 Health Data Analytics). On a balanced scorecard, one might see an outcome moving from achieving the goal to being outside of the goal level. When this occurs, it is not uncommon for an organizat ion to require leaders to submit an explanation, along with a corrective action plan designed to return the outcome to the goal level of performance.

Triggers can also be derived from authoritative sources supported by expert clinical and quality management literature or the organization's own policies, procedures, performance data, or clinical experience and expertise. For example, the use of benedryl and narcon can be a trigger for the Pharmacy to identify drug reactions and overdoses . They are often selected, developed, and/or adapted by clinical or operational experts, as appropriate, and are approved by the department/service and/or QI Team. They may be set at a trigger point rate or at a higher control limit

	-- Control limits allow for a "normal" range of variation, based on acceptable differences in patients, practitioners, and practice -- Control limits help identify "special causes" of problems that are noticeably outside the "normal range of variation" -- Upper and lower control limits are often set by standard deviation measures once data has been averaged (see Chapter 4 Information Management) Pre-established upper and/or lower specification limits *for meeting patient nee* based on patient interviews or surveys, e.g., patient wait time in the primary care clinic not longer than 15
Qualitative & External Triggers	• Patient feedback • Staff feedback • Strategic planning/quality planning • Organizational quality initiatives • Internal benchmarking and/or goal-setting • External feedback (agency, reference database, benchmarking, etc.) • Quality improvement team impetus to improve • Relevant practice guidelines • Scient ific, clinical, and management literature

Rate-Based Triggers must be stated correctly, using both a numerator and a denominator . For example:

For a community health clinic, a trigger set at ">0.2%" for the indicator, "Patient complaints about medical care are kept to a minimum", means that intensive analysis is necessary if the rate of complaints goes higher than 0.2% (or >.002 if not stated in percentage terms). If there are more than 3 complaints in a total of 1500 patients seen per month, intensive analysis required.

The rate is calculated by dividing the total number of patient complaints by the total number of patients seen per month. This is a rate-based tr igger that is consistent with both definition and intent. The administrator, service manager, or quality improvement team will determine the extent of the in-depth look at the issue, which will be more urgent if there is a progressive trend over a period greater than two quarters.

PERFORMANCE AND PROCESS IMPROVEM ENT

Benchmarking processes are beneficial to performance improvement efforts in that they are useful in analyzing systems or processes that are out of compliance, weak, or not delivering as they should. Also benchmarking assists in evaluating new processes or treatments to be aware of the successes and pitfalls of other organizations. Re-evaluat ing resource intensive processes with other organizations is another use of benchmarking, especially if the other organizations have found more efficient ways to do the process. Benchmarking can be utilized to motivate an organization to engage in improvement, help individua l practitioners understand where their performance is weaker than others are, and to stimulate healthy competition (AHRQ – Benchmarking, n.d.). Key to effective benchmarking is to be sure you are comparing the same processes in both organizations, processes that you are comparing apples and apples. For example, if you are addressing falls in the Intensive Care Unit (ICU), be sure to utilize the other organization's ICUs' processes and not a medical/surgical unit's processes.

In healthcare, quality management activities are increasingly dependent upon accepted national standards of care and practice guidelines as "benchmarks" for the development of performance measures/indicators, and as the impetus for action and improvement in care . However, these standards of care and practice guidelines cannot always be implemented exactly as they are written. They must be examined and a determination must be made as to whether to implement all or parts of the process or if the culture of the organiza tion must be changed first. Without changing the culture of the organization, pathways are more difficult to implement. When pathways first came about in the early 1990s, many organizations had difficulty implementing them. Physicians felt pathways were "cookbook" medicine and did not buy into the process. Other disciplines did not understand why this new way of documenting was needed. The lawyers of many healthcare organizations felt the pathways should not be kept in the medical record, which often resulted in duplicate charting.

Benchmarking can be either internal or externa l. Internal benchma rking identifies best practices within an organization . It can be used to compare best practices within the organization and to compare organizational practices over time (Lovaglio, 2012). External benchmarking involves utilizing compa rative data from other organizations to determine performance and identify improvements that have been successful in other organizations. The broader the perspective of what is being benchmarked, the greater the reliance should be placed on outcomes measures. If the perspective is a narrow one, such as a specialty , or individual practitioners, then process measures are more useful. By using process measures rather than outcome measures, process measures lead to straightforwa rd interpretation and remet.lidl action is clearer . Outcome mec15u rc!; look at a broader picture, such as mortality rates, and all of the specific reasons for the outcomes may not easily be explained.

In the comparison, it is important to assure that definition sets for the numerator a nd denominator are as similar as possible. If different definitions are utilized the benchmarks will be of no use for comparison . There must also be similar data collection methods utilized and the populations should be of adequate sizes over a sufficient amount of time in order to have a statistical ly relevant number of

Balanced Scorecards were developed in 1992 by Robert Kaplan and David Norton as a performance measurement system. Their system looked at the financials of the organization, but also the customer, business process, and learning measures (Balanced Scorecard, n.d.). The balanced scorecard moved from a performance measurement system to a strategic planning management system enabling organizations to translate their vision and strategy into action. The balanced scorecard is frequently utilized at the administration, Quality Council, medical staff leadership, and governing board levels (see Communication at the end of this chapter).

Dashboards display data pulled from systems and processes within varied departments to provide a "snapshot" of performance at given points in time, e .g., monthly or quarterly, and allow leaders to gauge how well the organization is performing overall. Baianced scorecards provide focus on critical outcomes; alignment between and across levels of the organization; accountability, with performance levels and persons responsible; and communication of strategy throughout the organization .

Each portion of the balanced scorecard includes the major objectives to be obtained, measures of those objectives, target values of the measures, and initiatives or action programs to be initiated to meet the objectives (Balanced Scorecard, n.d.). Several possible objectives and possible measures are listed in Table 13. This list is by no means comprehensive and in fact, the objectives and the measures will be different for the many types of healthcare organizations . The scorecards/dashboards from the different departments of the organization contain data for their areas that meet the same types of information, but they also contain more specific information than is found on the balanced scorecard. The data from the different departments are condensed and aggregated to be included on the balanced scorecard. As the scorecard rises through the organization, the measures become more global and by the time it reaches the governing board level, there are about 10-15 specific measures that are compilations of what has been put together at the lower levels, giving them an overall snapshot of the organization's status. The information on the balanced scorecard then is utilized to clarify strategy, communicate strategic objectives of the organization, assist in planning, setting targets, and aligning strategic initiative, and provide strategic feedback and learning.

Table 13: Potential Scorecard Objectives and Measures

Potential Scorecard Objectives and Measures	
Objectives	**Possible Measures**
Community Perspective	• # community-based services or projects (new/linked to needs assessment) • # volunteers • # uninsured patients
Customer Perspective (patients, physicians, employees, other customers)	• Satisfaction (patients, physicians, employees) • Point of service survey results (patient services, key suppliers/partners)

literature and trying to emulate the practice described . Evidence-based practice "is the integration of best research evidence with clinical expertise and patient values" (Sackett et al., 2000, p.11). Clinical expertise encompasses "the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in ... more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care" (Sackett et al., 1996, p.71).

EBP incorporates not only the perspective of the clinician but also the perspectives of the patient. The evidence may also include, but not be limited to, patient-repo rted occurrences, clinician-observed episodes, and research-derived evidence of state-of-the-art patient care and practices. EBP uses a holistic approach to the incorporation of evidence. In fact, benchmarking is a major factor in the establishment of evidence-based practices. In this case, the benchmarks are found in a review of the scientific research identifying what the evidence says is the best practice. These best practices are then utilized to improve processes and outcomes, to develop evidence-based clinical guidelines and pathways, and for many other purposes. EBP informs practice by the analysis of multiple relevant research studies and different forms of evidence related to the issue or practice of concern.

The initial step is to clearly identify the practice problem, issue, or clinical area of concern for which the evidence is sought. The development of a PICO or PICOT question guides the search for the research evidence . The "P" stands for population, problem, situation; the "I" stands for intervention or issue; the "C" stands for comparison; the "O" stands for outcome; and a "T" stands for time. It is not always necessary to have a comparison or time component in the question (Melnyk & Fineout-Overholt, 2015). An example of a PICO question could be: P = pneumonia patients in the ER; I = early initiation of antibiotics; C = using the process as it is now; 0 = quicker recovery for the patient. Said a different way: In pneumonia patients that come through the ER, is an earlier initiation of antibiotics more effective than the current practice resulting in the patient recovering and being discharged sooner? The PICO question is the foundation for a focused literature search.

The next step of EBP is to conduct a literature search of scholarly sources and then critically evaluate each article for the strength and quality of the evidence. This includes asking questions such as: how rigorous and reliable is the evidence? What is the magnitude of the effect of this evidence? How precise is the evidence of effects? What evidence is there of side benefits or side effects? What is the financial cost of applying or not applying the evidence; and is the evidence relevant to the particular situation that it is to be applied to (Melnyk & Fineout-Overholt, 2015). To assist practitioners in answering these questions, there are several hierarchy models that can be utilized; all are similar . The strength of the evidence is determined by ranking the evidence based on the type of research, the highest being systematic reviews or meta-analysis of randomized studies and the lowest being expert opinion. Two common EBP evidence hierarchies are the Melnyk hierarchy of evidence and the Johns Hopkins evidence rating scale . As seen in Table 14, Level 1consists of the strongest evidence to utilize, and Level VI consists of the weakest evidence to use in the EBP.

All such guidelines are considered, in quality improvement language, "specifications of process" or "specifications of care," based on the best scientific evidence of effectiveness combined with expert opinion. They describe "typical" treatment for "typical" patients and provide a framework for discussing patterns of care for cohorts of patients (patients with similar risk, comorbidity, severity of illness, and expected outcomes). Table 15 displays the differences between clinical practice guidelines and clinical pathways.

Table 15: Clinical/Critical Paths versus Clinical Guidelines

Clinical/Critical Paths versus Clinical Guidelines	
Clinical/Critical Paths	**Clinical Guidelines**
"Critical path analysis (CPA) is a management approach that can be used for monitoring, ana lysis, and prediction of success of its time- bound operational activities. Management model of **clinical** trial (CT) still needs exploration and research. **Critical path** analysis (CPA) is a management approach can be used for monitoring, analysis, and prediction of success of its time-bound operational activities." (Kumar & Chakraborty, 2016).	**"Clinical** Practice **Guidelines** (CPGs) are seen as the gold standard of evidence-based care. Because of their influence, these **guidelines** can have profound legal and economic effects. Despite their proliferation and influence, the trustworthiness and quality of guidelines have been seriously questioned and they have been implicated as drivers of overtreatment." (Simmons, Cosgrove, Shaughnessy & Bursztajn, 2017).
"Understanding how to identify and improve clinical pathways has proven a key tool in quality improvement. These techniques originated beyond healthcare, but are increasingly applied to healthcare. This paper outlines the history of the technique transfer and how to use in clinical practice." (Lerner, C., Cheung, R., Klaber, R., & Hibbs, N. ,2016).	**"Clinical** practice **guidelines** provide a framework against which quality of care is measured. Recommendations contained within **guidelines** are used for decision-making not only within the **clinical** domain but also other related issues within the health systems. As such the **use** of research evidence for formulating recommendations contained in a **guideline** is a global standard to ensure **guideline** quality. The paper briefly reviews **how** the need for and **use** of evidence in **guideline** development shaped up historically and then provides an overview of the four typologies of **guideline** development mechanisms at the country level." (Bhaumik, 2017).

reconstruction of the head and neck from January 1, 2014 through December 31, 2014. Continuous variables were compared among 4 groups using analysis of variance or Kruskal-Wallis test, and categorical variables were compared using x2 test or Fisher exact test where appropriate. The primary predictor variable was use of the clinical pathway. Groups included patients treated by surgeon A during periods before and after implementation of a postoperative clinical pathway . Two groups treated by surgeon B also were evaluated during the same periods and served as external controls. Each period covered a span of 6 months. Outcome variables across groups were evaluated, including length-of-stay metrics, infection rates, transfers to the intensive care unit, and unplanned return to the operating room. Figure 1. The clinical pathway implemented by surgeon A beginning July 1, 2015. **Conclusions** The results of this study suggest that implementation of a clinical pathway can be beneficial for efficient management of postoperative care in the setting of microvascular head and neck reconstruction . More predictable and shorter lengths of stay are achievable and the clinical pathway serves as a valuable means of improving communication of the clinical care team. (Yetzer, Pirgousis, Li, & Fernandes, 2016).	

Clinical Practice Guideline (CPG)

The definition of a clinical practice guideline emphasizes two important aspects of a guideline that should be represented in well-developed evidence-based guidelines: being based on a systematic review and assessing, the benefits and harms of recommended care and alternative care options. Early into the use of CPGs there were many failures . Many of those were a result of developing the guidelines without the representative disciplines, or the correct individuals, that were to use them. In one hospital developing pneumonia CPG, there were two physicians on the team. However, these

Another resource for clinical practice guidelines is the Department of Veterans Affairs/Department of Defense (VA/DoD) http://www.healthquality .va .gov. Additionally, medical and nursing specialty organizations also develop clinical practice guidelines although the metrics for monitoring are not incorporated. No organization should simply adopt the guidelines that are found at these sites, but must first examine the evidence and determine what within the guidelines can be transferred to that organization to improve care. Not everything that is done in these -guidelines can be implemented in every healthcare facility.

There are barriers and facilitators for nurses using the clinical practice guidelines (Jun, J., Kovner, C., Stimpfel, A., 2016). Internal factors affecting the implementation of clinical guidelines include attitudes and perceptions and knowledge . External factors include the clinical practice guidelines themselves, resources such as time, staffing, supplies, equipment, and logistics, leadership, and the organizational culture.

There are many reasons that guidelines are used in healthcare today. As the industry is changing and reimbursement models are modified, appropriate guidelines are needed to set expectations and guide reimbursement both in acute care and in ambulatory practice. Medicare's system for evaluating the quality of care and reimbursement guidelines includes tracking of healthcare and physician quality indicators based on guidelines.

The passage and implementation of the 2010 Patient Protection and Affordable Care Act has stimulated research to see if quality and reimbursement will be affected. This research will continue as the US healthcare system continues to transition. Evidence based guidelines will be reviewed, revised and implemented based on the needs of those who provide and receive care, as well as those who pay for medical care.

Clinical Pathway and Clinical Algorithm Development

National practice guidelines offer solid baseline information for the development of organization-specific clinical pathways (clinical management plans). In addition, practice guidelines help in the development of clinical algorithms to support clinical pathways. For example, physicians can support the effectiveness of a clinical pathway for ventilator-dependent patients by developing an acceptable weaning protocol or algorithm. Another example is physician development of algorithms for the prescription of appropriate antibiotics, based on infectious agent, for patients with pneumonia who are being treated by the team in accordance with a pneumonia clinical pathway.

Accreditation & Regulations

The Joint Commission (TJC) and National Committee for Quality Assurance (NCQA), as well as other accreditation and regulatory agencies, require the selection and implementation of clinica l practice guidelines, along with evaluation of their effectiveness . The guideline selection is based on the

	- Timely performance of therapies and procedures • Improving communications, e.g., orders, transports consultations, discharge • Reducing variation in physician practice patterns • Offering flow-charted information to QI Teams for the selected diagnoses, procedures, and conditions and ongoing variance tracking after QI actions have been implemented • Providing the basis for ongoing, as well as special, monitoring of diagnoses, procedures, and conditions. Chart review can be performed, concurrently or retrospectively, using the clinical pathway as the patient management tool
Clinical pathways facilitate implementation of capitated managed care contracts	• Predicting preadmission/pre-procedure visits, length of stay, resource use, aftercare, and expected outcomes for specific diagnoses, procedures, and conditions for use in marketing and negotiating with employers, HMOs, and other healthcare purchasers • Focusing the attention of all care providers on maximizing each visit or day of care for the patient, that operationalizes concerns about costs per visit or day of care, effective use of resources, and progress toward meeting stated patient care objectives

To develop an effective clinical path system, the focus, diagnoses, procedures, and/or conditions must be identified, ideally by organization leaders, based on accurate, in-depth analysis of available data. The percentage of the patient population to be included must be defined with patient groups selected based on high volume, high cost, high risk, or problem-prone data . In addition, leaders should seek to identify those diagnoses, procedures, and conditions that have wide variability in processes (management by opinion, not standard) and clearly need a new process designed to bring the clinical system under control. Not all diagnoses require a clinical pathway. A routine appendectomy or vaginal delivery certainly does not require a pathway to establish the plan of care. The clinical path must be developed by a team consisting, at the least, of all those who provide direct care to the identified patient group. The clinical path that is developed should not change clinical staffing requirements. It also should consider the entire episode of illness, outlining care requirements for each care discipline and each level of care, including ambulatory, inpatient/alternative delivery, and aftercare. In developing a pathway, Table 18 describes some steps that should be completed.

objectives (home health or other ambulatory settings)
Listing categories of care in **rows**
Outlining **anticipated care requirements and outcomes** for each level/day of care and category, using existing data, medical record review, and team input
Pilot testing the accuracy of the clinical path while care is being rendered, redesigning as necessary to reduce potential for unnecessary variation
Identifying, documenting, and tracking variances over time, looking for better practice and continuing redesign as necessary, or introducing other process improvements to further reduce variation

Acute Care versus Other Settings Clinical Pathways

Clinical pathways in any healthcare setting help identify clinical outcomes of processes as well as the most efficient and effective processes and methodologies to utilize. Better and best practices, clinical variation, and cost savings can be utilized for improvement in the pathways. However, the setting of the care provided makes a difference in how the pathway is constructed and utilized. Acute care, rehabilitation facilities and other clinical settings pathways must account for the differences in site and intensity of services provided; acute care provides "continuous" (24-hour) care, day by day. Other care settings such as outpatient facilities (clinics, home health, etc.) have intermittent care. These outpatient settings for care use objectives or visits in columns on clinical paths instead of patient days. The disciplines that work with the patient may also be different. In home health care, they employ the skilled nurse and home health aide, but contract with other disciplines, e.g., PT, OT, speech/language, social services, and nutrition. Clinics may only employ physicians, advanced practitioners, and LVNS (LPNS)s to deliver the care in that setting. Some healthcare settings have control of the environment of care, but home health does not control the home environment. Some healthcare environments have computerized electronic health records and others do not. The computerization vs. non-computerization can impact the effectiveness of the pathway implementation in different healthcare settings.

Adjusting for Severity/Complexity of Illness

The goal of all severity of illness or complexity of illness systems is to group patients into homogeneous categories that reflect the extent or seriousness of the disease process. Severity of Illness is defined as the degree of risk of immediate death or permanent loss of function due to a disease. Clinical findings are used to assign a severity rating, ranging from "no risk" (O) to "death" (5), depending on the system. A Severity of Illness System is a computerized measurement, which adjusts ICD-10-CM diagnosis codes and/or DRG designation for hospitalized patients based on the severity or extent of the illness treated. The severity of illness system is used to adjust for patient complexity, so that physicians and other groups can compare resource utilization, complication rates, and length of

to improve patient care, services, and treatment. Regardless of a healthcare organization's relationship to their accreditation agency, the concept of commitment to improving organization performance in key functions and processes is relevant and valuable to quality care and to marketplace success.

All organization functions (which include patient care) are the responsibility of departments, services, and settings, as applicable . Regardless of healthcare setting, every organization can use the quality management/performance improvement function to monitor, analyze, and improve the processes associated with the provision of care and services.

Two functions that relate administratively to performance improvement are Organizational Leadership (Chapter 2) and Health Data Analytics (Chapter 4). Many other processes related to functions become a part of the Quality Control/Measurement activities of ancillary and support service departments: patient assessment, patient treatment (e.g., medication use), patient/family education, staff orientation and training.

Written department or service specific quality management/performance improvement plans are not required for licensure or accreditation, but detailed documentation of expectations and methodologies is very important to the integrity and accountability of the process within each department/service (see Performance Improvement Plans in a previous section in this chapter).

Depending on the approach used for performance improvement in the organizat ion the department/service staff should participate in identification of organization wide functions, processes, and outcomes relevant to that department/service. Identification of indicators to measure the performance of the function, process, outcome, data collection, analysis and interpretation of the data/information received, and quality improvement or quality planning activities to improve performance of existing processes or to design new processes are also needed.

Each department/service is expected to focus primarily on the improvement of intra and inter departmental processes and associated outcomes. Specific involvement is determined by the scope of services provided, quality control requirements, and/or the organization's strategic plan and quality initiatives . Department/service staff will necessari ly serve on quality planning and quality improvement teams, ideally organized around important functions, required organization wide review processes, or clinical processes appropriate to that department's/service's scope of care and service. Each department/serv ice is also expected to participate as appropriate in organization wide strategic and quality planning activities, in the select ion of Strategic Quality Initiatives, and subsequently in the roll out of those initiatives.

!clinical Process Review!

Clinical process review includes monitoring and analysis of those clinical processes that: 1) affect a large percentage of patients, and/or 2) place patients at serious risk if not performed well, or

In general, the clinical processes reviews fall into the following review categories :

- Indications/appropr iateness
- Preparation/dispensing
- Administration/performance
- Monitoring effects
- Patient education

Indications/appropr iateness category deals basically with the orders of the practitioner. Aspects of the ordering include the correct order, appropriateness of the order, correct patient, and so forth. The preparation and dispensing category includes getting the patient ready for a procedure, preparing a medication for administration, preparing blood products for administration, and so forth. The administration or performance category is the actual performance of the task and if it was done correctly. The monitoring of effects entails looking for the consequences of the actions taken . Patient education refers to educating the patient and/or family about what is or will be happening to the patient. One can take any clinical process and monitor the process based on any of these five categories .

Operative and Procedure Review

The organization prioritizes those procedures that pose considerable risk to patients. Procedures may carry risk of complications or expose the patient to unnecessary risk if performed when not indicated, not performed when indicated, or performed poorly or incorrectly. This includes all operative procedures and any other invasive procedures done outside of a surgery area, such as a central line insertion completed at the patient's bedside. Also included in a review is any procedure, invasive or non-invasive, that requires moderate sedation. This monitoring would include inpatient, outpatient, Operating Room/PACE, emergency department, radiology, GI lab, cardiac catheterization lab, clinics, and other clinical service settings where invasive procedures are performed.

A ll individuals and disciplines providing the services must be included in the monitoring as appropriate to the subject of the review. This means that only the practitioner who orders the procedure would be involved if only indications/appropriateness is being monitored. There will be more than just the practitioner involved if the surgical procedure itself is what is being monitored. The medical staff must conduct the review when the individual licensed practitioner with clinical privileges becomes the focus of the review.

Processes involved in this monitoring include, but are not limited to the selection of the appropriate procedure, patient preparation for the procedure, performance of the procedure and patient monitoring, post-procedure monitoring and care, and post-procedure patient education. Procedure-specific monitoring criteria must be approved by the medical staff for the screening activities involved

IBtood and Blood Component Usel

While not all healthcare organizations administer blood or blood products, it is important to know how to monitor these components. Because it is a clinical process, the same categories in the clinical process listed above pertain to this monitoring. The monitoring should include aspects of the ordering of the blood, the distribution, handling and dispensing, the administration and the monitoring of effectiveness monitoring for adverse reactions is also necessary along with the patient education regarding the transfusions. Again, this monitoring is an interdisciplinary process involving all types of individuals who are involved with these processes. There should be policies and procedures related to blood and blood component process measurement, assessment, and improvement results that decrease the variation in transfusion practices.

Examples of screens for monitoring and analysis of blood and blood component use include, but are not limited to, all confirmed non-hemolytic transfusion reactions, the most important to patient outcomes, transfusions with the highest volume or risk, and those aspects with access/availability problems. Screening criteria for the appropriateness of the ordering of the blood or blood components typically are obtained from the American Association of Blood Banks (AABB).

Mortality Review

Mortality review is an integral part of the quality management activities of every provider of direct patient care. Many organizations include the morbidity review with the mortality review. The mortality review involves physicians, nursing, and other clinical services as appropriate. Mortality review is to be done with unexpected mortality cases to determine if: the patient's death was justified or possibly preventable, all treatments were appropriate considering prognosis, all appropriate patient care measures were provided, delays in care were present, and if the level of care was justified considering prognosis and treatment provided. Many times, this review includes a combination of mortality data review for patterns and trends and individual case review . If morbidity is included with the mortality review, topics such as the use of rapid response teams and code blue calls are evaluated for appropriateness and effectiveness . In the hospital, the rapid response team and code reviews frequently occur in the critica l care reviews.

Autopsy requests and results, organ donation requests, Do Not Resuscitate (DNR) status and other such topics are usually covered in the mortality review. There is often a group of medical staff department-specific data summaries (trended over time) that should include at least:

- Total deaths, all departments and each department/service
- Overall mortality rate and mortality index with comparison data
- Number of deaths by specialty/section, major diagnostic category, Diagnostic Related Groups (DRG), or as specified in CMS mortality data summaries

certain levels of care, procedures, or treatments, and appropriateness of discharge or termination of treatment.

Utilization Management (UM) is often the title of the overall actions regarding the utilization of resources when caring for patients. Utilization Management staff, case managers, case coordinators, or other types of staff, compare all documented patient signs, symptoms, complaints, diagnoses, test results, treatments, and other available data with established criteria or clinical/critical pathway. InterQual Criteria and Milliman Care Guidelines are two commonly used sets of criteria that examine the medical necessity and appropriateness of healthcare services. These criteria can be used in multiple types of healthcare settings. Severity of illness and intensity of services provided are some of the issues weighed by the reviewer in comparing each case with criteria. Cases with non-specific diagnoses and/or non-confirming test results are either discussed with the attending physician or referred to a Medical Director/ Physician Advisor, or both.

Table 19: Ways to Define the More Severe Patient Cases

Ways to Define the More Severe Patient Cases
• Severity of illness or the extent that an organ system has lost function
• Risk of mortality or the likelihood that the patient will die
• Prognosis – the prognosis states the probable outcome of an illness including the likelihood of improvement or deterioration, the likelihood for recurrence, and the probable life span of the patient
• Treatment difficulty or patient management challenges – management problems might include things like close monitoring, supervision, and sophisticated procedures or equipment
• Intervention needs – refers to the changes in the severity of the illness that would be likely to occur if there was a lack of immediate or continuing care
• Resource intensity – takes into consideration the types and amounts of diagnostic and therapeutic services required to manage a particular illness

Utilization Management applies many of the aspects of quality management to make improvements. These include data analysis charts and graphs (Chapter 4 Health Data Analytics), communication tools such as standing orders, and practice guidelines, as well as dashboards, performance measures and other information in this chapter, and leadership principles (see Chapter 2 Organizational Leadership).

Action Process

In the hospital, and other types of healthcare organizations, the medical staff is responsible for acting on physician-related utilization problems, once confirmed. The Medical Director/Physician Advisor may intervene with the attending physician directly (documenting the action for the UM Committee and the appropriate medical staff department). The UM Committee or, better yet, the appropriate medical

provide a critical transfer point regarding the patient's critical information, treatment, and continuity of care. Ineffective handoffs can result in adverse events and patient safety risks (Johnson & Arora, 2016) (See Chapter 5 Patient Safety). Handoffs are not limited to the hospital setting but rather occur throughout the healthcare system as the patient is transferred to another practitioner for services. The handoffs are not limited to nurses either, but rather include all healthcare providers such as physicians, respiratory specialists, physical therapists and so forth, including transporters, and others in the areas that could take a message or pass on a message or other information. These handoffs require the transfer of information about the patient, and an opportunity to ask questions, clarify and confirm the information.

To ensure patient safety, there must Le effective handoff communication between caregivers (sender and receiver). The CMS Conditions of Participation discuss the necessity of clear communication at handoffs particularly related to safe medication administration . The Joint Commission National Patient Safety Goals requires hospitals and other healthcare organizations to have processes in place for handoff communication, which provides for the opportunity for discussion between the giver and receiver of patient information. These communications could include the patient's condition, care, treatment, medications, services, and any recent or anticipated changes to any of these.

In fact, The Joint Commission, in September 2017, issued its Sentinel Event Alert Issue 58 which addresses inadequate hand-off communication (TJC – Handoff, 2017). The Sentinel Event Alert describes common underlying causes, and recommends specific steps to be taken in order to reduce the risk and future occurrences. One of the findings discussed in this alert is that a study by the Accreditation Council for Graduate Education found that only 69 percent of clinical learning environments did not have a standard hands-off process. Among the interventions suggested in this alert, standardized critical content to be communicated must be implemented and followed, conduct face-to-face handoffs, and leadership support is crucial.

The skill of the handoff communicator, as well as their knowledge and experience, may dictate the amount and type of information and data that is communicated. Every shift and every type of practitioner may report differently (TJC – Handoff, 2017). The variability of the handoff process lends itself to information not being adequately communicated and places patient care at risk. For example, a nurse may forget to state that her patient's intravenous (IV) bag had only lOOmls in it the last time she checked, and the oncoming nurse does not go and visit her patient immediately, which resulted in an empty IV bag and possible clotting at the IV site. Another example is when one physician hands off his patients to another physician, but neglects to tell the oncoming physician that the patient lost a lot of blood in the OR that morning, without a replacement of the blood because the hemoglobin and hematocrit were not back from the lab yet.

Over time, several improvements have been made to the handoff process, often with inconsistent results. One handoff model that has seen a lot of success in improving the communication of patient

essential elements. NTOCC has descriptions and examples of each category of interventions.

Table 20: Seven Essential Intervention Categories for Patient Transition to Another Facility

Seven Essential Intervention Categories for Patient Transition to Another Facility	
1	Medication management
2	Transition planning
3	Patient and family engagement and education
4	Information transfer
5	Follow-up care
6	Healthcare provider engagement
7.	Shared accountability across providers and organizations

The Case Management Society of America (CMSA) formed the NTOCC to develop recommendations on actions that healthcare could undertake to improve transition of patients. The NTOCC recommended transition of care measures in 2008 that focus on certain structural elements that promote safe transitions of care. They also propose process measures that evaluate the timeliness and completeness of information transferred between settings and providers. Outcome measures should be developed to evaluate the adverse events that occur as a result of the transition of care. Additionally, there should be measures of efficiency including inappropriate utilization of resources, unnecessary readmissions, and duplication of tests. The patients' and providers' experience and perspectives regarding the transition process should be measured (NTOCC – measures, n.d.).

The National Quality Form (NQF) is another source of transition of care measures. The NQF has endorsed 12 measures that assess coordination of care. Of these 12 measures, three are directly related to the transition of care. The three measures (0647, 0648, and 0649) relate to the transition record and its timely transmission to the next level of care (NQF-Transition, 2012).

The Joint Commission (TJC) has a Portal with Transition of Care information on their website. Once on the TJC site, click on Topics and the portal will be listed there. The information comes from The Joint Commission and other healthcare organizations (TJC, 2017). This information is available to all organizations and the topics cover most spectrums of healthcare organizations. On this portal site, there are hot topics, podcasts, articles and publications, resources, tools, webinars, and educational materials.

!Episodes of Care!

An episode of care is defined as the care provided for a particular condition for a given length of time across the continuum of healthca re in an integrated health system . The National Quality Form in 2010

PERFORMANCE AND PROCESS IMPROVEMENT

The Affordable Care Act added a new Internal Revenue Service (IRS) requirement for healthcare entities and public health systems (Stoto, 2013). Hospitals must conduct a Community Health Needs Assessment (CHNA) every three years. The assessment must describe the community served, identify existing health care resources, and prioritize the health needs of the community. Once this is completed, the hospital must develop and implement an action plan to meet the needs identified within the community .

The Public Health Accred itation Board (PHAB) requires health departments to participate in or conduct a collaborative process with others in the community (Stoto, 2013). The health departments must conduct a planning process and develop/implement a community health improvement plan, which has a performance measurement system to monitor the achievement of the objectives of the improvement plan.

The Institute for Healthcare Improvement (IHI) has encouraged implementation of their Triple Aim which addresses health of a population, the quality of care, and the per capita cost (Feeley, 2014). Feeley states that to have a high impact in population health, leadership is going to have to change their leadership behaviors and become person centered, have front line engagement, relentless focus, transparency, and be without boundaries.

The Institute of Medicine (IOM) conducted a study, commissioned by the Robert Wood Johnson Foundation, to examine the measurement, laws and funding that influence the health of the public (!OM-Public Health, 2010). The committee suggested that changes need to be made in the processes, tool, and approaches used to gather information concerning health outcomes and failure to achieve the desired outcomes. The IOM stated that there must be measurement of the environmental failures, such as a lack of healthy food, adequate housing, and transportation issues. The report further calls upon the Health and Human Services department to develop a standardized set of measurements that address health outcomes and indicators of community health, as well as a single, broad measuring tool for public health. This standardization of measures and tools would enable comparison of data across geographic and other areas with an apple to apple comparison.

There are already several initiatives that are aimed at improving population health. The IHI has campaigned to improve health through their 5 Million Lives initiative and now with their Triple Aim initiative. Another community initiative is the Healthy People 2020 initiative of the Office of Disease Prevention and Health Promotion (ODPHP) within the U.S. Department of Health and Human Services (HHS). Aimed at disease prevention, Healthy People 2020 is a United States' initiative to promote community health. Healthy People 2020 provide science-based, 10-year national objectives for improving the health of all Americans (Healthy People, n.d.).

The Healthy People Consortium is a diverse, motivated group of agencies and organizations nationwide that are committed to achieving Healthy People 2020 goals and objectives. Consortium

Management: The act or art of conducting or supervising something or the judicious to use of means to accomplish an end

Therefore, we combined the definitions for risk in healthcare to be the probability that something undesirable will happen. It implies the need for avoidance. Strict risk avoidance in the traditional Risk Management philosophy is more limited in focus and reflective of insurance risk. This type of risk primarily is to prevent or minimize potential financial loss with patient, visitor, volunteer, healthcare professional, and staff as secondary loss avoidance.

Enterprise Risk Management (ERM) is a broader more complex concept reaching all key areas of the organization/healthcare system . It is considered a holistic, disciplined approach, addressing risks from all sources across and beyond the organization that would threaten strategic goals and objectives and affect the organization's ability to create value. Regulations and accreditation standards associated with Risk Management Programs encompass the philosophy of the enterprise risk management definition. This holistic approach brings into the management of risk the efforts and skills in all areas of the organization. These efforts must have the high-level support of all senior leaders and the board of directors in order to be successful.

A Risk Management Program encompasses all parts of the organization, both clinical and non-clinical aspects. Program components are listed in Table 21. And while all of these components are important and the Risk Manager is usually responsible to assure these components are happening, others in the organization can be responsible for the day-to-day functioning for these components. For example, often the employee programs/workers compensation is delegated to the Human Resources department or to the Employee Health practitioner.

Table 21: Risk Management Program Components

Risk Management Program Components
• Loss prevention and reduction (clinical and administrative components)
• Claims management
• Safety/security programs
• Patient relations programs
• Contract and insurance premium review
• Employee programs/workers compensation
• Resource and support system review
• Linkage with quality, patient safety, and utilization management

An dverse Patient Occurrence (APO)! or adverse event is an unexpected, untoward event with actual or potential negative impact on the patient, or person. An occurrence report should be completed for every adverse event that occurs. A !Potentially Compensable Event (PCE)j is an APO that might result in a lawsuit or claim based on the degree of actual or potential impact on the patient. In most healthcare organizations, the Risk Manager has been given a list of PCEs that the facilities insurance company wants to be notified about if they should occur. The insurance company then examines the record and makes a determination if the event truly is a potentially compensable event. If it is, then the medical record should be sequestered to prevent any alteration to the original record.

Once a PCE has been identified, the records and any equipment involved in that event should be sequestered . The staff should be aware that if an adverse event occurs and there is equipment involved, it should be taken out of services and sent to the risk manager's office. This would include any equipment, medications, syringes and supplies in use at the time of the event. If this is not accomplished at the time of the event, it is too late to sequester these items. If later it is determined that the event was not a PCE, these items can be discarded as appropriate, or placed back into the inventory for use.

Whenever the event is determined to be a PCE, the medical record must also be sequestered to assure that the medical record of the incident is a true and unaltered document. The Risk Manager must sign legal papers indicating this when the records are sent to attorneys during a lawsuit. If the medica l records are on paper, the record of the visit where the event occurred should be copied. The original must be placed under lock and key, usually in the Risk Management office, and the copy is placed back in medical records in case the patient comes to the facility again for patient care services. If someone wants to add a late entry to the record, the individual should be escorted to a private room, and the escort should remain in the room after giving the individual the original record, an appropriate form to write on and a pen. The individual must date, time and sign the entry, as well as indicate that it is a late entry. The individual is not allowed to remove or cross out anything in the record. If the medical records are electronic, the Information Management department should make the record read only once the patient is discharged following the event. If an individual wants to add a late entry, the Risk Manager should call the Information Management department to unlock the record and then to relock it after the entry is made.The electronic health record software will capture who made any entries and when then they were entered.

There are numerous other ways to identify the risk in an organization in addition to the occurrence/incident report. One of the best ways is through communication with the staff and management. These individuals can provide valuable information about processes and the potential weaknesses of those processes. Many times, staff will not fill out an occurrence report, but will tell someone about the occurrence. In one hospital, a patient died in surgery and there was no occurrence report. The Quality Manager and the Risk Manager found out about the occurrence two days later through 'gossip' and talking with various individuals in the organization. Of course, by that time, it was

- Category G: Permanent patient harm
- Category H: Intervention required to sustain life
- Category I: Patient death

In a study of three leading hospitals published in *Health Affairs* in April 2011, the Global Trigger Tool found 10 times the number of adverse medical events than both voluntary reporting and AHRQ's Patient Safety Indicators (Classen, Resar, Griffin, Frederico, Frankel, Kimmel & et al., 2011).

!Risk Analysis!

Once potential risks are identified, they must be analyzed in order to determine their significance. A tool that is commonly utilized when an adverse event occurs is a Root Cause Analysis (RCA) (see Chapter 5 Patient Safety). An RCA is designed to find the root cause of the adverse event, and is usually used where there has been a sentinel event. If potential for risk is identified, then a Failure Mode and Effects Analysis (FMEA) (see Chapter 5 Patient Safety) should be used to identify the risk and attempt to eliminate the risk before an adverse event occurs. Once the root cause has been identified then the event can be utilized to determine the amount of risk there is that the event could repeat itself.

There are two techniques utilized to manage risk: Risk Control and Risk Financing (Marhon, 2011). Risk Control consists of techniques that can be used to prevent or reduce loss. Risk Financing consists of techniques that can be utilized to pay for the losses that have occurred . Risk Control is achieved through risk avoidance, risk shift, or risk prevention. Risk transfer consists of risk retention or risk transfer. Table 22 lists the different strategies for risk control and risk financing and their definitions.

Table 22: Risk Control and Risk Financing Techniques

Risk Control and Risk Financing Techniques		
Risk Control (Controlling the events)		Developing and implementing policies, processes, and systems to limit or avoid risk involved with exposure area
	Risk Avoidance	Eliminating the risk exposure, e.g., not offering a particular service
	Risk Shifting	Moving liability responsibility from an internal to an external source (e.g., using a contract service or making referrals, while still possibly retaining some risk due to ostensible agency
	Risk Prevention	Eliminating or minimizing adverse events associated with financial loss (e.g., use of unit-dose medications to reduce dosing errors)
Risk Financing		Funding real or potential loss through:

and prevention except possibly for employee health. Managed Care Organizations consider these activities to be the responsibility of the practitioner and provider organizations rather than the MCO.

The Infection Preventionist's role encompasses an ongoing review and analysis of healthcare-associated infection data (based on the organization-approved definition), risk factors and special studies for infection prevention and control. The Infection Preventionist processes include identification through cross-contam ination of surveillance data and case finding, analysis of data and investigation of significant infections, prevention through strategies to reduce risks and prevent infections, control of infection prevention activities, reporting surveillance data, identified cases, and reporting improvements in reductions over time in risks, trends, or actual infections.

In terms of the surveillance activities, the organization must determine the approach and criteria used for surveillance . Most organizations have found that 100% surveillance is not effective in identifying where to begin to make improvements. Thus, most organizations have moved to targeted surveillance where specific services, patient populations, procedures, and/or types of infections drive the surveillance. This is often called 'focused' surveillance . In addition to this type of surveillance, problem-oriented or outbreak response surveillance is also utilized. This type of surveillance is conducted to measure the occurrence of specific infection problems, or to confirm an outbreak . It is then utilized to identify, and monitor the improvement effectiveness in eliminating the problem or outbreak . The individual who facilitates this data collection process should be trained on appropriate use of statistics and data (see Chapter 4 Health Data Analytics).

\Environment Safety Program

Environment of Care Committee (EOC), sometimes called the Safety Committee, is a multidiscipline committee that is responsible for the care of the environment and the individuals that function within that environment . This committee is not to be confused with the Patient Safety Committee which will be discussed in Chapter 5 Patient Safety and which concerns itself with the safety of the patient. This committee includes representation from throughout the organization but specifically includes members of the Facilities staff, senior leadership, quality improvement staff, the Infection Preventionist and the Risk Manager. This committee is charged with monitoring seven areas of the organization: Safety, Security, Fire Safety, Hazardous Materials, Medical Equipment, Utility Management, and often Emergency Management. Each of these seven areas is required to have indicators developed that monitor the effect iveness of each area . Some of the activities that are discussed at these meetings can include air quality issues, handling of hazardous materials, safety issues, needle sticks, employee injuries, and so forth as appropriate to the particular healthcare setting.

One of the functions of this committee is to conduct a periodic survey (often called rounding) throughout the facility on a routine basis to identify hazard, potential areas where risks, infections and other issues can occur . It is important that the Quality, Infection Preventionist, and Risk Management

routine meetings for data analysis and peer review on behalf of the full department. The chair is delegated the responsibility to act between meetings. Medical staff departments and physicians in other healthcare settings are actively involved in clinical review activities, but no longer carry the sole responsibility for organization wide activities. In other healthcare settings, performance improvement is structured under an interdisciplinary quality committee, such as the Quality Council, chaired by a physician leader, with other physician participants.

The overall effectiveness of physician/licensed independent practitioner (LIP) participation in organization wide quality management/performance improvement activities, leader involvement, and participation on teams should be evaluated along with the department specific and Medical Executive committee activities. This evaluation can b integrated into an annual organization wide reappraisal of the quality management/performance improvement strategy and approach .

Physician peer review is discussed below in the Practitioner Appraisal Process section of this chapter . However, it is pertinent here to discuss the review for physician group reviews. Many physician groups are under contract with a healthcare organization where they work. Typically, these practitioners are the anesthesiology, emergency, radiology, and pathology groups among others. What is distinct about these groups is that the practitioner must be a member of the group to practice in a specific healthcare organization if the organization has contracted to utilize only the practitioners in that group. This means that if a non-affiliated practitioner wishes to work at a certain healthcare organization and this individual is not part of the contracted group, the individual will not even be considered for appointment. There are always exceptions, but this is a common practice.

Also, distinct within these group practices is that the group conducts its own peer review for its members . If a healthcare facility has one specific radiologist, for example, that practices in that organization, other members of the radiology group will double read a certain amount of the radiographic studies that are performed, looking for concurrence of the findings . If there is not concurrence, then appropriate actions are taken by the group based on the extent of the findings . The contract between these practitioner groups and the healthcare facility must explicitly state that the results of this peer review by the groups will be shared with the healthcare facility and vice-versa. More information about practitioner peer review can be found later in this chapter.

!Nursing Monitoring!

The nurse executive and other nursing leaders participate in and/or support all of the listed activities that impact the safety and quality of care provided to patients. The nurse executive is the active leadership role for nursing with the hospital's governing body, senior leadership, medical staff, management, and other clinical leaders in the decision-making structure and process of the delivery of nursing care, treatment, and services within the healthcare organization.

Total # patients w/National Pressure Ulcer Advisory Panel (NPUAP)-AHRQ Stage I, II, Ill, or IV ulcers I # patients in prevalence study
Physical restraints
Healthcare-associated infections : catheter-associated urinary tract infection (CAUTI); central line-associated blood stream infection (CLABSI); ventilator-associated pneumonia (VAP)
RN education/certification: highest nursing degree, plus specialty certifications for all full time, part time, and as needed employees with direct patient care responsibilities at 50% or greater time
RN satisfaction survey
Lactation consultant hours – Percent total lactation consultant hours supplied by RN; Percent of total lactation consultant hours supplied by agencv staff of licenses categories; Total lactation consultant FTE per 1,000 live births
Unassisted falls
Patient volume (for ED, perioperative services, and ambulatory)
Device days (for CAUTI, CLASBI, and VAP)
Nurse turnover
Physical/sexual assault (for psychiatric areas)
Care coordination (for inpatients and ambulatory)
Births data (for hospital)
Nursing care minutes (for perioperative services)
Readmissions (for hospital, from Medicare's Hospital Compare website)

Adapted from American Nurse, 2015

Patient Satisfaction Review

There is more to quality measurement than discussed previously. The services that are provided to patients are an extremely important element to satisfaction and now to the reimbursement of care. This section of the chapter will discuss measurement of several patient satisfaction quality functions.

!Patient Satisfaction!

As customers, the patients/members offer organizations vital information for validating quality of care and services, or for prioritizing needs for improvement in delivery processes. It also impacts the bottom line of the facility and can add to or negate the effectiveness of marketing and success . Feedback is based on perceptive quality and it may take the form of complaints, positive or negative perceptions of care, or even innovative ideas for improvement . It is important to note that while there are measures of specific disciplines, overall perceptions of satisfaction can be impacted by something as simple as parking.

Patient satisfaction is one of the key factors in quality management and performance improvement that provides perceptive quality information and helps measure outcomes of care and service. Patient

complete statements dealing with different patient experiences, like "Adequate information and directions for patient and family." Respondents tend to compare each subsequent question and response (if a scale is used) to the first response, even if the questions are unrelated. Most satisfaction surveys use scales (e.g., 1-5, disagree-agree or worst-best) to assure that degrees of satisfaction or dissatisfaction can be evaluated and used to improve care and service. Always follow-up on stated quality concerns, both with the patient and within the organization.

!consumer Assessment of Healthcare Providers and Systems (CAHPS') Surveysl

The Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys are developed by the Agency for Healthcare Research and Quality, and are utilized by CMS, NCQA, Veterans Health Administration (VHA) and Department of Defense (DOD) and others. All CAHPS surveys and technical support are in the public domain and may be utilized by anyone for free (CAHPS, 2015). Downloadable kits of survey questionnaires and report tools standardized to allow comparison of consumer experience across health plans, population groups, or over time . The core items that are part of all of the surveys are shown in Table 24.

Table 24: Items Shared by Different CAHPS Surveys

Items Shared by Different CAHPS Surveys	
Core Items - applicable across populations and delivery systems	• Enrollment/coverage and provider relationship • Getting needed care: Finding doctor, seeing specialist, getting necessary care,treatment, tests,delays due to approval • Getting care quickly : help by telephone, appointment timeliness, office wait • Utilization of health services: Emergency department and office visits • Doctor communication: Listening, explaining, respect, enough time • Office staff : Courtesy, respect, helpfulness • Global ratings doctors, health care, and health plan • Health status : Rating of overall health • Demographics
Supplemental items	• Communication/use of interpreter • Chronic conditions • Dental care; behavioral care; pregnancy care • Prescription medicine • Transportation • Specialist referrals • Claims processing; cost sharing; multiple plan coverage Medicaid enrollment

	It was originally developed for the Choctaw Nation Health Services, but it has been adapted for use by other tribal nations.	
Cancer Care	The Cancer Care survey assesses the experiences of adults with cancer treatment provided as an inpatient or outpatient setting. These settings include Independent community oncology practices, Cancer centers at community hospitals, Cancer centers at academic medical centers. This survey is based on the CAHPS Clinician & Group Survey.	Shared decision making; Information from providers; Access to care;
Child Hospital	The Child Hospital Survey is a standardized questionnaire for parents/guardians (referred to as parents) of children 17 and younger who have been inpatients. The Child version asks parents to report on both their child's inpatient experience and their own experience with their child's inpatient stay. In contrast to the Adult Hospital Survey, which is implemented by CMS, the Child Hospital Survey is fully supported by AHRQ's CAHPS User Network.	
Clinician & Group	The CAHPS Clinician & Group Survey (CG-CAHPS) asks patients to report on and rate their recent experiences with clinicians and their staff. The Clinician & Group Survey includes standardized questionnaires and optional supplemental items (see next column) for adults and children. The latest version was released in July 2015.	Cultural Competence Health Information Technology Health Literacy Patient-Centered Medical Home
Dental Plan	The CAHPS Dental Plan Survey asks adult patients in a dental plan to report on their experiences with care and services from a dental plan, the dentists, and their staff. This survey was developed for the TRICARE dental plan, but it has been adapted for other uses.	None
Experience of Care & Health Outcomes (ECHO) (Behavioral Health)	The Experience of Care and Health Outcomes (ECHO) Survey asks health plan enrollees about their experiences with behavioral health care and services provided by either managed behavioral healthcare organizations or managed care organizations. The ECHO Surveys include standardized questionnaires and optional supplemental items (see next column) for	Supplemental items specific to Behavioral Health patients

	disabilities, people with acquired brain injury, and people with severe mental illness.) The survey may be administered in person or by telephone .	
Home Health Care **	The Home Health Care Survey asks adults receiving home health care about their experiences with home care providers, staff and agencies. The Centers for Medicare & Medicaid Services (CMS) began national implementation of this survey in 2010. This instrument focuses on patients who receive skilled home health care services from Medicare-certified Home Health Agencies (HHAs) . Skilled services refer to health care services provided by nurses and therapists including physical, occupational, and speech-language therapists.	None
Hospice * *	This survey measures and assesses the experiences of patients who died while receiving hospice care and their primary informa l caregivers.	None
In-Center Hemodialysis **	The CAHPS In-Center Hemodialysis Survey asks adults with end-stage renal disease about their expe riences with care from dialysis facilities. The Centers for Medicare & Medicaid Services (CMS) began national implementation of this survey in 2014. Both dialysis facilities and End-Stage Renal Disease Networks (known simply as Networks) can use this tool to measure and improve the patient-centeredness of their care	None
Nursing Home	The Nursing Home Surveys include standardized questionnaires for adults who have been residents of a nursing home and their families. The CAHPS Nursing Home Surveys include three separate instruments. Two of the surveys ask current and former residents about their experiences in the nursing home. The third one asks families of residents about their experiences with the nursing home. • Long-Stay Resident Survey. An in-person structured interview for long-term residents. • Discharged Resident Survey. A mail questionnaire for recently discharged short-stay residents. • Family Member Survey. A mail questionnaire for resident's family members .	None

- Behavioral health practitioners re: a new documentation system

Patient Complaints & Grievances

The patient has a right to register a complaint or file a grievance concerning the healthcare organization or the quality of care and a right to timely review and resolution. The patient also has a right to multiple levels of appeal of denials of treatment, level of care, benefits, or coverage, and a right to timely review and resolution. CMS, as part of its Conditions of Participations (CoPs), has laid out what a grievance is and how it must be handled by healthcare organizations . The hospital and managed care CoPs will be described here. Other healthcare organizations should refer to their appropriate CMS CoPs and also to their state laws. Some states have enacted laws that are stricter than those of the CMS.

There are many similarities and differences between the Hospital and Medicare Managed Care Health Plans in terms of the CoPs regarding complaints and grievances. In hospitals, the Co P's (§482.13(a)(2) - §482.13(a)(2)(iii)J allow for both complaints and grievances whi le in the Managed Care CoP's [Chapter 13, Medicare Managed Care manual] all complaints are considered grievances . Here, however, the health plans must distinguish between the grievances and appeals. Both hospitals and managed care plans must respond to grievances in a timely manner and must maintain a written record for each grievance. Table 26 lists the requirements of both the hospital and managed care CoPs for grievances and comparisons are made when appropriate.

For hospitals, a complaint is defined as a minor verbal request that can be resolved quickly. Examples of a complaint include complaints about the room temperature, housekeeping issues, food and beverage preferences, or changing the bed. The patient must be informed as to how to file a grievance if the patient so desires. If the complaint is postponed for later resolution, referred to another staff member for later resolution, requires investigation and/or requires further actions for resolution, it becomes a grievance. If the complaint is a written complaint, it automatically becomes a grievance . A complaint is resolved when the patient is satisfied with the actions taken.

If after the patient is discharged from the hospital, the patient or representative calls (verbal communication) regarding the patient care received, and it would have been treated as a complaint if it had been voiced as an inpatient, it should be treated as a complaint not a grievance. However, if it is in writing, or if the person voicing the complaint requests it be treated as a grievance, it must be treated as a grievance .

For managed health plans, an appeal is defined as a complaint or dispute concerning organization determinations . The determinations by the organization to approve or not allow certain treatments, procedures, or medications prescribed in their plan to be utilized, are addressed through appeal procedures rather than grievance procedures. Organization determinations include, but are not limited to, complaints concerning the benefits an enrollee is, or believes he/she is entitled to receive. This

information on how to contact the QIO.	Response of receipt of complaint must include telling patient/representative how to contact the QIO.
Must attempt to resolve all grievances as soon as possible.	Must attempt to resolve all grievances as soon as possible.
	If more than one issue in grievance, issues must be addressed separately.
Seven days is considered a reasonable timeframe for resolving most gr ievances.	**Twenty-four hour** response to patient /representative if expedited grievance, if health plan needs to extend timeframe to make an organization determination or reconsideration OR if health plan refuses to grant a request for expedited organization determination or reconsideration.
If cannot review, investigate, and resolve issue within 7 days – must inform patient or representative in wr iting that still working on resolution; must include that hospital will follow-up with a written response within a stated number of days.	
Upon resolution of the grievance, **written notice of resolution** must be sent to the patient/representative; This letter must include the contact person for the hospital, be in a language and manner patient/representative can read and understand, and must provide adequate information to address each item in grievance, and the date of completion.	Upon resolution of the grievance, **written notice of resolution** must be sent to the patient/member/representative, but **no later than thirty days** after grievance is received.
Not required to include statements that could be in a legal action against the hospital. Not required to provide an exhaustive explanation of what was done to investigate and resolve the grievance.	
Grievance resolution: when patient /representative is satisfied with actions taken.	**Grievance resolution:** when pdlenL/member /representative is satisfied with actions taken.
If patient/representative is not satisfied with resolution provided, the hospital can still consider resolution closed if all hospital CoPs are being met.	
Hospital must **maintain all documentation** of efforts and compliance with the hospital CoPs.	

(Adapted from CMS Hospital and Managed Care Conditions of Participation) (CMS-Grievance, 2017)

PERFORMANCE AND PROCESS IMPROVEMENT

6. Make care affordable

CMS will embed in each of their six goals their four foundational principles: 1) Eliminate Racial and Ethnic Disparities; 2) Strengthen Infrastructure and Data Systems; 3) Enable Local Innovations; and 4) Foster Learning Organizations. CMS is working with multiple organizations and quality efforts to achieve these goals.

!Hospital Quality Initiative/Value-Based Purchasing!

The Hospital Quality Initiative is considered the Value-Based Payment (VBP) initiative that is required by Congress under Section 1886(0) of the Social Security Act. This program makes value-based incentive payments to hospitals based on their quality measures and improvement from a baseline time period (CMS – Hospital VBP, 2013). Prior to this law's enactment, hospitals were paid under the Hospital Inpatient Quality Reporting program which paid for a hospital simply reporting their quality measures. Through these revisions to the Social Security Act, hospital VBP measures must be included on Hospital Compare website (see transparency, later in this chapter) for at least one year and specified under the Hospital Inpatient Quality Reporting (IQR) program. In 2010, the U.S. DHHS launched the HealthCare.gov site to obtain insurance coverage with their 'Compare Care Quality' link connecting to the Hospital Compare website.

In the beginning, hospitals with at least 10 cases for at least 4 applicable measures during the performance period would receive a score. Hospitals with at least 100 Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys during the performance period would receive a Patient Experience of Care score. The totals of these scores determine if there will be an additional reimbursement, a loss of some reimbursement, or no additonal reimbursement.

The VBP calculations are based on data from four different types of domains: Patient and Caregiver-Centered Experience of Care/Care Coordination, Safety, Clinical Care, and Efficiency and Cost Reduction. Each of these 4 types of domains is worth 25% of the Total Percentage Score (TPS) (CMS-Hospital VBP, 2017). Each of the areas, except the patient and caregiver-centered care area, are assessed on their Achievement and Improvement scores. Achievement points are awarded by comparing an individual hospital's rates for each measure in each domain during the performance period to all hospital rates from the baseline period. Improvement points are awarded by comparing an indivdiual hospital's rates for each measure in each domain during the performance period to the same individual hospital's rates from the baseline period. The number of points received in each of these areas are based on whether the hosptial rates at or above the benchmark, at or below the achievement threshold (assessment)/basel ine period rate (improvement), or between the achment threshold/baseline period rate and the benchmark. The Patient and Caregiver-Centered Experience score is based on the sum of the HCAHPS base score and the hospital's HCAHPS Consistency score. The consistency score is calculated by comparing each of the hosptial's Patient Experience of Care measures rates during the performance period to that of all the hospitals' rates from the baseline

period. The score is detemined in the same manner as the assessment and improvement scores (CMS-Hospital VBP, 2017).

Once these scores have been determined for each measure in these domains, the greater of the hosptial's achievement or improvement points for each measure are combined for the domain score. Then each domain score is multiplied by 25% (starting in FY2018) and then added together to determine the TPS. In FY 2018, if hosptials have sufficient dat;i in at least three out of four domain scores they will receive a TPS. Based on the TPS score, the hospital can loose up to 2.00 percent of their reimbursement (CMS-Hospital VBP, 2017).

Home Health Quality Initiative (Home Health Compare)

Home Health agencies are mandated by CMS to complete and report the Outcome and Assessment Information Set (OASIS). In January 2010, home health agencies were required to complete a revised version of the OASIS data set (OASIS-(). This revised OASIS tool includes data items supporting measurement of rates for use of specific evidence-based care processes, such as pressure ulcers, pain management, influenza and pneumococcal vaccination (CMS – OASIS, 2017).

Since Fall 2003, CMS has established the 'Home Health Compare' website where a subset of OASIS-based quality performance information is displayed for transparency. The posted measures indicate how well the home health agencies are doing with outcome measures and process measures. Some of the data displayed include data obtained from Medicare claims.

The OASIS tool items include core items of a comprehensive assessment for adult home health patients completed upon admission to the home health services. The OASIS data is used to monitor patient outcomes with the purpose of identifying opportunities for improvement. However, the OASIS data is also utilized for clinical assessment, care planning, and other agency needs, which leads to incorporating the OASIS into the assessment processes at the home health agency.

The OASIS tool is completed on admission to the home health agency and then repeated at set timelines . Recertification occurs every 60 days after the patient is admitted, and within two calendar days of a significant change in the patient's condition. It must also be completed after an inpatient stay, when a patient is transferred to an inpatient facility from the Home health agency, when they are discharged from home health services, and if they die at home (CMS – OASIS, 2017).

Compliance with the pay-for-reporting performance requirement is measured through the use of the "Quality Assessments Only" (QAO) formula (CMS – OASIS, 2017). Only those OASIS assessments that contribute, or could contribute, to creating a quality episode of care are included in the computation. The QOA formula based on this definition is the (# of quality assessments x 100) divided by (# Quality Assessments + # Non-Quality Assessments). For 2018 and thereafter, the Home Health Agencies must score at least 90 percent on the QAO metric of pay-for-reporting performance or be

subject to a 2 percentage point reduction to their market basket update for CY 2019 and thereafter (CMS – OASIS, 2017).

Nursing Home Quality Initiative

In 2002, CMS developed the Nursing Home Quality Initiative (NHQI). The 'Nursing Home Compare' website displays the data from every Medicare and Medicaid certified nursing homes in the U.S. This initiative requires nursing homes to submit the Minimum Data Set (MDS), currently MDS Version 3.0, when a person (regardless of payer) is admitted to the nursing home and on a periodic basis thereafter . The MDS is repeated quarterly, at discharge, for tracking, and other needs. The MDS is a clincial assessment of residents in Medicare/Medicaid nursing homes. The assessment includes measures for functional, clinical, psychlogical, psycho-social functioning and life care wishes . The information from the MDS is then transmitted to the respective state database, which then forwards it to the national MDS database at CMS (CMS – MDS, 2017).

The Resident Assessment Instrument (RAI) is utilized to develop the resident's plan of care . It consists of three parts which include the MDS, a Care Area Assessment (CAA) a nd the RAI Utilization Guidelines. The CAA is used to interpret the MDS information and identify a Care Area Trigger which identifies residents who have or are at risk for functional problems and indicates that further assessment is needed. The Care Area Assessment (CAA) is completed for the trigger areas to determine if interventions and care planning is needed. The CAA Summary is utilized to document the care area triggered and the decisions made during the CAA . The Utilization Guidelines provide instructions for when and how to use the RAI (RAI, 2014) .

The MDS assessment data is also utilized to monitor the quality of care of the nursing home. The MDS results are used to identify potential care problems in a nursing home, to identify quality improvement opportunities in a nursing home, for consumers to understand the quality provided by a nursing home, and with CMS for long term monitoring and program planning. The MDS is also used for non-critical hospitals with a swing bed agreement. The assessments are required to utilize the MDS for reimbursement under the SNF PPS (RAI, 2014).

Skilled Nursing Facility (SNF) Quality Reporting Initiative

The Skilled Nursing Facility (SNF) Quality Reporting Initiative was established by the IMPACT Act of 2014, which required submission of standardized data by SNFs and several other healthcare agencies. The Act required the submission to CMS data from three quality domains. In addition, the Act required the submission regarding resources use, hospitalization, and discharge to community. The Act was finalized in 2016 in the FY2016 SNF PPS final rule. The baseline for reporting was set as data from October 2016 through December 2016. Beginning in FY 2018, payment rates will be reduced by 2 percent for any SNF that does not comply with the data submission requirements. Critical access hospitals (CAH) with swing beds are not required to report their quality measures through the SNF

Quality Reporting lnitative. However, non-CHS swing beds are required to report data through this initiative (CMS-SNF, 2017; CMS-SNF Requirements, 2017).

The MDS assessment data is also utilized to monitor the quality of care of the SNF, with an addition of the SNF Part A PPS Discharge Assessment . However, the MDS was modified for SNF to include three new quality measures: Falls with Major Injury; New or Worsened Pressure Ulcers; Percent of patients with and Admission and discharge Functional Assessment and a Care Plan that addressed function. In addition, the FY 2017 SNF PPS final rule adds the Drug Regimen Review conducted with follow-up for identified issues (CMS-SNF Requirements, 2017).

Long Term Care Hospital (LTCH) Quality Reporting Program

The Patient Protection and Affordable Care Act of 2010, created the LTCH quality reporting requirements. Every year, before the next fiscal year, CMS publishes the quality measures LTCHs must report. Then in 2014, the IMPACT Act mandated that LTCHs' submit standardized patient assessment data with regard to quality measures, resource use, and other measures. It further specifies that the data be standardized so that the results could be exchanged with post-acute care providers and other providers to facilitate coordinated care and improved patient outcomes (CMS-LTCH, 2017) . If LTCHs fail to submit the required quality data, there will be a two percentage point reduction in their annual payment update.

LTCH measures are based on three domains: Continuity assessment record and evaluation (CARE); CDC's National Healthcare Safety Network (NHSN); and Medicare Fee-for-Service Claims-based measures. Beginning July 2018, four new measures will be added to the CARE domain (CMS – LTCH Reporting, 2017).

End-Stage Renal Disease (ESRD) Quality Initiative

The End-Stage Renal Disease (ESRD) Quality Initiative was developed in 2013 to promote CMS activites to improve the quality of care of ESRD patients. This initiative is part of the ERSD Quality Incentive Program. With this program, outpatient dialysis facilities will have reduced payments (Value-based Payments) if they do not meet or exceed certain performance measures . The maximum current payment reduction is 2%. The scores obtained by these facilities that treat ERSD patients can be found on the 'Dialysis Facility Compare' website . Each facility is also required to post a Performance Score Certificate which lists the total score and the performance of each quality measure identified for that year. The program's specific measures, weights, and formulas may change on a yearly basis (CMS-ERSD, 2017).

Inpatient Rehabilitation Facilities (IRF) Quality Reporting Program

The Inpatient Rehabilitation Facilities Quality Reporting Program is mandated by Section 3004(a) of the Patient Protection and Affordable Care Act (ACA) of 2010. The required measures must be submitted

or receive a 2% reduction in the annual payment update. The measures reported are determined every year by CMS by October 1(CMS – Rehab, 2015).

For each quarter in the next calendar year (CY), the data for those measures are reported on a quarterly basis, with the first reporting for CY 2015 being submitted by August 15, 2015. The measures that are reported yearly include measures from the IRF Patient Assessment Instrument, CDCs National Healthcare Safety Network (NHSN) measures, and Medicare Fee-for-Service Claims-Based measures. New measures were incorporated in this QRP in FY 2017 (CMS – IRF, 2017).

Physician Quality Reporting Program/MIP

The Physician Quality Reporting Program (previously known as the Physician Quality Reporting initiative) was developed to allow individual Eligible Professionals (EPs) and group practices to report quality of care measures to Medicare. However, 2016 was the last year for PQRS. The government is transitioning to the Merit-based Incentive Program (MIP) (CMS-PQRS, 2017).

The Quality Compare Program was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Physician Compare, 2017). This system rewards for value and outcomes to physicians and other eligible clinicians through the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APM). The program was initiated in January 2017 (transition year), and as of the printing of this book, it has now entered year two. The MIPS program is being phased in over three years, and is changing based on feedback from users and others. The program continues with the weighting of Quality, Advancing Care Information, Improvement Activities, and Certified Electronic Health Record Technology (CEHRT) use. There are individually tailored flexibilities for groups of 15 or fewer clinicians. The program is continuing many of its year one (transition) policies to facilitate the completion of the initial program in year three . In year one, the 2017 MIPS performance consisted of 60% Quality, 25% Advancing Care Information, and 15% Improvement Activities (CMS-QPP Measures, 2017).

The APM program, also in its second year, allows incentive payments for providing high quality and cost effective care. The incentives can be selected from specific clinical conditions, a care episode or a population. During the performance year 2017, all eligible clinicians working on the Advanced APMs are eligible to receive a five percent APM Incentive payment in 2019. The APM program is being modified in its second year to allow clinicians to receive payments ottered by payers other than Medicare starting in 2019. This establishes an applicable revenue-based nominal amount standard for other payers. This program is changing provisions to make it easier for clinicians to participate in APMs which will then quality the clinicians to incentive payments. The program is also reducing the burden on the clinicians and to simplify the program. The program is continuing many of its year one (transition) policies to facilitate the completion of the initial program in year three (CMS-QPP Measures, 2017).

The 'Physician Compare' website, like the other compare sites allows a search by individual practitioner, by group practices, and by other clinicians enrolled in Medicare (Physician Compare, 2017). There are four datasets from which the information is obtained. The Physician Compare National Downloadable file provides general demographic and Medicare quality program participation. The Physician Compare 2015 Individual EP Public Reporting – Performance Scores database contains data from the PQRS and non-PQRS Qualified Clinical Data Registry. The Physician Compare 2015 Group Public Reporting – Performance Scores database contains performance rates for the 112 group 2015 PQRS measures. The Physician Compare 2015 Group Public Reporting – Patient Experience database contains the performance rates for eight Consumer Assessment of Healthcare Provider and Systems (CAHPS) for PQRS measures. Unfortunately, only a sub-set of measures from these datasets are included in Physician compare, so some practitioners will not be represented in the data provided. Physician Compare now includes quality of care performance scores for a small number of group practices

Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)

The Centers for Disease Control and Prevention (CDC) is the national public health institute of the United States. The CDC is a federal agency under the Department of Health and Human Services. Its main goal is to protect public health and safety through the control and prevention of disease, injury, and disability. The CDC focuses national attention on developing and applying disease control and prevention. The National Healthcare Safety Network (NHSN) is a tracking system utilized by the CDC to identify infection prevention problems by facility, state or specific quality improvement project, to utilize the information obtained for benchmarking, to comply with mandatory public reporting state and federal mandates, and to encourage national efforts towards the elimination of healthcare-acquired infections. Organizations participating in this database network include acute care hospitals, psychiatric and rehabilitation hospitals, outpatient dialysis facilities, long-term care facilities and ambulatory surgery centers. The NHSN website, found in the website list at the end of this chapter, provides definitions, guidelines for data collection and other information for the NHSN indicators. Data from NHSN is utilized by the CMS and state facilities to meet reporting requirements for healthcare organizations submitting data to NHSN (CDC, 2017).

NHSN has several components that are available for reporting. The one most commonly utilized in healthcare is the Patient Safety Component which consists of four modules that focus on device-associated healthcare acquired infection module, procedure-associated surgical site infection module, antimicrobial use and resistance module, and Multidrug-resistant organism and *Clostridium difficile* infection (MDRO-CDI) module. Instructions and standardized surveillance methods and definitions are included in the Patient Safety Component manual. Another area available for reporting is the Long- term Care Component which is utilized by most long-term care types of facilities. This component consists of three modules: MDRO/C. *difficile* LablD event; Urinary Tract Infection; and Prevention Process Measures. There is also a Hemodialysis Component which is utilized by outpatient dialysis centers. The last component is the Healthcare Personnel Safety (HPS) Component. There are two

modules in this component: Healthcare Personnel Exposure module and the Healthcare Personnel Vaccination module. Healthcare organizations are increasingly entering data for this last component (NHSN-Patient Safety, 2017).

ccreditation RequiredMeasures!

One method accepted by the US health care system is to measure, identify problems, and maintain quality in the accreditation process. The agency usually associated with hospital accreditation is the Joint Commission . The Joint Commission also accredits other entities such as home care or ambulatory care. Other agencies also conduct accrediting processes, from a variety of organizations to nursing educational programs. NCQA is one of the most common ambulatory care accrediting organizations. However, one thing that accrediting bodies have in common is that they include the measurement of federal regulations in their standards. The federal government is responsible to assure the United States that certain laws are being met. This is delegated to the states to enforce, as is validating the work of accrediting bodies or sending in federal employees to perform an assessment (see Chapter 6 Regulatory, Accreditation, and External Recognition for accreditation organization specifics).

!core Measures!

The Joint Commission, in its accreditation standards, requires healthcare organizations to monitor specific processes and outcomes. For hospitals they also require the organization to report data via Core Measures, which may also be submitted to CMS. For other types of facilities, the data is received by The Joint Commission through the OASIS and MDS data submissions.

Core Measures monitor the hospital's use of recommended healthcare treatments that scientific evidence shows produce the best results. The core measures are specific clinical measures that provide an assessment of the quality of care provided in a given focus area. Table 27 lists the current Core Measure Sets for hospitals. Both CMS and the Joint Commission require hospitals in the United States to report their compliance with dozens of these measures and submit data annually which are referred to as the core measures. With the Joint Commission, the Core Measures are part of the accreditation process. For CMS, the core measures are linked to pay for performance and the national Value Based Purchasing (VBP) program (seen previousliy in this section) . The care categories and required detailed elements of the core measures are changed from time to time (Core Measures, 2017).

Currently, hospitals submit their data as a combination of chart-abstracted and eCQM measure sets as a result of the CMS Fy 2018 IPPS final rule. The eCQM data consists of a minimum of four eCOM measures that are submitted for a minimum of one self-selected calendar year quarter . Five chart-abstracted measures must still be abstracted monthly and submitted quarterly for the entire year. The eCOM measures and the abstracted measures must be applicable to to the services provide and the populations served. All hospitals with OB services are required to report on the PC-01 measure, and if

the hospital has 300 or more live births, the hosptial must also report on the remaining chart-abstracted measures (FAQ-ORYX, 2017).

Table 27: The Joint Commission Core Measure Sets (2018)

The Joint Commission Core Measure Sets (2018)		
Measure Set Abbreviation	**Measure Set Name**	**Comments**
AMI	Acute Myocardial Infarction	eAMl-8a
CAC	Children's Asthma Care	eCAC-3
ED	Emergency Department	ED-1, ED-2 or eED-1, eED-2
EHDI	Early Hearing Detection and Intervention	eEHDl-la
HBIPS	Hospital Based Inpatient Psychiatric Services	Required for free standing psychiatric hospitals; available for selection for general hospitals with psychiatric units. HBIPS-1, HBIP-2, HBIPS-3, HBIPS-5
IMM	Immunization	IMM-2
OP	Hospital Out Patient	OP-18, OP-23
PC	Perinatal Care	Required for facilities with at least 300 live births per year PC-01, PC-02, PC-03, PC-04, PC-05, ePC-01, ePC-05
STK	Stroke	eSTK-2, eSTK-3, eSTK-5, eSTK-6
SUB	Substance Use	SUB-1, SUB-2, SUB-3
TOB	Tobacco Treatment	TOB-1, TOB-2, TOB-3
VTE	Venous Thrombosis	VTE-6, eVTE-1, eVTE-2

Adapted from TJC, 2018

The Core Measure Sets for the Critical Access Hospitals (CAH) are all submitted as eCQMS. The CAH must report six measures that are applicable to their populations served by the facility and the services that are provided. The eCQMs may be selected from any of the eCOM measures found in Table 27. Small hospitals with an average daily census of 10 or fewer inpatients must report six measures that are applicable to their populations served by the facility and the services that are provided. The eCOMs may be selected from any of the eCOM measures found in Table 27. Psychiatric hospitals that are freestanding facilities are required to report the four HBIPS measures from Table 27. General hospitals with inpatient Psychiatric units are not required to report the HBIPS measures to the Joint Commission. However, these General hospitals with Psychiatric units, may report on the TOB, SUB, and IMM measures, but the data must include all applicable inpatients across the organization regardless

of location, setting of care, and payment source . Children's hospitals, LTCHS and IRFs do not submit any data to the Joint Commission at this time (FAQ-ORYX, 2017).

IHEDISI

HEDIS® is a core set of standardized health plan performance measures released in 1993 by the National Committee for Quality Assurance (NCQA), in partnership with managed care plans, purchasers, consumers, and the public sector of healthcare. The set of measures are utilized to evaluate performance on important dimensions of care and service and used by more than ninety percent (90%) of U.S. health plans. HEDIS data is then utilized to indicate where opportunities for improvement exist. HEDIS has been expanded so that now it covers health plans, and also physicians, PPOs and other organizations. HEDIS data is required for NCQA accreditation, and is also utilized for consumers and employers in reviewing health plans. The HEDIS data is displayed in NCQA *Quality Compass,* the largest database of comparative health plan performance information (HEDIS, 2017).

The latest edition (2018) of HEDIS consists of measures across six domains of care for health plans and over 3 domains for physicians (HEDIS, 2017). NCQA has established a mechanism to update the HEDIS measures yearly. The CAHPS 5.0 Survey is embedded into the HEDIS program (HEDIS – Quality Compass, 2017). Table 28 displays the five domains as they pertain to both health plans and physicians (NCQA-HEDIS, 2017).

Table 28: HEDIS Domains of Measures

HEDIS Domains of Measures	
Health Plan	• Effectiveness of Care • Access/Availability of Care • Experience of Care • Utilization and Risk Adjusted Utilization • Relative Resources Use • Health Plan Descriptive Information
Physicians	• Effectiveness of Care • Access/Availability of Care • Utilization

Data collection is done once a year in the Spring. For each HEDIS® measure, there is a technical definition and description of the population, with instructions for data collection and reporting. Specifications describe how each measure is to be calculated and provide definitions for each numerator and denominator. Separate calculations are required for commercial, Medicaid, and

Medicare risk populations. HEDIS data collection is moving to eMeasurement, which is being tested at this time. For more information on HEDIS, refer to the website list at the end of this chapter.

THE ANALYSIS PROCESS!

In this "Information Age," we are inundated with data. The trick is to know what to do with the data. We need a systematic way to aggregate, display, and analyze the data, even once it is "organized," to turn il into good information for decision making. Of course, first the data has to be submitted in a timely manner and delivered in the format that ensures it will be ready to use. Without these steps, we will have no opportunities to improve and/or no evidence of improvement. Chapter 4 Health Data Analytics contains information on the analysis of the data collected, but the analysis process itself will be presented here.

The analysis process operates most effectively when it is collaborative, with involvement of those most familiar with the process and/or outcome under review. Aggregation and preliminary analysis may be performed by an appropriate individual in the department or service area or perhaps by the quality professional. However, responsibility for interpretation and final analysis (conclusions and recommendations) rests with the accountable team, committee, department/service, or the Quality Council, as delineated.

Any time the performance of an individual practitioner becomes the focus, the appropriate peer review body must assume responsibility for the analysis and any necessary action.

The analysis process answers one or more of the following questions:

- What is our current level of performance?
- Patient/family needs and expectations met?
- Outcomes of care processes as expected?
- What is the stability of our current processes?
- Is there need for more intensive analysis?
- Are there areas that could be improved?
- Was a strategy to stabilize or improve performance effective?
- Were design specifications of new processes met?
- Are we consistent with our priorities for process improvement?

The questions are asked in advance of the data collection. The data that are essential to answer the questions is clearly identified and defined as the first step in the monitoring process. The type of data identified is important to know and understand early in the process since the analysis of the data will require certain information. The proper tools utilized to analyze the data differ with the different types

of data collected. The goal of analysis is to compare the aggregate level of actual performance for each indicator with the designated triggers/signals/benchmarks.

Self-comparison of the data and monitoring of it over time is used by most of the healthcare organizations. The internal patterns and/or trends over time are utilized to identify the organization's improvement processes through the use of the upper and/or lower control limits or design specification levels, pre-established criteria or performance expectations, and single sentinel event or total number of occurrences .

Comparison with others assists the organizations in identifying how their data relates to the performance of similar processes and outcomes in other organizations (reference-based).

Comparison with standards/guidelines/regulations assists the organization with regulatory and accreditation compliance in designing new or redesigning old processes.

Comparison with best practices and benchmarks can be either internal or external to the organization. The information on benchmarking earlier in this chapter assists the organization with identifying improvement opportunities and measuring the effectiveness of the improvements made.

Initial Analysis

For each process being monitored, the organization must **first** collect data to determine if the process is meeting the expected outcomes. The organization must identify the team, committee, department/service, or individual qualified and responsible for the aggregation, initial analysis or interpretation of the data and for in-depth/more intensive measurement and analysis if necessary. The organization should **secondly** specify time tables for the data aggregation must be established. The data should be analyzed at regular, adequate intervals specified by the department/service/team/setting. This should be determined based on the volume of patients, services, or procedures and consider the degree of impact on direct patient care, including risk of sentinel event. **Third,** the analysis should be performed at the designated time intervals. The analysis should include a review for accuracy, validity, and reliability of data. It should be coordinated with other known, related data to permit comparisons and to review for possible patterns or trends. The organization should look for undesirable variation in data compared to baseline, previous measurement periods, or other appropriate comparisons and then determine it immediate action, continued measurement, or intensive analysis is necessary. **Lastly,** the organization should identify any individual cases or sentinel events requiring in-depth analysis and identify any obvious problems, patient risks, or opportunities to improve. Triggers for intensive analysis should be identified, including, but not limited to:

- Sentinel events

- Levels of performance or patterns/trends at significant and undesirable variance from the expected, based on appropriate statistical analysis
- Performance at significant and undesirable variance from other similar organizations
- Performance at significant and undesirable variance from recognized standards
- Depending on the setting:
  - Hazardous conditions (circumstances significantly increasing the likelihood of a serious adverse outcome)
  - Significant medication errors
  - Major single or pattern discrepancies between preoperative and postoperative diagnoses, including pathologic review
  - Confirmed transfusion reactions
  - Significant adverse drug reactions
  - Significant adverse anesthesia-related events

!intensive Analysis!

Intensive analysis (additional investigation or special study) is initiated when undesirable variation in performance has occurred or is occurring presently. Intensive analysis is performed by those individuals who are most familiar with, and can best assess all facets of, the particular process or aspect of care or service such as qualified clinicians, key function area staff, and/or the interdisciplinary/cross-functi onal team members. These individuals must be able to evaluate appropriately aggregated and displayed data/information (totals, percentages, summaries, graphs), specific patterns and trends tracked over time, and relevant specific cases (peer review). When **prioritizing** for intensive analysis the organization must include consideration of real or potential effect on patient care and service, available organization resources, and the organization's mission and priorities.

Intensive analysis seeks to identify and/or clarify opportunities to improve care and service processes, significant deficiencies/probl ems in care and service processes, the scope and severity of those problems and possible causes of problems/root causes of variations. This includes the identification of special cause and common cause variation (see Chapter 4 Health Data Analytics).

Outcomes of the Analysis Process

Analysis may result in opportunities to improve systems, knowledge, and individual behavior. When no problems or opportunities to improve care and service are found after sufficient time ek1pses (e.g., 6 months, 1year), the indicators, triggers, data collection methods, and analysis procedures should be reevaluated to determine their utility in measuring the performance of the specified processes.

Documentation of all monitoring and analysis activities must be completed and maintained for a period of time, as designated by the organization, accreditation standards, and/or state/federal laws.

This includes all worksheets, statistical summaries, minutes/summary reports, and other relevant reports. This documentation should display in some manner the assessment, analysis, conclusions, recommendations and/or actions, and the rationale utilized.

Analysis Process Steps

The analysis process steps are listed here in a general nature and will vary by each organization based on their organization's important functions .

1. Data is collected for prioritized performance measures and is ongoing and with targeted studies.

2. Ongoing systematic aggregation and initial analysis of data occurs with the frequency of aggregation and analysis predetermined/appropriate to measure(s). The process should include interdisciplinary analysis when appropriate. The judgments made should include whether the design specifications for new or redesigned processes were met, what the level of performance and stability of existing processes is, opportunities, priorities, and possible changes for improvement, and whether prior changes in processes resulted in improvement.

3. Utilization of statistical tools and techniques are appropriate to the data collected . Run charts and histograms should be utilized to display summary and comparison data. Control charts should be used to display variation and trends over time . Pareto charts should be utilized to prioritize where to start work, and the type and cause of variation should be assessed.

4. Performance should be compared over time and with other sources, to identify internal patterns, trends, and shifts. External sources for comparisons can be found in literature, evidence-based practice guidelines, performance measures, reference databases, standa rds. ORYX and other accreditation requirements can also provide comparisons. The comparisons, internal and external, should be utilized to identify excessive or undesirable variability, unacceptable levels of process and outcome performance, and best practices through comparison, benchmarking, experts,and literature.

5. Intensive analysis occurs when indicated, if performance varies significantly and undesirably from the expected, other similar organizations, recognized standards, if sentinel event occurs, and/or if specific clinical events are triggered.

6. Determine if there is a need for change determined and possible changes identified.

7. Depending on team's responsibilities and timing, the following may occur at end of the intensive analysis process or may be part of improvement process: the change is selected, plans are made for pilot/implementation across the organization, and/or new performance expectations or measures are elected.

More information on the above analysis topics can be found in Chapter 4 Health Data Analytics.

DISSEMINATION OF PERFORMANCE IMPROVEMENT INFORMATION

After the analysis has o urred, the results need to be reported throughout the organization and to external users. Without communication, the actions taken will not be utilized and incorporated into the processes where the changes are needed. For example, if a team establishes a pathway or guideline for the adult patient with pneumonia, having identified and included best practices, and the results are implemented, but not communicated to the pediatric practitioners, the care of the pediatric patients with pneumonia will not be impacted.

Communicate measurement, analysis, and improvement activities to all those who have an appropriate need to know. All appropriate teams, departments, services, committees, and organization leaders (governing body officers, chairs, medical directors, managers, administrative staff) and the governing body must be provided enough information for decision-making, to meet their responsibilities for maintaining and improving the quality of patient care. It is important to include faciiity staff in the discussion of quality issues, potential actions, and results of the improvement actions. Communicate to staff organization-wide so they can benchmark with each other as appropriate.

The team, department/service, and organization leaders should disseminate information throughout the organization as necessary and appropriate, giving consideration to the need to retain the confidentiality of all patient and practitioner identifiers, all peer review findings regarding individual patient management issues and findings clearly linked to adverse occurrences/events determined to be PCEs (Potentially Compensable Events).

Refer to the medical staff or designated peer review body the responsibility for assessment of all issues with a patient or independent practitioner identifier attached, assuming that peer review is necessary. In those states with legislation pertaining to the non-discoverability of peer review information, it is prudent to have the medical staff or designated peer review body approve the Quality Management/Performance Improvement Plan, including the occurrence/event reporting system as a component. They also need to write clear policies and procedures dealing with the flow of all patient-identified and practitioner-identified information through appropriate peer review processes and maintain all patient- and practitioner-identified QM/PI information separately and locked, as a peer review activity.

\REPORTING MECHANISMS

\summary Reports of QM/Pl Activities!

Everyone in the organization has a right and a responsibility to know and respond to the results of QM/Pl activities, to which, they have committed. The level of data detail will vary, based on the need to know and also based on the individual's specific responsibilities, e.g., job description, team, committee, department, and site. Valuable, concise input to administration, the medical staff or other physician groups, the governing body, and the healthcare system, if applicable, hopefully will impact decision-making and strategic/quality planning.

The governing body generally receives quarterly a:id annual summary reports. To reach the entire organization, summary reports of successful QM/Pl activities may be reported at management meetings and then disseminated by managers and supervisors through staff meetings. Leaders may present QI/Pl summary reports (e.g., balanced scorecard and strategic initiatives) at periodic and annual organization wide staff meetings. Table 29 lists suggested communication methods for different types of reports.

Table 29: Suggested Communication Methods for Reports

Suggested Communication Methods for Reports	
Items to be reported	**Details**
Aggregate and trend reports (monthly, quarterly, semi-annual, and annual)	- Feedback on relevant performance measures/indicators to teams, committees, departments, staff and leaders to: -- Maintain commitment -- Identify patterns/trends -- Encourage action -- Track unresolved issues for intensive analysis -- Track resolved issues to sustain improvement - Needed data to track performance daily, weekly, monthly, quarterly, annually, or on demand - Comparisons year-to-date, year to year, against reference databases and benchmarks
Quality improvement project reports (team activities)	- Initial project statement/charter - Project process/progress reports - Project summary reports and "storyboards"
Minutes addressing performance improvement	- Findings - Conclusions - Recommendations - Actions - Follow-up
Department/Unit Level	Email is an effective way to communicate if a trail of when

	information is shared is desirable Many emails are never read and are simply deleted For communication to be effective, utilize eight times and eight ways. Some examples are: Bulletin boards, White Boards, Posters Staff meetings Presentations Department/Unit Committees

!Reporting to the Governing Board!

A summary report of quality management activities must be provided to the governing body on a periodic basis as defined in the Quality Improvement Plan. Most organizations report to the Governing board quarterly with goal/benchmark and previous year comparisons, and then provide an annual summary report. Typical annual reports to the governing board include: all process and system failures, the number and type of sentinel events, whether the patients and the families were informed of the event, and all actions taken to improve safety, proactively and in response to actual occurrences.

Any report to the Governing board should include a summary/progress report of all quality planning and quality improvement projects, particularly those prioritized as Strategic Quality Initiatives, and key patient safety activities. A suggested list of performance measures that should be reported to the Governing board throughout the year are displayed in Table 30. Some of these topics, such as evaluation of contract services, may be delegated to the administration of the organization. Other topics reported will be determined by the type of organization, strategic priorities (clinical and operational) of the organization, and the services provided. The senior quality professional should always attend those governing board meetings at which reports will be presented. Reports may go directly to the full board or they may be presented to a delegated board committee, such as a board quality improvement committee or a joint conference committee.

Table 30: Performance Measure (Quality Indicator) Data and Information Reported to the Governing Board

Performance Measure (Quality Indicator) Data and Information Reported to the Governing Board
- All key performance improvement activities, including (see also Performance Improvement Processes, this Chapter): -- Status of strategic quality initiatives; -- Status of quality planning and quality improvement projects for key processes; -- Significant patient care and safety issues identified, actions taken, and results, including

sentinel/adverse events, root cause analyses, actions, and outcomes;

-- Summary performance measure and trend data (prioritized by the governing body), as applicable to the organization, including, but not limited to:

--- Balanced scorecard or dashboard data, including links to patient safety and quality of care

--- Clinical outcome data for key functions or services

--- National Patient Safety Goals compliance

--- Adverse occurrence data/trends (actual and potential) and key rates, e.g., medication errors, mortalities, and as prioritized

--- Risk management prevention and intervention activity summaries

--- Pertinent cost data for key services

--- Healthcare-associated infection rates and infection control activities

--- Utilization trends: Admissions, patient days, encounters, etc., as applicable; average length of stay (ALOS); unplanned admissions/ readmissions; discharges against medical advice (AMA)/left without being seen (LWOBS)

--- Satisfaction survey trends: patient, staff (professional and organization)

--- Complaint trends: patient, professional staff, organization staff

--- Staff turnover/absenteeism and staffing effectiveness data

--- Patient wait times

--- Liability claims and other financial data, e .g., total claims and average cost per claim, cost per case, cost avoidance, cost of quality (COQ), and cost of poor quality (COPQ), denials of payment

-- External reviews/studies/reports

-- Performance appraisals

- Evaluation of contract services

- Summaries of media stories

Itntegration within the Organization!

There should be an effort to link specific QM/Pl activities, (e.g., strategic quality initiative successes) to the organization's strategic goals and values and its commitment to quality. The strategic initiatives of the Quality/Performance Improvement plan should include some strategic initiatives from the strategic plan, but also others that are identified by the Qua lity Council. However, patient safety strategic initiatives should be included in both the organization and performance improvement goals and objectives.

In order to do this, there must be integration of the information gathered during individual QM/PI activities into the organization wide quality management/performance improvement strategy and other key organizational functions as relevant and appropriate. There is also a need to integrate the information into medical staff and the organization's department/unit staff efforts . Staff should be made aware of how their results from the monitoring compare with the rest of the organization in order to identify opportunities for improvement for the department/unit.

The quality and performance improvement efforts should also be integrated with the reappraisal/reappointment of medical staff members, as applicable, in addition to the clinical privilege delineation of all independent practitioners, and the assessment of competence for all clinical practitioners. The medical staff departments and committees should be aware of how their results from medical staff monitoring compare with other departments and specialties, as well as the general organization, in order to identify opportun ities for improvement.

The annual organization wide strategic and quality planning and objectives selection process, including specific Strategic Quality Initiatives, should be based upon findings from measurement, analysis, and improvement activities of the organization over the past year. The planning and setting of priorities must focus on the results of the functional, quality improvement, and quality planning team activities. Other organizational functions that should also be considered include utilization management activities and trends, risk management activities and links to patient safety and quality, infection surveil!ance and control findings, trends, and actions, including prevention, patient safety activities, trends, and results. The evaluation of/renegotiation with contracted services and the evaluation of/renegotiation with managed care plans or providers, also provide useful information.

ttransparencyl

Transparency of healthcare costs and quality information enables consumers to compare the quality and price of healthcare services and make informed choices. Transparency however, means different things to different people. Different segments in healthcare have developed efforts toward transparency, but it is difficult for the consumers to be able to understand and compare the information from one site to another. It is essential in any healthcare organization to utilize transparency to assist in improving quality and cost. It is also essential that the healthcare organizations display the information in a format that consumers can read and understand.

In 2012, the Health Policy Institute of Ohio reported that 91% of Americans feel that having information about costs is important before receiving health care. However, only 12% of consumers report having used the internet to obtain such information on provider costs (Health Policy Institute of Ohio, 2012). Consumers are most interested in the information that applies to their particular circumstances . This includes information about specific practitioners/providers, procedures that the consumer is considering, and about the out-of-pocket cost to the consumer. Whether they have insurance or not consumers are interested in information about patient experiences and the

differences between clinical outcomes (U.S. Government Accountability Office, 2014). Table 31 shows how transparency of cost and quality information impacts the consumers.

Transparency of healthcare pricing and performance through public reporting is a growing expectation on the part of consumers, accrediting agencies, payers, employers, and government . In August 2006, President George Bush signed an Executive Order to direct federal agencies involved with administering or sponsoring federal health insurance programs, to increase transparency in pricing and quality. In 2009, President Barack Obama, in his U.S. Department of Health and Human Services (HHS) Open Government initiative, identified transparency and data sharing as a key component of the program. In this program, all leaders of executive agencies and departments are directed to develop plans increasing transparency, collaboration, and participation in all federal government activity. This includes the HHS and the Center for Medicaid and Medicare Services . As a result of this initiative, the Health Indicators Warehouse and the Community Health Data Initiative were developed. In March 2011, in response to the Patient Protection and Affordable Care Act (PPACA), the HHS published its National Strategy for Quality Improvement in Health Care. This strategy builds on the need for transparent information for consumers to utilize when choosing healthcare . Two of the goals of the National Quality Strategy, better care and affordable care, directly relate to the cost and quality of healthcare (Health Policy Institute Ohio, 2012).

In December 2013 through December 2014, the U.S. Government Accountability Office conducted a study requested by Congress to study the transparency reports of the CMS to determine what is available to consumers, the characteristics of effective transparency tools, and limitations in the CMS transparency tools in providing cost and quality information. This study identified that consumers do not find the information from process of care measures useful. The consumers are looking for information on their participular care needs. They want data on cost estimates from their particular insurance coverage, not just the insurance agency (U.S. Government Accountability Office, 2014).

Table 31: How Transparency Impacts the Consumers

How Transparency Impacts the Consumers		
Price transparency	Quality transparency	Price and quality transparency impact on health Core spending
Usage is low, but interest is high	Publicly releasing quality data simulates improvements among hospitals	Price transparency limited potential to reduce regional price variations and competition among practitioners
Limited incentive or ability to shop	Reporting is inconsistent and	Lack of

around for care	uncertain for effective patient-centered care and patient safety	coordination and consistency among transparency initiatives
Limited understanding of price and quality data	Tracking quality of care may lead to quality improvements and changes in clinical beh;:iviors	Transparent cost and quality data supports pay for value rather than for volume of service
Limited knowledge of total costs and out-of-pocket costs	Consumer impact can be limited based on amount of area competition	

Adapted from Health Policy Institute of Ohio, 2012

The Quality Professional shares responsibility for ensuring that the information is collected in a nonpunitive, open, truthful environment for both internal and external reporting. The data must be collected according to the definitions provided to the organization and that the data is being reported to. The accuracy and timeliness of quality data and information collected and submitted, e.g., performance measures and accreditation and licensure reports are essential. The Quality Professional must ensure compliance with public reporting requirements and encourage process changes to improve compliance with reportable cHnicai performance measures and the guidelines they support . Participation in voluntary reporting opportunities that offer incentives, e.g., increased reimbursement is also important.

!Public Reporting!

There are many public and private entities where healthcare organiations are reporting quality information that will be displayed to the public. These "Report cards" are comparative summaries of actual performance against key indicators (performance measures) from the health plans, providers, or communities.

There are several websites where the consumer and others can go to determine where they might want to search for comparison information. One such website is the Agency for Healthcare Research and Quality (AHRQ) with a compendium for health care report cards. This website allows quieres for health care report cards for hospitals, home health, behavioral health, health plans, dialysis facilities, long term care, individual physicians, and medical groups/clinics. A search results in from 1 to 72 different organizations, based on the type of healthcare provider listed.

Several of the most commonly utilized healthcare report card entities will be discussed in this section. There are many more that are available for use, but these seem to have received the most attention.

The Center for Medicare and Medicaid Services (CMS) have developed multiple comparison websites for different types of healthcare organizations. Table 32 displays the current and proposed CMS comparison websites. Each of these websites contain data from only the Medicare patients, and not any private pay patients. The websites have their own criteria that is based on the data collected at CMS from the different programs in each area. All of these websites allow you to query by location and other factors as appropiate. The Physician Compare site only tells the viewer if the practitioner is participating in different CMS physician initiatives and not the data concerning the parctitioner's quality practice within those initiatives.

Table 32: CMS Data Comparison Sites

CMS Data Comparison Sites		
CMS Comparison Site	**Established Year**	**Website**
Nursing Home Compare	1998	www.medicare.gov/nursinghomecompare/search.html
Dialysis Facility Compare	2001	www.medicare.gov/dialysisfacilitycompare/search.html
Home Health Compare	2005	www.medicare .gov/homehealthcompare/search.html
Hospital Compare	2005	www.medicare.gov/hospitalcompare/search.html
Physician Compare	2010	www.medicare .gov/physiciancompare/search.html
Hospice Quality Reporting	2017	www.medicare.gov/hospicecompare/
Inpatient Rehabilitation Facility (IRF) Quality Reporting	2016	www.medicare .gov/inpatientrehabilitationfacilitycompare/
Long-Term Care Hospital Quality Reporting	2016	www .medicare .gov/longtermcarehospitalcompare/

The Joint Commission's Quality Check and Quality Reports

The Joint Commission's Quality Check® is a search engine and comprehensive directory of healthcare organizations that are accredited or certified by The Joint Commission providing comparative Quality Reports to the public. The Quality Report includes accreditation or certification information, special quality awards, compliance with the National Patient Safety Goals (Met, Not Met, Not Applicable), and the performance on the National Quality Improvement Goals (Hospital ORYX core accountability measures), including HCAHPS® Survey (patient satisfaction) results and CMS 30-Day Mortality and 30- Day Readmissions Measure Files.

NCQA's*Quality Compass"*

The Quality Compass contains several different transparency tools. NCQA began releasing its own HEDIS• compilation in August, 1996. The Quality Compass· is a national database of trended, comparative performance, resource use, and accreditation information from more than 90% of America's health plans and, beginning in 2008, preferred provider organizations (PPOs). It is available for purchase by employers, benefit managers, the media, health plans, consultants, policy makers, and others. According to NCQA, the information assists in contracting decisions; setting performance improvement direction, priorities, and actions; monitoring improvement; and, in general, establishing accountability. In terms of the consumer and employees, the Health Plan Report Card is the tools to utilize. An employee or consumer may obtain information on one or more health plans in a given geographic area of the U.S. by clicking on the Report Card tab and then selecting health plans, clinicians, or other organizations. This will allow the consumer to select the health plan or clinican and view the information available. There are multiple types of reports that the consumer can view.

HealthGrades

HealthGrades, an independent for-profit healthcare ratings company, was founded in 1999. Ratings and comparisons for physicians, dentists, and hospitals are offered to the public, some free and some for a fee. HealthGrades evaluates hospital quality for clinical outcomes from 36 conditions and procedures and adjusts for each patient's risk factors, such as, age, gender, and medical condition Medicare medical claims records for the most recent three-year time period are also utilized. The physician information is obtained from patient satisfaction, experience match, and the quality of the hospital where a physician provides care. The consumer can search on the type of procedures and conditions, the type of hospital, dialysis centers, group practices, physicians, and dentists.

Consumer Reports

Consumer Reports collects data for health-Insurance plan, hospital and heart bypass surgical rankings. The health-insurance rankings are derived from the rankings of the National Committee for Quality Assurance. The hospital rankings are determined based on the hospital's patient safety score, as well as individual measures relating to patient experience, patient outcomes, and certain hospital practices. The consumer can search the hospital rankings by city, county, state, or the name of the hospital. The heart bypass surgery rankings are derived from performance data submitted to the Society of Thoracic Surgeons, a nonprofit organization that represents doctors who operate on the chest. The groups in these ratings are those that agreed to share data with Consumer Reports.

US News & World Reports

US News utilizes analyzed objective data from multiple sources. One source is a federal data set known as MedPAR that contains details of every traditional Medicare paid hospital admission. Also utilized are publicly available data from the Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention on six common types of healthcare-associated infections, as well as a

measure of complications associated with joint-replacement operations, and data from federally mandated patient-satisfaction surveys.

Truven 100 Top Hospitals Report

Truven analyzes data from approximately 5,000 hospitals in 16 adult and 10 pediatric specialties. Truven also rates data on the best physicians, health plans, Medicare plans and nursing homes.

The resulting rankings are comprised of equally weighted measures of key organizational functions and outcomes – financial stability, operational efficiency, patient safety, quality of inpatient and outpatient care, and customer perception of care. Truven is also piloting rankings from other areas such as the emergency department efficiency, extended outcomes, and the financial health of the system. The health systems identified as the top 15 health care systems in 2015 were found to have a lower cost per episode, better survival rates, fewer complications, and better patient safety and core measures adherence than their peer systems.

There are other healthcare report card entities that can be identified, but it is suggested that facilities identify one such entity that they will consistently utilize to show their progress towards inprovement of quality and cost. The facilities can then explain more clearly to their customers how they are making improvements and lowering costs.

PEOPLE IN THE PERFORMANCE IMPROVEMENT PROCESS

In the pursuit of quality care and services, we have stated that healthcare must build "quality organizations" to be successful. The organization is really only as "quality" as its people. People management is the personalization of strategic leadership and a corporate culture committed to quality. Moreover, management that is truly "of, for, and by the people" is, by definition, participative. This section of the chapter will focus on individuals who must be involved in the quality management process in order to have a successful program.

There is a growing understanding of the impact and value in organizations of "networks of trust." Networks represent the "collective cognitive capabilities" in the organization: the flow of tacit knowledge (the circulation of information) between people who trust each other enough to engage. Whereas the organization chart basically indicates the formal rules of authority, the human network is how work actually gets done.

In high-trust cultures, people feel free to speak candidly together about their impressions of organizational strategies, quality, safety, satisfaction, and ways to improve. Innovation opportunities increase and costs associated with oversight management tend to decrease . Certain people play critical networking roles, and they may not show up on the organizational chart .

If the power of networks is well understood, leaders place appropriate value on human exchange and encourage the flow of knowledge and ideas. There are at least six core networks or layers of knowledge in an organization's culture:

- Work (exchange of information in daily work)
- Social ("check-ins" inside and outside the workplace for information)
- Innovation (collaboration/sharing new ideas)
- Expert Knowledge (expertise and advice)
- Career Guidance/Strategic (advice about the future)
- Learning (improve existing processes or methods)

Managing Relationships

It is central to quality management knowledge that the quality of products and services provided to external customers (non-employees) is determined in large part by the quality of the relationships between internal organization customers, processors, and suppliers . The quality professional, along with the organization, is responsible for facilitating relationships as much as systems and processes.

Relationships are considered "good" when there are long-term commitments, communications are C:ea; and there is mutual trust that is operationalized. Good relationships are formed when people's needs are known, understood, and respected; when conflict is resolved through negotiation; and when honest attempts are made to meet and exceed those needs. Time spent in developing rapport and solid working relationships with colleagues, QI team members, physicians, community, etc., will stand the quality professional and others in the organization in good stead for successful quality management.

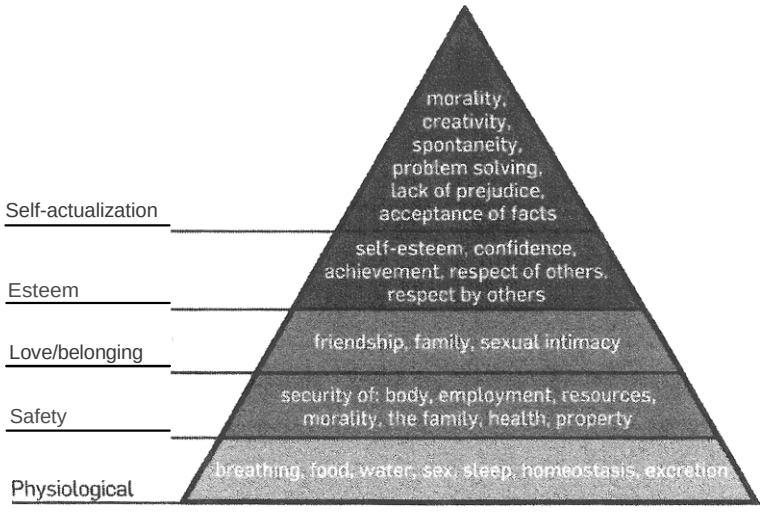
There are always structural and cultural obstacles to overcome. When attempting to implement interdepartmental or cross-functional quality improvement activities, several common obstacles may be encountered. Often departments are organized traditionally, based on a professional discipline, rather than organized by service line or flow of patient care. There is typically a lack of time to meet as a team. There is often a traditional focus on individualized patient care, which can impede interest in system and process issues. Likewise, physicians have been trained to think of patients as unique individuals and not as cohorts of populations. The goal, and challenge, is to create an environment where both foci are .:ippropriate: the patient is the center of quality improvement efforts, both at the individual level (variances from clinical path, case-specific issues, etc.) and at the population/patient flow level (clinical path or practice guideline development and process improvements).

MOTIVATION THEORIES

There are many motivation theories that have been developed, with some better known than others. While these theories are all widely accepted, no one theory fits all situations or individual. The manager must be aware of the different major theories and apply them to the personnel they work with, and for. Therefore, the quality professional also should be aware of these theories and how they can affect the interaction and motivation of the various healthcare team members.

One of the most basic motivational theories is that of **Maslow's Hierarchy of Need** (Maslow, n.d.). Maslow's theory states that the person's unsatisfied needs are the primary influences on an individual's behavior, or the real motivators. The theory states that there is a hierarchy of needs, from the most immature to the most mature, that must be at least partially fulfilled in ascending order before behavior patterns change and mature (Figure 4). If the physiological needs are not met, then the other four levels of need cannot be met. It is only until the first four levels of need are met that the self-actualization level can be achieved. Maslow suggests that managers should seek to understand employees' needs and need levels and use these to motivate behavior rather than assuming a particular motivational theory or management style.

Figure 4: Maslow's Hierarchy of Need



Theory X and Theory Y are two opposing management theories explained by Douglas McGregor Theory X and Y (n.d.). Theory X assumes that employees have a dislike for work and only work for the paycheck. These employees need to be directed and they avoid responsibility. They need to be

supervised at every step. Theory Y assumes that employees feel that the expenditure of physical and mental effort in work is as much a need as is play or rest. They do not need much supervision, and seek and accept responsibility. Table 33 displays the comparison of these two theories. The manager must determine which theory of motivation pertains to which employees and then plan their management techniques accordingly.

Table 33: Comparison of Theory X and Theory V

Comparison of Theory X and Theory V	
Theory X Assumptions	**Theory V Assumptions**
People dislike work and need to be threatened and controlled to work hard enough	People are self-motivated
People do not take responsibility and desire job security	People want responsibility and are committed to the organization
People like specialized and repetitive work	People like work organized around wider areas of skill and knowledge; Encouraged to develop expertise & make suggestions for improvements using imagination, creativity and ingenuity
Management should be authoritarian with centralized control; management controls all aspects of the job; Rigid policies and procedures, job descriptions, work rules, and negative reinforcement are imposed without employee input	Management should be participative allowing involvement of employees in the decision making process; Participative problem solving is encouraged
Organizations use carrot and stick approach with performance evaluations for control and raises	Organization uses appraisal processes but is separate from organizational controls; Frequent opportunities for promotion
Works well in large scale production operation and unskilled production line work	Works well in organizations designed for professional services work

Herzberg's **Motivation-Hygiene Theory** of job enrichment is another important motivation theory (Herzberg, n.d.). Fredrick Herzberg studied the different aspects of satisfied and dissatisfied employees. Drawing on Maslow's need hierarchy, Herzberg identifies work place satisfiers and dissatisfiers. He determined that the factors that lead to satisfaction (motivation factors) are different from the factors that lead to dissatisfaction (hygiene factors). He contends that motivation is in the job content (e.g., the work itself, achievement, recognition, responsibility, growth and advancement), like Theory Y . However, if the hygiene factors, or job environment, are negative or dissatisfactory (e.g., company policy and administration, supervision, working conditions, interpersonal relations, safety, or salary), morale and productivity suffer (Maslow need levels 1-3). Dissatisfiers must be removed, as they are barriers to motivation, however removing them does not establish motivation. To motivate

staff, you also have to focus on the satisfaction factors. Table 34 lists the factors for satisfaction and dissatisfaction.

Table 34: Factors for Motivation-Hygiene Theory

Factors for Motivation-Hygiene Theory	
Factors for Dissatisfaction (eliminate)	**Factors for Satisfaction {build into work environment)**
Company policies	Achievement
Relationship with supervisor and peers	The work itself
Work conditions	Responsibility
Supervision	Recognition
Security	Advancement
Salary	Growth
Status	

EAMS & MEETING

In this section of the chapter, we will be discussing teams, team methodologies, meeting management and documentation. Every organization regardless of size or organization type will need to apply this information either to establish teams or to evaluate for opportunities to modify processes in these several areas.

Teams

In the 1990s, the focus of quality in the institutional health care environment shifted from the traditional segregated departmental practice to a multi-disciplinary team process. This mirrored the increasingly popular view of holism and primary care in health care. For example, when children are two or three years old, they may enjoy playing house. One child usually takes one role and another takes another role. Observing this it seems as if they are interacting separately, or performing parallel play. That is similar to many multidisciplinary groups. They are all in the same room, maybe focused on the same process, but each member focuses on the contributions his or her discipline can make, and not necessarily on the entire process. Critical care committees are an example of how this was done in the past.

Following those 1990s teams, came the interdisciplinary team. With an interdisciplinary team, members all work with the same focus. Again, as children grow older, when they play house, you can observe that there is more give and take, discussion and collaboration with decision making. That is the current preferred model of team collaboration. The concept of teams has expanded both globally and beyond the focus of health care to many industrialized nations and their health care programs. The concept of these teams is now in specific target populations, social work activities, and reimbursement practices.

The improvement of quality in healthcare organizations is dependent on teamwork, partly because providing care and service is complex, with many handoffs between practitioners/workers, and partly because healthcare workers like working with other people. How the organization and the quality professional accept, lead, and participate in group process will determine the success of the performance improvement strategy.

Teamwork and Group Process

This next section will describe 'what' teams are and what they can be expected to accomplish. A group is a collection of individuals who affect the character of the group and who are in turn affected by the group. Group dynamics are determined by the various combinations of individual interests, abilities, and personalities . Group success is inevitably tied to the organization's corporate culture, leadership's commitment to quality as a key organization wide value, and the subsequent degree of empowerment and resources given to the group. There should be 6 to 8 members of the team, but no more than 10, whose membership is based on close work with the organizational function, processes, or topic.

The Role of Teams in Quality Management

A team is a group of people who perform interdependent tasks to work toward a common mission. Some teams have a limited life: for example, a design team developing a new product, or a process improvement team organized to solve a particular problem. Others are ongoing, such as a department team that meets regularly to review goals, activities and performance . Understanding the many interrelationships that exist between organizational units and processes, and the impact of these relationships on quality, productivity and cost, makes the value of teams apparent (Teams, n.d.).

Quality Improvement (Qi) Teams must be comprised of appropriate clinical and non-clinical staff at various levels in the organization. Teams may be temporary as in a task-associated team, or permanent such as a team dealing with a specific topic such as medication management . If they are permanent, they may be diagrammed on the organizational chart, along-side departments, services, and committees.

Team members are the backbone to the success of the team. Teamwork involves the team members working collaboratively ,through generation of ideas, discussions, utilizing understanding that the team members bring different ideas and experiences to the team, and that only by working together will the team be successful.

A team is needed to achieve a common purpose and better results than individuals working alone would achieve (interdependence identified) . A team is utilized to maximize the expertise and perspectives available in the organization, often when participative management is the leadership style. When a planned change or new process design will impact current work practice, a team should be utilized to help obtain buy-in from the staff. Teams play a large role when successful

implementation of the problem solution or process design/redesign depends on buy-in from persons across the organization. Teams are also valuable when resistance to change is high, but change is inevitable.

All teams will move between four stages throughout the performance of their work: Forming; Storming; Norming; and Performing. Psychologist Bruce Tuckman developed this sequencing in 1995 to describe the way most teams act on their way to completing their task (Forming, n.d.) (Improving, n.d.).

In the Forming stage, team members are getting to know each other . The Team leader plays a large role here in bringing the members of the group together and establishing the ground rules, etc. There is little progress towards meeting the goal of the team during this phase. This phase may last a long time as team members are oriented and educated on what the team's role is and how they fit into the team. In this stage, the team leader should direct the team and establish clear objectives for the team.

In the Storming stage, team members begin to push against the boundaries, particularly when there is a conflict between team members' working styles. The team members are beginning to realize that there is more to this task than they anticipated. In this stage, there could be challenges towards the leader's authority, and the team roles, the goal of the team, resistance towards taking on certain tasks, or challenges if the team members are uncomfortable with how the team is moving along. In this stage, the team leader should work to build trust and good relationships, resolve conflicts, and remain positive and firm.

In the Norming stage, the team members begin to come together, resolving their differences, appreciating the strengths of other team members, and respecting the leader's authority. The team members are moving to cooperation instead of competitiveness. The team members are more likely to ask other team members for help, ask others for feedback or their opinion. The team members have become committed to the team's goal and start to progress in that direction. The team leader could attempt a team building exercise but should also step back a little and allow the team members to begin taking on responsibility for the team's progress.

In the Performing stage, there is work toward the completion of the goal. There is minimal friction and the team is working well together . The leader at this time is able to deleg.:itc work to the members and feel assured that it will get completed . The team leader should delegate tasks and projects to the team members, and begin focusing on the advancement of the team towards its outcome.

The team does not move straight from Forming to Performing, and then remain there. If there are any changes to the team or their charge, then the team can go all the way back to the Forming stage again . If someone leaves the team and is replaced, that new individual is definitely in the forming stage and will pull the team in that direction. As new tasks are identified, the team may move back and forth

through the Storming and Norming phases before they move into the Performing phase for those tasks.

frypes of QI Teams)

The word team is often used in many ways. In quality/performance improvement, teams are frequently utilized to determine how to make improvements to processes that have been identified by the organization. The team is brought together to make the improvements and then disbanded once the improvements have been made. The use of work teams (or QI teams) to improve quality and productivity is based on the knowledge that teams foster greater employee involvement and, subsequently, commitment to the organization's success. Work teams vary widely in focus and degree of autonomy from informal *"ad hoc"* groups assigned to resolve specific short-term problems to permanent, "self-directed" teams.

Functional teams are organized to improve processes in a given important function, e.g., patient care, medication management, infection control, environment of care, safety, or information management.

Cross-functional teams are organized to cross the boundaries of existing organizational structures, be that functions, departments, or disciplines. Most "functional" teams are actually cross-functional because they cross department or discipline lines, even though their focus is on one function, e.g., information management.

Clinical teams are organized around a clinical condition, service line, DRG, diagnosis, or procedure, to improve all associated processes of care and service on a prioritized basis, perhaps through a Strategic Quality Initiative. Clinical path development is a common task performed by this team.

Operational teams are organized to improve management and support (nonclinical) services or perhaps Strategic Quality Initiatives.

Ongoing teams can be functional, clinical, or operational, and are mostly cross-functional and multidisciplinary in composition. These teams may replace committees, are permanent, and may be self-managed, e.g., the Quality Council.

Ad hoc teams are formed to address one important issue or task, e.g., a root cause analysis, a Strategic Quality Initiative, a failure mode and effects analysis (FMEA), or a particular project. *Ad hoc* teams are comprised of those with the most knowledge of, and information about, the issue under study and includes those with subject matter expertise. Generally, once the project is complete and the process change or new design has been implemented and been proven to work, the team disbands.

Self-Directed Work Teams share responsibility to complete a whole piece of work or service, are trained cross-functionally, share many management responsibilities, and are given broad decision-

making authority with access to all information needed to make good decisions. These teams have more autonomy with the organization and thus have more responsibility than the other types of teams listed above. Self-Directed teams do their own planning, setting of priorities, organizing and managing the budget, scheduling and assigning work, coordinating with others, measuring their performance, solving problems, taking corrective action, evaluating their effectiveness, and even hire/evaluate own staff {depending on the organization).

Many of the above listed types are Interdisciplinary Teams . If one department forms a team, department staff may be the only members on the team . Nevertheless, often the process being improved has interdisciplinary individuals who have some ownership with the process.

!Roles within Quality Improvement Teams!

!selection of Team Members!

This section will discuss the 'how' of team processes and management. Among the initial tasks of performance improvement initiatives is deciding who will be included on the team and establishing their roles during the initiative. Individuals with intimate knowledge of the topic at hand are invaluable to the team, especially staff members. Others who are stakeholders or process owners should also be included. People with performance improvement methodology skills can guide the team through the phases of process change. It could be beneficial to have someone with an unusual or different point of view on the team to stimulate individual creative thinking and prevent team members from just following the ideas of the leaders. Physicians or other champions are valuable members and can communicate with others outside of the team to help achieve buy-in to the process changes . Champions can often be found in any aspect of the organization, but these individuals are the ones that support moving towards the goal of the team and sometimes are anxious to get moving in that direction. They can add to the success of the team by communicating to others what is happening as the team moves forward and why that is important. Physician champions should have a good working relationship with colleagues and the day-to-day leader(s), and be interested in driving the change in the system . A physician/provider who is an opinion leader in the organization makes an effective champion.

!Roles!

Great projects can be severely damaged when people do not understand their roles and how those roles relate to the project deliverables . Healthcare quality professionals are frequently called upon to lead and facilitate performance improvement teams. The project team leader must be crystal clear about the expectations and requirements a re for each of the team members. The facilitator is basically guiding the team in a manner that helps the team function easily and efficiently . The facilitator should not have an interest in the outcome of the team. Table 35 lists the duties of the members of the team. It is important that someone on the team, or the sponsor, be able to directly or indirectly engage the financial support that will be needed by the team.

Table 35: Team Roles and Basic Tasks

Team Roles and Basic Tasks	
Role	**Basic Tasks**
Sponsor	Senior leader advisor to the team
Facilitator	Assists the team leader in planning meeting and developing the agenda; Ensures the participation of all team members, monitoring the .lgcnda, and keeping track of time • Make it simple for the team to function • Keep team on task • Guides activities such as brainstorming, cause mapping, risk analysis, etc. • Manage team dynamics • Teach and support • Help the team leader with assignments, needs between meetings, plan changes, team tool techniques, prep for presentations • Seek opinions of all team members • Coordinate ideas and test for consensus • Assist team in applying QI tools and techniques • Summarize key points • Provide feedback to the team
Leader	Fully understands the processes targeted for improvement and the breath of the project in order to effectively lead the meetings e Prepare for meetings • Conduct meetings • Assign activities to team members and participate in carrying out assignments between meetings • Provide direction • Assess progress • Interface with other teams and support resources • Represent the team to management • Follow up with team members as necessary • Documentation (minutes, other records) • Communicate with team, facilitator, sponsorichampion, and the organization
Team member	Agree to contribute their knowledge and insights to the project; Agree to support suggested improvements; Facilitate 'buy-in' for changes that result in improvement • Attend regular meetings

	• Participate willingly • Is engaged in working to reach the goals of the charter • Treats others the way he/she would want to be treated • Realize that the work of the team is accomplished outside of the meetings • Assist the team leader with documentation and meeting management • Help critique and improve the meeting process • Share experience and knowledge • Listen to others and remain open to all views and ideas • Complete assignments between meetings • Communicate effectively with colleagues regarding team's work/progress and seek input/buy-in • Participate in team QI/Pl process • Understand role in implementation and monitoring
Champion	Has influence within the organization; Should be credible with an ability to persuade others; Is knowledgeable on the topic, provides education, and supports staff; Acts as a liaison between the unit and the process improvement team; Should have a strong belief in patient safety and safety culture • Participates as a member and sometimes subject matter expert • Encourages and supports team, particularly to the organization and leadership
Time keeper	• Keep the team within designated meeting time constraints for discussions, brainstorming and other team tool sessions, and ending times
Recorder	• Keep minutes and other records to meet documentation requirements and facilitate team recall
Ad hoc member	• Comes and goes on the membership roster, as expertise is needed by the team

!Facilitator/Coach!

The team facilitator serves as internal consultant or coach to the team. The facilitator does not care about the outcome of the team, but rather about the team process itself. If the facilitator is involved in the content of the process being changed, there is no objectivity to move the team along. For example, for a clinical improvement team, a staff member facilitator who works in accounting would be beneficial to this team.

As a facilitator, teambuilding, listening skills, communication skills, organization skills, and data analysis skills and knowledge of performance improvement methodologies are needed. The facilitator does not have to come up with the answers to the questions at hand, but rather guides the team to do so.

There is a valuable comprehensive team facilitation tool kit (Facilitator, n.d.) produced by the University of Wisconsin Madison. While the kit focuses on application in the university setting, it can easily be used by he;:ilthcare as well. It is available as a free online download. See website list at the end of this chapter. If your google 'Facilitator Tool Kit' you will find many other toolkits that you could utilize.

\ream Leaded

One member is appointed team leader as the person who "owns" the process examined and has the responsibility and authority to lead the improvement project. The team leader is an active member of the team and is interested in the outcome of the team efforts. Many times, the leader is chosen and is involved in choosing the other team members. The team leader establishes the content for the meeting, runs the team meeting, and summarizes at the end of the meeting. If the team leader has never held that position, a strong facilitator should be appointed to the team. The facilitator will run the first several meetings as the leader learns the leadership role, and then the leader can gradually take on the role with the support of the facilitator. The team leader is not responsible for the entire decision-making and is not responsible for the team's success or failure. A team leader should have the following ten skills: communication, organization, confidence, respectful, fair, integrity, influential, delegation, facilitator, and negotiation (Scott, n.d.).

!ream Membe

The team members are responsible for working with the team leader to identify the opportunity for improvement, identify the issues, process flows, and root causes of the problem. They are responsible to collect and analyze the data and then to recommend corrective action/changes. Once approved by the team sponsor, the team members are responsible to implement the action plan and to assure that the monitoring is done and that a successful outcome can be achieved.

Team members need the skills of listening, sacrificing, sharing, respecting others views, questioning, working hard, and persuading (Gaston, n.d.). The team member must understand what skills and ideas they bring to the team and what they need others to bring to the team. The team member must also be aware that in the beginning, the work will be done within the meeting itself. As the project progresses, most of this work will be accomplished outside of the meeting and then reported at the next meeting.

!Recorder & Timekeeper Roles

Both the recorder and timekeeper roles should be rotated throughout the team members. The person who is taking notes, or watching the time, will not be able to participate in the discussions as much as others on the team.

The recorder should be appointed to help document and maintain a record of the team's work. **The timekeeper is charged with** maintaining the timeliness of meetings.

ponsod

The team sponsor is a key leader or clinician who is passionate about the need for improvement. The sponsor reviews and supports the team's work, providing context, guidance, and direction. This individual maintains the overall responsibility, authority, and accountability for the team effort. The sponsor or the Quality Council will select/approve the project, facilitator/coach, team leader, and team members. This includes ensuring that all stakeholders have appropriate input into the project and the team process and outcomes. The sponsor continually monitors the decisions and planned changes of the team and assures that they are in alignment with strategic goals. Ultimately, the sponsor implements changes the team is not authorized to make.

Role of the Healthcare Quality Professional

The healthcare quality professional is predominantly a coordinator of the "team process." He or she is the resource person, a centralized repository for both receipt and dissemination of information about the organization's quality strategy, structure, processes, and outcomes. In team coordination, he or she may oversee multiple teams and activities; orchestrate information flow to the Quality Council, governing body, and organization; and may serve as trainer and/or facilitator for certain teams.

The quality professional may *serve* as a member on certain system-wide strategic initiative teams or on the organization's strategic planning team. There are occasions when the healthcare quality professional is asked to serve as team leader, but these should be rare requests, such as when the organization wide quality strategy is being redesigned and the quality professional is the obvious expert.

!Performance Improvement Team Establishment)

The performance improvement team will follow the performance improvement model selected by the organization, such as the POCA model. Before the team is established, the need for such a team must be recognized. This can occur in several fashions: There can be a request to the Quality Council for a team; a department may join with another department to begin a performance improvement team; or leadership may identify a need for the team. There must be a mechanism identified in the organization as to who has the responsibility for the oversight of performance improvement teams and this

group/department must be aware that a team is being formed. The Quality Council and leadership of the organization should be involved to assist in the determination as to whether the team is truly needed and if there are available resources .

Problem Statement/Charter

Once it has been identified that there is a need for a performance improvement team, a problem or opportunity slalement should be developed. I he problem statement should indicate what the problem is, who has the problem, when the problem occurs, how often it occurs, what causes it and its overall impact. The problem statement should be concise, specific, and measurable and specify what is impacted (Charter, n.d.). The statement should not mention either causes or remedies. However, be cautious that the problem statement is not too simplistic, especially if the team members are aware of the problem. Team members must understand the context and the significance of the issue. The budget should be included in the problem statement, and the total cost will need to be considered throughout the team's progress. There is a need for the team to have an open-minded approach to discover root causes of problems.

Ground Rules

The ground rules are the code of conduct for the team. It is important to set and review the ground rules at the beginning of the first team meeting and then briefly at each subsequent meeting. The team members should establish the ground rules themselves . The ground rules may include: turn off cell phones or put on vibrate; no side bar conversations; everyone's input is equally important; start on time; end on time (or sooner); answer cal!s/pages outside of the meeting room; all membeis should participate; respect everyone's ideas and opinions; it is OK to get up to meet your needs.

\orient/Educate the Teaml

The team needs to be able to work together successfully in order to address the problem statement. In order to accomplish this, a sense of cohesion must be developed. The team must have a sense of openness, where the group members get to know their teammates and understand that each member brings new ideas and diverse viewpoints to the team. The team members must be willing to listen to others and elicit their ideas. Trust and self-disclosure are critical for the team. These elements develop, as every team member is willing to self-disclose and be honest and respectful with other members. Group members must be willing to support one another as they work toward an action plan. A sense of team loyalty and group support will need to be developed as they learn to collaborate with each other (Pearsall & Venkataramani, 2014) (Center for Teaching Excellence, n.d.).

In addition to the orientation of the team members to each other, the team members will require Just-in-Time training regarding the performance improvement tools that they will be utilizing within the team process. There may be members of the team who have never utilized these tools and others who are experienced users. There should be a need assessment completed and the beginning educational

effort undertaken. As each tool is utilized for the first time, more education regarding that tool can take place. There should be an ongoing analysis of the effectiveness of this training with additional training provided as needed (Heathfield, 2017). Twelve tips for building a successful team are listed in Table 36.

Table 36: Tips for Building a Successful Team

Tips for Building a Successful Team	
Tips	**Comments**
Clear Expectations	Leadership communicates its expectations; Team members understand why the team was created; Team members have adequate time, resources of people, money;
Context	Team members understand why they are on this team; Team members understand why teams are utilized to make these improvements; Team members understand how what they are doing on the team affects the organization's goals, principles, vision and values;
Commitment	Team members want to participate on this team; Team members feel the team's efforts are important; Team members commit to accomplishing the teams mission;
Competence	Team members feel they have the appropriate members on the team; Team members feel the members have the knowledge, skill, and capability to accomplish this mission;
Charter	Team has developed their own mission, vision and strategies to accomplish the mission; Team has defined and communicated its goals, anticipates outcomes and contributions, timeliness, and how it will measure the outcomes of the team's efforts;
Control	Team members have the empowerment and freedom to feel ownership to accomplish the mission; Team members understand their boundaries; Limitations (monetary & time resources} are defined at the beginning of the project; Team members hold each other accountable for project timelines, commitments, and results;
Collaboration	Team understands team and group process; Team members understand the stages of group development; Team can approach goal setting, problem solving, and process improvement together;
Communication	Team members understand the priority of tasks;

	Team members communicate clearly and honestly with others; Diverse ideas are brought into discussions;
Creative Innovation	Organization values creative innovation with creative thinking, unique solutions, and new ideas; Organization rewards people who take reasonable risks to make improvements; Organiz;:ition provides training, education, and other such items to stimulate new thinking;
Consequences	Team members feel responsible and accountable for the team's achievements; Rewards and recognition to both the team and individuals are given when teams are successful;
Coordination	Teams are coordinated by a central leadership team (ie: Quality Council} that assists groups with needed resources; Cross-functional and multi-department teams are common and working together effectively; Organization is moving toward a customer-focused process-focused orientation;
Culture Change	Team-based, collaborative, empowering, and enabling culture change; Organization plans to use failures for learning and support of reasonable risks;

Adapted from Heathfield, 2017

tteam Processl

At this point the team will begin the improvement process applying the improvement model utilized within the organization itself (i.e.: PDCA, etc.). An excellent resource to use is The Team Handbook, by Scholtes,Joiner, and Streibel, last published in 2003.

The team should develop a project timeline and determine what the deliverables may be. The role each team member will assume can also be determined at this point. A JGantt chartl may be utilized to plan the project and establish the timeline necessary. This timeline should be reviewed at every meeting to determine if the team is progressing as planned. (See Chapter 4 Health Data Analytics). Although the timeline is developed at the beginning of this process, it can be modified as needed throughout the team process.

If there has not been data collected to indicate the extent of the problem, this must be undertaken first. Once those data are obtained and analyzed,then the team can begin to identify what needs to be done to improve the process and/or outcome .

Choosing approaches to fix a situation can range from extremely simple and perhaps cost-free to very complex and costly. A very effective tool is cause mapping. This tool and others can be found in Chapter 4 Health Data Analytics. The team must keep in mind that interventions need to be specifically chosen to address specific barriers to improvement. The intended target group that will receive or use the intervention must be identified and then the intervention tailored for that group. Having a multidisciplinary team select interventions provides input from a variety of vantage points. Ideally, representatives from the target groups should also be able to provide the performance improvement team with their input on the intervention selection.

Getting a team of people to come to a consensus on a subject or agree to a course of action to take can certainly be challenging. It is possible that the entire group may not be in full agreement on every single aspect of the issue at hand, but at least they are willing to be flexible enough to allow forward momentum and progress with the initiative. Getting to consensus usually takes time and may include clarifying sticking points, re-visiting the purpose and goals of the group, and then moving toward at least some level of agreement. Sometimes it is inching toward the goal of consensus. Other times, the participants can easily move forward. If there are many people involved in the decision-making, it may impede progress. Voting can be accomplished in person, via email with voting buttons attached, or even during conference calls. At times, multi-voting may be necessary to allow the committee members to work through issues inch-by-inch rather than wholesale. Keeping the lines of communication open and maintaining cool heads is important. It is very easy to get frustrated at this stage. Keep moving toward the goals, even if progress is slow . Care must also be taken to prevent strong personalities from dominating the group and manipulating others to agree with their position.

Throughout the team process, the team leader should be communicating with the team Sponsor to assure that the team is processing in a manner acceptable to the organization. The team should never be allowed to get to the action plan phase and have the leadership of the organization determine that their action plan is not feasible to implement.

Once the action plan is formulated and approved for implementation, the team members must determine how to implement it. Sometimes it is best to implement it on a pilot basis and then make improvements before it is rolled out to the entire organization. The team must participate in the monitoring of the project timelines and deliverables to ensure that the implementation is working well. The team should coordinate the processes involves with the education, implementation and then measurement of success of the efforts. The same measurement tools used in the beginning of the team's work should be again utilized to determine if the desired outcome has been achieved. If the desired outcome has not been achieved, the team must repeat the process and implement the revised action plan, then measure again. Once the desired results have been obtained, the team's work is not over. They must determine a way to sustain the results.

In order to sustain the measures, monitors must be put in place to measure if the process/outcomes are performing as desired. Potential measures that can be utilized, depending on the type of improvement project, include but are not limited to: achieving project goals; raising awareness; process change sustainability; enhanced patient safety; achieving benchmarks; leadership support; data trends in the right direction; expanding the pilot into other units/areas; increased patient/staff satisfaction; and a return on investments (ROI). It has to be determined who will conduct the ongoing monitoring and analysis. If the process does not remain where it should be, and the results start to slip back towards old habits, an intervention needs to be initiated as soon as possible to bring the process back into compliance.

!Evaluation of Team Performance!

The simplest way to determine if the performance improvement team was effective is to ask these three basic questions:

1. Did the team reach the goal(s) that were stated in the charter?
2. Did the team follow the performance improvement model?
3. Were individuals responsible in completing their assigned tasks?

If the answers to the questions were affirmative, then the team completed the task that it was charged **to do. !f not, there vvas a process failure somewheie along the way .**

A more in-depth evaluation may be needed to be able to make improvements in how future teams work together. There are numerous team effectiveness evaluation tools that can be found on the internet.

Once such tool, *'Team Effectiveness Evaluation Summary',* was developed by the University of Minnesota in September 2013 . This tool examines the team in terms of the vision, team roles, processes utilized, relationships, external influences, outcomes and team behaviors. It can be found in the website list at the end of this chapter.

A second evaluation tool was developed by MindTools. This tool evaluates the team based on team development, feedback, participation and articulation, managing conflict, group roles and structure, team member development, and understanding and collaboration. The website for MindTools can be found in the website list at the end of this chapter.

[Meeting Management!

The definition of meeting is, "a coming together of two or more people, by chance or arrangement" (Lauby, 2015, p.). Meetings that are productive and well organ ized are well accepted by staff,

whereas meetings that are disorganized and not productive are determined unnecessary. Therefore, it is up to the person holding the meeting to be sure that it is truly needed.

There are only three reasons to hold a meeting. The first reason is to provide information that cannot be easily or effectively conferred by other means. The second reason is to create an opportunity for decisions to be made. These types of meetings are held when decisions need to be made, when information needs to be utilized to accomplish a goal or task. The last reason to hold a meeting is to allow feedback and discussion, such as a focus group, or as a post implementation meeting to determine what worked and what did not (Lauby, 2015).

It can be helpful to classify meetings or agenda items in a meeting by the type of communications involved. This allows participants to have realistic expectations of their role and to be prepared. Table 37 lists three types of meetings/agenda items and examples of each.

Table 37: Meeting and Agenda Items by Type and Examples

Meeting and Agenda Items by Type and Examples	
Type of Meeting / Agenda Item	**Examples**
Information	• Briefings • Explain/present policy • Nonnegotiable issues • Some types of training
Discussion	• Brainstorming • Eliciting decision suggestions/input • Planning • Negotiating
Action	• Planning for results • Group decision making • Problem solving

!Effective Meetings!

Meelings are more than just showing up at .:i ccrt.:iin time and sitting in a room until it is c:ompleted. The leader's job is to be certain of the need for the meeting, conveying the need to the participants and conducting the meeting in an organized and productive manner. However, no matter how well the meeting planning is done, if the members in the meeting are not willing to participate, the meeting will not be successful. Therefore, the meeting leader must have a set of skills that can be effective in keeping participants engaged and also keeps the meeting moving through the agenda in a timely manner.

Preparing agendas, committee/meeting reports, and minutes should be more than just busy work. They are the communication tools that need to be utilized effectively to communicate to the members of the meeting and to others. They are documents that capture the work being done, and lay out the framework for what comes next. They are the documentation that certain topics were discussed and decisions were made. They are necessary for oversight agencies and others to examine to determine if items were discussed as required and to determine where the group is in accomplishing their goals and charter . Paying careful attention to the details in these documents is important.

The literature defines many essential steps to having an effective meeting. Neal Hartman (2014) describes seven steps to an effective meeting.

- The first is that there must be a clear objective for the meeting. Standing meetings without a clear reason for each meeting are not a good use of the participant's time.
- The second step is to consider who is invited to the meeting. It should be determined who really needs to be at the meeting. The attendees should be determined based on the need for the meeting and what the specific goals to be accomplished.
- The third rule is to stick to the agenda . The agenda should include the amount of time allotted to each specific item. All participants should have a copy of the agenda.
- The fourth step is to keep the meeting moving. Do not allow one individual to monopolize the conversation.
- The fifth step is to start on time and end on time. Do not delay the start if not all attendees are there. Do not conduct the meeting for longer than 60 minutes if, at all possible.
- The sixth step is to 'ban technology'. Do not allow attendees to use their phone or computers unless it is directly involved with the information in the meeting. One source suggests treating the technology issue as only allowing its use as if the participants were 100 miles away from the facility .
- The seventh step that the leader must follow-up. It is important to send out the minutes or the highlights of the meeting to all who attended and others that need to have the information, including any team members who were not present, within 24 hours of the meeting. Document the responsibilities and tasks assigned, as well as the deadlines.

!Before the Meeting!

Assure that everyone who is to attend the meeting is aware of the time and place. Ask attendees to let you know ahead of time if they are not going to be able to attend the meeting. When you send them the reminder notice about the meeting, include the agenda so that they are also reminded about what

they are to bring or discuss at the meeting. This allows attendees to be prepared for the meeting so that they can be actively engaged.

When preparing the agenda, the chair of the meeting should be notified as to what is on the agenda and determine if the chair wishes to add or clarify any items. Also, assure that those individuals responsible for presenting items are prepared to present them. The flow of the agenda will differ depending on the type of meeting. If there has been a previous meeting, then the first item on the agenda should be the approval of the minutes from the last meeting. Corrections, additional items or deleted items can be clarified prior to the approval. Putting the most important items at the beginning of the agenda assures that they will be addressed in the meeting. Should the meeting run overtime and the important items are left till the end, then they may not be effectively a ddressed. G'-:nerally, old business is discussed before the new business, but sometimes this can lead the participants into the discussion of some new business. The leader should not let this happen, and should bring the discussion back to the current item and the agenda . As mentioned previously, there should be time limits for each item on the agenda. This will help keep the meeting on track. An additional annotation on the agenda could be an indication, if the item is for information only for discussion or if a decision is needed.

!During the Meeting!

Begin the meeting on time even if individuals are not there yet. Assure that the attendees all have a copy of the agenda or that it is posted so that they can all see it. If you have a quorum, you can start with the approval of the previous meetings minutes. If there is not a quorum, then start with an item on the agenda that requires discussion and then move back to the top of the agenda when a quorum is present. Begin the meeting by stating the purpose, sharing what the goals are, and then review the agenda. Clarify your role in the meeting as the leader.

If this is the first meeting of the group, ground rules should be established . Four ground rules should always be followed, with the addition of others deemed as appropriate. The four ground rules are a must and apply to all attendees. They are: (1) participate, (2) focus, (3) maintain momentum, and (4) reach closure. A ground rule about confidentiality may also be appropriate . The ground rules should be posted at all times during the meeting.

As you move through the agenda items, keep the momentum and keep to the established timeline in the agenda. If the conversation is wandering off the topic, bring it back by announcing to the group that they need to get back on topic. If there are sidebar conversations, ask those in the conversation if they would like to share what they were discussing with the group. If the planned time on the agenda is not sufficient to close a topic, ask the group what they wish to do. It may result in some out of meeting work on the topic that can be carried over to the next meeting.

Many resources suggest that at the end of every meeting, the agenda should include a 5 to 10minute period for feedback to evaluate the meeting. Other resources suggest obtaining the feedback after the first meeting and after every so many meetings as established by the organization. Of course, the feedback can also be conducted throughout the meeting,if so desired.

Always end the meeting on time and if possible, on a positive note. The leader should review the actions taken and the assignments and set the time for the next meeting. This again reminds all attending of their responsibilities between meetings so that the next meeting can run smoothly.

Meeting Minutes & Documentation

Following the meeting,the best practice is to send the attending members, and others as appropriate, a summary of the meeting or the meeting's minutes within 24 hours. In reality, a more manageable time frame for the minutes would be within a week. Dispensing the minutes in a timely fashion ensures shaper memory and greater accuracy.

The minutes should stand by themselves. Whenever someone asks you for a copy of the minutes, they are given only the minutes and not all the attachments. Therefore, if the minutes are vague, the reader cannot tell what really happened. The golden rule to follow when writing minutes is to "close the loop". If the reader can read the minute sections and then say to themselves "and?", then the loop has not been closed. The minutes may state that something was discussed - And? What was the discussion about and what was the result of the discussion? If the minutes state that the item was presented, the remaining question is and what happened? Every item should have a short statement that ties up the loose ends. There does not have to be a detailed discussion about what happened but it should be clear what did happen. Table 38 lists some examples of inappropriate and appropriate phrases for the minutes.

At the time the minutes are completed, items that need follow up should be added to the agenda for the next meeting. The agenda outlines for each meeting can be developed for the entire year. When an item needs to appear on a certain meeting agenda, it can be placed there when the minutes of a meeting are written. For example, if it is determined at a meeting that there needs to be follow-up of a report from a PI team at the next meeting, (see Table 38), then the item is placed on the next agenda when the minutes of this meeting are produced. If this meeting was held in July and the item needs to be discussed in a meeting 3 months away (October), then it can be placed on the October agenda when the July minutes are written. This helps to prevent items being dropped from the agenda due to someone forgetting to include it. Accreditation surveyors often follow the items in agendas/minutes through to the resolution of the item. If something is not in the minutes when it should be, it raises questions that would not need to be raised if this technique is used.

Table 38: Examples of Closing the Loop in Minutes

Examples of Closing the Loop in Minutes		
Agenda Item	**Inappropriate Minutes**	**Appropriate Minutes**
Quality Dashboard	Quality dashboard was presented. See attached.	Quality dashboard was presented. See attached. There was no discussion concerning the dashboard. **OR** The quality dashboard was presented. See attached. Discussion concerning the fall rate being above the benchmark. Continue to monitor and discuss again at the October meeting.
PI Team – Turnaround OR Time	The team presented their report – see attached. They are working on the process.	The team reported that they have implemented their interventions and are now collecting data to determine the effectiveness. Will report on progress at the next meeting.
PI Team – Patient Flow	The team presented their report and the results of the implementation. See attached.	The team presented their report and the results of the implementation. See attached. The result shows that the time from the admission order to bed assignment was reduced from over an hour to less than 30 minutes. The team is commended for all their hard work.
Infection Prevention Committee Minutes	The infection prevention rates were presented – see attached.	The minutes were presented from the last meeting. Important issues include infection rates in the ICU, MRSA outbreak, and flu immunization progress. The Infection Prevention Committee has developed an action plan for reducing the infection rates and handling the MRSA outbreak . Further reports will be presented at the next committee meeting and at this meeting.

THE PRACTITIONER APPRAISAL PROCESS

The medical staff bylaws, rules, and regulations establish a framework for medical/professional staff activities and accountability and are subject to governing body approval. They relate to all licensed independent practitioners with clinical privileges in the care of inpatients, emergency care patients, and patients in home care, ambulatory care, and long-term care. Membership on the medical staff requires an application process, including credentialing, privileging, and appointment.

The credentialing and privileging processes are extremely important in that there are legally required processes that protect the patient, physician and the organization. The credentialing and privileging processes are utilized in healthcare to assure that licensed professional practitioners have the credentials required for the position and the ability to perform the tasks or privileges required. The credentialing and privileging processes will be described in an overview in this section, however, if you have a position such as a Medical Staff Coordinator, then you will need to explore other avenues to obtain the knowledge necessary to function in that position. In addition, if you would like to learn more about what happens when credentialing is not done correctly, purchase the book Blind Eye, by James B. Stewart. This nonfiction book is about Michael Swango who was allowed to practice without a medical license, and the patients who suffered the consequences. Michael Swango is an American serial killer and a former physician. It is estimated that Swango has been involved in as many as 60 fatal poisonings of patients and colleagues, though he only admitted to causing four deaths (Montaldo, 2017). He was sentenced in 2000 to three consecutive life terms without the possibility of parole, and is serving that sentence at the ADX Florence supermax prison near Florence, Colorado.

All of the processes described in this section pertain to the physician and other Licensed Independent Practitioners (LIP) including allied health practitioners who are credentialed and privileged through the medical staff. This includes dentists, podiatrists, psychologists, chiropractors, advanced practice nurses, CRNAs, nurse practitioners, midwives, physician assistants, mental health providers, and other such specialties. Some accreditation organizations such as The Joint Commission may allow an equivalent process to the medical staff credentialing and privileging processes for the allied health professionals, but the processes have the same principles as will be discussed here.

The extent to which the credentialing and privileging processes are carried out will also vary with the type of healthcare facility where the practitioner applies to practice. For example, in home health, there is no credentialing or privileging done except for the verification of the physician's license in the state where the patient resides. Managed care organizations only credential the practitioners and do not award any privileges since these practitioners do not care for patients at the managed care offices. The practitioners will be credentialed and receive privileges at the locations where they see patients. At the other end of the spectrum, the hospital credentialing and privileging processes are very specific and complex.

Appointment/Reappointment

Medical Staff Membership

The medical/professional staff includes fully licensed physicians (doctors of medicine and osteopathy) and may include other licensed individuals permitted by law and the organization to provide independent patient care services (e.g., psychologists, podiatrists, dentists). Healthcare organizations and their medical staffs make the determ ination regarding what types of licensed independent professional practitioners will be allowed to practice at a specific organization . This decision must be defined in writing and applied equally to all applicants . Certain types of facilities do not require the services of certain types of practitioners. For example, if the organization does not deliver babies, there will be no need for neonatal practitioners at that organization. An ambulatory surgery center would not require an intensivist to be on staff. Some hospitals will employ midwives to help deliver vaginal births, but other facilities may determine not to use midwives. Some organizations determine that they will utilize groups of specific practitioners, and if a practitioner in that specialty, such as Anesthesia, is not a member of that specific anesthesia group practice, the application for that practitioner will not be accepted .

Process Leading to Appointment

Applicants begin by submitting an application for appointment. The application itself may be created by the state, the organization, or other sources as defined by law within that state. Applicants supply requested information, consent to the inspection of pertinent records and documents, agree to be bound by the bylaws, rules and regulations, and request specific clinical privileges.

Once credentialing is completed and specific clinical privileges are granted, the appropriate department recommends appointment to the Medical Executive Committee, which then sends their recommendation to the governing body. The appointment requires approval of the governing body or a designated committee of the governing body.

Initial Appointment

The full appointment period is determined by the bylaws, but cannot exceed three years in managed care organizations or two years in other organizations such as those accredited by The Joint Commission. At the time of appointment, the practitioner is awarded a specific category of membership depending on the categories listed in the medical staff bylaws. Each organizalion and medical/professional staff determines the number and type of categories available and specifies the privileges associated w ith each category. Table 39 demonstrates categories of the medical staff that are common ly utilized. Allied Health professionals are not appointed into any of the categor ies listed in Table 39 . For a new privilege, a practitioner undergoes a focused professional practice evaluation based on the guidelines set by the medical staff. The Focused Professional Practice Evaluation will be addressed later in this chapter.

Table 39: Categories of Medical Staff Membership

Categories of Medical Staff Membership	
Category	**Definition**
Active	Members providing most of the medical services and performing most of the administrative functions of the medical staff. Criteria for Active staff status vary, but usually the member must admit at least a specified number of pi:lticnts annually, may vote, hold office, and serve on committees.
Courtesy	Members whose practice at the institution is limited but who have the privilege to admit on an occasional basis (defined in the medical staff bylaws). Sometimes members choose Courtesy status to avoid the Active staff requirements to serve on committees, etc., relinquishing prerogatives to vote and hold office.
Consulting	Members who serve as consultants to other admitting physicians and are not members in any other staff category. They do not vote or hold office.
Affiliate	Members who do not actively practice at the institution (perhaps due to the use of hospitalists) but are important resource individuals for medical staff quality management/improvement activities. They may serve on *ad hoc* committees or provide peer review, but do not vote or hold office.
Community	Members who do not practice in the facility, but who want/need affiliation with the facility. They do not vote or hold office.
Honorary/retired	Members who rarely practice at the facility, but who are well respected by their peers and are so honored or formerly Active members who have retired. They do not vote or hold office.

Re!appointment

Reappointment includes reappraisal of the activity of the practitioner over the time period from last appointment, including both credentialing and privileging. Reappointment is granted for the time period specified in the bylaws or policies/procedures, but never for longer than two years for acute care hospitals and other healthcare organizations. The time period is three years for a managed care organization.

Re-credentialing consists of submission of an application as previously occurred during the initial credentialing, and updating the information concerning current activity, licensure and certifications/registrations, liabilities/claims leading to judgments against the practitioner, and malpractice insurance coverage. All information that was reviewed at the time of appointment, except

information that does not expire, such as education achieved, must be re-verified at the time of reappointment. In addition, if any new credentials, education, or other information has been obtained since the last appointment, it must also be verified at this time.

Re-privileging consists of a review of the current competency, quality management activities, and peer review activities of the practitioner. It also includes a review of other reasonable indicators of continuing qualifications, peer and departmental recommendations, review and renewal of specific clinical privileges, and compliance with continuing medical education requirements. Some organizations also review attendance at medical/professional staff, department, and assigned committee and team meetings. Again, following the re-credentialing and re-privileging processes, the information is sent to the appropriate department who recommends reappointment to the Medical Executive Committee, which then sends their recommendation to the governing body. Reappointment requires approval of the governing body or a designated committee of the governing body.

Credentialing of Licensed Independent Practitioners

Credentialing and privileging are two distinctly different processes. The credentialing process occurs before the privileging process is begun. A ***Licensed Independent Practitioner*** (LIP) is any individual who is professionally licensed by the state (U.S.) and permitted by the organization to provide patient care services without direction or supervision, within the scope of that license. Medical doctors (MDs), doctors of osteopathy (DOs), dentists (DDSs), podiatrists (DPMs), and doctors of chiropractic (DCs) are LIPs in all U.S. states. Certain Allied Health Professionals are also Licensed Independent Practitioners who are credentialed in a manner the same as the medical staff LIPs or through an equivalent process if allowed by the accrediting organization utilized by the facility .

Credentialing is the verification of the practitioner's right and competency to provide patient care in the appropriate setting. The credentialing and re-credentialing process involves verification of compliance with pre-determined standards and criteria concerning:

- Current, valid (state in U.S.) license to practice
- Drug Enforcement Agency (DEA) registration or Controlled Dangerous Substances (CDS) certification
- Relevant training and education
- Current competence
- Board certification, if so stated
- Work history
- History of loss of license and felony conviction; history of loss or limitation of privileges or disciplinary actions; challenges to, or voluntary and involuntary relinquishment of, licensure or registration

- Voluntary and involuntary limitation, reduction, or loss of clinical privileges or termination of membership
- Professional liability claims history resulting in settlements or judgments paid; evidence of unusual pattern or excessive number of professional liability actions resulting in final judgment against the applicant
- Current malpractice insurance coverage
- Evidence of physical ability to perform the requested privilege (or) inability to perform essential functions of the position

These and other items may be different for certain types of organizations and their accrediting bodies. The accrediting body's standards should be reviewed to determine exactly what is required by the accrediting organization your facility utilizes. There must be a written process that is followed during the credentialing process, which describes the actions that the facility must undertake to credential an individual practitioner. The credentialing information obtained must be maintained in a confidential manner to assure that the files are only available to authorized individuals. However, the credential files are considered discoverable in a court of law.

!Primary source verification! is required at the time of initial credentialing and re-credentialing for all elements required by the state or the applicable accreditation organization. This means that direct contacts must be made with licensing states, certifying agencies, educational institutions, insurance carriers, state medical boards, and perhaps other institutions where the practitioner has privileges. Copies of these documents are not allowed to be accepted as verification since these copies could be digitally altered. However, there are some, nationally recognized organizations (Table 40) that have been identified as "primary source" which means that they are designated equivalent sources in verifying specific items during the credentialing process: Utilizing these organizations eliminates unnecessary time and money being spent on this process.

Centralized credentialing is another attempt to refine this verification process to streamline the demands on practitioners to complete multiple applications, credentialing and privileging processes, and perhaps medical staff appointments. If a practitioner is practicing at several sites within a healthcare system, the practitioner would have to be reappointed at each facility, but it may not occur at the same time throughout the organization . This would necessitate the practitioner completing multiple re-appointment applications and each facility having to absorb the costs of each reappointment credentialing. By utilizing a centralized credentialing process, healthcare organizations have one center that completes all the credentialing verification for a given practitioner at one time for all facilities within the system. The practitioner has one reappointment date, which is the same throughout the organization. The essence of the system is one credentialing (and perhaps appointment) application and one-time primary source verification for all providers, and then one reapplication and information collection process, including profiling for current competency for re-

credentialing and perhaps reappointment. A secure-access Intranet site is utilized for systems seeking to centralize the application and credentialing processes.

Instead of organizations performing this centralized credentialing themselves, many organizations delegate the credentialing/re-credentialing function to credentials verification organizations (CVOs). CVOs are accredited themselves by accreditation organizations, so they must meet identified standards. The contracting organization however must provide sufficient oversight of the CVO and process to ensure accuracy, timeliness, and completeness.

Table 40: Nationally Recognized Primary Source Organizations for Medical Staff Credentialing

Nationally Recognized Primary Source Organizations for Medical Staff Credentialing
• American Medical Association (AMA) Physician Masterfile-primary source; {medical school and residency completion plus additional profile information)
• American Osteopathic Association (AOA) Physician Database (pre-doctoral education); AOA Council on Postdoctoral Training; Osteopathic Specialty Board Certification-primary sources
• American Board of Medical Specialties (ABMS)-primary source (board certifications)
• Educational Commission for Foreign Medical Graduates (ECFMG)-primary source
• Federation of State Medical Boards (FSMB) Disciplinary Data Bank-primary source (actions against a physician's medical license)

Credentialing in Managed Care Settings

There are multiple accreditation agencies that accredit managed care organizations, but they basically have the same types of credentialing requirements. The credentialing function may be performed by the health plan or may be delegated to participating medical groups and independent practice associations (IPAs). At the health plan level, if not delegated to a CVO, the credentialing function may be housed in the quality management department, case management department, provider services, or contracting department . Managed care credentialing standards requires that a physician be directly responsible for the credentialing function and that a designated committee, generally called the Credentialing Committee, make recommendations regarding credentialing decisions, using a peer review process.

Managed care credentialing standards apply to licensed independent practitioners with whom the Managed Care Organization (MCO) contracts or whom it employs who treat members outside the inpatient setting and who fall within its scope of authority and action. Certain hospital-based physicians with independent contracts to treat MCO members (e.g., anesthesiologists providing pain management) must also be credentialed. In behavioral health, in addition to physicians, those who must be credentialed include all practitioners who are licensed, certified, or registered by the state to

practice independently. Managed care organizations do not award privileges to its practitioner members, since no actual patient care is provided at the managed care organization . Privileges are only awarded at the facility where the practitioner practices.

Privileging of Licensed Independent Practitioners

Once the applicant's credentialing process is completed, it is time to move into the privileging process. Once the centralized credentialing office or CVO has completed the credentialing, the application and file are returned to the specific facility where the applicant wants to practice. While the credentialing process can be outsourced from the facility, each individual facility must award privileges to the practitioner for use in that facility. This process must always be setting-specific, based on services available, so it has to be accomplished at each provider site. If the facility does not perform a specific procedure, does not have patients with certain diagnoses, or does not have the staff or equipment to perform a procedure, the practitioner may not receive privileges for that procedure or to treat that group of patients.

"Privileging" is granting permission to provide specific medical or other patient care services in the organization, within well-defined limits, based on the individual's professional license and his or her experience, scope of practice, competence, ability, and judgment and on the organization 's ability to provide and support the service. The granting/renewing of clinical privileges (and basic credentialing) is performed regardless of medical/professional staff membership status, if applicable.

Delineation of Privileges

Clinical privileges are granted individually, based on criteria established by the organization, usually using privilege lists or groupings that are specific to each department, section, service, or specialty. The criteria are established by the medical staff to determine the level of competency appropriate for each privilege, e.g., the number of procedures that must be performed every reappointment cycle for the practitioner to be considered currently competent and to retain the privileges. Core privileges focus on a criteria-based core set of basic privileges that a practitioner within a certain specialty should be able to perform competently based on the education, residency, and internship received. Any privilege beyond those basic privileges must be individually selected and the practitioner must show competency in order to receive those privileges. Any licensed independent practitioner given the privilege to admit patients must be a member of the medical staff .

Privileges are granted for the time period specified in the bylaws or policies and procedures, but for no more than three or two years as defined by the accrediting organization. Upon initial application, the information concerning the competency of the practitioner is obtained through the credentialing process review of education, malpractice findings, reference checks, and other such information. During the periodic reappraisal process set by the organization, the privileges must be re-requested

and be renewed, revised, a dded, or deleted, based on information from the practitioner's practice patterns and review for the reappointment period.

A practitioner may also apply for a new privilege at any time during the reappointment cycle. However, when this occurs, the practitioner must demonstrate the competencies required for that privilege. For example, when bariatric surgery first became accepted surgery, the practitioner who requested this privilege had to meet the criteria established by the medical staff. This frequently required a set number of didactic trainings and a set number of proctored procedures to demonstrate the competency. The practitioner would then reapply for this privilege at the time of reappointment, even if the time period is less than a full reappointment cycle.

Advanced practice practitioners may be awarded clinical privileges as defined by the medical staff bylaws, yet they are not members of the medical staff. Many times, allied health practitioners have standing guidelines that define their scope of practice rather than clinical privileges. It is very important that each facility utilizing advanced practice allied health practitioners understand the scope of practice that is permitted by the state licensing organization and the resulting clinical privileges awarded by the facility . The facility does not have to allow the practitioner to receive privileges for all that the state organization has within their scope of practice, however the facility may not award privileges that are beyond that scope of practice. These individuals often have medical staff sponsors who are responsible for the standard of care provided by these individuals.

There may also be primary care community physicians who are members of the medical staff but who do not have any privileges, and do not admit or care for patients in that setting. These practitioners may order outpatient tests and services even though they do not have hospital privileges. In fact, any medical practitioner can order outpatient tests and procedures even if not a member of the medical staff if they meet the following CMS §482.54 Condition of Participation requirements:

- Practitioner is licensed in the state where the patient receives the care (including Home Health Services)
- Practitioner is acting w ithin his/her scope of care
- Practitioner is acting in accordance with state law and polices of the medical staff to order such outpatient tests or care
- Practitioner is responsible for the care of the patient as an outpatient

Practitioner Continuing Education (CE) is required by most states for renewal of the professional license. Many accreditation organizations also require continuing education for renewal of clinical privileges. There is a move within the healthcare industry to require that the continuing education be in the areas of the requested privileges, but this is not required in most cases.

Special Privilege Statuses

The majority of the time privileges are awarded for the three or two year period, or until the next reappointment time. However, there are two exceptions to this rule, and these are based on the clinical needs of the facility.

Temporary Privileges

Temporary privileges are awarded to practitioners in only two circumstances. Both types of temporary privileges may only be awarded for a period of up to a total of 120 days. If the practitioner is needed for a longer period of time, the practitioner must apply for membership in the medical staff of the facility. The length of time that a practitioner can provide patient care under temporary privileges should be closely monitored, as should the care provided.

The first type of temporary privileges is those given to a locum tenens practitioner. Locum tenens privileges are given to a practitioner who will be working at the facility to either meet an identified clinical need or to replace a practitioner who will be absent from the facility for a period of time. For example, if an anesthesiologist takes a 30 day vacation, the facility will need to find a temporary physician to fill in for the practitioner so that the number of surgeries can continue in the facility's anesthesiologist's absence. The locum tenens anesthesiologist will stop practicing there when the staff anesthesiologist returns. A separate example would be if a hospital does not have a neurologist on staff, but a patient with a clinical need for a neurologist is admitted, then a locum tenens neurologist is brought on staff. The neurologist would stop practicing at that facility when that specific patient no longer requires the neurologist's care. Both of these types of locum tenens practitioners would have to go through credentialing and privileging process, but in an abbreviated format as defined in the medical staff bylaws that provides a minimum amount of verified information and with the approval of the hospital CEO and the Medical Staff president or designee.

The second type of temporary privileges are awarded to applicants to the medical staff who have been through the credentialing and privileging processes and who are needed or wish to practice in that facility prior to the completion of the approval process. The application must have no red flags, or indications that there may be a question about any of the content in the application. Red flags could include gaps on a physician's resume, resignations from healthcare facilities, multiple reports to the National Practitioner Data Bank (NPDB), a high number of malpractice suits, or insurance reduction in coverage over a period of time, and resignations for reasons other than relocation, illness, and/or retirement. Red flags also include withdrawals of applications for joining a medical staff, and receiving weak or minimal inquiries from other hospitals with very limited information. The application must be reviewed per medical staff bylaws for the temporary privileges.

Emergency & Disaster Privileges

Emergency privileges are awarded during an emergency to existing members of the medical staff that allow them to perform tasks outside of their delineated privileges to save a patient's life, limb or organ. When a practitioner with the appropriate privileges arrives, the emergency privileges are relinquished by the first practitioner.

In a **disaster,** any volunteer independent licensed practitioner who has a picture identification badge demonstrating membership in a hospital medical staff, and/or membership on one or more disaster management teams, or other specific organizations, may be allowed to practice at a healthcare facility during the disaster. Any volunteer practitioner is permitted to do everything possible to save a life or protect a patient from further or serious harm within the scope of his/her license, regardless of membership status, credentialing status, or approval of specific privileges. Once the disaster has been declared as being over, or if a practitioner on the medical staff of the facility arrives to take over, then the volunteer practitioner must relinquish those privileges. The facility should make every attempt to verify at a minimum the license, and must provide oversight of the care provided by the practitioner. Specific requirements for the Emergency and Disaster privileges can be found in the standards of the accreditation agency utilized by the facility.

!Evaluation of the Practice of Licensed Independent Practitioners!

The evaluation of Licensed Independent Practitioners is an ongoing process that begins when the first privileges are delineated and continues until the individual no longer practices at the facility. There are multiple means that are utilized to accomplish this ongoing evaluation. Not all types of organizations utilize all these methods discussed here, but each could be applicable to multiple healthcare settings.

!Practitioner Profilin

At the time of reappointment, these data from the various methods of evaluation to be discussed here are utilized to provide information to assist the Medical Executive Committee in the determination of the privileges to be renewed, discontinued, and so forth with each practitioner.

At the time of reappointment, a practitioner profile should be developed that summarizes the practitioner's practice during the reappointment cycle. Profiles are practitioner-specific data and information summaries are used in the reappraisal process, usually in conjunction with re-credentialing and re-privileging activities. All independent practitioners and other practitioners with delineated clinical privileges, whether or not they are medical staff members, are profiled, and based on an ongoing measurement process. Department chairs, section chairs, medical/clinical directors, or chief medical officers, depending on the setting and structure, must review the profile data for both positive findings and any areas of concern.

Practitioner profiles offer the opportunity to summarize all measurement and assessment activities for each privileged practitioner and should be compared to aggregate information when applicable . Practitioner profiles represent a "closing of the loop" for performance monitoring and analysis, helping to effectively communicate appropriate findings to those leaders who need to know.

This profile should be constructed utilizing the information from the Ongoing Professional Practice Evaluation (OPPE), the Focused Professional Practice Evaluation (FPPE), the peer review that has been completed, and other such indicators monitored by the facility and the practitioner departments and groups. Ideally, profiling should be as concurrent as possible, with review, analysis, and reporting at least quarterly, to identify better practices, as well as permit appropriate intervention in quality of care and patient safety issues.

In tracking the "WHO" of care as well as the "WHAT" and "HOW," we owe it to our practitioners to document current competency and care well done-the positive outcomes of the measurement and analysis activities-and "best practices", along with any significant, confirmed negative variations.

The content in the practitioner profile will differ by the type of practitioner and the type of facility that is completing the re-credentialing/re-privileging process. Table 41 lists the types of elements that could be included within the practitioner profile.

Practitioner profiles must be maintained in a strictly confidential environment, electronic or hard copy. The Practitioner profile and other practitioner practice information should **NOT** be kept in the Credentials file. The credentials file is discoverable, while the performance improvement information is protected from discovery in most cases. The Quality file, which should include the practitioner profile, cannot be kept in a separate file immediately behind the credentials file as it is then considered part of the credentials file. It should at a minimum, be kept in a different locked file drawer, or better yet in a different locked file cabinet, or even better in another room. If the file is kept electronically, it must be password protected. The Quality information should be released only in accordance with bylaws, rules and regulations, and/or policy, to authorized individuals or committees, within the limits of the law.

The practitioner profile should be reviewed and signed off by, Medical directors and/or peer review committee chairs in managed care organizations/health plans or networks and by Department chairs, at the time of reappraisal for reappointment to the medical staff and re-privileging in hospitals; or by the Chairperson of the Interdisciplinary Practice Committee, which may be responsible for recommending to the governing body privileges for allied health professionals.

Table 41: Potential Items for a Practitioner Profile

Potential Items for a Practitioner Profile
Findings from all applicable department-specific and organization-wide required measurement processes

Aggregate Peer review findings
Monitoring of clinical processes, e.g., mortality review findings; complications and other peer-reviewed events with ratings below standard of care; performance on core measures compared to aggregate
Monitoring of clinical outcomes
Use of operative and other procedures placing patients at risk, e.g., unplanned return to operating room
Use of medications
Use of blood and blood products, e.g., usage not meeting criteria after peer review (inpatient and outpatient)
Significant infection surveillance findings, e.g., total inpatients w/verified clean wound infections; total verified inpatient healthcare-associated infections
Utilization management findings, e.g., readmissions related to previous hospitalization w/in 30 days; total inpatient stays and average length of stay (ALOS); separate total inpatient and outpatient procedures
Information concerning patient care activity in the organization, e.g., numbers of patients admitted or treated, numbers and types of procedures performed
Outpatient activity, e.g., unscheduled inpatient admissions due to adverse outcome from outpatient procedure
Pharmacy and therapeutics function
Patient safety findings, including adverse events, root cause analyses
Risk management findings
Medical record review
Pertinent findings/successes resulting from QI Team activities
Pertinent findings from external review, including the Quality Improvement Organization (QIO), State Department of Health, private review and case management companies, and managed care organizations/health plans
Information concerning fulfillment of administrative responsibilities, e.g., meeting attendance, committee membership, QI team participation, productivity, etc.
Other items identified by the medical staff in the facility/organization/medical group

longoing Professional Practice Evaluation (OPPE)i

Ongoing Professional Practice Evaluation (OPPE) is the ongoing measurement and analysis of each practitioner's performance relative to existing privileges, including licensed independent practitioners and others with clinical privileges granted by the organization. All practitioners require that OPPE be done, not just those with performance issues. OPPE was first required by only The Joint Commission (TJC), but is now also required by the Healthcare Facilities Accreditation Program (HFAP) accreditation standards. However, any number of types of healthcare organizations can undertake programs such as

OPPE with the licensed independent professional practitioners. The specifics of each accreditation program's OPPE standards should be reviewed when establishing or modifying the OPPE process.

The purpose of OPPE is to provide an ongoing evaluation of the practitioner's performance to assist the practitioner in making improvements in his/her practice and patient safety. Conceptually it is similar to the report cards that students receive throughout the year. Elementary and secondary students receive a report card every six weeks . The parents then encourage the students to mnke improvements before the next report card is issued. In OPPE, it is designed for the practitioner to identify his/her weak spots and then undertake efforts to improve those areas of care and performance. The Joint Commission and HFAP expectations are that hospitals use data to evaluate practitioners and, if necessary, intervene if there are issues that impact the provision of safe patient care. This intervention could include additional focused review, proctoring for a period of time, up to limiting or revoking existing privileges for that practitioner (OPPE, 2017).

The OPPE reports must be completed more than once a year. The TJC considers once a year to be a periodic evaluation rather than an ongoing evaluation. Therefore, to meet the intent of the standards, the OPPE reports should be completed no less than every nine months, leading to at least three reports every two years. However, the Joint Commission's Frequently Asked Questions for OPPE caution about not having the third OPPE completed before the reappointment is conducted. TJC suggests that three, six, or eight months should be the time periods to be considered when establishing or modifying this prog;am (OPPE-FAQ, 2017). In order to accompiish this, many organizations have determined to spread the different department OPPE reports throughout the rotating cycle, due to the number of medical staff, advanced practice professionals and the others that must be evaluated throughout the facility.

The medical staff defines the exact processes to be utilized at that facility to meet the OPPE standards. Each department and specialty determines the type of data to be collected. Each specialty must have objective measureable measures that relate to the practice and privileges of that specialty. There may also then be objective measureable indicators that can be utilized by other specialties within the facility. For example, the Gastroenterologists who perform moderate sedation may want to identify an indicator regarding the use of reversal agents. They may also determine an indicator to look at the length of stay of a certain type of patient population. The indicator data may be obtained by direct observation, periodic chart review, monitoring practice patterns, or by discussions with other caregivers.

The information obtained from the OPPE process should then be integrated into performance improvement activities, including educational efforts for the entire department or specialty. The department chair should review the information from all members of the department/specialty and can then identify areas of needed improvement or education for the entire department or specialty. The department chair may be able to identify a specific practitioner(s) who is/are providing the best

care and can then utilize that person(s) to help educate others within the department/specialty. The information in the OPPE report must also be reviewed with each individual practitioner to assist that practitioner in making improvements to his/her care.

At the time of reappointment, the information from the ongoing professional practice evaluation should be included in the reappointment process. This can be accomplished through the practitioner profile and/or by including the OPPE reports in the reappointment file. After the reappointment process is completed, the information MUST return to the quality file and be kept separate from the credentialing file, as previously discussed.

!Focused Professional Practice Evaluation (FPPE)[

Focused Professional Practice Evaluation (FPPE) is a privilege-specific, time-limited process to validate practitioner competency when there is no current performance documentation for the requested privilege(s) at the organization, or when concerns arise about a practitioner's ability to provide safe, high quality patient care. FPPE was first required by only The Joint Commission (TJC), but is now also required by the Healthcare Facilities Accreditation Program (HFAP) accreditation standards. However, any number of types of healthcare organizations can undertake programs such as FPPE with the licensed independent professional practitioners. The specifics of each accreditation program's FPPE standards should be reviewed when establishing or modifying the FPPE process.

The FPPE process must be defined before it is utilized in an organization to be sure that it is applied evenly across the organization. There are four components that must be utilized when developing this process: Criteria for conducting performance evaluations; method for establishing the monitoring plan specific to the requested privilege(s); method to determine the duration of performance monitoring; and circumstances under which monitoring by an external source is required (FPPE-FAQ, 2017). When conducting the FPPE, only activities performed at that organization may be utilized to evaluate the practitioners' ability to perform a specific privilege. The process must include when external peer review may be required, and how that will be accomplished . More information about this portion of the FPPE process will be discussed below in the Peer review section.

There are two related parts to the FPPE process. The first part is directly related to the privileges requested by a practitioner . It applies to both new applicants and to existing practitioners who request a new privilege. When a new privilege is requested, the practitioner must demonstrate competency regarding the performance of that privilege (FPPE -FAQ, 2017). There is no exception for practitioners who are board certified, or have documented experience or reputation. There could be a tiered approach utilized. The type and length of the review can be different due to different privileges, the type of the practitioner, and experience of the practitioner. For example, if a resident performs his/her residence at a certain facility and then applies for membership to that facil ity, the time period for the focused review of the privileges delineaed many be different from a resident who performed his/her residency elsewhere but then determine to apply for membership at this facility.

The second part of FPPE addresses what has been previously called Peer Review. The standards require medical staff to develop criteria to be utilized to determine if practitioner performance issues can be identified that may affect the provision of safe care (FPPE-FAQ, 2017). This part of FPPE states that the medical staff should develop triggers that indicate a need for performance monitoring of a practitioner's care for the provision of safe, and quality patient care. These triggers can be either a single incident or patterns or trends that are identified. Triggers include sentinel events, complaints, undesired patterns or trends, or other obvious events. The OPPE results m;:iy ;:ilso indicate a need for a more focused review of a practitioner's practice. Incident reports may also lead to the need for FPPE of a practitioner's practice.

!Peer Review\

Peer review is intensive, in-depth review involving either an individual practitioner or patient or group of identifiable patients. It may result from the findings of ongoing performance measure data collection and initial analysis, utilization review, infection surveillance activities, occurrence or event reporting, a sentinel event, team QI/PI activities, and/or data aggregation with internal or external comparisons (averages or benchmarks). It is a significant component of practitioner appraisal.

The purpose of peer review is to identify patterns outside recognized standards, behavior problems, or other circumstances, which endanger the safety or care of patients. It is also used for upgrading the practitioner's clinical knowledge, enhancing his/her medical practice, reducing medical errors and improving patient safety and care. Peer review is used to protect patients, assure due process to the practitioner under investigation and preserve the immunity of the medical facility and medical staff. The analysis of cases should be reviewed for the following factors: clinical management, timeliness of medical interventions, adherence to a facility's clinical pathways and/or established guidelines for medically appropriate care, medical record documentation, professional conduct, and other reasons as requested by the facility.

Documentation of the peer review must be maintained in the practitioner's quality file, not their credentialing file. Peer review information is protected by law from discovery. If it is kept in the credentials file, it loses that protection. Federal statutes and state laws have determined how much protection is given to keep this information undiscoverable. The HealthCare Quality Improvement Act and the Patient Safety & Quality Improvement Act are two such federal statutes. These acts basically state that any actions that are handled appropriately by the health care facility through the facility's peer review committee are protected under the peer review process. This would include the documents, evaluations, minutes, and other such materials

If the medical staff bylaws, and written peer review policies and procedures are not followed, the information can become discoverable. If the peer review information is discussed outside of the peer review process, there is a loss of protection. The peer review protection can also be waived by any which individual committee member in informal discussions with colleagues. Physicians should not

place any notations in a patient's chart regarding peer review activities. The physicians should also not involve or discuss the peer review actions with the patient or others outside of the peer review process.

In the provider organizations, peer review is the responsibility of the appropriate department, section, or specialty and generally is delegated to a committee. Some hospital medical staffs and medical groups now use a multidisciplinary physician peer review committee to provide case-specific review and evaluate all physician care, obtaining specialist peer review for specific physicians as deemed necessary. In managed care, health plans may describe the required peer review activities under the Quality Management Committee. Regardless of where the peer review is completed, the committee must consider their conflict of interest policy, possible actions based on findings, corrective action plans, and any required reporting to the state medical board, to the National Practitioner Data Bank (NPDB) (www.npdb.hrsa.gov), and to other contracted entities.

The peer review process typically results in a rating of the care provided by the practitioner. Peer-reviewed findings generally are ranked, e.g., by following a simple four-point scale, such as the one listed below:

1= Peers would have managed care in the same manner

2 = Patient outcome unaffected by the variance

3 = Peers would have managed care differently

4 = Negative outcome resulted from the variance

Organizations will implement their own language for the above ranking that supports the processes at that facility. There is even discussion in the literature to use a three ranking system. The specific system that is utilized must be consistent throughout the facility for all peer review that is conducted. At the time of reappointment, the aggregate number of peer review findings is typically included in the practitioner profile. When this occurs, the number recorded on the practitioner profile must include a denominator value of the total number of cases that were reviewed, which were rated 1to 4.

Typically, peer review begins with an initial screening of data to determine if the medical staff established criteria for a process has been met. The established criteria must be approved by the medical staff before it is utilized for this purpose. If the criteria have not been met, then the file is sent to the peer review process established for the appropriate review. Some examples of initial screening indicators but not limited to these, would be Radiology film and Pathology slides over read; EKG over reads; Blood usage review; and Operative and invasive procedure reviews. Other types of reviews would include reviews of house-based physicians and single specialists. If the criteria are met, the peer review case is scored utilizing a value of 1. When a value of 3 or 4 may be assigned to a peer review case, the practitioner(s) involved must be invited to come to the next meeting and present his or her

side of the story. If a score of 3 or 4 is assigned to the case, then there must be action taken to address the issue with the practitioner involved. The medical staff will determine the appropriate action to be taken. Throughout this review process, there must be documentation to support every step in the process.

INTERACTING WITH CONSULTANTS

The quality professional is called upon to develop, implement, direct, coordinate, facilitate, and manage over time so many different slices of the organization's quality pie. For this reason, the quality professionals are in a unique position to recognize if and when external consultative support may be necessary. Consultants may help relieve pressures stemming from knowledge, time, or staffing gaps. The critical success factor, however, is getting the right person.

Word of mouth tends to be the best method of obtaining a good consultant or consulting firm. References for consultants do not have to be as restrictive as when referring an employee. The rules for fulltime employee references do not apply to a reference for an independent consultant. The Request for Proposal (RFP) process can be very cumbersome when multiple RFPs are received. If RFPs are utilized, they should be a closed RFP, which is sent to a small number of consultants. The RFP should be as explicit as possible by clearly defining the project and the requirements of the consultant (Proposal, n.d.).

Selection of a Consultant

The key to a successful association with consultants is a strong working relationship. A contract is important, but a relationship of mutual respect, trust, and confidence is the basis for getting the work done on time and in accordance with your specifications. The organization must decide the type of consultant they desire. Consultants are frequently utilized for interim managers, interim staffing needs, and for project management. Within project management, there are again three types of consultants. The project management consultants can point out problems and give recommendations for improvements, or complete both of those and then assist with actually accomplishing the product or improvements. Table 42 lists the steps that should be taken during the discovery and hiring process for consultants.

Table 42: Consultant Selection Process Steps

Consultant Selection Process Steps
Consultant Selection Process Steps: • Set goals for the project. What exactly do you want the consultant to do for you? • List everything you need done. Can the consultant deliver? • Decide, on the basis of the goals and needs, what type of consulting you want:

- Project management, with a team approach?
- One highly organized consultant to complete the project on time, then leave?
- What type of expertise and resources do you expect the consultant to have or have access to?
- What is the budget? How much can you spend to get the job done?

- Network: Talk to colleagues: [Word of mouth referrals are valuable references.}
  - Which consultants/companies do they recommend and why?
  - Which do they not recommend and why?
- Check out the advertising (mail, email, web sites, and journals): Do they promise to deliver the services you need?
- Make a list of the positives and negatives for each consultant/company. On that basis, narrow the list to no more than four or five.
- Interview the "finalists" by telephone, presentation, or proposal.
- Ask for references (or the last three clients) and call each one to get their opinion of the company and people.
- Ask for disclosure and explanation of any relationships the consultant/company has with vendors.

Communication with Hired Consultants

Once the consulting company is hired, it should be an immediate priority of both the organization and the consulting agency to each identify a team leader. Any communication between the organization and the consulting team must flow through the respective team leaders. If this chain of communication is not maintained, several issues may arise. A staff member from the organization may ask a specific consultant to send him/her a policy that can be modified for the specific setting. The consultant team member sends the policy to the organization team member. If the team leaders are not informed of this action, they may assign the same activity to two other individuals within each organization. This leads to confusion and misunderstandings.

Deliverables

It is incumbent on the hiring organization to identify what is expected of the consultant with regard to time, material, staff, and expertise (knowledge, problem solving, creativity, innovative ideas). The relationship between the consultant(s) and the organization must be explained and accepted. This includes what the organization expects, the accessibility of the consults, if the consultants will remain onsite or off site, and how the communication between the two organizations will be handled.

The exact deliverables must be identified prior to the contract being signed. The details of the deliverables will frequently drive a portion of the cost of the consultation. For example, if the client requires a verbal report versus a detailed written report, the cost of the consultation may be different. The time frames and deadlines that are required must be stated and agreed upon. The consultant should have the ability to execute quickly, to produce value, and to bring speed to value. These expectations and deliverables become the basis upon which the organization monitors the consultant(s)' performance, progress and results.

The organization must confirm in the contract that all information or knowledge gained while working on a project either belongs to the organization or can be used and modified by the organization on an ongoing basis. The respective team leaders must meet together and participate, or have designated participants in all consultant activities for ongoing deployment; monitor all deliverables to hold consultant accountable.

!OM/PI/PS/ACCREDITATION ORIENTATION, TRAINING, AND EDUCATION!

In the age of quality/performance improvement, education is the "name of the game" for the entire organization, and the quality professional must assume the role of facilitator, educator and consultant, more than the role of doer. The quality professional must understand both performance improvement and educational concepts and their implications within the organization and be able to teach them to others. The quality professional must have good teaching skills and workable plans to implement new ideas. The quality professional must also evaluate the effectiveness of the educational training, especially if it concerns utilizing performance/quality training for teams.

!orientation of Quality, Risk, Patient Safety, Accreditation, and Utilization Management!

Every individual who works for the organization requires three stages of orientation : the organization, the department, and the job. As is commonly known, the organizational orientation is quick information loaded in several days. The new staff members are not going to remember much of the material introduced to them during those first few days.

As such during the first organization orientation program, an overview of the quality arena in macro concepts should be presented. The organization's commitment to quality of care and patient safety should include all pertinent statements, such as quality management philosophy, continuous quality improvement concepts, performance improvement model and how these fit with the mission, vision, and values of the organization. This should also include an introduction to the roles of risk and utilization management.

When the new employees move to their department, a more in-depth orientation should occur. Typically, a departmental orientation feels like a scavenger hunt to find items such as the fire hydrants, exits, utility rooms, nutrition rooms, supply rooms, equipment, and such are located. Within that

department orientation however, should be the identification of how the specific department applies the performance improvement principles to identify and to improve processes within the clinical and non-clinical departments . This should include employee and visitor safety processes. It should be emphasized that all staff members of the department are to be actively involved in improving quality and patient safety, reducing risk, and as appropriate the utilization aspects of the department. This could include display of PI materials for staff and others to see within the department, attendance at a department quality meeting, and so on. It also could include the process used when the employee identifies opportunities for improvement within the department. It is important to emphasize early on that all members of the department are involved in the performance improvement process. If this is not accomplished in the departmental orientation, it must be introduced in the job specific orientation.

As the new employee begins the orientation to their specific jobs, the orientation should include aspects of quality, risk, patient safety, accreditation, and as appropriate utilization . It is important to note that performance improvement is not limited to only clinical areas, but should be ingrained throughout all departments of the facility. What the employee does in their work filters into quality improvement and even the quality control processes. Most new employees have an orientation checklist to complete, especially if it is a clinical position. This orientation checklist could include some aspect of data collection, analysis, improvement, etc., or simply meeting with the individual{s) who are doing those jobs on the unit. It is important for the new employee to recognize that performance improvement can be as simple as changing a form, moving equipment around in the department, or other relatively easy changes to improve work processes and patient care.

!orientation and Training Topics|

Different levels of positions need different levels of quality, performance, risk and utilization orientation and training. Table 43 contains a list of topics that could be utilized at all levels of the organization.

Table 43: Example of Potential Orientation Topics

Example of Potential Orientation Topics
• QI/PI philosophy, management, and methods
• Organizational culture, mission, vision, and values
• Patient- and other customer-centered performance improvement
• Important organization functions
• Teams, team process, and team process tools, as applicable
• Shared expertise, information, and ownership
• Change process
• Confidentiality and conflict of interest
• The organization's QM/PI approach and methodologies

- Statistical process control, data collection and analysis, as applicable
- Specific current PI activities:
  - Strategic quality initiatives and alignment with strategic goals
  - Performance measures-organization wide (e.g., a balanced scorecard), cross-functional, and relevant department-specific, as applicable

The governing board, senior administrative leaders and medical staff leadership, (as well as all others in the organization), require an understanding of the quality, performance improvement, risk, patient safety, accreditation, and utilization activities and processes conducted within the organization. These individuals are less likely to be involved in the detailed improvement efforts, but are held responsible to assure that these activities are occurring as needed. These individuals will be more responsible for the identification, prioritization, and resolution of the issues and opportunities for improvement. At this level, the orientation and training should include:

- The required accreditation orientation topics
- The specific organizational application of quality
- QM structure, system, processes, and improvement "approach"
- Strategic goals and initiatives
- Organization wide performance measures, e.g., balanced scorecard
- QI teams *(Ad hoc* and ongoing/cross-functional) and empowerment of teams to make decisions
- Linkages between measurement and analysis activities and QI team contributions
- Communication linkages between governing body, administration, practitioners
- Development, facilitation, and leadership of QI teams

The directors and department managers are the individuals who must motivate their employees to identify opportunities for improvement, participate on teams, make improvements, and most importantly, sustain the gain from improvement efforts. Licensed independent practitioner department and committee leaders also will be involved at this level to some degree. These individuals should receive the orientation and training of the leaders of the organization as listed above. Directors, managers, and licensed independent practitioner leaders should also receive training regarding the corporate mission, vision, values, and cultural philosophy about people; the patient population served and type and nature of care provided; and the individual staff/practitioner member needs. Topics that may be included in the departmental leader level are shown in Table 44 . In addition, it is important to assure that they are competent in assisting their staff about how to carry out improvement activities and how to engage their staff in the processes of identifying and making improvements.

Table 44: Director/Manager/Department Level and Above Orientation and Training

Director/Manager/Department Level and Above Orientation and Training
For: - QM/PI staff, including all reviewers - Department managers and medical directors - Administrative leaders - Medical staff/practitioner leaders, members, panel, or group - Governing body
<u>Orientation</u> should include information about; - Organizational mission, vision, and values - Governance, policies, and procedures - Department/service policies and procedures - The individual's job description - Performance standards/expectations - The organization's plant, technology, and safety management programs, and the individual's safety responsibilities - The organization's quality management/performance improvement activities and the individual's role in these activities - The organization's infection control program and the individual's role in preventing infection, if applicable

Staff and licensed independent practitioner orientation, training, and education are based on the identification of opportunities for improvement, participating in making the improvements and sustaining the gains from the improvement efforts. Specific training such as data collection, analysis, and data display may be essential for specific members of the department staff and practitioners, but remember that if the information is not utilized, then it is often not remembered when it is needed.

Just-in-time training should occur when the improvement teams are established based on the needs of the team members and the improvement opportunity. All of the tools and other processes that could be utilized within the team should be included. This will serve as a refresher for some and as new education for others.

!Education/Training Program Development Process!

The educational program development process is very similar to the performance improvement process. The concepts of Plan, Do, Check, and Act can be identified. There are three tables included here that contain additional information for an effective teaching/learning process.

Plan: The plan dimension begins with a needs assessment of the topics requiring education. It also includes the identification of who needs what training, how will they best learn, what are the necessary outcomes of the training, and what resources are available.

Once the needs assessment is completed, the goals and learning objectives are identified. It is also important to determine how the goals and objectives will be measured. The leadership must also support this educational plan.

The learner characteristics are identified. Learners have different expectations and learning styles. An auditory learner learns best by hearing, so a lecture would be appropriate . A visual learner learns best by seeing and being able to draw a picture of what is being described or discussed. A tactile learner learns best by touching and doing. It is likely that any group will be composed of all three types of learners, and appropriate instructional strategies should be utilized. Lecture, demonstrations, and discussions are all effective tools.

The educational course is then developed. The course materials are selected and the instructors are selected and trained. A pilot test course should be done, and the appropriate revisions made, before the actual course is conducted.

Do: The course is administered.

Check: Two types of checks should be conducted. The first is an evaluation to determine if the goals, objectives, and outcomes were accomplished . This might include fewer falls, lower use of restraints, more medication error reporting, more immunizations being given on time, etc., depending on the type of improvement project. The second check should be the gathering of input from the class attendees to determine what worked well and what did not.

Act: Changes should be made to the educational program before it is administered again. This can include the exclusion or revision of the topics presented, the addition of supplemental information, a change in Lhe setting in which the education was held, or other such activities .

Tables 45, 46, and 47 provide other information about adult education, and teaching tactics that the quality professional may find useful.

Table 45: Adult Learning Concepts

Adult Learning Concepts
Adults: • Are motivated to learn when THEY identify they have a need to learn • Are motivated by societal or professional pressures that require a particular learning need • Can be motivated to learn when the benefits of a learning experience outweigh the desire to resist • Use their knowledge from years of experience as a filter for new information and do not change readily • Learn best from their own experiences • Prefer to determine their own learning experiences • Like some lectures. All lectures won't be liked by all adults • Like small group discussion • Want practical answers for today's problems • Enjoy practical problem solving • Hate to have their time wasted • Like physical comfort • Like tangible rewards and benefits from training • Refreshments and breaks establish a relaxed atmosphere and convey respect to the learner

Table 46: Dimensions of Effective Teaching

Dimensions of Effective Teaching	
Instructor knowledgeable	• Being accurate, factual, and up-to-date in healthcare quality • Directing staff, physicians, administration to useful research and references • Objectively identifying and analyzing concepts, principles, and problems
lr.t ::,,action skills	• Establishing and maintaining :.:.pport • Controlling interaction to meet the objectives • Creating a climate of mutual respect • Stimulating active participation • Eliciting lively exchange/discussion • Reading body language to determine if minds are being turned off or on
Organization and clarity	• Getting the message across • Making oneself understood • Systematically and effectively: - Stating learning objectives - Presenting ideas in a logical progression - Placing emphasis where appropriate - Summarizing succinctly and timely - Using well chosen examples and illustrations
Enthusiasm and stimulation	• Awakening interest and stimulating response • Using movement, humor, voice inflection to prevent boredom • Conveying charisma, self-confidence, and an enjoyment of teaching

Table 47: Teaching Tactics

Teaching Tactics
• Involve learners in the lesson: - Identify their needs - Ask questions - Role play, discussion, writing • Provide reinforcement/feedback to the learners: - Smiling, gestures - Knowledgeable answers to questions • Utilize effective questioning techniques • Exhibit enthusiasm: - Focus on the audience - Act enthusiastic, even if not feeling like it at the moment • **Be a professional role model:** - Practicing skills, standards, and values to be developed by others - Being accessible - Providing opportunities to discuss practical applications of knowledge and skills and apply problem solving approaches - Being self-confident and self-critical - Assuming responsibility - Recognizing one's own limitations - Showing respect for others • **Utilize appropriate teaching methods/learning activities:** - Lecture - Discussion - Discovery or inquiry-oriented discussion, case study - Socratic (asking questions) - Independent study units, small groups, case study - Demonstration - Practice - Role playing (scenario) - Simulation (script) - Testing

This chapter presented an overview of performance and process measurement. The information in this chapter is key in establishing and maintaining performance improvement for the organization. Without strong, committed leaders, the chances of having a strong robust improvement program is decreased even with the information provided here. The leadership must support and communicate that support to all in order for an improvement program to be able to sustain its efforts overtime. As a Quality/UM/RM/PS/accreditation manager you are also a leader, and while you may not have positional power, you have expertise and influence that is key to your organization's success.

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WEBSITES

PERFORMANCE AND PROCESS IMPROVEMENT

Agency for Healthcare Research and Quality (AHRQ)	http://www.ahrq.gov
AHRQ Community Quality Collaboratives	https://ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/l ocalnetworks/index.html
AHRQ Effort to Prevent and reduce Health Care Associated Infections	https://www.ahrq.gov/research/findings/factsheets/errors-safety/haiflyer/index.html
AHRQ Health Care Report Card Compendium	https://caha ps.ahrq.gov/apps/rcc.aspx
Case Management Society of America (CMSA)	http://www.cmsa.org
Center for Disease Control (CDC)	http://www.cdc.gov
CDC National Healthcare Safety Network	http://www.cdc.gov/nhsn/index.html
CMS - Strategy	https://www.cms .gov/Medicare/Qua lity-1nitiatives-Patient-Assessment-lnstruments/QualitylnitiativesGenlnfo/CMS-Quality-Strategy.html
Consumer Assessment of Healthcare Providers and Systems (CHAPS)	https://cahps.ahrq.gov
Consumer Reports Healthcare Rankings	http://www.consumerreports.org/cro/hea lth/index.htm
Department of Veteran Affairs Clinical Practice Guidelines	http://www.healthquality.va.gov
Dialysis Facility Compare	https://www.medicare.gov/dialysisfacilitycompare/search.html
FDA's Reduce Medication Errors Working to Improve Medication Safety	http://www.fda .gov/Drugs/Reso urcesForYou/Consu mers /ucm143553.htm
Focused Professional Practice Evaluation (FPPE)	http://www.jointcommission.org/jc_physician_blog/ oppe _fppe_tools_privileging_decisions/
Global Trigger Tool	http://www.ihi.org/resources/Pages/Tools/lHIGlobalTriggerToolforMeasuringAEs.aspx
Harvard Business School (HBS)	http://www.hbs.edu
Health & Human Services (HHS)	http://www.hhs.gov
Health & Human Services (HHS) Measure Inventory	https://www.qualitymeasures.ahrq.gov/hhs/index.aspx
Health Data Transparency Basics	http://www.healthpolicyohio.org/wp-content/ uploads/2014/01/transpa rencybasics.pdf

Health Grades	http://www.healthgrades.com
HEDIS	http://www .ncqa.org/HED ISQualityMeasurement/HEDIS Measures.aspx
Home Health Compare	https://www.medicare.gov/homehealthcompare
Hospice Quality Reporting	https://www.medicare.gov/hospicecompare
Hospital Compare	https://www.medicare.gov/hospitalcompare/search. html
Hospital COPs for Complaints and Grievances	https://www.ems.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetterOS-42.pdf
Inpatient Rehabilitation Facility (IRF) Quality Reporting	https://www.medicare.gov/inpatientrehabilitat ionfacility compare/
Institute for Healthcare Improvement (IHI)	http://www.ihi.org
Institute for Safe Medication Practices (ISMP)	http://www. ismp.org
Insurance Coverage	https://healthcare.gov
The Josie King Story	http://www.josie king.org/thejosiekingstorydvd
Long-Term Care Hospital Quality Reporting	https://www.medicare.gov/longtermcarehospitalcompare/
Managed Care COPs for Co- plaints and Grievances	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c13.pdf
Maslow's Hierarchy of Need	http://www.abraham-maslow.com/m_motivation/Hierarchy_of_Needs.asp
Michael Swango	https://www.thoughtco .com/profile-of-joseph-m ichae l-swango-973127
Mind Tools -Team Evaluation	http://www.mindtools.com/pages/artic1e/newTMM_84.htm
National Guideline Clearinghouse	http://www.guideline. gov
National Patient Safety Foundation (NPSF)	http://www.npsf.org
National Practitioner Data Bank (NPDB)	http://www.npdb .hrsa.gov
National Quality Forum (NQF)	http://www .qualityforum.org
National Quality Measures Clearinghouse	http://www.qualitymeasures.ahrq.gov
NCQA Quality Compass	http://www .ncqa.org/tabid/177/Default.aspx
Nursing Home Compare	https://www.medicare .gov/nursinghomecompare/search .html
Ongoing Professional Practice	http://www.jointcommission.org/jc_physician_blog/oppe

Evaluation (OPPE)	_fppe_tools_privi leging_decisions
Physician Compare	https://www.medicare.gov/physiciancompare/search.html
Quality Check	http://www .qualitycheck.org
Quality Compass	http://www.ncqa.org/tabid/177/Default.aspx
Regional Health Improvement Collaboratives	http://www.nrhi.org/about-collaboratives
Robert Wood Johnson Foundation National Healthcare Reports Directory	http://www.rwjf.org/en/library/research/2013/09/national-directory .html
Swango, Michael	https://www.thoughtco .com/profile-of-josep h-michael-swango-973127
Team Effectiveness Evaluation Summary	http://www1.umn.edu/ohr /prod/grou ps/ohr/@ pub/@ohr/documents/asset/ohr _asset_ 455436.pdf
TeamSTEPPS	http://teamstepps .ahrq.gov/about-2cl_3.htm
TeamSTEPPS Online Course	http://ts!ms.org/login/index.php
The Institute of Medicine (10M) Eight Standards Categories	http://iom.nationalacademies.org
The Joint Commission Quality Check	http://www.qualitycheck.org
The Role of Teams	http://asq.org/learn-about-quality/teams/overview/overview.html
TJC Portal with Transition of Care Information	https://www.jointcommission.org/toc.aspx (UPDATED LINK)
Transition of Care	https://www .jointcommission.org/toc.aspx (UPDATED LINK)
Triple Aim	http://www.ihi.org/Engage/1 nitiatives/TripleAim/Pages/default.aspx
Truven Health Analytics 100 Top Hospitals	http://100tophospitals.com/studies-w inners/15-top-health-systems
Types of CAHPS Surveys	https://cahps.ahrq.gov/surveys-guidance/index.html
University of Michigan's Team Facilitation Tool Kit	http://oqi.wise. edu/resourcelibra ry/uploads/resources/Facilitator%20Tool%20Kit.pdf
URAC.	http://www.urac .org
US News Healthcare rankings	http://health.usnews.com
World Health Organization	http://www.who.int

HEALTH DATA ANALYTICS

CHAPTER 4

Susan Mellott, Kathleen Tornow Chai

CPHQ Examination Content Outline Task Statements For This Chapter	
Organizational Leadership	
1.A.7	Assist in evaluating or developing data management systems (e.g., data bases, registries)
1.B.1	Assist the organization in maintaining awareness of statutory and regulatory requirements (e.g., CMS, HIPAA, OSHA, PPACA)
	Health Data Analytics
2.A.1	Maintain confidentiality of performance/quality improvement records and reports
2.A.2	Design data collection plans: a. measure development (e.g., definitions, goals, and thresholds) b. tools and techniques c. sampling methodology
2.A.3	Participate in identifying or selecting measures (e.g., structure, process, outcome)
2.A.4	Assist in developing scorecards and dashboards
2.A.5	Identify external data sources for comparison (e.g., benchmarking)
2.A.6	Collect and validate data
2.B.1	Use data management systems (e.g., organize data for analysis and reporting)
2.B.2	Use tools to display data or evaluate a process (e.g., Pareto chart, run chart, scattergram, control chart)
2.B.3	Use statistics to describe data (e.g., mean, standard deviation, correlation, t-test)
2.B.4	Use statistical process control (e.g., common and special cause variation, random variation, trend analysis)
2.B.5	Interpret data to support decision-making
2.B.6	Compare data sources to establish benchmarks
2.B.7	Participate in external reporting {e.g., core measures, patient safety indicators, HEDIS bundled payments)
Performance and Process Improvement	
3.A.2	Assist with establishing priorities
3.A.3	Facilitate development of action plans or projects
3.B.2	Use a range of quality tools and techniques (e.g., fishbone diagram, FMEA, process map)
3.B.3	Participate in monitoring of project timelines and deliverables
3.B.6	Document performance and process improvement results

Patient Safety	
4.A.3	Participate in risk management assessment activities (e.g., identification and analysis}
4.8.3	Use safety principles: b. high reliability c.systems thinking
4.B.4	Participate in safety and risk management activities related to: a. incident report review (e.g.,near miss and actual events} b. sentinel/unexpected event review (e.g., never events)

Words and titles of sections that refer to task statements from the CPHQ Exam Content Outline are indicated throughout the Handbook with a ox around the texq.

For many individuals when they hear the terms quality improvement and performance improvement they only think of the clinical aspects of a healthcare facility. This view is as limiting as a driver only looking at whether or not the car needs gas. Eventually the car breaks down because no attention was paid to the oil light or the tire inflation light. Information management in healthcare is more than simply analysis of the patient medical record. The information within a healthcare system encompasses all aspects of the business. All of this information should be utilized for performance improvement throughout the facility.

There are many instances where participants have little or no information management knowledge or ability to use this knowledge to its fullest potential in performance improvement. The level of Information Literacy (IL) of the individuals who are trying to make improvements and decisions is important. Understanding Information Literacy is to understand all its components . From a research perspective, Information Literacy involves having the following skills: ◦Be able to identify, evaluate, and select search tools; Have thorough knowledge of search strategies; Be able to evaluate and select sources accordingly; Adhere to legal and ethical practices when using IL skills" (Robertson & Felicilda-Reynaldo, 2015, p. S26). Another source, the American Library Association, describes an information literate individual as one who knows what information is needed, knows where and how to abstract that information efficiently and effectively, critically evaluates the information and its source, adds the selected information to one's own database, uses the information effectively to accomplish the desired purpose and understands the economic, legal, and social issues surrounding the use of information, and accesses and uses information ethically and legally (ACRL, 2000) .

Many years ago, all the information one needed to run a hospital was kept in detailed logs or ledgers: financial data, patient data, staffing data, and so forth. However, more and more of the data are kept in computer systems. The utilization of these computer systems evolved over time, with little recognition that both clinical and non-clinical data often need to be combined to get to the necessary information that will guide organizational decision-making.

HEALTH DATA ANALYTICS

What follows in this chapter are several sections on information management. The first section describes data, including definitions and sources, data collection techniques, ethical and legal issues when dealing with data, and the use of information technology. Next this chapter discusses processes used to transform the data into information, including measurement and display. The final portion of the chapter deals with using the data as information to demonstrate optimal outcomes or effect changes needed for improvement.

DATA

In today's quality driven health care environments, valid data is needed to provide support for changes. Statistically valid data, that assists in identifying better and best practices, and in explaining patterns of care, are valuable in identifying problems in the provision of care.

Two definitions are important to understand information management: "Data" is the collection of uninterrupted observations or facts. "Information" is what happens when data are aggregated together, analyzed, and interpreted into a form useful for decision-making. For instance, suppose a medical surgical unit had three patients who experienced falls with injury in the last month. That is data. It becomes information when you apply statistics to define the rate, severity, and outcomes. This additional information will allow the user to understand not only the severity of the issue, but also what actions may need to be taken. The goal of information management is to utilize data to support decision-making to improve processes and outcomes.

There are pressures to produce reliable and valid information to improve aspects of healthcare. These pressures are both internal and external to healthcare organizations. Quality improvement leads one to utilize information that is reliable and valid. Deming's Total Quality Management principles presume the need to base decisions on timely and accurate data, not on wishes or hunches. Statistical quality control demands use of factual information.The integration of clinical and financial data is increasingly important for financial survival in this age of diminished reimbursement . The transparency of data on the internet allows consumers to be aware of how a healthcare organization operates, how the practitioners practice, and what outcomes and costs are associated.

Where are these data found?

Healthcare information is used in clinical/service decision-making, organizational/strategic decision-making, performance improvement efforts, education, and research. There are at least three types of information systems utilized in healthcare to assist with decision-making and the care of patients: Administrative Information System; Clinical Information System; and the Decision Making Information System. The Administrative Information System includes the financial, billing, inventory, supplies management, human resources, risk management, and quality management, information, as well as policies and procedures. The Clinical Information System includes the electronic medical record, pharmacy, and laboratory data. The risk and quality management utilize the Clinical Information

System to gather the patient data that are needed to identify opportunities for improvement. The Decision Making System, sometimes known in business as decision support, takes information from the other two systems and additional information and uses it to assist the organization in the decision-making processes. Most organizations and practitioners utilize Administrative and Clinical Information Systems, but decision-making systems are seldom used because the coordination, leadership, and integration required involves many individuals and layers within an organization (Byrne et al., n.d.).

Prior to integration of information in larger software systems organizations had two basic data keepers; Finance and the Health Information Management (HIM) Department or the Medical Record Department. However, it has been suggested that, "HIM could be headed for the C-suite. Corporate HIM directors-an emerging role that is expected to grow by 2025-are beginning to form within integrated health systems with multiple hospitals. These corporate HIM directors manage a set of functions being carried out by HIM professionals within various hospital departments, rather than managing HIM within the traditional HIM department structure" (Dimick, 2012, para 25).

!Aggregate Datal

Information comes from data which must be collected and aggregated. The organization must have a process for aggregation and summarization of data that is consistent with its nature and will impact patient care. During the development of the collection process, it should be determined what groups or persons are responsible for the treatment of data. There should be time frames established for tabulation, display of raw data, statistical analysis, and reporting. The data must be aggregated and displayed, summarizing and trending over time. This allows the users to determine the type, cause ,or extent of problems, and to determine the type and cause of best practices. The data must be summarized in ways to permit meaningful interpretation and formulation of accurate conclusions regarding the quality of patient care and services. Since many individuals are visual learners, graphic displays should be used whenever reasonable to enhance understanding of analyses.

When data are collected, it is just that: a set of data points that have been collected. It is not until we aggregate and summarize the data points that we have information about what is happening,and then we can determine what needs to be done, if anything, to make improvements. If a picture is taken outside in a town on a certain day, it only shows what the weather was like at that point in time. It cannot be used to describe or predict the weather at any other point in time; it is a piece of data. However, if the pictures are arranged in a photo album, with one for every day in the month, the user can begin to describe what the weather is like in that town for that month. The data points have become information. Information can then be utilized to make decisions about whether one is likely to need a coat when going outside during the particular month.

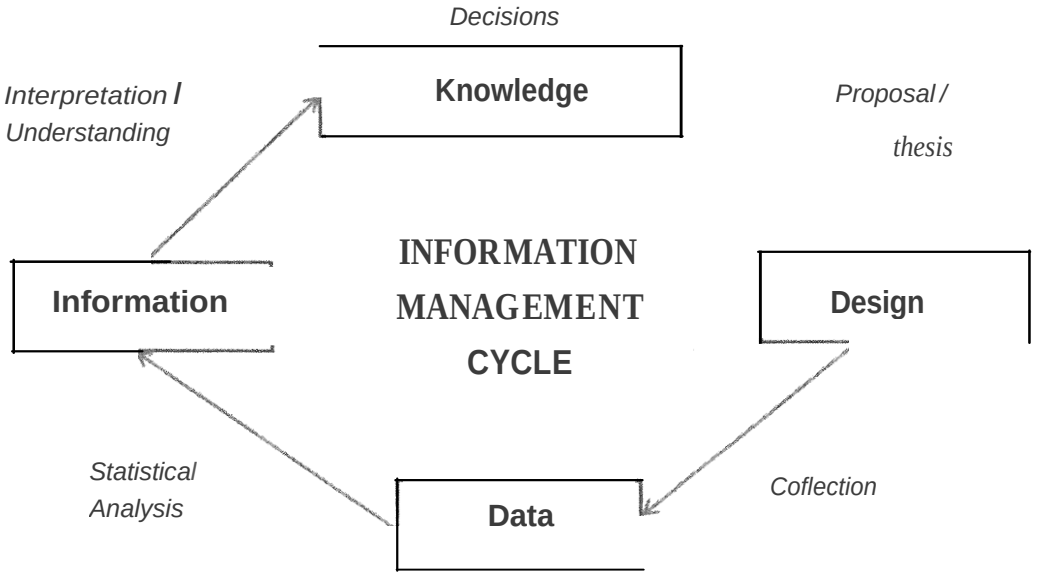
If we are to make appropriate decisions to truly improve care and services over time, we must collect quality data that converts into understandable, useful information:

DATA c:>c:> leads to c:>c:> INFORMATION c:>c:> leads to c:>c:> KNOWLEDGE

c:>c:> leads to c:>c:> DECISION MAKING

Without good data, we rely upon our opinion, logic, intuition, rationalization, rumor, and/or hearsay to lead us to recommendations and hopefully appropriate action to improve the quality of care and service. In essence, we had no defined process for decision-making. In a database model of decision-making, the information management function closely resembles the scientific method, as shown in Figure 1. In this figure, work flows from the design to knowledge. The design is based on the proposal/hypothesis, which leads to data collection, and then through statistical analysis, leads to information. Information then must be interpreted and understood to lead to knowledge and knowledge leads to both appropriate decision-making and to additional hypotheses to be tested by this cycle.

Figure 1: Decision-Making Process



Quality professionals must collaborate with other collectors, analyzers, and users of data to learn of all information resources available. Issues with data collection include: Access to the data/information (authority, securities, etc.); Availability of data/informat ion in the form/format needed; and Timeliness of data/information access (how close to real time is data collected, downloaded, etc.).

!Data Definitions!

When developing a questionnaire or other data collection tool,there are certain terms that need to be understood and considered, especially if clinical performance measures are being collected.

ensitivit: The ability of a measure, test, or tool (study design, screening tool, or lab test) to identify and select *all positive* cases or specified variations or deviations (all cases in the category), with few "false negatives". This means that the creator includes all of the appropriate descriptors of the data to be gathered. The developer must determine how sensitive/inclusive the measure should be. For example, if the collection tool just asks for the number of falls, then that is all the data provides.The recipient would not be able to determine what shift the fall occurred, where the fall occurred, and so on. However, if the collection tool was inclusive enough to ask for the number of falls, the unit on which the fall occurred, and the shift it occurred on, then the tool is more sensitive and the data can beanalyzed inwaysthat provides moreinformation.

peci ficit : The ability of a measure, test, or tool to differentiate between the cases wanted and those similar, but not in the desired category, and to *exclude* those *negative* cases - fewer "false positives". The question to be asked is what do you want and not want to include. However, if the question is too specific, it may not be sensitive enough. The tool may specifically address the patient who is 65 years of age or older. No one who is younger than 65 will be asked to answer the questions.

llitratificationl : The classification of data into homogeneous groups or subsets. If the user wants to stratify the results, then the collection tool must be able to gather all the needed information to allow for the stratification of the data. An example would be the study of Urinary Tract Infections (UTIs) by organism, by catheterization, by surgical procedure, and by nursing unit. All this information must be captured within the collection tool.

lusabifit: The relative ease with which the indicator can be understood or the tool can be used. Have you ever taken one of those surveys or tests that states "If you answered yes, go to question 23. If you answered no, go to question 42"? This type of collection tool can be very confusing and thus not very easy to complete.

IRecordabilit : The ability of the indicator or tool to identify, capture, and measure the needed information. When answering questions on a Scantron form, the bubbles must be completely filled in. If a mistake is made, the marking in the bubble must be completely erased without tearing the form. This represents difficulty in recording the answers to the questions.

!Goal A numerical value that defines the significance level of the data that is desired for decision-making.

_____: A numerical point at which there should be some action taken (see Chapter 3 Performance and Process Improvement).

jrhresho/: A numerical point below which the data should not fall or the point or level at which something begins or changes.

!Benchmarhl: A standard or point of reference against which data may be compared or assessed.

Indicators and tools that are developed and utilized must be both reliable and valid. Reliability is defined as the ability of the indicator or collection tool to measure in a reproducible way what it is supposed to measure. Validity is defined as the capability of the indicator or collection tool to measure what it is supposed to measure; its predictive value as a measure of quality. There are numerous ways to determine reliability and validity and these will be discussed here.

!Reliability and Validit

!Reliability!:

Reliability is the ability to reproduce the same results if there are no interventions or changes between measurements. Also, if there is an intervention between measurement, then the results should move in the direction that is desired. There are two different kinds of measurement of reliability: Test/Retest and Interrater Reliability.

Test/Retest Reliability is simply what it sounds like. A question, survey, test or other such tool can be used to measure an indicator or collection tool twice. If there is no change then the indicator or tool is said to be reliable. If there is a change and it is in the desired direction, that also indicates reliability. For example, if a class was given a pretest on ceramics, then sat through a lecture that was on ceramics, when they were post-tested you would expect their score to rise on the posttest about ceramics. If the lecture was about quality, and the post-test was the same or similar to the pretest, there should be no change in the student scores. That would indicate that the ceramic test is not a reliable tool to utilize to measure the effects on a lecture about quality. So, in one case it would be reliable (ceramic lecture) but in the other case it would not (quality lecture).

The other kind of reliability can be determined through Interrater Reliability test. This is utilized when you have more than one person utilizing an indicator or data collection tool and you need each individual to interpret and apply the indicator or tool in the same manner. To obtain Interrater Reliability, the indicator/tool should be developed and then the data collectors must be educated as to how to apply the indicator and/or utilize the data collection tool. Once that has been completed, each data collector must complete a data collection experience on several records or other items being examined. For example, there are three individuals who are going to collect data on the completeness of the medical record documentation. Each of the three individuals could possibly interpret where and

how to collect the data differently from the other two individuals. This could result in incomplete data. With Interrater Reliability, the data collection tool would be developed and the individuals educated as discussed. The first of the three individuals would be given three records and instructed to collect the data utilizing the tool that was developed. When that individual is done, the second individual is asked to collect the same data on the same medical records utilizing the tool, and so on until all the individuals have completed the extraction of the data . The data collected by all three individuals is then compared together and a rate of agreement determined. An interrater rate of 95% agreement should be the goal to have 'reliable' data collected. If there is not a 95% agreement, then there is either something unclear about the tool or the education that was given.Changes should be made and then the testing repeated until there is at least a 95% agreement.

&a1idit

Validity is the ability to measure what is really desired to be measured. If the data collection occurs utilizing a topic that is not correct, then there will be data that is not usable for that project. For example, the ceramic test discussed in the Reliability text above is a reliable tool,but it is not valid to utilize for a lecture on quality. There must be reliability of an indicator/tool before there can be validity of that indicator/tool. There are three types of validity that will be discussed here: Face validity, Criterion validity, and Construct validity.

Face Validity is the least valuable and precise of the validity tests. Face validity simply means that the indicator/tool "looks" like it covers the topic. It is clear that the ceramic test does not apply to the quality lecture, but the quality test look like it does apply. Unfortunately, face valid ity may be misleading. Continuing with the quality lecture example, while the test has face validity one must determine if it includes the topics include in the lecture or is it just general quality information. Relying on face validity is not good enough in healthcare.

Criterion Validity is the type of validity that should be utilized for most of the healthcare definition and collection tools. Criterion validity utilizes some criteria that have been developed previously to write the indicators or the content of the tools. This could be as simple as utilizing the policy and/or procedure requirements for the measurements. The items in those documents would be the criteria to utilize to ask the questions. Also, the criteria of what you want to know could be developed and then the questions written from that criteria. For example, if the Outpatient Surgery department would like to know how their Day Surgery patients are doing after they go home, the department could determine what it is that they want to know. This could include if the patient is having pain, any bleeding, any difficulty getting medications, and so forth. These would then form the basis for the questions to be asked.

Construct Validity is an even higher level of validity, but this type of validity is difficult to determine. Constructs are defined as an idea or theory. It is a subjective versus objective measure, is not based on empirical evidence and thus can be elusive to measure. Patient satisfaction is a construct and thus

hard to measure. Your personality type, how happy or hungry you are, and how excited you are to see someone are all constructs and thus hard to measure. This has led to most healthcare organizations utilizing tools from organizations such as Press Ganey, Gallop, and NRG Picker to measure the patient satisfaction of their patients. Without research and statistical measures, healthcare facilities would often not be able to develop these types of measurements.

!DataInventor

Many healthcare organizations know that data is being collected throughout the organization. However, many do not know where the data is coming from, what definitions are utilized, how the data is being analyzed, or where it is reported. A database application can be utilized to maintain this information for use throughout the organization. The purpose of a data inventory is to identify the data that individuals actually need so that the information can be accessed without duplication of efforts. "If you're going to undertake a data inventory, your output should be structured so that the next person doesn't have to repeat your work . Identify the data that is moving across various systems, as this indicates key information that is being shared. Categorize this data by subject area . You will inevitably find that there are inconsistent versions of the data, enabling you to identify data disparities. You can then begin to develop a catalog of key corporate data that will form the basis of your data dictionary" (Levy, 2010).

A data inventory can be utilized to keep track of all data and related documentation and information that is being created or acquired. The data inventory consists of what the data means, how and where it was collected, what definitions were utilized, how the data was analyzed, who owns the data, who has access to the data, who manages the data, and how the data can be used and shared.

Since the data inventory will be utilized by many different individuals, the departments that will be involved should be included in the design and implementation, including someone from the IT department who will be involved in creating the database . Involving all these individuals can encourage them to be part of the maintenance of the data inventory system. To begin this process, all of these individuals will collect the information that is needed to be entered into the project. The success of this project will depend on the quality and accuracy of the information input into the system. In order to obtain high quality and accuracy, the team members must be trained as to how to collect the data. The team must determine exactly what is to be collected and in what format. The team must also determine if they are going to collect data used for internal and/or external purposes.

The organization and the team must determine what information to include in the data inventory. It must be determined what data is currently being used and by whom . During this collection process, it will be noted if there is duplication in the use of the data being collected throughout the organization. An example of this duplication would be if the ED is a designated Chest Pain Center, they must send data in monthly to the Chest Pain Center Accred itation Agency. The Emergency Department may collect their data from the ED and Cardiac-Cath Lab logs. Many of these measures are the same or

similar to those collected for CMS Core Measures, which are collected from the medical record itself. The organization may determine that these two measure sets are very similar and could be collected by one group and shared with the other instead of being collected in two different parts of the organization.

The reason that the data are being collected must also be determined. There is often data that are collected because it "always has been collected". There may not be any current need for the data or information produced from those data. This is called the DRIP principle or "Data Rich but Information Poor" when data is collected but not analyzed into information. It may also be determined that the data were once useful in the form it was collected, but now it needs to be collected differently in order to have better information about a process or system. It must also be determined with whom the data and information must be shared for use in decision-making processes. Once the scope of the data needed is determined, it can be collected and maintained in the data inventory. This must be maintained over time, so the data inventory process must be repeated frequently as determined by the organization. An individual in the quality department should be assigned the task of keeping data updated. The inventory should be updated on an annual basis or when major changes are implemented.

!Potential Data Sources!

The potential sources of healthcare data are numerous and vary depending upon the type of facility and the type of care given. Data sources can be internal or external to the organization. In Tables 1and 2 are listed potential internal and external sources of healthcare data.

Data that comes from internal sources have many benefits but there are also weaknesses. One of the benefits is that data are available for analysis and use as soon as it is collected. Internal data are best utilized when there is a desired change to a process or an outcome. One of the weaknesses is that there frequently is little reliability of the data collection method and thus the data may not be correct.

Table 1: Internal Example of Data Sources

Internal Example of Data Sources
• Patient/client records
• Ongoing quality control/measurement summaries
• Patient surveys, interviews, questionnaires
• Staff surveys
• Direct observation
• Clinical reports/profiles (pharmacy, lab, blood bank,etc.)
• Medication records

- Clinical review findings, e.g.:
  - Operative/other procedures
  - Medical record review
  - Medication use
  - Blood/blood component use
  - Pharmacy and therapeutics function
  - Mortality reports
  - Autopsy reports
  - Functional outcome status
- Variance reports, e.g., clinical paths
- Demographics/registration data
- Indexes, registers, and logs
- Infection control reports
- Occurrence/other generic screening reports/summaries, including sentinel events and root cause analyses
- Risk management/claims reports
- Utilization/case management reports
- QI team reports
- Patient safety reports and \FMEA\s
- Environmental safety reports
- Patient bills
- Case mix reports
- Financial reports
- Clinical research reports
- Department/service QM reports and minutes (physician/LIP, nursing, and ancillary/support services)
- Self-assessment/pre-survey reports

Data which comes from external sources also has benefits and weaknesses. One of the benefits is that the data from the organization can be combined with the data from other facilities. This *gives* the facility an opportunity to benchmark with other facilities that are similar to the one submitting the data. Several weaknesses include the fact that the data are frequently not available for months after it is collected. This makes the data less useful when attempting to change processes or outcomes, as these may have changed since the time the data were collected.

Another weakness is the fact that the different organizations collecting and reporting data may not have used data definitions in the same manner. This could result in data that are not similar to that in the facility that will be utilizing the comparison results. Another weakness is the fact that external data can be old when published for use and infrequently updated. Data from the Center for Disease Control (CDC) that is posted online is often two or more years old. In 2016, the CDC posted its *2014 National and State Healthcare-Associated Infections Progress Report* online. In this report, the data is from 2014 and is compared to the national baseline obtained in 2008-2009 (CDC, 2016).

Table 2: External Example of Data Sources

External Example of Data Sources
• Reference databases/performance measure report systems/compilations (e.g., CMS National Quality Initiatives, Maryland Quality Indicator Project, HED1s , etc.) (see also Transparency and Public Reporting in Chapter 3 Performance and Process Improvement)
• Accreditation reports
• State inspection/licensure reports
• Third party payer and employer reports
• CMS and QIO reports
• Registry reports
• CDC reports
• Recent scientific, clinical, and management literature (e.g., MEDLINEPlus)
• Sentinel event alerts (e.g.,The Joint Commission)
• Evidence-based practice guidelines and clinical algorithms/protocols (medical colleges and boards; National Guideline Clearinghouse)
• Well formulated/updated performance measures (e.g., National Quality Measures Clearinghouse)
• Validated clinical pathways
• Identified best practices
• State/regional/national rates and thresholds
• Comparative report cards

An example of how data are processed when sent from an external source is the process used by The Joint Commission and CMS with their Core Measure sets. Data are collected for a quarter (for example, January, February, and March) and then sent to a vendor, usually in the month following the quarter (April). The vendor then 'scrubs' the data. The vendor will apply statistical processes to determine if

there are errors in the data. If it is not "clean", the data may be sent back to the facility for correction. Some vendors select certain patient records to be abstracted by a second person at the facility to determine if it has been extracted correctly (inter-rater reliability), as another source of data verification . Once the vendor has completed this process, the data from different facilities are combined in the database for analysis. The reports are then produced and sent to facilities for their utilization. This process will typically take one to two months, or more. Results are then sent to The Joint Commission or CMS by the end of the fourth month (July) after the initial quarterly data collection was complete. It is at this point that the Joint Commission and CMS again repeat data scrubbing and the combination of all data into the database for the measures. It is then sent to facilities and posted on the internet, usually 1-2 months after it was received by the vendor (September). By this time, many healthcare facilities have already begun to r11ake changes to processes and the data have lost some usefulness .

In order to make healthcare data more accessible and useable, the government and other agencies have established programs that will help them obtain aggregated data. Although many such programs exist, meaningful use, ICD-10, indexes, and registers will be discussed.

!Benchmarking!

The term "benchmark" was defined above. It is very useful when using data since a benchmark sets the standard the organization wishes to achieve and gives guidance to the usefulness of its own data. Sometimes the benchmark is O or 100%. For instance, Medicare and Medicaid (CMS) implemented regulations in 2010 regarding payment for healthcare acquired infections. When these preventable infections occur, CMS imposes financial penalties for them. Thus, the benchmark is 0. Other benchmarks are not so strict and allow an organization to move toward improvement without an all or nothing approach. For instance, patient/customer satisfaction is required to be measured in many organizations, and the data are usually aggregated, analyzed and sent back to the organization by an external vendor who provides benchmarking data from organizations who perform well.

However, there are several factors that need to be considered when using internal or external data to compare outcomes. The first is similarity between institutions. Comparing data related to patient falls should be done between similar institutions. It would not be reasonable to compare an acute care hospital's rate of falls with that of a skilled nursing facility, or even a mental health facility that offers acute care. The populations of each organization are not similar so the findings would not be comparable. The same caution would apply when fall data are being compared internally. The critical care unit or the medical surgical unit should not have the same goals, as the care that is given to patients in each of these areas is very different, as a re the patients.

Secondly, when comparing data between one place and another, it is useful to compare only rate based information. Going back to falls, unit A & B in the acute care hospital may both be medical surgical units. However due to the building structure one unit houses 30 patients and the other unit

houses 15 patients. There needs to be a way to compare them but it is not the number of falls. 5 falls in one month on the unit that houses 30 patients is not the same as 5 falls the same month on the other unit. So how do we compare? The literature describes 2 different ways, one being more accurate than the other. The unit that has 30 beds may have a monthly census of 150 patients. Therefore, the rate of falls for that unit is 5/150 or 3.3% of the patient fell. The unit that houses 15 patients had a total of 100 patients so that unit's fall rate is 5/100 or 5%. An even more accurate denominator is the number of patient days. Patient days are calculated by multiplying the number of patients, by the number of days each stayed. Therefore, the unit with 30 beds and 150 patients has 450 patient days, and 5 falls/450 patient days equals 0.011 falls per patient day. The smaller unit with 100 patients had 200 patient days. 5/200 means that this unit had 0.025 falls per patient day. Which unit has more falls?

Benchmarking is something that is frequently done but beware of the pitfalls related to comparing apples and oranges. Sometimes the answer is not clear and you may end up with fruit salad.

!GENERAL DATA COLLECTION METHODOLOG

Timeframes

Data can be collected in several different timeframes.

jProspectivej data collection occurs prior to care being rendered. Before a patient is accepted in a Rehabilitation or Home Health facility, someone from the receiving facility goes to the patient to assess if the patient meets the requirements for admission. For an acute Rehabilitation facility, for example, the patient must be able to tolerate three hours of physical therapy a day.

jconcurrentj data coiiection occurs while care is being rendered. Medical record review is best conducted while the patient is still receiving care. If nothing has been done, it can be corrected while the patient is still being treated. For example, AMI (Acute Myocardial Infarction) data is often collected while the patient remains in the hospital. In many organizations, this process serves as a checklist and reminds individuals to make sure the process is in place, improving data as it is collected.

jRetrospectivej data collection occurs after the care is rendered. For example, mortality data can only be collected retrospectively. Sometimes quality monitoring occurs retrospectively as a chart review to determine if there are patterns and trends in the data.

jFocusedl data collection occurs when only cert.:iin topics are the focus of the data collection. The data are based on predetermined priorities (nonprobability sampling), rather than measuring the entire population (100%). Infection control and prevention utilizes focused data collection based on the types of infections that occur in the facility. Focused monitoring occurs with predetermined, high priority (high frequency/volume, high risk, problem-prone) issues, based on previous study, mandated criteria (e.g., CMS, accrediting body), or other baseline information. Issues, processes, or even practitioners

"focused out" may require periodic measurement by the representative sampling method in order to verify that improvement is maintained or to validate current competency.

Once the time frame of the data collection is determined, the type of data collection must be selected. The data collection methods can be accomplished through the review of paper records or through an automated method such as an electronic health record. The types of data collection methods listed in Table 3 are only a sample of those which can be utilized.

Table 3: Data Collection Methods

Data Collection Methods	
Type of Collection Method	**Description of Method**
Continuous or periodic measurement	Routine, systematic collection of information over time, either concurrently or retrospectively, e.g., utilization review; tracking of structure, process, or outcome indicators (performance measures); blood or medication use reviews, etc
Targeted studies or audits	Generally retrospective, criteria-based assessments of care, using document review (or a combination of document and encounter/claims data), focusing on structure, process, and/or outcome
Service-specific studies	Based on the major services provided, functions performed, and problems identified or suspected (usually document review or check sheets/logs for processes)
Generic screening (events/occurrences/incidents)	Reporting each occurrence (retrospective) of a predetermined list of possible untoward events, typically used for actual or potential adverse and sentinel events and tracking over time for patterns/trends
Medical records	Concurrent (preferred) or retrospective review of inpatient, outpatient, emergency, home health medical records, etc.
Summary reports	Retrospective of patient and staff occurrences (incidents or critical events), clinical complications, infections, utilization, services, committees, research, organizational evaluations, credentialing, special studies
Daily logs	Concurrent review of surgical, neonatal, emergency, cancer registry, urgent care, clinic, etc.

Monthly data logs, check lists, etc.	Statistical data to be tracked over time, e.g., number of encounters/admissions, referrals or transfers, C-Sections/ VBACs, radiology procedures, deaths, newborns <500 gms, etc. Rates can also be calculated and tracked, then summarized and displayed in graph form
Financial reports	Concurrent and retrospective d.ita including case mix, claims, reimbursements, denials, costs per case, etc.
Direct observation and referral	Informal or criteria-based surveillance (concurrent) of process of care and compliance with established procedures or standards
Surveys or interviews	Patients, staff (concurrent or retrospective) written or face-to-face questions concerning perception of care delivery, outcomes, and problems
Reports from external agencies or reference databases	Retrospective data, which are usually received months after the data, has been collected

!Population & Samplin

One of the steps in developing the design of a data collection project is to determine the population to be studied and to determine if sampling is required. Unless the population is small in number, sampling **will** be utilized. The type of sampling utilized has a great effect on what can be done with the data and information obtained. The population can be static (not changing) or dynamic (changing) and this will affect the type of sampling that is utilized.

The population is defined as 100% of the possible group to be studied, whether they are individuals, objects, events and so on. Some examples of populations include:

- All cases encountered/admitted for a particular diagnosis
- All cases with a particular treatment or procedure performed
- All cases with a particular complication identified
- All physicians/licensed independent practitioners, or from a certain department or discipline
- All the patients who received care in a clinic during the month
- All cases with a particular medical device ordered

When the total population is small, such as in a small rural or critical access hospital where only 10 units of blood were transfused in a year, then all of the population (units of blood) should be reviewed.

There is power in having a larger sample size, but in healthcare, it does not necessarily make sense to wait until you have a larger number of transfused units of blood before the units are monitored. Sampling is not appropriate with very small populations. In most cases, the population is larger and sampling will need to be used.

A sample in statistics is a subset of a population or a group drawn from a larger population. The purpose of sampling is to measure only a portion of a total group or population for high volume aspects of care and service in order to achieve an accurate representation of the entire target population (such as all ambulatory patients, a specific procedure, diagnosis, DRG, or all cardiologists), and to generalize the results to the larger population based on sample findings.

In determining the type of sampling to utilize, there are several factors to consider. The first factor to consider is the characteristics of the population that the sample must represent. You want to have a sample that is representative of the characteristics of this specific population which you are studying. Another factor that must be considered is the location and time period from which the sample must be drawn. If the sample must be obtained within a short period of time, or if travel to collect the sample is prohibitive, this will affect which type of sampling is utilized. The type of sampling technique utilized must assure that the sample accurately represents the population. If you are looking at patients with Pneumonia and you only select your sample from those patients seen in three months out of the year, you are not accounting for the effects the weather and other factors that might affect these patients. The selection of a sample also must not introduce a bias. Selecting your sample to assure that your assumptions are supported is introducing a bias into the study.

There are two types of sampling: Probability and Nonprobability sampling. The names tell you whether you can generalize your findings to the population or others. Probability sampling increases the probability that the findings can be generalized to other populations. Nonprobability sampling lessens the probability that the findings can be generalized to others. In healthcare, we typically use a combination of probability and nonprobability sampling. The more probability sampling is used, the higher the opportunity to generalize the findings. Probability sampling introduces statistical techniques into the selection process, thus permitting the reviewer to draw inferences about a population. It assures that each case in the population has an equal and independent (random) chance of being selected, therefore, the final sample is "representative" of the entire population.

[ypes of Probability Sampling Techniques)

imple Random) sampling that uses a Table of Random Digits (available in all statistical software) to select the persons/cases from a list of every case in the defined population, with each case having an equal chance of being selected. This is similar to putting all the names into a hat and pulling out one name to receive a door prize. Everyone present has an equal chance of being chosen to be included in the sample .

Wtratifled Random! sampling utilizes two or more homogeneous categories or dimensions of a population and samples an appropriate number of persons/cases that are representative of the category. The studies regarding the signs and symptoms of heart attacks needed to study women and men since heart attacks appear different in each group. Equal numbers of the women and the men would be chosen randomly and then included in the study .

Wystematic Randoml sampling utilizes a system to select the sample. All of the population is !isled and then the first case is randomly selected; and then selecting every nth case, thereafter, based on standard/fixed intervals, e.g., every 5th referral to a specialist by a primary care physician in an HMO after random selection of the first case.

vTpes of Nonprobability Sampling Techniquesl

Nonprobability sampling is an intentionally-biased way to sample, involving qualitative judgment about an issue that is suspected to be common or widespread. Examination of a relatively few cases is assumed to be enough to reveal the nature of the problem and its probable causes. However, since this methodology does not include techniques to estimate the probability that each case will be included, the results cannot be generalized to the entire population without further study.

lconvenience! sampling utilizes data that is most readily available, e.g., all patients seen in the Emergency Department (ED) in a given week . If convenience sampling is utilized, the findings could not be generalized easily to patients that come to the ED at any other time.

!auotal sampling utilizes portions or percentages of persons/cases in a stratified population (subset), e.g., 10% of male patients with both diabetes and heart disease. A quota sample limits the ability to draw conclusions outside of those studied because there may be differences between those who were chosen and not chosen . In the example provided, 10% of the male patients do not assure that the entire population is similar to those selected due to the small number sampled.

IPurposiv sampling selects persons/cases/issues because they demonstrate a **desired characteristic** that can be measured against specific, predetermined criteria, e.g., all patients over age 60 with total hip replacements. Purposive sampling was utilized in the first heart attack studies, which were only conducted utilizing male heart attack patients because they came to the ED with a heart attack more often than the women. As we now know, women experience different symptoms than men when experiencing a heart attack .

!sampling Size!

There are ways to determine the necessary sample size in research, but there are no such rules for to determining the best sample size of quality monitoring and performance improvement projects. However, there are several general guidelines. In general, the larger the sample size the more

predictive the findings will become. For example, if there are 20 people in a room and you ask the first four people how many children they have, you may get answers such as zero, one, two, and one. If you were to ask the people to raise their hands if they have the same number of children (zero – one), a number of hands will go up. The small number of four people sampled usually does not yield findings that describe the entire group. However, if you were to ask ten people (50%) there should be fewer hands raised when asked if they do have more children than those that were polled. There may be one person who is different and has the highest number of children among this group.

A general rule of thumb that has been followed by many organizations is 5% or 30, whichever is greater in the population being studied . If this rule is followed, thirty records, events, etc., can be measured and deemed adequate. It is not until there is a population of 600 to choose from that 5% equals 30. How the apply the 5% or 30 rule is a matter of choice. If there is a large population to be studied every month, then 30 records a month should be audited. If there is a small population to be studied every month, then 30 records a quarter would be a better sample size. Several of the accreditation organizations, such as The Joint Commission and NCQA, have established their requirements for sample size and these should be utilized as appropriate.

Other considerations in determining the sample size and type of sampling utilized will depend on what is being studied. If licensed independent practitioners are being studied, a representative sample of the medical records of all the practitioners should be studied, which is not usually considered completely random. For example, if blood utilization is being monitored, every practitioner who ordered blood should be included in the review of the records over time.

Successive samples can be measured, an average (arithmetic mean) calculated for each sample and a frequency distribution made of these means. The data will approximate a normal distribution that is a symmetrical bell-shaped curve (See the discussion of a standard deviation later in this chapter).

If there is only one sample, then use "N" to designate that sample; if samples are taken from each of several populations or groups, use a small "n" for each sample. For example, if the total number in the sample is 50, the sample size would be represented as N = 50. If a portion of the sample are men and some are women, they would be represented as "Males n = 30", and "Females n = 20" (HyperStat, n.d.).

\Data Collection Tools!

The type of tool used to collect data will depend upon what you are trying to measure. When selecting a tool to utilize or develop, you want to keep the tool as short and simple as possible. However, you need to make sure you include all the data elements that you want to measure. The data definitions previously discussed must be considered in the selection of the tool that will be used. Computerizing the data collection tool should always be considered. This will enable the data to be analyzed easily

and decrease the chance of data entry errors that occur when someone inputs the data from paper into the computer. All tools have pros and cons you need to choose the tool that best fits your needs.

!Data Sheets/Work Sheets! are frequently utilized for extracting data from the medical record. If developing the tool yourself, you need to pilot it before it is used for data collection. If the data sheets are created elsewhere, you need to determine if extra columns or rows are required to assure you capture all of the data you need. One of the drawbacks of using this a collection tool that is on paper, is that it runs the risk of data entry errors.

!check Sheets/Tally Sheets! are other forms for recording data. These tools are designed to facilitate interpretation directly from the form. These tools are useful when you are counting something to see how often it occurs. These tools limit the detail collected to that which is listed on the forms and limits the amount of analysis that can be done with the data collected.

!surveys/Questionnaires! are frequently used to get feedback from a large group, e.g., assessment of how patients feel about the care they have received. Surveys are also used in employee and physician satisfaction measurement. An educational needs assessment is often conducted in the form of a survey. This tool is best for assessment of customer needs, expectations, or satisfaction. The survey/questionnaire can include open ended questions for the person to enter text as answers to questions. This limits the data analysis that can be done since this is considered qualitative data (see Data Types iater in this chapter). The survey or questionnaire could also utilize yes or no responses or use of a Likert scale to broaden the scope of possible answers and allow the responder greater choice in how the question is answered . One of the drawbacks of surveys is the low level of response typically received. If there is a return of 30%, the data collection is considered successful. Frequently though a smaller percentage of responses is received. While this does not negate the purpose of the data collection, the small numbers received will hinder the probability of generalizing the results. Another drawback of the use of surveys is the time frame over which the survey is distributed to the responders. The closer to the time of the experiences in question to when the survey is distributed, the greater the response will be. The method of delivering the survey (paper vs. computerized), the length of the survey, and the difficulty in completing the survey, all contribute to whethe r the survey is completed or discarded by the responder . The language of the survey must also coincide with the primary language of the responder. The surveys that are produced by companies such as Press Ganey, Gallop, and NRC Picker will have construct validity, while those developed otherw ise will only have criterion validity at best (see Validity discussion in this chapter).

A JFocu!> Groupl is frequently used to determine how a particular group of representative individua ls feels about a certain topic, product, etc. Focus groups are often utilized in qualitative studies. A focus group is used to generate ideas and help formulate interview questions to be utilized later. Focus Groups use open-ended questions to obtain qualitat ive input from those in attendance (Schmidt & Brown, 2015). Groups consist of six to twelve participants with a common interest. The persons in the

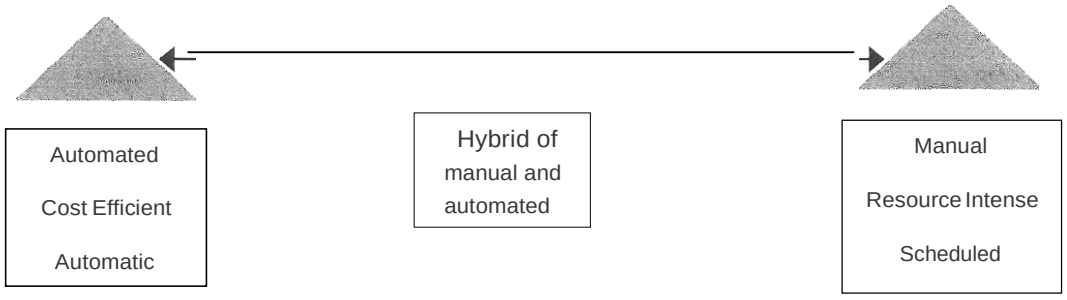
focus group should not know each other well. The researcher or data collector can act as the facilitator of the group or as an observer who listens and takes notes. A focus group is typically audio or visually recorded. There can be multiple groups that are asked the same questions in the same order in each group. Upon completion of all the groups, the responses are transcribed and reviewed and the answers given separated into groups during the analysis. Since the answers received are qualitative data, the analysis is limited, but can be very valuable. The focus group can be helpful in that it brings all the participants to one location for the data collection, and usually the participants who agree to attend are willing to voice their opinions and insights with the group. One of the barriers to the use of focus groups is that the recording, transcription and analysis can be very expensive and time consuming. In addition, since participants were purposively selected, the findings are not very generalizable.

!collection Principles and Concepts!

Data collection is a process that begins with assessing what data are needed, and whether or not it is possible to collect. If the organization has developed a data inventory, as previously discussed, this assessment will be expedited. If time and resources are scarce, one might want to start by seeing what data are available and then retrofitting the needed information to information available.

Data collection support organizational functions that require performance measures/indicators . Organizational leaders identify interdisciplinary quality teams to oversee the design of data collection methods, maximize the use of data already being collected, minimize duplication of effort, maximize accuracy, maximize the organization's computer capabilities, and coordinate data collection efforts across departments, services, and QI Team activities . The group (department, service, committee) or QI Team with the most knowledge of the process being measured will be best able to set triggers for further analysis, identify sources for data collection, and determine the most appropriate data-collection methodology . The collection methodology can be paper based, automated or a hybrid of both of these (Figure 2).

Figure 2: Data Collection Continuum



In deciding what data to collect, you need to determine what data adequately describes actual patient care provided or service rendered (point of care). In addition, it is important to use accurate measures, including, as necessary, generic screens, rate-based indicators, objective criteria, survey or interview results, and feedback from patients, families, staff, and vendors. The data must also be applicable to the specific measure/indicator that is utilized. Detailed criteria may be necessary, either to obtain adequate data for a specific measure/indicator or to provide objective evaluation of a process or pattern.

The individuals selected to collect the data will depend on the type of data being collected, their knowledge of the issues, the method of collection, and other factors. The data should be collected at a frequency and duration sufficient to evaluate effectively the care and service under consideration. For example, patient/customer satisfaction data are important measures that can change quickly, so the organization wants to make sure data are collected at least monthly, and reported and analyzed with minimal delay. Waiting for quarterly data would delay intervention and might put the organization at risk of having to "catch up." Base the frequency and duration of data collection/compilation on the number of patients affected by the care and service being measured, the degree of risk involved in the care or service and the regularity with which the aspect of care or service is rendered.

!Data Collection Process!

!coordinate Data Collection!

When it is time to collect the data, it is best to review the processes described to this point. The purpose for the performance measure should have been determined and the population of interest defined. The sampling method(s) of the population established and the measures determined (including the numerator and denominator. If you need a refresher on numerator and denominator, try the Khan Academy quick tutorial (found in the website list at the end of this chapter).

How the data are to be analyzed must be determined up front. Determine the appropriate statistical and non-statistical tools for data analysis (see Data Analysis later in this chapter). Determine how you will want to display the information obtained from the data. This will assure that all the necessary and desired data will be collected in the correct format to do the desired analysis.

Collect a baseline sample to determine the usefulness of the collection tool. This needs to be done to assure that the tool collects the required data and the ease of recording the collected data. Once the tool has been verified for this project, the personnel who will collect the data must be trained. This will assure inter-rater reliability of the data collectors and assure that the data is collected in the same manner every time (see Reliability discussed later in this chapter). If software is not used to collect the data, the personnel must be trained on how to enter the data correctly into the computer database.

!validate Data lntegrit

Once the data is collected, it must be organized and scrubbed (validated), before it can be analyzed. Many times, there are mistakes in the data, so it is important that you review the data looking. Check for obviously incorrect (out-of-range) numbers. For instance, maybe the math is done wrong and it adds up to more or less than 100%. Are the answers scored correctly? Validate a few to see.

One way to validate the data collection is to have someone not involved with the first data collection recollect data for a small portion of the sample already collected. The second collection should yield the same results as the first data collection. If it does not, then the data collected is suspect, and a larger sample should be studied. Data that are not the same on both collections should not be utilized, unless validated on a third try.

!using Excel to Validate Data Col/ecte

This is best done in an electronic format such as Excel or Access (for more information about Excel, a spreadsheet program, and Access, a database program, go to the website list at the end of this chapter). Most often, Excel is used. It is best to keep all of your data on a single worksheet. Each piece of information you have been collecting data on or variable should have its own column and correspond to just on piece of information. Do not utilize a zero if there are no data available for a cell. The zero becomes a value that will be utilized by the statistical software. Instead, be sure that there are data for every cell. If you are using numerators and denominators to figure percentages, ratios, etc., utilize two columns, one for each variable and a third column for the derived variable (percentage, ratio, etc.). If you are going to utilize codes for data, put the codes in a separate worksheet. If you think that you will remember the codes when you return to the data, you may be mistaken. You can also write notes about the data, but that should also be in a different worksheet. You should note for each variable if it is nominal, ordinal, interval, or ratio since this information might be needed for data analysis . You also need to be consistent with how you enter the data. If the data requires a 'No' response, do not use 'negative' or 'neg'. If everything is in CAPS, keep it all CAPS. If you are using UpPeR and LoWeR cAsE, keep it the SaMe. Also, assure that there are no spelling errors or typos. It is best to restrict the number of people who will enter the data, or make certain they understand the data entry standards that are being utilized. Enter the data exactly as collected and do not guess, approximate, or round up/down.

It is best to make a copy of the original data and use the copy to scrub the data. You can call the original data "original" or "raw data". To "scrub the data" means to examine the data for obvious errors. If you make a mistake in scrubbing the data, you can refer back to the original data. Table 4 lists the type of items to look for when scrubbing your data. Excel also has formulas that can be utilized to assist with cleaning the database. Make sure terms are used consistently.

Table 4: Items to Look for When Scrubbing Data

Items to Look for When Scrubbing Data
• Obvious errors as you look over the data
• Check for difference in how dates are entered
• Blank cells
• Negative numbers when there should only be positive numbers
• Positive numbers when there should only be negative numbers
• Numerator larger than Denominator it this should not be possible
• Variables expressed differently within a column
• Numbers that are greater than zero if they should not be greater than zero
• Calculate the minimum, mean, and maximum for each column looking for errors or erroneous outliers

LEGAL AND ETHICAL CHALLENGES WHEN DEALING WITH DATA

[Protected Health Information[

The Health Information Management department (which today has many other titles including Medical Records, HIM, Heaith Information Technology, etc.) has a critical role in information management. It is in this department that medical records are transcribed, coded and stored (unless the records are electronic), and all components verified and data transmitted to external agencies as required by law. There is a close relationship between the Health Information Management department, the Quality Management department, and the Information Technology department. These departments may fall under the same umbrella and report to the same department head or manager. They must work together to assure there is the required technology and software in place to meet the information needs of the organization. There are currently national initiatives that make this collaboration a necessity. The regulations and rules requiring the use of ICD-10, meaningful use of certified electronic health record (EHR) technology, and common data formats are currently driving this collaboration.

In August 2003, the Institute of Medicine (IOM) and the Department of Health and Human Services started a movement toward electronic medical records (EHR capabilities, 2003). A committee of the Institute of Medicine of the National Academies identified a set of eight core care delivery functions which the electronic health records (EHR) systems (also called electronic medical record – EMR) should be capable of performing in order to promote greater safety, quality and efficiency in health care delivery. The eight core functions of an EHR are: (1) health information and data; (2) result management; (3) order management; (4) decision support; (5) electronic communication and connectivity; (6) patient support; (7) administrative processes and reporting; and (8) reporting and

population health. This list of key capabilities was used by Health Level Seven (HL7), one of the world's leading developers of healthcare standards, to devise a common industry standard for EHR functionality that would guide the efforts of software developers. The report was sponsored by the U.S. Department of Health and Human Services as part of a public and private collaborative effort to advance the adoption of the EHR systems.

In January 2015, the Office of National Coordinator for Health Information Technology of the Department of Health and Human Services released a report called *Connecting Health and Carefor the Nation, A Shared Nationwide Interoperability Roadmap* for achieving EHR secure information exchange and use of EHR's in healthcare systems (ONC, 2015). This report focuses on actions that need to be taken to enable individuals and providers throughout the continuum of care to send, receive, find and use a common set of electronic healthcare information nationally by the end of 2017 (Conn, 2015). The common data sets consist of 20 basic elements including patient demographics, lab test results, and identifiers for a patient's care team members. The plan also includes a call for both the government and private sector to provide additional incentives for interoperability.

Common Formats

In 2005, the Patient Safety and Quality Improvement Act (Patient Safety Act) and the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) (PSA, n.d.) authorized the use of common formats for information so that patient information can be sent from one computer system to another. This is different from meaningful use in that this encompasses the entire electronic patient record and not just certain quality measures. The common format was specifically developed for use with Patient Safety Organizations (PSO) and adverse event reporting. The common formats were developed by the Agency for Healthcare Research and Quality (AHRQ) for use in acute care hospitals and nursing homes. The common formats are divided into two categories: generic formats that apply to all patient safety events; and event-specific formats that relate to certain high-frequency event types. These include patient safety events that reached the patients (incidents), patient safety events that did not reach the patient (near misses), and unsafe conditions that increase the probability of a patient safety event occurring (PSA, n.d.).The Common format is currently utilized in the hospital and long-term care facilities.

These common formats include common definitions (as defined by the National Quality Forum) and reporting formats to allow the PSOs to obtain data concerning adverse events from multiple settings, and then utilize the large sample of information to determine trends, patterns of care and best practices in the participating organizations . This format will allow the aggregation of data that has to be de-identified (organization and patient information removed from the data) in order to determine new opportunities for safety improvements, increase healthcare practitioners working together in such initiatives, and to help with the understanding of how to improve patient safety (Common Format, 2017).

The event-specific formats currently include Blood or Blood products, Device or Medical/Surgical Supply, HIT, Falls, Healthcare Associated Infections, Medication or other Substance, Perinatal, Pressure Ulcer, Surgery or Anesthesia, and Venous Thromboembolism. Other common formats are being developed and are open for public review and comment at the NQF website.

!Health Information Exchange (HIE)!

Health Informc1lion Exchange allows both health care professionals and patients to appropriately access and securely share vital medical information electronically. Practitioners can share the results of a visit with the patient and the patient can access their medical record from the computer in their home. Hospital, clinic and other such records can be shared in the same manner. Sharing of the medical record through a secure connection allows for better decision making at the point of care, and allows providers to avoid readmissions, avoid medication errors, improve diagnoses, and decrease duplicate testing. Where one practitioner used to have to fax lab results to another practitioner treating the patient, results can now be accessed through a health information exchange. There are currently three key forms of health information exchange:

- Directed Exchange – ability to send and receive secure information electronically between care providers to support coordinated care
- Query-based Exchange – ability for providers to find and/or request information on a patient from other providers, often used for unplanned care
- Consumer Mediated Exchange – ability for patients to aggregate and control the use of their health information among providers

These exchanges provide a method for improving quality and safety of patient care by reducing medication and medical errors, stimulating consumer education and patient involvements in their own health care, increasing efficiency in documentation management, eliminating redundancy, improving public health reporting, reducing health related costs, and many other factors. Health Information Exchanges are currently operating in many states including Maryland, Colorado, Delaware, Massachusetts, New Hampshire, Maine, Pennsylvania, Indiana, Missouri, Utah, and others.

!E Medical Record!

The medical, clinical, or health record is the primary legal document, as well as the primary data source (either electronic or paper) for recording and ascertaining the quality of healthcare delivery to patients. The purpose of the medical record is multifold. The medical record provides for: continuity of care: communication among practitioners; legal protection for the patient, practitioner, and the organization; and data/information for quality/performance measurement, assessment, and improvement. It also confirms the identity of the patient, supports the diagnosis and justification of need for treatment, documents the course and results of treatment, and is used to determine the reimbursement rate and justification of claims.

The contents of the medical record must be sufficiently detailed and well-organized to enable the practitioner responsible for the patient to provide continuing care to the patient, know the condition of the patient at a specific time, and review the diagnostic and therapeutic procedures performed and the patient's response to treatment. The medical record documentation is where a consultant will render an opinion after examination and review of the medical record. Other practitioners use the information in the medical record when assuming the care of the patient at any time. The information in the medical record is also used for the retrieval of pertinent information required for utilization and quality management activities.

The type of facility where the patient is receiving care determines the exact contents in the medical record. The patient in a clinic will have different content than one in a hospital setting, long-term care facility and so on. In many facilities, the documentation in the medical record is driven by some form of accreditation and/or licensure. The Centers for Medicare and Medicaid Services (CMS) has laid out required content for organizations that treat Medicare and Medicaid patients. Accreditation organizations and the type of facility drive the need for certain types of documentation. The documentation in a rehabilitation facility and an outpatient behavioral health facility will be different based on the type of patients that utilize those services . There are, however, some common elements in all medical records . A history and physical examination, laboratory and radiology reports, progress notes, discharge information and other items are usual common items.

The medical record is used as a monitoring or review tool in the electronic or paper format. The medical record review is best accomplished in a concurrent manner while the patient is receiving services from the organization. With concurrent review, items that have been missed can be completed and any over use or under use can also be remedied on the spot. Concurrent review is often used for Core Measures and reviews where the data will be sent outside of the organization and aggregated by others then analyzed. There are cases when prospective and retrospective reviews are useful. When a patient is discharged from a hospital setting and going to a rehabilitation or home health setting, an individual from those settings comes to the hospital and reviews the medical record prospectively to determine if the patient is a candidate for rehabilitation or home health services. Monitoring for mortality review obviously cannot be done concurrently and is an example of when retrospective monitoring is appropriate. Both concurrent and retrospective monitoring are commonly utilized in research studies. The content that is reviewed depends on the type of information being monitored. This will be discussed later in this chapter.

!confidentiality and Security of Patient Information!

Confidentiality in healthcare deals with the patient's personal right to privacy and with the need for the organization to maintain the confidentiality of all information pertaining to !peer review!. In addition, the measurement and analysis of the quality of patient care provided by licensed independent practitioners is held in a secure and confidential manner.

lcon[identia/ lnformationl is information that one keeps or entrusts to another with the understanding that it will be kept private and not shared. Webster defines confidential as secret or private; trusted with secret or private information (Confidential, n.d.). An example of confidential data is your Social Security number. You give it out as needed, but it can under certain circumstances become discoverable by others.

!Protected Information! is information that cannot be obtained by others or used in a court of law. Webster defines protected as to cover or shield from exposure, injury, damage, or destruction . At times in healthcare, this type of information is called privileged information. Webster defines privileged communications as those statements made by a client to his counsel, attorney, or solicitor in confidence. Such communication cannot be disclosed without the consent of the client (Privileged Communication, n.d.). The amount of protection given to patient specific quality information has become less clear with the advent of collaborative QI, since the emphasis is on total organizational involvement in the process, involving the sharing of pertinent information so improvement can be made and sustained. In addition, QI adds the dimension of improving services that are nonclinical and administrative (governance, management, and support processes). It is very likely that courts of law will not agree that state "evidence codes" protect such information from legal discovery. \Peer reviewl data (see Chapter 3 Performance and Process Improvement for more information on Peer Review) is protected data, but state regulations have weakened the protection afforded in some states such as California and Florida.

It is the intent of every healthcare organization to prevent unauthorized access to individually-identifiable health information. Individually-identifiable health information is any information that can be tracked back to an individual patient. The Health Insurance Portability and Accountabi lity Act of 1996 (HIPAA), Sections 261-264 ("Administrative Simplification" legislation), requires health plans, providers, and healthcare clearinghouses ("covered entities") that transmit any protected health information (PHI) electronically, to protect the privacy and security of health information. A primary principle of HIPAA is that it is unlawful to use patient information in ways that are inconsistent with the patient's original authorization. With that said, the law does permit both use and disclosure for treatment, payment, or health operations, as long as the privacy of the information is maintained and use or disclosure is limited to the "minimum necessary" to accomplish the intended purpose (HIPAA, 2017).

In general, HIPAA requirements that impact most healthcare entities in the U.S. include, but are not limited to: ensuring the confidentiality, integrity, and availab ility of all electronic protected health information (ePHI) that the covered entity creates, receives, maintains, or transmits; protection against any reasonably anticipated threats or hazards to the security or integrity of ePHI; protection against reasonably anticipated uses or disclosures of ePHI not permitted under the HIPAA Privacy Rule; and to ensure compliance to these rules and regulations.

The HIPAA regulations concerning privacy and security add both clarity and complexity to the handling of patient information. The HIPAA "minimum necessary" rule means that, access to "protected health information" (PHI) is to be limited to those persons or classes of persons who have a need to know in order to carry out their roles and responsibilities; and for each person or class of persons, the organization must identify the category or categories of information to which access is needed and conditions appropriate to such access.

In October 2017, the HHS Office for Civil Rights clarified that HIPAA regulations allow health professionals to share health information with a patient's loved ones in emergency or dangerous situations. The patient's loved ones should be informed as they are crucial to preventing or lessoning serious events and imminent threat to patient. Healthcare workers misunderstandings to the contrary persist and create obstacles to family support that is crucial to the proper care and treatment of people experiencing a crisis situation, such as an opioid overdose. Health care providers have broad ability to share health information with patients' family members during certain crisis situations without violating HIPAA privacy regulations {HIPAA-Opioid, 2017).

Well-defined policies must be in place regarding the use and disclosure of medical information, encompassing all patient-identifiable record systems maintained within the organization. These systems generally include the medical record, as well as abstracts, studies, registers,etc.,in any form, e.g., paper, electronic, audio, or Internet. It is a HIPAA requirement that with psychiatric cases, psychotherapy information is maintained separately and made available as necessary. While it is not a HIPAA requirement, often, the electronic and other media files from radiologic exams and other such studies are not kept in the medical record, but should be considered a part of the medical record.

The provider is responsible for safeguarding both the record and the informational content against loss, defacement, tampering, and unauthorized use. Written policy must stipulate just how the provider complies with state statutes and accreditation standards. The patient is considered the "owner" of the information in the U.S. and can access and copy that information by signing a release form. HIPAA and laws in most states recognize the patients' reasonable right to access, inspect, and copy their health information. The organization's policy should address the release of records to patients or their representatives. The HIPAA privacy regulations give patients access to their health information, the right to amend (add corrections, but not delete) their medical records, and the right to a rewr u of disclosures of their information.

!consent and Use of Patient Information!

In most healthcare settings in the United States, patients give advance written consent (assent; agreement) when registering, for medical and surgical treatment, and for release of information for payment even though such consent is optional under HIPAA. The consent for others to view the patient's medical records for medical and surgical treatment includes the provision, coordination, or management of healthcare services by one or more providers, consultation between providers, and

referrals from one provider to another. Consent also typically includes the release of sufficient medical information to the payer to assure payment (including information necessary to confirm benefits entitlement) establish the necessity for treatment, and validate orders and charges.

)tnformed Conseng

In addition to the consent and use of patient information discussion above, patients are also required by law to be well informed concerning the care they receive. Adequate information is provided to the patient or legal representative in order for the patient or legal representative to make a rational, informed decision to permit medical-surgical treatment. The patient is free to reject recommended treatment . The law in most states in the U.S. requires that consent must be obtained from the patient or from a person authorized to consent on the patient's behalf before any medical or surgical procedure can be performed. Touching a patient without authorization to do so may be considered a legal wrong called a "battery." Certain exceptions apply in emergency situations.

Two types of consent forms should be obtained: a general admission or treatment consent, as applicable (information provided by the organization, but not necessarily by the practitioner); and a special consent form for highly technical testing, medical, or surgical treatment (information provided by the practitioner). The exact requirements for informed consent for the testing or medical/surgical treatment varies by state.

The principles supporting informed consent stem from the patient's right of self-determination espoused in the 1972 court case, *Canterbury v. Spence* (See Chapter 7 Legislation Initiatives). In this case, a 19-year-old male was experiencing back pain. When medications did not control the pain, Mr. Canterbury went to the hospital to have a laminectomy performed by Dr. Spence. After surgery, the patient was fine on the first post-op day until he fell getting out of bed in the hospital, and was paralyzed from the waist down. Mr. Canterbury stated that Dr. Spence never informed him or his mother that the surgery could result in paralysis. Following the lawsuit and appeals, it was determined, that Dr. Spence and the hospital were at fault for not disclosing all the possible information about the risks connected with this surgery. In 1975, the Patient's Bill of Rights was published by the American Hospital Association, which included the patient's right to know information vital to participating in making his or her own treatment decisions (Canterbury, n.d.).

Information for special procedures must be provided by the practitioner performing the procedure and must include the full extent of the treatment plan; the extent of the side effects and risks involved; alternative treatments available; and the risks of non-treatment. To constitute proof of consent a written consent must contain certain elements. These elements include: (1) the exact name of the procedure for which the patient is consenting; (2) the consenter's understanding of the nature of the procedure, alternatives, risks and benefits involved and the probable consequences of non-treatment; (3) the date of consent; (4) the patient's signature prior to the procedure, and the signature of a witness. There may be different requirements established by individual states, so more information

than this may be required. The procedures that require consents are also established by individual states.

Such written consent may or may not be obtained in primary and specialist care office practices. Patients give separate informed consent prior to performance of specific surgical, radiological, and other invasive and high-risk procedures.

llnternal Usel

Generally, written authorization by patients is not required for use of the patients' personal health information by the provider organization. The consent for treatment completed at the time of registration provides the consent for PHI access for many internal activities. Because of HIPAA, standard practice in the U.S. is to provide the patient with a "Notice of Privacy Practices", to inform them of possible intended uses of identifiable health information and their right to restrict use or disclosure, and to get a written acknowledgement of receipt of the Notice, if possible. A notice of this information is often posted in a prominent location in the facility. Table 5 lists who and when PHI is utilized in healthcare organizations without the specific written authorization of the patient. Most organizations require a signed Confidentiality Agreement from all employees, as well as from designated committee members and individual licensed independent practitioners who are involved with reviewing medical record information and/or participating in clinical quality management activities. All information about these activities must be screened to be sure that legal mandates and organizational policies concerning confidentiality and "minimum necessary" access are followed.

Table 5: Internal Use of PHI Without Specific Written Authorization

Internal Use of PHI Without Specific Written Authorization	
Allowed Access to PHI Without Patient Authorization	**PHI Utilized in These Healthcare Functions**
Governing body, and designees, to ensure quality of patient care	Quality, patient safety, accreditation, PI, utilization, and risk management, including case management and care coordination
Chief Executive Officer (CEO)	Competency assurance activities, e.g., staff performance evaluation, Licensed Independent Practitioner (LIP) credentialing and reappraisal, and jpeer reviewl
Physicians and healthcare personnel involved in the care	Infection surveillance and control
Chiefs of clinical services and clinical department directors, along with designated committees, for performance measurement and/or individual performance evaluation, including lpeer reviewl	Patient safety

Duly appointed committees/QI teams of the organization, in determining the quality of care and requisites for accreditation, and all support staff	Education of patients' families
Health information management/medical record personnel	Other auditing, legal, insurance, business, and general administrative activities
Designees of the CEO as needed reearding legal and risk management concerns or health services planning	

)External Us

Written authorization (permission) by the patient or his/her legal representative is required for release of medical record information (all "protected health information") in individual-identifiable form outside of the organization that is responsible for the record, unless permitted or required by law or regulation. The HIPAA Privacy Rule requires a valid "Authorization to Disclose" for all protected health information, except as otherwise permitted in the privacy rule as described in Table 6. Each Authorization to Disclose must contain at least the information provided in Table 7.

Table 6: Written Authorization is Not Required for External Disclosure of PHI

Written Authorization is Not Required for External Disclosure of PHI
• Pursuant to law or statutory regulation, e.g.: - Reporting of communicable diseases, births, deaths, etc. - Disclosures to the Department of Health and Human Services (DHHS) to enforce HIPAA, e.g., investigating complaints regarding preventing access oi improper use of patient information for marketing - Fraud and abuse detection and compliance
• To medical personnel to the extent necessary to address a genuine medical emergency
• Permitted under certain circumstances for the conduct of research
• To other covered entities or providers for treatment, payment, or healthcare operations when the recipient has a healthcare relationship with the individual
• To share health information with a patient's loved ones in emergency or dangerous situations such as Opioid abuse

Table 7: Authorization to Disclose - Core Elements

Authorization to Disclose - Core Elements
• Specific information to be used or disclosed
• Identification of person(s) or class of persons authorized to use or disclose the information
• Identification of person(s) or class of persons to whom the use/disclosure is made
• Description of purpose(s) of the requested use or disclosure (or "at the request of the

individual" if patient-initiated)
- Expiration date, event, or statement related to purpose for use or disclosure
- Signature of individual and date (if legal representative, description of authority)
- Right of individual to revoke the authorization in writing and procedure
- Whether covered entity will or will not alter treatment, payment, enrollment, or eligibility of benefits
- Statement of possible re-disclosure by recipient without federal privacy protection

!Meaningful Usej

Meaningful use is a qualification in order to receive federal funding for health information techno logy . Implementing provisions of the American Recovery and Reinvestment Act of 2009 (Recovery Act), the Medicare EHR incentive program was designed to provide payments to eligible professionals (EPs), hospitals, and critical access hospitals (CAHs) that are meaningful users of certified EHR technology. The Medicaid EHR incentive program provides incentive payments to eligible professionals and hospitals for efforts to adopt, implement, upgrade or meaningfully use certified EHR technology (Meaningful Use, 2017).

Meaningful Use (MU), in a health information technology (HIT) context, defines minimum U.S. government standards for using electronic health records (EHR) and for exchanging patient clinical data between healthcare providers, between healthcare providers and insurers, and between healthcare providers and patients.

There are three parts of the meaningful use portion of this act:

1. Using certified electronic health records in a meaningful way such as e-prescribing
2. Using certified electronic health record technology to electronically send and receive health information to improve quality of care
3. Using certified electronic health records technology to send clinical quality and other measures to required organizations

In order to accomplish these parts of meaningful use, the Office of the National Coordinator for Health Information Technology developed and issued *Standards and Certification Criteria for Electronic Health Records* (CEHRT). These have become the standards and certification criteria which met for with meaningful use certification.

Hospitals and clinical practices are required to utilize electronic health records and to have their technology certified for meaningful use. This requirement includes hospitals that are paid under the Inpatient Prospective Payment System (IPPS), Medicare Advantage hospitals, and Critical Access hospitals (CAH), as well as children's hospitals, physicians,dentists, chiropractors, nurse practitioners,

certified mid-wives, and physician assistants. The requirements for hospitals are different from those for practitioners, but similar in intent.

Meaningful use is divided into three stages. Stage 1,which began in 2010, focused on promoting adoption of EHRs. Stage 2, finalized in late 2012, increases thresholds of criteria compliance and introduces more clinical decision support, care-coordination requirements and rudimentary patient engagement rules. Stage 3, focuses on robust health information exchange as well as other more fully formed meaningful use guidelines introduced in earlier stages. All three stages have been updated after the dates mentioned above. Stage 3 was finalized in October 2015. Healthcare providers can only prove compliance with meaningful use while using government-certified EHR technology, CEHRT, mentioned above. Meaningful use criteria for healthcare providers are written by CMS, with input from the Office of the National Coordinator for Health IT (ONC). EHR vendors, however, get their systems certified under rules written by the ONC, which currently are updated yearly. Some years CEHRT rules are voluntary, in other years they are mandatory (Meaningful Use, 2017).

The reporting of compliance began in 2011. Hospitals and practitioners have to attest to fulfillment of criteria established for each stage of meaningful use. There are three stages of compliance where the measures established must be attested. Hospitals and providers must achieve meaningful use under the Stage 1criteria before moving to Stage 2, and meet Stage 2 criteria before moving to Stage 3. The CMS, in August 2017, has moved the requirements for hospitals to meet Stage 3 requirements until 2019.

On November 4, 2016, CMS established the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (see Chapter 3 Performance and Process Improvement). MACRA includes the Merit-based incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models. The new MIPS program is for certain Medicare-enrolled practitioners and it consolidates components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare EHR Incentive Program for Eligible Practitioners. The Medicare EHR Incentive Program replaces the meaningful use rules discussed above for physicians. MIPS focuses on quality – utilizing a set of evidence-based, specialty-specific standards and practice based improvement activities, cost, and use of CEHRT. MIPS was developed to support interoperability and advanced quality objectives in a single, cohesive program for practitioners that avoids redundancies (CMS-Physician, 2017).

ICD-10

The ICD-9-CM (Clinical Modification) coding scheme has been used in the United States since 1979 . Since that time, many things have changed in healthcare. The ICD-9-CM coding scheme no longer is clinically accurate so the ICD-10-CM (U.S. diagnoses) coding scheme was released on October 1, 2015. The release of the ICD-10-CM coding scheme had been delayed twice. However, the ICD-10 coding

scheme, developed and published by the World Health Organization (WHO), has been used in most other developed countries for morbidity applications for years (ICD-10, 2017).

All healthcare organizations that are required to adhere to the Health Insurance Portability and Accountability Act (HIPAA) must convert to ICD-10-CM. The diagnostic codes have been adopted for all healthcare settings and their use with HIPAA. In ICD-10-CM a "provider" is defined as a physician or any qualified health care practitioner who is legally accountable for establishing the patient's diagnosis. The ICD-10-CM/PCS codes will be updated annually each October (ICD-10, 2017).

The ICD-10-CM coding system has several distinct advantages over the ICD-9-CM coding scheme. In the ICD-10 -CM coding, there are 69,823 codes compared to 14,035 ICD-9-CM codes. The ICD-9-CM codes are five characters long and all numerals. The ICD-10-CM codes are up to seven characters of letters and numbers. These additional codes are relevant to ambulatory and managed care encounters . They allow for sub-classifications, laterality, greater clinical detail, increased level of specificity, and a more specific code assignment. The ICD-10-PCS (Procedure Codes) are for hospital inpatient procedures only. They do not affect the Current Procedural Terminology (CPT) codes for the outpatient procedures.

The World Health Organization offers ICD-10 training materials online. The website can be located in the web list at the end of this chapter. This training can be used for self-learning or classroom education . The site includes a User Guide, Full ICD-10 training modules and the Cause of Death Certificate Version. The website also provides a link for interaction with a group of specialists.

Once the transition has occurred, there are implications for the resulting data and on quality measures. ICD-10 codes can impact the quality measures utilized in the Meaningful Use eMeasures. Definitions of certain indicators will change with the revision of the coding system. Examples of changes include fractures, pressure ulcers, and myocardial infarctions. In ICD-9 fractures were considered only in the sense that one happened. In ICD-10, laterality and specificity of the type of encounter are now coded. Pressure ulcers in ICD-9 had two codes: location of the ulcer (only 9 locations to choose from) and the stage of the ulcer. In ICD-10, location and stage are combined into a single code, and additional codes address laterality and other information regarding Stage 3 and 4 ulcers. Myocardial infarction was coded in ICD-9 as acute if it had duration of eight weeks or less. With ICD-10, the time period was reduced to four weeks or less, and other codes are added to indicate if a second acute infarction occurred within those four weeks (ICD-10 – Quality, 2017).

Annual additions and/or changes in definitions and the addition of new codes will make it difficult to compare data for a while after implementation of ICD-10. Some of the data will not be compatible with data obtained through JCD-9 coding. Users of data must be trained to understand the differences, so that the information is not misinterpreted during analysis and reporting. Changes will affect both internal and external data. The Quality practitioner should examine the effect that these changes in

definition and coding specificity will have on data the organization is currently collecting. Those who are going to collect data must also be educated as to how their data collection plan needs to change with this implementation.

Indexes

Indexes are permanent collections of medical record data required by state laws. They refer to collections of different types of data based on specific topics. The Indexes are used to locate cases for record maintenance, statistics, and research. Think of the old paper card indexes used in libraries. By looking at a paper card index, you could determine the location of the book you were looking for. In the current library environment, many of these Indexes are maintained on a computer instead of on paper.

Healthcare uses a number of different indexes, but the most common one is the Master Patient Index (MP!). This is a permanent file of all patients seen in the organization, with dates, names of the attending physicians, and medical record numbers. The Master Patient Index is considered the most accurate index of patient information in most organizations.

Other common indexes include the Physician Index, Disease index, and Surgery Index. The Physician index lists cases attended by individual physicians and are maintained for a minimum of ten years. The Disease Index contains the principle and some secondary diagnosis codes with individual patient information and it is also maintained for ten years. The Surgery Index contains the principle and some secondary procedures in a manner similar to the Disease Index.

Registers

Registers are the permanent chronological listings for maintaining certain statistics. A common Register is the Emergency Department Register listing each patient who came to the Emergency Department for treatment, the order of arrival, and other information about the patient. Information contained in this type of register would be the patient's identification, medical record number, diagnosis, tests performed, name of physician who saw the patient, and the discharge site (whether it was at a home, an outpatient setting, admission to a hospital, or some other location).

Other Registers that are commonly used in healthcare settings include, but are not limited to: patient registers for inpatients or outpatients; Deaths/Autopsies/Coroner's cases/Fetal deaths; births; deliveries; Surgical/Procedure logs; Cancer and other disease registers; and medical device implant logs (mandatory under the FDA).

These registers are useful in the studying of diseases and disease prevalence. Registries have been shown to lead to improved health outcomes and reduced costs of health care. For example, if a physician in a private practice keeps a registry of patients with chronic diseases, the data obtained

from this registry can be aggregated by disease and the most effective interventions could be identified. If there is a multi-practitioner practice, then the outcomes of patients with a specific disease could be compared between practitioners and the best practice among these practitioners could be identified. This examination of such data could lead to improved care for all the patients in the practice with that particular disease. In a study by Stefan Larsson (Anonymous, 2011) described in the editorial section of The Lancet, a registry for cystic fibrosis in Sweden was reviewed. This registry is estimated to have averted about 500 patient years of Pseudomonas infection and a cost of $230 million from 2000 to 2009. This cost savings accounted for about 2% of the total costs for care of cystic fibrosis.

Information Technology and Systems

An information system is the sum of all manual and/or automated systems . These systems are designed to provide and coordinate information that can be used in decision-making. Manual information systems have been utilized in healthcare settings, but the current movement is to automate the process into the electronic health systems to meet the needs of the organization. Health records, billing and charge records, medical record coding, surgery data, admissions data, infection data, and other vital information are all being computerized. Over the past ten years, the United States government has passed laws, rules and regulations that encourage healthcare entities such as hospitals, long-term care facilities, and practitioner offices to implement computerized information systems .

The goal of this movement is to encourage use of integrated electronic information systems that link quality, utilization, risk management, patient safety activities and infection control data with existing patient, clinical, management, and financial databases. Eventually these systems will allow for the flow of information not only within a facility, but also to other facilities and organizat ions, including the federal government, insurance companies, and research databases. There are a number of health systems have an electronic medical record that all acute hospitals within that system utilize. There are many differences in the programs used by different departments. For example, inpatient-nursing records may be housed in one system, while operating room and emergency room records, physical therapy treatments, and pharmacy data may be housed in another system.

Unfortunately, most of these systems do not yet allow transfer of patient information to other acute care hospitals, nor do they allow information to flow throughout the particular facilities. All of this is changing, but not rapidly enough.

Information Management Functions

The information management function is shared by all entities of the organization. Typically, this is spearheaded by the Information Systems Management department and the Health Information Management department (which used to be called the Medical Records). In organizations that are highly automated, the oversight of the maintenance of the systems may fall under a Chief Information

or Technology Officer. Information Management may or may not include clinical people. In addition, due to the inclusion of financial information, this area often falls under the purview of the CFO.

Framework for Enterprise Information Management

Information management is a dynamic process. There are a number of key elements that need to be included. They are laid out in the following table that comes from AHIMA, the American Health Information Management Association. Table 8 lists the latest, though still evolving, characteristics and functions of Health Information Management (HIM) in an enterprise information management environment.

Table 8: Health Information Management Roles

Health Information Management Roles		
Information Building Blocks	**EIM Goals**	**Key Functions**
1. Information Integrity	To continuously improve the value of the information asset by ensuring that data and content are accurate, reliable, up-to-date, consistent and "fit for use"	• Architecture, definitions, and relationships, including metadata • Data accuracy audit, structured and unstructured data • Data provenance or lineage • Error correction/amendments • Interface and upgrade assurance
2. Information Use	To correlate and cross-reference data and content requirements to the range of clinical and business needs and ensure that those who rely on information have the requisite tools and skills to use it effectively	• Clinical applications • Quality measurement and improvement • Patient access • Information exchange • Business applications • Research and secondary uses
3. Confidentiality and Protection	To ensure that personal health information and business information are available only to authorized persons and used only for authorized purposes and that security risks and vulnerabilities are proactively managed	• Access controls • Confidentiality/privacy • Security • Authentication • Business continuity • Audits of compliance

4. Life Cycle	To develop a common understanding of the life cycle of patient medical record and other key business records and explicit plans and processes for their retention and disposition, accounting for clinical and business needs and legal and regulatory requirements for creation and maintenance	• Retention policies and practices • Disposition policies and practices • Audit of records, clinical and corporate
5. Information Governance	To ensure that the organization has the leadership and organizational structures, policies, procedures, technology, and controls for enterprise information management that represent the highest standards for legal, ethical, and business practice serving patients and stakeholders and advancing the public good	• Transparency of policies, procedures, and standards • A culture of ethical stewardship • Compliance with applicable laws, regulations, other requirements • Enhance the value of managed information assets • E-discovery

Adapted from Kloss Strategic Advisors LTD (Retrieved from Dimick, 2012)

Within the next 5-10 years, information management will take on a new approach. Linda Kloss (2013) for the Iron Mountain Incorporated predicts that the next generation for information management and governance will (Kloss, 2013):

1 View information as an asset that must be deliberately managed
2 Encompass patient records and other clinical and business data, information and records, files, and reports
3 Put in place and continuously improve on the component functions reflected in the model
4 Encompass the life cycle of information and records
5 Be guided by effective governance and stewardship values and policies, focusing on getting it right where it matters most
6 Strive for measurable and sustainable improvement

!computerization & Software Selection and Implementationl

Computers and automation have been utilized in healthcare for many years, but it has been only in the last 15 years or so that the automation has moved into the arena of bedside care. Computerization has been utilized in finance and administration, but the electronic health record has brought this technology to patient care. It is now more important than ever that all the members of the healthcare team be involved in the selection of computer systems and software programs for the organization.

There are multiple aspects of selecting a computer system and software for use in the organization. It is not a process to be undertaken quickly and requires a team effort to assure that the computer system and software are applicable and usable with the information system already in use in an organization. All parties who could be affected by the choice should be represented in considerations of the appropriate equipment and software for the organization.

An automated information system should organize data sources in useful formats. The user inputs data that is then manipulated by the computer software . The output of the data must be in a format, such as Excel, that can be easily utilized by the requester of that data. Integration of data from several sources is also important. For example, it may be necessary that data from the medical record and the billing software be combined . There should be a short time between data collection and report availability. The closer to the point of collection that the data is used, the more meaningful it will be. Programs must also be written to condense information to allow meaningful analysis. Too much information can slow or even prohibit decision-making .

One of the challenges when choosing automated systems is that, as much as a number of departments think they "own" the system, it is the responsibility of the leaders of the organization. For instance, the Pharmacy system is important to the Pharmacy, the Chief Information Officer, the billing department, the clinical users including nurses, doctors, a_ llied health professionals, the compliance department, those who review recalls, materials' management, the quality department, medical records, infection control and risk management, and those who credential practitioners. If the system is selected without the input of these areas, problems can be expected. Ideally, senior leadership should mandate that all players who may be involved in the input, throughput or output of the automated system be present at system acquisition discussions.

There are several key issues to be considered in selecting a computerized quality management system. The present performance and future computer needs of the organization-wide quality strategy should be the starting point for discussions. If the organization is part of a larger healthcare system, there may be a need for all the facilities to utilize the same quality management system so that the data can easily be shared. Senior leaders of the organization will also have strategies and concerns that must be incorporated into the decision making process.

Financially, the cost/benefit and cost/effectiveness analysis of purchasing commercial software versus developing the software in-house using available business and database packages must be considered by the senior leaders of the organization. If commercial software is purchased, the software company will maintain and provide updates to the software. However, if the software is written in house, it may better meet the needs of the organization, but then the organization must maintain and update the software. Other important financial issues to consider include data storage (both on-site and off-site), data back-up, and system downtime to make the necessary updates. The organization must also consider the computer knowledge, capability, and training needs of staff. This will influence the choice of software.

In this discussion; consideration of selection of a computerized quality management system is the example. The same issues apply to the selection of any computerized system. The quality management system does not stand alone, but is linked to the other software systems in the organization. Depending on the type of healthcare facility and the capabilities of the organization, necessary elements of a quality management information system may include coordinated monitoring, analysis, and improvement processes, including performance measures/indicators, criteria, screen selection, as well as data collection.

!Evaluating and Selecting Software to Support QM/Pli

Software to meet organization-wide quality/performance improvement needs varies tremendously in terms of capabilities, comprehensiveness, and price. The process required to appropriately evaluate organizational needs and priorities, evaluate the many varied software products as to their adequacy and applicability in meeting specified needs, and then determine whether and what to buy, takes time, energy, and a team approach. This selection process is organized in six steps consisting of: (1) obtaining a commitment from senior leadership, (2) selecting a team, (3) identifying system requirements, (4) evaluating potential vendors, (5) evaluating and selecting the software, and (6) negotiating a contract. While it is usually a team of organizational leaders and departments that select the software and computer equipment necessary, the quality professional must be involved in these processes, if the system being selected is a quality management system.

The requirements of system features are extremely important to consider. In one organization, a new CFO wanted to purchase a new billing software system. The CEO gave him permission to do so, and the CFO purchased the system. Once it was installed however, it was discovered that the software would not communicate with the laboratory software, the pharmacy software, and multiple other software utilized within the facility. There was not a team effort in the selection of the software, and as a result, the facility did not have a functioning information management system.

Organization issues which are unique to a quality system management software selection include an assessment of the current automation of the various users, such as the number, types of computers, locations, and the ability of them to interface with each other and with any new software. Overall

information system goals and needs must be identified. It is best to look toward an organization-wide, comprehensive, fully-integrated database and reporting system. Real or perceived barriers to implementation of an integrated or interfaced system need to be identified for: Quality, Case/Utilization, Risk Management operations; performance measurement; case review; medical/professional staff management and credentialing; and data/information exchange, analysis, and reporting. Current and future data and report needs must be identified. Corporate requirements or proposed system upgrades/changes should also be determined.

User needs include the need for real time/timely, accurate information, and ease of system use. This information can be identified through questionnaires/checklists, specific user group sessions for brainstorming, and "Wish lists". These user needs must be prioritized as essential, desired - but not required, or as optional (the nice extras). Table 9 lists items to consider in the evaluation of necessary system features.

Table 9: System Features to Consider in Selecting Software

System Features to Consider in Selecting Software
1) Ability to use current hardware
2) Ability to interface with current software
3) Ability to download information from a mainframe or cloud
4) Ability to permit easy/timely access to information by specified users
5) Ability to integrate, process, and produce reports as required or desired (without requiring a programmer)
6) Flexibility in changing indicators, criteria, screens, data collection method, report formats, etc.
7) Statistical data analysis
8) Graphic and tabular data display
9) Capacity to network personal computers or terminals in all locations
10) Potential for interface with severity systems and other mandated systems
11) Data storage and data exchange capabilities
12) Electronic (Web-based) capabilities for operational and clinical decision support
13) Human Factors issues
14) Ease of use

!Evaluate Potential Vendors!

Vendors who have software that meet the requirements discussed above must be carefully evaluated based on satisfactory performance with other organizations, product history and implementations, product, maintenance, education and training of users, help desk response time, and upgrade service capabilities .

!Evaluate and Select Softwarel

Based on a comparison of each product against the identified organizational requirements, comparison of vendor software products against those requirements will take place. Decide in advance which specifications cannot be compromised and what is the time frame for development and installation necessary for project success.

Often a Request for Information (RFI) will provide an initial way to compare vendors, as will an internet search, contacts with colleagues at similar organizations, and attendance at conferences. The team must develop clear, objective criteria for software evaluation. They must also compare potential software with respect to, the ability to meet requirements, compatibility with existing and desired hardware or other software, cost (purchase price, maintenance fee to vendor, and internal cost of implementing, deploying, and maintaining) and extent of service.

Representatives of the team should conduct enough site visits in similar institutions with the software already in place to evaluate each vendor software. Visits to present and past users is one of the best ways to determine the features, and issues with the software or vendor.

The team will then perform a cost/benefit analysis for all products, being evaluated. This includes review of vendor contract agreements to determine which vendor will provide the software.

Lastly, the team and the senior leaders of the organization will enter final negotiations with at least two vendors to maintain some type of comparison. The lawyers of the organization should also be involved for legal advice regarding purchase or maintenance contracts and warranty provisions, as well as distribution of financial risks appropriately between the user and the vendor.

MEASUREMENT

Once data has been collected and verified, it is time to begin statistical and other analysis of the data. Before we get to that part, it is important to understand the various sorts of data that might be available.

!Data Basics!

There are two basic types of data: **Categorical data and Continuous data.** There are distinct characteristics, uses, and statistical processes associated with each type. This part of the chapter will discuss the similarities and differences between these two types of data.

!categorical datal (sometimes called **Attribute data)** are data that have been categorized and counted. Nominal and Ordinal data fall into this type of data. Categorical data basically consists of how many things have the same name and thus in the same category. If you are in a classroom, you can count how many people are named Susan, Fred, Terry, and so on. You will then know the total number of

individuals who have each of the names you counted. For example, in healthcare you can count how many patients have Congestive Heart Failure or Pneumonia.

Categorical data is not measured. It is based on counts of members of discreet categories, therefore this sort of data is also known as **"discrete"** data. Categorical data exists only as whole numbers, (e.g., number of procedures performed, members, patients, births, deaths, occurrences) . The data can then be expressed in a percentage, such as, Congestive Heart Failure patients are 20% of <111 the patients treated. Categorical data is **qualitative data** in that it relies on specific descriptions of qualities to establish categories, such as blood type, intensity of burn, or physician specialty. Qualitative data can also include statements about observations, such as data drawn from case studies, focus groups, or interviews.

If you are counting things that simply have different names, you are creating **nominal data.** If the things you are counting have a sense of order, you are using **ordinal data.** Ordinal data consists of scores that exist on an ordered scale, i.e., an arbitrary numerical scale where the numerical value of a particular category has no significance beyond its ability to establish an ordering of a set of data points. An example might be the number of patients in the pre-op unit, the number in the surgery suites, and the number in the post-op unit. There is a sense of order here in that the patient will have to register, then go to pre-op, and then to surgery, and then to post-op.

\Continuous data! (sometimes called **Variable data)** is measured on a continuous scale rather than discreet categories. Continuous data is expressed in **specific measurement units** (whole and/or fractionaij indicating the amount or quantity of what is being measured. Continuous data is also called **quantitative data** because of the measurement of the interval between any two points as a quantity. Blood glucose and oxygen consumption are examples of quantitative data.

Measures that have an equal interval between each integer form **interval data.** However, in interval data there is no true zero point and thus ratios are not meaningful. An example of an interval scale is temperature . The difference between 40 and 80 degrees is the same as that between 60 and 100. However, it is not true that 80 is twice as hot as 40 since the zero point is set arbitrarily, and measures below zero are as meaningful as those above. If the data have equal intervals between each integer, and zero is absolute (a value cannot go below zero), then this type of continuous data is called **ratio data.** It is meaningful to say that twenty pounds is twice as heavy as 10 pounds, and something weighing less than zero is meaningless. Examples of ratio data include scores on a test, infection rates, respiration rates, height, weight, and voiume.

As seen in Table 10, the type of data that you are dealing with determines what you can do with those data. If you are using Categorical data, you can determine if there are significant differences between 2 groups by using the Chi Square test, but if you have Continuous data, you would utilize the t-Test to determine the difference between 2 groups of scores. Throughout the remainder of this section of the

chapter, we will be returning to this table as we explain data analysis. It is recommended that you copy this figure and keep it at your desk as you work with different data so that you will utilize the proper tools for the type of data that you have obtained.

Table 10: Types and Uses of Data

Types and Uses of Data		
Type	**Categorical / Count**	**Continuous / Measured**
Also Known As (AKA)	Attribute Discrete Nominal Ordinal Qualitative	Variable Quantitative Interval Ratio
Examples	# Members, Patients, Births, Procedures, Occurrences, Gender	Age, Height, Weight, Temperature, Time, Charges (money), LOS
Usually Reported as	% in each category (whole numbers)	Mean Median Minimum Maximum Percentiles (whole and fractional units)
Usual statistical test of difference between 2 groups	Chi Square	T test
Usual display tools	Table Scorecard Histogram Pareto	Run chart Control chart Scorecard (not the best to use) Data display over time = use run or control chart

Basic Statistics (Mom, Baseball, Apple Pie, Statistics)

This section looks at statistics in two ways . First will be a conceptual view of each type of statistical measure so that the reader can understand what each statistical test is, when to use it, and what it tells us. The second will be an explanation of the calculations for those who do not have a computer to do the calculations for the test .

!Descriptive Statistics!

Table 11describes the basic statistics that can be used with descriptive data. This table should be used as a reference for when you use descriptive data.

Table 11:Type of Descriptive Statistics That Can Be Utilized with Categorical/Continuous Data

Type of Descriptive Statistics That Can Be Utilized with Categorical/Continuous Data			
Data Type	**Distribution**	**Central Tendency**	**Variability**
Nominal	Frequency, Percentage	Mode	
Ordinal	Frequency, Percentage	Median, Mode	Range, Minimum/Maximum
Interval/Ratio		Mean, Median, Mode	Range, Minimum/Maximum, Standard Deviation, Variance

Adapted from Houser, 2012

!central Tendency - Mean, Median, Mode, Weighted Mean!

The term **Central Tendency** describes a set of measures that indicate what the 'middle' value is or the typical value of data. The statistical measures that display central tendency are the mean, the median, and the mode (Central tendency, n.d.). Each one is utilized for a different purpose and with different types of data. When an individual is asked to calculate measures of central tendency, it is sometimes helpful to organize the numbers from lowest to highest, especially if the math is to be done by hand. For example, the set of numbers given may be: 375, 109, 663, 29, 390, 56, 110, and 444. If these are rearranged from lowest to highest (29, 56, 109, 110, 375, 390, 444, and 663) it is often easier to visualize the median and the mode without having to do much math.

The \Mean] is frequently referred to as the average . To determine what the mean is, you simply add all the numbers together and divide by the number of integers in the set of numbers.

For example, the mean of 2, 4, 6, 8, and 10 is equal to 6. The mean is used with interval and ratio types of data.

Astronomical numbers overly influence the mean. Astronomical numbers, or outlier data, are numbers that are very different from the remaining numbers. When one or more numbers are very different from the other numbers, the mean is 'pulled' toward these astronomical numbers. In the numbers below, 100 is astronomically different from the other numbers listed.

For example, with numbers such as 2, 4, 6, 8, and 100, the mean is 24.

As is apparent from this example with a mean of 24 it is very different from the first example. Thus, with astronomical or outlier data, the mean does not really indicate the middle of the data. Therefore, it is better to utilize the \median].

Sometimes it is necessary to give more weight to certain data points. In this case a *!weighted M ean!* is utilized. This will be discussed later in this section .

The *!Median!* is the 'middle number' with an equal number of values above and below the median. The median can be used with the ordinal and interval data types. Arranging your numbers from lowest to highest facilitates the determination of the median – the middle number.

For example, in the seven number series 29, 56, 109, 110, 375, 390, and 444, you can place your fingers on the outer numbers (29 and 444) and then walk them in. This results with both fingers on top of each other on the number 110, which is the median or middle of these numbers .

When there is an even number of numbers, such as 23, 55, 66, 79, 83, 98, you can again walk your fingers in and they will land next to each other rather than on top of each other . You then must take these two numbers (66 and 78 in this example) add them together and divide by 2. With this set of numbers the median is 72.

As previously stated, when there is an astronomical value, such as in the numbers 2, 4, 6, 8, 100, it is better to use the median for the measure of central tendency. The mean of these numbers is 24, but the median is 6. This better describes the middle of the data. This is useful for example when calculating the length of stay that has several patients staying longer periods of time than the rest of the patients.

The *!Model* is the most frequently appearing number. The data may have one or more modes. No math is required to determine this value. This measure of central tendency is best utilized with nominal data . It can also be used with ordinal, interval, and ratio data; but there may be no identifiable mode due to the spread of the data.

Utilizing the numbers 2, 4, 4, 6, and 8, there are two 4's and so the mode is 4.

In the numbers 23, 23, 34, 45, 45, 56, and 88, the values 23 and 45 both appear twice so 23 and 45 are both the mode.

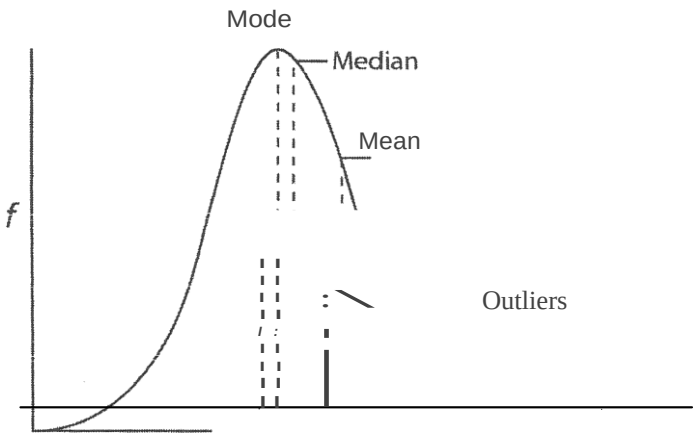
With the numbers 3, 3, 4, , ' S, 6, and 8, the value 5 occurs th r ee Li mes so it is the mode.

However, w ith the numbers 29,56, 109, 110, 375, 390, 444, and 663, each number appears only once, so there is no mode in this data set.

Itmportant Facts to Remember about the Mean, Median, & Mode]

- In a 'normal' unimodal symmetrical distribution, the values of the mean, median and the mode are the same.
- In an asymmetrical or skewed distribution or curve, the mode falls at the highest point, the mean falls somewhere towards the tail of the distribution, and the median lies between the mean and the mode (Figure 3) .
- In an asymmetrical or skewed distribution or curve, it is better to utilize the median than the mean to indicate the middle of the values.
- With repeated samples of the same type, the mean is a more stable value from sample to sample, and the mode is the least consistent value.

Figure 3: Mean, Median, & Mode



!weighted Meanl

There are times when some numbers are worth more, or carry more weight, than others carry. One example in healthcare is the annual reimbursement that hospitals receive. A certain portion of the reimbursement is calculated on the quality data submitted and the remainder is calculated based on HCAHPS patient satisfaction scores. The quality data portion counts more than the patient satisfaction portion.

When calculating the weighted mean, there are two numbers per set of data. The first number is the value of what was measured, and the second is the weight assigned to the measure as a portion of the whole. Table 12 shows the way to calculate the weighted mean utilizing the following example :

Table 12: Weighted Mean

Weighted Mean			
Domains	Score	Weight (%)	Multiply S x W
Clinical Process of Care	82	10	820
Pt. Experience of Care	58	25	1450
Outcome	92	40	3680
Efficiency Measure	67	25	1675
TOTAL		100	7625
Total Performance Score		(7625/100)	

The CMS Fiscal Year 2016 Hospital Value Based Purchasing (VBP) Percentage Payment Summary Report states that there are four quality domains. In Table 12, those measures are represented in the first column on the left. The Scores in column 2 (not real scores) are the calculated values (CMS – VBP, 2015) of each of these domains. The Weight is the proportion of the whole that each domain was worth in FY 2016. The score and weight for each domain are multiplied together as seen in column 4. The weight column (column 3) is now added to the total line (100) and the multiply column (column 4) figures are added together to the Total line (7625). The total of the Multiply column (7625) is then divided by the total of the Weight column (100) giving you the weighted mean, in this case, the Total Performance Score of 76.25.

!Dispersion of Data - Range, Frequency, Standard Deviation!

The term *!Dispersion!* refers to how variable, scattered, or spread the data is in a distribution. Common measures of dispersion in statistics are the range, frequency distribution, and the standard deviation (Dispersion, n.d.).

The !Range! is the simplest of dispersion statistics . The range tells you the lowest and highest numbers in a set of numbers, but it does not tell you anything about the numbers between those two values. The range is frequently cited as the smallest number, a comma, and then the largest number . Another way to calculate the range is to subtract the smallest number from the highest number in the range of values . The number obtained demonstrates the number of integer spaces between the lowest and highest numbers.

For example, if the numbers include 2, 4, 6, 8, and 10, then the range can be expressed as 2, 10 or as 8 (10-2=8). However, if we also look at the range of 102, 104, 106, 108, and 110, that range can be expressed as 102, 110 or also as 8 (110-102=8).

The 2, 10 and the 102, 110 are more expressive of where the data lies, and if readers wish, they can easily calculate the number of integers between the two numbers.

!*Frequenc y Distribution* are a logical and systematic arrangement ("rank-ordering"} of numerical data from the highest to the lowest, or lowest to highest, values. Frequency distributions are commonly seen in three formats: Simple, grouped, and cumulative frequency distributions . In a simple frequency distribution (f = frequency), all possible values between the highest and lowest reported measures (range) are listed in one column. The number of times each numerical value appears in the set of data is listed in an adjacent column.

SIMPLE FREQUENCY DISTRIBUTION TABLES

Individual Test Scores (Ranked highest to lowest)	*t*
125	1
124	3
123	2
122	2
121	3
120	4
119	0
118	4
117	1
116	2
115	5
etc.	
	N = 27

A Grouped frequency distribution (i = width of class interval), is utilized when the range of values from highest to lowest (or lowest to highest) is wide . The single measures are grouped together in blocks (class intervals), each containing an equal number of possible values {width of the class interval). Generally, between 10 and 20 intervals should be used. Interval (i) is the width of a class of grouped data, including both high and low values . The "i" for the class of data, 116-125, is 10.

GROUPED FREQUENCY DISTRIBUTION TABLE

Grouped Test Scores	*1*
(Ranked lowest to highest)	
56-65	42
66-75	70
76-85	99
86-95	74
96-105	52
106-115	40
116-125	22
i = 10	N = 399

With a Cumulative frequency distribution, at each value or point in the distribution column, the cumulative frequency is calculated as the sum of the frequency of that value or point (or **class** of values) the frequencies of all points or classes of smaller value .

CUMULATIVE FREQUENCY DISTRIBUTION TABLE

Grouped Test Scores	*1*		
(Ranked lowest to highest)			
56-65	42	42	
66-75	70	112	{42 + 70)
76-85	99	211	(42 + 70 + 99)
86-95	74	285	
96-105	52	337	

106-115	40	377
116-125	22	399

N = 399

!*Relative Frequency/Percentage!* is defined as a calculation of proportion, or a part-to-whole relationship. It can also be stated as the **percent** of the total number of individuals, objects, or events occurring at each value or group cf values. The percentage is calculated by dividing the part-the single individual, object, or event (or one group of individuals, objects, or events)-by the whole, the total number (N) of cases in the group, study or collection of data, and multiplying by 100:

$$\frac{\text{Part [individual case or group]}}{\text{Whole [N; total cases]}} \times 100$$

A !*Ratio!* is also defined as a proportion – a fixed relation in number, degree, etc., between two similar things. An example is a ratio of surgical site infections (numerator) to surgical procedures performed (denominator) for general abdominal surgeries (the group). A mathematical ratio is usually expressed as a decimal. A ratio can also be used to express relations between group, such as One Group: Similar Group.

In a proportion, the quantity in the numerator is also a part of the denominator (part of the whole) . If calculating the difference between two ratios, e.g., 50:1,000 versus 200:5,000, you must first seek a common denominator (the higher of the two: 5,000). Then multiply both numerator and denominator of the lower ratio by 5 (since 5,000 is 5 times greater than 1,000):

50 X 5 and 1,000 X 5 = 250:5,000

Then subtract the lowest numerator from the highest:

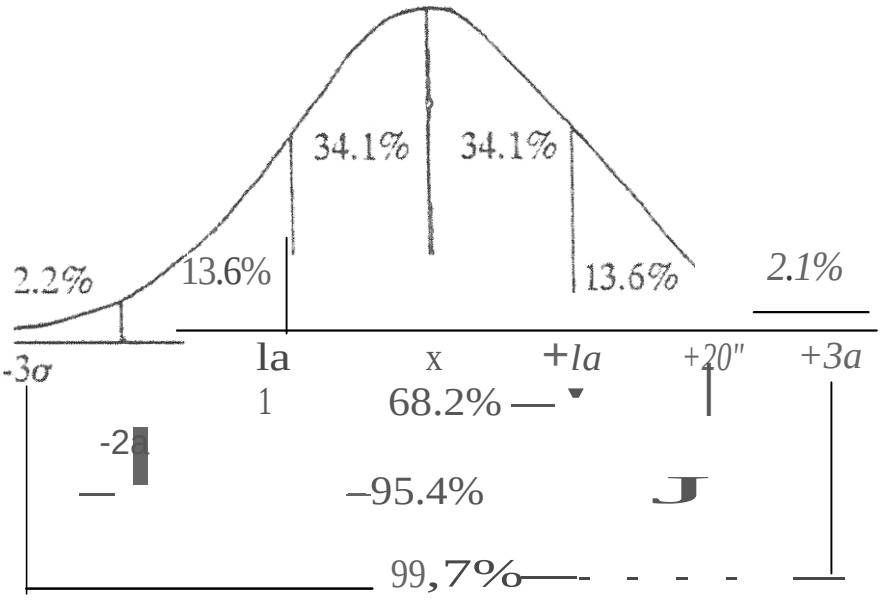
The difference between 250:5000 and 200:5,000 is 50.

futandard Deviation! is another measure of the spread of a distribution – a computed value describing the amount of variability in a particular distribution. The more the values cluster around the mean, the smaller the amount of variability or deviation. The standard deviation is the square root of a measure called the variance. The variance is the arithmetic mean of the squared differences between each value and the mean value. Now that we have lost you, let us make this simpler and then retl,Jrn to the more statistical interpretation.

All of the students who have gone to school are familiar with the bell curve. Most data with a strong central tendency look like this when plotted. The bell-shaped curve typically has a mean drawn as a line through the middle of the curve. Unfortunately, we do not often find a perfect 'normal' bell curve in reality, but we often assume that our data approximate a 'normal' bell curve. If the standard deviation is not at the center of the curve, it is said to be skewed to one side or another. If the left side gets drawn out further to the left, it is sa id to be negatively skewed, and if the right side gets drawn out further to the right, it is said to be positively skewed. When skewed, the mean will be pulled to one side or the other depending on how it is skewed (see previous discussion of Mean and Median). For the sake of the discussion at this time, we will assume that we have a normal bell bell-shaped distribution of values in the dataset, as in Figure 4.

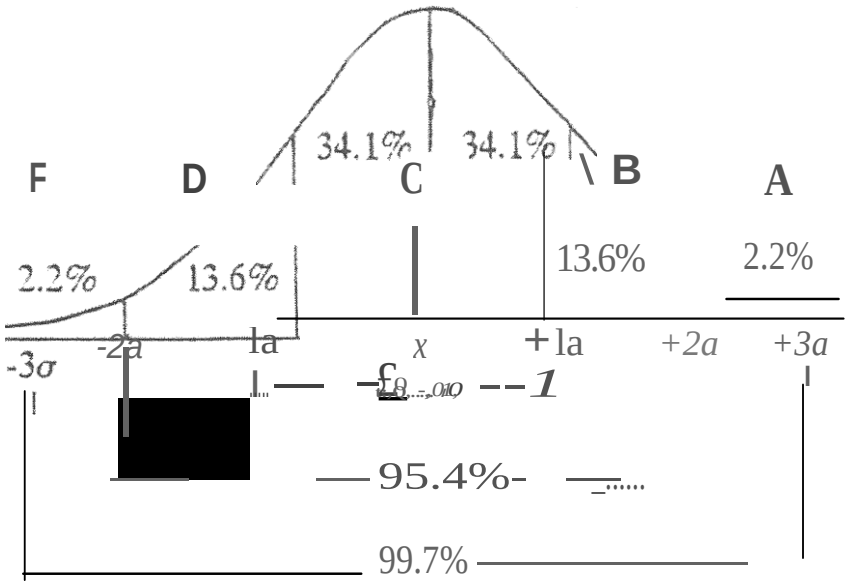
In Figure 4, the lines to the immediate left, and right of the mean indicate 1standard deviation away from the mean. The (J symbol stands for standard deviation. In a normal distribution 68.2% of all values will fall between these two lines. The next set of lines outside the first standard deviation line represents two standard deviations away from the mean and accounts for 95.4% of all the data. The third lines away from the mean are three standard deviation from the mean, and 99.7% of all data lie between these third set of lines. There remains 0.3% of values that are unaccounted for w ithin 3 standard deviation.

Figure 4: Standard Bell Curve



Let's explain this in another way with the bell curve often used for assigning grade in schools (called "grading on the curve") (Figure 5).

Figure 5:Grade Bell Curve



In school, there are times when an exam is too difficult and the students all score very iow. Grading on the basis of each student's percent correct score would be too severe – too many students would fail. The alternative is to grade on the curve – the bell curve. This process uses the mean and standard deviation of the distribution of the entire class's actual scores to determine grades. As in Figure 5, everyone scoring 2 standard deviations above the mean gets an A, 1standard deviation above gets a B, and so forth. For example, if the test mean was only 45 and the standard deviation 15, everyone scoring at or above 75 gets an A (45 + [2x15]), everyone at or above 60 (45 + 15) and below 75 gets a B, etc. If it is desired that more than 2.2% of the class gets an A, then the cutoff might be lowered to 1.5 standard deviations, i.e., 67 .5 (45 + [1.5x15]). Grading on the curve assumes that the actual scores on the test are distributed like the bell-shaped curve in Figures 4 and 5, which may not be the case . However, this process can be used – and is often used – when the distribution of measures (e.g., test scores) is not exactly bell shaped.

Understanding what the standard deviation and the bell curve tell you is very important for the healthcare quality professional. The principles of this statistical tool are applicable in many settings. For example, in a Nursing Home or other Long Term Care setting, the length of stay (LOS) of patients will vary. It can be determined what the mean LOS is, and then the standard deviation can be determined. Knowing what types of patients stay the shortest time vs. the longest time may be

information that can help identify what factors are contributing to the longer LOS. Look at Figure 5, 68.2% of the patients would be around the mean (in the portion where the grade C is). The further away to the right or the left would be those patients who have notably longer and shorter LOS. So, the facility should look at those patients who come and go quickly (the 5% at the left of the graph) to determine if the Long Term Care setting is appropriate for that type of patient . Similarly, the 5% to the right might be the focus of concern regarding adequacy of intervention.

In an outpatient clinic or physician practice, the practice may wish to determine the time patients spend in the office when they come for an appointment. The clinic/office collects the data for a month, and then determines the mean and standard deviation of the data. The data can then be used to determine what is making the difference in the length of time spent at appointments. In ti'1is case, the outpatient clinic would examine the nature of the patients that are in the sections furthest away from the middle to see why they are different than the 68 .2% in the middle. We will return to the use of the standard deviation as we explain other tools described in this chapter.

When creating a pathway or guideline, it is understood that not all patients will be able to stay on that pathway or guideline . However, these care tools need to be written for the more homogenous group of individuals that account for the 68.2% of individuals who are included within +/- 1 SD from the mean (See the C area in Figure 5). Patients who are outside of the first standard deviation may be able to begin on the pathway or guideline, but due to comorbidities, complications, and so forth, differences will need to be accounted for outside of the pathway or guideline (these would be the patients who are represented in Figure 5 as the A's, B's, D's and F's).

For example, if there is a pathway or guideline for a patient having a hip replacement, approximately 68% of the patients (the C's) should be able to stay on that pathway. However, perhaps a patient with a history of CHF develops symptoms of CHF after the surgery due to being overloaded with fluids during the surgical process. This patient cannot remain on the pathway or guideline (would appear in the A, B, D, or F portions of Figure 5). With trending of these types of patients who are not in the middle C section, the organization may be able to determine if a sepa rate pathway or guideline could be developed for hip replacement patients who have a history of CHF which limits the fluids in surgery and includes a bifurcation for those patients that do develop CHF post operatively .

Calculating the Standard Deviation (SD) from the Mean

Before the **SD** can be determined, the mean **(M)** is found (the average of all scores) . Then the deviation, or distance, of each score **{X)** from **M** must be calculated . Each deviation **("x")** is obtained by subtracting **M** from each score **("x" = X - M).** A small **"x"** means little deviation. The variance is found by squaring each **" x",** then finding their sum and dividing by the total number of scores **(N).** The Standard Deviation **{SD)** is the square root of the variance.

Summar y of how to find the **SD:**

1. Find **M** (Sum raw scores and divide by **N);**
2. Subtract **M** from each raw score to obtain each **"x";**
3. Square each **"x"** value;
4. Find the variance or **SD2** (Sum the **"x"** squares and divide by **N);**
5. **SD** = square root of the variance.
6. **SD** tells the "average" number of score units by which individuals, objects, or events deviate from the mean.

The number of Standard Deviation units each score is from the Mean can be used as an alternate unit of measurement instead of the raw score.

What this means:

- If a Test is given and the mean exam score (**M**) = 65; and the **SD** = 10.
- The "average" amount by which individuals deviate from **M** = 10 units.
- If a score = 85 (20 points > **M),** the n, the score's deviation from **M** is 2 Standard Deviation better (+2 **SD)** better than the "average" and is therefore very good (in the upper 2.2%).
- If a score = 35 (30 points below **M),** the score is 3 Standard Deviation worse (-3 **SD)** than the "average" and is a very poor performance (worse than over 99% of other scores).

We will return to the use of the standard deviation as we explain other tools described in this chapter.

Parametric & Non-Parametric Statistical Tests

There are two broad categories of statistical tests which are utilized in determining what information the results of the tests are telling us: Parametric and Nonparametric tests (Polit & Beck, 2012).

Parametric tests assume that the distribution of the data is normal (i.e., a bell-shaped curve) and then estimate its parameters. Parametric tests require that the data be interval or ratio. Parametric tests are more powerful in describing data than nonparametric tests. If the sample size is large, the assumptions of normal distribution is likely to be true and small violations will not affect statistical decision-making based on the results of the tests. However, if the sample size is small the distribution may not be normal, it is better to utilize nonparametric tests for the data even if it is interval or ratio data.

Nonparametric tests do not involve the same assumptions about the data as the parametric tests do. The parameters of the data are not estimated, and there is less concern about the actual distribution of the data. Nonparametric tests are best utilized when the data are not interval or ratio data, when the distribution of the data is not normal, and/or when the sample size is small.

Table 13 shows which tests are parametric and nonparametric and with which type of data they are best used.

Table 13: Parametric & Nonparametric Tests

Parametric & Nonparametric Tests				
	Level of Measurement	**Group Comparison 2 Groups**	**Group Comparison 3 Groups**	**Correlational Analysis**
Nonparametric tests	Nominal	X^2	X^2	Phi Coefficient
	Ordinal	X^2	X^2	Spearmen's Rho
Parametric tests	Interval / Ratio	t Test	ANOVA	Pearson's r

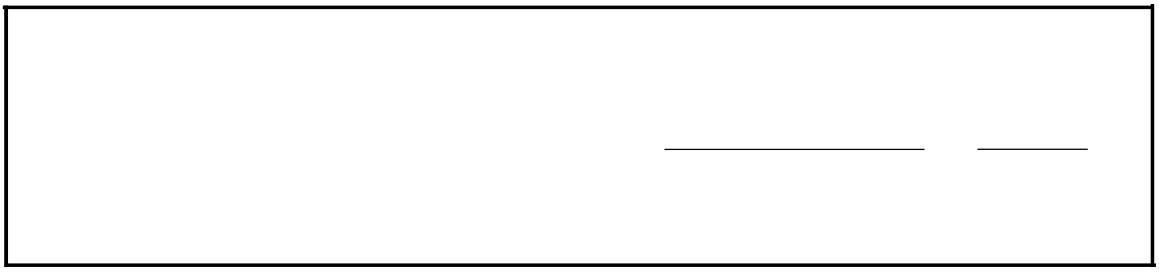
Adapted from Polit & Beck, 2012

NOTE: If sample size is very small or distribution of the data is non-normal, use nonparametric tests.

Chi Square (X^2) & t-Test – Tests of Statistical Significance

As shown in Table 10 Types and Use of Data, the Chi Square and t-Test are utilized to determine the difference between two groups. The Chi square is used with the categorical data and the t-Test is used with the continuous data. Both of these test result in a 'p' score. This p-score indicates if there is statistically significant difference between the two groups. While both tests produce a p-score, the methodology utilized to obtain the p-score varies with each test. It is best to describe what the statistical significance looks like before we explain each test. This description is a conceptual description designed to help the reader understand what the p-score represents. The statistical calculations of the p-score will follow each of the tests described below (Saint-Germain, 2001).

Figure 6: p-Score Results



The p-score will be a number between O and 1. When the p-score is between O and 0.05 (shaded area in Figure 6) the difference between the two groups/scores is said to be statistically significantly different. This means if measured again, the p-score will remain between O and 0.05 unless there has been an intervention. If the p-score is between 0.05 and 1.0 then the difference between the two groups/scores is said to have occurred by chance. This means that if measured again, the p value may

be different *(NOTE:* Refer to this Figure as you read about the Chi Square and the t-test in the next few pages).

A good conceptual example of this is marriage and divorce. When two individuals get married, they feel as if they complement each other and together they feel they make a better whole. This concept is a depiction of a test result where the p value is 1.0 and where the two groups are exactly, the same. However, if these individuals get a divorce, it is often because they have grown apart and feel very different from the other person. In many cases, they have nothing in common (represented by the O in this figure). However, there are some times when the two individuals will never be 100% different, such as when there is a child involved. Each individual will be connected together by the child therefore; they will never be 100% different. However, the remaining difference is so great that it can be said they are two very different individuals with very little in common. This is represented in Figure 6 by the shaded area between O and 0.05. The individuals are statistically significantly different but not 100% different. However, every married couple has days when they feel closer or further apart from the spouse. Often, this is the result of something one of them said or did. The difference between them is not statistically significantly different and can change when one says I am sorry, or brings flowers and/or other gifts to the other. This is represented by the line from 0.05 to 1.0 where there are differences noted by the individuals but they are not significant differences.

The ***Chi Square (X^2) test*** is used to determine if the distribution of two variables differ from one another. The Chi Square test can only be utilized on the actual numbers obtained and not with the percentages that are calculated. The question asked should be: Is there a significant difference between the groups or conditions being compared with respect to the counts or rates of a particular occurrence, event, or outcome?

An example of how the Chi Square test is utilized is the Comparison of long-term care facilities A and B (Table 14) on the number of healthcare-associated lower respiratory infections (Refer to Figure 6 as needed). The numbers in each box represent the patients with each outcome in two different 6-month samples:

Table 14: Long Term Care Example of Chi Square

Long Term Care Example of Chi Square				
	January -June		July - December	
	Facility A	Facility B	Facility A	Facility B
Infection	5	4	12	2
No Infection	95	96	88	98
Total (N)	100	100	100	100
XI	$xi = 0.116$		$X^2 = 7.680$, p = <.01	
	No difference		Significant difference	

In July – December time period in this example, the difference between infections in Facility A and Facility B is statistically significant as indicated by the p=<.01. However, in the January to June data, there is no statistical difference between the two facilities. This means that from July – December something has happened to make the two facilities so very different. If that cause is not uncovered and removed then there will continue to be statistically significant differences between the infection rates in these two facilities.

To calculate the Chi Square, the data must be placed in a 2x2 table similar to the one utilized in the below example . In this case, we will use data from two facilities identified as a, b, c, and d. The total (n) is then calculated (n = a + b + c + d).

Facility A	Facility B
a	b
c	d

The formula for calculating the X^2 is:

$$X^2 = \frac{n(ad-bc)2}{(a+b)(c+d)(a+c)(b+d)}$$

Once X^2 is determined, the degrees of freedom must be determined . In the above example, the degrees of freedom (df) is 1. The degrees of freedom is calculated as:

Degrees of Freedom (df) = (# rows – 1) (# columns – 1)

A Chi Square Distribution Table is then utilized to look up the X^2 value utilizing the degrees of freedom to determine the level of significance (p-value) of the observed x2, which will be between the values of 0 to 1.0.

The ***t-Test*** is utilized to compare two groups on the same measured variable using means (averages) of each group to see if they indicate real (significant) difference, or a difference likely to have occurred by chance (refer to Figure 6 as needed). The example that demonstrates this statistical test is comparing the average number of cigarettes smoked per month by smokers who had a heart attack (Ml) before age 65 (Group A) *vs.* smokers who did not have a heart attack (Ml) before 65 (Group B). In order to calculate the t-Test value, the number in the group (N), the mean of the group (M), and the sld ndard deviation of the group (SD) must be determined for each group separately.

	Ml < 65 (Group A)	No Ml < 65 (Group B)
Total (N)	13	9
Mean (M)	27.1	15.0
Standard Deviation (SD)	7.3	12.5

The formula utilized to calculate the t value is:

$$t = \frac{M(a) - M(b)}{\sqrt{\frac{SD(a)^2}{N(a)} + \frac{SD(b)^2}{N(b)}}}$$

So, in this example:

$$t = \frac{27.1 - 15.0}{\sqrt{\frac{7.3^2}{13} + \frac{12.5^2}{9}}}$$

$t = 2.61$; $df = (13\text{-}1) + (9\text{-}1) = 20$ so, $p = <.02$

The difference between the average number of packs of cigarettes smoked per month for the two groups (27.1 vs. 15.0) is a significant difference and not likely to be due to chance.

Type Iand Type II Errors

When calculating the relationship of one variable to another there is always a chance of making a mistake regarding the relationship between the variables in the real world beyond your sample . If a mistake is made, it will be either a Type I or a Type II error (Types of error, 2017).

A Type I error occurs when one assumes that there is a relationship between the two variables when there in fact is no relationship. The probability of making a Type I error is called alpha. Typically, in the social sciences, an acceptable alpha is 0.05. This means that there is a 5% chance of making a Type I error. However, in public health, the acceptable alpha is frequently set at 0.01. This indicates the very small likelihood of assuming that there is a relationship between the two variables when there really is no relationship.

A Type II error occurs when one assumes that there is no relationship between two variables when there in fact is a relationship. The probability of making a Type Ii error is called beta. Unfortunately, reducing the likelihood of one of these types of errors increases the chances of the other type of error.

A Type I error, where a relationship is thought to exist, when it really does not, is the worse of the two errors. Therefore, Type I errors should be avoided, if possible. The level of alpha is affected by the size

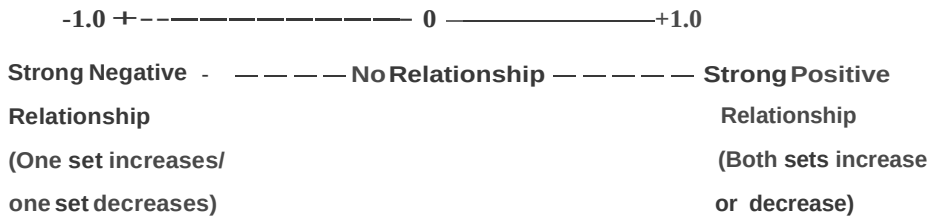
of the samples. If there is a weak relationship between two variables or the alpha is set very small, a larger sample size will be needed to be able to reach statistical significance.

\Regression Analysis - Scatter Diagrams\

Regression Analysis is a statistical technique that allows one to compare the entire distribution of observations of one measurement (or variable) with the entire distribution of another measure in order to determine how strongly the two sets of variables are interrelated (correlated).

A ***Correlation Coefficient*** **(r)** is the value computed in regression analysis that expresses the strength of the relationship between the two sets of measures. The numbers associated with r range between 0 and plus or minus 1.

An r approaching +1.0 indicates a strong positive relationship between the measures, with both sets of measure either increasing or both decreasing together. An r approaching -1.0 indicates a strong negative relationship, with the numbers of one of the measures increasing as the numbers of the other measure decrease. Measures with no significant relationship will have an r of approximately zero (O).



The ***cotter Diagram)*** is one way to display the possible relationship between two sets of data (variables), looking at how closely they correlate. This assists in the data analysis and outcome evaluation. The correlation may represent a possible cause-and-effect relationship, depending on the nature of the variables . The two variables utilized are called either the independent variable or the dependent variable. The independent variable is the one that is varied or manipulated and presumably has some effect on the dependent variable. The independent variable is often referred to as the 'cause' and the dependent variable is the presumed 'effect'.

Graphically, the correlation coefficient (r) expresses the degree to which the dots on the scatter diagram form a straight line. A regression equation is the formula for the line that best fits the dots of the scatter diagram. The regression equation can be used to predict the expected value of one variable based on a particular value of the other variable. In the example scatter diagram with a strong correlation, the dots nearly form a line; with a moderate correlation, the dots roughly form a line; and

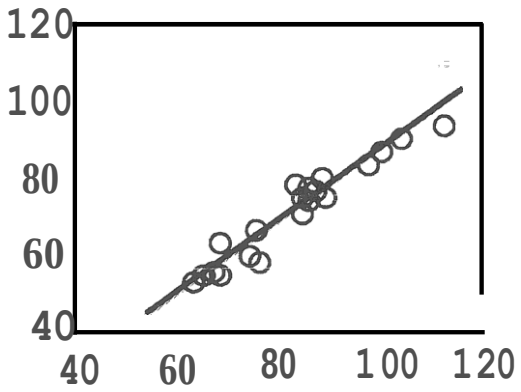
with no correlation, the dots cannot be said to form a line at all. On the scatter diagram, the Dependent variable should be on the Y-axis and the Independent variable displayed on the X-axis.

Let's look at some Scatter Diagrams to illustrate these points:

1st Example - (Figure 7): "Strong Positive Relationship" [r = +.80]

Both the heart rate as measured by the nurse and as measured by the monitor correlates positively (both sets of numbers increase or decrease together, as you would hope). The relationship is strong; the points approximate a straight line (each point = a comparison of two heart rate measures on the same patient at approximately the same time). This relationship represents a correlation that is expected, but is *not* one of possible cause and effect.

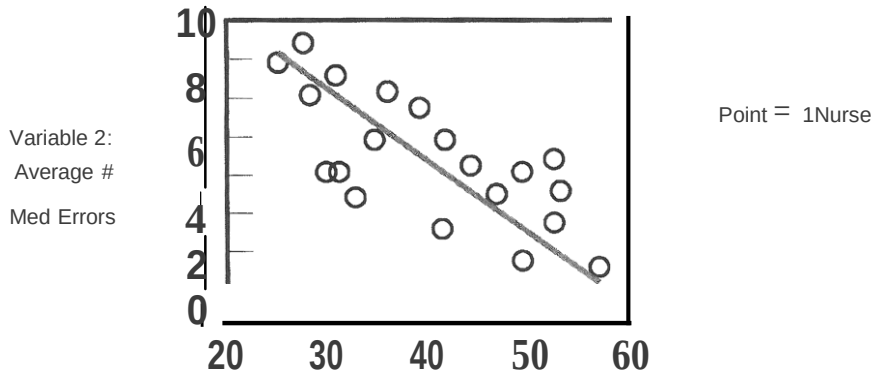
Figure 7: Scatter Diagram - Strong Positive Relationship (r = + .80)



2nd Example - (Figure 8): "Moderate Negative Relationship" [r=-.45]

The average number of **medication errors** made by each nurse in a critical care unit did not correlate positively with an increase in the number of hours worked per week over a six-month period. In fact, there were more errors generally by those with the fewer number of hours worked. The relationship between measures here is considered moderate **(r** is not too far towards -1.0), and "nega tive" (as the number of hours increased, the number of errors tended to decrease). Here there may be a cause and effect relationship given the nature of these variables).

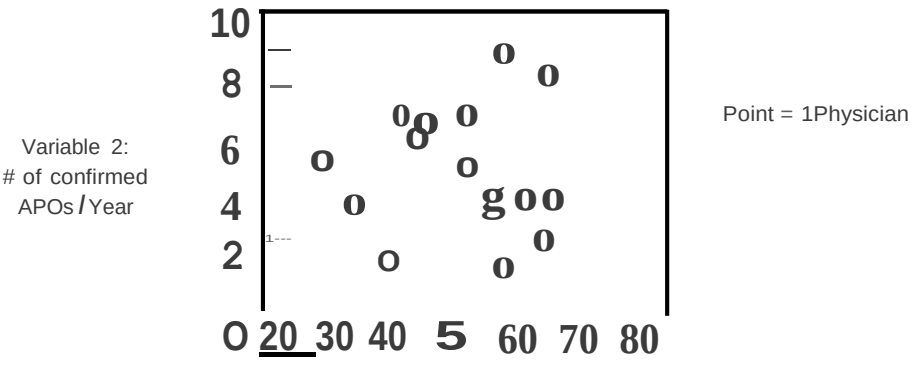
Figure 8: Scatter Diagram - Moderate Negative Relationship (r = - .45)



3rd **Example - (Figure 9); "No Relationship" [r = approx. OJ**

There is no relationship between the number of **confirmed adverse patient occurrences (APOs)** per year and age of physician.

Figure 9: Scatter Diagram - No Relationship (r = .00)



An important point is that if there is a 'Positive Relationship' found, it does not mean that the relationship is what you want or do not want to happen. Conversely, a 'Negative Relationship' is also not necessarily negative or positive. It is simply the way in which the lines go. For example, a scatter diagram of the Independent va riable of calories consumed vs. the amount of weight someone gains is a positive relationship . However, to most individuals an increase in weight is not positive.

While the Scatter Diagram is a pictorial representation of a Regression Analysis, the analysis itself is more stringent because it is mathematically calculated.

Multiple Regression Analysis

A Multiple Regression Analysis is similar to a simple regression analysis except that it includes multiple independent variables that are predicting (or potentially affecting) the dependent variable. An example of a multiple regression would be a determination of how much a diabetic diet, medication, and activity affect the HAlc value. The HAlc value is the dependent variable and the diet, exercise, and medication are the independent variables. A multiple regression will calculate how much effect the diet has on the HAlc, how much effect the exercise has on the HAlc, and how much effect the medication has on the HAlc. It will also calculate how much effect a combination of these independent variables has on the HAlc.

The outcome of a multiple regression analysis is expressed as a multiple correlation coefficient or R. Unlike the regression analysis where the calculated value ranges from -1 to +1, in the multiple correlation coefficient does not have any negative values. The R ranges from O to 1.00 which demonstrates the strength of the relationship between several independent variables and the dependent variable, but it cannot demonstrate the direction of the relationship (positive or negative) (Polit, & Beck, 2012).

Confidence Interval

A confidence level represents the level of probability that a sample parameter is truly representative of the population. It is usually set at 95% (the ".05 level"). Calculations using this standard assume that there is a 95% chance or probability that the sample mean and standard deviation are the same as the population, and that the results are not due to chance, but can be replicated. Most statistical packages have the capability to calculate the confidence interval.

A confidence level, statistically calculated, involves a test for significance, and is generally represented by the p-value, e .g., p = <.05. As the p-value decreases, significance increases-i.e., the % probability increases.

A p-value of p = < .05 means that relationships in the data are "significant" statistically; therefore, the team members have more "confidence" that they can trust the data and make decisions accordingly. If the p-value is p = < .01, confidence in decision making is even higher (99%); relationship in the data are more significant, and even better represents the whole population and results are even less likely due to chance.

Interpercentile (Interquartile Range - IQR) Measure

The interpercentile or interquartile range refers to the variation of the data between the first quartile (25th percentile) and the third quartile (75th percentile), or somet imes described as the middle 50% of the data values. This assists the evaluation of extreme outliers, but is not often reported in studies.

The most commonly utilized interquartile range is the baby growth chart utilized to determine the distribution of selected body measurements in children.

Statistical Process Control

One concept that should be explored is that of statistical process control. It is defined as the use of measurements to study a process with the goal of making it perform in a certain way, conform to standards, and continuously improve (developed by Walter A. Shewhart in the 1920s to improve processes at AT&T). The objective is to distinguish common from special causes of variation to make good management decisions (Shewhart, 1931).

According to Webster's New World Dictionary, variation is "change or deviation in form, condition, appearance, extent, etc., from a former or usual state, or from an assumed standard." Variation generally refers to the whole process or a step in the process. A variance is "a changing or tendency to change; degree of change or difference; divergence; discrepancy" . This term generally refers to specific data or information (Variation, n.d.).

It is true that all processes vary and no process functions exactly the same way over a period of time. Some variation is desirable, some is wasteful, and some may be harmful. So how do we meet the demands for accountability and improvement when processes always vary? First, we must understand the variation.

According to Walter Shewhart (1931), process variation is of two types: Random or Common Cause, and Assignable or Special Cause Variation.

)Random or Common Cause) variation is intrinsic to the process itself; naturally occurring "noise" in the process; "inliers". For example, patient response to medication will always vary within the cohort of patients, and even for one patient over time. "Common causes" refer to situations, usually within patient care systems and processes that are more ongoing, chronic, and persistent. These common causes contribute to the "normal range of variation" within a process. The goal of quality improvement is not to eliminate, but to reduce variation in a process enough to produce and sustain "stability".

Common causes may also contribute to what are considered the less than desirable parts of a process. Usually finding and resolving common causes of problems or variation is more time-consuming and may be more difficult for departments, services, or quality improvement (QI) teams. The resolution of common causes of problems is often considered to be key, to continuous, incremental improvement of the quality of care and services rendered to patients. In this case, there needs to be no focused or case-specific review. Process redesign or improvement is necessary.

ssignable or Special Causel variation is extrinsic to the usual process; related to identifiable patient or clinical characteristics, idiosyncratic practice patterns, or other factors that can be tracked ("assigned") to root causes. "Special causes" refer to sentinel events, one-time occurrences, or other unique, out- of-the-ordinary circumstances that give rise to a variation from what is normally expected. Special causes are usually more easily identified and resolved, either by departments or by QI teams. Special causes account for the majority of what we call "outliers" — those problems that generally contribute to the "tails" of a normal, bell-shaped curve representing a particular process.

When a special cause variation is identified, case-specific focused review and root cause analysis are needed to identify the cause and take action. Such variations, if negative, can be fairly quickly changed, or eliminated . Positive variations should be analyzed for possible replication as better or best practice.

tatistica/ thinkin understands and views work as a process. It recognizes that the processes and the measurement data they produce will exhibit variation, and that the variation should be appropriately responded to reduce the variation to improve quality (Shmula, 2017).

A process is in good statistical control when the it is (1) stable over time (demonstrated through measurement data); (2) operated in a stable, consistent manner with no arbitrary changes in process steps or conditions; (3) the "process aim" is set and maintained at the proper level, based on quality control specifications or target values; and (4) the average or normal process variation (control limits) falls within the specification limits (expectations) . See Control Charts under Display Techniques, in this chapter.

Walter Shewhart's understanding of causes of variation led him to develop a methodology to chart a process and quickly determine when a process is "out of control." This ongoing measurement and analysis is known as Statistical Process Control (SPC). As long as assignable or special causes of variation exist, we cannot make accurate predictions about process performance and probable outcome. Once assignable causes are eliminated, we can call the process "stable" and can measure the "capability of the process" by rates of deficiencies or rates of achievement of desired outcomes. At this point, we have the data we need to perform the in-depth analysis that leads to improvement. For example, a diabetic tracking his/her daily blood sugars would want them to remain in statistical process control.

Display and Statistical Tools are used to measure performance, and collect and display data different variables. Commonly utilized display and statistical Laois include Tables, Pie Charts, Frequency Distributions, Histograms, Bar Charts, Pareto Charts, Run Charts and Control Charts. The appropriate display of information is a key responsibility of the Quality Professional. How data is presented may determine whether an appropriate decision is made and appropriate action taken. Since measurement and assessment are more and more dependent on the analysis of patterns and trends, how data is aggregated and displayed is critical to the outcome and ultimate effectiveness of the process.

There are many Quality Improvement Tools which are used for different reasons. Tools are developed to be utilized when identifying a problem, for data analysis, solution planning, and outcome evaluation. Table 15 displays the tools and when they are best utilized. Each of these tools will be described in this section. The emphasis will be on what the tool is, when it should be utilized, and what it tells you. This portion of the chapter will be divided into two sections: Statistical Tools and Process Tools. The Scatter Diagram, a statistical tool, was previously discussed (see Regression Analysis), so it will not be repeated here.

Table 15: Quality Improvement Process Tool Selection Matrix

I	Problem Identification	Data Analysis	Solution Planning	Outcome Evaluation
Check Sheet	./	./		./
Run Chart	./	./		./
Control Chart	./	./		./
Bar Chart/ Histogram		./		./
Scatter Diagram		./		./
Pareto Chart	./	./		./
Brainstorming	./	./	./	./
Nominal Group Technique			./	
Delphi Technique			./	
Multivoting	./		./	./
Cause-and- Effect (Fishbone)	./	./	./	
Interrelationship Diagram		./	./	./
Lotus Diagram	./	./	./	./
Affinity Diagram	./	./	./	
Flowchart	./	./	./	
Value Stream Map	./	./	./	
Process Map	./	./	./	

A3 Problem Solving Tool	✓	✓	✓	
Force Field Analysis			✓	
Task List	✓	✓	✓	✓
Gantt Chart	✓	✓	✓	✓
Prioritization Matrix	✓		✓	

Quality Improvement Tools

Tables

Organized and summarized data for a sample, population, a given set of criteria, screens, etc., can be displayed by using tables (see the example in Table 16). Infection Control surveillance data or other specific measurement data (e.g., medication usage or wait times) can also be viewed over time with the use of tables, though graphic display may prove more interesting (Table 17).

Table 16: Demographic Information Table

Demographic Information Table				
Newly Diagnosed Medical Conditions in Children Participating in a Community Health Program				
CODE # (pt-school)	**SEX**	**AGE**	**RACE**	**INITIAL**
01-01	M	7	W	Impetigo, Conjunctivitis
02-01	F	8	W	Blepharitis, Malnutrition
03-04	F	8	B	Urinary tract infection
04-07	F	7	A	Heart murmur
05-01	M	9	W	Enlarged tonsils
06-04	M	8	B	Hearing deficit, Eczema
07-07	M	9	L	Myopia, Heart murmur, URI

There are several issues with the use of tables displaying data over time. First, if the information displayed is without any guidance as to what is important within the table (Table 17), then it will be difficult for the reader to tell easily what is important within the table.

Table 17: Table with Information Over Time

Table with Information Over Time									
		Goal	Actual						Aver.
			Jan	Feb	Mar	Apr	May	Jun	Jul	
	Nosocomial infection	<7	7.1	6.9	5.1	6.2	7.1	3.4	4.4	5.7
	Nosocomial decubitus	<2.0	0.8	0.9	0.0	1.9	2.3	3.3	2.5	1.7
	Patient fall with significant injury	0	0.0	0.0	0.2	0.2	0.0	0.1	0.5	0.1
	Medication error harm	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Mortality Rate		24.20%	27.50%	7.80%	26.00%	26.00%	16.20%	20.90%	21.20 %
	Restraint utilization (%)	<8%	6.0%	13.0%	6.0%	10.0%	8.0%	5.0%	15.0%	9.0%

Many organizations use traffic light coloring to indicate where to focus on the table. The red, yellow, and green colors (shown here with shading) of the traffic light indicate that the organization needs to stop and focus on the red data, use caution with the yellow data, and be confident that the green data is where the organization wants it to be. The main problem with this type of table is the arbitrary boundaries that are set to distinguish between the different colors. Table 18 displays an example. In this table, the values of the colors are set for each measure. With the Mortality rate, there is no goal so there is no color provided for those results. While this gives the reader an idea of whether the data are acceptable or not, it does not demonstrate the common cause variation of the data over time. The data value may be in the green zone one month, the yellow next, and then back to the green during the third month. This does not indicate that action be taken to change this outcome, even though it has been changing color zones. It does not indicate that there is a pattern or trend, but rather is

expected variation . There are better tools that can be utilized with data that is aggregated over time, and those tools, run and control charts, are discussed later.

Table 18: Table with Color Coding of Information

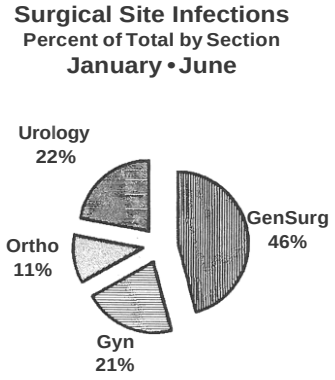
Table with Color Coding of Information									
	Goal	Goal	Actual						Aver.
	Acceptable								
	Unacceptable		Jan	Feb	Mar	Apr	May	Jun	Jul	
	Nosocomia infection	<7	7.1	6.9	5.1	6.2	7.1	3.4	4.4	5.7
	Nosocomial decubitus	<2.0	0.8	0.9	0.0	1.9	2.3		2.5	1.7
	Patient fall with significant injury	0	00	00	0.2	0.2	0.0	0.09	0.5	0.14
	Medication error harm	0	'0.0	0.0		0.0	00	0.01	0.0	
					0.0					0.0
	Mortality Rate		24.20 %	27.50 %	7.80 %	26.00 %	26%	16.20 %	20.90 %	21.2%
	Restraint utilization	<8%	6.0%	13.0%	6.0%	10.0%	8.0 %	5.0%	15.0%	9.0%

Pie Graph

A Pie Graph is a display of relative frequency (percentages) of the proportional relationships within a dataset when there are only a few divisions or categories and the total of all categories is 100% (Figure 10).

A Pie Graph is usually used to display parts of the whole in percentages . The full "pie" or circle represents 100%, and each segment calculated as a percent of 360 degrees, e.g., 10% percent is calculated as 36 degrees. The Pie Graph is not frequently used in healthcare as other depictions of the data display the information in a better format, such as a Bar Chart (see Figure 14 below).

Figure 10: Pie Graph - Surgical Site Infection by Section

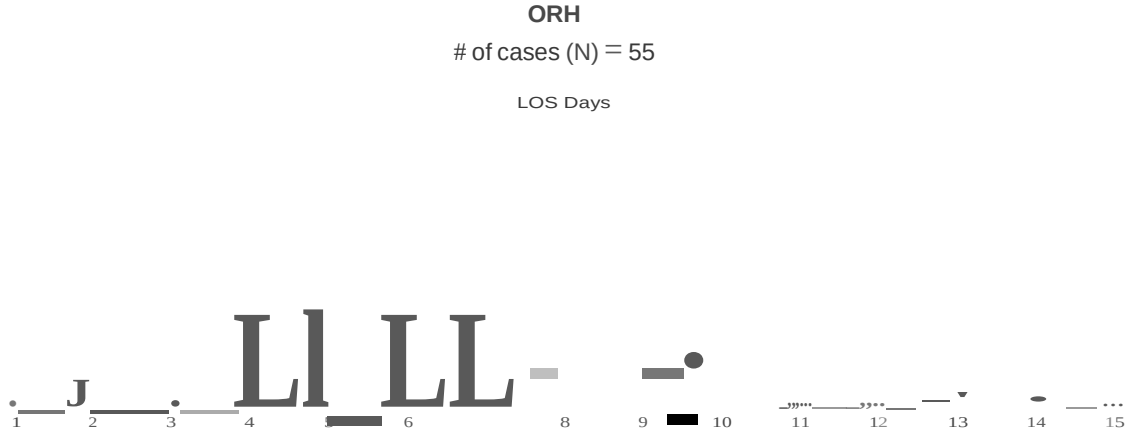


Frequency Plots

A Frequency distribution is a graph, designed to display the location, spread, and shape of the data. The frequency plot has two axes: The horizontal baseline (X axis or abscissa) covers the elements of interest and the vertical axis (Y or ordinate) indicates the frequency of this element in the data. Other names for a frequency plot include a dot plot, a stem-and-leaf plot, and a histogram. These tools can best be utilized to assist in data analysis and outcome evaluation. The frequency plots reveal one of two types of curves of the data. In a Symmetrical curve, the two sides of the curve are identical if the graph is folded in half perpendicular to the baseline (e.g., bell-shaped or rectangular). In a Skewed curve, the curve is positively skewed if it tails off to the right side of the midline and negatively skewed if it tails to the left side of the midline (Provost, & Murray 2011).

A *Dot plot* is a graph that utilizes a dot for each unique value. This frequency distribution is best utilized when there are a small number of sample values (Figure 11).

Figure 11: Dot Plot - Length of Stay for CVA (Stroke)



A *Stem-and-Leaf Plot* is more like a table where each data value is split into a stem and a leaf. The stem value is the first number(s) in the value (Provost, & Murray 2011). The leaf is the remaining number in the value. When graphed, the stem values are listed down and the leaf values are listed appear to the right of the stems (Table 12).

Figure 12: Stem-and-Leaf Plot of Patient Weights

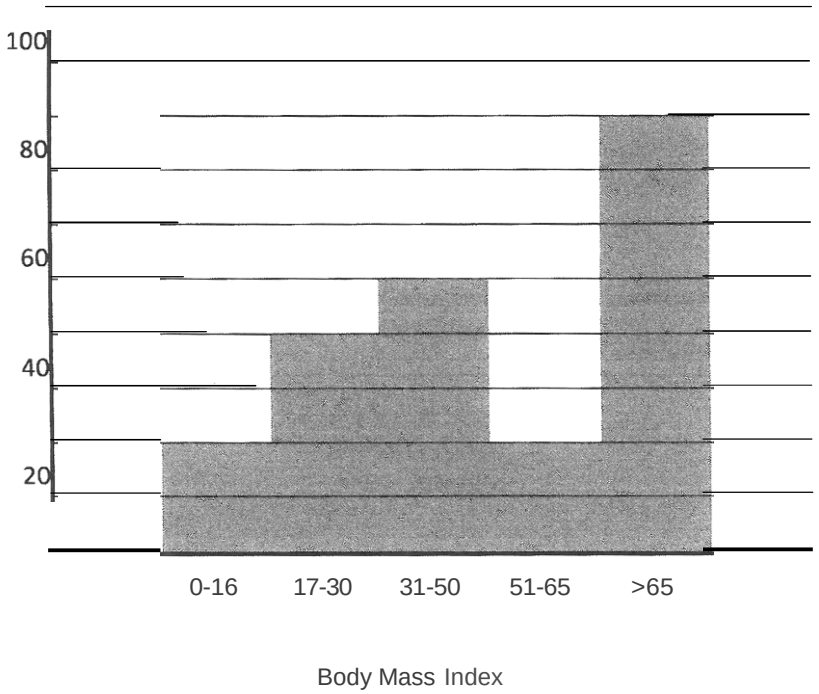
Patients Weights (lbs.)

STEM	LEAF
10	9
11	2 2 5
12	5 9
13	2 5 7
14	9
15	
16	3 5 8
17	2 4 6
18	5
19	2
20	9

This stem-and-leaf plot shows that there is one patient who weighs 109 lbs. and one patient who weighs 209. It also shows two patients who weigh 112 lbs. each.

A !Histogram! is a bar graph of the frequency of one continuous variable. Because frequency is actually a continuous variable, the bars are "blended" by connecting them at the frequency midpoints so the bars are no longer discrete (Figure 13).

Figure 13: Histogram of Body Mass Index (BMI) of Patients Receiving Home Health Services



General procedures for graphing dot and histogram frequency distributions:

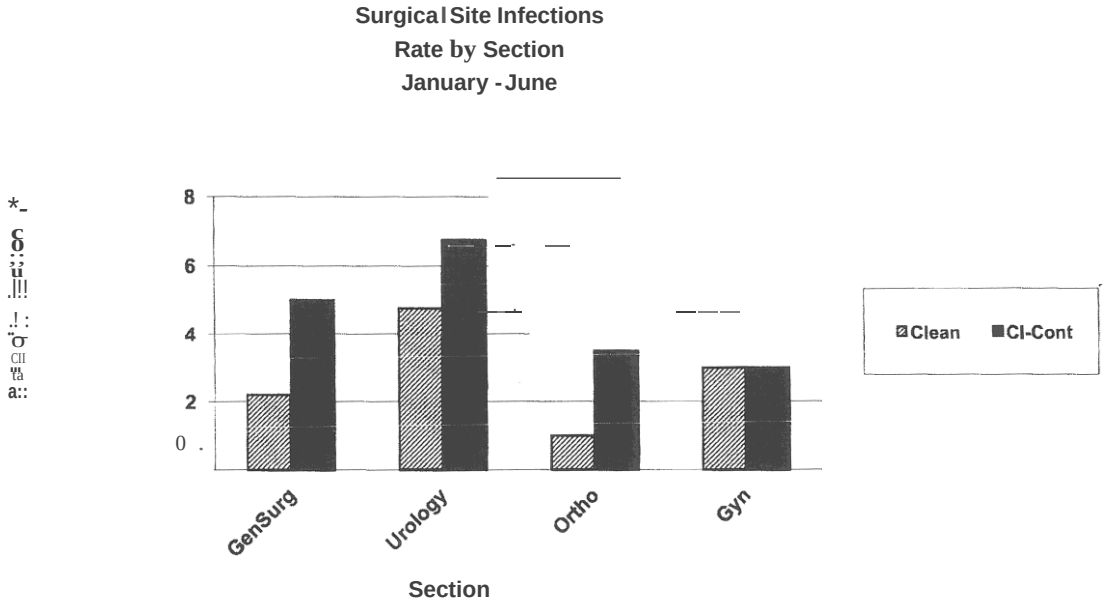
- Horizontal baseline (X axis) = scores or measures
- Vertical (Y axis) = frequencies or percent of cases
- The length of the vertical axis is 60-75% of the baseline length
- Label each axis very carefully, including:
  - What each element represents (captions)
  - The numerical values of each element (with consistent intervals)
- The lowest values for each axis start at the lower left of the graph
- In frequency histograms label midpoints of intervals
- Label each graph, including:
  - A concise title
  - Time period
  - Total number of observations
  - Number of observations for each subgroup (if appropriate)
  - Keys/legends as appropriate

!Bar *Charcj*

A Bar Graph or Bar Chart is a display of comparisons between different groups or a collection of discrete objects or events that cannot be ordered so it is not considered a frequency distribution, but looks very similar to a Histogram. It emphasizes the groups' discreteness with respect to two or more categorical variables. Each set of bars represents a category. In Figure 14 for example, the number of surgical site infections are displayed for each of four sections . In the figure, a Clean wound refers to a wound produced by uncontaminated sharp objects, such as glass or a surgical incision. A Clean-Contaminated (Cl-Cont) wound refers to a wound that is a dirty wound that may have been contaminated.

Figure 14: Bar Chart - Surgical Site Infections - Rate by Section

Clean and Clean-Contaminated



abeling a Line or Bar Graph:

In general-though there are exceptions-labeling the graph involves the following guidelines:

The independent variable, such as trials, groups, conditions, time period, age, etc. (categorical data), is plotted along the baseline-X (horizontal) axis.

The dependent variable-the response measure of the characterist ic being measured, e.g., average responses, time, percentages, or magnitude of response, etc. (continuous data)-is indicated on the **Y** (vertical) axis.

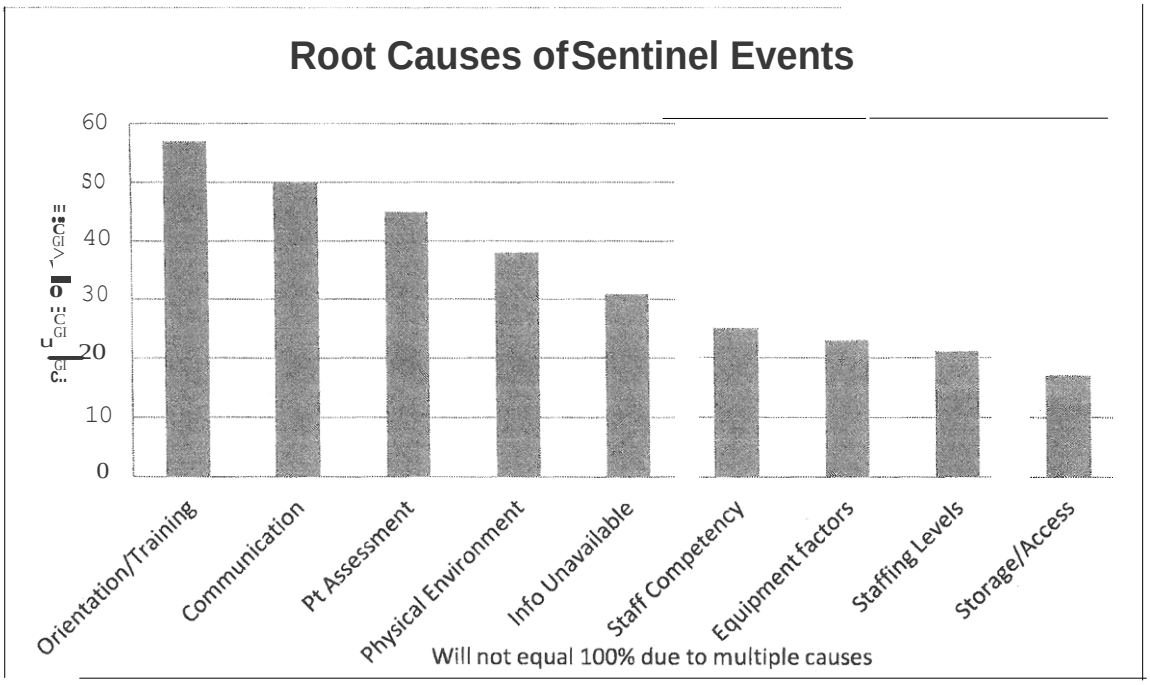
!Pareto!

A Pareto Diagram is a special form of vertical bar graph with bars in rank order of occurrence from highest to lowest. It offers a comparison of causes of problems, characteristics of a product or service, or variables in a process and rank-orders (prioritizes) them, with the most common cause or most frequently occurring characteristic or variable graphed first (on left side of graph). Each bar represents a different problem, characteristic, or variable. The Pareto chart is best used in problem identification, data analysis, and outcome evaluation.

The purpose of a Pareto Diagram is to determine where to focus improvement efforts, looking for the "vital few" from the "useful many" to determine where to start to make improvements. The Pareto Principle of 20% of the whole represent 80% of the problem is the theory behind this tool.

Typically, in healthcare, a Simple Pareto Diagram (Figure 15) can be utilized to determine where to begin improvement efforts. However, at times, a more Complex Pareto Diagram (Figure 16) needs to be utilized to determine mathematically where the largest portion of the problem lies.

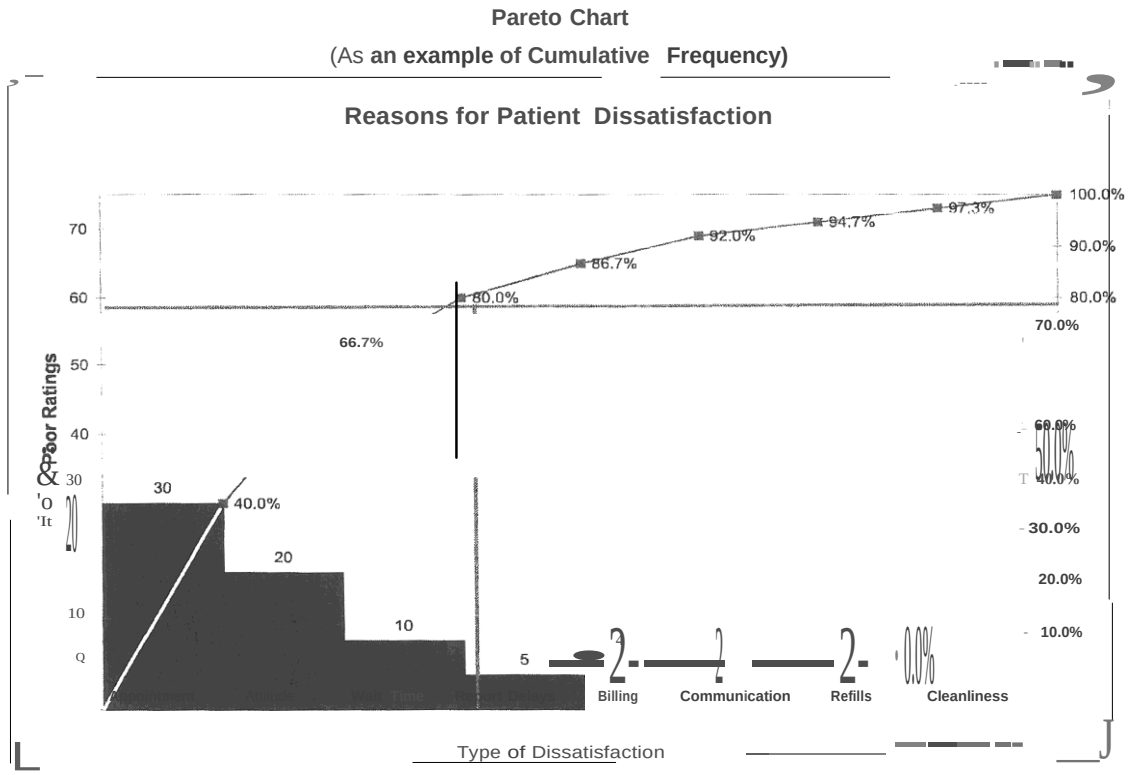
Figure 15: Pareto Diagram – Simple



If you were to develop a Pareto of all the DRGs that your organization utilizes, you would probably not be able to visually identify the 80% problem. Therefore, the Advanced Pareto chart should be used. The Advanced Pareto looks like the usual Pareto, but with more information which statistically identifies the 80% where the performance improvement efforts need to begin. The Advanced Pareto

includes a percentage line on the right vertical axis that corresponds to the values on the left axis. This left vertical axis should be based on the total number of observations in the data being analyzed. In Figure 16 the total amount of data is 75, so the left axis includes all possible data should they be displayed in one column, which would be 100% of the data (right vertical column). Fifty percent of the data (right vertical column) is equal to 37.5 (left vertical column), and so on. The values of each column are then added together with a notation made above each column. In Figure 16, the first column (30) is added to the second column (20) to get a value of 50, or 66.7% of the data The third column is added to that value to show that the first 3 columns encompass 80 % of all the data. This continues until all of the columns are added together for 100% of the data. The notations are then joined together by a line as shown in the figure. At this point, the 80% level is located on the right vertical axis and a line drawn to the left over to the right vertical axis. The point at which this line crosses the line connecting the notations indicates that 80% of the data is to the left of that point, and that is where improvement efforts should focus .

Figure 16: Pareto Diagram - Advanced



Pareto Drill Down

In healthcare, more information is needed to be able to better identify exactly where to start to make improvements. Pareto Diagrams provide the ability to **drill down** to the finer details of the problem. This allows the team to identify where the largest part of the problem truly lies.

For example, one hospital which has an active surgical schedule is finding that there are too many delays in getting patients out of the PACU. The delay in PACU is causing a delay in surgeries. The hospital tracked PACU discharge delays greater than 1 hour from August through November, which showed some improvement (Figure 17), but not any significant improvement. It was determined that the data needed to be utilized to drill down to identify the reasons for the delay, and a Pareto was developed (Figure 18).

Figure 17: Percent of Patients Recovering > 1 hour in PACU

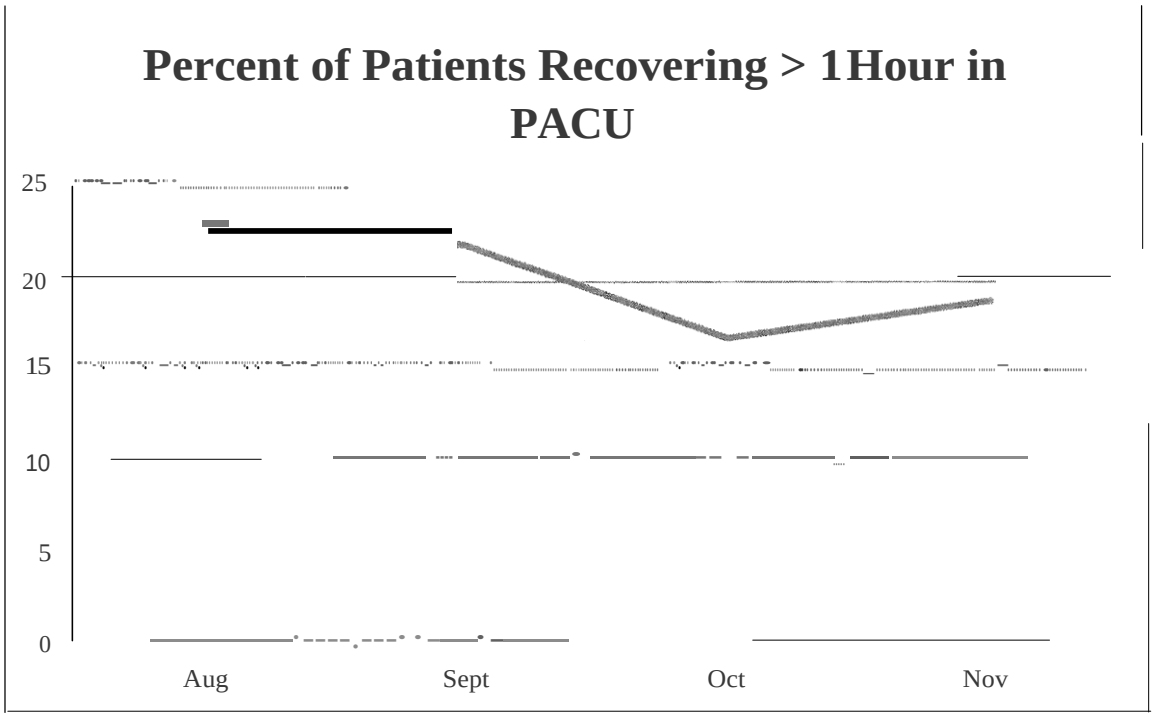
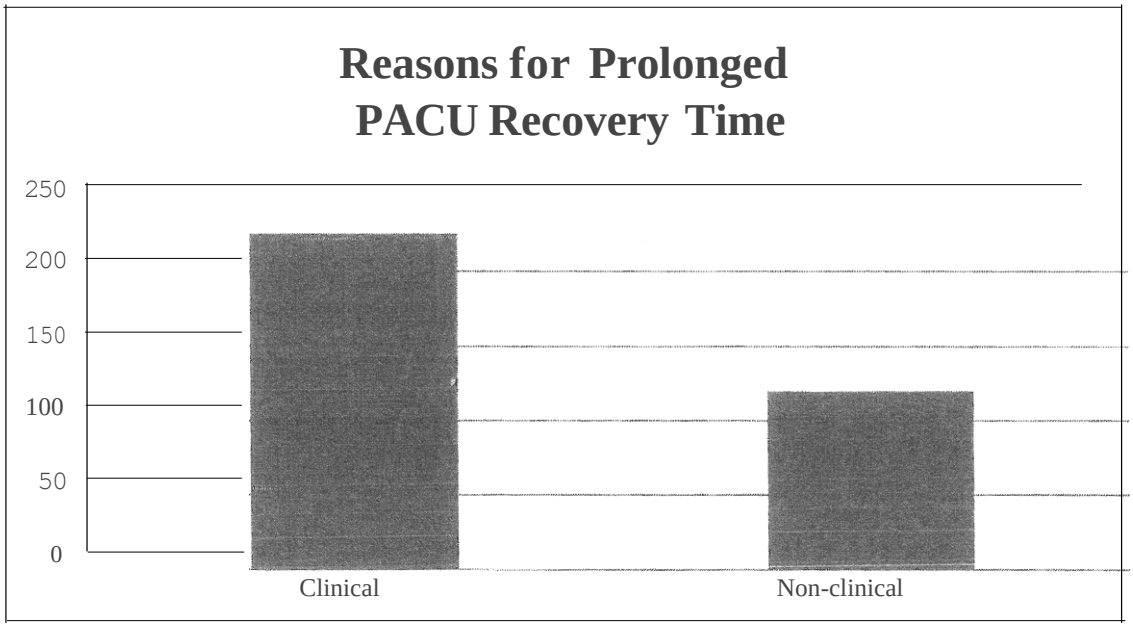
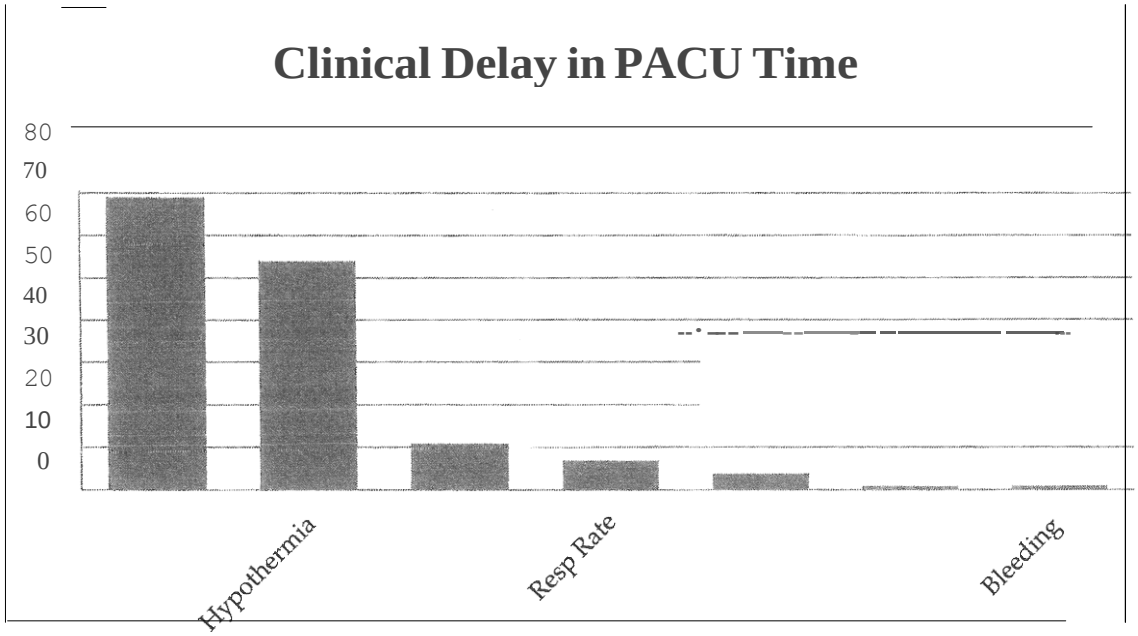


Figure 18: Reasons for Prolonged PACU Recovery Time



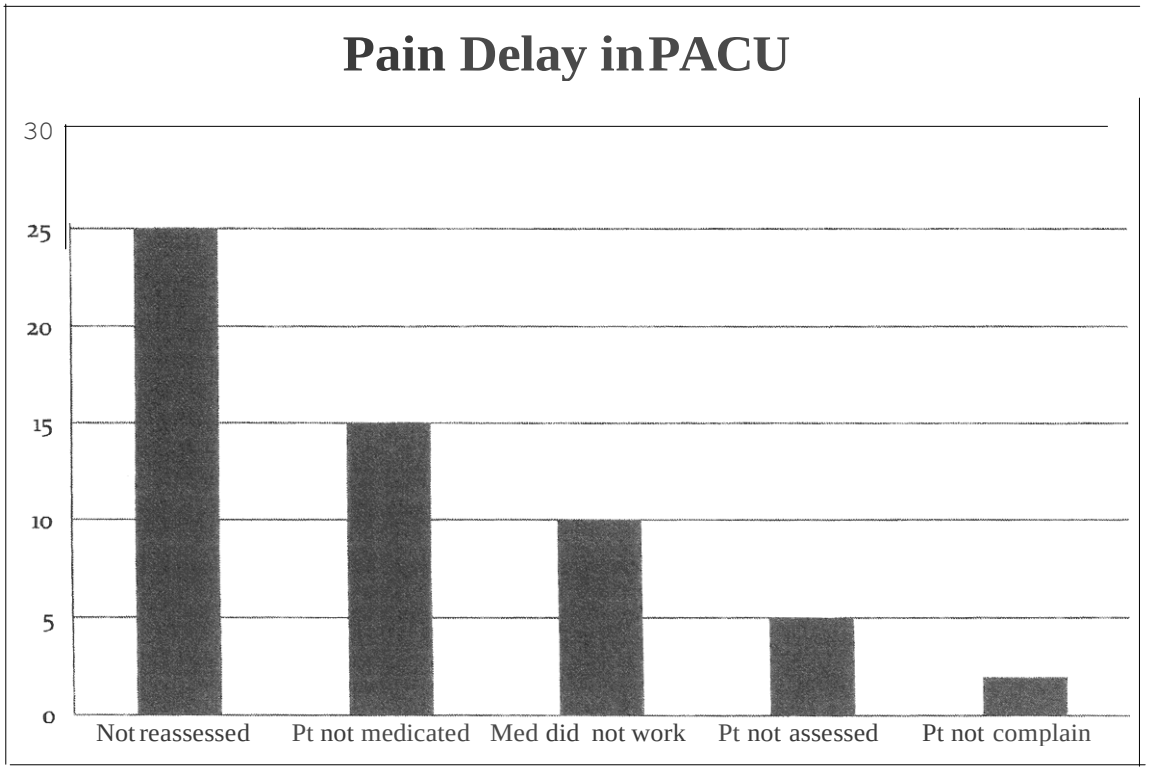
While this was a good first attempt, the Pareto does not really tell the team anything. Everyone already knows that there are clinical and non-clinical issues attributing to these delays, so more drill down is required. It was determined to drill down on the clinical issues first with another Pareto chart (Figure 19).

Figure 19: Clinical Delay in PACU Time



It is clear from this Pareto that pain and hypothermia are the main reasons for the delays in discharging the patients from PACU. Thus, these are the areas where the team should start in determining how to make improvements . Two teams were assembled, one for each of these issues. When the Pain team met for the first time, they determined that 'pain' was a large issue and that perhaps another drilldown on pain would be helpful (Figure 20).

Figure 20: Pain Delay in PACU

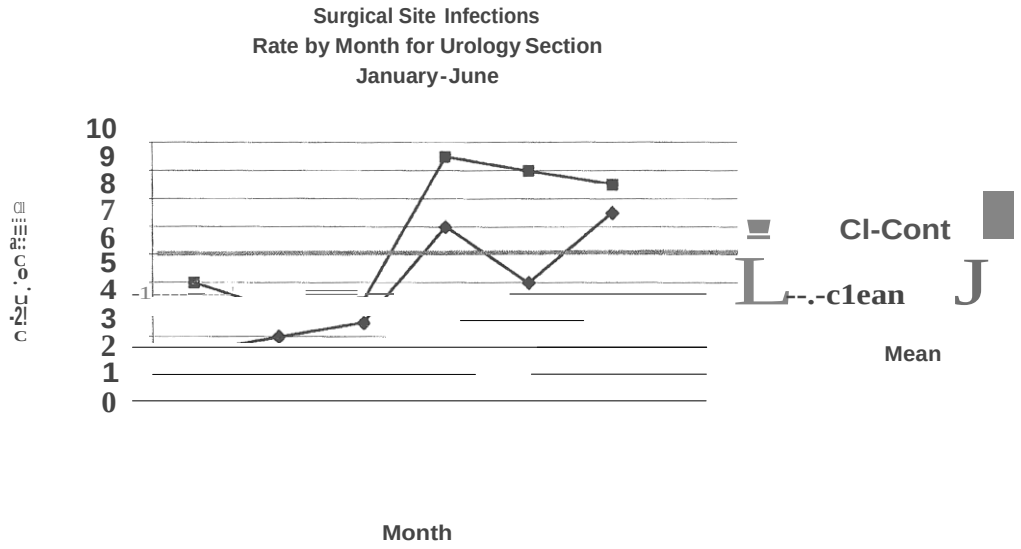


With the information provided from this last Pareto, it is now clear to the pain team that the patients are not being reassessed for the effectiveness of the pain medication, or the patient was not even medicated for the pain if they were assessed. These areas are where the team will focus their efforts to decrease the delay in the PACU.

!Run Chart!

The Line Graph or Run (Trend) Chart is a display of performance changes with systematic increases or decreases in the value of some variable over time. It can be either a comparison within one group when conditions change over time or a comparison between two groups in the same study. Each data point, plotted horizontally, is a measurement of an output from a process (Figure 21).

Figure 21: Surgical Site Infections Run Chart



A *Sun Chard* provides a running record of a process over time and it can be used with any kind of data. It is the tool of choice for continuous or measured data, and should be utilized with categorical or count data if the data is to be displayed over time. It is best utilized in problem identification, data analysis, and outcome evaluation. It requires no statistical calculations. It often includes a horizontal mean or median line.

A Run Chart including the control chart helps to answer the following questions:

- What is baseline performance for the process over time?
- How much variation is there in the process?
- What kind of variation is it, special or common cause?
- Is the process changing over time?
- Was the change really an improvement?
- What predictions can be made about the process from the data?

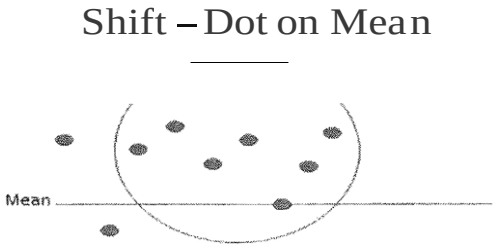
The Run Chart should start as soon as there are data available, and then continue to add data as it becomes available. After there are 10 data points, then a mean or median line can be added, and this will provide more data to help interpret the Run Chart.

There are three probability-based rules that can be used to interpret the data on the Run Charts: a Shift, a Trend, and an Astronomical value. The first of these rules is based on a probability of 5% or p=0.05 indicating that there is a very small probability that chance has made the data act in this

manner. The second and third rules are based on comparison to random patterns of data. All three of these rules should each be applied to a set of data, but not all three rules have to be met to indicate that there has been a change in the data (Provost, & Murray 2011) .

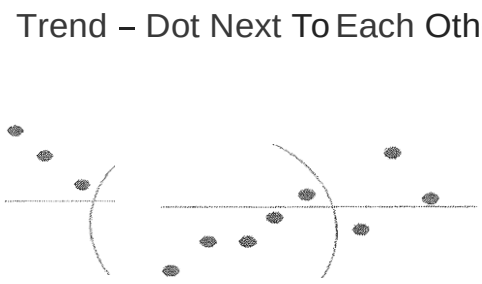
A occurs when six or more points consecutively appear above or below the mean or median. Values that fall on the mean/median itself do not count in terms of the start, break, or end of a shift, and are not included in the count for a shift (Figure 22).

Figure 22: Run Chart - Shift



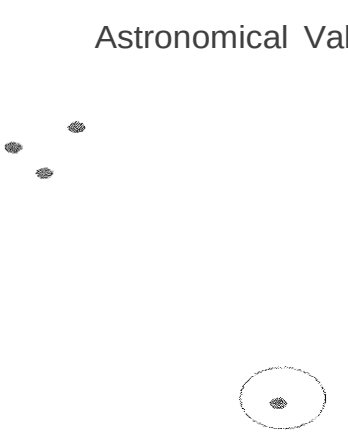
A *ITren* consists of five or more consecutive data points (some people count six or more points) gQ!!) g up or going down. This rule does not care whether the consecutive dots are above or below, or crossing the mean/median . However, if two or more consecutive data points are the same, one of them is not counted (Figure 23).

Figure 23: Run Chart - Trend



An *stronomical Value!* occurs when there is one value which is greatly different from the other data values on the run chart. It would be a va lue that is highly unlikely to occur again, and would appear as an outlier (Figure 24).

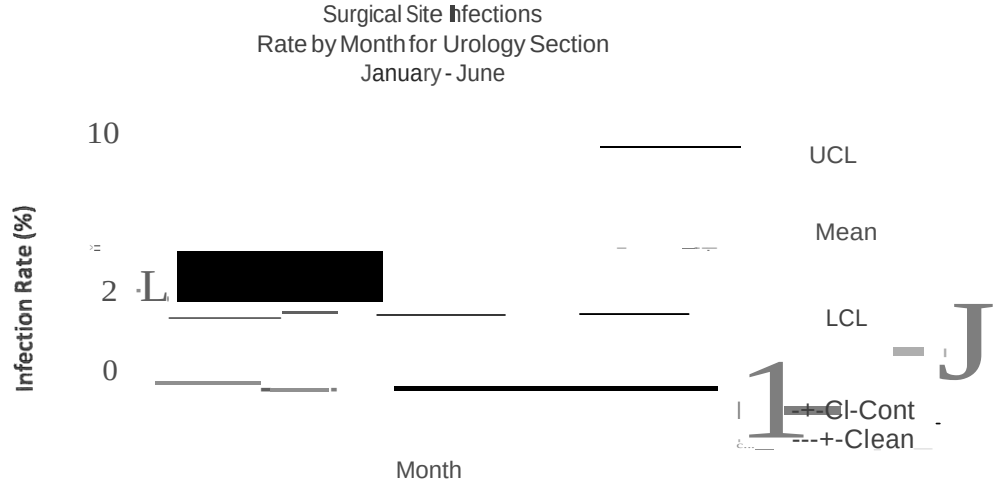
Figure 24: Run Chart - Astronomical Value



!control Chart!

A control chart is a line graph/run chart that compares actual performance or change over time to the mean and includes both upper (UCL) and lower control limits (LCL). It is a display of normal variations and special cause variations over time. It is best utilized with continuous or measured data; and can assist w ith problem identification, data analysis, and outcome evaluation. The Control Limits provide the basis for determining the capability of the process (the degree of control) and to identify special causes (Figure 25).

Figure 25: Surgical Infections Control Chart

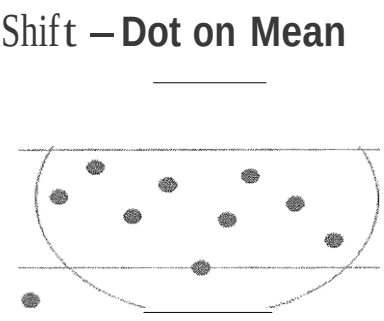


Control charts are more precise than run charts in identifying special cause variation in the process being measured. Data that falls between the control limits are deemed to represent a predictable variation in a "common cause," controlled system. This variation in the data will form a normal distribution, which is the bell-shaped curve. The upper and lower control limits represent the end-most "tails" of the curve. While mathematically different, they can conceptually be thought of as being l, 2, or 3 standard deviations (sigma) away from the mean (see Standard Deviation previously discussed in this chapter). The upper and lower control limits are usually set at ± 3 SD (standard deviations), or 3 sigma, from the mean, representing that 99.7% of the data should fall within those limits. Most national organizations as CMS and The Joint Commission utilize this control limits. Two sigma limits (95.4% of data will fall between these limits) can serve as "early warning signs" if clinicians are uncomfon:able with waiting until a data point exceeds 3 sigma before taking action.

There are many special cause rules that indicate a special cause variation, but three are utilized most often in healthcare (Provost, & Murray 2011). These special cause rules are similar to the probability-based rules utilized with Run Charts . These three rules are (1) a shift, (2) a trend, and (3) any value outside of the upper or lower control limits. If any of these properties are found in the data, then it represents **special cause** variation necessitating intensive analysis.

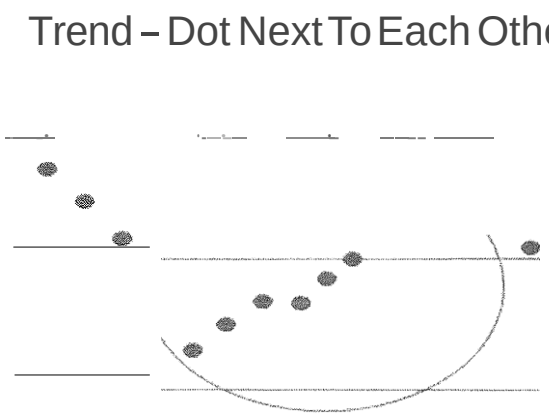
The first rule is a *hif4* which consists of eight or more consecutive points in a row above or below the mean. As in the rule for the Run Chart, a point exactly on the mean does not count or cancel the shift because it is neither above nor below the mean (Figure 26).

Figure 26: Control Chart - Shift



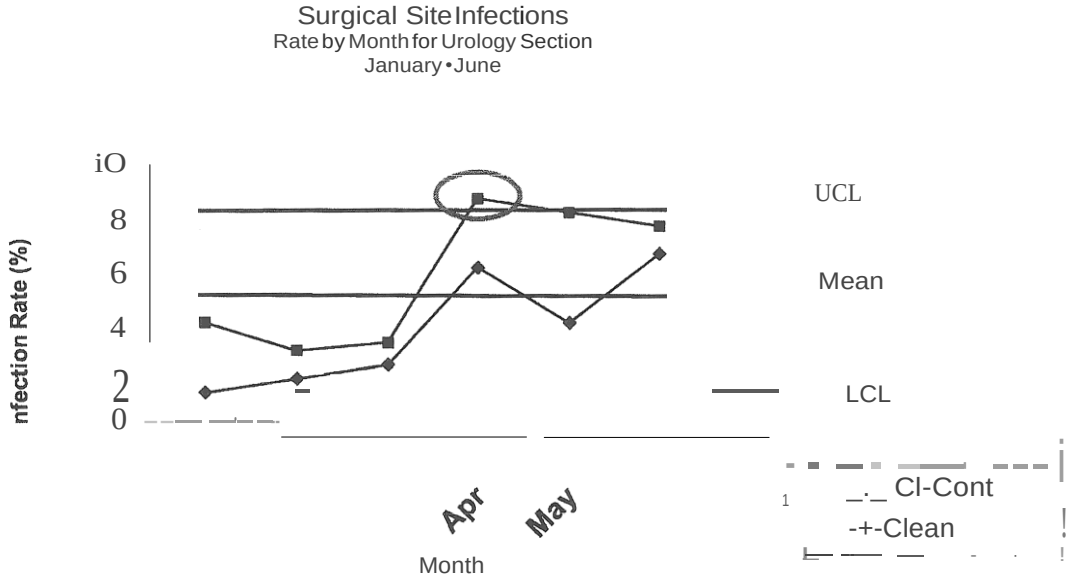
The second rule, la *trendl* consists of six consecutive points going up or coming down. This rule is also similar to the Run Chart rule where two or more consecutive dots of the same value, only the first one
counts since the dots do not go up or down, but remain the same. Again, the mean does not figure into this rule at all (Figure 27).

Figure 27: Control Chart - Trend



The last rule is exactly as it sounds, any data point *!outside of the upper or lower control limid* (Figure 28).

Figure 28: Control Chart – With Dot Outside Upper Control Limit



Process Tools

Process tools are utilized in quality improvement and quality planning to generate ideas, understand current process and root causes, and prioritize improvements. These tools are not discussed in any particular order, but are grouped together with other similar tools.

Brainstorming

Brainstorming is a structured group process used to create as many ideas as possible in as short a time as possible, (e.g., one session), and to elicit both individual and group creativity. Lists generated in this process may relate to problems or topics, components of a process, indicators, criteria, elements for data collection, and possible solutions. Brainstorm ing can be structured, unstructured, or rapid brainstorming. With structured brainstorming, everyone in the group gives an idea in rotation or passes until the next round (a type of "nominal group process"). With unstructured brainstorming, the participants in the group give ideas as they come to mind. Finally, with rapid brainstorming, small groups have two minutes to generate ideas using flip charts and scribes who rotate, and then sha ring each group's ideas with the other groups. This process is repeated two or three times.

There are six steps of brainstorming: Definition of the subject and direction of the session; allowing time for initial, individual thought; establishment of a time limit for the entire session; requesting ideas according to the predetermined structure; keep circling the issue until all ideas are recorded (using a flip chart or overhead projector so all can see); and clarification of all ideas are generated to assure accuracy and understanding.

Nominal Group Technique

Nominal Group Technique is a similar technique used to give everyone on the team/group an equal voice in brainstorming, problem selection, or resolution (Sample, 1984). When the team/group is new, or some members are more vocal, or the issue is controversial, ideas and/or the most important issues are brainstormed in silence, written down, then shared one idea per person at a time, and recorded on a flip chart. In this process ideas are clarified, but not criticized.

Each idea is then rated by each participant, e.g., top five ranked from 5 points down to 1 point independently and anonymously. Votes within the team/group are tabu lated, and a report prepared or discussed with the large group in a structured brainstorming format.

Multivoting

Multivoting is a technique used to prioritize a long list of possibilities or alternatives and to move a team toward consensus. The goal is to end up with the "critical few" ideas upon which to focus the team's attention. Multivoting begins with a brainstorming of ideas as previously discussed . The group then considers similarities, redundancies, etc., on a brainstormed list of ideas in order to eliminate any overlap. Each team member is asked for input to prevent wrongful tampering with an idea. If the team

agrees, then combine duplicate or similar ideas, being certain the team agrees on new wording. Number each item on the new list. Determine how the group wishes to rate each of the items that are on the list. There are multiple ways to do this. One method is to ask the participants to pick a certain number of items (for example 10) on the list that the participant feels are the most important items on the list. Another method would be to give each participant dots of a different color that represent a differenf number of points. The participants then place the dots, one dot per item, on the list next to the items they feel are important.

Once the votes are counted or the dots are placed, someone adds up the number of points for each item. The items with the most selections or points are determined and the others are deleted. The group again individually votes for a lower set number (now maybe 5), or placement of dots (less dots than before), and the calculation of points is again done. This continues until a reasonable number of items are left that the group can work on.

Delphi Technique

The Delphi Technique is a tool used to reach team consensus concerning a particular goal or task . The technique can be used whether or not the team is in session or if members are in different locations. A questionnaire or listing of possible options is drafted by the team or the team leader to tap each individual's views or attitudes, possibly including a requirement to vote, concerning the team goal, task, or project. The questionnaire or listing is circulated anonymously , during, before, after, or in place of team meetings. After each round, the questionnaire or listing is revised and recirculated until consensus is reached. Each round includes a request for comments, questions, objectives, criteria, etc., that participants deem most appropriate. Verbal discussion is used at each team meeting to review the results and gainconsensus.

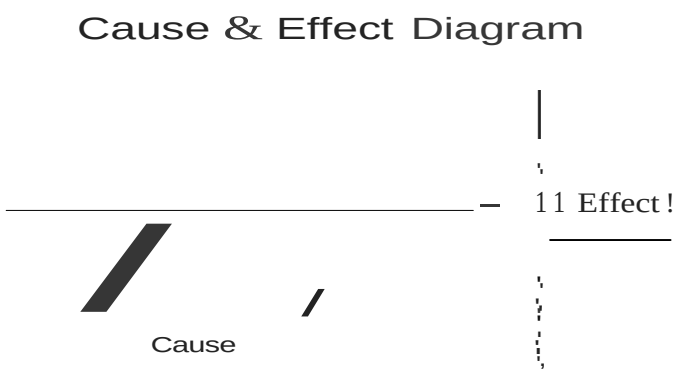
Icause & Effect Diagram (Ishikawa)!

The Cause & Effect Diagram (Figure 29) is a display of the relationship between some "effect" and all the possible "causes" impacting it. It is also often ca lled a "fishbone" or "Ishikawa" diagram . It is a tool generally used to gather all possible causes as an overview. The ultimate goal is to uncover the root cause(es) of a problem. The specific problem can be stated as a negative or positive outcome ("effect") of a process. A negative effect could be the late transfer of patients from the skilled nursing facility to home health facilities . A positive effect could be the need to develop a new service, or educational program. The diagram is a visualization of relationships between the outcome of a particular system or process, the major categories of that system or process (the cause; main branches), and sub-causes (sub-branches off main branches).

The Cause-and-Effect diagrams can be built to analyze dispersion (Why does a particular cause or dispersion happen?); classify processes (identify all steps); or **enumerate** causes (same as dispersion,

except that all possible causes are first organized in list form, then placed in the main cause categories).

Figure 29: Cause & Effect Diagram



To construct a Cause & Effect diagram, begin with the outcome/effect on the right of the paper, halfway down. Draw a horizontal line across the middle of the paper with an arrow pointing to the outcome. Draw diagonal lines angled from the horizontal line away from the outcome . There needs to be at least two lines, but limit the number of lines to less than 6-8 as more would become too complicated and the ideas diluted. These lines will be used to display the causes of the effect that is being studied. Brainstorm to identify possible main causes of the outcome and add them to the chart using horizontal lines (parallel to the main outcome line) touching the appropriate diagonal line. Possible sub-causes of main causes can be identified by using the "Five-Why" technique described in the !Root Cause Analysis\ process in Chapter 5 Patient Safety. The team then needs to evaluate the draft diagram to determine the accuracy of the placement of issues and lines.

You can label the diagonal lines before or after the brainstorming. However, if you label them before the brainstorming, the pa rticipants may be blinded to other possibilities as they will focus on the categories listed in the drawing. If there is a good facilitator to record the brainstorming ideas, the facilitator can group like ideas together and then name the diagonal line based on what is brainstormed and grouped on that line. If it is determined that the diagonal lines should be pre-labeled prior to the brainstorming, there are conventional labels that can be applied. Industry utilizes the 5 M's: Manpower, Materials, Machines, Methods, and Management. In healthcare, there are the 5 P's: People, Provisions {supplies), Policies, Procedures, and Place (environment).

Once the diagram seems appropriate to the team, evaluate the diagram for obvious improvement options, causes already resolved or eliminated, causes easily resolved or eliminated, issues raised which require more in-depth assessment to be understood, significance, etc. Use whatever statistical tools are necessary to collect data, draw accurate conclusions, and pursue appropriate solutions. It is

very important to study the relative frequencies of the different causes before acting to change the process.

Once all of these factors are considered, the team should determine which of the diagonal lines could be improved easily and quickly. That diagonal line should be circled and numbered (#1). Change theory demonstrates that there should be quick wins when possible so that those involved can see that there are improvements being made. This will help those that are unsure to see that there is positive movement in this area. Then identify the diagonal line that will take the most work and the longest time to make the changes and sustain them. Circle this line and number it as the last one to be tackled. For example, if there are four diagonal lines, this line should be #4; if there are five diagonal lines, this one should be labeled #5. Next move to the remaining diagonal lines and determine which ones should be numbered #2, etc., up to the last number already labeled. By the time improvement processes reach the last diagonal line, some of the items will already have been improved based on the gains made with the other diagonal lines.

Interrelationship Diagram

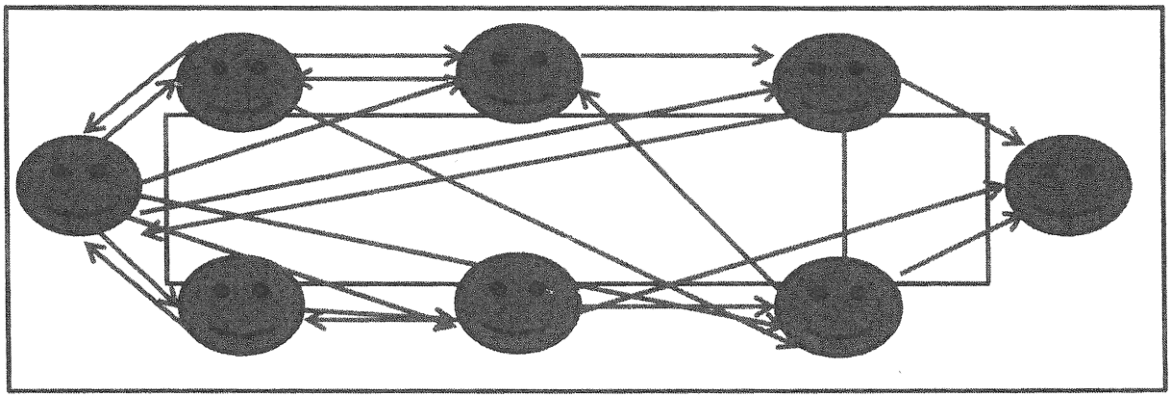
An Interrelationship Diagram is a tool that allows a team to analyze all the interrelated cause-and-effect relationships and factors involved in a complex problem, distinguish between issues that serve as drivers and those that are outcomes, as well as describe desired outcomes. It should be used to help a team understand the relationships among issues within a process. It can also be utilized to assist in identifying root causes (Interrelationship, 2015).

In order to create an interrelationship diagram, a problem statement should be developed and then issues related to the problem. These issues may be identified through brainstorming or with the use of other tools discussed in this book. The items are then each placed into a circle pattern. Using any issue to start with, identify if there are any cause-and effect relationships with each issue in a circle. It needs to be determined whether there is **no** relationship, a weak relationship, or a strong relationship between the two issues. If a cause & effect issue is identified, determine which of the two issues is the cause and which is the effect. An arrow is then drawn from the issue that is the cause to the issue which is the effect. If there is a strong relationship, the line drawn should be a solid line. If there is a weak relationship, the line drawn should be a dotted line. Lines are not to be bi-directional. If both issues affect the other, then draw two lines, with one going in each direction. Once this has been completed for all the issues, count the number of arrows pointing to an issue and the number leaving an issue. The issues with the high number of arrows leaving it are considered a driver. A high number of arrows going into an issue indicate that the issue is an outcome. The driver issues are usually addressed first, and then the outcome issues.

An Interrelationship Diagram can be used to analyze the dynamics of a meeting to determine - who talks a lot and who is quiet during the meeting. When a person talks, the arrow line goes from the person talking to the person to whom the dialog is intended. By the end of the meeting, it can be

determined if someone dominates the meeting and if one person is being shut down by another (Figure 30).

Figure 30: Interrelationship Diagram



Affinity Diagram

An affinity diagram is an organizational tool most often used at the beginning of a team 's work to organize large volumes of ideas or issues into major categories. The ideas may have come from the group's initial brainstorming session. "Affinity" means close relationship or connection or similarity of structure. Therefo re, when developing an Affinity Diagram, it is most important to determine the primary issue and major related subgroups in order to grasp the appropriate relationships, links, or connections.

There are only three kinds of supplies, which are needed: a wa ll, sticky notes, and markers. All of the participants will have some of the Post-It notes and a marker. A pen or pencil will not be readable from far away. Once the primary issue is defined in broad terms, the participants brainstorm ideas, listing one per Post-It note, and posting those on the wall. After all the brainstorming has been completed, two or three individuals go up to the wall and without talking to each other, sort the sticky notes into categories of similar or like ideas. The group then discusses the groupings and provides a concise title for each one. The Affinity diagram is then drawn on paper, based on the major groupings, linking the ideas related to each group (Figure 31).

Figure 31: Affinity Diagram

Lotus Diagram

The Lotus Diagram is a tool to expand thinking around a single topic. The expansion may include types, categories, details, or questions around a theme. It is one simple, but effective way to organize output from Brainstorming. It is also a useful way to organize discussion during planning, e.g., Strategic or Quality Planning. The identification of a topic is the first step to be accomplished and recorded in the center box. Next, the team needs to determine the type of expansion of the topic that needs to be accomplished. The responses are copied into the boxes around the Lotus (center) box. The responses are then placed into the center box of the 8 peripheral 3x3 cubes as displayed in Figure 32.

Figure 32: Lotus Diagram

	Orientation			X			New Teams
			Orientation	X	New Teams		
	W		W	**EDUCATION**	y		y
			Leadership	Z	Physicians		
	Leadership			Z			Physicians

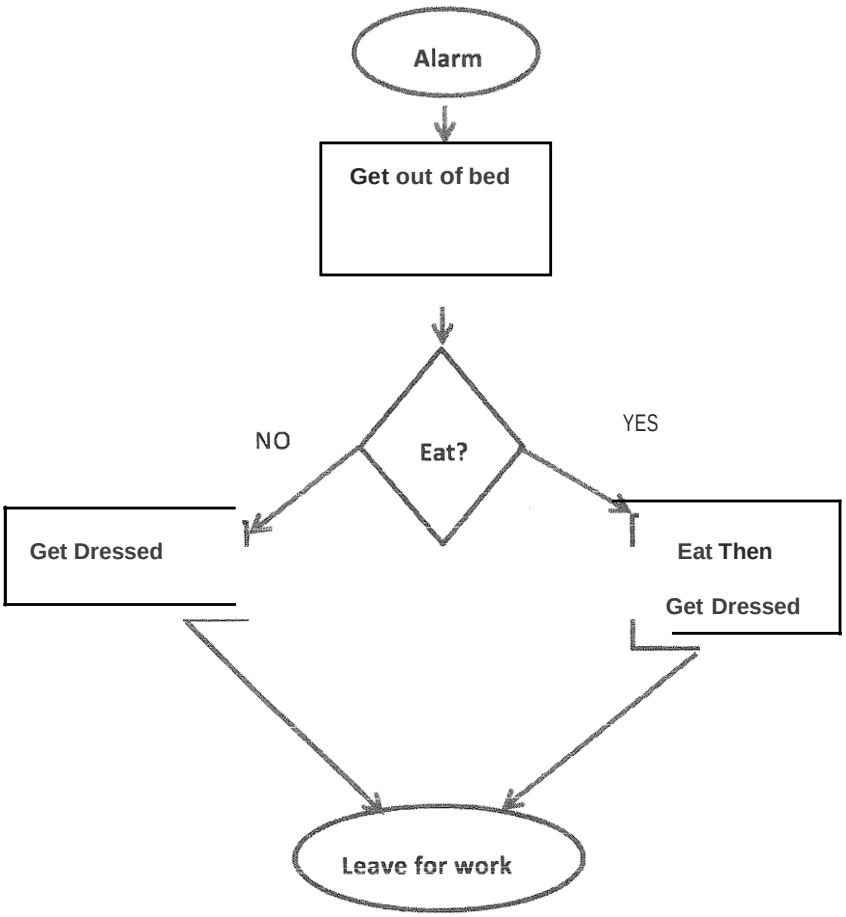
IFlowchar

A flowchart is a pictorial representation displaying all the steps in a process and their interrelationships . It displays the actual sequence of steps and their interrelationships in a specific process in order to identify hand-offs (appropriate and inappropriate), inefficiencies, redundancies, inspections, and waiting steps. It can also be utilized to display the ideal sequence of steps, once the actual process is known.

Flowcharts can be used to identify and describe a current process; to proactively look for potential process weaknesses or failures, e.g., !Failure Mode and Effects Analysis (FMEAJI; to analyze problems to determine causes, e.g., !Root Cause Analysis (RCA)!; to redesign the process as part of improvement action; and to design a new process. It can also be used to identify whether there is a process and when questioning whether the actual process meets current policy/procedure.

There are several steps to be utilized in developing a flow chart. First the team must determine the boundaries (the start and stop points) of the process under review. These may change later as the process is studied in more depth. The team must then brainstorm to identify all activities, hand-offs, and decision points in the process. Once these have been identified, they are placed in sequence, paying attention to repetitions, disconnections, etc. Figure 33 demonstrates such a flowchart.

Figure 33: Flowchart



In developing the flowchart there are certain established shapes that have meaning in the flowchart. The start and stop points are always an oval. A box or rectangle represents the action steps or activity in the process. Each time a decision needs to be made it is represented by a diamond. Every diamond must have two or more exit points from the diamond itself which must be clearly labeled. Arrows connect the ovals, boxes, and diamonds throughout the diagram. If there is more than one "output" arrow from an activity box, it probably requires a decision diamond. All of these symbols are utilized in Figure 33.

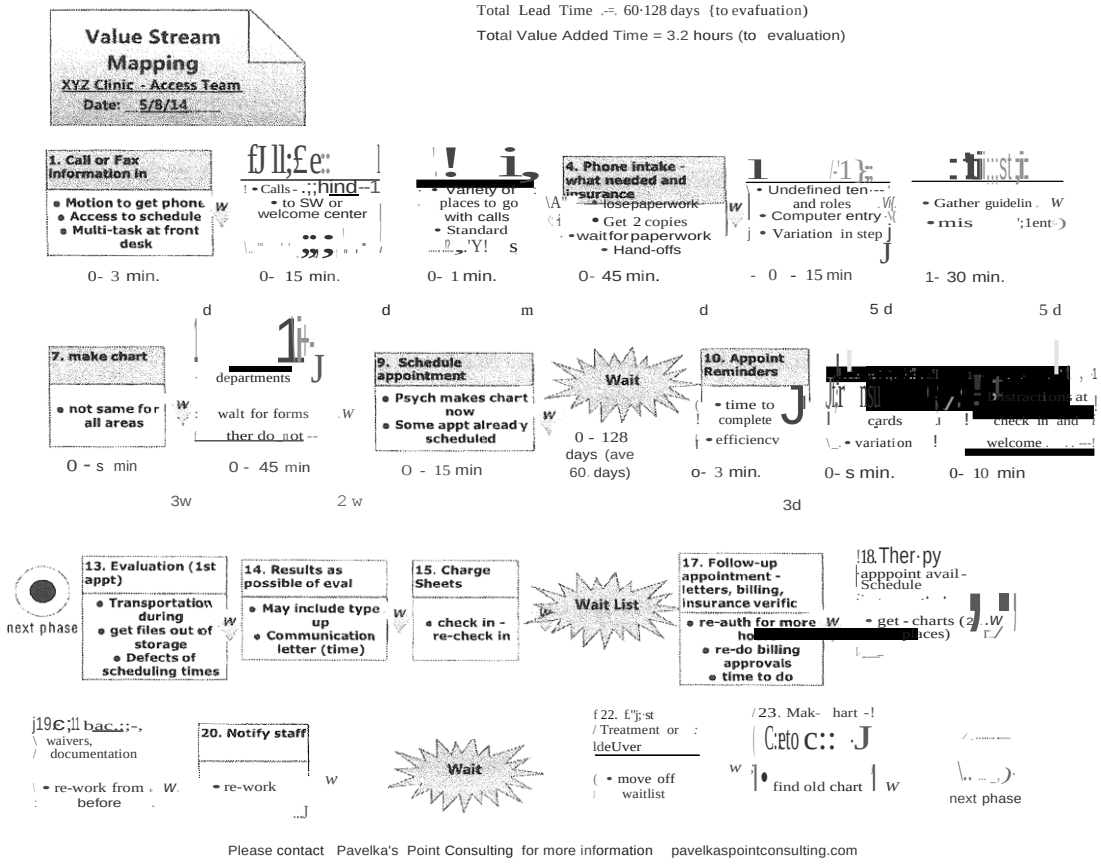
Once the flowchart has been developed, it can be used to determine what changes might be needed. Analyze the flowchart, looking for process "glitches" such as inefficiencies, omissions/gaps, redundancies, barriers, etc. Also, look for the smooth parts of the process to use as models or "best practices" for improvement. Decide whether to correct steps within the current process, design a new process, or do corrections first then redesign in the future. If utilizing the flowchart with an IFME, look for places where there is a potential for failure that could result in a patient care or other problem.

Value Stream Map

A Value Stream Map is utilized at a high level to identify the value and non-value steps in a process from start to end of the process. Once the areas of non-value are identified, a process map may be used to provide more detail about the area that has less value. It is then from the process map that the identification areas of needed improvements can be made and an action plan developed and implemented.

The Value Stream Map typically contains a SIPOC table, which stands for Supplier, Input, Process, Output, and Customer (see Table 19). In each of the columns of the table (boxes in the table below), the high level data are placed, including upstream and downstream links. The team requires a narrow charter (focus) of what is to be mapped, being specific to the process being mapped. The team must be composed of the individuals who do the work, understanding the inputs and outputs of the process. The team members must also be able to identify the resources that will be needed to perform the tasks, and the demands of the outputs (McInnes & Dean, 2012).

Table 19: Value Stream Map



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Before the columns in the table can be filled, the team must identify what the demands of customers are, the maximum demand (what the system can tolerate), the historical demand (what the usual demand is), predicted market changes in demand (what the future may bring), and how the product or services may evolve over time. Once these have been determined, the team can begin to identify the SIPOC column contents. In order to complete this step, the team should use sticky notes so that the ideas or steps in the process can be rearranged based on the teams input. The actual process being mapped should be observed and interviews should be conducted with those actually doing the process. The process should be recorded with the sticky notes without making any judgments as to what is happening. The time it takes to complete each part of the process should be captured, and determine if the steps are completed one at a time or batched together. The team members should record what resources are required before each step in the process is undertaken. The amount of time that patients, staff, and/or others have to wait in line, or wait for something, needs to be included, as well as how things are prioritized and sequenced. Once this step is completed, the Value Stream Map can then be constructed utilizing the standard icons for this tool. These icons can be found on the internet or in printed materials such as *The Lean Memory Jogger* (Mcinnes & Dean, 2012) for Healthcare. Aftei the map is constructed, a lead-time chart is completed below each portion of the value stream map utilizing the time data gathered . After this step, the team is ready to identify where improvements are needed. There may be need for a further drill down on particular steps and that is where the process map can be a valuable tool. It can be used to identify the waste and unnecessary steps that should be removed.

Process Map

A process map is a series of detailed steps or actions performed to achieve a specific process. It is very similar to a Flowchart. Process maps are utilized to document processes, identify areas of rework, and to generate ideas for improvement. After the improvements are made, a new graph can then be utilized to illustrate how the process was improved. Process maps can be used in brainstorming possible changes to the process, to revise or create policy and procedures for processes, to identify possible outcomes of a process, and to orient/educate staff members. The symbols utilized in a process map are the same as those utilized in a flow chart.

A3 Problem Solving Tool

The A3 tool is a problem solving approach built around the POCA model previously discussed in Chapter 3 Performance and Process Improvement. This tool is a method of structuring thinking, and a communication tool for reporting problems and improvement suggestions to management. !t is a concise summary of the problem and a possible solution. Several formats may be utilized for the A3 tool, and these can be found on the internet and in Lean and Six Sigma books and articles. Work is done on one 11 x 17 form that includes: Background, Current Conditions, Goal, Analysis, Proposal, Plan, and Follow Up (Figure 34).

Figure 34: A3 Tool

PDMAI	The A3 Problem Solving Process
	Issue Summarize the issue. Be creative to engage the reader.
	Background Define the problem and why change is needed.
	Current Condition Include graphs, numbers, and facts that clearly depict the "as is" state in a way that invites analytic questions.
	Problem Analysis What are the root causes for problems? Keep asking "Why?" to drill down. 1. Problem o Why? o Why? o Why? 2. Problem o Why? o Why? o Why? 3. Problem o Why? o Why? o Why?
	Target Condition Include graphs, number, and facts that clearly depict the "desired" state as well as the gap between current and desired states. Title / To / By / Date
	Countermeasures These are the proposed actions to address each root cause. Start with all ideas and archive those that don't pass group evaluation. Root Cause | Countermeasure | Benefits | Evaluation
Assess: Compare the results before the change, with the results after the change. Are the results improving? What other solutions could be tried to improve the results? **Improve**: Implement new solutions and continue to measure results. How do our results compare to others?	**Implementation Plan** This is a miniature summary of a more detailed Gantt or "To- Do" list. Reviews are usually both periodic & upon completion. What | Who | When | Outcome Cost | Cost Benefit/Waste Recognition Cost | $$$ Test **Follow-Up**

The background consists of why is this important to examine at this time. What is the business case that you are trying to solve or analyze? It should be stated concisely and communicate to others why you are addressing this issue. The current conditions consist of where is the process at this time. What is going on? What is the symptom that brings this issue to the organization's attention? How often does it happen? In addition, is there a pattern of occurrence? This area should include data, facts, charts, graphs and other such tools.

The goal is stated as succinctly as possible with the target that is desired. What is the specific change you want to accomplish? How will you measure success? The graph must be stated in measureable or identifiable terms. Many times, this is the outcome of a !Root Cause Analysis (RCA)) as discussed in Chapter 5 Patient Safety. It should include why you are experiencing this problem and what constraints are preventing you from reaching your goal or target. You can utilize fishbones and other quality tools to display this information and state the analysis as simply as possible.

The proposal is the countermeasures you feel are needed to reach your goal or target. What alternatives should be considered? How will you choose the option and what criteria will you utilize to do so? How will your choice impact the root cause to change the current situation and achieve the goal/target? The .P.@.!'.l is what specifically needs to be implemented and who will be responsible for the implementation .This should include a timeline with who, what, when, where, and how. The follow up then consists of how you will know if the desired impact has occurred. What issues or remaining problems can be anticipated? it wiii also identify any failure modes that have been identified that will require further action.

Force Field Analysis

A Force Field Analysis is used by a team when a proposed solution to a problem will require significant change, and it is important to analyze the potential impact and chances of success. The team can, thus, be proactive, anticipating both possible resistance to change and ways to minimize it. Kurt Lewin, an American social psychologist, developed this technique to look at both the "driving forces" that move a situation toward change and the "restraining forces" that block the movement. If no change occurs, it is because the opposing forces are equal, or the restraining forces are too strong. Sometimes the two sides are title strengths and weaknesses . It is the goal to 'strengthen' the strengths, and to 'weaken or remove' the weaknesses . Figure 35 represents a template for a Force Field Analysis.

Figure 35: Force Field Analysis - Integrating Quality, Utilization, and Risk Functions

Force Field Analysis - Integrating Quality, Utilization, and Risk Functions	
Driving Forces (Strengths)	**Restraining Forces (Weaknesses)**
Shared mission and vision for quality in the organization	Loss of autonomy
Reduced duplication of effort; staff efficiency	Changes in job descriptions and workload
Balanced approach to decision making regarding cost, quality, risk	Loss of focus on specialty area
Shares Staff (cross training)	Staff turnover with leadership change

In order to create a Force Field Analysis in a template (such as Figure 35), list in two columns all the driving (strengths) and restraining (weaknesses) forces affecting a desired change. Discuss the overall value of the proposed change and then the team comes to a consensus about priorities for effecting change. Include in the planned solution actions to diminish or eliminate the restraining forces while strengthening the driving forces.

Checklist/Task List

A checklist or task list is a listing of things to do or obtain in order to keep the team on schedule, to help team members remember commitments (e.g., the Safety Surgical Checklist), or to inventory information. Joseph Juran called it a "memory jogger". A task list can be converted to a detailed action plan if appropriate. In Figure 36, the checklist is designed to inventory information and to display how often something occurs or does not occur.

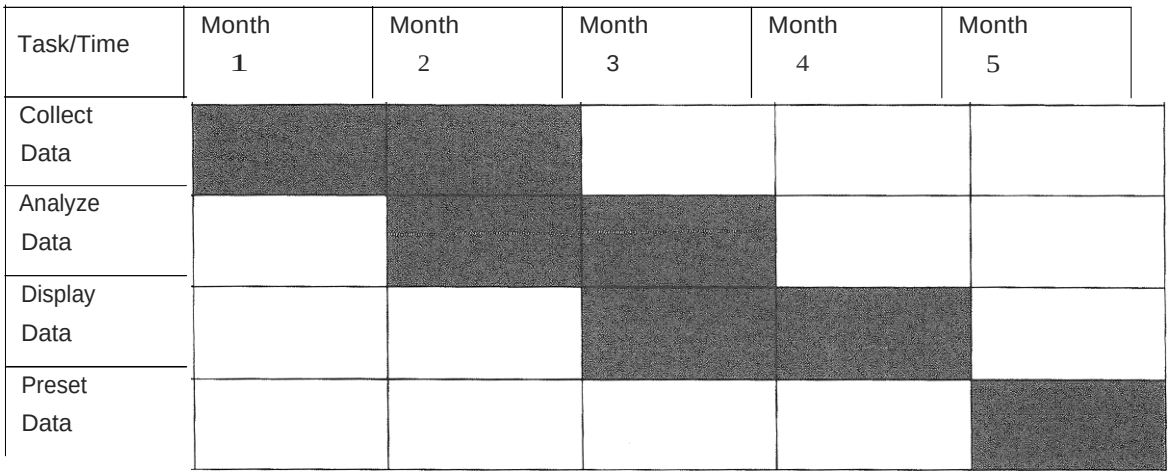
Figure 36: Checklist

Errors	Jan	Feb	Mar	Apr	May	June	TOTAL
Type 1	1111	II	II	1111	1111	II	18
Type 2			II		III	II	7
Type 3	I	I	III		1111	1111	13
Type 4				1111		1111	8
TOTAL	4	3	7	8	11	12	46

!Gantt Chart!

A Gantt chart is a !project-planning tool! for developing schedules. It is a graphic display (a type of bar chart) of the individual parts of a quality improvement process as bars on a horizontal scale. The Gantt chart includes a list of tasks (process steps) and estimates of time and/or people resources required to complete the quality improvement effort. Most project-planning software includes Gantt charts. Figure 37 displays a Gantt chart that shows the estimated time of a project from initiation to presentation. Instead of columns representing time, you could also use the Gantt chart to assign who is responsible for what steps in the process.

Figure 37: Gantt Chart



iPrioritization Matrix!

A Prioritization Matrix is a tool used to select one option from a group of alternatives whether problems or solutions, or to put options into priority order if all need to be done. it promotes decision-making and consensus (Figure 38).

First, the matrix must be prepared with options, problems or solutions down the left side and criteria and total score coiumns across the top of the matrix. List the items that need to be improved or decided upon down the left side of the matrix. They do not have to be listed in any certain order. Next, determine the criteria to be utilized to help make the decision regarding the priority order . The criteria should all be phrased either positively or negatively so that the rating can be applied consistently. A point system must then be developed. Typically,a 1to 5 Likert Scale is utilized with one being of low significance/importance and five being of high significance/importance based on the criteria. A zero should never be utilized.

In order to apply the criteria equally to each of the options/problems/solutions, the user should not take an item from the left column and apply the ranking horizontally across all criteria. Instead, each criteria should be taken and applied vertically down each of the items in the left column. This will allow the rater to apply the criteria in the same manner to each of the items. There does not have to be only one use of a number per column. In Figure 38,the cost column contains two items rated a two in cost. The value placed there is independent for each item in the left column. Once each of the items have been rated utilizing each criteria, each row is added horizontally and the total placed in the last column in the appropriate cell. Once all rows have their totals displayed, the course of action will become clear. The items in the left column will be rank ordered with the highest score determining the first item to be addressed. Also in Figure 38, "longer hours" has the highest score, and thus should be undertaken first in order to improve patient access to the clinic. The physician numbers should be

addressed second or maybe even at the same time as addressing the longer hours. Adding a toll-free number can then be done after the other two items have been accomplished.

In order to create this Prioritization Matrix, one of two methodologies is usually applied. The entire team in one meeting can brainstorm together to determine the numbers to go into each cell. This will allow the team members to hear and hopefully understand the rational and viewpoints of the other members on the team. The alternative, and sometimes-easier, approach is prior to the meeting, to have each member of the team independently, enter their own numbers and submit the Prioritization Matrix to the team leader, who then combines all the individual scores into the final sheet. Then the results are presented at the team meeting and everyone will have had input as to what the desires should be.

Figure 38: Prioritization Matrix

PRIORITIZATION MATRIX

PROJECT: IMPROVE PATIENT ACCESS TO CLINIC

Clinic Access	Quality Impact Criteria				Total
Options	Safety	Pt. Outcome	Pt. Satisfaction	Cost	Score
Toll-Free #	1	3	5	2	11
Longer Hours	3	5	4	4	16
Physician Numbers	5	5	1	2	13

Likert Scale = 1(lowest), 5 (highest)

THE DATA IS COLLECTED AND DISPLAYED. NOW WHAT?

The entire point to performing measurement is to give the leaders and others involved in the improvement process information that will be the basis for decision making - strategic, operational, clinical, and education decisions. However, doing what we have already discussed is not enough. Frequently, the individual presenting the information must analyze the data (which is discussed following this section) and create a report that provides analyzed data (information) and potential actions that should be taken.

Analysis and Interpretation

Analysis is the process of studying and interpreting aggregated and displayed data and drawing valid conclusions leading to a decision. Initial Analysis and Interpretation of data usually is the responsibility of those persons closest to the process being measured, or perhaps the team that is chartered to

design/redesign or improve the process. It may be performed by one or more persons participating at appropriate stages of the QM cycle/PI process and may involve one or more of the following steps :

- "Eye-balling" the data in its current form (raw or aggregated)
- Comparing the data to triggers, thresholds and benchmarks
    - [riggers\ are tools to find clues about adverse events. The Institute for Healthcare improvement has developed "trigger tools" in areas such as medication administration and global trigger tools. For instance, some organizations ana lyze the use of Narcan, a medication that is used to reverse the effect of narcotics, to identify overdosing. Many other tools are available on the IHI website
    - [hresholds\ are levels of improvement expected and if that level is not reached, it is expected that action will be taken. An example would be an organization that requires its patient satisfaction to be 90% or above. Any time patient satisfaction is below that level, action must be taken
    - A lbenchmarkl is a standard one compares to what has been achieved by another organization that one wishes to emulate . In the example immediately above, the organization achieves 85% patient satisfaction but cannot seem to get any higher. They find that a similar hospital using the same patient satisfaction tool achieves 95% regularly. They plan a visit to the organization to see what processes they have in place to achieve that level, identifying which processes to copy in order to achieve this benchmark of patient satisfaction
- Coordinating some or all aggregation tasks (tabulation, summarizat ion, statistical testing, display) to clarify the data
- Validating accuracy, validity, and reliability
- Comparing to other known, related data to determine need for intensive analysis
- Identifying and sepa rating issues for lpeer review\ from process issues

Intensive Analysis is the responsibility of those persons with the knowledge, expertise, and experience to study the process issue in-depth: those who know which questions to ask, and how to best interpret the resulting information . The outcomes of such analysis include determ ination of degree, type, and possible causes of process variation, and if validated, whether process improvement is necessary .

Regardless of who is to analyze the data, there must be certain questions asked (Table 20). These questions are essentia l in that they will help to determine the type of analysis to be utilized. These analysis methods include the identification of patterns, trends, and variation; group analysis by teams; analysis by peers; and special analysis for root cause analysis.

Table 20: Analysis Process Questions

Analysis Process Questions
• Does the accumulated data **adequately represent the group** being measured? Are all predefined diagnoses, conditions, procedures, tests, events, locations, time frames, etc., included?
• Is the sample size large enough to render fair interpretation?
• Is the accumulated data accurate? Have adequate validations been performed or crosschecking measures been taken?
• For each indicator measured, has the trigger (if applicable) for intensive analysis been reached?
• If comparison levels are used how does actual performance compare to the previous year; internal, regional, or national norms; internal or external benchmarks, etc.?
• Is demonstrated performance consistent with the stated indicator/expected outcome/standard?
• Is there a gap between demonstrated performance and the stated indicator that identifies a need for action to effect change? Is the gap based on an isolated case or on a pattern or trend? Is change needed?

A *pattern* is an identifiable arrangement of data (a grouping or distribution) suggesting a systematic or predictable relationship. An example of a pattern would be a positive correlation between patients' heart rate taken by a nurse and that taken by a monitor and plotted on a scatter diagram.

A trend is a key type of pattern indicating a general tendency or direction of events or conditions, usually over a significant period of time . An example of a trend might be decreasing infections from surgeries over a period of six months.

Looking for patterns and trends in data over a period of time is an attempt to understand variation in the process being measured. Part of the responsibility of participating in analysis is to assure that the data is appropriately displayed so that patterns and trends can be detected.

There are basically two approaches for depicting variation. A static display (like snapshots with a camera) describes the process and occurs with simple tabulation, calculations of measures of central tendency (Mean, Median, Mode) and measures of dispersion (e.g., Range, Variance, Standard Deviation), and aggregated forms, (e.g., Tables, Pie Charts, Histograms, Pareto Charts). A dynamic display (like pictures with a video camera) shows variance over time (Common and Special Cause) and occurs when data are plotted on Run or Control Charts.

Each approach helps convert data to information. The person or team must decide when to use each approach and how to move from information to knowledge and decision.

Analysis by interdisciplinary teams or peers, as applicable, includes the determination of the degree of success in meeting the "standard" or expected outcome for each performance measure for which data are collected in a process of care or service. The data can indicate an "acceptable" range of variation, current performance level, a trigger for intensive analysis, a brer1ch in acceptable performance rather than an appropriate "exception", and a need for change, or opportunity to improve, a particular process. If a "clinically relevant" issue or concern suggesting real or potential adverse patient impact is identified by a performance improvement team, and specific individuals or cases are involved, the issue must be referred to the appropriate peer group for further review.

!Peer Review! is the key to fair interpretation of practitioner-specific or case-specific information collected in the assessment process. Those with professional experience, expertise, and judgment in the particular healthcaie specialty must determine what constitutes current competency for practitioners, and must perform any necessary peer review . Clinically relevant findings with real or potential adverse patient impact require a commitment to take corrective action or initiate change. This type of review was discussed in Chapter 3 Performance and Process Improvement.

!Root Cause Analysis Process! which may also be utilized in the analysis of the data, will be described in Chapter 5 Patient Safety .

iviore information on the analysis of data/information can be found in Chapter 3 Performance and Process Improvement.

!Documentation, Reports & Meeting Minutes!

¡Management of Quality Information Documentation!

Documentation of information is critical. There are many ways that information is documented in a healthcare organization. Of course, there is the patient's medical record, which was discussed earlier in this chapter. It is impossible to list all possible types of documentation, but several are listed in Table 22.

Table 21: Types of Documentation

Types of Documentation
Documentation includes, but is certainly not limited to: • Medical record (manual and electronic) • Minutes of meetings

- QI team project descriptions/p lans
  - Quality Initiative teams (e.g., pneumonia or asthma care; new community-based clinic)
  - Key function teams (e.g., information management-new Internet applications)
  - Ad hoc teams (e.g., diabetes clinical path or hypertension disease management)
  - Organizational process teams (e.g., patient safety)
- QI team project progress reports
- QI team project summary reports
- QI project "storyboards"
- Performance measure trend reports
- Ongoing measurement/quality controlsummary reports/"function reports"
- Special study reports

  Confidential lpeer review! worksheets and reports
- Practitioner profiles
- Report cards (see Healthcare Effectiveness Data and Information Set (HEDIS®) in Chapter 3 Performance and Process Improvement)
- Annual quality, utilization, risk management program evaluations (as applicable)

!Action Plans[

Once the data have been analyzed to produce the information required, and actions that need to be taken to make improvements or to sustain the gain has been identified, then an action plan needs to be developed and implemented. After the implementation, there needs to be another collection of data to determine if the desired results were obtained (See PDCA and similar information presented in Chapter 3 Performance and Process Improvement).

The action plans should include a statement concerning what is to be improved, what the goals of the improvement effort are, and the various steps to be completed to achieve the goals. There should also be a timeline dnd an assignment of who will be involved in each step. It is also an absolute necessity that the outcome of each step be something that can be utilized to move to the next step, or which contributes to the overall desired goal. As the team moves through the action plan, there should be commun ication with the senior level sponsor of the team. This is to assure that the team stays on course and does not wander into an area that the administ ration of the organization cannot/will not accept as a result of the action taken. There should also be a team commitment to be mutually accountable to assure that the timeline and the deliverables are completed within the planned time frame.

!Management of Documentation of Meetings and Reports!

It is the responsibility of every member of a QI Team, committee, or service who has participated in quality management activities to review and approve both the accuracy and the completeness of the documentation of those activities. Documentation includes, but is certainly not limited to: Minutes of meetings; QI team project descriptions/plans; QI team project progress and summary reports; QI project "storyboards"; Performance measure trend reports, including those sent to external agencies; Ongoing measurement/quality control summary reports/"function reports"; Confidential peer review worksheets and reports; Practitioner profiles; Dashboards & Balanced Scorecards; and Annual quality, utilization, risk management program evaluations (as applicable).

The documentation must be easy to read and displayed in a fashion that the reader will understand what is being conveyed in the report. If there is a graphic presentation of the information, there are various means to identify points of interest on the graphs. Some of these include the use of arrows, comment clouds, circling the important information, the use of color, and many more. Refer back to the graphic tools described in this chapter to identify how these methods can be utilized.

Above all, when the information is ready to be presented to individuals in the organization, it needs to be tailored to the individual levels in the organization. For example, information presented to the Governing Board should be a condensed version of what is presented at the department level where the information is to actually be utilized to make improvements. The information should be reported to all areas of the facility which may benefit from the information, not just the area that collected the data. For example, if data is collected after an action plan has been implemented regarding the use of antibiotics in the emergency department with adults who present with pneumonia, the findings should also be presented to the Pediatrics department who may also be able to utilize the information for their patients. In all cases, the information must be returned to the individual users/departments/units where the data are to be utilized to make the improvements required, or for sustaining successful improvement efforts. All quality information that does not pertain to one specific individual should also be communicated to the Quality Council (see Chapter 3 Performance and Process Improvement) for their use.

\Meeting Minutes!

Minutes from meetings and other activities are important information that leads to decision-maki ng at all levels. It is important that the minutes stand by themselves and do not depend on attachments to explain what happened at the meeting. There should be enough information in the minutes themselves to demonstrate what was discussed in the meeting and the outcome of the discussion (See Chapter 3 Performance and Process Improvement for more information).

The content of minutes, in general, should include the meeting date, the time meeting was called to order and adjourned, attendance and who was not in attendance, old business that is a follow up from

a previous meeting or outstanding issues, new business related to performance improvement activities and operations, and an authorized signature approving the content. Both the old and new business sections should each include a summary of discussion, conclusion, and action and should also include a timeframe in which the action is scheduled to be taken. Actions that need to occur can then be carried over to the next meeting's agenda as old business.

There is no one format that is acceptable . Each organization must determine a format that is best for their organization to utilize. The format should include the agenda items, which then lead to the information that was discussed for each item, recommendations or actions needed, and follow up that needs to occur at the next meeting. The discussion and action items include an evaluation of how effective the action taken was and if more improvements are needed. The same numbering system should be used in the minutes as was used in the agenda for the meeting.

Key Elements that need to be Addressed:

- The agenda items should include all topics to be discussed, where the meeting will be held, and the time for the meeting. The agenda should be created from the outstanding items from previous meetings, plus any new business for the meeting. The items listed in the agenda should all be included in the minutes of the meeting, w ith the same numbering and ordering as the agenda.
- Meeting minutes should stand by themselves and give the reader all of the information needed to "know" what happened at the meeting. The minutes should list who attended, who was excused from the meeting, those who were absent, and any guests that were present .
- When someone asks for a copy of the minutes, any attachments presented at the meeting are usually not included. If the minutes simply say 'see attachments' then the reader will not have any idea about what happened during the meeting regarding that item. For every item that is on the agenda, there should be something in the minutes to describe what was presented, any discussion that followed and the results of that discussion, what conclusions were made, what actions need to be taken, and who is responsible to assure that those actions occur .
- The minutes should be distributed as soon as possible after the meeting so that the attendees and those who missed the meeting will have the information they need to follow up prior to the next meeting.

In conclusion, the best way for a healthcare organization to demonstrate improvement is using data. Gone are the days when your reputation as a hospital, HMO or insurance company was based on the "word of mouth" informat ion shared in the community. Today, the organization's reputation is based on very specific information: Publicly reported data on clinical and service outcomes, accreditat ion status and reports including Magnet status, newspaper articles detailing events that are brought to the

attention of the public, financial reports that make their way into the public purview, publicly reported data on physicians and mid-level practitioners, and in some organizations local or state information made public. What we do with the data is essential. We cannot ignore it now or in the future. It is the basis of reputation, reimbursement, and solvency.

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Chest Pain Center Accreditation Agency	http://www .scpcp.org/Services/CPC.aspx
Common Formats	http://www.qualityforum.org
Common Formats	https://www.psoppc.org/psoppc_web/publicpages/commonFormatsHV2.0
Decision Making Systems	http://www.hea Ithit.gov sites/default/files/aeds-lesson s-in-cds-implementation-deliverablev2 .pdf
Dispersion of Data	http://www.quickmba.com/stats/dispersi on
Dot Plot of Length of Stay (LOS) for CVA (Stroke)	http://www .qimarcos.com
Excel, as spread sheet program	http://products .office.com/en-us/excel
Finance and the Health Information Management (HIM) Department or the Medical Record Department	http://library.ah ima.org/xpedio/groups/public/docu ments/ahima/bok1_049692. hcsp?dDocName=bokl_049692
Health Information Exchange	http://www.healthit.gov/HIE
Histogram of BM!	https://openi.nlm.nih.gov/detailedresult. php?img=PMC2880689_kjim-25-162-g002&req=4
ICD-10	http://www.cdc.gov/nchs/i cd/icd 10cm.htm
IHI Trigger Tools	http://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx
Information Literacy	http://www.ala.org/acrl/search/site/information%20 literacy%20standards?f%5B05D=hash%3Ar4swl
Information Management	http://www.ironmountain.com/Knowledge-Center/Reference-Library/View-by-Document-Type /White-Papers-Briefs/R/Redefini ng-the-Role-of-Health- Information-Management-in-the-New-World-of-Information-Governance.aspx
Interrelationship Diagram	http://www.smartdraw.com/interrelationship-diagram/
Khan Academy	http://www.khanacademy.org
Meaningful Use	http://www.cms.gov/EHRIncentivePrograms
National Quality Forum (NQF)	http://www.qualityforum.org
Numerator and Denominator	https://www.khanacademy .org/math/pre-algebra/fractions-pre-alg/understanding-fractions-pre-alg/v/numerator-and-denominator-of -a-fraction

Process Tools: Interrelationship Diagram	http://www.smartdraw.com/interrelationsh ip-diagra m/
Pt Safety Act	https://www. pso.ahrq.gov/legislation/act
Pt Safety Rule	http://www. pso.ahrq.gov/legislation/rule
Standard Deviation	http://www.quickmba.com/stats/centralten
TJC sample size	https://manual.jointcommission.org/re leases/TJC2013A/SamplingC hapterTJC.html
WHO ICD-10 Interactive Self Learning Tool	http://apps.who.int/ classifications/ apps/icd/icd10training/

PATIENT SAFETY

CHAPTER 5

Jacque Cole, Michelle Franklin, Susan Mellott, Kathleen Tornow Chai

CPHQ Examination Content Outline Task Statements For This Chapter	
Patient Safety	
4.A.1	Assess the organization's patient safety culture
4.A.2	Determine how technology can enhance the patient safety program (e.g., electronic health record (EHR), abduction/elopement security systems, smart pumps, alerts)
4.A.3	Participate in risk management assessment activities including identification and analysis
4.B.1	Facilitate the ongoing evaluation of safety activities.
4.B.2	Integrate safety concepts throughout the organization.
4.B.3	Use safety principles: a. human factors engineering b. high reliability c. systems thinking
4.B.4	Participate in safety and risk management activities related to: a. incident report review (e.g., near miss and actual events) b. sentinel/unexpected event review (e.g., never events) c. root cause analysis d. failure mode and effects analysis

Words and titles of sections that refer to task statements from the CPHQ Exam Content Outline are indicated throughout the Handbook with a lbox around the tex.

"So long as it involves humans, health care will never be free of errors...but it can be free of injury".
Donald Berwick

During the 1990s the push was on to build a **quality** culture in our healthcare organizations. Then in 1999, a groundbreaking report, *To Err is Human: Building a Safer Health System* was published. It set all of healthcare on a different path, a **patient safety** culture (IOM, 2015). The Institute of Medicine (IOM) published *To Err is Human,* and soon thereafter, *Crossing the Quality Chasm,* laying the groundwork for a patient safety culture. The race is still going, but at a tortoise's pace.

In the *To Err is Human* report, it was estimated the number of hospital deaths related to preventable medical errors was possibly as great at 98,000 per year . This became headline news and thus the current patient safety movement was born. This report also resulted in a series of congressional hearings with governmental agencies, professional groups, accreditation organizations, insurers, and others, who responded swiftly with plans to develop reporting systems . By imposing reporting requirements, people and organizations were thought to be held accountable. However, reporting requirements alone do not make systems safer.

We have seen advances in reporting of errors, and the Agency for Healthcare Research and Quality (AHRQ) annual reports continue to indicate *death related to error* remain similar to the statistics cited in 1999 (Clancy, 2009). However, as reported in 2016, "While it is clear that the frequency of adverse events declined substantially from 2010 to 2014, it is less clear why this improvement occurred" (Kronick, Arnold, & Brady, 2016). The authors in this article discuss the problems with inconsistent data definitions and other challenges but also identified four possible reasons for the improvement that has been seen. One of the first reasons given was that evidence based improvement methods had been introduced by AHRQ in error reporting for areas such as central line associated blood stream infections and the implementation of that evidence had reduces errors in particular areas. A second reason that the numbers decreased may have been that tools and technical assistance were developed by those who were studying medical errors with which to implement consistent processes for improvement that may have had an effect on improvement. For example, "The Centers for Medicare & Medicaid Services Partnership for Patients initiative p;ovided extensive technical assistance, reaching more than 80% of acute care hospitals throughout the country" (Kronick, Arnold, & Brady, 2016). Next, with the focus on medical errors, hospitals needed data to demonstrate their progress and error rates and th is data was beginning to be mandated so outside agencies were used to generate and display data that was consistent and used consistent data definitions. Finally, hospital leadership, including chief financia l officers became very attentive when the Centers for Medicare and Medicaid (CMS) began to impose fines for certain medical errors. It then became an issue important across the organizat ion.

The goal in quality and patient safety is to prevent death and injury from preventable medical errors through system wide changes. By developing strategies to recognize, prevent and mitigate harm from errors inherent in complex systems, we have the greatest potential to affect outcomes for our patients. Learning from events,and using that information to improve or prevent new events, is critical to develop ing these strategies. However, the process is undermined by the difficulty health care professionals have in adm itting or discussing these events.

Not all errors result in harm or injury. Every day physicia ns, nurses, pharmacists and other care team members recognize and correct errors, usually preventing harm. The key is to differentiate between individual factors and factors attributed to the system or process design, and then redesign the process to reduce or eliminate errors and latent conditions. Health care often consists of large, complex problems that require thoughtful, multifaceted responses by individuals and teams . This

chapter has highlighted some of the ways we can redesign systems for safety, through technical processes, understanding likely sources of error and being committed to finding effective ways to reduce errors in our organizations.

This chapter will look at the comprehensive work done to address overall quality and safety of care and the associated outcomes since the release of the IOM *To Err is Human* report. This report will be presented as a foundation, followed by what has been done and what is currently being done to improve patient safety. By the end of this chapter, the reader should be able to examine their own organization and implement ideas to help their organization decrease errors and improve patient safety.

WHAT IS PATIENT SAFETY?

Before we get into the *To Err is H uman* report, there is a need for some definition and discussion about basic patient safety concepts. The assumption of safety in the provision of healthcare is as fundamenta l as care itself. ***Primum non nocere-fi rst ,*** **do no harm-is** the main phrase we all know from the Hippocratic Oath taken by physicians (Hippocrates, n.d.). Safety is the most basic dimension of performance necessary for the improvement of healthcare quality. Safety is the underlying reason for risk management, infection control, and environmental management programs. It is the reason we insist on qualified clinical practitioners and support staff.

Patient safety is a subset of safety. Organizations must be aware of all safety risks throughout the facility. Safety was discussed in the Environment Safety Programs and Risk Management sections of Chapter 3 Performance and Process Improvement. The safety of all individuals in a healthcare setting is ultimately important. However, patient safety is the current activity of safety and is focused more on the individual's safety within clinical areas, rather than the overall safety of the organization. As facilities move toward a Highly Reliability Organization (Chapter 2 Organizational Leadership) to drive out error and decrease the variability of practice, patient safety is a major area of importance.

According to the AHRQ, **patient safety** is defined as:

> *"Patient safet y is a discipline in the healthcare sector that applies safet y science methods toward the goal of achieving a trustworthy system of healthcare delivery. Patent safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes the recovery from, adverse events."* (Emanuel, et al., 2009, p. 6)

This definition states patient safety is both an emergent discipline, and a way of doing things. Patient safety seeks high reliability of a system filled with risk. Therapeutic interventions are where medical errors occur, and where patient safety must be focused .

Grober and Bohnen (2005) define a **medical error** as *"an act of omission or commission in planning or execution that contribute or could contributes to an unintended result"* (p. 42). This definition contains the key domains of error causation of omission (failure to do the right thing) and commission (doing the right thing wrong), as well as planning and completing a process. It also indicates faulty processes can result in error, even if there is not an adverse outcome; such as when a patient receives the wrong medication but there is no harm to the patient.

Grober and Bohnen (2005) go on to define an **adverse event** as the *"unintended injur y to patients caused by medical management ... that results in measureable disability, prolon ged hospitalization, or both"* (p. 40). Since not all adverse events are a result of error, many prefer to use the term **preventable adverse events.**

The Joint Commission defines a **sentinel event** as *"...an unexpected occurrence involving death or serious ph ysical or psychological injury or the risk thereof. The phrase 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome" (l-lAS* Glossary, 2012, GL-35). 'v'v'ith every sentinel event, a Root Cause Analysis must be completed in a timely manner with implementation of an action plan. Another name for a sentinel event is a **never event.** A never event is an event that should never happen and if it does, immediate invest igat ion and remediation is required. The Centers for Medicare and Medicaid (CMS) defined 28 never events in 2008.

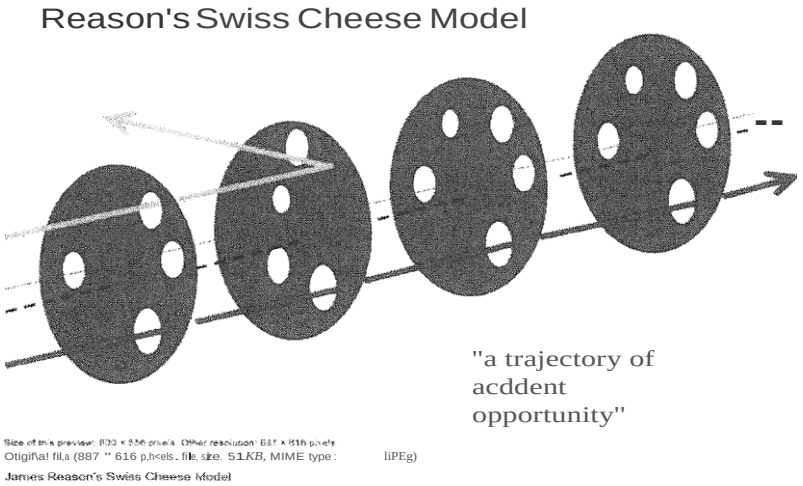
In 2011, the list was modified and expanded to 29 events and the National Qua lity Forum (NQF) changed the 'never event' term to 'Serious Reportable Events (SRE j'. The iist of locations and facilit ies this applies to has been expanded beyond hospitals to ambulatory and office based surgery centers, skilled nursing facilities and doctors' offices and clinics (Torrey, 2017) .

A **near miss** is defined as a potential medical error, which is caught prior to the administration to a patient. For a near miss, it is best to complete a Failure Mode Effectiveness Analysis (FMEA) or a Root Cause Analysis (RCA) even though it did not reach the patient. An example of a near miss is: the pharmacy fills an IV order and sends it to the nursing unit for a patient. Prior to administer ing the IV, the nurse double checks the order and identifies the mixed IV solution is not correct . The IV bag is sent back to the pharmacy and another bag with the correct ingredients is obtained for the patient. This would be a major medical mistake should it have reached the patient (Grober & Bohnen, 2005, p. 41).

One basic safety concept becoming fa irly well known is the Swiss Cheese Modei developed by John Reason (Figure 1). The concept behind this model is one where catastrophic errors do not occur in isolation. Rather there are multiple opportunities for errors to occur. It is only when the systems align in a certain way, and the fa il-safe mechanisms all fail, therefore creating the opportun ity for the catastrophic event to occur (Reason, 2000).

Each slice of Swiss cheese has holes in it, but as demonstrated in Figure 1,the hole location will not be consistent to allow a straight line to be drawn from the front to the back. There is a barrier preventing further passage through the cheese. One failure (hole) occurs but does not contribute to another failure (Duke, 2016). For example, the wrong patient is brought into the OR suite and prepped. Before the surgery starts, a time out is called and someone realizes it is the wrong patient in the suite for the procedure. This stops further errors from occurring. It is only when the holes all line up one after another, a catastrophic event occurs. Continuing with our surgery example, a patient is brought into the surgery suite but no one checks the patient's arm band, so they do not know if this is the correct patient. The surgeon is in a hurry to start and rushes through the time out. The OR staff are not really ready to start, but no one speaks up and the surgery starts. The surgeon begins the surgery to remove the cataract in the right eye and is upset when the lens available is not the correct one to be inserted in that eye. Someone runs to get the correct lens, which the surgeon implants. When the patient is taken to the recovery room, the staff realizes the surgery should have been performed on the left eye. All of these errors (holes) had to line up perfectly for this adverse event to occur.

Figure 1:James Reason's Swiss Cheese Model



Emanuel et al. (2009) describes several other basic principles of patient safety . The first principle is patient safety emerges from systems design. Patient safety depends on systems which make risky interventions reliable. The more complex a system is, the more chance there is for error, especially when there a re different systems work ing together. Safety systems have many components . The safety systems are comprised of procedures, the environment, the design of the material used, the training, and the culture of the team caring for the patient. All of these can contribute to errors.

A second principle is patient safety is designed for the nature of illness. When a patient comes to a healthcare setting and is already ill,then something in their body has a lready gone wrong, so failu re to

provide the correct care causes further harm to the patient. This can happen with a missed diagnosis, or with underuse or inappropriate use of tests and or treatments . Most conditions are common and thus patients can be treated with standardized protocols and/or guidelines to help minimize error. The standardization decreases the opportunities for errors.

A third principle is **patient safety is dependent on open learning.** There must be a culture of openness among all team members so learning can occur when errors arise. Patient safety combines principles of adult education and effective behavioral learning with traditional approaches to caring for patients. When errors occur, the team should learn from those errors. Patient safety depends on organizational and personal accountability, but it also recognizes most errors are caused by flaws in the process rather than the person.

The last principle is **trustworthiness is essential to the concept of patient safety.** The members of the healthcare team must trust each other to speak up when an error or a potential error is identified.

fWHAT DOES THE IOM REPORT STATE WE SHOULD DO?[

The IOM (2000), *To Err is Human* Report was released to stimulate the healthcare industry to develop a patient safety culture and thus to decrease medical errors and preventable adverse events. The report states one of the causes of medical errors is the decentralized and fragmented nature of health care delivery. Patients are seen by a number of different practitioners who do not have information from their other practitioners. The primary practitioner completes the annual physical and lab work, assures immunizations are up to date, and treats the patient for common illnesses. The cardiologist sees the patient for heart disease, but focuses only on the cardiovascular system. The gastroenterologist sees the patient when there is a gastrointestinal illness, or a need for a colonoscopy, and so forth. These three practitioners do not routinely share information, even though all three are treating the same patient. This results in overuse of diagnostic tests, possible duplication of medications, and confusion for the patient and family. The cardiologist may prescribe a medication for high cholesterol, but the primary practitioner may decide to change the medication. When the patient returns to the cardiologist, he/she may not have all of the current information needed to treat the patient. The patient may forget about changes in medications or forgets about the changes have occurred between cardiology visits.

Other deterrents to patient safety, according to the report, include practitioners' concerns about medical liability, lack of preventative services, and a lack of incentives from third-party purchasers of health care to provide the financial incentives to health care organizations to improve patient safety and quality.

The IOM (2000) report lays out a comprehensive strategy that government, health care providers, industry, and consumers can use to begin reducing medical errors. The authors contend what is needed to improve patient safety is already known, and if utilized, can decrease medical errors

without other interventions being developed. The IOM felt if these known improvements were utilized, 50% of medical errors would have been reduced by 2004, five years after the report was released. As stated earlier in this chapter, this has not occurred, even over fifteen years later.

The IOM (2000) report recognizes the majority of medical errors are not results of 'individual recklessness' or actions of an individual or group intent on doing harm. More often, the errors are results of faulty systems, processes, and conditions lead individuals to make mistakes, or at least fail to prevent mistakes . As a result of these conclusions, health systems need to be designed to make it harder for an individual to make a mistake, and easier to do the correct thing. When an error occurs, the individual who made the error should not be reprimanded, as this has not shown to be effective in making the system better nor preventing someone else from making the same error. The focus should be on the process itself and the individual who made the error should learn from the mistake.

Four categories of errors were identified in the IOM report: communication, treatment, preventative, and other. The communication errors include an error or delay in the diagnosis, failure to order indicated tests, use of outmoded tests or therapies, and/or the failure to act on the results of monitoring or testing. The treatment errors include an error in the performance of a procedure or test, an error in the administration of the treatment, an error in the dose or method of using a drug, avoidable delay in treatment or responding to a test result, and/or inappropriate care. Preventative errors include failure to provide prophylactic treatment and/or inadequate monitoring or follow-up of treatment . And lastly, other errors include failure of communication, equipment failure, and other system failures . Healthcare organizations must be aware of these categories of error as they examine the patient safety risks in their organization.

The !OM (2000) laid out a four-tiered approach to developing a strategy to improve patient safety :

- Establish a national focus to create leadership tools, research, and protocols to increase the knowledge base about patient safety
- Identify and learn from errors by developing a nation-wide public mandatory reporting system as well as encouraging healthcare staff, practitioners, and the organizat ion to participate in voluntary reporting systems
- Raising performance ex pectations and standards for improvements in patient safety through the professional organizations, group purchasers, and so forth within healthcare
- Implementing patient safety systems in healthcare organizations and systems to ensure safe practices at the deliveryarea

The IOM report also called on Congress to create a Center for Patient Safety which would set national patient safety goals and track the progress being made in meeting those goals. The Center for Patient

Safety would then be charged to implement research, identify prototype safety systems, provide tools for identifying and analyzing errors, and recommend additional improvements. The IOM report suggested this center should be housed within the Agency for Healthcare Research and Quality (AHRQ), which already had a large infrastructure for quality and patient safety.

With the development of a mandatory reporting system, the states would be required to develop a process to collect information regarding adverse events which result in death and serious harm. The reporting system should start with hospitals and then progress to other healthcare organizations. This system would hold healthcare organizations accountable for these errors and lead to transparency to the public and others. At the time of the 1999 report, about one third of the states already had such a system in place.

Voluntary reporting systems would complement the mandatory reporting. These voluntary systems should focus on a much broader set of errors and issues, especially those which do not result in major harm or death. The voluntary reporting systems should be utilized to examine the processes producing these errors before there is harm or death. in order for this to be possible, Congress would have to enact laws to protect the confidentiality of the information collected.

The definition of minimum performance levels for health professionals and healthcare organizations should be established through regulatory and other means such as licensing, certification, and accreditation.The values and culture of healthcare professionals and healthcare organizations, as weii as professional organizations, should also be utilized to establish standards regarding patient safety and what is expected from practitioners and staff. Larger purchasers of healthcare, healthcare insurance and individual consumers can also assist in changing the environment to increase patient safety.

The healthcare organization must develop a culture of patient safety. The workforce and processes should focus on improving reliability and safety of care for patients. Patient safety should be an organizational goal and an initiative all healthcare organizations strive to improve . Systems for continuously monitoring patient safety must be developed and utilized to make improvements. Simply collecting the data does not improve a process or system. The data must be used to identify areas for improvement and then to measure if improvements have occurred and are sustained.

jWHAT HAVE WE DONE & HOW EFFECTIVE HAS IT BEEN?!

Very soon after the *To Err is Human* (IOM, 2000) report was released the government and the private sector responded. Congress launched a series of hearings on patient safety, and then in December 2000 allocated $50 million to the AHRQ to manage the many patient safety projects and initiatives. Between December 1999 when the report was first published and the time of publication of the Report Brief in 2000, less than a year later, AHRQ had already implemented the items found in Table 1 (IOM, 2000). In addition to the AHRQ, other groups such as the National Academy for State Health

Policy, National Quality Forum, Leapfrog Group, the Council on Graduate Medical Education, and the National Advisory Council on Nurse Education and Practice, were all involved in activities to increase patient safety.

Table 1: AHRQ Initial Activities After *To Err is Human* was Published

AHRQ Initial Activities After *To Err is Human* was Published
• Developing and testing new technologies to reduce medical errors
• Conducting large-scale demonstration projects
• Supporting multidisciplinary teams to develop new knowledge to be utilized in the demonstration projects
• Supporting projects for better understanding of how the environment affects the ability of providers to improve safety
• Funding researchers and organizations to develop, demonstrate, and evaluate approaches to education of providers and others in order to reduce errors
• Developing in a booklet for consumers to utilize to improve the quality of care they receive

In 2013, the AHRQ published a report based on the examination of published research regarding Patient Safety Practices that had been completed between 1999 and 2011 (AHRQ, 2013). AHRQ defines a Patient Safety Practice (PSP) as a process or structure that reduces the probability of adverse events occurring in the healthcare system across a range of diseases and procedures. The PSPs were evaluated on the evidence of the outcomes of the safe practices and on the factors that influence their use and effectiveness. A systematic review of 18 studies was conducted (Table 2). Another brief review was conducted for 23 additional studies that were already well established. The materials were divided into: Adverse Drug Events; Infection Control; Surgery, Anesthesia, and Perioperative.

Table 2: Patient Safety Practices Recommended for Implementation by AHRQ

Patient Safety Practices Recommended for Implementation by AHRQ	
Strongly encourage implementation	• Hand hygiene • Barrier precautions to prevent healthcare-associated infections • "Do Not Use" list of hazardous abbreviations • Preoperative checklists and anesthesia checklists • Use of real-time ultrasound for central line placement • Bundles include checklists for central line insertion and care • Bundles include head-of-bed elevation, sedation vacations, oral care with chlorhexidine and subglottic-suctioning endotracheal tubes

	• Interventions to reduce urinary catheter use, including catheter reminders, stop orders, or nurse-initiated removal protocols • Multicomponent interventions to reduce pressure ulcers • Interventions to improve prophylaxis for VTE
Encourage implementation	• Multicomponent interventions to reduce falls • Use of clinical pharmacists to reduce adverse drug events • Computerized provider order entry • Medication reconciliation • Obtaining informed consent to improve patients' understanding of the potential risks of procedures • Use of surgical outcome measurements and report cards such as the American College of Surgeons National Surgical Quality Improvement program • Practices to reduce radiation exposure from fluoroscopy and computed tomography scans • Documentation of patient preferences for life-sustaining treatment • Rapid response systems • Utilization of complementary methods for detecting adverse events/medical errors to monitor for patient safety problems • Team training • Use of simulation exercises in patient safety efforts

Healthcare organizations and practitioners readily acknowledge errors occur in the provision of care. It is known the longer a patient occupies a bed in a healthcare facility, the more likely the development of infection or other complication. Yet what is implicitly known does not reduce risk or increase patient safety. Therefore, further actions are necessary to reduce the risk of errors.

Government & Accreditation Efforts

Patient safety has become an initiative involving the federal government as well. The Patient Safety and Quality Improvement Act of 2005 (PSQIA, 2005) established confidentiality and privilege protections for patient safety. It is associated with quality of care and freedom from accidental injury or harm from a failed process or procedure. The act states, no matter how it is defined, an organization must have a culture of safety. This means certain actions surrounding patient safety improvement activities are protected and confidential. It helps those involved in an improvement project associated with patient safety to work as transparently as possible. It encourages the reporting and discussion of an adverse event, near miss, or other dangerous condition.

The PSQIA also established Patient Safety Organizations (PSOs) to standardize event data collection and reporting to the PSO without the fear of legal discovery or disciplinary action. PSOs were approved by ARHQ beginning in 2008 and began accepting data in 2009 (Clancy, 2009). The PSO Privacy Protection Center (PSOPPC) was created by AHRQ to assist the PS0s in rendering the data non-identifiable as to the organizat ion, patients, practitioners and others mentioned. The PSOPPC also maintains the "common formats" (see Chapter 4 Health Data Analytics) software the PSO utilizes, which contains common definitions and reporting formats to make data comparable (PSO, 2017). Thus, if a healthcare organization joins a PSO, they can benefit from comparative results at the national level, across PSOs, and across a larger group of provider types . The PSO data can assist healthcare organizations to discover underlying causes of incidents, near misses, and unsafe conditions in healthcare delivery. The PSO also provides expertise to work with healthcare organizations to decrease events and improve quality, and to identify patterns of rare events (PSO, 2017). A listing of Patient Safety Organization Programs can be found at the PSO website in the list at the end of this chapter . This website is routinely updated with those organizations working under the confidentiality and privilege protections of the PSQIA.

The Centers for Medicare and Medicaid Services (CMS) began withholding Medicare reimbursement October 2008 for 10 healthcare-acquired conditions (HACs) (CMS – HACs, 2017). These conditions were not present on admission (POA), but developed during the time the patient was under the care of the hospital, nursing home, etc. HACs are usually high cost or high volume or both, and could reasonably have been prevented through the application of evidence based guidelines. For current HACs, see the Hospital Acquired Conditions website listed at the end of the chapter. In 2015, the number of conditions was increased to 14. The website for that list can be found in the table at the end of the chapter.

Accreditation Standards

In response to the lOM *To Err is Human* Report, accreditation bodies like The Joint Commission, National Committee for Qua lity Assurance (NCQA) and URAC modified their Quality Management standards to meet the call for "regulators and accreditors to require health care organizations to implement meaningful patient safety programs", and to focus greater attention on performance measures of patient safety for both health care organizations and health care professionals.

In 2014, The Joint Commission (TJC) moved all ot their patient safety standards into a chapler enlitled Patient Safety Systems, in the hospital manual effective January 1, 2015. No new standards were added. The chapter describes how leaders and others can utilize the standards to improve quality of care and patient safety. It also demonstrates how the hospital systems must be integrated to achieve compliance with the standards .

!Patient Safety Goals and Safe Practices!

In 2003, The Joint Commission established National Patient Safety Goals for all healthcare organizations they accredited. Soon after, other entities established patient safety goals or safety practices. These different organizations' safety goals and practices will be covered in this section.

!WHO Collaborating Centre for Patient Safety Solutions!

The World Health Organization (WHO) Collaborating Centre for Patient Safety Solutions was established in 2005 to identify, evaluate, adapt, coordinate, disseminate and accelerate improvements in patient safety worldwide (WHO, 2017) . The Collaborating Centre has built an international network composed of key organizations and individuals with expertise in patient safety, such as accrediting bodies, national patient safety agencies, professional societies, and others. The Joint Commission and The Joint Commission International are partnered with the WHO to contribute to the endeavor .

In 2009, the WHO developed a 19-item Surgical Safety Checklist to decrease errors and adverse events during surgery . It is also designed to increase teamwork and communication (W HO, n.d.). Use of this checklist has shown a decrease in morbidity and mortality. It is being used for many types of surgery around the world, and can be customized to meet specific needs. In 2015 they came out with the Safe Childbirth Checklist and Implementation Guide (WHO, 2015). This checklist "targets the major causes of maternal and newborn complications and deaths, including post-partum hemorrhage, infection, obstructed labor, preeclampsia and birth asphyxia".

!National Quality Forum (NQF)!

The National Quality Forum (NQF), a not-for-profit membership organization, was incorporated in May 1999, and has been focusing on patient safety for over 10 years. One of its charges was identifying a core list of preventable, serious adverse events . The NQF has identified measures for medication safety, healthcare-associated infections, falls, pressure ulcers, surgical complications, workforce issues, and other subjects (NQF-1, 2015). Because gaps still exist, the NQF changed their approach and developed a standing committee to examine measures and determine what should be kept, added, and deleted, based on established criteria . The Patient Safety Committee's work to oversee the NQF Patient Safety measures has been divided into phases . In Phase one, published in January 2015, they endorsed eight measures and rejected another eight measures. The endorsed measures are displayed in Table 3.

Table 3: NQF's Phase 1Endorsed Patient Safety Measures

NQF's Phase 1Endorsed Patient Safety Measures
(0138) National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcomes Measure
(0139) National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream

Infection (CLASBI) Outcomes Measure
(0555) INR Monitoring for Individuals on Warfarin
(0556) INR for Individuals Taking Warfarin and Interacting Anti-infective Medications
(0541) Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category
(0684) Percent of Residents with a Urinary Tract Infection (Long-Stay)
(2337) Antipsychotic Use in Children Under 5 Years Old
(2371) Annual Monitoring for patients on Persistent Medications

Phase two will be evaluating topics including, but not limited to: fall screening and risk management ; medication reconciliation; measures from applicable settings such as skilled nursing facilities and inpatient rehabilitation facilities; unplanned admission-related measures from non-hospital settings; all-cause and condition specific admission measures; condition-specific readmission measures; and measures examining length of stay (NQF – 2, n.d.). Currently, NQF has prioritized five measures that have demonstrated the need for more measurement . This effort is based on the National Quality Strategy that was last revised in January, 2017. These five areas include: Adult Immunization, Alzheimer's Disease and Related Dementias, Care Coordination, Health Workforce, and Person-Centered Care and Outcomes (National Quality Strategy, 2017).

The Institute for Healthcare Improvement (IHI)

The IHI has been working to improve patient safety for many years (IHI – Pt. Safety, 2015). The IHI had a tool called 'The Improvement Map', but they are no longer utilizing or supporting the tool. They now provide a website for their patient safety resources, which can be found in the website list at the end of this chapter. The IHI's goal for patient safety is to work with others "to build safety into every system of care, ensuring patients receive the safest, most reliable care across the continuum" (IHI – Pt. Safety, 2015, p. 1). The IHI focuses on innovations which will create the system level changes across organizations at all levels. They work with organizations to move from separate silos to system level reliability for patient safety, and to build measures and early warning systems for patient safety, as well as for transparency. They have published How-To guides which include evidence-based care components, along with how to implement the components and measure the resulting improvements. Some of the areas of these guides include medication reconciliation, high alert medications, surgical site infections, and others.

The tool IHI utilizes to accurately identify adverse events and to measure their rate over time is called the Global Trigger Tool (IHI – Pt. Safety, 2015) . By tracking adverse events over time, the organization can determine if the changes being made are improving patient safety. The IHI also has Leadership Guides to assist leaders in these processes, and numerous other resources free. For individuals to learn more about patient safety, the IHI Open School has nine free and quick online courses available by subscription.

At this time, the Institute for Healthcare Improvement (IHI) and the National Patient Safety Forum have joined to make further patient safety improvements (IHI 2017). There are four areas in the spotlight: A New Emergency Checklist for Office-Based Surgery, Closing the Loop: A Guide to Safer Ambulatory Referrals in the EHR Era, Collaborative Improvement Positively Impacts Culture Change to Improve AMI Care, and The Link Between Physician Wellness and Patient Safety.

Ifilj RQ PatiE!nt Safety Indicators!

The AHRQ Patient Safety Indicators (PSIs) are a set of risk-adjusted measures which screen for potential in-hospital complications and adverse events following surgeries, procedures, and childbirth (AHRQ – Pt. Safety, n.d.). They are part of a set of software modules for AHRQ and were originally released in 2003. The indicators are divided into two domains, hospital-level indicators and area-level (county, state) indicators. They are free to utilize and the user receives comparison data from similar facilities. The Patient Safety Indicators can be downloaded from the website list at the end of this chapter. AHRQ states the indicators are useful not only to improve patient safety, but also for comparative public reporting, pay-for-performance initiatives, and to identify potentially avoidable complications. At this point there are 26 indicators including 18 provider level indicators developed for hospitals (AHRQ-Fact Sheet, 2017). This is an ongoing collaborative process.

!National Patient Safety Goals!

The Joint Commission's National Patient Safety Goals (NPSG) are based on past sentinel event information, and they include specific recommendations and/or approved alternative approaches (TJC-NPSG, 2015). The goals are included in accreditation decisions, as appropriate for each type of entity surveyed. The Joint Commission uses a panel of practitioners and patient safety experts to oversee the development and annual updating of the National Patient Safety Goals {NPSGsj and requirements for **all** accreditation programs, and the Disease-Specific Care Certification Program. Changes for 2018 include NPSG.07.03.01 — multidrug-resistant organisms (MDROs) : Has been applicable to hospitals and critical access hospitals and is now applicable to nursing care centers and NPSG .07.04.01 — central line-associated bloodstream infections (CLABSIs): The elements of performance (EPs) for hospitals and critical access hospitals have been reordered, and the goal has been modified to allow organizations to determine the appropriate time frame for educating staff and licensed independent practitioners.

Each year the goals are evaluated for compliance. Other aspects of patient safety, such as reported sentinel events, and nationally reported issues are identified for possible new goals. For 2015, no new goals were added, but the goal on the use of oxygen in the home (Home Health) was modified. When a goal has been implemented successfully for the majority of the accredited organizations, or for other reasons, the patient safety goal is moved into the standards, making way for new goals to be adapted . The current National Patient Safety Goals can be downloaded from the Joint Commission website indicated in the website list at the end of this chapter.

Patient Safety Management - The Program

Up to this point, there really is not a good user-friendly guide to setting up a patient safety program. The following is a starting point and not an all-inclusive list. This information is also helpful if you assume a new position or need to review your current program to identify areas for improvement. As with any organization, one must have the support of the senior leadership. In some organizations, this starts with the Board of Directors and the executive leadership team. Without the support of senior leadership, no program, no matter how well planned and developed, will survive.

Leadership

Patient safety must be considered a strategic priority by the leaders of the organization . The leaders must be educated about patient safety, be given ongoing safety briefings, understand how processes must be embedded with patient safety goals, and measure harm levels over time.

In 2006, the Institute for Healthcare Improvement (IHI) developed a white paper, *Leaders in Patient Safety,* to assist health care leaders in the development of the patient safety program. The IHI considers leadership to be the critical success factor for an effective patient safety program. This responsibility cannot be delegated to others. This white paper (Botwinick, Bisognano, Haraden, 2006) recommends the following eight steps for leaders to follow to achieve patient safety and high reliability in their organizations .

1. *!Establish Patient Safety as a Strategic Priority* Every healthcare organization must have patient safety as one of the organization's strategic priorities. This strategic priority then should be found in all of the plans of the organization, especially the Patient Safety Plan and the Quality Improvement Plan (See Chapter 3 Performance and Process Improvement). The leadership must assess and establish a supportive patient safety culture, address the organization's infrastructure, and learn about patient safety and improvement methods.

2. *!Engage Key Stakeholders!* These key stakeholders include the Governing Board, leaders, physicians, staff, patients and families (See Chapter 2 Organizational Leadership) . These individuals need to be educated about patient safety, and engage in discussions about patient safety. The agenda of meetings should give patient safety the same amount of time as finr1nr.ial issues on the agenda.

3. . *!communicate and Build Awareness!* The leaders should routinely engage in leader rounds throughout the organization, engaging staff, practitioners, patients and others in discussions about patient safety (See Chapter 3 Performance and Process Management). Within the departments, there should be education and other activities to address patient safety directed towards the functions of the department. This could include safety briefings, huddles, utilizing

SBAR (Situation, Background, Assessment , Recommendation), and the utilization of Crew Management (see below in this chapter).

4. *[Establish, Oversee, and Communicate System-Level* Aim[The leaders should develop a strategic plan with identified system-level goals (see Chapter 2 Organizational Leadership). These goals then need to be communicated throughout the organization, as appropriate, so the organization can meet these goals. For example, the quality plan should include the patient safety strategic objectives. The education and IT departments should include organization goals regarding implementation of new software.

5. *[Measure Harm Over Tim* The leaders should utilize a dashboard or balanced scorecard to observe data over time for important factors identified for the organizat ion. This might include mortality rates, triggers for adverse events, Root Cause Analyses (RCAs) and Failure Mode and Effects Analyses (FMEAs), and other such patient safety information (See Chapter 3 Performance and Process Improvement and Chapter 4 Health Data Analytics for more information. See information presented below for RCAs & FMEAs).

6. *fuupport Staff and Patients/Families Impacted by Medical Errors and Harm!* The patient and family, as well as the staff who made an error, will all require support after a medical error occurs. The appropriate disclosure of information and an apology to the patient/family are discussed later in this chapter.

7. *lign System StrategY, Measures, and Improvement Project.s!* The organization must align their strategic initiatives between various parts of the organizatio n, such as between quality improvement and financial plans. There should be oversight of improvement projects, with monitoring and revising if changes are not forthcoming. The national initiatives must also be integrated in this process. (See Chapter 3 Performance and Process Improvement for information onthe Quality Council).

8. *!Redesign Care Processes Increase Reliabilit* Reliability is the key concept imbedded in patient safety. Reliability ensures the patient receives the appropriate test, treatment, or medication at the appropriate time (see Chapter 4 Health Data Analytics for information on reliability). This can be accomplished by the use of rapid response teams, CPOE systems with decision support, and many other means. Another concept utilized is the decrease of variability. The standardization of care with guidelines and pathways leads to decreased variability and thus increased reliability of care (See Chapter 3 Performance and Process Improvement for information on guidelines & pathways).

Another leadership resource from IHI is the *Governance Leadership of Safety and Improvement.* It states the governing board's responsibility for ensuring and improving care. This cannot be completely

delegated to the medical staff and executive leadership. Rather the ensuring safe and harm-free care to the patients is the Board's job and is at the very core of their fiduciary responsibility (IHI-Pt. Safety, 2015).

!Gener ic Components of the Program!

The healthcare organization is complex, with many systems and processes impacting the quality and safety of patient care. The specific patient safety program **includes at least:**

- Infrastructure: senior leaders roles, patient safety officer, governance teams, software
- Clear linkage with the quality strategy; Integration of all related functions and safety programs; Alignment with strategic goals (See Chapter 2 Organizational Leadership and Chapter 3 Performance and Process Improvement)
- Policies, procedures, and education to reduce and control risk to patients and staff (See Chapter 3 Performance and Process Improvement)
- An occurrence/event/incident reporting process
- Mechanisms to participate in national patient safety initiatives (see above in this chapter)
- Proactive activities to identify high-risk processes and implement actions to reduce avoidable risk (e.g., FMEA, clinical risk and environmental assessments) (see below in this chapter)
- A process for immediate response to medical errors and sentinel events
- Performance measurement, tracking, and analysis (see Chapter 4 Health Data Analytics)
- Improvement activities (see Chapter 3 Performance and Process Improvement)
- Documentation and reporting (see Chapter 4 Health Data Analytics)

All healthcare organizations across the continuum are expected to implement specific patient safety programs, as defined by CMS and accreditation standards. A general overview of the major components is listed in Table 4. All organizations should review the appropriate standards for their type of healthcare organization. The information in this table is taken from select accreditation standards.

Table 4: General Components in a Patient Safety Program

General Components in a Patient Safety Program
1. The patient safety program is an organization wide program implemented by the leadership.
2. Individuals leading the interdisciplinary group to manage the patient safety program

include, but are not limited to, directors, managers, safety officers, and clinical leadership including practitioners, nurses, ancillary personnel, and other frontline clinical staff.

3. The scope of the patient safety program includes the full range of patient safety issues, from potential or no-harm errors to hazardous conditions and sentinel events.

4. All departments, programs, and services within the organization should participate in the patient safety program.

5. As part of the patient safety program, the leaders create procedures for responding to system or process failures. ***Note:*** Responses may include continuing to provide care, treatment, and services to those affected, containing the risk to others, and presenting factual information for subsequent analysis.

6. The organization leaders provide and encourage the use of systems for blame-free internal reporting (culture of safety/Just Culture) of a system or process failure, or the results of a proactive risk assessment.

7. The organizat ion leaders define "sentinel event" and communicate the definition throughout the organization.

8. The organization conducts thorough and credible root cause analysis in response to sentinel events.

9. The organization leaders make support systems available for staff who ·have been involved in an adverse or sentinel event. ***Note:*** support systems recognize conscientious health care workers who are involved in sentinel events are themselves victims ("second victims") of the event and require support . Support systems provide staff with additional help and support as well as additional resources through the human resources function or an employee assistance program. Support systems focus on the process rather than blaming the involved individuals.

10 Selecting one high-risk process and conducting a proactive risk assessment (FMEA) should occur at least every 18 months.

11 The organization should analyze and then use information about system or process failures (and the results of proactive risk assessments) to improve patient safety and to reduce the risk of medical errors.

12 . The lessons lea rned from root cause analys is, system or process fa ilures, and the results of proactive risk assessments should be shared with all staff providing services for the specific situation,and up the chain of command to the governing body.

13 Annual written reports to the governing body might include things like:

1. All system or process failures

2. The number and type of sentinel events
3. Whether the patients and the families were informed of the event
4. All actions taken to improve patient safety, both proactively and in response to actual occurrences
5. The determined number of distinct improvement projects to be conducted annually
6. All results of the analyses related to the adequacy of staffing

14. The leaders encourage external reporting of significant adverse events, including voluntary reporting programs in addition to mandatory programs. ***(Note:*** Examples of voluntary programs include, but are not limited to, The Joint Commission Sentinel Event Database and the U.S. Food and Drug Administration (FDA) MedWatch. Mandatory programs are often state initiated).

!Physician Participation\

In addition to the physician leader participation in the development and implementation of the patient safety program as a strategic initiative, there are specific ways in which all physicians and other practitioners can facilitate patient safety/clinical risk management efforts. These include, but are not limited to, the following:

- Identify general areas of potential risk in clinical aspects of patient care/safety
- Participate in identified patient safety initiatives such as hand hygiene, time out, and so forth
- Report any medical error to Risk Management or other designated department
- Help design programs to reduce risk in clinical aspects of patient care
- Develop criteria for identifying specific cases with potential clinical and safety risk
- Evaluate specific cases identified as having potential or real clinical risk
- Participate on teams to correct problems in the clinical aspects of patient care and patient safety identified through performance improvement and risk management

!Patient Safety Officer!

The Patient Safety Officer (PSO) has primary responsibility to coordinate and serve as a resource for the development, implementation, review, and ongoing refinement of the patient safety program. The Patient Safety Officer must also encourage leadership performance measurement and staff incentive programs which support patient safety improvement. The PSO acts as a liaison for patient safety issues to and between the CEO, senior leaders, governing body, Patient Safety Team/Comm ittee, organization, and external organizations.

The PSO coordinates patient safety education and activities which support the patient safety program (e.g., governing body presentations and leadership rounding) (IHI, 2017). While the PSO is not always the team leader, the PSO will coordinate activities of the Patient Safety Team/Committee and how they integrate with other relevant teams such as QI/PI, RCA, and FMEA teams. The coordination of the development and periodic review and revision of patient safety policies and procedures is another role of the PSO. The PSO also establishes and facilitates proactive risk assessments and risk reduction activities, and the changes necessary to improve patient safety throughout the oreanization.

Communication is a major responsibility for the PSO. The PSO must develop mechanisms for organization wide communication and dissemination of patient safety information, including educational activities, to promote organization wide understanding of and commitment to patient safety practices. The PSO promotes a computerized, non-punitive error reporting process throughout the organization and participates in the trend analysis, review, and investigation of identified patient safety issues as warranted. The PSO also has the responsibility to review and facilitate the use of medical error information, including internal trend reports and external reporting programs and resources. Some resources include The Joint Commission Sentinel Event Alerts, FDA Safety Alerts, *ISMP Medication Safety Alertt* (biweekly email newsletter), ECRI Institute Alerts Tracker, NPSGs, Leapfrog, AHRQ, IHI, and many others (see the last part of this chapter and website list at the end of this chapter).

Other responsibilities of the Patient Safety Officer include but are not limited to the estabiishment and facilitation, appropriate response and investigation processes for adverse events, including front-line response, intervention with patient/farnily and support of involved staff, and root cause analysis. The PSO works closely with Risk Manager and Quality Manager as the domains of all three frequently coincide with patient safety issues and concerns.

Role of the Quality Professional

The Quality Professional is often designated as the Patient Safety Officer (PSO) because of the integral part patient safety plays in the effectiveness of the overall quality strategy and the similarity of roles. Even if not designated the PSO, the Quality Professional must have knowledge of, and be able to help facilitate and coordinate, all of the leadership and program activities described above.

The Quality Professional must be knowledgeable of all related safety activities in the organization and must participate as necessary to maximize patient safety efforts, e.g.:

- Facilitate integration with related organization functions, including infection surveillance, control,and prevention and environmental safety processes
- Minimize duplication of effort in policy/procedure development, education of staff and patients, data collection and aggregation, and communications

- Coordinate event/occurrence reporting and performance measurement and prioritize available patient safety data and information for analysis, reporting, and decision making
- Ensure reactive activities, such as root cause analysis (RCA), and proactive activities, such as failure mode and effects analysis (FMEA), are conducted timely, efficiently, and effectively
- Coordinate the flow of information to all who need to know

Patient Safety Plan

To have a successful patient safety program, there should be a written patient safety plan. The goals and objectives of the plan are then utilized to move the patient safety program forward. The Patient Safety Plan should define and describe the organization's commitment and approach to providing a safe environment. The patient safety plan may be written as a major component of the performance improvement plan itself. Often this is the best way to insure clear integration. Table 5 lists the general components, which should be included in a Patient Safety Plan. As you can see, many of the components are very similar to those in the performance improvement plan.

Table 5: Written Patient Safety Plan General Components

Written Patient Safety Plan General Components
• Purpose • Mission, Vision, Values (organization) and Commitment • Goals (strategic) and Objectives • Scope • Responsibilities: Board of Directors; Quality Council/Patient Safety Team; Medical Staff; Patient Safety Officer; Hospital and Medical Staff Department Directors and Chairs; Employees, Medical Staff Members, and Volunteers; Patients • Important Processes: Identification of patient safety issues; response to a patient safety incident; event/incident reporting; managing serious, potentially serious, and sentinel events; communication of unanticipated outcomes; non-punitive reporting; E!motional support of individuals involved in an incident; external reportine requirements; proactive risk assessment; National Patient Safety Goals; IHI Improvement Map; design and redesign of processes; patient safety education • Confidentiality • Program Evaluation, at least annually Important Processes and Reports to include:

- Regulatory agencies and accrediting bodies w ith oversight authority, listing of their standards and how the organization documents the compliance with those standards. These may include Occupational Safety and Health (OSHA), National Patient Safety Goals, Patient Safety Organizations, Sentinel Event Reporting, FDA Recall Alerts
- Update of the policy noting how risk is addressed by the organization, including who shares Lhe r isk (i.e., insurance, patient, etc.)
- Reassessments of the program due to changes in legislation, insurance policy, or additional exposure due to a change in the programs and services offered by the organization
- Education efforts related to safety and risk reduction and prevention
- Quarterly reports to the Board related to safety issues

!Documenting How You Incorporate Patient Safety Throughout the Organization!

In addition to the Patient Safety Plan, other documentation must be maintained to reflect how the organization addresses the following items (Table 6). This can be a part of the Patient Safety Plan, or in policies and procedures. The documentat ion can be maintained in various parts of the organization. For example, the liability information could be in the Risk Management Plan instead of the Patient Safety Pian. Piease note this is not an all-encompassing list, but rather it should serve as an initial effort only.

Table 6: Documentation of Incorporation of Patient Safety throughout the Organization

Documentation of Incorporation of Patient Safety throughout the Organization
A. Basic Duties of Care
a. Basic Duties of Care and Liabilities
i. Basic duties of direct providers (independent practitioners)
1. Comply with statutory duties such as drug laws
2. Obtain proper consent for medical care
3. Render care not substantially inferior to like providers
ii. Liabilities of physicians/independent practitioners
1. Lack of documentation of treatment
2. Inadequate work-up (based on accepted standards)
3. Acts of others (e.g., nurses) if exercising control ("borrowed servant" or "captain of the ship" doctrine)

4. Failure to attend or follow up
5. Mistaken identity (along with the institution)
6. Misdiagnosis, if based on inadequate examination and testing
7. Wrong diagnosis followed by improper treatment causing injury
8. Wrong treatment, procedure, surgical site, based on diagnosis
9. Treatment outside field of competence
10. Abandonment (neglect or failure to follow up after the acute stage of illness -- unilateral termination of the physician-patient relationship without notice to the patient)
11. Failure to obtain informed consent
12. Failure to seek consultation or refer to a medical/surgical specialist
13. Use of unprecedented procedures, unless approved by a respectable minority of medical opinion
14. Failure to order diagnostic tests considered to be a "matter of common knowledge"
15. Failure to obtain results of diagnostic tests ordered
16. Infections resulting from failure to utilize proper procedures/precautions
17. Aggravation and/or activation of a preexisting condition if injury results
18. Premature dismissal or discharge

iii. Liabilities of nurses

1. Adm inistration of drugs inconsistent with prevailing statutes, nurse practice acts, or institutional policies
2. Failure to follow physician/independent practitioner orders
3. Failure to report significant changes in a patient's condition
4. Failure to take con ed verbal or telepho11e orders
5. Operating room sponge/instrument miscounts
6. Patient burns
7. Patient falls
8. Failure to report defective equipment
9. Failure to follow established nursing procedures

10. Negligent handling of patient valuables

b. Create a process with safety in mind

i. Near miss reporting

ii. Coach the reporter; positive reinforcement for future reporting

c. Risk Management vs. Risk Avoidance vs. Risk Mitigation

i. Find the oops before it happens

d. Educate staff regarding patient safety issues

i. "It starts before the offer letter" – how safety is addressed in the interview

ii. Annual education efforts

B. Incorporating Patient Safety into the Quality Management Processes

a. Assess and Plan

i. Assess the organization's patient safety culture

ii. Determine how technology can enhance the patient safety program

1. Automated audits

2. Computerized physician order entry (CPOE)

3. Barcode medication administration (BCMA)

4. Electronic medical record (EMR)

5. Abduction/elopement security systems

6. Human factors engineering

b. Monitor to determine current status and need for improvement

c. Implementation and Evaluation

i. Assist with implementation of patient safety activities

1. Education of staff regarding patient safety issues

2. For every implementation there is a monitor for ongoing evaluation

ii. Facilitate the ongoing evaluation of patient safety activities

1. Near Misses

iii. Participate in patient safety activities

1. Patient safety goals review

2. Incident report review

3. Sentinel/unexpected event review 4. Rootcause analysis (RCA) 5. Failure mode and effects analysis {FMEA) (proactive risk assessment) 6. Identification of reportable events for accreditation and regulatory bodies
C. Prevention a. Sentinel Event Alerts from Joint Commission b. Reports and findings leading to focus on patient safety c. Risk Management vs. Risk Avoidance vs. Risk Mitigation i. Internal review of processes to prevent future events
D. Reportable Events a. Levels of events b. Steps i. Notification of Administration of a POSSIBLE reportable even ii. Development of a fast track investigation iii. Report iv. Follow-up v. Dealing with the media

Patient Safety Management

!safety Culture!

A generally accepted definition of Safety Culture is a paraphrase of several organization's and dictionary references: The safety culture of an organizat ion is comprised of values, attitudes, perceptions, competencies, and behaviors, which determine the commitment to, and proficiency of, an organization's health and safety management. An organization's safety culture is characterized by communication founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures. The outcomes of these efforts may be reflected positively or negatively.

All healthcare organizations should periodically assess where the organization is in terms of their patient safety culture. The culture of the organizat ion impacts the culture of the organization . An organization with a culture of fear of retribution, for example, will not be very open to reporting errors or potential errors. On the other hand, an organization with a recognized 'Just Culture' leads to

process changes, not individual retribution, and has a better patient safety culture (see next section of this chapter).

The safety culture assessment helps identify and measure conditions in healthcare organizations which lead to adverse events and patient harm. The assessment diagnoses the current safety culture and tracks change over time. It raises patient safety awareness, helps prioritize quality strategies, and provides an opportunity for internal and external benchma rking. The survey is the baseline from which action planning and system/process changes can begin (AHRQ – Assessment, 2015). The survey has sound psychometrics, is free to use.

The Agency for Healthcare Research and Quality (AHRQ) released the ***Hospital Survey on Patient Safet y Culture*** in November 2004 with the first Comparative Database Report released in 2007. The 2010 Report has grown and was based on voluntary data submission from 885 hospitals. Currently, there are forms of the Patient Safety Culture Survey available for hospitals, medical offices, nursing homes, community pharmacies, and ambulatory surgery centers (AHRQ – Assessment, 2015). The surveys in each of these types of healthcare organizations are staggered with surveys occurring every two years. All organizations who submit the survey receive the corresponding Comparative Database Report. This report can be used to:

- Raise staff awareness about patient safety
- Diagnose and assess the current status of patient safety culture
- Identify strengths and areas for patient safety culture improvement
- Examine trends in patient safety culture change over time
- Evaluate the cultural impact of patient safety initiatives and interventions
- Conduct internal and external comparisons

If a healthcare organization does not qualify to utilize the AHRQ surveys, the organization can develop their own survey, but are then not able to obtain comparative results from other organizations. In this case, the organization should consider what is important to their environment in terms of a patient safety culture. The survey forms themselves are available on the AHRQ website so the organization can pick and choose questions from these different surveys and then analyze the data and benchmark with themselves.

One word of caution is required here. Do not bite off more than the organization can chew. This means the organization will be expected to address the areas which indicate improvement is needed. In a large organizatio n, this may be too labor and resource intensive for the leadership to approve . It may be better to identify the high-risk areas first . For example, in a hospital, high-risk areas include but are not limited to, the ICU, the ER, Labor and Delivery, and Surgery. One year, the survey could be focused

on one or more of these high-risk areas. Then two years later, when the survey is repeated, these areas should again complete the survey, but other areas should also be selected to participate. In this manner, the organization can measure progress made and identify the improvement needs in other areas of the organization. It may even be found the improvements made in the high-risk areas can also be implemented in other areas of the organization.

uust Culture!

People can and will make mistakes. It does not matter who the person is, what they do for a living, or how much they are paid. We all make mistakes. Most of the time the mistakes are not premeditated errors. The healthcare system, based on the type of work done, must attempt to eliminate as much error as possible from its culture. In a 'Just Culture' all employees, practitioners and others understand the mission and the vision of the organization guides them to do the best they can in completing their job. Just culture is obtained in organizations where everyone knows the company's values and how they are expected to make choices to protect those values. Everyone has a job to protect the patient and others and to be part of the solutions to reduce the risk of errors. *"Most serious medical errors are committed by competent, caring people doing what other competent, caring people would do"* (Berwick, n.d., p.1).

Most errors are a result of a process and not necessarily the individual. The processes somehow enable mistakes to happen. Of course, human factors (later in this chapter) play an important factor in whether an error occurs. The Just Culture structure defines what behavior should be undertaken for the individual who directly makes the error. The previously mentioned Swiss cheese model demonstrated errors do not occur in isolation, but are associated with a number of smaller errors leading up to a catastrophic error. Just culture recognizes this to be a true statement (Just Culture, n.d.).

Just culture defines three possible behavior choices that an individual makes and needs to manage (Just Culture, n.d.). A 'human error', which is an inadvertent action, a lapse or a mistake, is the first behavior choice. When a human error is made, the individual should be consoled regarding the mistake. The process should be examined and managed through changes in choices, processes, procedures, training, and so forth. An example of this might be starting an operative procedure without a time out.

An 'At-Risk Behavior' is the second behavior choice (Just Culture, n.d.). With this behavior, the individual chooses to do something that may unintentionally lead to a situation where harm occurs. The person does not necessarily recognize the possible risks and results of their actions, or feel the risks are insignificant or justified. An example of this risk would be looking at a billboard while driving a car. With this beh;:ivior, the individual should be coached as to the consequences of the actions and where better choices should have been made. The organization should remove incentives for at-risk behaviors, incentivize healthy behaviors, and increase situational awareness.

The last behavior choice is 'Reckless Behavior' where the individual consciously chooses to put themselves and/or others in harm's way (Just Culture, n.d.). The risk is identified but is ignored. It is with this type of behavior there should be severe consequences related to the behavior, such as remedial action or punitive action.

To achieve just culture the organization must have reasonable values and expectations, knowing there will be mistakes made (Just Culture, n.d.). There must be good system design to catch and recover from human errors and equipment failures. The company must direct and manage the behavioral choices of its employee, practitioner, and so forth, as described above. There must be learning systems in place to allow the organization to learn from the errors and to make improvements in the processes to prevent further mistakes from occurring if possible. Lastly, the organization must treat every individual and event with accountability and justice . There must be an unbiased and fair manner utilized regardless of the severity of the error.

Establish Learning Boards

One tool of many to be used on a unit is the Learning Board (Figure 2). This tool is frequently used with the CUSP program, which is described toward the end of this chapter. The learning board is posted on the unit and utilized to display safety concerns identified by staff, practitioners, and others. It is up to each organization as to where this learning board is displayed on each unit, and thus determines if patients and/or others may also view the board. Any person may place safety concerns on the 'Identified' section of the board. Through staff meetings, leadership WalkRounds and other such activities, the prioritization of the safety concerns is determined and the appropriate individuals assigned to each initiative.

A designated individual on the unit is appointed to aggregate the data and to report the data to the appropriate individuals. The learning board promotes visibility of specific concerns and what is being done to resolve the concerns/issues. This transparency demonstrates to the staff and others their input is critical to having a well-functioning patient safety program. Being able to anonymously report concerns in this manner may be valuable for the staff and others to report the safety concerns without fear of reprisal.

Figure 2: Learning Board

Learning Board			
Visual	Identified	Active	Resolved
Measures	# of defects identified/ Month	# of defects without action > 30 days	# defects resolved in past 30 days
	Data collection: Count on the first day of each month	Data collection: Monitor and move	Data collection: Count on the first day of each month

Patient Safety Leadership Rounds

Patient Safety Leadership Rounds or WalkRounds was developed by Allan Frankel, MD, to increase awareness of safety issues by all clinicians (HRET, 2010) . Dr. Frankel, Director of Patient Safety at Partners Healthcare, spent three years working with the Health Research & Educational Trust to study the implementation of these types of rounds and identified staff and practitioners developed new insights into patient safety . The WalkRounds occur in patient care areas of the organization and demonstrat e to staff the organization is committed to patient safety . The WalkRounds also provide an informal method for leaders to talk to staff and encourage reporting of errors as well as reporting to staff the accomplishments of the organization in eliminating or decreasing the effect of the errors (IHI-WalkRound, 2017). Table 7 lists the objectives to be gained by utilizing these leadership WalkRounds.

Table 7: Twelve Objectives of Patient Safety Leadership WalkRounds

Twelve Objectives of Patient Safety Leadership WalkRounds
• Increase awareness of safety issues by all clinicians
• Engage senior leadership with frontline staff about patient safety issues
• Provide opportunity for leadership to openly discuss operational failures, safety and harm from front line staff
• Educate staff about patient safety concepts such as Just Culture
• Encourage frank & open discussion in a unit setting
• Obtain information collected from staff about barriers to safety
• Assure the information collected affects actions or resource allocation
• Utilize the Learning Board
• Elicit information to be collected and aggregated in a useful manner

WalkRounds cannot simply start without preparation of senior leadership and unit participants. The leadership must have buy-in with the concept and agreement of the need to be consistent with the WalkRounds . The WalkRounds should consist of a senior leader, a scribe, the Patient Safety Officer and/or Quality Professional, and the manager/director of the unit. The scribe captures comments, concerns, and safety events. There must be a plan to provide feedback from the rounds to other leaders of the organization (HRET, 2017; IHI-WalkRounds, 2017).

The WalkRounds should be scheduled based on the staff's schedule and not the leaders' schedules. It is common knowledge the nursing staff are the busiest at certain times during the day,depending on the type of unit or department. The first thing in the morning is not a good time for rounds due to the patient care to be accomplished in the morning or after shift change. The WalkRounds should occur on all shifts so all staff members have opportunities to voice their concerns and have buy-in with the process. The WalkRounds should occur weekly for at least a year to reinforce to the staff and others the commitment from the leadership is not a one-time occurrence . Some organizations announce when the WalkRounds wil! be occurring and others do not. Some organizations assign specific leaders to specific units/depa;tments which can build trust between all who participate (HRET, 2017; IHI - WalkRounds, 2017).

The manager of the unit/department should know several days in advance the WalkRounds will be done on their unit/department. When the WalkRound team arrives in the area, a brief opening statement/introduction should occur. This opening introduction should be scripted so that all of the senior leaders make the same statement, and set the stage for open discussion. The senior leaders should be given some potential general questions in advance they may ask to get the discussion started. Table 8 contains a sample list of questions provided by the Institute for Healthcare improvement. The patient safety discussions can occur in a variety of ways. They can be informal discussions in the hallways, individual conversations, conversations with employees in a specific position {such as all Patient Care Assistants (PCA) on a unit), and or conversations in the same location every week. It is also important for leadership to elicit concerns from patients and families during these WalkRounds . It is important to take a camera along on the WalkRounds so that others can 'see' issues. At the end of the session,there should be a scripted closing statement to indicate there will be work done to examine the information provided, and identify and prioritize the improvements to be made.The participants should be asked to talk with others in the unit/department about the concepts discussed during the meeting. It is important there is follow up and feedback to the staff about the issues discussed during the WalkRounds . Regular safety briefings or other meetings should also be conducted throughout the organi1ation regarding the issues raised, and to communicate what is being done to improve patient safety (HRET, 2017; IHI-WalkRounds, 2017).

Table 8: Sample WalkRound Questions

Sample WalkRound Questions	
Question	Examples
Can you think of any events in the past day or so which resulted in prolonged hospitalization of a patient?	Appointments, treatments, procedures scheduled but missed Miscommunications Delayed or omitted medications or treatments
Have there been any near misses that almost caused harm to the patient but didn't?	Finding the wrong drug sent up from Pharmacy and almost administered but caught before it was IV pump mis-programmed, but the alarm sounded prior to the infusion beginning Physician wrote orders on the wrong patient and the nursing staff caught the error before anything was done to the patient
Have there been any incidents lately where you think a patient was harmed?	Infections Surgical complications or errors Complications from medications
What aspects of the environment are likely to lead to patient harm?	Consider the movement of patients throughout the organization Consider communication Consider computer issues and EHR issues
Is there anything we could do to prevent the next adverse event?	What information would help? Consider environment and workflow Consider interactions between clinicians
Can you think of a way in which a system or the environment does not work consistently?	Not enough information Requirements don't make sense Requirements are unnecessary and time-consuming
What specific intervention from leadership would make your work with patients safer?	Organize interdisciplinary teams to evaluate specific problems Assist in changing the attitude of certain groups Facilitate interaction between specific groups
What would make WalkRounds more effective?	Informal hallway conversations instead of group meetings Individual conversations Enough time to really discuss issues

How are we actively promoting a blame-free culture and working on developing a blame-free reporting policy?	Do not penalize individuals for inadvertent errors Employees who report potential or actual errors and adverse events in a timely manner are provided immunity

Adapted from IHI-WalkRounds, 2017

/\t the conclusion of the WalkRounds, the da la collected must be trended and improvement tracked. The Health Research & Educational Trust (HRET, 2017) has developed a database in Microsoft Access to allow information to be tracked beginning at the time it is gathered during the WalkRounds. The database is free and can be downloaded from the WalkRounds Database listed in the website links at the end of the chapter.

[ethnology and Its Effects on Patient Safet

Technology has been expanding in healthcare at an exponential speed. Many of the new technologies were thought to be the answer to patient safety and quality issues. While new technology has remedied many issues, it has also created new ones now needing to be addressed. Several of these technology advances will be discussed here with the positives and negatives resulting from their use.

Top Patient Safety Issues and Hazards – 2017/2018

Beginning in 2014 the Emergency Care Research institute's (ECR i i Patient ·safety Organization (PSO) issued the first *'Top 10 Patient Safety Concerns for Healthcare Organizations'* for multiple healthcare settings, such as hospitals, ambulatory care centers, doctor's offices and nursing homes (ECRI, 2017). The ECRI also releases the *'Top 10 Health Technology Hazards'* every Fall. The Top 10 lists are designed as a starting point for healthcare organizations to identify any of the risks and to begin to prioritize the issues at their organization. Organizations contribute data to the PSO in a protected manner, as discussed previously in this chapter, as a result of the Patient Safety and Quality Improvement Act. This information is then compiled and analyzed to create these lists.

In 2017 there are two recurring patient safety issues and seven new issues (ECRI, 2017) (Table 9). It is also interesting to note there are four concerns/issues the same on both the Patient Safety and Hazards lists. These lists were compiled by two different teams and yet these same concerns surfaced on both lists. This should cause organizat ions to place additional attention on these items. More information about these lists can be found on the ECRI's website listed in the website list at the end of this chapter.

Table 9: ECRI's Top Ten Patient Safety and Hazards Lists, In Rank Order of Significance

ECRI's Top Ten Patient Safety and Hazards Lists, In Rank Order of Significance	
Top 10 Patient Safety Concerns 2017	**Top 10 Health Technology Hazards 2018**
1. Information management in EHRs	1. Ransomware & other cybersecurity threats to healthcare delivery can endanger patients
2. Unrecognized patient deterioration	2. Endoscope reprocessing failures continue to expose patients to infection risk
3. Implementation and use of clinical decision support	3. Mattress & covers may be infected by body fluids and microscopic contaminants
4. Test result reporting and follow-up	4. Missed alarms may result from inappropriately configured secondary notification devices and systems
5. Antimicrobial stewardship	5. Improper cleaning may cause device malfunctions, equipment failures, and potential patient injury
6. Patient identification	6. Unholstered electrosurgical active electrodes can lead to patient burns
7. Opioid administration and monitoring in acute care	7. Inadequate use of digital imaging tools may lead to unnecessary radiation exposure
8. Behavioral health issues in non-behavioral-health settings	8. Workarounds can negate the safety advantages of bar-code medication administration systems
9. Management of new oral anticoagulants	9. Flaws in medical device networking can lead to delayed or inappropriate care
10. Inadequate organization systems or processes to improve safety and quality	10. Slow adoption of safer enteral Feeding connectors leaves patients at risk

!computerized Physician/Provider [AHRQ]/Prescriber [NOF] Order Entry (CPOE)i

A computerized physir:i;in order entry (CPOE) system allows the clinician to enter directly an order into the computer rather than writing on paper. The order entered through the CPOE is electronically transmitted directly to the pharmacy or other department where it is then linked to the patient's other information in the electronic health record. Most systems interface with clinical decision support systems (CDSSs), which include suggestions or default values for drug doses, routes, and frequencies and may also check for drug allergies, drug-drug interactions, drug- laboratory values, drug guidelines, or prompt for corollary lab tests. CPOE was recommended to be implemented in the *To Err is Human* report and was one of Leapfrog's first standards (AHRQ – CPOE, 2014).

Another impetus for CPOE comes from the CMS Meaningful Use regulations. The measure for Stage 1 is: *"More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP {Eligible Practitioner } have at least one medication order entered using CPOE"* (CMS – CPOE, 2017, p. 1). In Stage 2 the measure for CPOE is *"More than* 60% *of medication, 30% of laboratory, and 30% of radiology orders created by the EP {Eligible Practitioner} or authorized providers of the EH's {Eligible Hospital} or CAH {Critical Access Hospital} inpatient or emergency department during the EHR reporting period are recorded using CPOE"* (CMS – Stage 2, 7014, p. 1). On November 14, 2016, CMS published a final rule with comment period that included changes responsive to stakeholder feedback and will result in continued advancement of certified EHR technology. The finalized changes will also utilize and result in a program result in more focused on supporting interoperability and data sharing for all participants under the Medicare and Medicaid EHR Incentive Programs (CMS – CPOE, 2017).

While CPOE has been shown to be quite effective in reducing error related to the prescribing of the medication, it has not been effective in errors occurring at the dispensing and administration stages of the medication process. Its effectiveness in reducing ciinicai adverse events is iess clear. Several studies have shown CPOE does not reliably prevent patient harm with a persistence of high rates of adverse drug events (AHRQ – CPOE, 2017). Other studies have seen the CPOE implementation be effective in preventing these types of events (Leapfrog, 2016). There is postulation the Clinical Decision Support Software (COSS) may account for the difference.

!Bar Code Medication Administration (BCMA) Systems!

The use of wireless, mobile (handheld) barcode medication administrat ion safety systems (BCMA) is now a community standard in hospitals. Barcode scanning is the oldest machine-readable identification system. Its use in BCMA sys_tems to reduce medication error rates and improve patient safety has been recommended by several organizations, including the Institute of Medicine and the National Patient Safety Foundation. The barcoding system has been utilized to assure the medication is administered correctly with the five rights of medication administration. It has reduced medication errors as much as 65% to 86% and adverse drug events have also decreased (PA, 2008).

The barcode is applied to each unit dose (item-specific identification) and scanned by nurses at the bedside to connect the right medication with the right patient. The BCMA system is useful on patient units for medication administration and laboratory specimen collection, in preoperative and postoperative areas, radiology, and emergency departments. Benefits for any inpatient setting include:

- Accuracy in confirming the "five rights" of medication administration: right patient, medication, time,dosage, and route

- Seamless integration with an electronic medication administration record (eMAR), pharmacy system, and the organization's information system, using an industry standard HL7 interface
- Comprehensive data for performance measurement and improvement

Studies have shown medication administration errors can be reduced if the barcode system is utilized correctly (PA, 2008). However, when first implemented, nurses and others found ways to "work-around" the proper use of the barcoding system . The work-arounds have led to unanticipated consequences when administering medications. One work-around was related to how the system documents the medication given when the scan is done. Some nurses identified they had been trained to give the medication before documentation so it circumvented the system. Retraining was needed. Another issue was the barcode on the patient's armband was too lightly printed or the armband reflected light so the barcode could not be read. There was also user error in operating the new equipment and there were equipment failures (Voshall, Piscotty, Lawrence, & Targosz, 2013).

Leapfrog, an organization of payers and others that look at Patient Safety and rate hospitals on specific indicators developed in collaboration with hospital leaders and vendors, recently published a Leapfrog standard with which they sill measure hospitals (Leapfrog, 2016). The four components of this measurement will include: 1. "Measurement of the extent of a hospital's BCMA implementation throughout the hospital with a focus on medical and/or surgical units (adult and pediatric) and intensive care units (adult, pediatric, and neonatal)"; 2 . "A hospital's compliance with both patient and medication scans at the bedside prior to administering medications"; 3. "The types of decision support that the hospital's BCMA system offers"; and 4. "A hospital's structures to monitor and reduce workarounds" (Leapfrog, 2016).

In a 2014 study, Seibert, Maddox, Flynn, and Williams examined how the use of the electronic medical record and barcode medication administration affected the accuracy of medication administration rates within two hospitals. They found after the implementation of the BCMA-eMAR system the accuracy rate of medication administration did increase, especially when wrong time medication errors were removed from the calculations . In hospital 1,the accuracy rate improved from 92% to 96% (P=0.000008) after the BCMA-eMAR was implemented. In hospital 2, the accuracy rate did improve significantly, (p=0.015) but not as significantly.

The above study is important because the use of barcoding, or similar technology, is required for hospitals under Stage 2 Meaningful Use's core measures. The objective is to automatically track medications from order to administration using technology and an electronic medication record. The Stage 2 Meaningful Use definition is *"More than 10% of medication orders created by authorized providers of EH's {Eligible Hospitals} or CAH's {Critical Access Hospitals} inpatient or emergency department (POS 21 or 23} during EHR {Electronic Health Record} reporting period for which all doses are tracked by eMAR"* (CMS - Stage 2, 2014, p. 4).

!Radio Frequency Identification (RFID)I

Radio Frequency Identification (RFID} is a type of automatic identification system, using digital memory chips embedded on tags to track medical devices, drugs, staff, patient, and so forth. The tag may contain information about the lot number and expiration date for medical supplies and drugs or allergies and blood type for patients, or the physical location of equipment and patients in real time. It comes in a variety of shapes and sizes and it has both read and write capability, whereas barcoding is rc;:id only. Each chip has a unique electronic product code. Data can be read by sensors trom a distance and through materials like clothing, wristbands, boxes, and paint, and can be transmitted to a host computer for processing and tracking. RFID tags do not apply or read well on metal or in fluids. Systems are more expensive than barcoding but may be more viable in the long term (RFID, 2007).

In healthcare, RFID is utilized for three purposes: asset management, patient care, and inventory management (RFID, 2007). The RFID is utilized in asset management to help the organization know where equipment is located throughout the building. The tags are utilized on IV pumps, surgical carts, and other such equipment to decrease a time lag in trying to locate needed equipment. It also helps to find the equipment when it is due for preventative maintenance, thus meeting the standards for equipment management, and assur ing the patient safety of the equipment. In inventory control, RFID is utilized to track supplies from receiving through the location whe re it is to be used. When it comes to the patient care uses, there are multiple uses from tracking patients who wander, or leave the unit for testing, surgery, treatments and so forth, to patient identification, to surgical sponge and instrument tracking when closing a surgical incision, and so forth. The RFID tags can also be utilized in abduction and elopement systems to let you know when an infant has left the unit.

A disadvantage of RFID is the expense of the equipment, both hardware and software. Also, in the past, there were questions as to whether the RFID frequency interferes w ith equipment, such as anesthesia equipment, but further advancements seem to have resolved the interference issue.

!Abduction/Elopement Security Systems!

According to the most recent available data, there were zero infant abductions from healthcare facilities between 2013 and May 2015. However, from 1983 – October 2017 there were 323 abductions from healthcare facilities with 15 of these abductions unsolved (NCMEC, 2017). Of these infant abductions, 72.53% were individuals personating a nurse or other healthcare worker while these infants were a patient in the hospital. Hospitals and other health care facilities must remain vigilant.

Active RFID technology is used increasingly for infant and pediatric security to prevent abduction. Abduction prevention systems usually have a soft self-adjusting bracelet placed around the infant or child's wrist or ankle. If the bracelet is removed or cut off, an alarm signals the nursing station and computer software, alerting the healthcare staff. Usually the facility incorporates door and elevator locks, and goes into "lockdown mode", if a bracelet is removed or if someone attempts to take the

infant/child through the door or down the elevator with the bracelet still on the child. Some systems utilize a mother/infant matching system, where the mother is given a tag or band with the same code as her infant's, to serve as an additional and automatic identification (Wyld, 2009).

Unfortunately, most healthcare facilities only utilize these systems on newborns/infants, when in fact children of all ages can be abducted from a facility . More than 350,000 family abductions occur in the U.S. each year, with 47% of these cases involving the concealment of a child, transporting out of state, or intent to keep the child permanently. The same type of abduction prevention systems can be utilized on pediatric units, clinics, emergency rooms, or other areas where children might be left alone. Unlike infants, children are usually abducted by family members (NCMEC, 2017).

It has been estimated between 25% and 70% of adults with dementia but still living at home will wander at least once. Of nursing home residents, 31% will be found wandering . In a 2006 study, it was estimated one in five people with dementia will wander (Lester, Ga rite, & Kohen, 2012). RFID is also useful to prevent elopement by wandering patients or residents, while still allowing more freedom for both patients and healthcare staff. This is generally helpful in settings where patients/residents are ambulatory, have short-term or long-term cognitive impairment, and may stray away from a location (wandering) or try to leave the unit without permission/needed supervision (elopement). As described above w ith infant and pediatric security systems, RFID devices can be linked to door locking mechanisms . The patient/resident wears a tag and strap designed to prevent removal. It works with systems which monitor and control specified exit doors. If a patient or resident approaches an exit, the door controller locks the door; if the door is open, an alarm sounds. Certain alert systems include options for central reporting, integration with other security systems, and real-time patient/resident locating.

Human Factors

Human Factors include how people interact with tasks, devices/machines (e.g., computers), the environment, other individua ls, related groups and teams, and the organization . Human Factors also include capabilities and limitations. According to the World Alliance for Patient Safety (WAPS), the science of human factors is the "study of the interrelationship between humans, the tools, and equipment they use in the workplace and the environment in which they work" (WAPS, 2009). Understanding these dynamics helps improve, through better design, the usability, reliability, efficiency, usefulness, and effectiveness of technology in meeting process outcome objectives, reducing errors, and ultimately improving patient safety and outcomes. While most root cause analyses (see information below) focus on the processes leading to a never event, the human factors a re not often studied. The aviation industry was one of the first industries to incorporate human factors it into their analyses of never events.

In a study by Th iels et a l. (2015), they identified alarming figures that detail how important human factors are in preventing never events in the surgical areas. Over 5 years they studied 69 never events

which occurred in the OR, endoscopy and radiology areas. Thiels et al. (2015) utilized the Human Factors Analysis and Classification System (HFACS), which was developed for aviation and utilized by several industries, including medicine, to code the human factors during those never events. The human factors were then divided into 4 categories for analysis: unsafe actions, preconditions for unsafe actions, oversight/supervisory factors, and organizational influences. Table 10 defines what is included in each of these categories. The rate of never events during this timeframe was 1in 22,000 procedures of which 35% were wrong procedure, 30% were wrong side/site errors, 28% were retained foreign object, and 7% were wrong implants. There was a mean of nine human factors attributed to each event. The results demonstrated 47% of the human factors were attributed to preconditions for unsafe actions, 41% to unsafe actions, 7.5% to oversight and supervisory actions, and 4% to organizational factors.

Table 10: Human Factors Categories

Human Factors Categories	
Category for Analysis	**Analysis of Cause**
Unsafe actions	Issues with failure to follow institutional policies and procedures/standards; bending/breaking the rules Errors 1) Percetual errors = inaccurate information; confirmation bias; misinterpretation of information 2) Decisional errors = honest errors in cognitive thought; inadequate treatment 3) Action-based errors = errors in thinking without significant conscious thought; failure to follow a verification process
Preconditions for unsafe actions	Environmental such as inadequate operation room lighting, construction, technology issues, etc Patient such as obesity, complex anatomy, etc Situational such as poor patient handoffs, emergent situations, etc Behavioral factors such as inadequate communication, attention on a single issue, overconfidence, inadequate vigilance, distractions, personal behaviors, etc
Oversight/supervisory factors	Supervisor oversight Planning difficulties Problem correction deficiencies Staffing difficulties Supervisor noncompliance

Organizational influences	Inadequacies in organizational culture Inadequacies in operational processes Resources management

Adapted from Thiels et al., 2015

From this study by Thiels et al. (2015), it can be reasoned the same types of human factor errors are occurring in other parts of the healthcare organization. There are multiple actions undertaken to begin to mitigate these errors. The first is to utilize system-based strategies focused on mitigating the cognitive and perceptual errors. Cognitive errors are problems with the way humans think at an unconscious level. Perceptual errors are crucial to the way humans organize and interpret their sensory impressions. Since individual human factors are substantial to preventing errors, there must be focus on individuals, in addition to focus on the system. In the Thiels et al. (2015) study, the top three factors contributed to the errors were cognitive factors . Communication failures ranked fourth . Cognitive factors and communication failures are therefore the highest priority areas of focus when working to mitigate these types of errors.

Historically human factor error was known as an unwanted incident and resulted in an incident report. Some organizations have started to update their terminology to Human Factor Error Reporting or Human Error Reporting. No matter what your organization calls the process, reporting of errors is very important to determine if there are trends to be investigated and potential process changes needing to be implemented. Some not all errors may be escalated to a Sentinel Event.

\RED RULES

Red Rules have been utilized in healthcare to signify when there is to be no bending of the rules. They are to be utilized to reduce the possibility of harm to patients through work-arounds. The Red Rules should be used selectively with the acts that could cause the highest probability of harm to patients. staff members, or others. One example of this use of the rule would be with a Time Out before surgery or a procedure is begun. If someone is violating a Red Rule, the staff should feel free to "Stop the Line" and not allow the process to continue until the issue has been corrected. According to Jones, & O'Connor (2016), Red Rules should be few in number, clear and obvious, identify the consequences for not utilizing the rule correctly, and focus on the decision-based (such as the Time Out) rather than the skill-based activities. There should be an emphasis on communication throughout the organization, especially as the Red Rules are being implemented.

\sentinel Event Process

Sentinel events and what the IOM report calls "adverse events" fall under the category of medical errors. They probably constitute a relatively small percentage of medical errors. However, they may compound to result in an adverse impact on patients, even if a specific "event" is never identified. Sentinel events are considered a special cause variation, falling outside the normal control limits of the

process of care. As such, intensive analysis must be performed in each case, whether the sentinel event occurs in the organization or is associated with services provided by or for the organization.

Careful investigation and analysis of all sentinel events, as well as evaluation of corrective actions, is essential to reduce risk and prevent patient harm. When a sentinel event occurs, a Root Cause Analysis (RCA) should be conducted to find the true root cause of the event. From analysis, an action plan is initiated and implemented. The RCA is conducted to identity whc1t really caused the event to occur ,:ind the action plan is developed to eliminate or minimize the root-cause so the event does not occur again. The RCA process is discussed later in this chapter.

In 1996, The Joint Commission (TJC) implemented its sentinel event policy. The policy was created to assist hospitals that experience serious adverse events improve safety and learn from the events. Since then, the policy has been part of the accreditation standards for all types of organizations accredited by The Joint Commission (TJC – Sentinel, 2017). Other accreditation agencies and CMS have similar standards which apply to the same type of analysis of sentinel events. For information on these standards of accreditation agencies and others, refer to Chapter 6 Regulatory, Accreditation, and External Recognition.

There are no complete, accurate databases with the information of all sentinel events. Several states and governmental agencies require sentinel and other adverse event reports to be sent to them. The Joint Commission has a database of the events voluntarily reported to them. This database does not contain all the sentinel events in healthcare organizations accredited by TJC because reporting is not required. However, the data from TJC represents a iarge sample of the types of events in various healthcare organizations. From 2013 through the first half of 2017 (latest data available at the time of this writ ing), the top four root causes were human factors, leadership, communication, and assessment (TJC – Sentinel, 2017). All types of healthcare organizations should focus their patient safety improvements with these four factors in mind.

pology & Disclosure!

When an adverse or sentinel event occurs, the patient deserves to know a serious unanticipated outcome/error occurred and the related details about the occurrence . As a practitioner, it may be difficult to admit to a patient something did not go as expected. All healthcare organizations must have a formal process for disclosing this information to the patient and as appropriate to family members, and to those responsible for patient safety within the organization. The organization process must determine whom the individual should be to make the disclosure to the patient. Some organizations require a licensed independent practitioner and others require the risk m.inager be present. The type of adverse event may determine who the individual should be to make the apology and disclosure. The process should also include how the information from the adverse event should be utilized to foster transparency and performance improvement efforts (NQF – Disclosure, 2009).

In 2009, the National Quality Forum (NQF) published the *Safe Practices for Better Healthcare 2009 Update: A Consensus Report,* which addresses the need for the apology and disclosure, and measures to be taken to create such practices in a healthcare organization (NQF – Disclosure, 2009). The report also addresses some of the difficulties in carrying out this disclosure. If the organization has determined the Licensed Independent Practitioner (LIP) be the one to apologize to the patient, however the practitioner was not involved in the adverse event occurrence, the LIP may not have all the facts about the incident, or may fear an increased liability as a result of the disclosure. Support systems to assist the patient and providers with this process must be in place. According to the report, communication with the patient should be timely, within 24 hours of the event if possible. It should include the facts about what happened, empathic communication of those facts and expression of regret, a commitment to investigate and, as possible, to prevent future occurrences of the event, and emotional support of the patient and family will be provided.

In addition to the apology and disclosure, the 2009 report (NQF-Disclosure, 2009) also discusses the care of the providers/caregiver(s) involved in the error as well as support staff and others involved. Caregivers are often called the "second victim" of the event. The number of second victims will vary from one to many. Due to the complexity of care and technology, and the knowledge about the Swiss cheese model (discussed earlier in this chapter), there may be multiple individuals who directly and indirectly contributed to the adverse event occurrence, due to system failures or human error. The harm to caregiver(s) and others involved in the event may manifest itself as increased depression, anxiety about future errors, loss of confidence, sleeping difficulties, reduced job satisfaction, and harm to their reputation. As a result of this harm, the caregiver may have loss of work time, may decide to change their profession, ,;1nd it may cause a disruption to their family and many other results.

The NQF report {NQF – Disclosure, 2009) further addresses specific guidance concerning the events that should occur concerning the second victims . Caregivers, according to this report, are considered clinica l providers, staff, and administration who are "involved" in the adverse events, either directly or indirectly. Indirect involvement includes those involved in the chain of errors or system failure. The report indicates there must be a formal evidence-based process in place to identify what happened in the event and the role of the individuals involved. The individuals involved in the event either directly or indirectly should be treated with respect and dignity. These individuals may be under extreme stress and discomfort . Those involved should be considered innocent of intentional harm until proven otherwise and should be treated by those interacting with them as if they themselves were in this position. A formal process should be utilized for the individual's co-workers to be able to express their personal feelings about what happened, and to receive help with forgiveness and personal support for those involved in the error. There should be a formal process where a designated team or individual is responsible to assure those involved in the error receive the care they need and to determine if they are "fit to work" for the protection of them and others. The individuals involved in the event should also be invited to be a part of the RCA or other investigation of the event. The exception would be if they were found to be under the influence of drugs, or alcohol, or if their behavior indicated they may

have intentionally contributed to the error. The requirement for disclosure did not change in the NQF Safe Practices for Better Healthcare (NQF-2010) but the document describes opportunities for further research and linkages to other safe practices within the organization.

[Root Cause Analysis (RCA)[

A root cause is defined as a factor that caused an adverse event and should be permanently eliminated through process improvement. A Root Cause Analysis (RCA) is defined as the approach, tools and techniques utilized to determine what the root cause of a problem is (ASQ, n.d.). The RCA can be utilized for multiple purposes. American Society for Quality (ASQ, n.d.) has identified five possible uses for the RCA, listed in Table 11. For more information on these uses of RCAs, they are detailed in the book *Root Cause Analysis: The Core of Problem Solving and Corrective Action,* which can be obtained from ASQ.

Table 11: Different Uses for RCAs

Different Uses for RCAs	
Approaches to RCAs	**Purpose**
Events & Causal Factor Analysis	Use with major, single event problems; Uses evidence gathered quickly and methodically to determine a timeline of what happened; Once established then causal and contributing factors can be identified
Change Analysis	Use with situations when a system's performance has shifted significantly; Examines changes in people, information, equipment, etc. which may have **contributed to the change in performance**
Barrier Analysis	Focuses on what controls are in place to prevent or detect problems and failures
Management and Oversight and Risk Free Analysis	Use of a tree diagram to examine what occurred and why it might have occurred
Kepner-Trgoe Problem Solving & Decision Making	Four phases of problem solving: Situation analysis; Problem analysis; Solution analysis, and Potential problem analysis

Most healthcare organizations are utilizing the RCA mainly after an adverse event occurs, and occasionally when there is a near miss. The RCA process should be used every time there is a sentinel event, without exception. In some organizations, an RCA is required when every event, such as the development of a pressure ulcer, is identified. The immediate analysis of the situation can result in changes to the systems involved before the event occurs again. Other organizations use the RCA for every near miss identified. The tool is not designed to be used before such an event occurs. In those situations, the organization would use the FMEA, which is the next topic in this chapter.

The RCA uses the *'5 Whys'* approach to identifying the root cause. With this approach, the team asks 'Why' five successive times, to systematically drill down to the real root cause. There may be times when less than 5 Whys are needed and other times when more are needed to identify the root cause(s). There may be more than one root cause . (Remember the Swiss cheese model discussed previously in this chapter) . In utilizing the 5 Whys, it is important not to leave any loose ends. If there is more than one answer to a Why question, the team must continue to drill down on both of those answers. The time to stop asking Why is clear, when you have identified a process, policy, or person as the root cause (Vidyasgar, 2015).

The root cause analysis should begin as soon as possible after the event occurs and is reported. It is important to have all involved either be interviewed individually or to write what happened from their point of view . This must be done as close to the event occurrence as possible. The longer the delay to this first step, the more detail will be lost from the participants' memory. Typically, a flow chart of what happened can be constructed with the information provided by these interviews/reports. The emphasis should be placed on identifying what happened, with less intent on who made the error.

The Joint Commission (TJC) provides a RCA tool on their website . This is a very comprehensive tool and it can be used in all healthcare settings, whether or not the setting is TJC accredited. The tool is divided into three parts: the incident itself, facility wide contributing factors, and the action plan based on the root causes. In the first part, the incident itself, the tool provides the areas of human factors, equipment factors, controllable environmental factors, uncontrollable external factures, and other factors for evaluation. Information needs to be gathered from prior to the event, as well as what happened during the event. In this part the information obtained from those involved in the incident should be used in the analysis of contributing factors. Part two, facility wide contributing factors, includes information from the entire organization which may have contributed to the event occurring, and which if not changed, could happen elsewhere in the facility . The areas examined in this part of the tool include human resources/staffing issues, information management/communication issues, environmental management issues, technology issues, and leadership issues . Leadership issues consist of corporate culture/risk reduction, encouragement of communication and clear communication of priorities. The third part, the action plan, defines the actions to be taken based on each root cause identified. The action plan must specify time frames and who is responsible for each part of the plan. The key here is the action must be implemented, have follow-up and assurances to compliance and sustainment occurring.

A couple of actual examples may help clarify these parts of the evaluation . The first example is a hospital with an outpatient Dialysis department in the hospital. A chronic patient receiving dialysis asked to be disconnected to go to the restroom. The patient returned to their bed and when the nurse came to reattach the patient to the dialysis machine, she found the patient with no pulse and not breathing. CPR was started and a Cold Blue was called. This is where it all started to go wrong. The crash cart in the department did not have a bed board attached so compressions were being done on

the bed rather than a hard surface. The suction equipment was also not with the crash cart. The nurses in the unit had never had an actual Code Blue before and were not familiar with the contents of the crash cart. The Code Blue team were not aware of where the department was now located since it had recently moved (Part 1). When the hospita l wide factors were examined (Part 2), it was found there never had been Code Blue drills conducted throughout the faci lity, and especially in the outpatient services area. It was identified there were environmental issues of moving the patient out of the Dialysis unit and through the hospital. It was also identified the new locations of moved units were not communicated effectively to those on the Code Blue team. All of these finding could be the root causes of why this event occurred.

In another healthcare organization, the individual who was responsible for conducting the RCAs and assuring the action plans we re implemented and sustained left the organization for other employment. The organization chose not to replace the position but to assign the duties elsewhere within the organization. However, this role was never assigned to another individual. As a result, the organization realized about 18 months later that no one was completing the RCAs and/or implementing the action plans. As a result, over 20 incomplete RCAs were sitting in a file cabinet . Upon examination, one of the early RCAs concerned a patient who fell and had a head injury. An action plan was developed, but it was never implemented. As a result, in the rest of the RCAs were two patient falls with injury. These may have been prevented, or at least occurred without injury if the action plan had been implemented house wide .

The National Patient Safety Foundation (NPSF, 2015) recently released their new recommendations for conduct ing a RCA. This document is called Root Cause Analysis and Action, or RCA^2 (RCA squared) which emphasizes the actions taken once the root cause has been identified. This new model can be utiiized to prioritize events, hazards and vulnerabilities in the systems of care. If actions resu!ting from the RCA are not implemented, then change cannot occur and the adverse event will likely occur again. This document can be found on the National Quality Forum (NQF) website listed in the website list at the end of this chapter.

!Failure Mode Effectiveness Analysis (FMEA)I

The Failure Mode Effectiveness Analysis is a tool designed to proactively and systematically evaluate a process to determine where and how it might fail, the effects of those failures, and to identify the portion of the process the most in need of change. Once the areas are identified, an action plan can be developed and implemented to prevent the failures from occurring or to reduce the effects should an event occur (FMEA, 2004). One of the main differences between the FMEA and the RCA is the FMEA is proactive (before an adverse event occurs) and the RCA is reactive (after an adverse event occurs). The steps in the FMEA are easy to do, but sometimes more difficult to understand when first utilized (FMEA, 2004).

Step 1 is to identify a process to evaluate with FMEA. If the team is utilizing a FMEA for the first time, it is best to choose a process without a lot of sub-processes. For example, medication administration has several processes including ordering, dispensing and administering the medication. As a novice to the FMEA, the team may want to only examine the administration portion of the overall process. When the members of the team have experience with the FMEA when the more complicated processes can be examined.

Step 2 entails establishing an interdisciplinary team. The team should include everyone involved in the process being studied. Some of the members of the team can participate only when their portion of the process is being examined. For instance, continuing with the medication example, when discussing how a medication is delivered from the Pharmacy to the nursing unit, it is important the transporters are involved in the discussion.

Step 3 consists of the team members developing a flowchart of all the steps in the process to be studied (FMEA, 2004). Every step in the process should be numbered from top to bottom, from 1to whatever number of step there are in the process. Once the process is flowcharted, the team needs to come to a consensus about the steps and their numbering. At this point, the team should begin using a table such as Figure 3 to record the information in the rest of the steps. The IHI has an interactive FMEA tool available for use instead of Figure 3 for this step onward, which will simplify the process for the team.

Step 4 the team will list all possible 'failure modes'. Failure mode is defined as anything that could go wrong, including items minor and/or rarely occur. Once this is completed, each failure mode should be examined to identify what would cause each failure mode to occur.

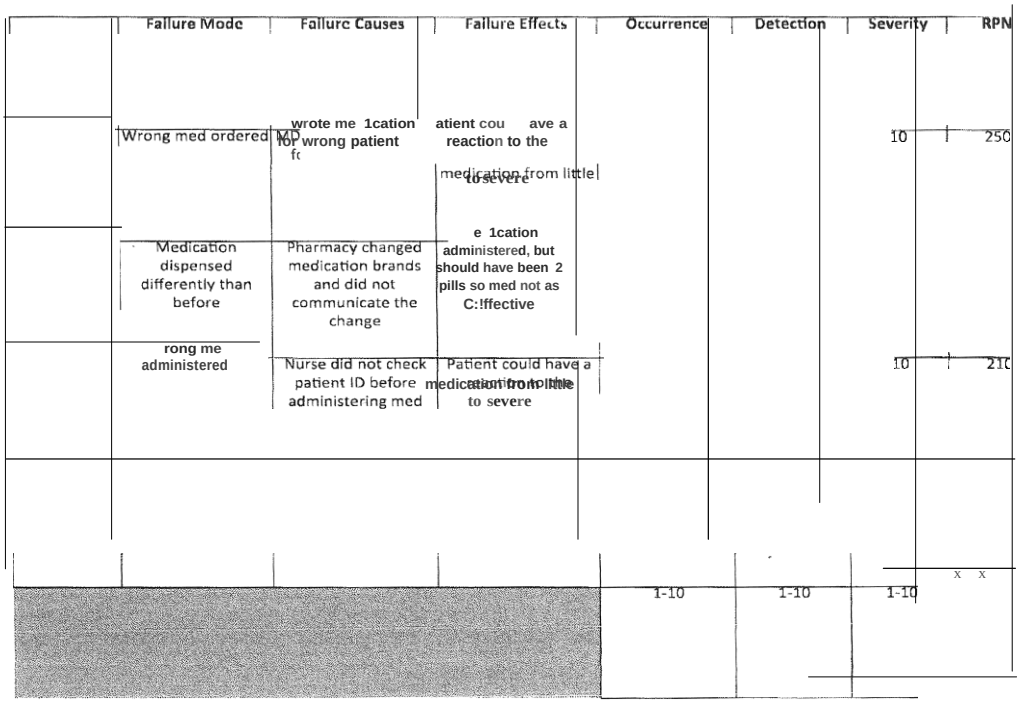
Step 5 is where the team will determine how likely it is the occurrence will occur, how likely it is the failure would be detected, and how severe the failure would be (FMEA, 2004). The resulting numbers of these rankings is called the Risk Priority Number, or RPN. For occurrence, the team will assign a score of 1to 10, with 1 meaning "very unlikely to occur" and 10 meaning "very likely to occur". For detection, the team will assign a score of 1to 10, with 1meaning "very likely to be detected", and 10 meaning "very unlikely to be detected" . For severity, the team will assign a score of 1to 10, with 1 meaning "very unlikely that harm will occur", and 10meaning "very likely that harm will occur".

In **Step 6,** the RPNs for each failure mode are multiplied together . The failure modes with the highest numbers are the ones the team should begin to work on improving first (see Figure 3).

Step 7 entails utilizing the RPNs for each of the high priority failure modes to develop an action plan for improvement (FMEA, 2004). To do this, the team members look at the scores (RPNs) for the occurrence, detection, and severity of each failure and develop the action plan from there. The team should analyze each potential cha nge to determine how much it might change the RPN if it were

implemented. Then a goal for improvement should be set and monitored to see if the goal is met. For example, the team may determine there should be a decrease of 25% of the baseline RPN total for one of the failure modes identified.

Figure 3: FMEA Calculation Table



As with many of the tools we utilize in healthcare, the FMEA was used originally in industry. The FMEA has been adapted by the Veterans Administration to a version entitled Healthcare Failure Mode Effectiveness Analysis (HFMEA), which they felt was a better fit for healthcare (VA, 2015). This model streamlines the hazard analysis steps in the FMEA with the use of a decision tree, and with a hazard score rather than a risk priority number. Table 12 represents a comparison of the FMEA and the HFMEA.

Tab!e 12:Comparison of FMEA and HFMEA Steps

Comparison of FMEA and HFMEA Steps	
FMEA	**HFMEA**
Identify a process to evaluate	Identify a process to evaluate
Establish a multidisciplinary team	Establish a multidisciplinary team
Flowchart of all the steps in the process	Flowchart of all the steps in the

	process
List all possible 'failure modes'	List all possible 'failure modes'
Determine and rate occurrence, detection, and severity	Determine severity rating and probability rating from separate tables
Multiply RPNs for each failure mode	Identify hazard score from hazard score matrix
Develop action plan	Decision: continue or stop based on hazard score and decision tree
	Develop action plan

Patient Safety Tools & Resources

There are many patient safety tools and resources to be utilized to help build and maintain a Patient Safety program. Several of these tools will be discussed here, but it is impossible to discuss all the sites available to help organizations improve patient safety .

Josie King Foundation

The Josie King Foundation was founded by a mother following the death of her 18 month old daughter. The child, Josie King, was admitted to a hospital with first and second degree burns from a hot bath. She healed from the burns and was getting ready to go home. Instead, she died from dehydration and a wrongly administered narcotic medication (IHI – Josie, 2015).

The Josie King Foundation is a non-profit organization whose mission is to prevent patients from dying or being harmed by medical errors (Josie, 2012). This foundation has programs and resources to tell Josie's story and educate healthcare workers, community members, patients, families, and others about patient safety. One very effective resource is a video of Josie's mother telling the story of Josie's care and her subsequent death. For more on this Foundation, go to the website list at the end of this chapter.

Institute for Healthcare Improvement - Open School

The Institute for Healthcare Improvement (IHI) developed the Open School to provide education to healthcare professionals interested in quality, patient safety, and other related topics (IHI-Open, 2017). Currently there are 253,725 students and residents registered on IHI.erg and 244,710 students and residents have completed an IHI Open School online course. Almost 50,000 students and residents have earned the basic Certificate of Completion by completing online courses in Improvement Capability, Patient Safety, Leadership, Person-and Family-Centered Care and Quality, Cost and Value modules. Participants in the Open School can also earn continuing education contact hours for completing the modules. The courses are free to students, residents, and professors. All others are charged a modest annual subscription. The Open School also provides a free library of activities the healthcare professional can use to educate others about the covered topics. Currently, the available

Open School courses are listed in Table 13. To learn more about the IHI Open School, go to we bsite list at the end of this chapter.

Table 13: IHI Open School Available Courses

IHI Open School Available Courses	
Course	**# of Modules in Course**
Patient SafP.ty	9 modules
Improvement Capability	8 modules
Quality, Cost, and Value	2 modules
Person- and Family-Centered Care	3 modules
Triple Aim for Populations	2 modules
Leadership	1module
Graduate Medical Education	7 modules

TeamSTEPPS

TeamSTEPPS is a teamwork system developed by the Agency for Healthcare and Quality (AHRQ) to help healthcare teams increase patient safety and make quality improvements. TeamSTEPPS has been described in Chapter 3 Performance and Process Improvement. The Crew Resource Management system is frequently utilized in combination with TeamSTEPPS.

Crew Resource Management

Crew Resource Management (CRivij is defined as a management system which makes optimum use of all available human factor and other resources to promote safety and enhance the efficiency. Kanki, Helmreich, Anca, (2010) has been used to improve the operations of flight crews since a 1979 NASA workshop. It is used primarily for improving aviation safety. CRM focuses on interpersonal communication, leadership, and decision making in the cockpit, which were identified as the most common factors leading to errors. In healthcare, like aviation, human error can cause devastating results.

CRM is a team training program, emphasizing the role human factors play in high-stress, high- risk environments. Safety, efficiency, and morale are considered to be the three primary outcomes of effective crew management. CRM is not as concerned about the technical knowledge and skills of the individual, as with the areas of cognitive and interpersonal skills needed to manage within a complex, critical environment such as healthcare.

In CRM, cognitive skills are the mental processes used for gaining and maintaining situational awareness, for solving problems and for making decisions . Interpersonal skills are considered the communication and behavioral activities associated with teamwork. It has been found the communication and behavioral activities often overlap with each other, and with the required

technical skills. Furthermore, they relate to single individuals and groups of individuals, which invariably need to interface with others in the healthcare arena. If you would like more information concerning Crew Resource Management, there is a tutorial available (7 modules) on the Crew Resource Management website listed in the website list at the end of this chapter

Comprehensive Unit-based Safety Program (CUSP)

The Comprehensive Unit-based Safety Program (CUSP) is a part of the AHRQ's Healthcare-Associated Infections Program focusing on generating evidence for the development and implementation of interventions to reduce healthcare associated infections (CUSP, 2017). The CUSP is a combination of teamwork, communications, and techniques to improve safety culture, and uses a checklist of proven practices. CUSP was first utilized to reduce central line-associated bloodstream infections, but can be used with any safety problem.

AHRQ has developed a Toolkit updated in 2017, for organizations to use in learning how to implement CUSP, and has numerous other resources to go along with training (CUSP, 2017). The CUSP is designed to be the foundation for physicians, nurses, and others to work effectively as a team. The Toolkit teaches participants how to combine clinical best practices and the science of safety. It is modular based and each module includes faci litator notes (proposed script), slides, videos and tools. When first learning the CUSP model, the new users complete six online modules to learn the core principles. After this training, the team can use the AHRQ tools specifically designed to apply the CUSP framework to decrease healthcare-associated infections . More information about the CUSP system can be obtained from their website, which is listed at the end of this chapter.

Centers for Medicare and Medicaid – Partnership for Patients: Better Care, Lower Costs

The Partnership for Patients: Better Care, Lower Costs was launched in April 2011 by the CMS Innovation Center and the Department of Health and Human Services (HHS) (CMS-Partnership, n.d.). It is a public-private partnership of 3,700 hospitals to make healthcare safer, more reliable and less costly. The Partnership currently provides resources regarding hospital-acquired conditions, healthcare-associated infections and hospital leadership and organizational culture. These may be obtained from the website list at the end of this chapter.

The Joint Commission - Sentinel Event Alerts, and Quick Safety Issues

The Joint Commission (TJC) provides Sentinel Event Alerts, Quick Safety Issues, and other information and resources, such as the Speak Up campaign on their website (TJC-Sentinel, 2017). Anyone can subscribe to receive the Sentinel Event Alerts via email when a new alert is issued. They are free to all whether or not the organization is accredited by TJC. Each organization is encouraged to review all of the Sentinel Event Alerts and to review their own organization to determine if the event could happen there. An FMEA may be appropriate to assist with this risk assessment .

The Joint Commission Center for Transforming Healthcare

Established in 2008, the Center for Transforming Healthcare works with leading hospitals and health systems, using a systematic approach, to analyze care breakdowns, discover underlying causes, and develop targeted solutions to complex problems (CFTH, 2015). The ultimate goal is to consistently provide quality healthcare in high reliable organizations. The Center is utilizing Robust Process Improvement (RPI®) tools such as Six Sigma, lean, and change management tools. At the time of this writing, the Center's initiatives are geared towards hand hygiene, hand-off communications, safe surgery, surgical site infections, heart failure hospitalizations, safety culture, falls, sepsis, insulin safety, and *C.diff* infections. There are currently 36 healthcare organizations/systems working on various aspects of these initiatives. The results of these initiatives are available as Targeted Solutions Tool®, which are available to Joint Commission accredited organizations .

Institute for Safe Medication Practices

The Institute for Safe Medication Practices (ISMP) is a non-profit organization formed 20 years ago to focus on preventing medication errors (ISMP, 2017). Through the work of ISMP, there have been changes in clinical practice, drug labeling and packaging, public policy, and in many more areas. The ISMP provides a voluntary national error reporting program and is also a Patient Safety Organization (PSO) in order to learn about the causes of medication and vaccine errors.

ISMP has many resources available to assist healthcare practitioners to prevent medication errors (ISM P, 2017). It has five medication safety newsletters for healthcare practitioners and consumers .The ISMP Nurse Advisor ERR® is published monthly providing nurses with detailed error reports, checklists, error reduction strategies, and more. This newsletter is free to nurses. The ISMP also publishes two ISMP Medication Safety Alerts®; one for acute care and one for community/ambulatory care. The remaining newsletters include an ISMP Long-Term Care Advise ERR® and a Safe Medication® newsletter. In addition to the newsletters, ISMP has medication safety tools and resources, webinars, guidelines, FDA Medication Safety Alerts, and much more. All these resources can be found at the ISMP website found in the website list at the end ofthis chapter .

!Agency for Healthcare Research and Quality – Patient Safety Netl

The Agency for Healthcare Research and Quality (AHRQ) has developed a section on its webs ite focused solely on patient safety information. The web -based resource is called the Patient Safety Net (PSNet) and contains the latest news and resources on patient safety (PSNet, 2017). The topics are retrieved from other sections of AHRQ, for easy access in one location. There are a iso resources provided by other organizations.

There are two main sections within this website (PSNet, 2017). The first one is the AHRQ PSNet Collection and it is comprised of resources pertaining to the patient safety community, based on set criteria. The resources must meet these criteria to be included. Resources consist of literature,

research, tools, and websites. The second section is the AHRQ PSNet Classics Selection, which contains review articles, empirical studies, reports and books with relevance to the patient safety arena. There are established criteria for this collection also. For more information concerning PSNet, go to the website list at the end of this chapter.

The Veterans Administration National Center for Patent Safety

The Veterans Health Administration (see website list at the end of this chapter) has made all of their resources available to the public: TIPS newsletter, Patient Safety Handbook, HFMEA, RCA, external patient safety reporting system.

Pennsylvania Patient Safety Authority

The Pennsylvania Patient Safety Authority (PPSA) was developed in 2002 and is one of the oldest state data repositories for collection of patient safety data (PPSA, 2017). The PPSA's job is to reduce and eliminate medical errors by identifying problems and recommending solutions. This charge is related to hospitals, ambulatory surgery facilities, nursing homes, birthing centers, and certain abortion facilities. The PPSA is a non-regulatory and non-punitive agency.

In addition to the collection and analysis of patient safety data, the PPSA develops and implements tools to assist facilities in the reduction of medical errors (PPSA, 2017). On their website, the PPSA publishes Patient Safety Advisorys, patient and consumer tips, news and information, and a long list of patient safety tools. See the website list at the end of this chapter to get more information. Recent reviews and analyses include Near-Miss Event Analysis Enhances the Barcode Medication Administration Process, Preparing for Unplanned Admissions to the NICU, Medication Errors in Outpatient Hematology and Oncology Clinics, and Warming Blankets and Patient Harm (PPSA, 2017).

WHAT REMAINS LEFT FOR HEALTHCARE TO DO?

It is obvious there is still a lot to be done to increase patient safety and reduce medical errors. There is no one set of actions that will work for everyone . Utilization of the resources above is a starting point, but each organization must determine what it needs to move forward. The Quality Professional and the Patient Safety Officer are two key individuals who can steer the organization in the direction of a patient safety culture, but they cannot do it alone. The leadership is critical. It must set the strategic goals and initiatives to integr.:itc p.:itient sa fety as an important part of the culture of the organization. It is a long road, but it can be traveled, with new paths to be discovered along the way .

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WEBSITES

PATIENT SAFETY

AHRQ's Patient Safety Practices	https://archive .ahrq.gov/news/newsroom/press-releases/2013/ptsafetypr .html
AHRQ's Patient Safety Indicators	http://www.qualityindicators.ahrq.gov/Moduies/psi_resources .aspx
AHRQ's PSNet	https://psnet.ahrq.gov/
Center for Transforming Healthcare	www .centerfortransforminghealthcare.org
CMS – The Partnership for Patients: Better Care, Lower Cost	http://partnershipforpatients.cms.gov/
CPOE – Stage 1	https://www.ems.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/l _CPOE_for_Medic ation_Orders.pdf
Crew Resource Management	http://www.crewresourcemanagement.net/
CUSP	http://www.ahrq.gov/professionals/ed ucation/curricuIum-tools/ cusptoolkit/index.htm l
ECRI Institute Alerts Tracker	https://www.ecri.org/com ponents/AlertsTracker /Pages/defa ul t.aspx
ECRI's Top Ten Patient Safety Concerns List	https://www.ec ri.org/Pages/To p-10-Patie nt-Safety-Concerns.aspx
ECRI's Top Ten Technology Hazards List	https://www.ecri.org/Pages/201 8-Hazards.aspx
FMEA Interactive Tool	http://app.ihi.org/Workspace/tools/fmea
Healthcare Acquired Conditions	http://www.stratishe a Ith.org/documents/HAC_fact_s heet.pdf
Hospital Acquired Conditions	http://www.c ms.gov/Medicare/Medicare-Fee-fo r-Service-Payment/Hospita lAcqCond/Hospita l-Acquired_Conditions. html
IHI Governance Leadership of Safety and Improvement White Paper	http://www.ihi.org/Topics/GovernanceLeadership/Pages/defa ult.aspx
IHI Leaders in Patient Safety White Paper	http://www.ih i.org/resources/Pages/1 HIWhitePapers/LeadershipGuidetoPatientSafetyWhitePaper.aspx
IHI Open School	http://www.ihi .org/education/ihiopenschool/Pages/default.aspx
IHI Patient Safety	http://www.ihi.org/Topi cs/PatientSafety/Pages/ default.aspx
ISMP Biweekly Newsletter	http://www.ismp.org/NEWSLETTERS/acutecare/default.aspx
ISMP Resources	http://www.ismp.org/tools/

Joint Commission Center for Transforming Healthcare	www.centerfortransfo rminghealthcare .org
Josie King Foundation	http://josieking.org/
Just Culture	httQS:LLwww.outco me-eng.coml david-ma rx-introduces-just culture/
Making Health Care Safer II	http://www.ahrq.gov/research/findings/ evidenee-based-reports/services/ qu◁lity/ptsafetys um.html
Patient Safety Organization Listings	http://www .pso.ahrq.gov/listed
Pennsylvania Patient Safety Authority	http://patientsafetya uthority.org/Pages/default.aspx
RCA2	http://www.npsf.org/page/rca2
Root Cause Analysis: The Core of Problem Solving and Corrective Action	http://www .asq.org/quality -press/display-item/?item=H 1363
Speak Up Campaign	http://www.jointcomm ission.org/topics/spea k_up_campaigns. aspx
Swiss Cheese Model	http://patientsafetyed .duhs.duke.edu/module_e/sw iss_chees e.html
TeamSTEPPS	http://teamstepps.ahrq.gov/about-2cl _3.htm
The Joint Commission	http://www .jo intcommission.org
The Joint Commission National Patient Safety Goals	http://www .jointcommi ssion.org/standards_ information/npsg s.aspx
The Joint Commission RCA Tool	http://www .joi ntcommission.org/sentinel_ event.aspx
To Err is Human	http://www.nationalacademies.org/hmd/-/media/Files/Repor t%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%20 1999%20%20report%2 Obrief.pdf
Top 10 Health Technology Hazards for 2015	http://www.ecri.org/Pages/2015-Hazards.aspx
Top 10 Patient Safety Concerns for Healthcare Organizations	http://www.ec ri.org/PatientSa fetyToplO
VA National Center for Patient Safety	http://www.patientsafety .va .gov
WalkRound Database	http://www.hret.org/quality/projects/wa lkrounds-database.sht ml
WHO - Patient Safety	http://www.who .int/patientsafety/en/
WHO - Multi-Professional Patient Safety Curriculum Guide	http://www.who.int/patientsafety/educa tion/curriculum/Cur ri culum_Tools/en/

REGULATORY, ACCREDITATION, AND EXTERNAL RECOGNITION

CHAPTER 6

Jacque Cole, Susan Mellott, Sarah Yelton, Michelle Franklin

CPHQ Examination Content Outline Task Statements For This Chapter	
Organizational Leadership	
1.B.1	Assist the organization in maintaining awareness of statutory and regulatory requirements (e.g., CMS, HIPPA, OSHA, PPACA)
1.B.2	Identify appropriate accreditation, certification, and recognition options (e.g., AAAHC, CARF, DNV GL, ISO, NCQA, TJC, Baldrige, Magnet)
1.B.3	Assist with survey or accreditation readiness
1.B.4.c	Participate in the process for evaluating compliance with internal and external requirements for: Documentation
1.B.S	Facilitate communication with accrediting and regulatory bodies
1.C.4	Develop/provide survey preparation training (e.g., accreditation, licensure, or equivalent)

Words and titles of sections referring to task statements from the CPHQ Exam Content Outline are indicated throughout the Handbook with a box around the text.

All healthcare organizations, regardless of setting, are subject to constant scrutiny. The organization striving for high quality seeks to continuously improve their care and services, aiming for full compliance with state law, federal law, interpretive regulations (see Chapter 7 Legislation Initiatives), and volunteers for accreditation under the appropriate agency . In addition, some healthcare organizations increasingly are looking at other industry recognized achievements and awards, including, but not limited to: 150 9001 registration, the Baldrige Performance Excellence Program, and the ANCC Magnet Recognition Program or Pathway to Excellence.

ACCREDITATION CONCEPTS

Accreditation is a voluntary survey process used by various non-governmental, independent, external agencies to assess the extent of a healthcare organization's compliance with applicable pre-established performance standards set by the agency. Accreditation involves both self-assessment and external peer review, focusing on organizational, not individual practitioner, performance . Many programs now include comparative performance measurement with like organizations, and the results are publicly reported on the agency's website .

The purpose of accreditation is to improve the systems and processes of care and, in so doing, improve patient outcomes. The healthcare organization must be prepared to provide adequate evidence of its compliance with each standard applicable to its operations. Accreditation surveys are common in the US. and they are increasing internationally.

The Centers for Medicare and Medicaid Services (CMS) is the United States of America's federal agency operating the Medicare program for elderly and disablP.ci indiv iduals, as well as the other programs we administer including: Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace. CMS is under the Department of Health and Human Services (HHS) and receives its oversight from the Office of the Inspector General (OIG). In addition, CMS works with states to manage the Medicaid program. Among CMS's goals is to ensure beneficiaries in these programs receive high-quality healthcare (CMS, 2017).

The Medicare Conditions of Participation (CoPs) originated in 1966, and underwent major revisions in 1986, to serve as the foundation for accreditation. The CoPs were first developed using the Avedis Donabedian theory which notes a good structure (e.g. safe, sanitary building and qualified personnel) would increase the likelihood of good processes for patient care and ultimately lead to good outcomes for the patient. The current CoPs and the CMS survey process focuses on prescribed structural elements, patient-focused performance, and functions of the organization from a federal compliance perspective. Table 1 lists the common threads, in no particular order, woven through the CMS regulations for different types of healthcare organizations.

Table 1: CMS Common Accreditation Threads

CMS Common Accreditation Threads
• Patient rights (advance directives, complaints and grievances, informed consent, dignity, support person,etc.)
• Preventing healthcare-associated conditions (falls, blood stream infection from vascular catheters, urinary tract infections from bladder catheters)
• Pain control
• Safe environment of care
• Care delivery (restraining of patients, sedation, waived testing, peri-operative care)
• Quality improvement
• Leadership involvement
• Disaster and emergency preparedness
• Individualized care planning (updating the plan as the patient's condition changes)
• Individualized education for the patient and caregiver
• Medication safety (medication reconciliation, high risk medication safety)
• Qualified care givers (verifying licensure for practitioners as well as ongoing continuing education and competency for licensed and unlicensed personnel)

- Preventive care (immunizations)
- Coordination of care (proper discharge planning, coordinating special needs, commun ication between care providers, timely sharing of medical records, etc.)
- Preventing overuse, underuse, and misuse of health care (i.e.: radiation safety, unneeded repeated tests, fraud, waste, abuse (FWA)
- Private and secure protected health and individually identified information

In the U.S., healthcare organizations must be certified as complying with the CMS Conditions of Participation . This is necessary in order to receive approval for payment for Medicare and Medicaid patients. In addition, many insurance carriers and self-insured employers, as well as many managed care plans contracting for healthcare services, require accreditation for providers to treat their patients. Those insurers requiring accreditation as a contracting issue may accept agencies other than The Joint Commission (TJC), Det Norske Veritus GL (DNV), or the National Committee for Quality Assurance (NCQA), depending on the type of organization (e.g., osteopathic hospital, rehabilitation hospital, ambulatory surgery center, medical group, managed care or home care).

In addition to the accreditation of provider organizations and health plans, within the last several years, external agencies have developed accreditation or certification standards for specific programs (e.g. disease management or care management, and certain functions, such as credentialing).

!Deemed Status!

For a healthcare organization to participate in and receive payment from the CMS or Healthcare Insurance Marketplace programs, it must be certified as complying with the standards, called Conditions of Participation, set forth in federal regulations . This certification is usually based on an onsite survey conducted by a state agency on behalf of CMS or the CMS regional office . However, if a national accrediting organization enforces standards meeting the federal Conditions of Participation, CMS may grant the organization "deeming" authority to conduct these types of surveys and "deem" each subsequent ly accredited health care organization as meeting the CMS certif ication requirements. The health care organization would have "deemed status" and would not be subject to a routine, separate survey and certification process conducted by the state or regional CMS office. If an organization selects the deemed status option and their accreditation survey is successful, the CMS approved accreditation agency then recommends to CMS the organization should receive certification. CMS makes the final determination on whether or not the organization will be Medicare certified. CMS retains the authority to conduct random validation surveys and complaint investigations for certified organizations. CMS has planned for 5% of the hospitals and organizations receiving federal reimbursement for healthcare will still require validation by CMS after an onsite accreditation survey by a deemed agency. This number has increased since 2014 (ASHE, n.d.).

Subsequent and ongoing legislation and regulations define requirements for accrediting agencies wishing to grant deemed status to accredited organizations. The regulations provide a mechanism by which accrediting agencies may apply to become authorized to confer deemed status. The accrediting agencies release survey information to CMS after each survey if deemed status is granted. CMS may release information from accreditation surveys if applicable to an enforcement action; otherwise, CMS keeps survey reports confidential.

All accreditation programs in the U.S. and internationally are "voluntary," as they are not a condition of licensure to operate a hospital or other healthcare organizations . Motivations to participate in accreditation include a true commitment to improvement in quality of patient care and services, and the willingness to be held accountable and be compared to like organizations . Other motivations include: to enhance confidence of the public/consumers, as a condition of payment for U.S. federal programs, to undergo a Conditions of Participation survey, as a requirement for contracting to provide services and receive reimbursement (most insurers, health plans, self-insured employers), and/or as a requirement for residency programs in academic medical centers (ASHE, n.d.).

!Healthcare Licensure in the U.S.j

Licensure is the mandatory act of granting and receiving a license to provide healthcare services in a state in the United States. A governmental regulatory entity, usually the state Department of Health Services or Division of Insurance, grants the license for the healthcare entity. Based on an onsite survey, sometimes requiring several visits, and compliance with all applicable state and federal laws and regulations, the agency grants and monitors the license. Corporate compliance plans can be important tools in maintaining licensure.

State and federal laws determine the type of facilities mandated to be licensed to operate. Typically, the following types of healthcare facilities are licensed: Acute care hospitals (medical and psychiatric), long-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, ambulatory surgery centers, skilled and subacute care, long term care, home care, hospice care, resident behavioral, mental retardation/developmentally disabled healthcare, rural health clinics, and assisted living facilities. The license specifies the number and type of beds permitted: acute, skilled, subacute, long-term, etc. If used for other types of patients or care, the organization must be able to convert all beds to the appropriate licensed number within 24 hours.

Most Managed Care Organizations (MCOs) are licensed or certified by their state Department of Corporations, Department of Insurance, or Department of Managed Care rather than the Department of Health Services. MCOs cannot contract with unlicensed providers or practitioners if a license is required.

Financial incentives in contracts (e.g., end-of-year profit and/or risk sharing, capitated payment, discounted charges or daily rates, controlled access) are beginning to impact the "same level of care"

standard in acute facilities . There are external pressures to use acute beds as holding beds for patients who are waiting to "transition" to skilled, subacute, or long-term care. There are also internal pressures to move less stable patients to lower levels of care. Use of beds and staffing in patterns noncompliant with the license will place the organization at risk for losing their license.

Compliance with Standards

Compliance with standards has become two-pronged with the advent of performance measures, in addition to the traditional written standards, as ways to measure accreditation appropriateness. The current prescribed, approved, and accepted, written standards in healthcare accred itation and certification have become or are becoming more practical in the sense of assessing *actual* performance ("performance-based") rather than *capacity* to perform. They also focus on processes and outcomes, not simply structure, patient care issues related to quality and safety, and the organization's efforts to manage patient care and to support process improvements resulting in good patient outcomes . Most agencies will accredit an organization if it is in "substantial" or "full" compliance with the standards overall, even if not with each individual standard.

The integration of comparative performance measure data into the accreditation process (e.g., NCQA's HEDIS®, Joint Commission's Core Measures, OASIS, Minimum Data Set (MDS), etc.) adds another set of standards. The better an organization meets the performance measure expectation compared to peer organizations, the higher the rating for the related portion of the process.

Achieving compliance with the accreditation/regulatory standards and then maintaining survey readiness is the goal for healthcare organizations. After all,the regulations are minimum requirements for quality and safe patient care. Virtually all of them are based on best practices, with the intention of providing the best possible healthcare for individuals. It can be challenging at times to meet the "letter of the law" of some regulations and accreditation standards, particularly when dealing with older buildings, with long established ways of doing things, and with the human factors adding complexity to care settings. If the organization is accredited or seeking to be, consider readiness a daily organization wide responsibility, regardless of setting. Survey readiness is not a once every 2-3 year proposition. Gone are the days when preparations occurred during the 10-12 months prior to the expiration of the accreditation certificate. For the quality and safety of the patients served, upholding the minimum standard of care is a daily and year-round endeavor .

If a surveyor finds any condition existing posing a threat (potential or actual) to public or patient health or safety, the surveyor may notify the chief executive officer of the organization and recommend denial of accreditation. Any recommendation of denial is reviewed by the accrediting agency before a final decision is made. The organization is offered an opportunity to discuss a reas of noncompliance, to submit jdocumentationl to demonstrate compliance or progress, and, with some accrediting agencies, to request a face-to-face interview or even a "validation" resurvey.

CCREDITATION SURVEY READINESSl

As you prepare for a survey, determine who will be the main points of contact with the surveyors . The main points of contact are the condu it for the survey team to work w ith through the preparatory, onsite and post review activities . Using and limiting yourself to one or two people helps keep communication in control and organized at all times.

There ore two main avenues for your communicalions: documentation preparation and logistics. If the communication is related to logistics (dates, time, hotel, and local transportation) more than the standards, utilizing an administrative assistant can work *very* well. This relieves the other person, usually a manager or above, to concentrate on the documentation preparations. Also, the administrative assistant can manage the team meeting times and locations; meals during preparations, onsite and post review activities; assisting with copies of the final prepared documentation, etc.

Preparedness/Continuous Readinessl

W hether preparing for a routine accreditationireguiatory survey or a disease specific certification survey, the process is basically the same. To begin, the individuals who are coordinating the effort must be very familiar with the regulatory requirements and elements of performance. Deemed accrediting agencies make available the standards and rationale to organizations choosing this method. Online and paper handbooks are available for purchase. The CMS regulations are online for download. There are seminars and educational meetings conducted by various organizations. Read the guidelines very carefully and look for time related words such as annual, months, and minutes. The organization is either in compliance or out of compiiance. For example, The Joint Commission has a regulation in the Comprehensive Stroke Regulations stipulating the time in minutes to get a patient from the helipad to the emergency department. When you see such regulations, do not leave things to chance. Take a timer and actually measure the time it takes, to be sure you are meeting the standard. The organization is held to the standard, the element of performance, the interpretive statement, the state code, expectations of expert agencies such as National Fire Protection Agency (NFPA), and the policies as set by the local organization. This section contains some practical suggestions and tips on how to navigate the survey process, which have been developed during actual healthcare surveys.

Most accreditation agencies use one or more of the following mea ns to assess compliance with applicable standar ds:

- Accred itation/Regulatory Readiness Te;im
- Review of documents demonstrating compliance
- Onsite observations by surveyors
- Verbal information gained by surveyors through interviews

- Examples of standards implementation
- Review of medical/health records
- Assessment of service/support systems
- I ntegration of performance measure data into scoring

!Delegated Entitie

Of note, if you are an organization which contracts with another organization to cover all or part of your services, you are still the accountable organization to a regulator. Your contracted entities, whether they are a delegated service or delegate entity, should be doing readiness activities prior to your review. As the main organization, you are responsible to review your delegates' activities as if they were your own departments and you are held accountable to any external regulatory oversight audit/review. There are some areas which can be deemed. If your contracted entity is accredited by a recognized accrediting organization you MAY be able to streamline your delegate oversight review.

!Accreditation/Regulato ry Readiness Teaml

Each organization should have an Accreditation/Regulatory Readiness Team or committee to create and implement a survey preparedness plan. This group is responsible for the implementation and improvement of processes in terms of existing and new accreditation and regulatory standards. This team most often consists of key leaders and managers who coordinate and oversee continuous readiness and survey planning efforts. The team members must have decision-making authority in the organization . The Quality Council, the administrative council, or a senior leadership survey team includes key QM/Pl leaders and sponsors/champions. Routine meetings are set to review environmental rounds, to establish a method of inspecting and following patients and processes through the care settings, to communicate accrediting agency and regulatory information, and to plan for dissemination of information. For example, in 2014 The Joint Commission (TJC) issued a new patient safety goal regarding the use of monitors with alarms .TJC has given organizations two years to implement this patient safety goal before they will begin to survey it in January 2016. The Accred itation/Regulatory Team's job is to assure implementation has been completed prior to the January 2016deadline.

Specific senior leaders (president, vice presidents, chief nursing officer, and administrative directors) should be designated to ensure compliance with the standards applicable to the areas for which they are responsible . In provider organizations, these leaders participate in regularly scheduled (announced or unannounced) environmental rounds.

The organization also needs to identify a medical/professional staff, Chief Medical Officer, or medical team of Licensed Independent Practitioner (LIP) leaders who have authority for quality and peer review and/or are required to participate in the survey process as medical directors, department

chairs, etc. They review quality, patient safety, utilization, and risk reports related to compliance with applicable standards.

\Accreditation/Regu latory Readiness Team Activities/Process Improvements\

The Accreditation/Regulatory Readiness Team should establish ongoing interdisciplinary teams (or use appropriate existing teams) at each site. These teams will be assigned portions of the standards for which they are responsib le. This is an ongoing effort and not a pre-survey effort to make improvement s . Each interdisciplinary team will consist of three to five members from clinical and administrative areas (e.g., senior leadership/leadership council perso1nel, as well as staff responsible for quality, performance improvement, case management, patient safety, and environment). Each team meets routinely, such as quarterly, to review compliance with the appropriate standards/regulations, improvements, and policies. The team members conduct patient and organizational tracers to identify areas of weakness or areas for improvement related to the standards.

The team leaders and members are well versed in the pertinent standards, operational policies, procedures, and practices and are able to identify compliance deficiencies. System problems found during environmental rounds, tracer activities (patient or process), or data tracking linked to standards should be followed up by the leader responsible for compliance. The administrative team (leadership) is the most effective in performing periodic walk-around inspections of all settings, departments, and services, focusing on selected standa rds each time. Provide a grid or log sheet outlining, for each standard, where/in what form appropriate \documentation\ may be found to prove compliance. This log will serve the administrative and clinical teams, but also will provide support to each person participating in the survey. If non-compliance issues arise, decisions can be made on the spot. A good a lternative or addition to the walk-around is to establish interview/focus groups for each important function or category of standards and each organization-wide required review process.

System changes often require the work of a quality improvement team over time, unless the problem involves simply failure to comply with an established clinical pathway, clinical practice guideline, protocol, or other standard operating procedure. The team will set priorities and recommend solutions to achieve compliance and provide leadership for implementing recommended solutions. Communication to organization leadership and appropriate staff concerning compliance is imperative.

\Learning the Regulations\

Once the team members have been identified, the initial steps involve compiling a listing of the requirements and then performing a gap analysis (self-assessment) to clarify what is in place and what has yet to be compiled or developed. Next, assign people to help fill the gaps. Using a series of notebook binders is one way to organize the information and required documents. A neatly organized and labeled binder (or series of binders) conveys attention to detail and helps the surveyor find all of the items easily and quickly. Handling of the documents electronically has also been successful.

External surveyors appreciate receiving information in a succinct and organized manner. Your organization's ability to achieve this will set the tone for success for the whole survey process.

All through the preparation process, it is wise to build in educational opportunities with leaders, managers, physicians, staff members, and patients when possible . Maximize teachable moments. Presenting the material in a variety of ways also helps the learners retain the information and makes it more interesting. Group meetings and 1:1talks both have their merits. Mock surveys help everyone to become more familiar with the survey process and be more relaxed and ready when the real survey occurs. The mock survey also provides the organization with a road map of identified issues to build action steps for improvement.

If it is planned to have an outside agency conduct a mock survey, it should be scheduled to allow the maximum time possible for implementation of their recommendations. As much as possible, the mock survey should incorporate all standards in effect at the time of the actual survey. However, most organizations do not need to hire a consultant or other group to perform the mock survey . Different departments in the organization could survey other departments . It is important to not have staff survey their own department, as a "new set of eyes" will see what the staff would miss. If the organization is part of a larger healthcare system, then like facilities in the system could be utilized to survey another facility .

It is also important to have each staff member educated on the rules, regulations and accreditation standards which are specific to their particular job. Most accreditat ion standards are noting this as an educational element to be completed. When individual members of the staff area trained, preferably on an annual basis, related to their particular job specific areas, additional training just prior to an audit/review becomes less daunting.

Oversight agencies want to see you access and evaluate the effectiveness of the training. Education and Tra ining are areas which can be coordinated with your Human Resources and Education Departments . They are very good about having tools which can computerize the key elements and areas needing to be taught with an electronic evaluation at the end of the session . Most education has been standardized and will need edits as regulations, rules and accreditation standards change.

IDocument Preparation

There are some specific documents surveyors will w ant to see during the visit. The accreditation and regulatory agencies typically provide Survey Activity Guides listing the spec ific documents . These will need to be collected prior to the survey. CMS or other oversight agencies also have document lists noting documents to be available during their visits.

Some healthcare entities organize their documents in an annually updated file box or notebook binder categorized with labeled dividers. Either way, the goal is to be able to present the documents in an

organized and timely manner. It is a good practice to have two identical boxes or binders – one to give to the surveyor for review and the other one to keep in the command center so the organization survey team sees exactly what the surveyor has been given to review. **Note:** It is also important the staff person compiling the documents accesses the most current policies, data, etc. which must be updated as changes are made. Review of the document box or binder prior to the survey by a senior leader, manager, or risk manager is necessary to prevent outdated or potentially inappropriate materials from seeping into the document compilation. Be aware the preparation of documents is an ongoing process. The ability of the organization to provide the documents immediately to surveyors upon arrival is a first step in demonstrating your organization's working continual readiness program to the survey team.

Tracers

A tracer is a record used to assess the movement of a patient through the health system . From entry to discharge the record is reviewed for completeness, individualized care planning, pain assessments, individualized education, patient involvement in goal setting, communication with the care team, discharge planning, and other components pertinent to the patient. A surgery patient, for example, would need a signed informed consent form, history and physical, anesthesia evaluation, airway assessment, time out procedure, and so on. For a patient who entered via the Emergency Department, a tracer might include assessing the time it took to be seen by a physician, how long it took to be admitted, and anything else delaying their care. The surveyors will visit the locations where the patient has traveied through the organization. They will review with staff at the spec ific location what did, or should have occurred in the specific area of review.

Tracers examining system processes such as medication use and information flow will a!so occur during the survey process . There should be a concerted effort by the healthcare organization to examine these processes and others stated in the Survey Guides. Again, there should be tracers performed moving through the organization as indicated by the process flow of the event.

When conducting mock surveys and tracers, use fresh eyes to look at your organization as if you had never seen it before. Put yourself in the place of the surveyor . Ask questions of the staff members; look around the environment. Search the electronic medical record for specific elements . Fine-tune and focus the training as the time frame for survey draws closer .

Education of Staff, Leaders, and Practitioners

The surveyors increasingly want to talk to the staff more so than to managers, but both must be prepared to answer questions. When making rounds and conducting tracers ask staff to 'show you' the specific activity, so they know the answers . For example, staff frequently will answer a question about a resource saying they can find it on the computer; but when put to the test, they cannot actually find it. If the staff depends on computer super users in the clinical areas to locate information on a routine

basis, and then ensure you have super users available during the survey process to identify the location of requested electronic charting.

Using quality tools for communication, such as eight times eight ways and affinity of like items, will assist in bringing information to the users understandably.

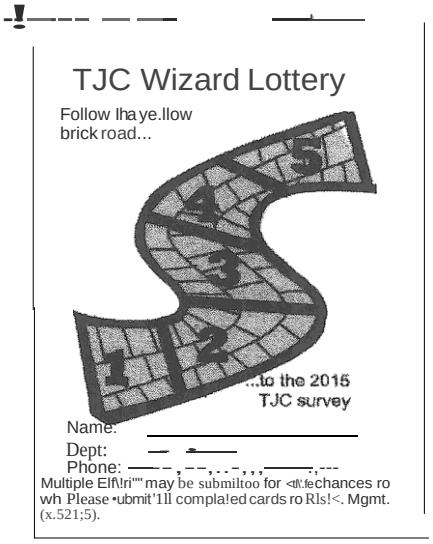
Slide presentations are particularly helpful to teach regulatory compliance information. Hearing and seeing the information can help the learners retain the key messages . If possible, take steps to attend a variety of committee meetings in order to share regulatory updates. Increased visibility of the regulato ry compliance staff can provide the organization with much needed support in their regulatory readiness activities.

Presenting regulatory compliance information via printed materials allows the reader to refer back to the document . Newsletters on the subject are available via many sources. A particularly good free monthly newsletter developed by a vendor containing both CMS and TJC information can be accessed online through the Patton website listed in the webs ite list at the end of this chapter. Organizations can also develop their own printed materials. Medical staff and employee newsletters can be developed and distributed throughout the organization .

Many other educational media are available or can be developed by the organization. While email is used frequently to send out updates, there is no guarantee emails are even opened. The organization's electronic education system is a wonderful means of conveying information if the system is used. Crossword puzzles, fill in the blank. games, and scrabble puzzles are easy to make or can be purchased from multiple sources. If the education is fun, even if mandated, more individuals will participate. Cafeteria tables can be used for education by adding tent cards with the patient safety goals or other such information. Colorful posters can be placed throughout the organization . The key to both the tent cards and the posters are changed out (using different color paper) on a regular basis to stimulate an individual to notice what is new.

With a little creative brainstorming, it is easy to find other fun and inexpensive educational ideas. One hospital chose the theme of a train going down the tracks. Every bit of information sent out in preparation for the survey had a picture of a train on a track depicting their journey. Another organization chose a Wizard of Oz theme. As the team members were talking with staff throughout the organization, they would ask the staff questions. If the staff member got the correct answer, or could find the correct information in their department/unit, they were awarded with a sticker. The sticker was placed on a card with a Yellow Brick Road on it (Figure 1). When the card was full of stickers, the staff member turned the card into the Risk Management office and received a reward. Once a month, one completed card was drawn for a larger reward (e.g., two movie tickets or a free meal in the cafeteria) .

Figure 1:Yellow Brick Road Card



!Regulatory Compliance Leaders Meetings!

Conducting ongoing monthly or bi-monthly regulatory compliance meetings keeps the regulatory emphasis in the forefront with department leaders as well as sen ior leadership. This approach provides another layer of staff involvement in the survey preparation process. During the meetings, section leaders provide a short presentation for the group on a particularly challenging or troub lesome regulation and lead a discussion on how to approach adherence to the requirement. The results of the above listed activities can also be discussed at these meetings.

!Preparations for the Days of Survey!

Preparing the governing board, senior leaders, survey team, physicians, and staff members for the actual survey day activities is very important. Before the survey, establish the following:

- Who is on the core survey team?
- Compile the requested documents.
- Who is to be contacted when the surveyors arrive? Compile a list with cell phone numbers, pagers, etc.
- Where will the command center be located?
- Where will the surveyor's home room be located? There must be computer access in this room, and assure the door can be locked for security purposes.
- Who will tour with the surveyor?

- Who will scribe and take notes during the survey?
- Who will be readily available in the command center?
- What supplies will be needed in the command center?
- Consider having a rolling computer case outfitted ahead of time with office supplies, laptop, power cord, flip chart markers, self-adhesive flip chart pages, organization directory, etc.
- For the governing board and members of expected interviews, prepare example proceedings such as questions and answers. Running practice interviews ahead of time is recommended.

SURVEY PROCESS

The actual survey process will vary with different accreditation agencies, but many of the activities are similar. Surveys for all accreditation agencies with deemed statuses are unannounced, which is becoming the industry standard. The number of surveyors is determined by the accrediting organization, with consideration of facility's size, types of patients, and services provided. Most surveys are conducted at least once every three years, but this is not the standard for all types of healthcare organizations and accrediting bodies. Information unique to each type of accreditation program can be found on their websites.

Surveyor Arrival

Any overseeing agency can visit an organization at any time. Any day of the week may be a survey day, even on the weekends, unless otherwise stated by the agency. A surveyor might visit at any time of day, even during the night shift. When it becomes known that the surveyor is on site or on the way, it is important to immediately begin notifying the key members of the survey team and activate the survey plan.

Surveyors may enter an organization via any entrance. Sometimes they are easy to spot as they will be in business dress with rolling computer cases wearing lanyards with identification. Ideally, staffs at information desks are prepared to greet surveyors. The surveyors should be asked to have a seat while the administration or designated individual is notified, or they can be escorted to the executive office. It is customary for surveyors to have identification for themselves and the organization they represent. They may also share their business cards with identifying and contact information. There are specific standards with deemed survey teams to verify the surveyors online by viewing photographs and background information of the surveyors onsite. If there is any question as to whether the person claiming to be a surveyor is actually a surveyor, it is best to verify through the agency.

Notify the senior leaders of the organization right away. In addition, it is common for the senior leaders to notify the governing board chairman. The governing board members are expected to be aware of and participate as possible during the survey .

At the time of arrival, there should be an announcement to the organization such as, "We welcome {accreditation/regulatory agency name} to our facility for their {# of days or type of} survey." This alerts all the staff and practitioners that there are surveyors in the building. This should be done for any type of survey/surveyor who is in your building, not just for the major accreditation surveys . If the organization chooses not to make the overhead announcement, then the staff and physicians need to be alerted, by some means, that surveyors are in house. Everyone needs to be on his or her best behavior during a survey, but patient safety processes need to be hard wired into their everyday practice. Being regulatory compliant needs to be how business is done all the time, whether a surveyor is watching or not. It is natural for staff and physicians to experience some level of stress having a surveyor in house. Regardless of the oversight entity, patient care should not be interrupted or unduly affected by the survey .

Entrance Interview

The surveyor or team will usually want to sit down for a few minutes with the organization's designated individuals, to go over why they are at the organization (triennial survey, complaint survey, revisit, disease specific certification, initial survey, etc.) and what the schedule of the day will be. It is very helpful for the surveyor to have an attendance iist with the names and titles of the attendees so he/she can refer back to it throughout the survey. The surveyor leads this meeting but usually allows questions from the group . This meeting is efficient, lasting 15 to 45 minutes, as the surveyor w ill want to begin the survey process as soon as possible.

A typical schedule for the day at an acute care hospital might include visiting clinica l units, observing medication administration, watching a time-out in surgery, assessing moderate sedation, reviewing prepared documents, visiting an outpatient care area, and touring the Emergency Department. A schedule for the specific type of survey and type of organizat ion being surveyed will be supplied by the accreditation or regulatory agency. Time is built in for lunch and document review. Typically, the survey day ends about 4:30 p.m., but this could vary depending on the circumstances surrounding the visit.

If the survey team is from a state agency or CMS, the expectation is they should not be allowed to move through the facility without being accompanied by a staff member. There should be a designated escort for each surveyor to guide them through the faci lity. Deemed agency surveyors and other accreditors may prefer their surveyors not be accompanied, but the organization has the right to assign someone as a guide . Ensure the survey team members have a private area for their computer set up and document review. Provision of information on the closest restrooms and exit doors is essential.

Surveyor Work Room

Escort the survey team to their home room for the duration of the survey. The ideal room for a survey team should be locked (to keep their items safe and protect the confidentiality of their notes), and conta ins: a telephone, the ability to connect to the internet, a printer connection, and a table large enough to accommodate several people. Some surveyors prefer to have an empty folder with their name on it for them to use during the survey . Some healthcare organizations make it a practice to provide a few basic office supplies and Kleenex in the home room. If only one surveyor is in-house, a smaller empty office can be used. It is a nice touch to provide creature comforts such as coffee, ice water, and light refreshments. Keep in mind, CMS employees may not be able to accept food unless it is being provided for the staff as well.

Command Center

There should be a command center established for the organization's accreditation/regulatory leaders, similar to what is utilized during a disaster. Bring the rolling computer case with supplies into the room. Be sure the command center staff has access to the regulations either online or in hard copy. Get the document boxes or binder housing the prepared survey documents. One or two people are usually enough to staff the command center. The ideal room is private, quiet, has a computer, conference phone, wall space for flip chart sheets, multi-person table, and located within or close to the executive offices . Flip chart sheets on the walls will be used to keep track of any issues identified, themes of scrutiny, potential citations, surveyor requested items, and the surveyor's positive comments, suggestions, and best practices.

If the surveyor asks for a form, policy, or procedure, the scribe with the surveyor should contact the command center to obtain the requested information. This will prevent the surveyor from getting duplicate information . Sometimes old, retired policies and procedures seem to surface during the survey. The organization should pay particular attention to assuring the documents given to the surveyor are the most up-to-date and current copies.

Staff Interviews with the Surveyor

There should be a scribe with the surveyor to note the surveyor's questions, what policies/forms are received, areas surveyed, staff and physicians addressed, and which patient records are reviewed. In virtually every survey staff members will be involved in talking with surveyors. The surveyor will ask caregivers specific questions to assess their care provided, practices, communication, and adherence to policies. Staff members may ask a surveyor to re-state a question if they do not understand what the surveyor is asking. Most surveyors are very happy to clarify what they are asking for and try very hard to put staff members at ease during interviews.

Patient Interviews with the Surveyor

Another valuable source of information for surveyors comes from the patients and their families. Who better to interview than someone who is experiencing the care first hand? Because of personal healthcare information confidentiality, the surveyor will ask permission to speak to the patient. Topics expected to be addressed during the interview include pain control, communication, medication reconciliation, and individualized education.

End of the Survey Day

It is typical for the survey team to hold a debriefing meeting at the end of each day or at the beginning of the next day to discuss how the survey is going. Managers and others should then be informed of what was found and what was troublesome to the surveyor. This will allow the staff to be more prepared and obtain needed information for the next day.

In some organizations, a senior leader will send a summary email communication to selected members of the leadership team at the end of each survey day. This keeps the leadership apprised of the daily findings, helps educate, and provides a means of support and encouragement for the team. Stress levels are naturally high during the survey process and this is one way to alleviate some of the stress and maintain connectivity with one another. It also assists with correcting any issues as soon as possible prior to the survey team's departure. The immediate correction may, in some cases, prevent additional action plans once the surveyors have left and completed their reporting.

At the End of the Survey

When the survey has been completed, the surveyor or survey team will hold an exit conference with the organization's leadership team to review preliminary findings. The CEO is typically asked who he/she wants at the exit conference. The official findings and citations will be provided in a written report from the surveying agency in approximately 10 days.

After the exit conference is over and the surveyors leave, a summary of the preliminary findings should be communicated as appropriate throughout the facility. It is common for a senior leader to send out a summary email to selected members of the leadership team. In addition, it is common to hold a leadership meeting to discuss the survey, what could have been improved, and what was learned. This keeps people apprised of the situation, helps educate, and provides a means of support and encouragement for the team. Stress levels are naturally high during the survey process and this is one way to alleviate some of the stress and maintaining connectivity with one another.

Regardless of the results, the organization should celebrate. If there is still more to be done, celebrate the work done so far, then in the next few days continue the journey to accreditation or regulatory compliance.

Unfortunately, after the survey is over, staff tends to relax and go back to old habits. However, sustainment of the high level of performance required by the survey standards is imperative to make permanent improvements. This sustainment will be a great accomplishment when the next survey rolls around and there is less work to be done.

After the Surveyors Leave

The day after the surveyor leaves, a meeting to review 'lessons learned and 'debriefing' is very educational for all concerned. During this meeting with all who participated in the survey, note everything from atmosphere to what documents needed to be obtained, from surveyor comments on improvements needed to suggestions for best practice, etc. Nothing is off limits. The subjects should not be limited to just regulatory but also include perception irnms. The key to the day after meeting is the comments and suggestions are fresh in everyone's mind. Some items may not ever be noted on the offic ial report or become an action item; but, if a reviewer sees and says something, your patients/families/visitors are seeing it too.

Once the fina l reporting is done and any action plans completed, make sure to share with staff through meetings, newsletters, posters, etc. both the positive and the 'needs work' items.

For a CMS or state survey, the organization receives a Statement of Deficiencies also known as a 2567 form . The organization then completes a detailed corrective action plan identifying the changes to be made, who is responsible for oversight, timelines, monitoring of the performance, and reporting structure within the organization. Other types of surveys have their equivalent type of report form.

Begin drafting corrective action plans for suspected citations as soon as possible. There is a tight timeframe for response associated with citations. The time varies with the accreditation/regulatory agency. Usually there is a set number of calendar days specified, in which the organization must submit action plans. Do not miss submission dates.

There are common elements to address in a corrective action plan regardless of the accreditation/regulatory agency. Table 2 includes some of the questions to ask and answer when writing the correction plan.

Table 2: Common Correction Plan Questions to Answer

Common Correction Plan Questions to Answer
• What was the main issue identified by the surveyor?
• What was the underlying cause of noncompliance?
• What specific steps will be taken to prevent this from happening in the future?
• Who is the senior leader responsible to monitor the action plan to completion?

- What timeframe is being established?
- What data will be collected to assess compliance?
- What are the data numerator and denominator definitions?
- What are the inclusion and exclusion criteria?
- What is the % goal for performance?
- Will a sample be monitored or will there be 100% monitoring?
- If a sample is used, how will the sample be chosen?
- How will progress toward compliance be monitored?
- Are progress reports going to be made to organizational committees or leaders?
- What steps are in place to ensure sustainability of improvements?

When noncompliance is noted, it can usually be traced back to leadership oversight. While a citation might be in one category, it is common to also receive also a connected leadership citation.

In any healthcare setting, patient care is more and more complex these days. Regulations are increasingly detailed, sometimes resulting in a greater number of citations than in the past. In addition, patients and visitors are savvy and they can file their own complaints directly with various oversight agencies. Sometimes agencies become aware of adverse situations at a healthcare organization through news media.

If CMS determines patients are not being cared for properly by a healthcare facility, and they find actual or potential patient harm, they have the power to declare an immediate jeopardy situation. This is extremely serious! It means there is a severe safety condition happening and the surveyor perceives is causing patient harm, or has the potential to do so . This puts the organization at risk of losing Medicare funding, which could be financially catastrophic, and could open the door to large legal liabilities.

Continuous Improvement and Sustainability

Identifying the root causes of a process failure, implementing changes, and monitoring the success of those interventions necessitates the use of an ongoing and structured performance improvement model (e.g., plan, do, check, and act). Making changes can be done quickly in some instilnces, but maintaining performance improvement is more challenging . It would be a shame to develop a process that leads to desired outcomes, then to later slide back into old inferior patterns and habits that caused the underlying problems in the first place. Being able to sustain improvements is imperative . More information can be found on this topic in Chapter 3 Performance and Process Improvement and Chapter 4 Health Data Analytics.

!u.s. HEALTHCARE ACCREDITING AGENCIE@

There are numerous healthcare accreditation agencies. Table 3 lists many of the U.S. healthcare accreditation organizations. Not all of the accrediting organizations can be described here. Websites are listed for more information and updates.

The most recent addition to the accrediting body list has arisen due to the electronic safety and security needs for healthcare. CAQH-Core is for the oversight related to the activities associated with healthcare information technology. *Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange {CORE) was established in 2005 as a national initiative. In 2012, CAQH CORE was named by the Secretary of the U.S. Department of Health and Human Services as the author of three phases of operating rules for Hf PAA-mandated standards for electronic transactions. Organizations that create, use or transmit administrative healthcare data (such as plans, providers and vendors) can earn CORE certification.*

CAQH CORE® (Committee on Operating Rules for Information Exchange) is an industry-wide collaboration committed to the development and adoption of national operating rules for electronic business transactions. Technical standards and the supporting operating rules specify the business actions required for each party to ensure a high volume of reliable electronic transactions {CAQH, 2017).

Implementation of the Phase I, II, and Ill CAQH CORE Operating Rules is mandated for all HIPAA-covered entities by the ACA (with the exception of requirements pertaining to acknowledgments). Implementation of the Phase IV CAQH CORE Operating Rules is currently voluntary. HHS will determine if the Phase IV CAQH CORE Operating Rules will be included in any regulatory mandates. CAQH CORE offers CORE Certification for Phases I, II, III, a·nd IV.

Table 3: Partial List of U.S. Healthcare Accreditation Agencies*

Partial List of U.S. Healthcare Accreditation Agencies		
Organization	**Accreditation**	**Website**
Accreditation Association for Ambulatory Health Care (AAAHC):	Ambulatory Surgery Centers, Medical and Dental Group Practices, Community and University Student Health Centers, Diagnostic Imaging Centers	www.aaahc.org
Accreditation Commission for Health Care, Inc. (ACHC):	Home Care Services	www .achc.org
American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF):	Ambulatory Surgery Facilities	www.aaaasf .org

American Associat ion of Blood Banks (AABB):	Standards for Blood Banks and Transfusions Services	www.aabb.org
American College of Radiology (ACR) :	Radiation, Oncology and Mammography	www.acr.org
American College of Surgeons - Commission on Cancer (ACS-Co():	Cancer Treatment Programs in Hospitals, Outpatient Centers and Freestanding Facilities	www.facs.org/quality-programs/cancer/accredited/benefitscoc/seekingaccred
American Correctional Association (ACA):	Minimum Correctional Facility Requirements	www.aca.org
American Lithotripsy Society (ALS):	Lithotripsy	www.lithotripsy .org
American Society for Histocompatibility and Immunogenetics (ASHI}:	Histocompatibility and Immunogenetics	www .ashi-hla.org
Center for Improvement in Healthcare Quality (CIHQ):	Acute Care Hospitals	www.cihq.org
College of American Pathologists (CAP), Commission on Inspections and Accreditation:	Clinical Laboratories	www.cap.org
Commission for Accred1tat1on of Rehabilitation Facilities (CARF}:	Hospital-based or Freestanding Medical Rehab'1lltat1on Centers, Adult Day Services, Assisted Living	www.carf.org
Commission on Accreditation of Ambulance Services (CAAS):	Home Care and Community Health Organizations	www.caas.org
Commission on Office Laboratory Accreditation (COLA):	Office Laboratory	www.cola.org
Community Health Accreditation Program, Inc. (CHAP}, a subsidiary of the National League of Nursing (NLN):	Home Care and Community Health Organizations	www.chapinc.org
Continuing Care Accreditation Commission	Continuing Care Retirement Communities	www.elderweb.com

(CCAC):		
Council on Accreditation (COA):	Outpatient Mental Health, Residential Treatment Centers, Alcohol and other Substance Abuse Treatment Centers, Therapeutic Foster Care	www.coanet.org
Det Norske Veritas Healthcare, Inc. (DNV) – National Integrated Accreditation for Healthcare Organizations (NIAHO):	Hospital Accreditation with ISO and CMS CoPs	www.dnvusa.com/industry/healthcare/index.asp
Electronic Healthcare Network Accreditation Commission (EHNAC):	Entities that send or receive HIPAA-Regulated Transactions or Transport/Process EDI Transactions	www.ehnac.org
Health Facilities Accreditation Program (HFAP) of the American Osteopathic Association (ADA):	Osteopathic Hospitals and Clinical Laboratories	www.hfap.org
National Commission for Correctional Health Care (NCCHC): QM Standards	Correctional Healthcare facilities	www.ncchc.org
National Committee for Quality Assurance (NCQA):	Managed Care Organizations	www.ncqa.org
Public Health Accreditation Board (PHAB), Centers for Disease Control and Prevention (CDC), and national partners:	National Voluntary Accreditation for Public Health Departments (new Fall 2011)	www.phaboard.org
The Joint Commission (TJC):	Multiple Accreditation Programs	www.jointcommission.org
Utilization Review Accreditation Commission (URAC)/American Accreditation Health Care Commission (AAHCC):	Voluntary Accreditation for Private UM Organizations, Case Management Organizations, Health Plans and Networks, Worker's Compensation UM, and Network Organizations and Three others	www.urac.org

***not a complete list of healthcare accreditation agencies**

[Disease Specific Certification[

Becoming certified as a disease specific provider is very popular and can do much to enhance a healthcare organizations' reputation in the community. Several agencies, as described below, offer certifications including in areas such as stroke, acute myocardial infarction, heart fa ilure, hip/knee replacements, vascular disease, dialysis, and many more. Also, some state agenc ies offer certifications in stroke care and ST-elevated myocardial infarction care. Specific information on the certification standards con be found on the appropriate certificalion agency's website. Some of the basic elements needed for disease specific certifications include:

- Eligibility related to treatment volumes
- Practitioner competency
- Ongoing professional educational requirements
- Use of clinica l practice guidelines or evidence-based practices
- Individualized care planning for the patient
- Team communication
- Data to evaluate processes and outcomes
- Ongoing Performance Improvement
- Comparison database
- Protection of personal health information
- Individualized patient education
- Community involvement

[Hospital Accreditation Organizations with Deemed Status[

At the time of this writing these four (4) CMS approved hospital accreditation organizat ions can provide deemed status. They are each discussed in detail below.

1. The Joint Commission (TJC)
2. Det Norske Veritas GL Healthcare (DNV GL Healthcare)
3. American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)
4. Center for Improvement in Healthcare Quality (CIHQ)

[The Joint Commission (TJC)[

The Joint Commission is an independent, not-for-profit organization that accredits and certifies more than 20,500 health care organizations and programs in the United States. The Joint Commission

accreditation and certification is recognized as a symbol of quality that reflects an organization's commitment to meeting certain performance standards (TJC, 2017). The Joint Commission surveys the types of organizations listed in Table 4.

Table 4: Healthcare Organizations Accredited/Certified by The Joint Commission (TJC)

Healthcare Organizations Accredited/Certified by The Joint Commission (TJC)	
Accreditation	Certifications
• Hospitals	• Comprehensive Cardiac Center
• Critical Access Hospitals	• Disease Specific Care Programs
• Behavioral Healthcare	• Palliative Care
• Ambulatory Health Care	• Healthcare Staffing Services
• Office-Based Surgery	• Integrated Care
• Home Care	• Medication Compounding
• Laboratory Services	• Perinatal Care
• Nursing Center Care	• Primary Care Medical Home (PCMH)
	• Patient Blood Management

The Joint Commission accreditation process is a three-year cycle, with one survey every three years, and a self-assessment, known as the Intra-Cycle Monitoring (ICM), done annually. On-site surveys are unannounced and generally conducted by a team including physicians, nurses, generalists, and life safety specialists. The Joint Commission Standards include elements of performance detailing the specific expectations required to meet the goal of a standard. There is an emphasis on data collection and analysis, but the actual quality management process is left up to the organization. The survey process includes patient and process/system tracers, where the surveyors follow a patient or process as it would/occur through the organization.

Over the past 10 years, the Joint Commission standards have been revised multiple times and ongoing changes are made to better align TJC standards with Medicare Conditions of Participation (CoPs). Some standards are considered more critical than others. An organization's final score, based on ability to meet the standards, is calculated at the Joint Commission Central Office where the final determination of accreditation category is decided.

The Joint Commission has additional requirements. Since 2003, all accredited organizations must meet all applicable approved National Patient Safety Goals (NPSGs). More information on the National Patient Safety Goals can be found in Chapter 5 Patient Safety. Hospitals are required to submit a set number of the Core Measures, as they are applicable to the organization. Other types of organizations

are required to submit other quality measures. The Joint Commission recommends a facility reports sentinel events, and TJC maintains statistics concerning occurrences of sentinel events . TJC publishes Sentinel Event Alerts, and makes recommendations for appropriate action to be taken to prevent the occurrence of those alert topics at another healthcare organization . The Sentinel Event Alerts are free. All healthcare quality practitioners, whether utilizing accreditation by TJC or not, should subscribe to these alerts. Once an alert is received, the organization should evaluate whether such an event could occur in their facility, conduct a gap analysis, and then take appropriate actions to prevent it from occurring.

Fees for accreditation include the direct cost of the survey, based on the size and complexity of the organization, and indirect costs related to the purchase of standards manuals, staff education, and the use of external consultants to assist with survey readiness. More information concerning The Joint Commission can be found at their website (see webs ite list at the end of this chapter).

!n 2016, the Joint Commission's multiphase process improvement project REFRESH has completed Phase II with additiona l deletion of hospital elements of performance in the EP Review Project. Phase Ill focuses on the evaluation of the elements of performance from the remaining accreditation programs. Following the completion of this phase the consolidations of existing requirements across accreditation programs (REFRESH, 2016).

The REFRESH project includes developing a different approach for identifying and communicating risk levels of deficiencies identified during a survey. The Survey Analysis for Evaluating Risk (SAFER) approach was developed to provide organizations with additional information related to risk of deficiencies in order to help prioritize and focus corrective actions. The development of this approach was driven by the Joint Commission's desire to allow organizations to see at an aggregate level area of noncompliance which will demonstrate for the organization significant components of risk analysis including the likelihood to harm and the scope of a cited deficiency (SAFER, 2016). All accreditation and certification programs are utilizing this matrix in their survey reports.

!Det Norske Veritas Healthcare (DNV GL Healthcare)[

DNV GL (Det Norske Veritas) Healthcare is a global risk management foundation headquartered in Oslo, Norway. DNV GL was granted deeming authority by the Centers for Medicare and Medicaid (CMS) for acute hospitals in September 2008 and for critical access hospitals in November 2010. There are currently over 500 hospitals that are DNV GL accredited . DNV GL utilizes a set of standards called National Integrated Accreditation for Healthcare Organizations (NIAHO) standards, which are closely aligned with CoPs, and designed to drive quality transformation into the core processes of running a hospital. These standards are less prescriptive than TJC standards and include compliance with the International Standardization Organization (ISO) 9001 certification by the fourth year of survey . NIAHO helps healthcare organizations meet their national accreditation obligations and achieve ISO 9001 compliance in the same seamless program . The hospital may choose to obtain ISO 9001 certification,

but not required in order to be surveyed by DNV GL (DNV GL, 2017). Table 5 lists the types of facilities that are accredited or certified by DNV GL.

Table 5: Healthcare Organizations Accredited/Certified by DNV GL

Healthcare Organizations Accredited/Certified by DNV GL	
Accreditation	Certifications
• Hospitals • Critical Access Hospitals • Ancillary Services	• Primary Stroke Center (PSC) • Comprehensive Stroke Center (CSC) • Acute Stroke Ready (ASR) • Managing Infection Risk Certification (MIR) • Hip & Knee Replacement Program Certification (HKRC)

DNV GL also has five certifications that combine elements from the hospital accred itation standards with other organizations (Table 5). The Primary Stroke Center (PSC) Certification program for organizations providing stroke treatment includes the NIAHO standards as well as the Guidelines of the Brain Attack Coalition and Recommendations of the American Stroke Association. The Comprehensive Stroke Center (CSC) Certification utilizes the standards as the Primary Stroke Center Certification, but this certification is designed for stroke centers that utilize the most advanced stroke treatment available. The Acute Stroke Ready (ASR) Certification is designed for smaller and rural hospitals that perform initial treatment of stroke patients. The Managing Infection Risk Certification (MIR) enables hospitals to reduce their risk of infection utilizing innovative assessments of risk. The Hip & Knee Replacement Program Certification (HKRC) recognizes facilities providing excellence in orthopedic surgery for hip and knee replacement and related procedures.

DNV GL has formed an alliance with the Accreditation Commission for Health Care (ACHC) for accreditation of ancillary services provided by DNV accredited facilities. The ACHC has deemed status for home health, hospice, DMEPOS, and other ancillary healthcare services. These will be discussed later in this section

The DNV GL accred1tat1on cycle is for 3 years. However , DNV performs annual, unannounced survey to help the -facility make continuous improvements . DNV attempts to have the same surveyors each time to facilitate teamwork and collaboration with the facility. The lead surveyor will consistently be the same. The survey team is comprised of physicians, nurses, administrators and life safety specialists. The focus is on improving healthcare quality and delivery while managing risk. Accreditation decisions take into consideration whether nonconformance with a standard can directly impact patient care or safety. All deficiencies require a written plan of correction.

Accreditation fees are based on the size of the facility, the average daily census, and the number of Full Time Equivalents (FTE's). The surveys include the annual survey, ISO assessment, and any follow-up activities. Standards and other materials are provided at no charge. The integration of ISO 9001 is unique to DNV. It is thought by some authors that the adoption of ISO 9001 structure and processes are associated with better employee productivity and safety as well as quality, market share, and financial outcomes. More information concerning DNV GL can be found on their website listed at the end of this chapter .

!ISO 9001 Standards!

The International Organization for Standardization in Geneva, Switzerland, issued the first version of the ISO 9000 series of standards and guidelines in 1987. The ISO is a worldwide certification agency focusing on the quality management systems of an organization. The European Common Market, now the European Commission (EC), requested a way to harmonize the various quality assurance standards from the different member countries. The word ***iso*** is Greek for harmonize. The goal was to eliminate redundant and perhaps conflicting requirements between customers and vendors across country boundaries . The basic assumption underlying the standards is that a good quality management process will satisfy the customer by reducing nonconformance in products and services (ASQ, 2017).

The original sets of five documents, standards ISO 9000 – 9004, were written primarily for the manufacturing industry. The 2000 and 2005 version language was much more generic and therefore more applicable to service industries like healthcare . ISO certification has been utilized in industry for many years and only recently has been applied to healthcare. In September 2015, the ISO 9001:2015 standards were released. The most significant difference is an update for Risk Management (ASQ, 2017).

ISO focuses on a process approach when establishing and utilizing a quality program. This approach emphasizes understanding and meeting requirements, the need to consider the added value of processes, and continual, ongoing improvement of the processes.

ISO 9001 standards (ASQ, 2017) are basically a Quality Management System focused on effectively meeting customer needs is the focus of the quality management system . The organization must consistent ly provide service/products meeting customer needs and enhance customer satisfaction through continual improvement of the system. The ISO standards are based on five components:

- Quality Management System - general and !documentation! requirements
- Management Responsibility
- Resource Management
- Service/Product Realization

- Measurement, Analysis, and Improvement

The Healthcare Facilities Accreditation Program (HFAP)

HFAP was originally created in 1945 by the American Osteopathic Association (ADA) to conduct an objective review of the unique services provided by osteopathic hospitals. HFAP has had deemed status from CMS since 1965. Their standards and accreditation program are now no longer limited to osteopathic healthcare organizations. Their standards are closely aligned to CoPs, as well as patient safety and quality of care standards. Approximately 80% of the HFAP standards can be cross-walked with the CoPs. The standards are provided free of charge to HFAP clients, and the standards change infrequently. Table 6 lists the types of facilities accredited by HFAP (HFAP, 2017).

Table 6: Healthcare Organizations Accredited/Certified by HFAP

Healthcare Organizations Accredited/Certified by HFAP	
Accreditation	Certification
• Acute Care Hospitals (General, Specialty, Long Term Acute Care) • Critical Access Hospitals • Behavioral / Mental Health Facilities • Ambulatory Care / Office-based Surgery Facilities • Ambulatory Surgery Centers • Clinical Laboratories	• Stroke Ready • Primary Stroke • Comprehensive Stroke

The survey process is a three-year cycle with unannounced surveys done by a team of three people, generally a physician, a nurse, and an administrative representative. The survey is designed to be educational and is based on the facility's ability to correct deficiencies during the survey process. The team scores each standard, which is weighted based on its impact on patient care. At the end of the survey, the organization is given a deficiency report and is expected to provide the HFAP central office with a corrective action plan. The corrective action plan must be approved by oversight body (HFAP) before the accreditation status can be determined.

The direct cost for the survey includes survey materials, online standards, newsletters, and publications of standard changes. Indirect costs include outside consulting for survey readiness preparation. More information concerning HFAP can be found on their website in the website list at the end of this chapter.

Center for Improvement in Healthcare Quality (CIHQ)

As of August 9, 2013, the Center for Improvement in Healthcare Quality (CIHQ), a privately held company, became the nation's fourth accreditation provider approved by CMS to deem acute care hospitals as meeting Medicare Conditions of Participation . The CIHQ accreditation is available to hospitals and all services and sites of care listed on their license. At the end of 2017, the CIHQ website states that 48 acute care hospitals have been accredited through CJHQ. Other services such as home health and long-term c.:irc services are not surveyed by CIHQ. The sldndards are based on the CoPs plus areas of patient safety and quality care. The CIHQ also provides disease specific certification for Stroke Ready, Comprehensive Stroke Center, Heart Failure, and Joint Replacement (Table 7). These certification surveys occur at the time of the hospital's main survey (CIHQ, 2017). CIHQ also awards program recognition via Center of Excellence designation to Long Term Acute Care, Rehabilitation Services in the acute care hospitals and for Environmental Health & Safety. The designations survey occurs during the organization's accreditation survey.

Table 7: Healthcare Organizations Accredited/Certified by CIHQ

Healthcare Organizations Accredited/Certified by CIHQ	
Accreditation	Certification
• Acute Care Hospitals	• Stroke Ready • Comprehensive Stroke • Heart Failure • **Joint Replacement**

The CIHQ survey length depends on the size and complexity of the organization. The surveyors typica lly are a team of 2 – 4 individuals with one being a facilities specialist. A full survey is conducted every three years, with a focused mid-cycle survey a pproximately 18 months after the full survey. The focused survey is generally one day with one surveyor .

The cost for the survey is dependent on the size and complexity of the organization, billed annually or quarterly, whichever the hospital prefers. Additionally, CIHQ provides standa rds, monthly audio conferences, templates for policies, forms and other such material, complementary attendance for two at their annual conference, a web-based reference library, and alerts to changes in the standards and CMS regulations. More information concerning CIHQ can be found on their website in the webs ite list at the end of this chapter.

Accr editation for Health Plans and other Managed Care Organizations, especially those actively involved in the Health Insurance Marketplace, Medicare or Medicaid

At the time of this writing there are three CMS approved health plan and managed care accreditation organizations are used for deemed status :

- National Committee for Quality Assurance (NCQA)
- Utilization Review Accreditation Commission (URAC)
- Accreditation Association for A mbulatory Hea lth Care (AAAHC)

iNational Committee for Quality Assurance (NCQA)j

The National Committee for Quality Assurance (NCQA) is a private, not-for-profit organization established in 1990 by the then Group Health Associat ion of America (now America's Health Insurance Plans) and the Ame rican Managed Care Review Associatio n. The organization works to improve healthcare quality via evidence-based standa rds, measures, programs, and accreditation . It operates on the formula of measure, analyze, and improve. It provides an evidence-based program for case-management accreditat ion ava ilable for uses in payer, provider, and community based organizations . The NCQA works with policymakers, employers, doctors, patients, and health plans, with the aim of building consensus in the industry. Table 8 lists the types of organizations acc redited by NCQA (NCQA, 2017).

Table 8: Healthcare Organizations Accredit ed/Certified by NCQA

Healthcare Organizations Accr edited/Certified by NCQA	
Type	**Programs**
Healthcare Accreditation Programs	• Accountable Care Organiz ations (ACO) • Health Plan (HP) (HMO, MCO, PPO, and POS plans) • Wellness & Health Promotion (WHP) • Case Management (CM) • Managed Behavioral Healthcare Organizations (MBHO) • New Health Plans (NHP) • Disease Management (DM) • Accreditation Users Group (AUG)
Certification	• Accredita tion and Certificat ion Users Group (ACUG)

	• Certification Ver ification Organizations (CVO) • Disease Management (DM) • Health Information Products (HIP) • Multicultural Health Care (MHC) • PCMH Content Expert Certification (CEC) • Physician and Hospital Quality (PHQ) • Utilization Management and Credentia ling (UM/CR) • Wellness & Health Promotion (WHP)
Distinction	• Behavioral Health Integration (BHI)
Recognition	• Diabetes Recognition Program (DRP) **Government Recognition Initiative** • Heart/Stroke Recognition Program (HSRP) • Oncology Medical Home • Patient-Centered Connected Care • Patient-Centered Medical Home (PCMH) • Patient-Centered Soecialtv Practice PCSP • School-Based Medical Home Program (SBMH)
Other	• Special Needs Plans Structure & Process Measures • Special Needs Plans Model of Care Review Process

NCQA offers a three-year accreditation to health plans with managed care organizations. Healthcare Effectiveness Data and Information Set (HEDIS) performance measure data is required annually with the accreditation status reevaluated based on those results. NCQA began incorporating HEDIS® data into the accreditation process in July 1999. HEDIS effectively evaluates the structure and functions of medical and quality management systems in M,maged Care Organizations (MCOs) (see Chapter 3 Performance and Process Improvement).

The Health Plan accreditation standards cover: Quality Management and Improvement; Utilization Management; Credentialing and Recredentialing; Members' Rights and Responsibilities, and Member Connections . Health Plan performance is based on selected audited measures from HEDIS® and adult

survey results from HEDIS/CAHPS ® which are both then combined with the standards compliance score, to determine the final score for the organization . The score determines the accreditation status of the organization. Audited HEDIS® results are submitted annually and the accreditation status is recalculated by product line based on those results. The changes are not subject to reconsideration .

NCQA's standards for Quality Management and Improvement of health plans include the program structure, program operations, health serv ices contracting, availability of practitioners, accessibility of services, member satisfaction, complex case management, disease management, clinical practice guidelines, continuity and coordination of medical care, continuity and coordination between medical and behavioral healthcare, and delegation of QI. Further information can be found in the standards for the specific program of interest. More information on NCQA can be found on their website in the website list at the end of this chapter.

Utilization Review Accreditation Commission (URAC)

The Utilization Review Accreditation Commission was previously known as the American Accreditation Health Care Commission (AAHCC) when founded in 1990 to establish standards for the healthcare industry. Its membership includes employer, consumer, regulator, provider, health plan, and workers' compensat ion representatives . The organization's initial focus was on voluntary accreditation of private external utilization management companies. As of this publication, URAC offers 24 accreditation and certification programs (URAC, 2017).

All accredited organizations must meet "Core Accreditation" standards . Table 9 lists the types of accreditation programs offered through URAC. Organizations performing the functions listed in Table 9 may apply for accreditation . This includes hospitals, health maintenance organizat ions, preferred provider organizations, third-party administrators, and provider groups.

Table 9: Healthcare Functions Accredited by URAC

Healthcare Functions Accredited by URAC
• Health and Dental Plan Programs
• Healthcare Management Programs
• Healthcare Operations Programs
• Pharmacy Quality Management Programs
• Provider Integration & Coordination Programs

The accreditation process includes a desktop review conducted by the accreditation team to identify compliance with the URAC standards. Documentation is submitted by the facility requesting accreditation . The required documents are outlined in the standards. This is followed by an on-site review where the survey team compares the desktop review with the on-site review. URAC surveyors

also conduct audits and other such activities while onsite. The Accreditation Committee makes the determination of the accreditation status based on the report from the survey team . More information regarding URAC can be found on their website in the website list at the end of this chapter.

Accreditation Association for Ambulatory Health Care (AAAHC)

The Accreditation Association for Ambulatory Health Care (AAAHC) is a private, non-profit organization formed in 1979. The association, with a flexible collaborative approach, accredits more than 6,000 organizations in a wide variety of ambulatory health care settings. Known in the industry as "Triple A HC", the AAAHC is the official accrediting organization for the US Air Force and the US Coast Guard. Table 10 lists some of the types of facilities accredited by AAAHC (2017).

Table 10: Healthcare Organizations Accredited/Certified by AAAHC

Healthcare Organizations Accredited/Certified by AAAHC	
Accreditation	Certification
• Ambulatory Surgery Center • Community Health Centers • Health Plans/OHPs/FEHB plans • Indian and Student Health Centers • Medical Home • Network • Office-based Surgery Centers • Primary Care	• Orthopedic Specialty • Orthopedic Advanced Specialty

Surveys are conducted every three years. Differences in the manuals and surveys depend on the type of facility, and whether or not the survey is for Medicare deemed status. Medicare deemed status surveys are unannounced. Random surveys between the 3-year cycles are also unannounced and typically have one surveyor for one day. Fees for the surveys are calculated based on the size, type, and range of services provided by the organization. Standard manuals may be purchased at an additional cost from the AAAHC website. Further information regarding AAAHC can be found on their website in the website list at the end of this chapter.

Commission on Accreditation of Rehabilitation Facilities (CARF)

The Association of Rehabilitation Centers (ARC) and the National Association of Sheltered Workshops and Homebound Programs (NASWHP) established the Commission on Accreditation of Rehabilitation Facilities (CARF) in 1966 to accredit rehabilitation facilities. CARF promotes the quality, value, and optimal outcomes of services utilizing a consultative accreditation process and continuous

improvement services, in organizations internationally . The CARF International group of companies currently accredits more than 50,000 programs and services at 23,000 locations. Table 11 lists the CARF Accreditation Programs (CARF, 2017).

Table 11:Healthcare Organizations Accredited by CARF

Healthcare Organizations Accredited by CARF
• Aging Services
• Behavioral Health
• Continuing Care Retirement Communities (CCRC)
• Child and Youth Services
• DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies)
• Employment and Community Services
• Medical Rehabilitation
• Opioid Treatment Programs
• Vision Rehabilitation Services

Each CARF accreditation program has a standards manual including quality standards for business practices, service processes, and specific programs and services. CARF updates its standards manuals annually, frequently providing clarification of standards based on feedback from users. Midyear changes are posted on their website. Facilities are surveyed every three years. Facilities may choose to become accredited in more than one standards area and as a result will have a blended survey . The organization may apply for accreditation in adult care and or pediatric care. CARF also offers specialty care certifications such as Stroke/Brain Attack. It is not required that a facility be accredited in every service area. CARF accreditation programs and services can also be utilized to survey any business entity such as an individual, sole proprietorship, partnersh ip, etc. Survey findings detail the standards for which the provider has not satisfactorily demonstrated conformance . Standards not met are addressed through a Quality Improvement Plan. The number of surveyors needed is determined by the number of persons served, number of sites to be visited, number of service areas to be accredited, and the geographic area to be covered. More information about CARF can be found on their website in the website list at the end of this chapter.

Other Healthcare Accreditation Agencies (not an inclusive list) Accreditation Commission for Health Care, Inc. (ACHC)

The Accreditation Commission for Health Ca re was established in 1986 by the home care and alternate healthcare providers. The accreditation process is designed to improve business operations, quality of patient care, and services. All major third-party payers recognize ACHC. ACHC also awards 5

Distinctions awards, most though deal with medications . Table 12displays the organizations accredited/distinctions by ACHC (ACHC, 2017).

Table 12: Healthcare Organizations Accreditation/Distinctions by ACHC

Healthcare Organizations Accreditation/Distinctions by ACHC	
Accreditation	Distinctions
• Ambulatory Care • Behavioral Health • DMEPOS (Medicare Deeming Authority) • Home Health (Medicare Deeming Authority) • Hospice (Medicare Deeming Authority) • Hospital (alliance with DNV GL) • Pharmacy (Specialty, Infusion, Compounding) • Private Duty • Sleep Lab/Center	• Behavioral Health • Hazardous Drug Handling (USP Chapter 800) • Infectious Disease Specific to HIV (medications) • Oncology (medications) • Palliative Care

ACHC has developed service specific standards, and have personal advisors to assist organizations in obtaining accreditation. The surveyors offer evidence-based practices to the organizations to assist them in making improvements. ACHC is an ISO 9001 certified organization since 2004. in 2008, the ACHC executives received training on the Baldrige criteria to assist them in achieving company-wide quality and sustainability . They continue to utilize Baldrige practices within the organizat ion. ACHC has formed an alliance with DNV for accreditation of many services within a health system . Fees for the accreditation process are all inclusive, with no added fees for surveyor travel, etc. The standards are downloadable from the website in the website list at the end of this chapter. After a five-day trial period, the organization can purchase unlimited access for all ACHC's service-specific standards.

Community Health Accreditation Program, Inc. (CHAP)

The Commun ity Health Accreditation Program accredits a range of home and community-based health services. CHAP has Medicare deemed authority for the accreditation of home health, hospice, and home medical equipment services. Table 13 lists the types of programs accredited by CHAP (2017).

Table 13: Healthcare Organizations Accredited by CHAP

Healthcare Organizations Accredited by CHAP
• Home Health (Medicare Deeming Authority)
• Hospice (Medicare Deeming Authority)
• Home Medical Equipment Services (Medicare Deeming Authority)
• Pharmacy
• Private Duty
• Public Health
• Infusion Therapy Nursing

The CHAP standards are built on standards of excellence, which look at the four following principles of an organization: the organization's structure and function consistently support its consumer-oriented mission; it consistently provides high-quality services and products; it has adequate human, financial and physical resources to accomplish its stated mission and purpose; and it is positioned for long-term viability. These standards of excellence support the scope and complexity of the programs CHAP accredits. The standards of excellence and service-specific standards of excellence are customized to the different accreditation programs.

The accreditation process includes a self-study of how the organization meets the CHAP standards and then a site visit by the surveyors. The site visit is usually unannounced and lasts 2 – 5 days, based on the organization size. The surveyors are assigned to the services where they have specific experience. They are required to have a minimum of 5 years of experience in one of the healthcare fields CHAP accredits. They must have at least a bachelor's degree in a related specialty, and at least 5 years management experience in a home or community-based health care organization. For more information concerning CHAP, refer to the website list at the end of this chapter.

External Quality Awards

Quality Professional Role

The role of the Quality professional in obtaining external awards is to:

- Determine goals to be achieved with obtaining the award
- Determine current state of compliance with the criteria
- Discuss current state and action needed with the leadership
- Determine action plan to meet criteria and timeline
- Develop and submit the application

!Baldrige Performance Excellence Program (U.S.)[

The National Institute of Standards and Technology (NIST) is the agency of the U.S. Department of Commerce managing the Baldrige award and program (Baldrige, 2017). Leaders in the United States realized during the 1980s American companies needed to focus on quality in order to be competit ive in the global market. The Secretary of Commerce, Malcolm Baldrige, was an advocate of quality management as a key to U.S. prosperity and sustainability . Congress named an award in recognition of his contributions ;:iftcr his sudden death in 1987.

The goal of the Malcolm Baldrige National Quality Award i•,:tially was to enhance the competitiveness of U.S. businesses. Congress created the award program to identify and recognize role- model businesses, to establish criteria for evaluating improvement efforts, and to dissem inate and share best practices. In subsequent years, it has been expanded to include health care and education organizat ions as wel l as nonprofit and government organiza tions. In April 2003, SSM Health Care became the first healthcare organization to receive the Award.

The Health Care Criteria for Performance Excellence, under the Baldrige Program, offers both a self-assessment framework and an optional award component. An organization must work on the criteria for a number of years before applying for the award. Table 14 lists the seven categories of criteria, the core set of values and concepts on which they are built. More information can be found on their website in the website list at the end of this chapter .

Table 14: Baldrige Award Criteria and Values

Baldrige Award Criteria and Values	
Categories of Criteria	**Core Sets of Values and Concepts**
1. Leadership 2 . Strategic Planning 3. Customer Focus 4. Measurement, Analysis, and Knowledge Management 5 . Workforce Focus 6. Operations Focus 7. Results	• Visionary leadership • Patient-focused excellence • Organizational and personal learning • Valuing workforce members and partners • Agility (capacity for rapid change and flexibility) • Focus on the future • Managing for innovation • Management by fact • Societal responsibility and commun ity health • Focus on results and creating value • Systems perspective

When an organization submits an application for the Malcolm Baldrige Award, the applicant receives a detailed feedback report from an independent, external assessment panel of experts. Some applications will lead to a site visit and ultimately to the award.

If chosen for a site visit, the organization undergoes a comprehensive evaluation of their processes and results. "Processes" refer to the methods used by the organization to address Categories 1-6 (refer to Table 14). These categories are scored with four factors known as ADLI:

Approach – the methods used to accomplish the process, the appropriateness of the methods to the organization's environment, the effectiveness of the methods, and the degree to which the approach is repeatable and based on reliable data and information;
Deployment – the extent to which an approach is applied in addressing items relevant and important to the organization, applied consistently, and used/executed by all appropriate work units;
Learning – refinement through cycles of evaluation and improvement, encouraging change through innovation, and sharing refinements and innovations with other relevant work units within the organization;
Integration – the extent to which an approach is aligned with the organizational needs identified in the organizational profile, the measures, information, and improvement systems are complementary across processes and work units to support organization-wide goals.

Category 7, "Results," refers to the organization's outputs and outcomes, and is scored with four factors known as LeTCI:

Levels - the current level of performance;
Trends – the rate of performance improvements or the sustainability of good performance;
Comparisons – performance relative to appropriate comparisons, such as competitors or similar organizations, and/or performance relative to benchmarks or industry leaders;
Integration – the extent the organization's results measures address important customer, product, market, process, and action plan performance requirements identified in the organizational profile; results include valid indicators of future performance; and results are harmonized across processes and work units to support organization-wide goals.

Annually, Baldrige Award winners are chosen from applicants whose scores are determined sufficiently high by a Board of Governors. The scoring system is at:
http://www.baldrige21.com/Baldrige%20Scoring%20System .html.

/Magnet Recognition Program"!

The Magnet Recognition Program· was developed by the American Nurses Credentialing Program to recognize health care organizations for excellence as evidenced by quality patient care, nursing excellence, and innovations in professional nursing practice. Developed by The American Nurses Credentialing Center (ANCC), Magnet is the leading source of successful nursing practices and

strategies worldwide. As of April 2017, there are 456 Magnet recognized healthcare organizations in the United States with 37 of those being Pediatric organizations (Magnet, 2017). A new manual is due to be published in 2019 and may contain information that is different from what is presented here.

The Magnet recognition program has three goals: promoting qua lity in a setting supporting professional practice; identifying excellence in nursing service delivery; and disseminating "best practices" in nursing services. Evidence-based criteria must be utili1ed to have a positive work environment for nurses and others in the healthcare organization.

There are 14 Forces of Magnetism that fit into five model components. The five model components are Transformational Leadership, Structural Empowerment, Exemplary Professional Practice, New Knowledge, Innovations, and Improvements, and Empirical Quality Results. Transformational Leadership is defined as being able to transform organizational values, beliefs, and behaviors to meet the demands and achieve the vision of the future. Structural Empowerment includes influential leadership to develop structures and processes supporting innovation through strategic planning, systems, policies, and programs. Exemplary Professional Practice refers to a comprehensive understanding and application of the nursing role with patients, families, communities, and the interdisciplinary team, and application of new knowledge and evidence. New Knowledge, Innovation, and Improvements are the contributions to patient care, the organization, and the profession. Lastly, Empirical Quality Results pertain to striving for benchmark and clinical outcomes data related to nursing, workforce, patient and consumer, and organizational outcomes.

Table 15 lists the 14 Forces of Magnetism and the 5 modei components. The model components are the primary basis for achieving magnet recognition. The Forces of Magnetism remain the foundation of the Magnet program. More about the Forces of Magnetism can be found on their website in the website list at the end of this chapter.

Table 15: Magnet Program Forces of Magnetism & Model Components

Magnet Program Forces of Magnetism & Model Components					
	Model Components				
Forces of Magnetism	Transformational Leadership	Structural Empowerment	Exemplary Professional Practice	New Knowledge, Innovations, Improvement	Empirical Quality Results
#1 Quality of Nursing Leadership	X				
#2 Organizational Structure		X			
#3 Management	X				

Style					
#4 Personnel Policies & Programs		X			
#5 Professional Models of Care			X		
#6 Quality of Care					X
#7 Quality Improvement				X	
#8 Consultation & Resources			X		
#9 Autonomy			X		
#10 Community & the Healthcare Organization		X			
#11 Nurses as Teachers			X		
#12 Image of Nursing		X			
# 13 Interdisciplinary Relationships			X		
#14 Professional Development		X			

Pathway to Excellence

In 2003, the Texas Nurses Association (TNA) established the Nurse Friendly designation aimed at improving the quality of patient care and the professional satisfaction of Texas nurses. In 2007, the American Nurses Credentialing Center (ANCC) acquired the program and in 2009 renamed it as the Pathway to Excellence Program. In 2010, the ANCC expanded the program to long-term care facilities . As of this writing, there are 155 healthcare organizations with this designation, of which 5 are in Switzerland, Thailand and Australia (Pathway, 2017) . In 2016, an Ohio hospice was the first hospice to become Pathway to Excellence certified.

ANCC's Pathway to Excellence® Program recognizes health care and long-term care organizations for positive practice environments where nurses excel. Any size healthcare facility may apply for the award. The benefits of the Pathway to Excellence designation include improvement to nurse

satisfaction, retention of nursing staff and leaders, inter-professional teamwork, high quality nursing practice, and supported business growth.

To qualify, organizations meet 6 practice standards (Table 16) essential to an ideal nursing practice environment. In the long-term care arena, additional standards are included (see Table 16). The organization conducts a process review to document their compliance with the standards. Three ANCC nursing experts review the documentation to determine if the standards are met. This is followed by an independent confidential survey completed by the organization's nursing staff, to validate the information submitted. This validation is designed to give the nurses a voice in the process.

Nurses are attracted to Pathway-designated institutions and respect their contributions, support for professiona l development, and nurturing work settings. Organizat ions may hold the Pathway to Excellence and the Magnet Recognition designat ions concurrently. More information regarding the Pathway to Excellence can be found on their website in the website list at the end of this chapter .

Table 16: Pathway to Excellence Hospital and Long-Term Care Standards

Pathway to Excellence Hospital and Long-Term Care Standards **All facilities:**
• Practice Standard 1: Shared Decision-Making
• Practice Standard 2 : Leadership
• Practice Standard 3: Safety
• Practice Standard 4: Quality
• Practice Standard 5: We ll-Being
• Practice Standard 6: Professional Development
Long Term Care facilities - Additional Standards:
• Certified Nurse Assistants (CNAs) are included in the nursing community
• Educational standards are temporarily established for Directors of Nursing (DON)
• Standards about staff education regarding zero tolerance of resident abuse and neglect; policies/procedures on the use of restraints and prevention of falls
• A person-centered model of care is understood

This chapter presented an overview of regulatory, accreditation and external reward programs. The responsibilities as well as perspectives on these topics from experts is key in quality improvement. Organizations without strong, committed leaders often find themselves missing something in the programs and processes as well as receiving accreditation/certification status for their organization . As a Quality/UM/RM/PS/accreditation manager you are also a leader, and while you may not have positional power, you have expertise and influence that is key to your organization's success.

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WEBSITES

REGULATORY, ACCREDITATION, AND EXTERNAL RECOGNITION

Accreditation Commission for Health Care (ACHC)	http://www.achc.org
Accreditation Concepts	http://www.med icare.gov
Accred itation Association for Ambulatory Health Care (AAAHC)	http://www.aaahc.org
American Association for Healthcare Engineering (ASHE)	http://www.ashe.org
Baldrige Performance Excellence Program (U.S.)	https ://www .nist.gov/baldrige
Baldrige Scoring System	http://baldrige21.com/Ba1drige%20Scoring%20System .html
Center for Improvement in Healthcare Quality {CIHQ)	http://www.cihq .org/home .asp
Commission for Accreditation of Rehabilitation Facilities (CARF)	http://www.carf.org
Committee for Affordable Healthcare (CAQH)	http://caqh.org
Community Health Accreditat ion Partner (CHAP)	http://www.chapinc.org
Deemed Status	http://www.ashe .org/advocacy/orgs/deemedstatus.shtm l
Det Norske Veritas (DNV GL)	http://www.dnvglhealthcare.com/
Healthcare Facilities Accreditation Program (HFAP)	http://www.hfap .org
ISO 9001	http://www.iso.org
International Society for Quality (ISQua)	http://www.isqua.org
Joint Commission International (JCI)	http://www.jointcommissioninternational.org/
Magnet Recognition Program	http://nursecredentialing.org/M agnet
National Committee for Quality Assurance (NCQA)	http://www.ncqa .org
Pathway to Excellence	http://nursecredentia ling.org/Pathw ay.as px
Patton Healthcare Education Newsletter	https://pattonhe.com/patton-hea lthcare-cons ulLing-newsletters/
The Joint Commission (TJC)	http://www.jointcommission.org
Utilization Review Accreditation Center (URA()	http://www.urac.org

LEGISLATION INITIATIVES

CHAPTER 7

Jacque Cole, Susan Mellott

CPHQ Examination Content Outline Task Statements For This Chapter	
Quality Leadership and Structure	
1.A.13	Recognize quality initiatives impacting reimbursement (e.g., pay for performance, value-based contracts)
1.B.1	Assist the organization in maintaining awareness of statutory and regulatory requirements (e.g., CMS, HIPAA, OSHA, PPACA)
1.B.5	Facilitate communication with accrediting and regulatory bodies

Words and titles of sections that refer to task statements from the CPHQ Exam Content Outline are indicated throughout the Handbook with a box around the text.

Throughout this chapter there will be references to specific laws and cases which have shaped the healthcare industry. There are two basic types of laws which will be referenced, public laws and case laws. The public laws will have the initials "P.L." within the naming convention of the law. Case laws will note the two parties who were in court together such as *Darling v. Charleston Community Memorial Hospital*.

The website links are in the text itself, but can also be found in the website list at the end of the chapter.

Editor's note: *The future of healthcare insurance coverage is expected to be changing with the new Presidential Administration. This chapter is reflective of the current industry as of December 2017. There are several tentative legislative and presidential orders in draft; but nothing absolute. Examples of tentative subjects include; Repeal Replace and Removal of Insurance Mandates.*

CORPORATE LIABILITY IN THE U.S.

From the very beginning of recorded evidence of the provision of medical care (Code of Hammurabi, around 2,000 B.C.), the responsibility for quality care rested solely with the individual who provided the care. There were, of course, no institutions with which physicians could share this responsibility.

When Benjamin Franklin founded the first U.S. hospital in 1752, the accountability of the governing body was limited to fundraising. For the next 200 years, the hospital operated legally as an "innkeeper," a place where physicians, totally independent ("independent contractors"), could bring

and treat their patients. Hospitals operated with "charitable immunity" from prosecution until 1939. In 1876, the Supreme Court of Massachusetts was the first American court to indicate a charitable institution is not responsible for its torts *(McDonald v. Massachusetts General Hospital,* 120 Mass. 432) (McDonald, 1876). In 1942, the United States Court of Appeals for the District of Columbia revealed "the charity immunity doctrine was built on a foundation of sand" *(Georgetown College v. Hughes,* 130 F.2d 810) (Georgetown, 1942). After the 1957 New York Court of Appeals' case of *Bing v. Thunig,* N.Y.2d 656 (Bing, 1957) the charitable immunity began to crumble. Until the malpractice cases of *Leneris v. Haas* (1955) and *Bing v. Thunig* (Bing, 1957), hospital governing bodies were seen to be responsible only for facilities, services, equipment, and supplies. In *Leneris v. Haas,* the court held the hospital liable for the negligence of employees under the doctrine of *" Respondeat Superior".* In the Bing case, the New York Court of Appeals ruled the doctrine of charitable immunity no longer applied. For more information on the historical charitable immunity provision, see page 498 – 500 of the *Flagiello v. Pennsylvania Hospital* case (Flagiello, 1965).

Then, in the landmark case *Darling v. Charleston Community Memorial Hospital* (Darling, 1965), the governing body and the hospital 1,vere found to have a "duty of care" to patients and were held accountable for the selection of medical staff and the quality of care rendered in the hospital. Both state licensure laws and The Joint Commission standards subsequently began to reflect this legal mandate. Since then, responsibility for patient care, as well as organizational authority over administration and the medical staff, has been vested with the governing body. In a subsequent landmark case, *Elam v. College Park Hospital* (Elam, 1982), corporate liability was further expanded to include the obligation to ensure effective medical staff peer review. The governing body divides and delegates these responsibilities to administration and the medical staff as appropriate.

In addition to the legai pressures for governing body accountability based on malpractice case law, there are now very strong financial pressures, supported through federal and state legislation. These financial pressures range from capitated reimbursement to fines and fees associated with regulatory compliance. Post World War II legislation brought the Hill-Burton Program (P.L. 79-725) (English & Knowledge Service Groups, 1946) with hospital capital expansion and increasingly high-tech medicine. Public policy created the insurance industry with all costs and charges covered without question. The ultimate "third party payment" program came with the Medicare/Medicaid Program (P.L. 89-87, 1965), with its open-ended "indemnity" reimbursement.

Accountability and Liability Pressures

Corporate and governing body responsibilities for the quality of healthcare services provided by their organization(s) increased dramatically due to pressures from Federal and State Government regulations and strategies, business, healthcare professionals and respective organizations and societies, and legal atmosphere and decisions.

LEGISLATION INITIATIVES

Liability, according to the Oxford Dictionary is being "legally responsible for something" (Liability, n.d.). In some states, there are monetary limitations to a liability. There are four main types of liability in healthcare.

- *Contractual liability* obligates the practitioners or organization to perform according to what is promised or advertised. A person takes on contractual liability when he accepts liability for the acts of another in a written agreement or contract. A "breach of contract" may be affected if a promised treatment or result is not performed or obtained, regardless of any negligence involved. Claims made by product manufacturers generally fall under contractual liability .

- *Tort liability* is legal responsibility for civil wrongs, including invasion of privacy, lack of consent, defamation of character, fraud and deceit, assault and battery, and negligence/malpractice. Tort liability litigation most often includes monetary compensation for both actual and punitive damages assessed by the courts, particularly if the tort is determined to be intentional. There are three types of torts : Strict Liability, Intentional and Negligence Torts. These are discussed more thoroughly in the next portion of this chapter.

- *Corporate liability* replaced charitable immunity as the doctrine dictating healthcare organizations' legal responsibility to patients. The doctrine of *Respondeat Superior* ("let the master be responsible") also known as *vicarious liability* (Respondeat Superior, n.d.) assumes organizational liability for the negligent acts of its employees and of "ostensible agents" .

  The doctrine of *"ostensible agency"* (vicarious liability) holds organizations liable for the professional conduct of licensed independent practitioners and other workers who are not employees (but may be under contract) when the patient associates the professional/worker with the organization and is not privy to contractual arrangements (Worsham, 2017). For example, physicians are presumed to be ostensible agents of a hospital unless there is clear evidence that the patient was informed, in advance of treatment, of the independent contractor status of the physician. Other examples include: a dialysis organization that sends their staff in to a facility to do dialysis treatments, or a lithotripsy truck that visits once a month to do lithotripsy.

- *Criminal liability* is legal responsibility for actions in violation of criminal law and punishable by fine and/or imprisonment.

- *Duty of care/duty to act* was developed from the *Darling v. Charleston Community Memorial Hospital* case previously discussed. There is an organizational liability for direct duties owed to the patient and for the quality of medical care. The organization is liable for negligence in the selection and monitoring of physicians . There is also organizational liability for breach of its duty to the patient to prntect him or her from acts of malpractice by an independent physician

(and now other licensed independent practitioners}, if the organization knew, had reason to know, or should have known of incompetence. The organization cannot defend itself on grounds that medical and other professional staffs are independent and self-governing. Consistent with duty to act or duty of care, the healthcare organization has a direct and independent responsibility to patients for ensuring the competency of its licensed independent practitioners and the quality of medical care provided. *Elam v. College Park Hospital,* 1982, added the hospital's obligation to set up effer.tive medical staff peer review for ongoing evaluation in order to identify otherwise unsuspected substandard practice.

- The doctrine *of Res lpsa Loquitur* ("The thing speaks for itself") refers to organizational or personal liability due to circumstantial proof of negligence. The existence and nature of the injury obviously proves a breach in standard of care or duty owed the patient, such as a sponge or clamp left in the abdomen, or removal of the wrong body part (Res lpsa Loquitur, n.d.).

Torts

There are three types of torts:*intentional torts; negligence; and strict liability*. Tort cases stem from a failure of the 'duties' noted above. They are defined by the intent of the duty failure . Generally, liability because of a tort only arises where the defendant either intended to cause harm to the plaintiff or in situations where the defendant is negligent. However, in some areas, liability can arise even when there is no intention to cause harm or negligence.

An intentional tort is a civil wrong that occurs when the person engages in intentional conduct that results in damages to another (Torts, n.d.). Striking another person in a fight is an intentional act that would be the tort of battery. Striking a person accidentally would not be an intentional tort since there was not intent to strike the person. It is the intent to do harm that makes the act an intentional tort.

Strict liability or absolute liability results from cases of defective products or se rvices . For example, cars recalled due to defective air bags. Any activity that is so dangerous to the public that there must be liability qualifies as strict liability (Liability, n.d.).

Negligence

Negligence is careless conduct that results in damage to another . It is the failure to follow the degree of care that would be followed by a reasonably prudent person in order to avoid foreseeable harm. It is behavior that is less than the standards of behavior established by law for the protection of others against unreasonable harm (Negligence, 2015).

In healthcare, a negligence lawsuit is referred to as Malpractice. Malpractice is a failure by a physician or other professional to use the care and skill that other members of their profession would use under

similar circumstances . When an accountant, doctor, attorney, or some other professional contracts to perform services, there is a duty to exercise skill and care as is common within the community for persons performing similar services. Failure to fulfill that duty is malpractice (Torts – Negligence, n.d.).

The reasonable person standard specifies that to the degree of care required of a person is that which an ordinarily prudent person would exercise under similar circumstances even though this standa rd degree of care might not have prevented the harm from occurring. This degree of care will vary in every situation. The "reasonable person" clause of this definition of negligence is what distinguishes negligence from assault and battery (Negligence, 2015).

The elements required for a person to establish negligence are: there was a presence of duty; there was a failure to act (breach of duty) according to the required standards of conduct/care; there was proximate causation of harm; and the harm was caused by the breach of duty. All four of these elements must be in place for the actions to be called negligent. For example, a physician driving by an accident has no duty to stop and offer medical assistance so the doctor would not be negligent if he keeps on driving.

Torts involve duties created by law. Just because someone is hurt does not mean that someone else must pay for the harm. There must have been a *duty,* which has been broken. A plaintiff will not be allowed to recover from a defendant if the defendant did not break a duty that was owed to the plaintiff. For example, if a burglar breaks into a house and trips over an item of furniture, the homeowner is not liable to the burglar because he had no duty to him. However, if a guest in a person's home trips over a piece of furniture, the homeowner may have a duty to that guest. The breach of duty must result from a voluntary act or failure to act.

In order for someone to be legally responsible for damages, it is necessary to show that the breach of duty was the cause of the harm. The term used here is proximate cause, which means that the person who has a breach of duty could foreseeably know that natural or probable consequences/harm could be caused (Negligence, 2015). The plaintiff must prove that any negligence of which the defendant is accused is the natural or probable cause of the plaintiff's injury. There may be an intervening cause, which comes after the original negligence of the defendant, which may reduce the amount of the defendant's liability. If this intervening cause is the substantial reason for the injury, then the defendant will not be li:ible at all (Torts – Negligence, n ct)

The final element of negligence is *damages.* A plaintiff may recover monetary damages to compensate for the multiple things such as the economic losses of lost wages and medical expenses, and the noneconomic losses of pain and suffering. Punitive damages designed to punish the defendant for his wrongdoing may also be appropriate . The punitive damages are generally only appropriate if the plaintiff can prove gross negligence or willful misconduct by the defendant . Many states have undergone tort reform, which limits the damages the plaintiff may receive.

REGULATORY AND LEGAL HINTS

All federal laws, regulations, final rules, and interim rules are published in the Federal Register. They can be found through the following government website. Under the section, "Federal Register Publications and Online Services" is a link to the Federal Register 2.0., (www.federalregister.gov). The most current issues are in a shortcut bar across the top of the web page.

New documents available for review ;:ind comment can be found at www.regulalions.gov.

Public Laws (P.L.) (Found under "Bill Searches and Lists")

- Congress www.congress.gov

Federal Bills and Reports

- House of Representatives www.house.gov
- Senate www.senate.gov

State Bills and Reports

- Each State Government has a website for bills, administrative rules and laws. Hint: Add your state's website to your favorites.

Regulations associated with the Social Security Administration

- www.socialsecurity.gov/OP Home/comp2/comp2toc.html

Case Law Resources

To find specific case laws there are several sources available on the internet:

- Justia U.S. Law http://law.justia.com
    - Case, Codes and Statutes, Regulations, Federal and State Laws.
    - This resource may have city codes where they are available.
- Several paid resources include:
    - Lexis Nexis http://www.lexisnexis.com
    - Westlaw http://www.westlaw .com

LEGISLATION INITIATIVES

U.S. HISTORICAL REVIEW - SAMPLE OF LAWS INVOLVING HEALTHCARE

1935

- **Social Security Act of 1935** (www.ssa .gov/history/35act.html) On August 14, 1935, the Social Security Act established a system of old-age benefits for workers, benefits for victims of industrial accidents, unemployment insurance, and aid for dependent mothers and children, the blind, and the physically handicapped.

1955

- ***Leneris v. Haas:*** Established hospital liability for employee and agent acts.

1965

- **P.L. 89-97: Social Security Act** (Titles XVIII and XIX: Medicare/Medicaid legislation for the aged, permanently disabled, and the indigent). This amendment referred to as Old-age, Survivors and Disability Insurance (OASDI). See the archives for more information on this amendment at www.ssa.gov/po1icy/docs/ssb/v28n9/v28n9p3.pdf
- ***Darling v. Charleston Community Memorial Hospital:*** Established institutional liability for the quality of medical care provided by physicians.

1972

- **P.L. 92-603: Amendments to Social Security Act**
- Professional Standards Review Organizations **(PSROs);** www.ssa.gov/policy/docs/ssb/v36n3/v36n3p3.pdf
  - Section 1160, quality assurance requirements for health care practitioners .

1973

- Health Maintenance Organization (HMO) Act (P.L. 93-222) required that HMOs accepting federal funds have a QA program. (www.ssa.gov/policy/docs/ssb/v37n3/v37n3p35.pdf)

1974

- Department of Health, Education, and Welfare (HEW) released U.R. Standards for PSRO review.

1975

- **Diagnostic-Related Groups (DRGs)** devised as a patient classification system by John Thompson and Robert Fetter at Yale.

1979

- *Quality Assurance Strategy for HMOs* published by the Federal Office of HMOs required that federally certified HMOs operate an internal QA program addressing both inpatient and ambulatory care, and participate in external reviews.

LEGISLATION INITIATIVES

1982

- **Tax Equity and Fiscal Responsibility Act (TEFRA)** (P. L. 97-248), Amendment to Section 143, Part B of the Social Security Act, provided incentive for effective UR:
  - Set cost-per-case limits for Medicare patients;
  - Authorized incentive payments to hospitals keeping costs below set targets.
  - www.socialsecurity.gov/OP_Home/comp2/F097-248.html
- TEFRA Title I, Subtitle C, S. 2 142 entitled the **"Peer Review Improvement Act"**
  - Replaced the PSRO program with the Utilization and Quality Control Peer Review Organization **(PRO)** program;
  - Required Medicare providers to release patient information to a PSRO or PRO for both utilization and quality review .
- ***Elam v. College Park Hospital:*** Expansion of hospital corporate liability.

1983

- Title VI of Social Security Amendments (P.L. 98-21) - **Prospective Payment System:**
  - Medicare reimbursement changed from reasonable cost to a pre-determined fixed price per discharge;
  - Set deadlines for implementation;
  - Set limits for determination of hospital cost base and for routine nursing costs;
  - Expanded PRO review to include all Medicare providers.
  - www.ssa.gov/OP_Home/comp2/F098-021.html

1985

- **Consolidated Omnibus Budget Reconciliation Act (COBRA)**
  - Joint Commission began the Agenda for Change to reformulate standards, redesign the survey process, and develop performance measures.
  - www.socialsecurity.gov/policy/docs/ssb/v49n8/v49n8p22.pdf

1986

- **Omnibus Budget Reconciliation Act (OBRA 86)** (P.L. 99-509)
  - www.socialsecurity.gov/OP_Home/comp2/F099-509.html
- **Health Care Quality Improvement Act** (P.L. 99-660)
  - www.socialsecurity.gov/OP_Home/comp2/F099-660.html
- **False Claims Amendment Act** (P.L. 99-562)
  - www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3153.pdf

LEGISLATION INITIATIVES

- ***Patrick v. Burget:*** A physician under review may file a federal antitrust claim against a hospital and physicians for their medical staff disciplinary action.

1987

- **Omnibus Budget Reconciliation Act (OBRA 87)** (P.L. 100-203)
  - www.socialsecurity.gov/OP Home/comp2/F100-203.html
- **Medicare and Medicaid Patient and Program Protection Act (MMPPPA)**
  - JCAHO: Name change to Joint Commission on Accreditation of Healthcare Organizations and implementation of Agenda for Change

1988

- **Medicare Catastrophic Coverage Act (MCCA)** (P.L. 100-360) enacted, then repealed, effective 1/1/90.
  - www.socialsecurity.gov/OP Home/comp2/F100-360.html
- **Clinical Laboratory Improvement Act (CUA)** enacted; most regulations effective 9/1/92

1989

- **Omnibus Budget Reconciliation Act (OBRA 89)** (P.L. 101-239)
  - Total quality management (TOM) and continuous quality improvement (CQI) concepts began to be applied to healthcare.
  - www.socialsecurity.gov/OP Home/comp2/F101-239.html

1990

- **Omnibus Budget Reconciliation Act (OBRA 90)** (P.L. 101-508)
- **Patient Self-Determination Act (PSDA)** (P.L. 101-508, Part of OBRA 90), effective 12/1/91
  - www.socialsecurity.gov/OP Home/comp2/F101-508.html
- **Americans with Disabilities Act (ADA)**
- **Safe Medical Device Act (SMDA)** (P.L. 101-629)
  - www .gpo.gov/fdsys/pkg/STATUTE-100/pdf /STATUTE-100-Pg3153.pdf

1993

- **Omnibus Budget Reconciliation Act (OBRA 93)** (P.L. 103-66)
  - www .socialsecurity.gov/OP _Home/comp2/F103-066. html

1996

- **Health Insurance Portability and Accotmtability Act (HIPAA)** (P.L. 104-191)
  - www.socialsecurity.gov/OP Home/comp2/F104-191.html

LEGISLATION INITIATIVES

1997

- **Balanced Budget Act (BBA)** (P.L. 105-33). Established Medicare+Choice, Part C of Title XVIII of Social Security Act, and State Children's Health Insurance Program (SCHIP).
  - www.socialsecurity .gov/OP Home/comp2/F105-033.html

1999

- **Balanced Budget Refinement Act (BBRA):** Program modifications.
- Institute of Medicine report on medical error, "To Err is Human" (11/99).
  - (iom.nationa lacademies.org/Im edia/Files/Report%20Fi Ies/ 1999/To-Err-is-Human/To%20Err% 20is%20H uman%201999%20%20re port%20brief. pdf

2000

- **Benefits Improvement and Protection Act (BIPA):** BBA program modifications (Medicare, Medicaid, and SCHIP).

2001

- Institute of Medicine report on the status of healthcare delivery in the U.S., "Crossing the Quality Chasm," released 3/1/01.
  - iom.nationalacademies .org/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx

2003

- **Medicare Prescription Drug, Improvement, and Modernization Act (MMA)** (P.L. 108-173)

  www .socialsecurity.gov/OP Home/comp2iF108-173.html

2005

- **Patient Safety and Quality Improvement Act (PSO Act)** (P.L. 109-41):
- Created Patient Safety Organizations (PSOs) and Network of Patient Safety Database (NPSD).
  - www.socialsecurity.gov/OP Home/comp2/F109-091.html
- **Deficit Reduction Act (DRA)** (P.L. 109-171) Impacted inpatient and dialysis PPS, Medicare demonstration projects, DME, physician fee schedule, therapy services, federally qualified health centers, home health, PACE, drug payments, Medicaid utilization data, administration, long-term care, false claims recovery, payment.
  - www.socialsecurity .gov/OP Home/comp2/F109-171.html

2006

- **Tax Relief and Health Care Act (TRHCA)** (P.L. 109-432) Established physician quality reporting system, with incentive payment.

- www.socialsecurity.gov/OP Home/comp2/F109-432.html

2008

- **Medicare Improvements for Patients and Providers Act (MIPPA)** (P.L. 110-275) For mental health, increased provider payments, Medicare co-payment parity (80-20 from 50-50) with other medical services; PQRI bonus payment increase.
  - www.socialsecurity.gov/OP Home/comp2/F110-275.html

2009

- **American Recovery and Reinvestment Act (ARRA)** (P.L. 111-5) Economic jumpstart support for Community Health Centers, Medicaid and prescription drug funding, immunization grants, National Institutes of Health medical research, state Health IT.
  - **Health Information Technology for Economic and Clinical Health (HITECH) Act,** enacted as part of the American Recovery and Reinvestment Act of 2009, to promote the adoption and meaningful use of health information technology. Subtitle D of the HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA rules.
  - **Omnibus Rulemaking** to strengthen the privacy and security protections for health information established under the Health Insurance Portability and Accountabi lity Act of 1996 (HIPAA).
  - www.socialsecurity.gov/OP Home/comp2/F111-005.html
- **Children's Health Insurance Program Reauthorization Act (CHIPRA)** (P.L. 111-3): Reauthorized CHIP and funded through 2013.
  - www.socialsecurity.gov/OP Home/comp2/F111-003.html

2010

- **Patient Protection and Affordable Care Act (PPACA) or (ACA)** (P.L. 111-148) Signed 23 March, 2010. Expanded health care coverage to 2/3 of uninsured Americans through a combination of cost controls, subsidies and mandates.
  - (www.socialsecurity.gov/OP Home/comp2/F111-148.html)
- **Health Care and Education Reconciliation Act** (P.L. 111-152) Signed 30 March, 2010. Changed some healthcare provisions in PPACA and added the Student Aid and Fiscal Responsibility Act as a rider.
  - (www.congress .gov/111/plaws/publ148/PLAW-111publ148.pdf)

LEGAL FOUNDATIONS FOR QUALITY PRACTICE

Federal Program Participation and Quality Improvement Organizations

There are numerous federal regulations governing healthcare, and they continue to increase and expand on an annual basis. Federal healthcare legislation is developed, massaged, and eventually passed by the United States Congress. It is then interpreted and implemented by the Department of Health and Human Services (HHS) and its subsidiary, the Centers for Medicare and Medicaid Services (CMS).

On June 14, 2001, U.S. Health Secretary Tommy Thompson announced a name and structure change for the Health Care Financing Administration (HCFA) to the Centers for Medicare and Medicaid Services (CMS). The federal agency, was split into three main divisions (CMS, 2017):

- The Center for Medicare Management: Fee-for-service program administration
- The Center for Beneficiary Choices: Beneficiary education and Medicare Advantage managed care programs administration
- The Center for Medicaid and State Operations: Oversight of programs administered by states, including Medicaid, the State Children's Health Insurance Program (SCHIP), and insurance regulation

Medicare and Medicaid

Medicare and Medicaid are two governmental programs that provide medical and health-related services to specific groups of people in the United States. In 1965, The Social Security Act (P.L. 89-97) was passed by Congress and signed by President Johnson. Titles XVIIi and XIX of the Act established the Medicare and Medicaid Programs, healthcare legislation for the aged, permanently disabled, and the indigent. Both Medicare and Medicaid are managed by the Centers for Medicare and Medicaid Services, a division of the U.S. Department of Health and Human Services .

CMS developed and administers the Conditions of Participation {CoPs) and Conditions for Coverage (CfCs), that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiar ies . For example, the Conditions of Participation for Hospitals are part of the Code of Federal Regulations. Hospitals must meet all of the Conditions established by Medicare and Medicaid to receive reimbursement for treating Medicare beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs/CfCs (COP, 2013).

LEGISLATION INITIATIVES

Revisions to the Conditions of Participation and Conditions for Coverage: Retrieved from http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index .html accessed July 8, 2015.

Medicare System

The Medicare program is an insurance program financed through taxes paid by employees and employers. The primary purpose of the program is to provide a health care safety net for individuals retired from the workforce. The three groups that are eligible for Medicare are individuals aged 65 and older who have paid into the system, certain individuals under age 65 who have disabilities, and individuals with End-Stage Renal Disease.

The Centers for Medicare and Medicaid Services (CMS) is given the responsibility by the Department of Health and Human Services to establish guidelines and regulations to implement federal legislative mandates concerning the Medicare Program. State or regional Quality Improvement Organizations (QIOs) are under contract with CMS to monitor the care provided to Medicare patients.

Medicare has four parts, A, B, C, and D. These parts can be subscribed to independently or in various combinations. The most commonly known part is Part A, which is the insurance for hospitalization, skilled nursing, certain home health services and other services . It is available without cost to individuals who paid Medicare taxes and certain other individuals. Medicare Part B is the medical insurance. There is a monthly premium and enrollees must be eligible to receive Medicare Part A. The Medicare Part C is also known as, the Medicare + Choice, or Medicare Advantage plans. These plans are additional coverage plans obtained from private insurance agencies to pay for the things not included in the Medicare Parts A and B. Medicare Part D, established in 2006, is a prescription drug plan purchased from private insura ce agencies. Part D requires a premium and deductibles. The purpose of Part D is to cover the gap when Medicare does not cover the cost of the medications. Table 1lists the items covered under Medicare Part A and Part B.

Table 1: Coverage for Medicare Part A and Part B

Coverage for Medicare Part A and Part B	
Medicare Part A	**Medicare Part B**
• Hospitalization for illness or injury • Inpatient psychiatric care • Care in a skilled nursing facility • Home health care for individuals with an illness or injury and meeting certain conditions. This benefit provides part time limited skilled nursing care and other therapeutic services.	• Medical and other services such as non-routine doctor visits, medical equipment, outpatient therapies • Clinical lab services • Home health care for individua ls with an illness or injury and meeting certain conditions. This benefit provides part time limited skilled nursing care and other

• Hospice care for individuals meeting certain conditions (must be terminal within 6 months as determined by a physician) • Blood given at a hospital or skilled nursing facility	therapeutic services. • Outpatient hospital services for diagnosis and treatment of injury • Blood • Preventative Services including bone mass measurement, colorectal cancer screening, diabetes monitoring, annual mammogram screening, pap smears and pelvic exams, prostate cancer screening and vaccinations

Medicaid System

The U.S. Federal Medicaid Program was established in 1965 under the same legislation as Medicare. Changes to the Medicaid laws come just as Medicare changes do-through budget-related legislation, e.g., the Balanced Budget Act (BBA) of 1997, Balanced Budget Refinement Act (BBRl1) of 1999, and Benefits Improvement and Protection Act (BIPA) of 2000. Medicaid is a federal-state assistance program rather than an insurance program like Medicare (Medicaid, n.d.).

The Centers for Medicare and Medicaid Services (CMS) has overall responsibility for the program, with the day-to-day administration delegated to each state through its own Department of Health, based on federal policy guidelines, limits, and payment rates. On the average, the Federal Government pays for approximately 57% of Medicaid expenditures, and the states pay for 43%.

!n most states, the program is offered to those individuals and families meeting certain iow- or no-income criteria who generally own no property, though home ownership is permitted in some states. Medicaid e ligibility includes children, parents, pregnant women, seniors and people with disabilities who need the health coverage to get healthy and stay healthy. Employment is not necessarily a determinant, but many who receive Medicaid have at least one person in the household who is working. Generally, Medicaid coverage has no co-payment requirements, deductibles, or premiums, and there is freedom of choice of provider, though eligibility requirements may be complex.

Approximately 50% of all Medicaid expenditures have been for long-term care at both skilled and intermediate levels or for care of the developmentally disabled. Another 26% has been for general hospital care. Medicaid reimbursement systems are established by each state, with federal approval, so they vary greatly. Variations include managed care capitated options, discounted charges, flat daily rates (regardless of level of care) and experiments with DRG reimbursements (Medicaid, n.d.).

Since it is a program where both the Federal Government and the State Government pay for the program, Medicaid continues to be the center of debate as states continue to wrestle with the pros

and cons of expanding their programs in response to the options available under the PPACA legislation (see PPACA legislation later in this chapter). The fifty states each have to decide if their state will participate in this program or not, and currently not all fifty are participating.

The positive outcomes of a Medicaid expansion would be to cover individuals up to 138% of the Federal Poverty Level (FPL). In 2013, this would have equated to households of one receiving $15,856 per year and for households of four receiving $32,499 per year. According to the PPACA rules, individuals between 100-138% of the FPL could access tax subsidies to purchase insurance through the exchange. The expansion would have also required coverage of the Essential Health Benefits (EHB). EHB include: Ambulatory Patient Services, Emergency Services, Hospitalization, Maternity and Newborn Care, Mental Health and Substance Use Disorder Services, Prescription Drugs, Rehabilitative and Habilitative Services & Devices, Laboratory Services, Preventive and Wellness Services and Chronic Disease Management, and Pediatric services, including oral and vision care. Most of these were already covered under the Medicaid plans.

The negative side is the costs to be incurred by the states . The first three years the Federal Government pledged to cover 100% of the cost difference . After the first three years, the percentage of cost different ial dropped incrementally adding the cost burden for the expansion to state budgets.

)Prospective Payment System (PPS)

In 1983, Congress adopted the Social Security Amendments of 1983, which included measures to establish a prospective payment system for Medicare inpatient hospital services (Scott, 1984) . The prospective payment system was designed to make reimbursements for care in a predetermined, fixed amount. CMS has created separate perspective payment systems since 1984 for acute inpatient hospitals, home health agencies, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, skilled nursing facilities, and federally qualified health centers (CMS – PPS, 2015). Each of the separate PPS's can be found at this CMS website : www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/index.html

A fee schedule is a complete listing of fees used by Medicare to pay doctors or other providers/suppliers. This comprehensive listing of fee maximums is used to reimburse a physicia n and/or other providers on a fee-for -service basis. CMS develops fee schedules for physicians, ambulance services, clinical laboratory services, and durable medical equipment, prosthetics, orthotics, and supplies.

Quality Improvement Organization and Medicare Scopes/Statements of Work

History of Professional Standar ds Review Organizations (PSRO)

LEGISLATION INITIATIVES

Professional Standards Review Organizations (PSRO) established by Public Law 92-603, Amendment to Social Security Act, in 1972, were physician-sponsored and established to assure services provided to Medicare and Medicaid patients worked and employed concurrent utilization review, including admission and continued stay review . The PSRO's have performed medical care evaluation studies and profile analyses, and have functioned like government agencies with annual federal grants as their funding source.

In 1982, Peer Review Organizations (PROs) were established by the Tax Equity and Fiscal Responsibility Act (TEFRA), 1982, in the "Peer Review Improvement Act" (S.2142, P.L. 97-248). This law replaced the federal PSROs and initiated contract bidding by competing review organizations, either nonprofit or for-profit (one per state), created geographic consolidation (QIO boundaries coincident with statewide or regional boundaries), and did not have delegated review .

In January 2002, the Peer Review Organizations (PRO) changed their name and focus to Quality Improvement Organizations (QIO). In 2014, the QIOs were split into two separate entities under the Q!O umbrella in order to improve the efficiency of their activities : Beneficiary and Family Centered Care (BFCC - QIO); and Quality Innovation Network (QIN - QIO) (CMS-QIO, 2017).

The primary purpose of the original PRO program was quality-protected cost containment. The current QIO Program is dedicated to improving health quality for Medicare beneficiaries . The QIO is an integral part of the U .S. Department of Health and Human (HHS) Services' National Quality Strategy for providing better care and better health at lower cost. By law, the mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries.

The QIO Program changes include separating case review from quality improvement, extending the contract period of performance from three (3) to five (5) years, removing requirements to restrict QIO activity to a single entity in each state/territory , and opening contractor consideration to a broad range of entities to perform the work. With the removal of the state restrictions, the number of QIOs was reduced and all QIOs now represent more than one state. Now, one group of QIOs will handle complaints while another group will provide assistance to support providers and suppliers in improving their care and services (Table 2).

Beneficiary and Family Centered Care (BFCC) -QIOs perform statutory review functions, including complaints and quality of care reviews for people with Medicare. They ensure consistency in the case review process while considering the local factors and needs. This will include general quality of care, medical necessity, and readmissions. There are also five Beneficiary and Family Centered Care areas with eight or more states and territories . There are only two agencies which have the contracts for these five areas (Table 2) (QualityNet, n.d.).

Quality Innovation Network (QIN)-QIOs provide to healthcare organizations education, outreach, and sharing practices that have worked in other areas. The QIN will utilize data to measure improvement, and will work with patients, families and community partners through communication and collaboration. QIN-QIOs also focus on targeted health conditions and priority populations to reduce the incidence of healthcare-acquired conditions . There are currently 14 Quality Innovation Networks, w ith each responsible for three to six states and/or territories. For example, Texas Medical Foundation is now the QIO for Arkansas, Missouri, Oklahoma, Puerto Rico, and Texas (QualityNet, n.d.).

Table 2: QIO Group Functions

QIO Group Functions	
Beneficiary and Family Centered Care (BFCC)	**Quality Innovation Network {QIN)**
• Quality of Care Reviews (includes complaints) • Medical Necessity Reviews • Higher Weight DRG Reviews • Readmission Reviews • EMTALA Reviews • Focused Reviews • Recommendations for Quality Improvement Initiatives (Oil's) & Technical Assistance • Discrimination Referrals • Patient and Family Engagement	Essential Functions: • Cham pion local-level, results-oriented change • Facilitate learning and action networks • Teach and Advise as technical experts • Integrated Communications Triple Aim (SoW): • Better Health • Better Care • Lower Costs

Adapted from CMS-QIO, 2017

QIOs are not federal agencies and are exempt under the Freedom of Information Act. The government contracts with the QIOs for their services. Data submitted to or used by the QIO is not discoverable . The QIO maintains the author ity to revoke or rebut waiver of liability transferred from the Fiscal Intermediaries to QIO's. Confidential information must be shared upon request of a state licensing agency, a certifying agency, and/or a national accreditation body, but only when that information is necessary for those agencies to conduct their certification/accreditation activities. Non-confidenlici l information must be supplied to anyone requesting and paying for such information.

Scope of Work

QIO activities with both beneficiaries and the medical communities in the state have increased in recent years. The activities of the QIO are known as the "Scope of Work" (SoW). They are numbered consecutively every 4 years. Each Scope of Work is outlined in the Federal Register and is based on

analysis of the previous SoW. The current 11th Scope of Work will be in place from August 1, 2014 through July 31, 2019. Table 3 contains the main focus of this SoW, which is based on the Triple Aim.

Table 3: CMS 11th Scope of Work

CMS 11th Scope of Work		
AIM	**Goal**	**Focus**
Healthy People, Healthy Communities: Improving the Health Status of Communities	Promote effective prevention and treatment of chronic disease	• Improving cardiac health and reducing cardiac healthcare disparities • Reducing disparities in diabetes care • Using immunization information systems to improve prevention coordination • Improving prevention coordination through meaningful use of HIT and collaborating with regional extension centers
Better Healthcare for Communities: Beneficiary-Centered, Reliable, Accessible, and Safe Care	1. Make care safer by reducing harm caused in the delivery of care	• Reducing healthcare-associated infections • Reducing healthcare-acquired
	2. Promote effective communication and coordination of care	• Coordination of care
Better Care at a Lower Cost	Make care more affordable	• Quality improvement through physician value-based modifier and physician feedback reporting program • QIN-QIO proposed projects that advance efforts for better care at lower cost
	Other technical assistance projects	• Quality improvement initiatives

Adapted from Stratus Health, (n.d.)

American Recovery and Reinvestment Act (ARRA) of 2009 (P.L. 111-5)

On February 13, 2009, in direct response to the economic crisis and at the urging of President Obama, Congress passed the American Recovery and Reinvestment Act of 2009 -- commonly referred to as the "stimulus" or the "stimulus package" (AARA, 2009) . This act encompassed many individual provisions including education benefits, home buying credits, new vehicle credits and home energy credits, to name a few. However, this law also added provisions for health care like the HITECH Act and Health Information Technology upgrades and grants to improve medical record connectivity and stimulate the adoption of an electronic medical record. Some states also took advantage of the additional funding available for Medicaid program expansions.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Division A: Title XIII of the American Recovery and Reinvestment Act (ARRA) of 2009 (P.L. 111-5), provided incentives for development and adoption of national health information technology (HIT) standards toward a fully interoperable health information system and "improved" the HIPAA privacy and security provisions (Subtitle D) (HITECH, 2009).

Medicare and Medicaid Health Information Technology, Division B: Title IV of the ARRA, provided incentive programs to eligible professionals, hospitals, and critical access hospitals to allow them to adopt, implement or upgrade electronic health records (CMS - EHR, 2017). The Incentive Programs allocated over $22 billion to stimulate adoption of (EHR) systems by designated practitioners, from 2011 through 2016. Physicians and other qualified practitioners in outpatient clinic settings apply for health information technology (HIT) stimulus money, up to $44,000 total over five years in the Medicare Incentive Program and up to $63,750 over six years in the Medicaid Program. Eligible hospitals and critical access hospitals that begin the Medicare or Medicaid Program between 2011and 2016 receive a $2 million base payment. By January 2015, more than 400,000 eligible hospitals and professionals had adopted or were meaningfully using EHRs. The CMS is currently working on adapting the EHR incentive programs to account for the changes that have occurred since this begun in 2011 (ARRA, 2009).

!Patient Protection and Affordable Care Act (PPACA)i

The Patient Protection and Affordable Care Act (P.L. 111-148), commonly referred to as "Obamacare", "Healthcare Reform", "Affordable Care Act", and "ACA", was signed into law March 23, 2010. It was immediately amended by the Health Care and Education Reconciliation Act (HCERA) (P.L. 111-152), signed March 30, 2010, included changes to the PPACA by adding the Student Aid and Fisca l Responsibility Act (PPACA, 2015).

Provisions

The bill is divided into 10 main areas, which are shown in Table 4. Most of the health-related provisions took effect between 2010 and 2014, with a few extending to 2018. Provisions include:

expanded Medicaid eligibility for those states which elected to accept the expansion; expanded Medicare Part D by closing the coverage gap ("donut hole") by 2020; a pilot program for tort reform; subsidization of insurance premiums; incentives for businesses to provide health care benefits; support for medical research, initiated the development of accountable care organizations; initiation of the health insurance exchange (marketplace); and several health insurance mandates. Since 2010, the PPACA has been modified many times. The U.S. Health and Human Services website at http://www.hhs.gov/healthcare/facts/timeline/timeline-text .html contains a list of changes year by year for your reference . The required preventive services mandated are based on the category A and B services by the Preventive Services Taskfo rce. The exact list is updated frequently and is found at: http://www.uspreventiv eservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations -by-date/.

Table 4: Ten Areas of PPACA

Ten Areas Of PPACA
• Eliminating the underwriting of pre-existing conditions
• Eliminating lifetime and annual limits on benefits
• Requiring coverage of preventive services, immunizations and coverage for pregnancy regardless of gender
• Extending dependent coverage up to age 26 on a parent's plan with the parent's permission
• Developing uniform coverage documents for health insurance comparisons
• Capping medical loss ratios
• Expanding the appeals process
• Creating the Health Insurance Exchange (renamed Health Insurance Marketplace) to assist the identifying of coverage options: www.HealthCare.gov
• Creating a re-insurance and Premium Stabilization Program
• Facilitating administrative simplification to lower health system costs

!Accountable Care Organizations!

Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who work together to give coordinated high-quality care to their patients, at lower costs. The ACO comes from the PPACA as one of the ways to increase coordination of care and reduce costs. An ACO is not a Medicare Advantage plan or an HMO. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the care they need and at the right time, without unnecessary duplication of services and while preventing medical errors. The ACO members will then share in the savings obtained through their coordinated efforts (CMS - ACO, 2017).

LEGISLATION INITIATIVES

With managed care, the patient pays the health plan and holds it accountable for care delivery. In an ACO ,the provider's accountability will still be through the contract with the health plan but the health plan will reimburse the ACO as a who le and not the individual provider. The ACO will then be responsible for dividing the reimbursement between all of the practitioners and facilities who participated in the ca re of the patient.

Medicare currently offers three ACO programs:

- Medicare Shared Savings Program is a program that helps Medicare fee-for-service program providers become an ACO and share the savings. The Shared Savings Program aims to improve patient outcomes and increase value of care by providing better care for individua ls, better health for populations, and lowering growth in expenditures (CMS – MSSP, 2017). The ACOs in this program will receive the savings when they lower their growth in health care costs, while meeting performance standards on quality of care, and putting patients first.
- Advance Payment ACO Model is a supplementary incentive program for selected participants in the Shared Savings Program. Selected participants in the ACO receive upfront and monthly payments, which they can use to make important investments in their care coordination infrastructure . This is usually for small ACOs who have a lack of ready access to the capital needed to invest in infrastructure and staff for care coordination (CMS-AP, 2017).
- Pioneer ACO Model is a program designed for early adopters of coordinated care who already have experience in coordinating care for patients across care settings. These provider groups can then move more rapidly from a shared savings payment model to a population-based payment model. The population-based payment model is consistent with, but separate from, the Medicare Shared Services Program. The population-based payment model is designed to work in coordination with private payers by aligning provider incentives. This in turn will improve quality and health outcomes for patients across the ACO, and achieve cost savings for Medicare, employers and patients. CMS is no longer accept ing applications for this kind of payment model (CMS – PACO, 2017).

LEGAL FOUNDATIONS FOR PATIENT PROTECTION

Patient Self-Determination Act (PSDA) of 1990

The Patient Self-Determination Act (P.L. 101-508), part of OBRA '90, took effect on December 1, 1991. The law requires that providers develop policies and procedures addressing a patient's right to refuse treatment and to execute an "advance directive" in accordance with individual state laws. The requirements apply to hospitals, nursing facilities, health plans, home care and hospice programs (Kelley, 1995). Section 1395cc(f) of the PSDA defines an advance directive as *a written instruction, such as "a living will* or *durable power of attorney for healthcare, recognized under State law (whether statutory or as recognized under State law (either statutory or case law) and relating to the provision of such care when the individual is incapacitated"* (Kelley, 1995).

There are six requirements of the law:

1. Written policies and procedure for living wills and durable power of attorney
2. Written information to adult patients concerning their rights
3. Documentation in the medical record concerning existence of advance directive
4. Care not to be conditioned on whether or not the patient signed an advance directive
5. Ensure compliance with advance directives, once executed
6. Provide education for staff and the community on issue _oncerning advance directives

Patient Rights and Responsibilities Legislation

Patients' Rights are established by federal law (e.g., Patient Self-Determination Act), state legislation, by professional organizations, such as the American Hospital Association, and by accrediting agencies, such as The Joint Commission and the National Committee for Quality Assurance. Patients' Responsibilities are generally defined in case law and by accrediting agencies, and include: following the instructions of their physicians and nurses, providing accurate and complete information, keeping appointments, and considering the rights of others. The Medicare, Medicaid, and Hill-Burton programs prohibit discriminat ion on the basis of race, creed, or color as a condition for receiving funds. A patient may not be detained in the hospital for inabl!ity to pay ("false imprisonment"), nor can a patient be discharged without his/her agreement. Patients with communicable diseases can be held by a health officer to prevent spread of infection. Psychiatric patients can be detained if they are considered to be dangerous to themselves or others.

!Health Insurance Portability and Accountability Act (HIPAA) of 199@

The Health Insurance Portability and Accountability Act of 1996 (H.R.1303, P.L. 104-191) was a major health insurance reform bill. The provisions generally were effective on July 1, 1997, though many have taken years to implement. The bill was updated in the Section 1104 of the PPACA in 2010 with new and expanded provisions. It requires health plans to certify compliance with standards and healthcare rules, and other items. The latest addition to the HIPAA compilation is the HIPAA OMNIBUS FINAL RULE, released by HHS on January 17, 2013 (HIPAA, 2017).

In summary, The Health Insurance Portability and Accountability Act (HIPAA) was enacted by the U.S. Congress in 1996. The Act is massive in scope. Title II of HIPAA, known as the Administrative Simplification Provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The Administrative Simplification Provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange (HIPAA, 2013). The HIPAA Privacy Rule

provides federal protections for individually identifiable health information held by covered entities (healthcare providers, health plans, and healthcare clearinghouses) and their business associates . The rule also gives patients an array of rights regarding their personal health information. The Privacy Rule permits the disclosure of health information needed for patient care and other important purposes. The Security Rule specifies a series of administrative, physical, and technical safeguards for covered entities and their business associates to use to assure the confidentiality, integrity, and availability of electronic protected health information.

Americans with Disabilities Act (ADA) of 1990

The Americans with Disabilities Act was enacted on July 26, 1990. It prohibits discrimination on the basis of disability in employment, public accommodations, state and local government services, public transportation, and telecommunications. The act prohibits discrimination on the basis of race, color, religion, sex, or national origin. In 1973, Section 504 of the Rehabilitation Act designated the ADA as an "equal opportunity" law for people with disabilities. The provisions dealing with employment and public accommodations are of the greatest interest to healthcare organizations and physicians (ADA, n.d.). Any person who has a record of having or is regarded as having a physical or mental impairment that substantially limits one or more of the person's major life activities, is covered by this act. The Act does not cover persons with sexual behavior disorder, bisexuality, compulsive gambling, use of illegal drugs, exhibitionism, gender identity disorders, homosexuality, kleptomania, pedophilia, psychoactive substance abuse disorders, pyromania, transsexualism, transvestitism, and voyeurism.

The Department of Justice's revised regulations for Titles II and Ill of the Americans with Disabilities Act of 1990 were published in the Federal Register on September 15, 2010. These regulations adopted revised, enforceable accessibility standards called the 2010 ADA Standards for Accessible Design, "2010 Standards." On March 15, 2012, compliance with the 2010 Standards was required for new construction and alterations under Titles II and fil. March 15, 2012, is also the compliance date for using the 2010 Standards for program accessibility and barrier removal (ADA – Title II, 2010) (ADA – TITLE 111, 2010).

LEGISLATION IMPACTING ORGANIZATIONAL ACTIVITIES

Corporate Compliance

Compliance with law and government reg1il;:itions is an expectation for all healthcare organizations. The impetus here has come from onerous penalties applied for violat ions in U.S. Federal and State healthcare programs. For most organizations, however, compliance is an intent arising from its heart: its organizational values and ethics and the commitment of its leaders.

In many organizations, a Chief Compliance Officer is responsible to establish and oversee processes necessary to prevent or quickly identify any inaccurate billing practices or actual misbehavior that might result in errors being investigated as fraudulent practice by the Office of Inspector General

(OIG). Quality professionals and risk management professionals are likely candidates for this role. In many smaller organizations, the Quality Professional will also have the Compliance responsibilities in a combined position.

The definition of compliance is to act in accordance with another's command, request, rule, or wish (Compliance, 2017). In healthcare, this translates to providing billing, reimbursing and monitoring services according to the laws, regulations, administrative rules and guidelines governing the organization.

In 1997, the Columbia/HCA Company was part of a fraud investigation initiated by a number of governmental departments in the United States. Later that year, Rick Scott resigned as Chairman. In May 2000, Columbia/HCA Healthcare Corporation agreed to pay the U.S. Government $745 million to resolve most of several Medicare fraud allegations, including home healthcare issues and laboratory claims billing. The probe first became public in March 1997. The case was settled in 2003 at a reported cost of $2 billion to HCA. This made it the largest fraud settlement in U.S. history (U.S. Dept. of Justice, 2010).

False Claims Act (FCA) of 1863 and 1986

Since the Columbia/HCA case, issues of compliance by healthcare organizations with federal and state regulations, particularly those related to billing and business relationships, has been a top priority for healthcare organizations and the government. The top compliance associated issues prior to the Patient Protection and Affordable Care Act are the False Claims Act (1863) and the False Claims Amendment Act of 1986 (P.L. 99-562) which are the basis for much of the current focus on fraud and abuse. There have been three additional amendments since the 1986 amendments (False Claims Act, 2011).

The Federal False Claims Act (FCA) was signed into law by Abraham Lincoln in 1863 to encourage private persons to report fraud against the Union, particularly war profiteers. Specific intent to defraud was necessary to prosecute. The False Claims Amendment Act of 1986 (P.L. 99-562) allows any citizen to file suit in federal district court against anyone who "knowingly presents" a false or fraudulent claim to the Federal Government (False Claims Act, 2011).

The law has been in effect since Civil War days, but was amended to increase incentives and protections for citizens who report, "crooked government contractors." Legislators became very interested in using the act to reduce false Medicare and/or Medicaid claims. There are those who see the act as an ideal way for healthcare personnel to report fraud when frustrated with the organization's failure to act. The FCA has determined that a pattern or practice that results in overbilling to the Federal Government is sufficient to prosecute a healthcare provider. A person who makes a mistake in the submission of false information does not violate the FCA (False Claims Act, 2011).

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The FCA Provisions note that the information provided by insiders is essential for the government in bringing a fraud action. The 1986 FCA amendments entitle the reporting individual(s) to 15 to 25% when the government intervenes in any litigation. If the government does not intervene and there is a judgment or settlement, the individual(s) is entitled to 25 to 30% of the recovery. The FCA provides for mandatory civil penalties of $5,500 - $11,000 per false claim, plus damages, government costs, and attorneys' fees (False Claims Act, 2011).

To report fraud, the hotline phone number is 1-800-HHS-TIPS (1-800-447-8477) or the individual can go to the website at https://forms.oig.hhs .gov/hotlineoperations/nothhsemployeeen.aspx.

Stark Law

The Stark Law, in three separate provisions, governs physician self-referral for Medicare and Medicaid patients. The law is named for United States Congressman Pete Stark, who sponsored the initial bill. Physician self-referral occurs when a physician refers a patient to another healthcare site or practitioner in which he/she has a financial relationship, such as ownership, investment, or structured compensation arrangement (Stark Law, 2013).

The Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) (P.L. 101-239), known as Stark I, barred self-referrals for clinical laboratory services under the Medicare program, and was in effective as of January 1, 1992. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) (P.L. 103-66), known as Stark II, expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid. Stark II also contained clarifications and modifications to the exceptions in the original law. Minor technical corrections to these provisions were included in the Social Security Amendments of 1994 (P.L. 103-432).

The Stark III final rule was published on September 5, 2007, at 72 FR 51012 in the Federal Register, and it became effective December 4, 2007 . This rule added more clarification as to what referrals are allowed and which ones are prohibited. More specific information regarding the Stark law can be found at www.starklaw.org.

Medicare and Medicaid Patient Protection Act of 1987 (P.L. 100-93)

The Medicare and Medicaid Patient Protection Act of 1987 (MMPPA) (P .L. 100-93) is referred to as the Anti-kickback Statute. The statute provides criminal penalties for certain acts impacting Medicare and Medicaid reimbursable services . Particularly, the statute prohibits the offer (solicitations) or receipt of certain remuneration in return for referrals for or recommending purchase of supplies and services reimbursable under government health care programs. The remuneration offer itself may entice an individual to refer a patient or recommend particular services or supplies to a patient, and is illegal. The Secretary of the Department of Health and Human Services is allowed to establish exceptions,

called safe harbors, to this rule to identify practices that do not violate the Anti-kickback Statute, which can be found at 42 C.F .R. §1001.952.

Compliance Programs

The best source for compliance program templates and guidance is on the Office of Inspector General website (oig.hhs.gov). The most recent addition to the OIG materials for Health Care Boards was published on April 20, 2015, by a collJboration of the OIG, Association of Hec1lthcare Internal Auditors, Healthcare Compliance Association and American Health Lawyers Association, (http://oig.hhs.gov/compliance/compliance-guidanee/docs/Practica 1-Guidanee-far-Hea lth-Care-Boards-on-Complianee-Oversight .pdf).

OIG Compliance Program Guidance

The OIG began publishing guidelines for establishing healthcare compliance programs with clinical laboratories in the *Federal Register* in March 1997. Subsequently compliance program guidance for specific areas (hospitals, home health agencies, third party payers, Medicare Advantage, managed care organizations, durable medical equipment suppliers, physicians in solo and small group practices, nursing homes, hospice, the pharmaceutical industry, and ambulance services) were developed.

According to the OIG, the plan must be unique to the individual entity's needs, exposures, and resources and to its particular corporate structure, mission, and employee composition. Canned or generic compliance programs are not acceptable to O lG (Matos, Heimer, Martin, Michalski, Roach, and Teplitzky, 2015). The Health Care Compliance Association is the professional organization to assist with this aspect of the compliance role. It offers training, certification, and publications committed to improving the quality and recognition of the healthcare compliance indust;y (http://www.hcca-info.org).

Elements of Compliance

To have a truly effective compliance program, organizations will need to create a culture of compliance. This is a top-level commitment, which is part of organizational values, ethics, and infrastructure. It is noteworthy that soon after the initial fraud investigation, Columbia/HCA replaced its chief executive officer, hired a corporate ethics officer, and initiated restructuring of its acquisitions nationwide (U.S. Dept. of Justice, 2010).

The OIG's document defines a comprehensive compliance program consisting of seven mandc1tory elements. Table 5 lists these elements.

Table 5: OIG Comprehensive Compliance Program Essential Elements

OIG Comprehensive Compliance Program Essential Elements
1. Conducting internal monitoring and auditing
2. Implementing compliance and organizational standards
3. Designating a Compliance Officer (not general counsel or CFO) who reports directly to the CEO and governing board
4. Conducting appropriate training and education
5. Responding appropriately to detected offenses and developing corrective action
6. Developing open lines of communication
7. Enforcing disciplinary standards through well-publicized guidelines

Self-Disclosure

If in the event the organization has an issue of non-compliance which could be found during an internal investigation, which could otherwise be reported by a whistle blower, the OIG strongly suggests the organization to do a self-report. The Office of Inspector General (OIG) has several self-disclosure processes that can be used to report potential fraud in Department of Health and Human Services (HHS) programs. Self-disclosures are voluntary and it has helped to decrease the Civil and Monetary Penalties (fines and fees) against an organization (OIG, n.d.).

Note: When self-disclosing, it is important to have your data available and an action plan in place. More information on self-disclosure can be found at http://oig.hhs.gov/compliance/self-disclosure-info/index.asp.

Healthcare Quality Professionals & Compliance Information

Three initial documents for a Healthcare Quality Professional to review are noted below. They focus on the education of the Board of Directors of a healthcare entity. They also give the new quality professional a nice overview of the interconnectivity between the compliance and quality specialties. From the corporate duties of care to monitoring of indicators, these will be good resources to have readily available in your web browser favorites.

- *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors,* OIG and American Health Lawyers Association, 04-02-2003, http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf

- *Corporate Responsibility and Health Care Quality – A Resource for Health Care Boards of Directors,* OIG and American Health Lawyers Association, 09-13-2007, http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFina1%209-4-07.pdf

- *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* OIG, Association of Healthcare Internal Auditors, American Health Lawyers Association and Health Care Compliance Association, 04-20-2015, http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf

The newest guide to assist in the measurement of Compliance was released in 7017. This guide is to help assess the effectiveness of the compliance program.

- Measuring Compliance Program Effectiveness: A Resource Guide
  Issue Date: March 27, 2017 by HCCA-OIG Compliance Effectiveness Roundtable
  Meeting: January 17, 2017 | Washington, DC
  https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide .pdf

National Practitioner Data Bank (NPDB)

The National Practitioner Data Bank (NPDB) is an electric confidential information clearinghouse dedicated to improving healthcare quality, promoting patient safety and preventing fraud and abuse. It contains information submitted from various sources regarding malpractice payments and certain adverse events concerning practitioners, providers, suppliers, and entities such as insurance companies. The reports from the NPDB are utilized by authorized organizations to make licensing, credentialing, privileging, and/or employment decisions . The information provided through the NPDB should be utilized to alert organizations that there may be a problem with the performance of a practitioner, entity, provider, or supplier. Additional information should be sought regarding the issue before a fina l decision is based on this information. Reports are confidential and are only released to organizations as specified in the NPDB regulations. Organizations and individuals who are subjects of these reports are allowed access to their information if they so desire (NPDB, 2015).

Title IV of P.L. 99-660 (HCQIA) led to the NPDB establishment. The HealthCare Quality Improvement Act of 1986 (HCQIA) was designed to protect peer review bodies from damage liability and to prevent incompetent practitioners from changing employers without disclosure of issues with care provision. The final NPDB regulations (45 CFR part 60) were published in the Federal Register in 1989, and opened in 1990 to support peer review and credentialing. Electronic queries were begun in 1992. In 1993, the National Committee for Quality Assurance (NCQA) (see Chapter 6 Regulatory, Accreditation, and External Recognition) adopted standards requiring the HMOs to query the NPDB (NPDB, 2014).

The Healthcare Insurance Portability and Accountability Act of 1996 created the Healthcare Integrity and Protection Data Bank (HIPDB) in order to collect data similar to the NPDB, but concerning fraud and abuse in health insurance and health care delivery. In 1997, the law changed to have the NPDB and the HIPDB coordinate their operations, since the reports received were similar at times. In 2010, the NPDB under Section 1921 expanded information received and distributed to include all licensure

actions taken against all healthcare practitioners and healthcare entities. In 2013, the HIPDB merged into the NPDB, creating one organization with all information collected and transmitted through the NPDB (NPDB, 2014).

The reporting obligations apply to federa l and state agencies, but also include "health plans," broadly defined to include all plans, programs, and organizations that provide health benefits directly or through insurance, reimbursement, or otherwise, including self-insured employers. The required reporting needs to occur on the website within 30 days of the final action, or the close of a monthly reporting cycle, whichever is the later. The information is confidential and access is limited. Table 6 lists the availab le information which may be conveyed to approved entities who query this information. However, hospitals, other health agencies, professiona l societiP.s, and QIOs are not authorized to receive certain adverse action reports as listed in Section 1921.

Table 6: Information Available through Queries to the NPDB (not including exceptions in Section 1921)

Information Available through Queries to the NPDB (not including exceptions in Section 1921}
• Medical malpractice payments
• Certain adverse licensure actions taken by State medical and dental boards
• Certain adverse clinical privileges actions
• Certain adverse professional society membership actions
• DEA controlled-substance registration actions
• Exclusions from Medicare, Medicaid, and other Federal health care programs
• Negative actions or findings by peer review organizations
• Negative actions or findings by private accreditation organizations
• State licensure and certification actions
• Federal licensure and certification actions

Clinical Laboratory Improvement Act (CUA) of 1988

Final regulations were issued for the Clinical Laboratory Improvement Act (CLIA) Legislation (42 U.S.C. 263a) on 2/28/92, most effective on 9/1/92. The Act resulted from a series of Wall Street Journal articles in 1987, exposing lab inaccuracies and fraud, untouched by regulation. The Clinical Laboratory Improvemenl Amendments of 1988 (CUA) regulations include federal standards applicable to all ll.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. The latest changes in the law occurred in 2012 with the passing of The Taking Essential Steps for Testing Act of 2012 (TEST Act). This act, addressed the requirements and enforcement of proficiency testing referral, with an amendment to the CUA 1988's certificate as stated in section 353 of the Public Health Service Act (42 U.S.C. 263a) (CUA, 2017).

Major components of the CUA include requirements and oversight by the Department of Health and Human Services (DHHS), and certification with submission of data on operations and quality activities . Accreditation is obtained through deemed organizations such as the College of American Pathologists (CAP) . The regulations require entities to follow standards involving physical facilities, equipment, quality monitoring policies, and qualifications of lab personnel. DHHS may invoke various penalties for noncompliance.

CMS works a long with the Centers for Disease Control (CDC) and the Federal Drug Administration (FDA) to assure clinical lab qua lity. The CDC's responsibilities for the national CLIA program include (CLIA-CDC, 2017):

- Providing analysis, research, and technical assistance
- Developing technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducting laboratory quality improvement studies
- Monitoring proficiency testing practices
- Developing and distributing professional information and educationa l resources
- Managing the Clinical Laboratory Improvement Advisory Committee (CLIAC)

The most significant aspect of the law is the authorization of DHHS to require proficiency testing for most types of procedures performed in labs. DHHS approves such programs, including that of CAP. DHHS requires an 80% standard, meaning that each test must be accurate in four of five challenges. Previously, C.A.P only required two cha!!enges.

Safe Medical Device Act (SMDA) of 1990 and FDA Safety and Innovation Act (FDASIA) of 2012

The Safe Medical Device Act of 1990 was an update to the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938 and 1976. This act requires reporting within ten (10) work days of any information that reasonably suggests that a medical device has caused, or may have caused, or contributed to a death, serious illness, or serious injury, either to the Food and Drug Administration or the manufacturer. Summary reports must be sent to the FDA on a semi-annual basis; January 31 for the preceding July through December, and July 31 for the preceding January through June (Samuel, 1991) (MDA, 1996).

A device user facility is defined as a hospital, ambulatory surgical fac ility, nursing home, outpatient treatment facility, or outpatient diagnostic facility, which is not a physician's office.

A medical device is any item (other than a drug or biologic) used to diagnose, treat, or prevent a disease, injury or other condition. If failure of diagnostic equipment results in a misdiagnosis or lack of

diagnosis that contributes to a death or serious illness or injury, the diagnostic equipment failure must be reported.

Serious illness or injury means either life-threatening, or resultant permanent impairment, and/or required medical or surgical intervention to prevent permanent impairment.

The primary impact of the 1992 Amendments on user facility reporting was to establish a single reporting standard for user facilities, manufacturers, and importers (MDA, 1992) . The medical device reporting rule published in the December 11, 1995, *Federal Register* Medical Device Reporting (MDR) added further definition to the law (MDA, 1996). This act was last updated in 2012 with the FDA Safety and Innovation Act (FDASIA), and includes the Medical Device User Fee Amendments of 2012 (MDUFA III) as well as other medical device provisions. MDUFA III will be in effect until September 30, 2017. It inc ludes performance goals and user fees paid to the Food and Drug Administration (FDA) by medical device companies when they register and list with the FDA and when they submit an application to market a medical device in the U.S. Other provisions of FDASIA begin immediately. These new amendments change the way the FDA approves clinical trials, provide a new de novo pathway for risk-based classification of devices, expand FDA's post-market surveillance capabilit ies, shorten the timelines for scheduling appeals and issuing decisions, and change the process for reclassification of devices (FDA, 2012).

Resources for the Full Federal Food, Drug and Cosmetic Act (FFDCA):

- 1938 and 1976. Chapter V: Drugs and Devices

  https://www .fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugand CosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm

- 1990 Amendment

  http://thomas.loc.gov/cgi-bin/bdguery/z?d10l:HR03095 :@ @ @ D&summ2=1& ITOM :/bss/dlOlguery.html

- Medical Device Amendments of 1992

  https://www.congress .gov/bill/102nd-congress/senate-bi 11/2783

- 1995 Amendment

  http://www.gpo.gov/fdsys/pkg/FR-1995-12-11/html/95-29906 .htm

- 2012 Amendment

  http://www.gpo.gov/fdsys/pkg/PLAW - 112publ144/pdf/PLAW-112publ144.pdf

Federal Occupational Safety and Health Act (OSHA) of 1970

The Federal Occupationa l Safety and Health Act (OSHA) of 1970 required employers to establish occupat ional safety and health programs and ensure safe and healthful working conditions for employees (OSHA, 2017). Assuring safe and healthful workplaces by setting and enforcing standards, a nd by providing training, outreach, education and assistance is the mission of OSHA. The main component of OSHA law is the General Duty Clause (29 USC 654) that applies to every employer and employee regardless of the type of workplace. It encompasses Lhe basic responsibilities of the employer and the employee .

> *Each employer: (1) shall furnish to each of his employees emplo yment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious ph ysical harm to his emplo yees; (2) shall compl y with occupational safet y and health standards promulgated under this Act.*
>
> *Each employee shall compl y with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act, which are ap plicable to his own actions and conduct* (OSHA – General Clause, 2015, Sec. 5. Duties).

Table 7 displays the top ten OSHA healthcare citations and the amount of penalty fines that were occurred between October 2016 and September 2017 . The figures for other industries can be found on the OSHA website (NAICS, 2017).

Table 7: Top 10 NAICS Code: 62 *Health Care Citations:* October 2016 through September 2017

Top 10 NAICS Code: 62 *Health Care Citations:* October 2016 through September 2017				
Standard	**Citations**	**Inspections**	**Penalty**	**Description**
Total	807	245	$1,663,355	*All Standards cited for Health Care and Social Assistance*
19101030	298	93	$656,120	Bloodborne pathogens
19101200	115	63	$95,836	Hazard Communication
19100132	27	20	$62,852	General requirements
19040039	25	25	$81,435	No Description Found
19100147	23	9	$100,603	The control of hazardous energy (lockout/tagout)
19100134	22	8	$20,565	Respiratory Protection
19101048	20	7	$59,719	Formaldehyde
19100303	19	16	$51,750	General requirements
19100305	18	14	$11,209	Wir ing methods, components, equipment for general use
19040032	15	11	$5,868	Annual Summary

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Adapted from Occupational Safety & Health Administration, NAICS Code: *62* Health Care and Social Assistance Citations (NAICS, 2017)

Most OSHA programs provide free consultation and training in key safety and illness-prevention issues pertinent to the workplace . Some states, including California, administer their own occupational health and safety programs in accordance with provisions of the Federal OSHA. OSHA establishes program structure and operations requirements (e.g. to post the injury logs for 3 months every year starting in February), but permits the state to manage the program, with federal monitoring. These states receive part of program funding from the Federal OSHA agency.

In July 2015, OSHA announced a new initiative that will focus on hospitals and nursing homes to evaluate work-related injuries and illnesses through inspections . The inspectors will focus on musculoskeletal disorders related to patient or resident handling, workplace violence, bloodborne pathogens, tuberculosis, and slips, trips and falls. OSHA considers all of these types of events as mostly preventable (OSHA's Office of Communications, 2015).

This chapter presented an overview of the Legislation that has impacted healthcare through the years. Legislation knowledge involvement is key in quality improvement, and organizations without strong, committed efforts to follow the regulations often find themselves missing something in the programs and processes. As a Quality/UM/RM/PS/accreditation manager you are also must have a working knowledge about the legislative requirements so that you can utilize that expertise and influence that is key to your organization's success.

REMEMBER: *The future of healthcare insurance coverage is expected to be changing with the new Presidential Administration. This chapter is reflective of the current industry as of December 2017. There are several tentative legislative and presidential orders in draft; but nothing absolute. Examples of tentative subjects include; Repeal Replace and Removal of Insurance M andates.*

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1995 Amendment	http://www .gpo .gov/fdsys/pkg/ FR-1995-12-11/htm l/95-29906.htm
2012 Amendment	http://www.gpo.gov/fdsys/pkg/PLAW-1 12publ144/pdf/Pl l1W-112publ144.pdf
ADA – Title II	http://www.ada.gov/regs2010/titlel 1_2010/titlel1_2010_regulations .htm
ADA - Title Ill	http://www.ada.gov/regs2010/title II1_2010/titlel1_2010_regulation s.htm
Ame rican Recovery and Reinvestment Act (ARRA) (P.L. 111-5)	https://www .socialsecurity.gov/OP_Home/comp2/F1 11-005.html
Balanced Budget Act (BBA) (P.L. 105-33)	www.socialsecurity.gov/OP _Ho me/comp2/F105-033.ht ml
Children's Health Insurance Program Reauthorizat ion Act (CHIPRA) (P.L. 111-3)	https://www.socialsecurity.gov/OP_Home/comp2/F1 11-003.html
!CMS Conditions of Participation (CoPs) and Conditions for Coverage (CfCs)	http://www.ems .gov/Regu lations-and-Guidance/Legislation/CFCsAndCoPs/index.htmi
Compliance Programs - Office of the Inspector General (OIG)	http://www.oig.hhs.gov
Compliance Programs - OIG Compliance Program for Healthcare Boards	http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidanee-for-Health-Ca re-Boards-on-Comp lianee-Oversight. pdf
Congress (Public Laws)	http://www.congress .gov
Consolidated Omnibus Budget Reconciliation Act (COBRA)	www.socialsecurity.gov/policy/docs/ssb/v49n8/v49n8p22.pdf
Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors	http://oig.hhs.gov/fra ud/docs/complia nceguidance/040203CorpRes pRsceGuide .pdf

LEGISLATION INITIATIVES

Corporate Responsibility and Healthcare Quality: A Resource for Health Care Boards of Directors	https://oig.hhs.gov/fraud/docs/com plianceguida nee/Corporate Resp onsibilityFinal%209-4-07.pdf
Deficit Reduction Act (ORA) (P.L. 109-171)	https://www .socialsecurity.gov/OP _Home/comp2/F109-171.html
False Claims Act (FCA) of 1863 and 1986 – Fraud Hotline	https://forms.oig.hhs.gov/hot lineoperations/nothhsemployeeen .as px
Federal Drug and Cosmetic Act - 1938 and 1976. Chapter V: Drugs and Devices	https://www.fda.gov/RegulatoryInformation/Laws EnforcedbyFDA/F ederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandD evices/default .htm
Federal Register 2.0	https://www .federa Iregister .gov/
Health Care and Education Reconciliation Act (P.L. 111-152)	http://www.congress.gov/1 11/plaws/publ148/PLAW-111publ148.pdf
Health Maintenance Organization (HMO) Act (P.L. 93-222)	www.ssa.gov/policy/docs/ssb/v37n3/v37n3p35.pdf
Health Insurance Portability and Accountability Act (HIPAA) (P.L. 104-19)	www.socialsecurity.gov/OP _Home/comp2/F104-1 91.html
House of Representatives (Federal Bills & Reports)	http://www.house .gov/
Institute of Medicine - Crossing the Quality Chasm	iom.nationalacademies.org/Reports/2001 /Crossing-the-Quality-Chasm-A-New-Health-System-for-th e-2 st-Century.aspx
Institute of Medicine - To Err is Human	iom.nationa lacadem ies.org/-/media/Files/Report%20Fi les/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20br ief .pdf
Justia U.S. Law (Case Law Resources)	http://law.justia.com
Lexis Nexis (Case Law Resources)	http://lexisnexis.com/
Measuring Compliance Program Effectiveness : A Resource Guide	https://oig.hhs.gov/com plia nce/101/files/HCCA-0 IG-Resource-Guide.pdf
Medical Device Amendments of 1992	https://www.congress.gov/bill/1 02nd-congress/senate-bill/2783
Medicaid System	http://www.medicaid.gov
Medicare Catastrophic Coverage Act (MCCA) (P.L. 100-	www .socialsecurity .gov/OP_H ome/comp2/F100-360.html

360)	
Medicare Improvements for Patients and Providers Act (MIPPA) (P.L. 110-275)	http://www.socialsecurity.gov/OP _Home/comp2/F1 10-275.html
Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (P.L. 108-173)	www .socialsecurity.gov/OP _Home/comp2/F108-1 73.html
New Federal Laws, Regulations & Rules	http://www.regulations.gov
Omnibus Budget Reconciliation Act (OBRA 86) (P.L. 99-509)	www.socialsecurity .gov/OP_Home/comp2/F099-509.html
Omnibus Budget Reconciliation Act (OBRA 87) (P.L. 100-203)	www.socialsecurity .gov/OP_Home/comp2/F 100-203.html
Omnibus Budget Reconciliation Act (OBRA 89j (P.L. 101-239)	www.socialsecurity.gov/OP _Home/comp2/F101-239.html
Omnibus Budget Reconciliation Act (OBRA 93) (P.L. 103-66)	www.socialsecurity .gov/OP_Home/com p2/F103-066 .html
OIG Compliance Program Guidance – Health Care Compliance Association	http://www .hcca-info.org
OSHA	https://www.osha.gov/pls/imis/industryprofile.stand?p_stand=Total &p_state=FEFederal&p_type=2&p_esize=
Patient Protection and Affordable Care Act of 2010 (PPACA) or (ACA) (P.L. 111-148)	http://www.socialsecurity.gov/OP _Home/comp2/F1 11-l48.html
Patient Safety and Quality Improvement Act (PSO Act) (P.L. 109-41)	www.socialsecurity.gov/OP _Home/comp2/F109-091 .html
Patient Self-Determination Act (PSDA) (P.L. 101-508, Part of OBRA 90)	www.socialsecurity .gov/OP_Home/comp2/F101-508.html
Practical Guidance for Health Care Governing Boards on Compliance Oversight	http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guida nce-for-Hea lth-Care-Boards-on-Com plianee-Oversight .pdf
Professional Standards Review Organizations (PSROs)	www .ssa.gov/po1icy/docs/ssb/v36n3/v36n3p3.pdf

LEGISLATION INITIATIVES

Prospect ive Payment System (PPS)	https://www.ems.gov/M edicare/Medica re-Fee-for-Serv ice-Payment/ProspMedicareFeeSvcPmtGen/index.html
Provisions - PPACA Modifications	http://www.hhs .gov/healthcare/facts/time line/timeline-text.html
Provisions - Preventive Services Taskforce	http://www.uspreventivese*rv i* cestaskfo rce.org/Page/N ame/uspstf-a-a nd-b-reco mmendations-by-date/
Regulations associated with the Social Security Administration	https://www.socialsecurity.gov/OP _Home/comp2/comp2toc.html
Revisions to the Conditions of Participation and Conditions for *Coverage*	https://www.cms.gov/Regulations-and-Guidance/Legislatio n/CFCsAndCo Ps/1ndex.html
Safe Medical Device Act (SMDA) (P.L. 101-629)	www.gpo.gov/fdsys/pkg/ST ATUTE-100/pdf/STATUTE - 100-Pg3153.pdf
Self-Disclosure	http://oig.hhs.*gov* /comp lia nee/se lf-disclosure-info/index.asp
Senate (Federal Bills & Reports)	http://www.senate.gov /
Social Security Act (Title XVII and XIX)	www.ssa.gov/po1icy/docs/ssb/v28n9/v28n9p3.pdf
Social Security Act of 1935	www.ssa .gov/history/3 5act.html
Socia l Security Administration Regulations	https://www.ssa.gov/OP _Home/comp2/comp2toc.htm l
Stark law	http://www.starklaw .org
Tax Equity and Fisca l Responsibility Act (TEFRA)(P.L. 97-248)	www.socialsecurity .gov/OP_Home/comp2/F097-248.html
Tax Relief and Health Care Act (TRHCA) (P.L. 109-432)	http://www.socialsecurity.gov/OP _Home/comp2/F109-432.html
Ten Areas of PPACA – Health Insurance Marketplace	https://www.Hea lthCa re.*gov*
Title VI of Social Security Amendments (P.L. 98-21) - Prospective Payment System	www.ssa.gov/OP_Home/comp2/F098-021.html
Westlaw (Case Law Resources)	http://www.westlaw .com/

Certified Professional in Healthcare Quality
Detailed Content Outline

(Adapted from http://cphq.org/UPLOADS/certification/CPH(l_Content_out!ine_-_effective_01-2018.pdf)

1. Organizational Leadership (35 items)

A. Structure and Integration

1. Support organizational commitment to quality
2. Participate in organization-wide strategic planning related to quality
3. Align quality and safety activities with strategic goals
4. Engage stakeholders to promote quality and safety (e.g., emergency preparedness, corporate compliance, infection prevention, case management , patient experience, provider network, vendors)
5. Provide consultative support to the governing body and clinical staff regarding their roles and responsibilities (e.g., credentialing, privileging, quality oversight, risk management)
6. Facilitate development of the quality structure (e.g., councils and committees)
7. Assist in evaluating or developing data management systems (e.g., data bases, registries)
8. Evaluate and integrate external best practices (e.g., resources from AHRQ, IHI, NQF, WHO, HEDIS, outcome measures)
9. Participate in activities to identify and evaluate innovative solutions and practices
10. Lead and facilitate change (e.g., change theories, diffusion, spread)
11. Participate in population health promotion and continuum of care activities {e.g., handoffs, transit ions of care, episode of care, outcomes, healthcare utilization)
12. Communicate resource needs to leadership to improve quality (e.g., staffing, equipment, technology)
13. Recognize quality initiatives impacting reimbursement (e.g., pay for performance, value-based contracts)

B. Regulatory, Accreditation, and External Recognition

1. Ass ist the organization in maintaining awareness of statutory and regulatory requirements (e.g., CMS, HIPAA, OSHA, PPACA)
2. Identify appropriate accreditation, certification , and recognition options (e.g., AAAHC, CARF, DNV GL, ISO, NCQA, TJC, Baldrige Magnet)
3. Assist with survey or accreditation readiness
4. Participate in the process for evaluating compliance with internal and external requirements for :

a. clinical practice guidelines and pathways (e.g., medication use, infection prevention)
b. service quality
c. documentation
d. practitioner performance evaluation (e.g., peer review, credentialing, privileging)
e. gaps in patient experience outcomes (e.g., surveys, focus groups, teams, grievance, complaints)
f. identification of reportable events for accreditation and regulatory bodies

5 Facilitate communication with accrediting and regulatory bodies

C. Education, Training, and Communication

1. Design performance, process, and quality improvement training
2. Provide education and training on performance, process, and quality improvement (e.g., including improvement methods, culture change, project and meeting management)
3. Evaluate effectiveness of performance/quality improvement training
4. Develop/provide survey preparation training (e.g. accreditation, licensure, or equivalent)
5. Disseminate performance, process, and quality improvement information within the organization

2. Health Data Anaiytics (30 items)

A. Health Data Analytics

1. Maintain confidentiality of performance/quality improvement records and reports
2. Design data collection plans:
    a. measure development (e.g., definitions, goals, and thresholds)
    b. tools and techniques
    c. sampling methodology
3. Participate in identifying or selecting measures (e.g., structure, process, outcome)
4. Assist in developing scorecards and dashboards
5. Identify external data sources for comparison (e .g., benchmarking)
6. Collect and validate data

B. Measurement and Analysis

1. Use data management systems (e.g., organize data for analysis and reporting)
2. Use tools to display data or evaluate a process (e.g., Pareto chart, run chart, scattergram, control chart)
3. Use statistics to describe data (e.g., mean, standard deviat ion, correlation, t-test)

4. Use statistical process control (e.g., common and special cause variation, random variation, trend analysis)
5. . Interpret data to support decision-making
6. Compare data sources to establish benchmarks
7. Participate in external reporting (e.g., core measures, patient safety indicators, HEDIS bundled payments)

3. Performance and Process Improvement (40 items)

A. Identifying Opportunities for Improvement

1. Facilitate discussion about quality improvement opportunities
2. Assist with establishing priorities
3. Facilitate development of action plans or projects
4. Facilitate implementation of performance improvement methods (e.g., Lean, PDCA, Six Sigma)
5. Identify process champions

B. Implementation and Evaluation

1. Establish teams, roles, responsibilities, and scope
2. Use a range of quality tools and techniques (e.g. fish bone diagram, FMEA, process map)
3. Participate in monitoring of project timelines and deliverables
4. Evaluate team effectiveness (e.g., dynamics, outcomes)
5. Evaluate the success of performance improvement projects
6. Document performance and process improvement results

4. Patient Safety {20 items)

A. Assessment and Planning

1. Assess the organization's culture of safety
2. Determine how technology can enhance the patient safety program (e.g., electronic health record (EHR), abduction/elopement security systems, smart pumps, alerts)
3. Participate in risk management assessment activities (e.g., identification and analysis)

B. Implementation and Evaluation

1. Facilitate the ongoing evaluation of safety activities
2. Integrate safety concepts throughout the organization 3. Use safety principles:
    a. human factors engineering

b. high reliability

c. systems thinking

4. Participate in safety and risk management activities related to:

a. incident report review (e.g., near miss and actual events)

b. sentinel/unexpected event review (e.g., never evets)

c. root cause analysis

d. failure mode and effects analysis

ACRONYMS AND ABBREVIATIONS

The following acronyms and abbreviations are used throughout the 30th Edition of **THE Janet A. Brown HEALTHCARE QUALITY HANDBOOK:A PROFESSIONAL RESOURCE AND STUDY GUIDE.**

ACRONYM	FULL NAME
AAAHC	American Association for Ambulatory Health Care
AABB	Association of Blood Banks
AAHCC	American Accreditation Health Care Commission
ABMS	American Board of Medical Specialties
ABQAURP	Healthcare Quality & Management Certification
ACA	Affordable Care Act shortened from Patient Protection and Affordable Ca re Act
ACE	Array of Clinical Evidence (ACE Star Model)
ACHC	Accreditation Commission for Health Care
ACO	Accountable Care Organization
ACS	American College of Surgeons
ACTION Ill	Accelerating Change & Transformation in Organizations & Networks Ill
ACUG	Accreditation and Certification Users Group
ADA	Americans with Disabilities Act
ADE	Adverse Drug Event
ADL	Activities of Daily Living
ADLI	Approach, Deployment, Learning, Integration
AE	Adverse Event
AHIMA	American Health Information Management Associat ion
AHRQ	Agency for Healthcare Research and Quality
ALOS	Average Length of Stay
AMA	Against Medical Advice
AMA	American Medical Assoc iation
AMI	Acute Myocardial Infraction
ANA	American Nurses Association
ANCC	American Nurses Credential ing Center
ANSI	American National Standards Institute [ISO]
AOA	American Osteopathic Association
AORN	Association of Operating Room Nursps
AP	Advance Payment ACO Model
APM	Advanced Alternative Payment Model
APO	Adverse Patient Occurrence
AQA	Ambulatory Care Quality Alliance
ARRA	American Recovery and Reinvestment Act (2009)
ASC	Ambulatory Surgery Center
ASHRM	Amer ican Society for Healthcare Risk Management
ASPE	Assistant Secretary for Planning and Evaluation

ASQ	American Society for Quality
ASR	Acute Stroke Ready
AUG	Accreditation User Group
BBA	Balanced Budget Act (1997)
BBRA	Balanced Budget Refinement Act (1999)
BCMA	Bar-Code Medication Administration
BFCC	Beneficiary and Family Centered Care
BHI	Behavioral Ilealth Integration
BIPA	Benefits Improvement and Protection Act (2000)
BPMN	Business Process Modeling Notation
BPOC	Barcode Point Of Care (alternative to BCMA)
BPRP	Back Pain Recognition Program
CABG	Coronary Artery Bypass Graph
CAC	Children's Asthma Care
CAH	Critical Access Hospital
CAHPS	Consumer Assessment of Healthcare Providers and Systems Survey
CAHQ	Council for Affordable Healthcare
CAP	College of American Pathologists
CAPS	CAPITAL LETIERS
CARF	Commission on Accreditation of Rehabilitation Facilities
CAUTI	Catheter-associated Urinary Tract Infection
CCA	Care Area Assessment
C-CDA	Consolidated-Clinical Document Architecture
CCMC	Commission for Case Manager Certification
CCRC	Continuing Retirement Communities
CDC	Centers for Disease Control and Prevention
C. *diff*	*Clostridium difficile*
CDS	Controlled Dangerous Substances
CDSS	Clinical Decision Support System
CE	Continuing Education
CEC	Content Expert Certification
CEHRT	Certified Electronic Health Record Technology
CEO	Chief Executive Officer
CfCs	Conditions for Coverage [CMS]
CFO	Chief Financial Officer
CFTH	Center for Transforming Healthcare
CG-CAHPS	CHAPS Clinician & Group Survey
CHAC	Community Health Accreditation Commission
CHAP	Community Health Accreditation Program
CHCQM	Health Care Quality and Management Certification
CHF	Congestive Heart Failure
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act (CHIPRA)
CHIRI	Child Health Insurance Research Initiative

CHNA	Community Health Needs Assessment
CI	Confidence Interval
CIHQ	Center for Improvement in Healthcare Quality
CIO	Chief Information Officer
CLABSI	Central Line Associated Blood Stream Infection
CLIA	Clinical Laboratory Improvement Act (1988)
CM	Care Management or Case Management
CMHC	Community Mental Health Center
CMO	Chief Medical Officer
CMQ/OE	Certified Manager of Quality/Organizational Excellence
CMS	Centers for Medicare and Medicaid Services
CMSA	Case Management Society of America
CNA	Certified Nursing Assistant
CNO	Chief Nursing Officer
COO	Chief Operations Officer
COPD	Chronic Obstructive Pulmonary Disease
COPQ	Cost OF Poor Quality
CoPs	Condition of Participation [CMS]
COQ	Cost Of Quality
CORE	Committee on Operating Rules for Information Exchange
CORF	Comprehensive Outpatient Rehab Facility
CPA	Critical Path Analysis
CPG	Clinical Practice Guideline
CPHQ	Certified Professional in Healthcare Quality
CPK	Core Body of Knowledge
CPM	Critical Path Method
CPOE	Computerized Physician Order Entry
CPR	Cardio-Pulmonary Resuscitation
CPT	Current Procedural Terminology
CQI	Continuous Quality Improvement
CR	Credentialing
CRM	Crew Resource Management
CRNA	Certified Registered Nurse Anesthesiologist
CSC	Comprehensive Stroke Center
C-Suite	Chief Officers Offices (CEO, CNO, COO, etc.)
CT	Clinical Trial
CTO	Chief Technology Officer
CTQ	Critical To Quality [Six Sigma]
CUSP	Comprehensive Unit-based Safety Program
CVO	Credentials Verification Organization
CY	Calendar Year
DC	Doctor of Chiropractic
DDS	Dentist
DEA	Drug Enforcement Agency

df	Degrees of Freedom
DHHS	Department of Health and Human Services
DM	Disease Management
DMAIC	Define, Measure, Analyze, Improve, Control [Six Sigma]
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DNR	Do Not Resuscitate
DNV GL	Det Norske Veritas
DO	Doctor of Osteopathy
DoD	Department of Defense
DON	Director of Nursing
DPM	Doctor of Pediatric Medicine (Podiatrist)
DRA	Deficit Reduction Act (2005)
DRG	Diagnostic Related Group
DRIP	Data-Rich, Information-Poor
DRP	Diabetes Recognition Program
EBP	Evidence-Based Practice
EC	European Commission
ECFMG	Educational Commission for Foreign Medical Graduates
ECHO	Experience of Care and Health Outcomes [Behavioral Health CAHPSJ
eCQM	Electronic Communication of Quality Measures
ECRI	Emergency Care Research Institute
ED	Emergency Department
EDI	Electronic Data Interchange
EEOA	Equal Employment Opportunity Act
EEOC	Equal Employment Opportunity Commission
EFQM	European Foundation for Quality Management
EH	Eligible Hospital
EHB	Essential Health Benefits
EHDI	Early Hearing Detection and Intervention
EHR	Electronic Health Record
EIM	Electronic Information Management
EM	Emergency Medicine
eMAR	Electronic Medication Administration Record
EMR	Electronic Medical Record
EOC	Environment of Care
EP	Eligible Professional
EPC	Evidence-based Practice Center
ePHI	Electronic Protected Health Information
ERM	Enterprise Risk Management
ESRD	End-Stage Renal Disease
f	Frequency
FCA	False Claims Act (1863) and Amendments (1986)
FDA	Food and Drug Administration

FDASIA	FDA Safety and Innovation Act of 2012
FFDCA	Federal Food, Drug and Cosmetic Act
FMEA	Failure Mode and Effects Analysis
FOCUS-POCA	Find, Organize, Clarify, Understand, Select-POCA
FPL	Federal Poverty Level
FPPE	Focused Professional Practice Evaluation
FSMB	Federation of State Medical Boards
FTE	Full-Time Equivalent
FY	Fiscal Year
F/U	Follow-Up
GB	Govern ing Body
GI	Gastrointestinal
GPRO	Group Practice Reporting Option
HAC	Healthcare/Hospital-Acquired Condition
HAI	Healthcare-Associated Infection
HBIPS	Hospital Based Inpatient Psychiatric Services
HBS	Harvard Business School
HCA	Healthcare Corporation of America
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey
HCBS	Home & Community-Based Services
HCERA	Health Care and Education Reconciliation Act
HCFA	Health Care Financing Administration
HCQIA	Health Care Quality Improvement Act (1986)
HCQM	Health Care Quality Management
HEDIS	Healthcare Effectiveness Data and Information Set
HEW	Health Education and Welfare
HFACS	Human Factors Analysis and Classification Systems
HFAP	Healthcare Facilities Accreditation Program
HFE	Human Factors Engineering
HFMEA	Healthcare Failure Mode and Effects Analysis
HHA	Home Health Agency
HHCAHPS	Home Health Consumer Assessment of Healthcare Providers and Systems Survey
HHS	Health and Human Services
HIE	Health Information Exchange
HIM	Health Information Management
HIO	Health Information Organization
HIP	Health Information Products
HIPAA	Health Insurance Portability and Accountability Act
HIPDB	Healthcare Integrity and Protection Data Bank
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health (HITECH) Act
HKRC	Hip & Knee Replacement Certification
HL7	Health Level Seven: international healthcare standards for electronic

	information interchange between computer systems
HMO	Health Maintenance Organization
HP	Health Plan
HPS	Healthcare Personnel Safety
HQ	Healthcare Quality
HQCC	Healthcare Quality Certification Commission
HR	Human Resources
HRET	Health Research and Educational Trusl
HRSA	Health Resources and Service Administration
HSRP	Heart/Stroke Recognition Program
IAP	International Accreditation Program [ISQua]
IC	Infection Control
ICD-10	International Classification of Diseases - 10
ICD-10 CM	ICD-10 Care Management Codes
ICD-10-PCS	ICD-10 Procedure Codes
ICF/IID	Intermediate Care Facility for Individuals with Intellectual Disabilities
ICM	Intra-cycle Monitoring
IC&P	Infection Control & Prevention
ICU	Intensive Care Unit
ID	Identification
IDN	Integrated Delivery Network
IDS	Integrated Delivery System
IHI	Institute for Healthcare Improvement
IM	Information Management
IMM	Immunization
IOM	Institute of Medicine
IPA	Independent Practice Association
I-PASS	Illness severity, Patient summary, Action list, Situation awareness and Contingency planning, Synthesis by receiver
IPPS	Inpatient Prospective Payment System
IQR	Inpatient Quality Reporting
IQR	Interquartile Range (Interpercentile)
IRF	Inpatient Rehabilitation Facility
IRO	Independent Review Organization
IRS	Internal Revenue Services
IS	Information System
ISBAR	Introduction, Situation, Background, Assessment, Recommendation
ISMP	Institute for Safe Medical Practices
ISO	International Organization for Standardization
ISQua	International Society for Quality in Health Care
IT	Information Technology
IV	Intravenous
JCAHO	See TJC
KSA	Knowledge, Skill, & Attitude

LASA	Look-Alike, Sound-Alike [medication names]
LCL	Lower Control Limit
LO	Leadership
LeTCI	Levels, Trends, Comparisons, Integration
LIP	Licensed Independent Practitioner
LOC	Level of Care
LOS	Length of Stay
LPN	Licensed Practical Nurse
LTC	Long-Term Care
LTCH	Long Term Care Hospital
LVN	Licensed Vocational Nurse
LWOBS	Left Without Being Seen
M	Mean
MACRA	Medicare Access & CHIP Reauthorization Act of 2015
MBHO	Managed Behavioral Healthcare Organization
MCCA	Medicare Catastrophic Coverage Act (MCCA)
MCD	Managed Care Organization
M&E	Monitoring and Evaluation
MD	Medical Doctor
MDA	Medical Device Act
MOR	Medical Device Reporting
MORO-CO i	Mulitdrug-Resistant Organism - *Clostridium difficile* Infection
MOS	Minimum Data Set
MEC	Medical Executive Committee
MHC	Multicultural Health Care
MIP	Merit-based Incentive Payment System
MIPPA	Medicare Improvements for Patients and Providers Act (2008)
MIR	Managing Infection Risk
M&M	Morbidity/Mortality
MMPPA	Medicare and Medicaid Patient Protection Act of 1987
MPC	Measurement Policy Council
MPFS	Medicare Part B Physician Fee Schedule
MPI	Master Patient Index
MRSA	Methicillin-Resistant Staphylococcus Aureus
MS	Medical Staff
MSO	Management Services Organization
MSSP	Medicare Shared Savings Programs
MU	Meaningful Use
n	Number in the Sample
N	Total Number
NAHQ	National Association for Healthcare Quality
NAICS	North American Industry Classification System
NASWHP	National Association of Sheltered Workshops and Homebound Programs
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention

NCMEC	National Center for Missing and Exploited Children
NCPS	National Center for Patient Safety [VA]
NCQA	National Committee for Quality Assurance
n.d.	No date
NDNQI	National Database of Nursing Quality Indicators
NFPA	National Fire Protection Agency
NGC	National Guidelines Clearinghouse
NHIN	National Health Information Network
NHP	New Health Plans
NHPPD	Nursing Hours Per Patient Day
NHQI	Nursing Home Quality Initiative
NHSN	National Healthcare Safety Network [CDC]
NIST	National Institute of Standards and Technology
NLC	National Learning Consortium
NLN	National League for Nursing
NLRB	The National Labor Relations Board
NPDB	National Practitioner Data Bank
NPSD	Network of Patient Safety Databases [AHRQ]
NPSF	National Patient Safety Foundation
NPSG	National Patient Safety Goal
NPUAP	National Pressure Ulcer Advisory Panel
NQF	National Quality Forum
NQMC	National Quality Measures Clearinghouse
NQS	National Quality Strategy
NTOCC	National Transitions of Care Coalition
OAS CAHPS	Outpatient Ambulatory Surgery
OASDI	Old Age, Survivors, and Disability Insurance
OASIS	Outcome and Assessment Information Set
OBRA	Omnibus Budget Reconciliation Acts (1980s and 1990s)
ODPHP	Office of Disease Prevention and Health Promotion
OIG	Office of Inspector General
OP	Outpatient
OPPE	Ongoing Professional Practice Evaluation [TJC]
OPS	Organ Procurement Organization
OR	Operating Room
ORYX	Joint Commission's Core Measures Program
OSHA	Occupational Safety and Health Act (1970)
OT	Occupational Therapist
P4P	Pay For Performance (also VBP)
PACE	Programs for All-Inclusive Care for the Elderly
PACU	Post Anesthesia Care Unit
PAR	Post Anesthesia Room
PBRN	Public Care Practice Based Research Networks
PC	Perinatal Center

PCA	Patient Care Assistant
PCE	Potentially Compensable Event
PCMH	Patient-Centered Medical Home
PCP	Primary Care Practitioner
PCS	Primary Stroke Center
PCSP	Patient-Centered Specialty Practice
PDC	Proportion of Days Covered
POCA	Plan-Do-Check-Act
PDC/SA	Plan Do Check/Study Act
PDSA	Plan-Do-Study-Act
PERT	Program Evaluation Review Technique
PHAB	Public Health Accreditation Board
PHF	Public Health Foundation
PHI	Protected Health Information
PHO	Physician-Hospital Organization (joint venture)
PHQ	Physician and Hospital Quality
PHR	Personal Health Record
PI	Performance Improvement
PICO	Problem, Intervention, Comparison, Outcome
PICOT	Problem, Intervention, Comparison, Outcome, Time
PITL	Point Interval Temporal Logic
PIV	Peripheral IV
p.L.	Public Law
POA	Plan Of Action
POA	Present On Admission
POS	Point of Service
PPACA	Patient Protection and Affordable Care Act
PPO	Preferred Provider Organization
PPS	Prospective Payment System (Medicare in USA)
PPSA	Pennsylvania Patient Safety Authority
PQRI	Physician Quality Reporting Initiative [CMS]
PQRS	Physician Quality Reporting System
PRO	Peer Review Organizations
PS	Patient Safety
PSDA	Patient Self-Determination Act (1990)
PSI	Patient Safety Indicator (AHRQ)
PSNet	Patient Safety Network (AHRQ)
PSO	Patient Safety Officer
PSO	Patient Safety Organization
PSOPPC	Patient Safety Organization Privacy Protection Center
PSP	Patient Safety Practice
PSQIA	Patient Safety and Quality Improvement Act of 2005
PSRO	Professional Standards Review Organizations
P&T	Pharmacy and Therapeutics Committee

PT	Physical Therapist
PVBP	Physician and other Professional Services Value-Based Purchasing (PVBP) Plan [CMS]
QA	Quality Assurance
QA & I	Quality Assurance and Improvement
QAO	Quality Assessments Only
QAPI	Quality Assessment and Performance Improvement (QAPI) Program (CMS)
QI	Quality Improvement
QIN	Quality Innovation Network
QIO	Quality Improvement Organization
QI/PI	Quality Improvement/Performance Improvement
QM	Quality Management
QM/PI	Quality Management/Performance Improvement
QM/QI/PI	Quality Management/Quality Improvement/Performance Improvement
QM/RM	Quality Management/Risk Management
Q/PI*	Quality/Performance Improvement
QPS	Quality and Patient Safety
Q/R/U	Quality/Risk/Utilization
QRM	Quality Resource Management
QRP	Quality Reporting Program
QSEN	Quality & Safety Education for Nurses
r	Correlation Coefficient
RAI	Resident Assessment Instrument
RCA	Root Cause Analysis
RCA^2	RCA Squared
RCT's	Random Control Trials
RFI	Request For Information
RFID	Radio Frequency Identification
RFP	Request For Proposal
RHICs	Regional Health Improvement Collaboratives
RHIO	Regional Health Information Organization
RM	Risk Management
RN	Registered Nurse
ROI	Return on Investment
RPI	Robust Process Improvement
RPN	Risk Priority Number [FMEA]
RWJF	Robert Wood Johnson Foundation
SAFER	Survey Analysis for Evaluating Risk
SBAR	Situation, Background, Assessment, Recommendation
SBMH	School Based Medical Home Program
SCHIP	State Children's Health Insurance Program
SCIP	Surgical Care Improvement Project
SD or 1	Standard Deviation
SE	Sentinel Event

SIMS	Surgical Indications Monitoring [InterQual criteria]
SIPOC	Supplier, Input, Process, Output, and Customer
SMDA	Safe Medical Devices Act (1990)
SNA	State Nurses Association
SNF	Skilled Nursing Facility
SOP	Standard Operating Procedure
sow	Scope of Work (CMS Contract with QIO's)
SPC	Statistical Process Control
SRE	Serious Reportable Event
SSM	Summary Survey Measures
STEMI	Segment Elevation Myocardial Infarction
STK	Stroke
SUB	Substance Use
SWOT	Strengths, Weaknesses, Opportunities, Threats
t	t-Test
TB	Tuberculosis
TeamSTEPPS	Team Strategies and Tools to Enhance Performance and Patient Safety
TEFRA	Tax Equity and Fisca l Responsibility Act (TEFRA)
Test Act	Taking Essential Steps for Testing Act of 2012
TJC	The Joint Commission
TNA	Texas Nurses Association
TOB	Tobacco Treatment
TQM	Total Quality Management
TR HCA	Tax Relief and Health Care Act
TPS	Total Percentage Score
UAP	Unlicensed Assistive Personnel
UCL	Upper Control Limit
UM	Utilization Management
UM/CR	Utilization Management and Credentialing
UMLAD	Unified Modeling Language Activity Diagram
URAC	Utilization Review Accreditation Commission
U.S.	United States
USP	United States Pharmacopeia
UTI	Urinary Tract Infection
VA	Veterans Affairs / Veterans Administration
VA/DoD	Veterans Affairs/Department of Defense
VAP	Ventilator Associated Pneumonia
VBAC	Vaginal Birth After Caesarian (Section)
VBP	Value-Based Purchasing (also P4P)
VHA	Veterans Health Administration
VTE	Venous Thrombosis
WAPS	World Alliance for Patient Safety
WHP	Wellness & Health Promotion
WHO	World Health Organization

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GLOSSARY:

HANDBOOK TERMS AND WORKING DEFINITIONS

The following terms are used throughout this 30TH Edition of THE Janet A. Brown HEALTHCARE QUALITY HANDBOOK: A PROFESSIONAL RESOURCE AND STUDY GUIDE.

Accountable Care Organization (ACO): Groups of doctors, hospitals, and other health care providers, who work together to give coordinated high quality care to their patients, at lower costs.

Accreditation: A voluntary survey process used by various independent, non-governmental external agencies to assess the extent of a healthcare organization's compliance with applicable pre-established performance standards set by the agency. Accreditation involves both self-assessment and external peer review, focusing on organizational, not individual practitioner, performance. Purpose: Improve the systems and processes of care (performance) and, in so doing, improve patient outcomes.

Adverse Event: Unintended injury to a patient resulting from a medical intervention [IOM Report *To Err is Human],* generally with lesser degree of severity that may be a precursor to a sentinel event.

Affinity Diagram: An organizational tool most often used at the beginning of a team's work to organize large volumes of ideas or issues into major categories.

Aggregation: Combining standardized data; gathering into a mass, sum, or whole.

Alignment: The translation of the work of each person into its proper relative position with the organization's strategic goals. Alignment in healthcare means that all the systems, functions, processes, process steps, departments, units, and people in the organization are working together, in synchrony with mission, vision, values, and strategic direction, to serve the key customer-the patient.

Ambulatory Care: All healthcare that is provided to patients who are not residing in healthcare institutions at the time the care is rendered.

Analysis: The translation of data collected during the monitoring process, through aggregation and interpretation, into information about the organization's level of performance along many dimensions, over time, and, where possible, compared to similar organizations, that can be used to change processes and improve performance.

Appeal: A request to change a previous decision made by the organization.

Application Software: A program, such as a word processor or spreadsheet that performs some specific useful task; an application of the computer to a particular area or need.

Appointment: Selection for membership in a medical/professional staff (e.g., hospital or medical group) or to a practitioner panel (e.g., preferred provider organization).

Appraisal: Initial evaluation by peers of a practitioner's competency to provide care and services to patients in or for a healthcare organization . Appraisal may include credentialing, privileging, proctoring, and appointment [See this Glossary for definitions].

Appropriateness: The degree to which care is "correct" and relevant to the patient's clinical needs, given the current state of knowledge.

Availability: The degree to which appropriate care is accessible and obtainable to meet the patient's needs.

"Balanced Scorecard": A performance measurement system based on and organized around the organization's strategic plan; a translation of mission, vision, and strategy into a balanced set of top-level-approved financial and non-financial measures that drive organ;zational change and improvement.

Baldrige Performance Excellence Program: An award program to identify and recognize role-model

businesses, to establish criteria for evaluating improvement efforts, and to disseminate and share best practices.

Benchmark: A comparative "best" as levelfor improvement.

Benchmarking: The continual process of measuring practices and services against the performance of recognized leaders at a particular function, regardless of "industry standard".

Beneficiary and Family Centered Care (BFCC) : Division of the QIO that performs statutory review functions, including complaints and quality of care reviews for people with Medicare.

Best Practice:

- A process, technique, or innovation producing superior results and driving best performance, with demonstrated improvement in quality,cost, safety, or other key organizat ion measures.
- The methods or steps used in a process, the outputs of which best meet customer requirements.

Brainstorming: A structured group process used to create as many ideas as possible in as short a time as possible,e.g., one session, and to elicit both individual and group creativity.

Breakthrough: Any sudden or significant solution to a problem that leads to further advances. It may be used in healthcare as a synonym for innovation or significant improvement, progress, or advance.

Capitation: Prepayment for services with a fixed number of dollars per member per month (PMPivi) on a per-person rather than a per-procedure basis, regardless cf the amount of care the member/patient receives.

Catheter-associated Urinary Tract Infection (CAUTI): A urinary-track infection resulting from an indwelling foley catheter.

Cause-and-Effect Diagram: A tool generally used to gather all possible causes as an overview, the ultimate goal being to uncover the root cause(es) of a problem.

Center for Improvement in Healthcare Quality (CIHQ): Accreditatio n agency with deemed status that accredits hospitals and other types of healthca re facilities.

Central Line Associated Blood Stream Infection (CLABSI) : A laboratory confirmed bloodst ream infection in a patient with a central line.

Central Processing Unit (CPU): The brain of the computer that processes instructions and manages the flow of information through a computer system .

Checklist/Task List: A listing of things to do or obtain in order to keep the team on schedule, to help team members remember commitments, or to inventory information.

Clinical Path: A prospective,detailed, strategic treatment regimen, or daily/intermittent protocol for patient care, designed to identify and integrate key activities, interventions, and services for certain patient conditions. Clinical paths are applicable across the continuum of care, e.g.,in acute care from pre-admission and pre-operative treatment through the hospital stay to discharge and post-discharge phases of care, including home care. Clinical/critical paths are designed to include clinical performance criteria for specified time periods or intervals,organized by categories of care needs, e.g., diagnostics,treatments, activity, medications, psychosocial, etc. They are useful tools for measuring actual performance.

Commission for Accreditation of Rehabilitation Facilities (CARF): Accreditation agency with deemed status that accredits rehabilitation hospitals and other types of healthcare facilities.

Communication: The act and art of giving and/or receiving information;a message.

Community Health Information Networks (CHINs): Networks forming to exchange data electronically among computer systems of various healthcare financing and delivery organizations in a defined geographic region.

Comorbidities: "Specific patient conditions that are secondary to the patient's primary diagnosis and

require treatment during the stay....Comorbid conditions must **co-exist at the time of admission,** develop subsequently, and affect the treatment received, the length of stay, or both treatment and length of stay." [Centers for Medicare and Medicaid Services (CMS)]

Competence: Job knowledge (understanding of facts and procedures), skills (performance of specific actions), and related behaviors (e.g., ability to work in teams).

Competency: The individual's ability to produce both the health and satisfaction of patients, as applicable, and meet the needs and expectations of other customers; the performance equivalent to stated requirements and to professional standards of care and practice.

Complaint: An oral or written expression of dissatisfaction. A person "registers" a complaint.

Complex Adaptive System: "*... a dynamic network of many agents...constantly acting and reacting to what the other agents are doing.... The overall behavior of the system is the result of a huge number of decisions made every moment by many individual agents."* [John J. Holland in *Complexity: The Emerging Science at the Edge of Order and Chaos* by M. Mitchell Waldrop].

Compliance: To act in accordance with another's command, request, rule, or wish. In healthcare, this translates to providing, billing, reimbursing and monitoring services according to the laws, regulations, administrative rules and guidelines governing the organization.

Complications: Concurrent diseases, accidents, or adverse reactions that aggravate the original disease **not present on admission** that may or may not have been preventable.

Conditions for Coverage (CfCs): Requirements that CMS has established that healthcare organizations must meet to participate in the Medicare and Medicaid programs.

Conditions of Participation (CoPs): Requirements that CMS has established that healthcare organizations must meet to participate in the Medicare and Medicaid programs.

Confidentiality: An organizational (facility/staff) and/or patient right, to the fullest extent of the law, to personal and informational privacy, including all identifiable health information and all identifiable quality management information.

Continuity of Care: The coordination of needed healthcare services for a patient or specified population among all practitioners and across all involved provider organizations over time.

Continuous Quality Improvement: A term used interchangeably with "Quality Improvement" to mean a management process or approach to the ongoing study and improvement of the processes of providing health care services to meet the needs and expectations of patients and others.

Copayment: A fixed amount (generally $10-$30) paid by the patient for each visit to a health plan clinician or for a specified service; the remaining cost is paid by the patient's insurance.

Core Measures: Sets of measures required of acute care hospitals for CMS and TJC accreditation.

Cost-Benefit Analysis: The process of placing monetary values (dollars in U.S.) on all costs associated with outputs (actual and predicted) and on all benefits (to patient/member and organization) to assist in comparing and setting priorities across different interventions and selecting which, if any, programs or services to provide. The analysis looks at costs and benefits both with and without the program or service, to the patient and organization, so an appropriate decision can be made.

Credentialing: The process of obtaining, verifying, and assessing the qualifications of a healthcare practitioner to provide patient care services in or for a healthcare organization or network.

Crisis management: 1) Forecasting potential crisis and planning how to deal with them *(proactive)* and 2) When a crisis occurs, identifying its full nature, intervening to minimize damage, and recovering *(reactive).*

Criterion/Criteria: A statement(s) of a specific level of achievement against which performance or care can be measured. A criterion further defines and explains, for measurement purposes, a standard, a

policy or procedure, or a clinical practice guideline or protocol. For example, in ANA Standards of Professional Performance, the Quality of Practice standard states: *The registered nurse systematicall y enhances the quality and effectiveness of nursing practice."* Specific measurement criteria define what sk ills and tasks are to be measured & assessed. *[Nursin g: Scope and Standards of Practice*, ANA, 2004]

(-Suite: A term used to describe corporate officers and directors. The term is derived from the use of the letter C in most high-level positions, such as Chief Operating Officer.

Culture: A basic set of assumptions about people, how people work together, and how work gets done.

Customer: One who receives a product or service, a "dependent" of the one providing the product or service (the supplier).

Data: Uninterrupted clinical observations, facts, or material, usually collected as a result of assessment activities.

Database: A collection of information arranged into individual records to be searched by computer.

Decision Making: Choosing from among alternatives to determine a course of action. There must be at least two options, or there is no decision, only forced choice.

Deductible: A fixed amount the patient pays per year before the insurer begins paying for covered costs of care . Deductibles are not required for most managed care plans. High-deductible (perhaps $5,000 per year) "consumer-driven" health plans are linked to Health Reimbursement Accounts or pre-tax Health Savings Accounts.

Delphi Technique: A tool used to reach team consensus concerning a particular goal or task.

Design: The intentions, plans, or stated expectations for systems and processes of care and service delivery, incorporating organizational mission, vision, and strategic plan; customer needs and expectations; knowledge-based information; and current performance in the field.

Det Norske Vertis (DNV): Accreditation agency with deemed status that acCiedits hospitals and critical access hospitals – originating in Norway.

Documentation: Information recorded, or the process of recording such information, in the medical record, meeting minutes, or other source document. The accuracy and completeness of the information, and the timeliness of recording, are quality issues related to documentation .

Effectiveness: The degree to which a desired outcome is reached; the degree to which care is provided in the correct manner, given the current state of knowledge, to meet the expected outcome.

Efficacy: The potential, capacity, or capability to produce the desired effect or outcome, as already shown, e.g., through scientific research (evidence-based) findings.

Efficiency: The delivery of a maximum number of "units" of healthcare for a given unit of health resources; "the relationship of outputs (services produced) to inputs (resources used to produce those services)." [JCI]

Electronic Data Interchange (EDI): The computer-to-computer transmission of business data in a standard format, which replaces a traditional paper business document.

Empowerment: Giving employees the authority and information they need to make wise recommendations or decisions and solve problems.

Evaluation: To determine the worth of or to appraise. !n performance improvement, evaluation is included in the analysis process.

Event: An occurrence thcJt is either deemed to be, or results in, a significant problem, e.g., an adverse event or sentinel event [both defined above], or is a "near miss" (almost happened).

Evidence-based: The best external evidence available, e.g., scientific research findings.

Failure Mode: The way that a process or sub-process can fail to function or fail to provide the desired result; an undesirable variation in a process.

Failure Mode and Effects Analysis (FMEA): A team-based quality improvement tool that prospectively assesses, identifies, and improves steps in a process to reasonably ensure a safe and clinically desirable outcome [NCPS]; a systematic mechanism to identify and prevent product and process failures before they occur.

Financial management: The study and control of money resources, including their acquisition, distribution, disbursement, and investment, to meet the goals and objectives of the organization .

Flowchart: a pictorial representation displaying the actual sequence of steps and their inter-relationships in a specific process in order to identify hand-offs (appropriate and inappropriate), inefficiencies, redundancies, inspections, and waiting steps and/or the ideal sequence of steps, once the actual process is known.

Focused Professional Practice Evaluation (FPPE): A privilege-specific, time-limited process to validate practitioner competency when there is no current performance documentation for the requested privilege(s) at the organization or when concerns arise about a practitioner's ability to provide safe, high quality patient care.

Force Field Analysis: A tool used by the team when a proposed solution to a problem will require significant change, and it is important to analyze the potential impact and chances of success.

Forecasting: Forecasting is the process of predicting what will happen in the future. The ability to forecast accurately and timely will prove to be a highly valued step in ensuring the strategies are set with clarity of purpose.

Function: A key area of responsibility and activity of healthcare organizations, such as leadership or performance improvement.

Gantt Chart: a project-planning tool for developing schedules; a graphic display of the individual parts of a quality improvement process as bars on a horizontal time scale.

Global Trigger Tool: IHI developed tool that uses triggers (clues) to identify adverse events through retrospective review of patient's medical records.

Goal: A numerical value that defines the level of the data that is desired to be obtained.

Grievance: A formal expression of dissatisfaction, usually written but may be oral. A person "files" a grievance.

Healthcare-Associated Infection (HAI): *"An infection acquired concomitantly by an individual receiving or who has received care, treatment, or services by a health care organization . The infection may or may not have resulted from the care, treatment, or services ."* Results from medical treatment and generally has been synonymous with "hospital-acquired".

Healthcare-Associated Infection Rate: The ratio describing the number of individuals with a healthcare-associated infection [numerator] divided by the number of individuals at risk of developing the healthcare-associated infection [denominator] . Rates may be stratified by specifying groups predisposed to infection risk, e.g., surgical site infections further stratified by type of procedure.

Healthcare Effectiveness Data and Information Set (HEDIS): Sets of measures required of facilities accredited by NCQA.

Healthcare Facility Accreditation Program (HFAP): Accreditation agency with deemed status that accredits hospitals and other types of healthcare facilities.

High Reliability Organization: Those that achieve zero defects in quality outcomes.

Improve: *"To take actions that result in the desired measurable change".*

Indicator: A measure used to determine, *over* time, the performance of functions, processes, and outcomes of an organization. The term "indicator" now means "performance measure", addressing an important governance, management, support, or clinical function or process. Indicators may be based on practice guidelines . Indicators include data definitions, as well as numerator and denominator

statements, to accurately specify what is being measured.

Information: Data transformed through analysis and interpretation into a form useful for decision-making.

Information Management: A function (set of processes) focused on meeting the organ ization's needs for information for decision-making.

Integration: The systematic coordination of key management functions concerned with the planning and design of quality processes, as well as the measurement, analysis, and improvement of patient care and services provided by the organization.

Interrelationship Diagram: A tool that allows a team to analyze all the interrelated cause-and-effect relationships and factors involved in a complex problem; distinguish between issues that serve as drivers and those that are outcomes; and describe desired outcomes .

Joint Commission International (JCI): Accreditation agency with deemed status that accredits internationalhospitals and other types of healthcare facilities.

Just Culture: An organization culture that defines what behavior should be undertaken for an individua lwho directly made a medical error.

Leadership: (1) The direction, guidance, and example given to others to get quality work done and achieve intended objectives. (2) The ability to take others where they otherwise would not go or to get others to do what they otherwise would not do.

Learning Organization: Organizations that are continually learning through the use of personal mastery, shared vision, mental models, team learning, and systems thinking.

Liability: The state of being legally responsible for something.

Licensed Independent Practitioner (LIP): Any individual who is professionally licensed by the state (U.S.) and permitted by the organization to provide patient care services without direction or supervision, within the scope of that license.

Licensure: The mandatory act of granting and receiving a license to provide healthcare services in a state in the U.S.A governmental regulatory entity grants and monitoring the license to operate.

Lotus Diagram: A tool to expand thinking around a single topic. The expansion may include types, categories, details, or questions around a theme.

Magnet: A program to recognize health care organizations for excellence as evidenced by quality patient care, nursing excellence, and innovations in professional nursing practice.

Managed Care: The careful planning and delivery of coordinated healthcare services in an integrated delivery system or network for an entire episode of illness and/or for wellness and health maintenance. Ideally, well-managed care maximizes value, integrating concerns for cost, quality, and access.

Management: The sum of the activities of planning, organizing, staffing, directing, coordinating, and working to improve human and material resources toward the achievement of stated goals.

Measurement: The planned, systematic process of quantifiable data collection, at a single point in time or repeated over time.

"Medicaid": The U.S. Federal Government health insurance for persons meeting low-income or certain other need requirements, managed by each state.

"Medicare": The U.S. Federal Government health insurance program for persons age 65 and over, those with permanent kidney failure, and those meeting certain requirements as disabled, managed by the federal Centers for Medicare and Medicaid Services.

Medical Error: An act of omission or commission in planning or execution that contribute or could contribute to an unintended result.

Minimum Data Set (MDS): Assessment of patients in long-term care settings, which also provides a set of performance improvement measures.

Mission: The written expression of the organization's overall, broad purpose and role (what/who the organization is). In a quality improvement environment, it is expected that the statement of mission will express a high-priority, comprehensive commitment to patient care, to quality in all activities, and to service to the community. The mission statement is the basis for the formation of organizational vision, values, goals, and objectives.

Monitoring: Keeping track systematically in order to collect information; keeping close watch.

Monitoring and Evaluation: Historically, a data collection process that focused on high-priority quality-of-care issues and was designed to facilitate problem solving and the identification of opportunities to improve.

Multivoting: A technique used to prioritize a long list of possibilities or alternatives and to move a team toward consensus.

National Committee for Quality Assurance (NCQA): Accreditation agency with deemed status that accredits managed care and other health plan services.

Near Miss Events: A potential medical error, which was caught prior to the administration or use for a patient or others.

Negligence: Lack of proper care, as judged by peers.

Negligent Conduct: Doing what a reasonable person would not do; failure to do what a reasonable person would do (based on set standards and under like circumstances and training). **Gross negligence** is failure to act if there is known or suspected risk resulting in adverse impact or death.

Negotiation: The art of conferring, discussing, or bargaining to reach agreement.

Never Event: An event that should never happen and if it does, immediate investigation and remediation is required. (Also, commonly called a sentinel event).

Nominal Group Process: A technique used to give everyone on the team/group an equal voice in brainstorming, problem selection, or resolution.

Nonprobability Sampling: Sampling design, which decreases the probability that the findings can be generalized.

Ongoing Professional Practice Evaluation (OPPE): Ongoing measurement and analysis of each practitioner's performance relative to existing privileges, including licensed independent practitioners and others with clinical privileges granted by the organization .

Organizationleaders: The group of individuals that sets expectations, develops plans, and implements procedures to assess and improve the quality of the organization's governance, management, clinical, and support functions and processes.

Organizational Ethics: Management of relationships with patients and the public under a set of principles of right conduct; conduct of business with patients and the public with respect, honesty, and integrity; and recognition and acceptance of responsibilities under law.

Outcome: The result(s) or effect(s) of the performance or non-performance of one or more functions or processes. An outcome represents the cumulative effect of one or more processes on a patient at a defined point in time.

Outcome and Assessment Information Set (OASIS): Assessment of patients in home health care settings, which also provides a set of performance improvement measures .

Patient-Centered Medical Home (PCMH): *"a model of the organization of primary care that delivers the core functions of primary health* care"-patient-centered, comprehensive, coordinated, accessible, continuously improved [Agency for Healthcare Research and Quality (AHRQ)].

Patient Safety: *"Freedomfrom accidental injury caused by medical care"* [Institute of Medicine].

Patient Safety Organization (PSO): An organization that receives deidentified patient health information for use in population health and in improving patient outcomes.

Patient Safety and Quality Improvement Act of 2005 (PSQIA): Federal law that provides privilege and confidential protections for patient safety work products.

Pattern: An identifiable arrangement of data (a grouping or distribution) suggesting a systematic or predictable design or behavior. Example: A positive correlation between patient's heart rate taken by nurse and that taken by monitor as demonstrated on a scatter diagram.

Peer Review: Review of an individual practitioner by a "like" practitioner with similar training and expertise.

Peer Review Organizations (PRO): Established to assure services provided to Medicare and Medicaid patients worked and employed concurrent utilization review. PROs were replaced by QIOs in 2002.

Performance: The effective execution or accomplishment of important functions and processes, with particular focus on those that increase the probability of desired outcomes; what is done and how well it is done to provide healthcare.

Performance Measure: A quantifiable process and outcome indicator used to monitor performance.

Performance Improvement:

- *"The continuous study and adaptation of a healthcare organization's functions and processes to increase the probability of achieving desired outcomes and to better meet the needs of individuals and other users of services." {Past Glossary, CAMH, TJC]*
- *"Data collection and analysis for the purpose of providing an indication of the organization's performance on a specified process or outcome." {Current Glossary, CAMH, TJC]*

Plan: The written document describing a particular program and all associated structures, processes, and activities. Plans discussed in the *Handbook* include those related to quality management, utilization management, risk management, information management, the organizational plan for patient care services, and the corporate compliance plan.

Planning: A systematic, organizationwide approach to the design, monitoring, analysis, and improvement of performance.

Practice Guideline: A generally accepted principle for patient management, with care specifications based on the most current scientific findings (evidence of effectiveness, hence "evidence-based"), clinical expertise, and community standards of practice. *"Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."* [Institute of Medicine]

Present on Admission (POA): Conditions that are present upon admission to a healthcare facility.

Preventable Event: *Unintended injury to patients not caused by an error.*

Primary Care: The point of entry into the healthcare system for non-emergency care, the point of first contact with the system, and the point of most frequent contact.

Prioritization Matrix: A tool used to select one option from a group of alternatives, be they problems or solutions, or to put the options into priority order if all need to be done, to promote objective decision-making.

Privileging: Permission to provide specific medical or other patient care services in the granting organization, within well-defined limits, based on the individual's professional license and his or her experience, competence, ability, and judgment and on the organization's ability to provide and support the service.

Probability Sampling: Sampling design which increases the probability that the findings can be generalized.

Problem: A deviation from an expected occurrence that cannot be justified as appropriate under the

given circumstances .

Process: In performance improvement, a goal-directed, interrelated series of actions, activities, events, mechanisms, or steps related to a function of care or service; a sequence that transforms inputs into outputs or outcomes.

Productivity: *"That bafance between aff factors of production that wiff give the greatest output for the smaffest effort"* [Peter F. Drucker].

Profiling: Ongoing documentation, tracking, and compilation of practitioner clinical activities and services (e.g., performance measure and peer review data and information), as well as QI/PI activities (e.g., teams, committees, leadership) for reappraisa l [See this Glossary].

Program: A pre-arranged outline of work to be done; a logical sequence of operations to be performed; a composite of all activities associated with improvement of organizational performance .

Prospective Payment System: A method of reimbursement that provides healthcare providers-facilities and licensed independent practitioners-with a pre-negotiated fixed set of payment rates for each type of patient or group of services. The payment rate remains unchanged regardless of operating costs.

Quality: Measurable: Compliance with, or adherence to, standards (or performance measures).

> **Appreciative:** The comprehension and appraisal of excellence beyond minimal standards and criteria, based on training and expertise.
>
> **Perceptive:** The degree of excellence that is perceived by the recipient or observer of care rather than by the provider.
>
> **An organizational definition:** "Quality is meeting or exceeding expectations at a cost that represents value to the customer."

Quality Improvement Organization (QIO): As part of the DHHS national Quality Strategy, replaced the PROs and is dedicated to improving health quality for Medicare beneficences.

Quality Innovation Network (QIN): Division of the QIO that provides healthcare organizations education, outreach, and sharing practices that worked in other areas. The QIN utilizes data to measure improvement, and works with patients, families, and community partners.

Quality Management: A planned, systematic, organizationwide (or networkwide) approach to the monitoring, analysis, and improvement of organization performance, thereby continually improving the quality of patient care and services provided and the likelihood of desired patient outcomes.
Quality Management is the quality umbrella, including quality planning, quality control/measurement, and quality improvement, based on the Juran Quality Management Cycle, also known as the **Quality Trilogy.**

Rapid Cycle Improvement: Utilizing traditional quality tools but expediting the change and the results.

Reappointment: Selection for continued membership in a medical/professional staff (e.g., hospital or medical group) or to a practitioner panel (e.g., preferred provider organization), based on reappraisal.

Reappraisal: Periodic reevaluation by peers of a practitioner's competency to provide care and services to patients in or for a healthcare organization. Reappraisal may include recredentialing, reprivileging, proctoring for a new privilege, profiling, peer review, and reappointment [See this Glossary for definitions].

Reliability: The ability of the indicator or collection tool to measure in a reproductive way what it is supposed to measure (interrater reliability).

Risk: The possibility of loss or injury; peril; a dangerous element or factor.

Risk Management: Clinical and administrative activities developed and implemented to prevent and

reduce, or identify, evaluate, and intervene with, risk of injury or loss to patients, staff, visitors, and the organization.

Risk Register: a listing of identified risks and its components, usually in table format, that supports the governing body, leadership, management, and teams seeking to develop, organize, implement, and/or maintain ERM or another new strategic initiative, function, process, or project. It is a **tool** for documenting priorities; summarizing and succinctly describing risks to be managed, based on probability and impact scores, by category; listing prevention or mitigation strategies; responsibility; timeline.

Root Cause Analysis (RCA): A systematic process for identifying the most basic or causal factor(s) under lying variation in performance, including the occurrence or possible occurrence of adverse events that might be prec1.;, :;ors to a sentine l event; the intensive, in-depth analysis of a problem event, e.g., a sentinel event, to learn the most basic reason(s) for the problem, which, if corrected, will minimize recurrence of that event.

Safety: The degree to which the healthcare environment is free from danger or hazard; the degree to which the healthcare intervention minimizes risks of adverse outcome for both patient and provider.

Scope of Work (SoW): QIO activities determined by CMS with both beneficences and medical communities in the state.

Sensitivity: The ability to measure, test, or tool (study design, screen ing tool, otr lab test) to identify and select all positive cases or spec ified variations or deviations (all cases in the category), using var iables to be examined - fewer false negatives.

Sentinel Events: *"An unexpected occurrence involving death or serious ph ysical or ps ychological injur y, or the risk thereof. The phrase "of the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious ad verse outcome."* [TJC Glossary]

Severity of Illness: The degree of risk of immediate death or permanent loss of function due to a disease. Clinical findings are used to assign a severity rating, ranging from "no risk" (0) to "death" (5), depending on the system.

Specificity: The ability to measure, test, or tool to differentiate between cases wanted and those similar, but not in the desired category, and to exclude those negative cases.

Standard of Care: A predefined outcome of patient care that the patient can expect from the encounter and that is accepted within the community of professionals, based upon the best scientific knowledge, current outcome data, and clinical expertise.

Standard of Practice: An acceptable level of performance or an expectation for professional intervention or behavior, generally formulated by practitioner organizations based upon clinical expertise and the most current research findings. Standards of care and practice are the building blocks of practice guidelines, critical/clinical paths, patient care policies and procedures, and indicators for quality management activities.

Statistical Process Control: The use of measurements to study a process with the goal of making it perform in a certain way, conform to standards, and continuously improve.

Storyboard: a visual display of the team and pertinent data/ information, analyses, and decisions made during the improvement process.

Strategic Leadership: Guidance or direction that is essential to meeting intended objectives or successfully implementing a plan of action.

Strategic Planning: An organizationwide/systemwide, ongoing look into the future.

Strategic Quality Initiative: A statement of intent and a strategy to improve care and services in a specific way; a high-level, leadership-driven, organizationwide decision, resulting from, or incorporated into, the strategic planning process.

Stratification: To break the whole down into its parts.

Structure: The arrangement of parts of a care system or elements that facilitate care; evidence of the organization's capacity to provide care to patients. Structure is causally related to process and outcome: structure leads to process and process leads to outcome.

System: *"A perceived whole whose elements 'hang together' because they continually affect each other over time and operate toward a common purpose."* [Senge]

Systems Theory: Systems theory is a way of looking at an organization holistically and breaking it down into a series of individual elements that interact with each other.

Systems Thinking: The belief that the behavior of all systems follows certain common principles, the nature of which can be discovered, articulated, understood, and used to make change. [Senge]

Team: A group of people working toward a common purpose for which they are interdependent and mutually accountable.

Threshold: A numerical point below, which the data should, not fall or the point or level at which something begins or changes

Timeliness: The degree to which care is provided to the individual at the most necessary or beneficial time and in accordance with the patient's perception of promptness.

To Err is Human: IOM groundbreaking report on the presence of medical errors in healthcare.

Tort: Legal cases that result from civil wrongs including invasion of privacy, lack of consent, defamation of character, fraud and deceit, assault and battery, negligence/malpractice.

Total Quality Management (TQM): A broad management philosophy, espousing quality and leadership commitment that provides the energy and the rationale for implementation of the process of Continuous Quality Improvement (CQI) within the organizationwide Quality Management Strategy. **Tracer:** A framework used to assess the movement of a patient through the healthcare system and the quality of care received.

Transparency: Enabling consumers to compare the quality and price of healthcare services and make informed choices. [U.S. Department of Health and Human Services)

Trend: A key type of pattern indicating a general tendency or direction of events or conditions, usually over a significant period of time. Example: The correlation between heart rates taken separately by nurse and monitoring device over a period of six months.

Trigger : A numerical point at which there should be some action taken.

Triple Aim: A framework developed by IHI that describes the approach to optimizing health system performance through population health, experience of care, and per capita cost of care.

Us: A term used to describe corporate officers and directors. The term is derived from the use of the letter C in most high-level positions, such as Chief Operating Officer.

Utilization Management: The examination, evaluation, and appropriate use of organization resources; an organizationwide, interdisciplinary approach to balancing cost, quality, and risk concerns in the provision of patient care.

Validity: The capability of the indicator or collection tool to measure what it is supposed to measure.

Value Statements: A listing of organizational values that support the mission and vision statements and guide strategic planning, decision-making, and the provision of all services.

Variation: A "change or deviation in form, condition, appearance, extent, etc., from a former or usual state, or from an assumed standard" [Webster's New World Dictionary].

Vision Statement: The organization's **intent and aspirations** for the future (what the organization strives to be). It should espouse forward thinking goal'.; for quality and customer service.

WalkRound: Leadership rounds throughout the healthcare organization in an informal manner to demonstrate to staff the organization's commitment to patient safety and talking with staff and patients encouraging them to report errors as well as accomplishments.

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