Healthcare: A Better Way

The New Era of Opportunity
Sir Isaac Newton is known to have said, “If I have seen further it is by standing on the shoulders of giants.” This certainly captures the circumstances of this book. The intent of the book is to provide the reader a concise overview of the challenges facing healthcare, the emerging solutions to those challenges and a glimpse of an exciting new future for our noble profession. As such, the book represents very little original thought on my part. Rather, it is a compilation of the works of many visionary leaders that I have had the good fortune of encountering throughout my professional career. I am deeply indebted to each of these great leaders for sharing their wisdom, insights and experience.

My good friend Brent James, MD, is a deeply inspirational leader who has patiently and steadfastly worked for three decades to improve healthcare and inspire healthcare leaders both nationally and internationally. He has had an immense impact on me and on countless others. David Burton, MD, recognized the importance of quality improvement early in his career, and through his visionary leadership as both a clinician and an operational leader he demonstrated that quality improvement could be successfully integrated into the complex process of care delivery. I do not know any two clinicians who have demonstrated this more effectively in a real-world care delivery environment than David and Brent. Robert Wachter, MD, has had a greater impact on increasing awareness of the issues related to patient safety and done more to advance the cause of patient safety than any physician leader I know. Bob’s book on patient safety, “Understanding Patient Safety” (Second Edition), is the quintessential resource on this important topic. Along with Dr. James, my dear friend, Molly Coye, MD, co-authored the seminal Institute of Medicine (IOM) reports To Err Is Human and Crossing the Quality Chasm. Molly has contributed greatly to advancing awareness of quality in healthcare and to our understanding of the role of emerging technologies in the future of care delivery. Steve Barlow, Tom Burton and Dale Sanders are phenomenally creative leaders in information technology (IT) and healthcare analytics, and they have incredibly deep experience in architecting and deploying successful technology and analytics solutions. Holly Rimmasch, RN, has two decades of experience in improving clinical care, including implementation of clinical and operational best practices. Cherbon VanEtten is knowledgeable in IT, analytics, clinical operations and education. She was a valuable member of the editing team. Dan Burton, the CEO of Health Catalyst®, is an imaginative, kind, intelligent and supportive leader who has skillfully guided Health Catalyst to ever-increasing success. Dan also had the wisdom and courage to support this project. Paul Horstmeier has launched and grown three different businesses and won numerous industry awards for quality and innovation. It is healthcare’s good fortune that Dan and Paul are now applying their deep experience to transforming healthcare. Leslie Falk, RN, provided her clinical expertise, and experience in engineering, business and
marketing. Leslie has been a joy to work with on this project. Sister Monica Heeran, CSJP, is one of the most supportive and thoughtful leaders I have ever known. Without her vision and willingness to take a risk with a young physician leader, my career would never have been the same. John Hayward has been a longtime mentor and friend. He has more passion for improving healthcare than any non-clinician that I have ever known. I am indebted to Elaine Dunda and Donn McMillan. Working alongside Elaine and Donn, I was able to gain deep, pragmatic experience in successfully implementing quality and safety into a complex integrated care delivery environment. Last, but certainly far from least, I would like to recognize the thousands of clinical and operational leaders across the country who are daring greatly and working tirelessly to improve care for patients and communities. They are an inspiration to all of us.

These are the shoulders on which I stand and on which this book is built.

John L. Haughom, MD
In the first chapter, we reviewed the historical, cultural, financial, practical, social and traditional forces that define and shape the U.S. healthcare system as it exists today. In this chapter, we provide an overview of the quality, safety and complexity challenges facing healthcare.
Quality challenges facing U.S. healthcare

The IOM has defined the quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” In its groundbreaking 2001 report, “Crossing the Quality Chasm”, the IOM proposed six aims for a quality healthcare system: patient safety, patient-centeredness, effectiveness, efficiency, timeliness and equity. Stated more simply, healthcare quality is getting the right care to the right patient at the right time, every time. It is noteworthy that the IOM framework lists safety as one of their six aims, in essence making patient safety a subset of quality. Some have argued that patient safety is a separate entity, but the fundamental point remains the same. We owe the patients we serve high-quality, safe and effective care. Although many clinicians tend to think of quality as being synonymous with the delivery of evidence-based care, it is noteworthy that the IOM’s definition is significantly broader and includes elements that are of particular importance to patients (patient-centeredness and timeliness) and to society (equity).

Although the IOM makes it clear that quality is more than providing care that is supported by science, evidence-based medicine still provides the foundation for much of quality measurement and improvement. For decades, the particular practice experience and style of a senior clinician or a prestigious medical center determined the standard of care. Without discounting the value of experience and mature clinical judgment, the model for determining optimal practice has shifted, driven by an explosion in clinical research over the past two generations. Over the past four decades, the number of randomized clinical trials has grown from fewer than 500 per year in 1970 to 20,000 per year in 2010. This research has helped define “best practices” in many areas of clinical care, ranging from preventive strategies for an elderly woman with diabetes to the treatment of the patient with acute myocardial infarction and cardiogenic shock.

Spending doesn’t equal care

Although the U.S. spends more money per person on healthcare than any other nation in the world, there is broad evidence that Americans often do not get the care they need. Preventive care is underutilized, resulting in higher spending on complex, advanced diseases. A Rand study published in 1998 demonstrated that only 50 percent of Americans receive recommended preventative care. Among patients with acute illnesses, only 70 percent received recommended treatments and 30 percent received contraindicated treatments. Patients with chronic diseases such as congestive heart failure, hypertension, ischemic heart disease and diabetes all too often do not receive proven and effective treatments such as drug therapies or self-management services to help them more effectively manage their
conditions. In another RAND study, patients with chronic disease received recommended treatments only 60 percent of the time, and 20 percent of the time they received contraindicated treatments.\textsuperscript{21, 22} This is true irrespective of one’s ability to pay — that is, for insured, uninsured and underinsured Americans. These problems are exacerbated by a lack of coordination of care for patients with chronic diseases.

Yet another RAND study, reported in the New England Journal of Medicine in 2003, concluded that American healthcare gets it right only 54.9 percent of the time.\textsuperscript{22} Additional highlights from the study included the following:

- Performance was strikingly similar in all twelve communities studied. Overall quality ranged from 59 percent in Seattle, Washington, to 51 percent in Little Rock, Arkansas. The researchers found the same basic level of performance for chronic, acute and preventive care.

- Quality varied substantially across conditions. For example, people with high blood pressure received about 65 percent of recommended care; persons with alcohol dependence received about 11 percent.

- Quality also varied across communities for the same condition. For example, care for diabetes ranged from 39 percent in Little Rock to 59 percent in Miami. Care for cardiac problems ranged from 52 percent in Indianapolis and Orange County to 70 percent in Syracuse.

- All communities did a better job of preventing chronic disease through screening tests (e.g., measuring blood pressure) and immunizations than in preventing other types of disease, such as sexually transmitted diseases, and in providing other types of preventive care, such as counseling for substance abuse.

- No single community had consistently the highest or lowest performance for all of the chronic conditions. The relative rankings of the communities changed depending on the aspect of care being examined.

- Everyone is at risk for poor care. Race, gender or financial status makes only a small difference in the likelihood of receiving recommended care. For example, women were more likely to receive recommended preventive care, but men receive better quality care for acute conditions. Previous studies have demonstrated disparities in care for blacks associated with invasive and expensive procedures, such as coronary-artery bypass graft surgery. However, based on the broad RAND measures, which assessed more routine care, blacks were slightly more likely than whites or Hispanics to receive recommended care for chronic conditions, whereas Hispanics were most likely to receive recommended screening.\textsuperscript{21}
Reforming to deliver improved quality of care

While many patients often do not receive medically necessary care, others receive care that may be unnecessary, or even harmful. Research has documented tremendous variation in hospital inpatient lengths of stay, visits to specialists, procedures and testing, and costs — not only by different geographic areas of the U.S. but also from hospital to hospital in the same community. This variation has no apparent beneficial impact on the health of the populations being treated. Limited evidence on which treatments and procedures are most effective, the inability to inform providers about the effectiveness of different treatments, and failures to detect and reduce errors further contributes to gaps in the quality and efficiency of care. These issues are particularly relevant to lower income Americans and to members of diverse ethnic and demographic groups who often face great disparities in health and healthcare.

Reforming our healthcare delivery system to improve the quality and value of care is essential to addressing escalating costs, poor quality and increasing numbers of Americans without health insurance coverage. Reforms should improve access to the right care at the right time in the right setting. They should keep people healthy and prevent common, avoidable complications associated with illnesses to the greatest extent possible. Thoughtfully constructed reforms would support greater access to high-quality, safe and effective care in contrast to the current system, which encourages more tests, procedures and treatments — many of which are at best unnecessary and at worst harmful and costly.

A conceptual framework for evaluating quality of care

In 1966, Avedis Donabedian, a physician and health services researcher, developed a conceptual structure-process-outcome framework for examining health services and evaluating quality of care.23 His framework has been widely used to measure the quality of care. Donabedian argued that before assessing quality we must come to an agreement regarding how we define it. The definition depends on whether one assesses only the performance of practitioners or also the contributions of patients and of the healthcare system, on how broadly health and responsibility for health are defined, on whether the “maximally” effective or “optimally” effective care is sought, and on whether individual or societal preferences define the optimum. One also needs detailed information regarding the causal linkages among the structural attributes of the settings in which care occurs, the processes of care and the outcomes of care.

According to the Donabedian Model (Figure 12), information about quality of care can be drawn from three categories: structure, process, and outcomes.23 Structure describes the context in which care is delivered, including hospital
buildings, staff, financing and equipment. Process denotes the transactions between patients and providers throughout the delivery of healthcare. Finally, outcomes refer to the effects of healthcare on the health status of patients and populations. While the Donabedian Model has limitations and there are other quality of care frameworks, it continues to be the dominant standard for assessing the quality of healthcare.23 In recent years, as clinical research has established the link between certain processes and improved outcomes, process measures have often been used as proxies for quality. Examples include measuring whether hospitalized patients with pneumonia received influenza and pneumococcal vaccinations, and measuring glycosylated hemoglobin (hemoglobin A1c) at appropriate intervals in outpatients with diabetes.

Donabedian went on to explore the link between benefits and cost (Figure 13). Imagine you are treating a patient and you are going to spend exactly the same amount of money each day in treating the patient. If you track cost over time (where the X axis is time moving ahead), your cost will go up at a constant rate, as shown in the top graph of Figure 13. As healthcare professionals, we usually try to use the things that work best first. If we use those treatments, we expect the patient to receive a benefit (green line). Eventually, we will exhaust the “first tier” treatments and we will need to turn to “second tier” treatments. As a result, while our costs continue to rise at a constant rate, the
benefit will taper off. As you move beyond point A, the benefit will drop off and the inherent risks are likely to rise, leading to a lower cost-benefit, as shown in the lower graph of Figure 13. Ideally, you would push for peak benefit for the patient, which is point B. Donabedian called this a “maximalist” approach. That is, you are seeking maximum benefit for the patient under your care.

Now, imagine we don’t think of just one patient at a time, but instead we are tasked with care delivery for a population. In addition, let’s accept reality: we have a finite number of resources at our disposal. In that situation, we are likely going to want to pay attention to a cost-benefit curve. This is the slope of the green line (benefits) divided by the slope of the red line (cost). Donabedian pointed out that if you want maximum benefit across a population you want to be at the peak of the cost-benefit curve (point A on the lower graph in Figure 13). Donabedian called this an “optimalist” approach because the focus is achieving the maximum benefit across a population, rather than for an individual patient. If we are going to spend more treatment money, we would prefer to find a patient located before point A, where the slope of the curve is still going up, indicating that patient will get more benefit than a patient beyond point A. Using this population perspective, it is apparent that there is a difference when focusing on the whole (population) rather than on an individual patient.

Donabedian’s intent was to foster a discussion about the ethics of patient care, particularly patient benefit as opposed to population benefit. If we are talking about a population, we have a responsibility to ask patients as a group how much healthcare they want to buy at what benefit and cost. Donabedian argued this was not a care provider’s decision. Instead, it was the decision of the population of patients — that is, society. In such situations, care providers have an obligation to help society understand the trade-offs.

Causes of practice variation

Practice variance can occur in the Donabedian Model categories of process and outcomes. Inappropriate variation is a known cause of poor quality and outcomes. Based on a detailed review of the literature, Dr. Brent James and colleagues have identified a long list of reasons for inappropriate practice variation.24 Here are the top four on the list:

- An increasingly complex healthcare environment. Over the last 50 years, we have witnessed huge changes in how care is delivered, with massive growth in complexity. In the 1950s, physicians had a small number of medications to choose from. Now, there are more than 10,000 prescription drugs and biologicals — and 300,000 over-the-counter products — available in the U.S.25 There have been equally profound changes in care delivery options and environments, including modern imaging techniques, highly sophisticated intensive care units
and surgical suites, catheter-based procedures, transplant services, minimally invasive techniques, and a host of other complicated options. Under the current system, care providers are being overwhelmed with complexity. As stated by David Eddy, MD, “The complexity of modern American medicine exceeds the capacity of the unaided human mind.”

Exponentially increasing medical knowledge. In 1998, Mark Chassin published an article tracking the publication of randomly controlled trials (RCTs) between 1966 and 1995. One look at Figure 14 and it is apparent that there has been an explosion in the production of published trials. The number of randomized clinical trials had grown to over 20,000 per year in 2010.

In 2004, the U.S. National Library of Medicine added almost 11,000 new articles per week to its online archives. That represented only about 40 percent of all articles published worldwide in biomedical and clinical journals. In 2009, it was estimated this rate of production had grown to one article every 1.29 minutes. Furthermore, Shaneyfelt estimated in 2001 approximately three to four years after board certification, general internist and internal medicine subspecialists begin to show “significant declines in medical knowledge.” He estimated that 15 years after initial board certification approximately 68 percent of internists would not pass the American Board of Internal Medicine certification exam. He went on to estimate that to maintain current knowledge, a general internist would need to read 20 articles a day, 365 days a year. Clearly, maintaining current knowledge has become a near impossible task for all clinicians.

Lack of valid clinical knowledge (inadequate evidence for what we do). There have been three published studies looking at the percentage of clinical care that is based on published scientific research. These studies have concluded that only between 10 percent and 20 percent of routine medical practice has a basis in scientific research. Thus, much of what we do in routine clinical practice is based on...
tradition or opinion. That doesn’t necessarily mean it is wrong, as much of it has likely been shown to work over time. However, it does suggest that healthcare delivery organizations should use their own data to determine the efficacy of clinical practice and to determine how to improve it over time. This implies the need to create a data-driven continuous learning environment. We will discuss that topic in greater detail in future chapters.

Overreliance on subjective judgment. Dr. David Eddy and others have demonstrated that the beliefs of experts with respect to a given clinical condition can vary over a very wide range and that subjective evaluation is notoriously poor across groups over time. For example, a group of experts was asked what overall reduction in colon cancer incidence and mortality could be expected from the routine use of fecal occult blood testing and flexible sigmoidoscopy. The answers varied between near 0 percent and over 90 percent, with a completely random distribution. Dr. Eddy’s intent was not to disparage the value of a specialist’s advice. The advice is valuable. Rather, it was to demonstrate that even the busiest specialist is dealing with a sample size that is too small to draw general conclusions. These findings and others have caused Dr. Eddy to conclude, “You can find a physician who honestly believes — and will testify in court to — anything you want.”

The underlying fragmentation of the healthcare system also contributes to poor quality. It impedes the flow and integration of the data necessary for healthcare providers to provide the best possible care. This fragmentation is not surprising given that healthcare providers do not have the payment support, incentives or other tools they need to communicate and work together effectively to improve patient care.

Challenges related to patient safety

In its seminal report, “To Err Is Human: Building a Safer Health System”, the IOM conservatively estimated that as many as 44,000 to 98,000 Americans die each year as a result of preventable medical error. While many articles on the topic of patient safety had been published prior to this, the IOM report crystallized and energized the discussion and debate regarding patient safety and harm, and launched the rapidly evolving and highly dynamic field of patient safety. Over the past decade, much progress has been made in our understanding of patient safety, and considerable progress has been made in reducing harm. This subsection will review the current state of our knowledge. While the goal is for this to be a reasonable review of patient safety, the reader is strongly encouraged to read “Understanding Patient Safety” by Robert Wachter, MD (second edition, 2012). This well researched, comprehensive and highly readable text is a must read for anyone interested in improving patient care.
The IOM report on harm has proven to be groundbreaking from many different perspectives, but the single and most influential fact emanating from the report was the number of deaths resulting from preventable patient harm. This number justifiably garnered significant attention and generated a long-overdue debate. This is not surprising given that it represents the rough equivalent of a fully loaded Boeing 747 crashing every day of the year! One can only imagine the attention an aviation disaster of this magnitude would generate among the public. Yet the number dying from preventable patient harm in U.S. hospitals had gone largely unnoticed prior to the IOM report.

In the early months following the publication of the report, some wanted to argue the accuracy of the number, but even if the numbers are off by half, this obviously still represents an unacceptable rate of harm (it is noteworthy that some knowledgeable experts have estimated the range of deaths from avoidable harm is actually higher). Even if you only accept the lower estimate in the IOM range, medical error is still the ninth leading cause of death in the U.S. It surpasses deaths due to motor vehicle accidents, chronic liver disease, alcohol-induced and drug-induced deaths (combined), and a variety of cancers, including breast, stomach and prostate. While staggering, these estimates of death due to harm only begin to scratch the surface of the problem, as they fail to measure the full range of adverse events stemming from injuries not resulting in death.

Regardless of how one measures it, medical error is an important indicator of quality in healthcare, reflecting the overuse, underuse and misuse of health services. Particularly in the case of misuse, preventable harm from medical treatment compromises patient safety and may result in injury or death. Variations in clinical care also undermine patient trust in the healthcare system. In the end, medical error and harm prevent healthcare providers from achieving their potential in service to patients. The social cost of harm is enormous, estimated to be between $29 and $38 billion per year, with about $17 billion of those costs associated with preventable errors.

The IOM and many patient safety experts stress that most medical errors reflect system errors rather than individual misconduct or negligence. This is an important distinction because engaging clinicians in reducing harm requires that we acknowledge that the problem is not fundamentally a “bad apple” problem. As Dr. Wachter said in his book, “Internal Bleeding: The Truth Behind America’s Epidemic of Medical Mistakes”:

*Decades of research, mostly from outside healthcare, has confirmed our own medical experience: Most errors are made by good but fallible people working in dysfunctional systems, which means that making care safer depends on buttressing the system to prevent or catch the inevitable lapses of mortals. This logical approach is common in other complex, high-tech industries, but it has been woefully ignored.*
in medicine. Instead, we have steadfastly clung to the view that an error is a moral failure by an individual, a posture that has left patients feeling angry and ready to blame, and providers feeling guilty and demoralized. Most importantly, it hasn’t done a damn thing to make healthcare safer.42

While it is true that most preventable harm is not a “bad apple” problem, Drs. Wachter and Peter Provonost have appropriately argued that we need to balance no blame and professional accountability.43 That is, we need to acknowledge that there are indeed some “bad apples.”

Reducing avoidable patient harm and advancing patient safety will require a comprehensive, intricate and thoughtful approach. To quote Dr. Wachter from the introduction to the second edition of his book:

“To keep patients safe will take a uniquely interdisciplinary effort, one in which doctors, nurses, pharmacists, and administrators forge new types of relationships. It will demand that we look to other industries for good ideas, while recognizing that caring for patients is different enough from other human endeavors that thoughtful adaptation is critical. It will require that we tamp down our traditionally rigid hierarchies, without forgetting the importance of leadership or compromising crucial lines of authority. It will take additional resources, although investments in safety may well pay off in new efficiencies, lower provider turnover, and fewer expensive complications. It will require a thoughtful embrace of this new notion of systems thinking, while recognizing the absolute importance of the well-trained and committed caregiver.”

As this quote indicates, there has been a concerted effort over the last decade to shift the focus of patient safety from a “blame and shame” game to a systems thinking approach. The fact is fallible humans will always be prone to error, particularly in increasingly complex environments like healthcare. Reducing harm and making care safer depends on creating systems in all care environments that anticipate errors and either prevent them or catch them before they cause harm. This approach has produced remarkable safety records in other industries, including aviation, and we are overdue in applying it to healthcare.

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— Dr. Robert Wachter
Avoidable error and harm categories

Safety experts including Dr. Lucian Leape, Dr. Wachter, Dr. Pronovost and others have organized the causes of avoidable errors and harm into the following logical categories:34

- **Medication errors.** Adverse drug events (ADEs) are a significant source of patient harm. The medication delivery process is enormously complex. On the inpatient side alone, it generally represents dozens of steps, and it is only marginally less complicated in the ambulatory environment. Taken appropriately, the thousands of medications available in clinical care today offer huge advantages to patients. Still, the thousands of available drug options and their complicated interaction with human physiology and each other leads to a significant incidence of near misses (5 to 10 percent) and actual adverse drug events (5 percent) in hospitalized patients.44

  The incidence of ADEs is significantly higher for high-risk medications like insulin, warfarin or heparin.45 In addition to patient harm, the cost of preventable medication errors in hospitalized patients in the U.S. is substantial, estimated at $16.4 billion annually.46 In the ambulatory environment, the incidence of harm and the costs are even higher.47

  Multiple solutions are required to address the issue of adverse drug events. These include several well-implemented technological solutions: computerized physician order entry (CPOE), computerized decision support, bar code medication administration, and radio-frequency identification (RFID) systems. It will also require addressing a number of process issues, including standardization, vigilance with respect to the “Five Rights” (right patient, right route, right dose, right time and right drug), double checks, preventing interruptions and distractions, removal of high-risk medications from certain areas, optimizing the role of clinical pharmacists, addressing the issue of look-alike and sound-alike medications, and implementing effective medication reconciliation processes, particularly at hand-off points.

- **Surgical errors.** There are over 20 million surgeries annually in the U.S. In recent years, a number of advances have resulted in significant improvements in the safety of surgery and anesthesia and reductions in harm and death.48 Still, a number of surgical safety challenges persist. These include persistent anesthesia-related complications, wrong-site surgeries, wrong patient surgeries, retained foreign bodies and surgical fires. One study indicated that 3 percent of inpatients who underwent surgery suffered an adverse event, and half of these were preventable.49

  Studies have also shown that there is a strong relationship between volume and safety. That is, surgeons need to perform any given surgery a certain number of times to attain a level of skill required
to minimize adverse surgical events. Addressing surgical safety will require a number of measures, including widespread adoption of safety principles already largely implemented by anesthesiologists (e.g., systems thinking, human factors engineering, learning from mistakes, standardization and comprehensively applying the “Universal Protocols” — including site signing and time outs), along with teamwork training, checklists and the use of best practices for minimizing retained foreign bodies and avoiding surgical fires.

Diagnostic errors. While they have received less emphasis, diagnostic errors are relatively common. For example, in the study that served as the basis for the IOM’s estimate of 44,000 to 98,000 annual deaths from preventable errors, 17 percent of the deaths were attributed to diagnostic errors.\(^5\) Furthermore, autopsy studies have demonstrated that 1 in 10 patients suffer a major antemortem error.\(^5\) Addressing this problem will require a number of measures, including avoiding fatigue, avoiding overreliance on past experience, improved training in cognitive reasoning and computerized decision support systems.

Person-machine interface errors (human factors engineering). Human factors engineering is an applied science of systems design that is concerned with the interplay between humans, machines and their work environments. Its goal is to assure that devices, systems and working environments are designed to minimize the likelihood of error and optimize safety. As one of its central tenets, the field recognizes that humans are fallible — they often overestimate their abilities and underestimate their limitations. This is particularly important in the increasingly complex healthcare environment, where fallible care providers are being overwhelmed by increasing complexity.

Many complex care environments have little or no support from modern technology for care providers, and in those that do have such support the devices often have poorly designed user interfaces that are difficult and even dangerous to use.\(^5\) Human factors engineers strive to understand the strengths and weaknesses of human physical and mental abilities. They use that information to design safer devices, systems and environments. Thoughtful application of human factors engineering principles can assist humans dealing with complex care environments and help prevent errors at the person–machine interface.

Errors at transitions of care (handoff errors). Transitions of care between care environments and care providers are common in clinical care. These handoffs are a common source of patient harm. One study demonstrated that 12 percent of patients experienced preventable adverse events after hospital discharge, most commonly
medication errors. Because they are so common, healthcare provider organizations increasingly are focusing on this type of harm.

Policymakers are also paying more attention to this type of harm. In 2006, the Joint Commission issued a National Patient Safety Goal that requires healthcare organizations to implement a standardized approach to handoff communications including an opportunity to ask and respond to questions. Because of studies showing very high 30-day readmission rates in Medicare patients (20 percent overall, nearly 30 percent in patients with heart failure), Medicare began penalizing hospitals with high readmission rates in 2012. All of this attention has stimulated a growing body of research focused on handoffs and transitions. This research is providing a deeper understanding of best practices, which have both structural and interpersonal components. These practices include standardized communication protocols (including “read backs”) and more interoperable information systems.

Teamwork and communication errors. Medicine is fundamentally a team sport. There is an overwhelming amount of evidence that the quality of teamwork often determines whether patients receive appropriate care promptly and safely. There are many clinical examples of this, including the management of a cardiac arrest (a so-called “code blue”), a serious trauma case, a complicated surgery, the delivery of a compromised infant or the treatment of an immune-compromised patient in isolation.

While the importance of teamwork is widely accepted, the evidence that it exists and that team members feel free to speak up if they see unsafe conditions is not strong. Over the last three decades, the aviation industry has learned the importance of teamwork and implemented state-of-the-art teamwork concepts which have had a dramatic impact on safety performance (Figure 15). Healthcare patient safety advocates have appropriately turned to the aviation industry to adapt their teamwork concepts to clinical care.

In addition, the JCAHO sentinel event program has provided evidence that communication problems are the most...
common root cause of serious medical errors, as shown in Figure 16.58

Well-functioning healthcare teams should employ appropriate authority gradients that allow people to speak up, utilize aviation’s crew resource training communication model (CRM), use effective methods of reviewing and updating information on individual patients, employ accepted strategies to improve communications including SBAR (Situation, Background, Assessment and Recommendation) and so-called “CUS words” (I am Concerned, I am Uncomfortable and I feel it is a Safety issue) to express escalating levels of concern, and constantly maintain situational awareness.

Healthcare-associated infections (HAIs). Healthcare-associated infections (HAI) are infections that people acquire in a healthcare setting while they are receiving treatment for another condition. HAIs can be acquired anywhere healthcare is delivered, including inpatient acute care hospitals, outpatient settings such as ambulatory surgical centers and end-stage renal disease facilities, and long-term care facilities such as nursing homes and rehabilitation centers. HAIs may be caused by any infectious agent, including bacteria, fungi and viruses, as well as other less common types of pathogens.

These infections are associated with a variety of risk factors, including:

- Use of indwelling medical devices such as bloodstream, endotracheal and urinary catheters
- Surgical procedures
- Injections
- Contamination of the healthcare environment
- Transmission of communicable diseases between patients and healthcare workers
- Overuse or improper use of antibiotics
HAIs are a significant cause of morbidity and mortality. The CDC estimates that 1 in 20 hospitalized patients will develop an HAI, that they are responsible for about 100,000 deaths per year in U.S. hospitals alone and that HAIs are responsible for $30 to $40 billion in costs. In addition, HAIs can have devastating emotional, medical and legal consequences.

The following list covers the majority of HAIs:

- Catheter-associated urinary tract infections
- Surgical site infections
- Bloodstream infections (including central line-associated infections)
- Pneumonia (including ventilator-associated pneumonia)
- Methicillin-resistant Staph aureus infections (MRSA)
- C. difficile infection

As they are to other common sources of harm, federal policymakers are paying attention to HAIs. The U.S. Department of Health and Human Services (HHS) has identified the reduction of HAIs as an agency priority goal for the department. HHS committed to reducing the national rate of HAIs by demonstrating significant, quantitative and measurable reductions in hospital-acquired central line-associated bloodstream infections and catheter-associated urinary tract infections by no later than September 30, 2013. The final results of this program are yet to be published.

By using a variety of well-tested policies and procedures, there is encouraging evidence that healthcare organizations can significantly decrease the frequency of HAIs.

Other sources of errors. There are a variety of other sources of significant patient harm in clinical care. These include patient falls, altered mental status (often due to over sedation), pressure ulcers and venous thromboembolism, harm related to inadequate staffing ratios, harm resulting from nonstandardization, errors due to lack of redundant systems, harm resulting from inadequate provider training, harm caused by caregiver stress and fatigue, etc.

The role of information technology and measurement in safety

Advanced information technology is playing an increasingly important role in patient safety. Technologies involved include Electronic Health Records (EHRs), CPOE, clinical decision support systems, IT systems designed to improve diagnostic accuracy, analytical systems, bar coding, RFID, smart
intravenous pumps and automated drug dispensing systems. It is important to note that skill is required to implement these systems in a manner that promotes safety while not increasing the rate of harm.

Measuring errors and rates of harm can be a difficult process. Traditionally, measuring systems have depended on voluntary reporting, but for a variety of reasons, it is clear these approaches significantly underestimate errors and harm. Other approaches, such as patient safety indicators drawn from administrative datasets, can be overly sensitive and therefore need to be augmented by detailed chart reviews.

Over the past decade, the use of trigger tools has emerged as a favored method to measure the incidence of adverse events in a healthcare organization. The most widely used of these is the Global Trigger Tool (GTT). Initially developed by David Classen, MD, and others, the GTT has been adopted and promoted by the Institute for Healthcare Improvement (IHI). The theory behind trigger tools is that some errors in care will produce a response that can be tracked, providing clues to possible adverse events. For example, the use of Narcan might indicate over sedation with a narcotic, and the use of Benadryl may indicate an allergic reaction. In most organizations, use of the GTT is fairly labor intensive, but some organizations have made progress in automating the process.

Several studies have looked at the GTT as a way to assess the state of patient safety with somewhat concerning conclusions. One study tracked the rate of adverse events in nine hospitals over five years and found no significant improvement in harm rates despite major efforts to improve patient safety. A study by the Office of Inspector General (OIG) found 1 in 8 Medicare inpatients experienced significant adverse events. Another study used the GTT to demonstrate that one in three hospitalized patients experienced an adverse event of some kind.

This concludes the high-level overview of patient safety. As mentioned at the outset, this overview is not designed to provide the level of detailed knowledge required for healthcare leaders to adequately implement a comprehensive patient safety program. Again, the reader is encouraged to read Dr. Wachter’s excellent book on the subject, “Understanding Patient Safety” (second edition, 2012).

**Viewing healthcare as a complex adaptive system**

Most would agree that healthcare is becoming overwhelmingly complex. In the 1960s, the typical general practitioner practiced in a privately owned office with minimal staff, subscribed to one or two journals, periodically engaged a specialist when necessary, conducted patient rounds in the hospital and did roughly an hour’s worth of paperwork a week. Specialists were completely independent, practiced primarily in the hospital, focused principally on a
particular body system, were in total control of their practice and interacted with administrators only when they needed some type of support (e.g., the purchase of new equipment).

Those days are essentially gone. As thousands of new drug therapies, sophisticated new forms of diagnosis and treatment, the need for computerization, demands for integrated care, rising demands for data-driven quality outcomes, increasing costs, growing legal liabilities, complex new regulations and a host of other complex, interrelated forces entered the scene, the complexity of clinical care grew exponentially. With these changes, the practice of care has become stressful and often times overwhelming for clinicians and non-clinicians: individual providers, nurses, general practitioners, specialists, administrators and senior executives.

Healthcare organizations are increasingly being viewed as complex adaptive systems. A complex adaptive system is a collection of individual entities that have the ability to act in ways that are not always totally predictable. Furthermore, the entity’s actions are interconnected: one entity’s actions can sometimes change the context for the other entities, and thereby impact the other entity’s actions in unpredictable ways. Examples of complex adaptive systems include the environment, the immune system, the stock market, a colony of insects, world financial markets and families.

Complexity science is the study of complex adaptive systems, the relationships within them, how they are sustained, how they self-organize and how outcomes result. Complexity science is increasingly being applied to healthcare for the reasons outlined above and it offers significant advantages for providers who are trying to understand and manage the growing complexity of healthcare. For those who would like to learn more about healthcare as a complex adaptive system, please read Appendix A.

In conclusion

In part 1, we examined the historical, financial, cultural, quality, safety and complexity factors that characterize healthcare today. In part 2, we will review the emerging concepts and methods that will enable healthcare providers to adapt and succeed in a rapidly changing and increasingly complex future.
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APPENDIX A: HEALTHCARE: A COMPLEX ADAPTIVE SYSTEM

Defining complexity science

Complexity science is the study of complex adaptive systems, the relationships within them, how they are sustained, how they self-organize and the outcomes that result. Complexity science is made up of a variety of theories and concepts. It is a multidisciplinary field involving many different areas of study, including biology, mathematics, anthropology, economics, sociology, management theory, computer science and others.

Complexity science is built on modern research and concepts that view systems as nonlinear and able to adapt to a changing environment. Complexity science considers characteristics of systems that are overlooked by conventional mechanical approaches. It offers a framework for studying complex adaptive systems, focusing on the patterns and relationships among the parts in order to understand and act on the unpredictable aspects of working with people in dynamic organizations.

A complex adaptive system is a collection of individual entities that have the ability to act in ways that are not always totally predictable. Furthermore, the entities’ actions are interconnected: one entity’s actions can sometimes change the context for the other entities and thereby impact the other entities' actions in unpredictable ways. Examples of complex adaptive systems include the environment, the immune system, the stock market, a colony of insects, world financial markets and families.

Mechanical versus complex theories

For centuries, scientists viewed the world and events as being linear. Their world was one where simple cause-and-effect rules could generally explain events and outcomes. Everything was viewed as a machine. If you carefully took the machine apart and gained understanding of the parts, you could then understand the whole. Scientists embraced the belief that the universe and all of its components could be dissected, understood and ultimately controlled.

However, in the modern era, this view of the universe and its parts began to falter. Despite intensive study, many systems did not behave in this manner. The weather, ecosystems, economics, political systems and, increasingly, organizations as they became larger and more complex, could not be predicted by mechanical theory. Despite using the most powerful computers in the world,
these types of systems, and others like them, remained unpredictable and hard to understand. Ultimately, as science entered the world of quantum physics, the reality that mechanical theory could not explain everything became more obvious. Increasingly, new discoveries made it apparent that the very smallest nuclear subcomponents simply did not behave in accordance with simple cause-and-effect rules. They were governed by a different set of principles.

As scientists in different disciplines explored these phenomena, a new theory began to emerge that better explained the behavior and outcomes of these complex systems: complexity theory. In a complex system, the system is made up of components that can act independently and interact in a way that is unpredictable. Yet these interactions, and the system as a whole, ultimately can be explained by complexity theory.

You can distinguish between systems that are fundamentally mechanical and those that are naturally adaptive. Conventional (mechanical) models are based on Newtonian scientific principles that view the universe and its subsystems as machines. In the Newtonian approach, the theory holds that by understanding simple, universal rules that control the system’s parts, future behavior of the parts is predictable with linear cause and effect. Even complex mechanical systems rarely produce unpredictable behavior. When they appear to, experts can generally sift through the data and determine the cause. For example, when a computer system crashes, it may appear that the outcome was unpredictable. However, more often than not, you can decipher the cause after a thoughtful and thorough review of the evidence.

A reasonable argument can be made that this framework for understanding how machines work guided the orientation of medicine around organ-based disciplines and physiological processes and healthcare organizations around linear, hierarchal relationships and rules.

Conversely, the agents within a complex system interact and connect with each other in random ways. Complexity science helps make regularities become apparent, it helps form a pattern that feeds back into the system, and it informs the interactions of the agents within the system and the behavior of the system as a whole. For example, if an organism within an ecosystem begins to deplete one species, the result will be a greater or smaller supply of food for others in the system, which affects their behaviors and numbers. Following a period of flux across all the different populations within the ecosystem, a new balance or steady state emerges.

**The growing interest in complexity theory**

The interest in complexity science has grown rapidly over the past decade. One of the reasons for this is the emergence of highly complex, worldwide challenges, including the environment, understanding the human genome, healthcare and medicine, economics, world markets, population growth and
telecommunications, to name a few. Another reason is the emergence of advanced computing resources with sufficient power to model large-scale, complex systems, to investigate new ways of approaching system design and to predict the outcomes for a given model. With advanced computing systems, experts are able to effectively study large-scale, complex, highly adaptive systems, like healthcare.

Organisms, people and organizations are parts of networks within complex adaptive groups. They interact, adapt and learn. For example, organisms are the adaptive agents within an ecosystem; antibodies are the adaptive agents in the immune system; humans are the adaptive agents in the political system; and organizations are the adaptive agents in the economic system. Each agent acts based on its knowledge and experience, and all agents interact together, while adapting to the environment. In complex adaptive systems, the parts have the freedom and ability to respond to stimuli in different and unpredictable ways. As a result, unpredictable, surprising and even innovative behaviors and outcomes become real possibilities.

Complexity theory and organizations

Although its roots are clearly in science, complexity theory is increasingly being used outside of science to help describe, understand and predict the behavior of other complex entities, including organizations. Complexity science can help you understand how an organization and its subcomponents adapt to their environments and how they cope with complexity and uncertainty. From the perspective of complexity science, organizations are not viewed as aggregations of individual static entities that behave in predictable ways. Rather, they are viewed as a dynamic collection of strategies and structures that are adaptive. That is, their collective behavior will evolve and self-organize in response to change, initiating events or collections of events that can be explained by complexity science. By understanding the tenets of complexity science, leaders of complex organizations can better understand and lead their organizations. However,

<table>
<thead>
<tr>
<th>Comparison of organizational system characteristics</th>
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<tbody>
<tr>
<td><strong>Complex adaptive systems</strong></td>
</tr>
<tr>
<td>Are living organisms</td>
</tr>
<tr>
<td>Are unpredictable</td>
</tr>
<tr>
<td>Are adaptive, flexible, creative</td>
</tr>
<tr>
<td>Tap creativity</td>
</tr>
<tr>
<td>Embrace complexity</td>
</tr>
<tr>
<td>Evolve continuously</td>
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</table>

Figure 105: Comparison of organizational system characteristics
this requires leaders to view and lead their organizations differently than they have traditionally.

Organizational management theorist Gareth Morgan, Ph.D., contrasted complex adaptive systems and traditional systems, as shown in Figure 105. Change and innovation are major characteristics of complex adaptive systems, as opposed to the simple, linear and additive relations that are characteristic of Newtonian, mechanical thinking. Behaviors and outcomes can be good or bad, advances or failures. Outcomes can occur either at the microsystem level (for example, an outcome resulting from a relationship of trust between a patient and a physician) or at the macrosystem level of care (such as the AIDS epidemic).

Complexity science views individual organizations as part of a connected web of interacting agents embedded in larger networks and systems, distinct from traditional top-down, linear, prescriptive, bureaucratic hierarchies. Living in this world of organizational interconnections can create an uncontrollable and oftentimes turbulent environment. The consequences of people interacting in a complex organizational system (especially those with slim resources) can contribute to leaders feeling like they are living in a world of unpredictable disruptions, not a world of understandable trends. As they continue to operate in this context, leaders need to become more skilled in managing contradictions and competing demands. In Figure 106, Morgan contrasts the leadership styles necessary to lead in a complex adaptive system environment as compared to a traditional system.

<table>
<thead>
<tr>
<th>Complex adaptive systems</th>
<th>Traditional systems</th>
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</thead>
<tbody>
<tr>
<td>Are open, responsive, catalytic</td>
<td>Are controlling, mechanistic</td>
</tr>
<tr>
<td>Offer alternatives</td>
<td>Repeat the past</td>
</tr>
<tr>
<td>Are collaborative, co-participating</td>
<td>Are in charge</td>
</tr>
<tr>
<td>Are connected</td>
<td>Are autonomous</td>
</tr>
<tr>
<td>Are adaptable</td>
<td>Are self-preserving</td>
</tr>
<tr>
<td>Acknowledge paradoxes</td>
<td>Resist change, bury contradictions</td>
</tr>
<tr>
<td>Are engaged, continuously emerging</td>
<td>Are disengaged, nothing ever changes</td>
</tr>
<tr>
<td>Value persons</td>
<td>Value position, structures</td>
</tr>
<tr>
<td>Shift as processes unfold</td>
<td>Hold formal position</td>
</tr>
<tr>
<td>Prune rules</td>
<td>Set rules</td>
</tr>
<tr>
<td>Help others</td>
<td>Make decisions</td>
</tr>
<tr>
<td>Are listeners</td>
<td>Are knowers</td>
</tr>
</tbody>
</table>

Figure 106: Comparison of leadership styles
Viewing healthcare as a complex adaptive system

As discussed in chapter 2, most people would agree healthcare is overwhelmingly complex. In the 1960s, the typical general practitioner practiced in a privately owned office with minimal staff, subscribed to one or two journals, periodically engaged a specialist when necessary, rounded on their patients in the hospital and did roughly an hour’s worth of paperwork a week. The specialist was completely independent, practiced primarily in the hospital, focused primarily on a particular body system, was in total control of their practice and interacted with administrators only when they needed some type of support (e.g., a new device).

Those days are essentially gone. As thousands of new drug therapies, sophisticated new forms of diagnosis and treatment, the need for computerization, demands for integrated care, rising demands for data-driven quality outcomes, increasing costs, growing legal liabilities, complex new regulations, and a host of other complex, interrelated forces entered the scene, the complexity of clinical care grew exponentially. With these changes, the practice of care has become stressful and often overwhelming for both clinicians and non-clinicians, from individual providers, nurses, general practitioners and specialists to administrators and senior executives.

As the healthcare environment becomes even more complex, it is increasingly exceeding the ability of the smartest and most well-trained clinician to consistently make the best possible decisions. Studies have shown humans can deal with approximately seven (plus or minus two) independent variables when making any given decision, regardless of how smart or how well educated they are. Yet clinicians encounter situations almost every day that require juggling far more than seven variables. For example, Alan Morris, MD, demonstrated there are about 240 factors to consider when adjusting a ventilator for a patient in an intensive care unit. Although Dr. Morris concluded that only about 40 of these were the most important, that number still vastly exceeds the ability of the unaided human mind.

Regardless of the clinical environment in which they practice, busy clinicians and health system leaders face multivariable, complex decisions every day. Given their human limitations, it is not surprising they would find it difficult to consistently make the right decision. As healthcare becomes even more complex, it will be increasingly necessary to build standardized processes, care environments and decision-support systems that allow clinicians and others to be the best they can be.

In Appendix A of the IOM’s Crossing the Quality Chasm report, Redesigning Health Care With Insights From the Science of Complex Adaptive Systems, Paul Plsek defined a system as “the coming together of parts, interconnections, and purpose.” While systems can be broken down into parts that can be individually interesting, the real power lies in the way the
parts come together and are interconnected to fulfill a given purpose. The U.S. healthcare system is made up of numerous parts (hospitals, clinics, laboratories, pharmacies, urgent care centers, imaging centers, physician groups, insurers, etc.) that are interconnected by patients and the flow of information to fulfill a specific purpose — improving and maintaining the health of patients and populations.

It is easy to demonstrate that the U.S. healthcare system and its many stakeholders (patients, care providers, operational stakeholders, payers, policymakers, society, etc.) represent a complex adaptive system. While there are certainly pockets of mechanical systems within healthcare, the individual parts and the collective whole largely represents a complex adaptive system.

In his book *The Checklist Manifesto: How to Get Things Right*, Atul Gawande points out that complexity theory divides decisions and problems into three general categories: simple, complicated and complex. Simple problems are ones in which the inputs and the outputs are known. These problems can be managed by following a set of rules. Complicated decisions involve significant uncertainty. In these situations, the solutions may not be known, but they are potentially knowable. Finally, complex decisions are decisions in which the actual formula for success is unknowable. You may have a general sense for what works, but you do not know with certainty what will work, nor do you know the outcome with any degree of certainty. Raising a child is a good example. You can raise children using the best available, experienced-based guidance, yet the outcome is definitely not predictable.

It is important to understand the differences between these three categories of decisions and problems because the approach you take needs to match the type of problem you face. For example, a surgical checklist or simple datasets have been proven to be good solutions for simple problems. However, a checklist or a simple dataset is unlikely to be of much help for a highly complex decision. The best approach to a complex decision is often to try something that seems to make sense based on your knowledge and the available data. You must then measure the results and often repeat the cycle many times in search of the best possible outcome. This data-driven approach is increasingly being used in clinical care and will be become even more common in the future.

Complexity science can guide your understanding of the healthcare system, a multilayered system driven largely by rapidly changing demands, technology and information. In healthcare, organization and practitioner components make up a continuously evolving system because of their innovative, diverse and progressive adaptations. Understanding the core processes of an organizational system is critical. Core processes are the building blocks of the organizational system.
Studying the interfaces and interactions of core processes allows health system leaders to ask questions based on flows and patterns among the processes, identify feedback loops, explore interfaces and interactions and ultimately recognize the elements of an efficient system. If the components of a complex adaptive system act collectively, broken healthcare system interconnections can be identified and changed. When interactions among these components encounter boundaries, those boundaries can constrain effective interactions and limit outcomes. For example, if the traditional silos that have characterized our healthcare system persist (e.g., physicians, hospitals, insurers, etc.), they will impede the development of efficient accountable care organizations that can effectively manage the health and wellbeing of populations.

Whether you look at population health management or individual patient care, the traditional approach to patient care delivery and health system leadership does not encompass the complexity and behavior of the whole system. In managing individual patient care, clinicians tend to pay attention to linear episodes of care, one organ or disease at a time. However, the body has multiple systems, and treatment directed to one organ system or disease potentially affects the entire body.

The same is true of health system leadership. Healthcare organizations tend to focus their resources on treating, restoring and maintaining their own system integrity. Like the human body system, the healthcare organization has multiple, interconnected components. Healthcare delivery organizations are complex organizational forms, and they operate in an environment that is among the most complex of the world’s organizational environments. Hundreds of different types of professionals and organizations interact to provide a wide variety of services to patients, their families and their communities. Fragmentation and specialization, much of it well intended, characterizes both the delivery of health services and healthcare policy. We often fail to appreciate how these separate components interconnect. Similar to multiple organ failure in illness, failure of healthcare organizations to reach their potential often results from a failure to understand relationships and interactions between subcomponents. This can lead to significant dysfunction, or worse, the failure of the system. It also prevents the realization of optimal care for patients and communities.

Going forward, complexity science will play an increasing role in the design of new care delivery systems and models (at both the microsystem and macro-system level) and in the development of new policies designed to shape and transform our healthcare delivery system. Readers interested in learning more about viewing healthcare as a complex adaptive system and the application of complexity science to healthcare can access a variety of available resources.20, 155, 156
APPENDIX B: UNDERSTANDING DATA TYPES IN HEALTHCARE

In chapter 4, we covered the concept of processes and systems, the elements of frequency distributions, how to understand the different types of variation (common cause and assignable) and how they relate to processes. We also reviewed the concept of statistical process control and how it helps differentiate common cause variation from assignable variation, how statistical process control (SPC) charts are created, how SPC charts are applied and tampering. Professionals involved in healthcare improvement should understand these concepts.

We will now turn our attention to the different type of data and the types of SPC charts associated with each data type. Some readers who are involved in improvement will find this information beyond what they need or want to know. The information is included for those who want to delve more deeply into the topic.

When applying statistical process control methods to healthcare, it is important to recognize and understand the different types of data one encounters. Data are the actual pieces of information that are collected or observed during the process of delivering care. For example, if you ask five physicians how many inpatients they are managing, they might provide you the following data: 0, 3, 1, 5 and 16 (the latter physician might be a hospitalist who covers an intensive care unit). These represent examples of discrete data.

Not all data are numbers. For example, if you record the gender of each of the patients in a physician’s practice, you might get the following data: male, female, female, male and female.

Most data fall into one of two groups: categorical (or attribute) data and numerical data. The characteristics of these data types are illustrated in Figure 107.

<table>
<thead>
<tr>
<th>Categorical data</th>
<th>Numerical data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nominal</strong></td>
<td><strong>Discrete</strong></td>
</tr>
<tr>
<td>Values or observations can be assigned a code in the form of a number where the numbers are simply labels. You can count but not order or measure nominal data. Examples: sex, eye color, etc.</td>
<td>Values or observations can be counted (1, 2, 3…) and are distinct and separate. Examples: the number of patients on a panel, the number of doses of a medication delivered, the number of instruments counted, etc.</td>
</tr>
<tr>
<td><strong>Ordinal</strong></td>
<td><strong>Continuous</strong></td>
</tr>
<tr>
<td>Values or observations can be ranked (put in order) or have a rating scale attached. You can count and order but not measure ordinal data. Examples: low/medium/high, poor/good/excellent, Stage I/Stage II/Stage III, etc.</td>
<td>You can measure continuous data. Values or observations may take on any value within a finite or infinite interval. Examples: height, weight, time, temperature, etc.</td>
</tr>
</tbody>
</table>

Figure 107: Data types
Categorical (attribute) data

Categorical data are observed variables that can be sorted into groups or categories based on their characteristics or attributes. Another name for categorical data is qualitative data. There are two types of categorical data seen in healthcare: nominal data and ordinal data.

As the name implies, nominal data refer to named categories. Nominal data are items that are differentiated by a simple naming system based on their observed characteristics or attributes, such as a person’s gender, marital status, ethnicity, birth date or a DRG category.

Nominal data often have two categories (“alive” or “dead,” “male” or “female,” “present” or “absent”). That is, it is binary. Nominal data can take on numerical values (such as “1” indicating male and “2” indicating female), but those numbers do not have mathematical meaning. For instance, you cannot add 1’s and 2’s for male and female together and have it make any sense. This type of data are most often summarized with counts, proportions or rates. For example, “a proportional of the total” is binary. Nominal data in binary form generally have a binomial frequency distribution. Proportion charts (p charts) are often used to describe attribute data. These represent the most common type of control chart in healthcare. There are also specific statistical tests that are used in analyzing nominal data (i.e., $X^2$ test, Fisher’s exact test, etc.).

Ordinal data mix numerical and categorical data. The data fall into categories, but the numbers assigned to the categories have meaning. They are ordered, named categories. Observations on an ordinal scale are set into some kind of order by their position on the scale. Observations may indicate things such as temporal position, superiority, worsening, etc. For example, rating a hospital or clinic on a scale from 0 stars (lowest) to 5 stars (highest) represents ordinal data. Other examples of ordinal data include low/medium/high, Stage I/Stage II/Stage III/Stage IV, and poor/fair/good/very good/excellent. Ordinal data are often treated as categorical, where the groups are ordered when graphs and charts are made. However, ordinal data contain more information than nominal data. Unlike categorical data, the numbers do have mathematical meaning. For example, if you survey 100 people and ask them to rate a hospital on a scale from 0 to 5, taking the average of the 100 responses will have meaning. This would not be the case with nominal data. This type of data is generally summarized with counts, proportions or rates. An example of a statistical test used in analyzing ordinal data is the Jonckheere-Terpstra test. The Jonckheere-Terpstra test takes advantage of the ordered categories. Therefore, it has more power than the statistical tests used on nominal data (e.g., $X^2$ test, Fisher’s exact test). From a practical perspective, more statistical power means a test can extract more information and is better able to detect assignable variation when it does occur.
Numerical data

These data have meaning as a measurement, such as a person’s height, weight, IQ or blood pressure. Alternatively, they are a count, such as the number of patients in a physician panel, an instrument count following surgery or how many patients a physician can see in a clinic every day. Statisticians often refer to numerical data as quantitative data. Numerical data can be further broken into two types: discrete and continuous.

- **Discrete data** represent items that can be counted. The most common form of discrete data are the cardinal numbering system (0, 1, 2, 3,…), which is commonly used in healthcare. Discrete variables are measured across a set of fixed values, such as age in years (not microseconds). A person will say, “I am 20 years old” — not, “I am 20.672 years old.” These are often arbitrary scales, such as scoring one’s level of satisfaction, although such scales can also be continuous.

- **Continuous data** represent measurements. These measures are tracked along a continuous scale that can be divided into fractions or described down to multiple decimal points, such as temperature. Continuous variables allow for infinitely fine subdivisions, which means that if your measurements are sufficiently accurate, you can compare two items and determine the difference.

There are two types of numerical data that are most often seen in healthcare: interval data and ratio data.

**Interval data** are measured along a scale in which each position is equidistant from the one before and after it. This allows for the distance between two pairs to be equivalent. Examples of interval data include a satisfaction scale rated from 1 to 10, temperature in degrees Fahrenheit and dates on a calendar. This type of data contain more information than ordinal data. Interval data are generally described using intervals on a real number line. Interval data do not have a meaningful zero. As a result, interval data cannot be multiplied or divided. The values for interval data cannot be counted, nor can they form meaningful ratios. Interval data are usually summarized using means and variances (standard deviations). An example of interval data is the Celsius or Fahrenheit temperature scale. A person’s temperature generally ranges from 95 to 105 degrees Fahrenheit. At any given time, one’s temperature can be 98.6 degrees, 99.2 degrees or any one of numerous other points along the temperature scale. Interval data are uncommon and rarely part of an improvement project in healthcare.

**Ratio data** are numbers that can form meaningful ratios. Examples in healthcare include weight, age, blood pressure, and cost. Ratio data can be either continuous (e.g., can take on any numeric value, such as cost or weight) or discrete (e.g., meaningful only at discrete values, such as number of children). Ratio data contain more information than interval, ordinal or nominal data. In a ratio scale, numbers can be compared as multiples of one another.
For example, a person can be twice as tall as another person. In addition, the number zero has meaning. Thus, the difference between a person of 35 and a person of 38 is the same as the difference between people who are 15 and 18. A person can also have an age of zero. Ratio data can be multiplied or divided because the difference between 1 and 2 is the same as the difference between 3 and 4, and, 4 is twice as much as 2. This type of data are summarized with means and variances (standard deviations). Statistical tests that use ratio data include ANOVA and regression analysis.

**Parametric and nonparametric distributions**

There are a variety of different SPC charts. The choice of which SPC chart you use depends on the underlying frequency distribution of the data type being analyzed. There are two general types of frequency distributions: parametric and nonparametric.

A parametric distribution is shown in Figure 108. Parametric frequency distributions have an equation that describes the shape of the frequency distribution. The equation has parameters (variables). Most useful distributions have a single parameter that is the mean, or average. A few distributions have two parameters (mean and variance). Some rare distributions add a third parameter (mean, variance and offset from origin).

The characteristics of parametric and nonparametric distributions are shown in Figure 109.

<table>
<thead>
<tr>
<th>Parametric and nonparametric distribution characteristics</th>
<th>Parametric</th>
<th>Nonparametric</th>
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<tbody>
<tr>
<td><strong>Assumed distribution</strong></td>
<td>Normal</td>
<td>Any</td>
</tr>
<tr>
<td><strong>Assumed variance</strong></td>
<td>Homogenous</td>
<td>Any</td>
</tr>
<tr>
<td><strong>Typical data type</strong></td>
<td>Ratio or interval</td>
<td>Nominal or ordinal</td>
</tr>
<tr>
<td><strong>Data set relations</strong></td>
<td>Independent</td>
<td>Any</td>
</tr>
<tr>
<td><strong>Usual central measure</strong></td>
<td>Mean</td>
<td>Median</td>
</tr>
<tr>
<td><strong>Benefits</strong></td>
<td>Can draw more conclusions</td>
<td>Simplicity: less affected by outliers</td>
</tr>
</tbody>
</table>
Statistical resolution or power refers to how well a statistical test can detect differences. Power is determined by data type (i.e., ratio data exceeds interval data, which exceeds ordinal data, which exceeds nominal data). Parametric distributions give better power and resolution than nonparametric distributions, but they make assumptions about the underlying frequency distribution that may or may not be true. This is why you have to understand the data type you are observing and be sure you know what the most likely distribution is for that data. Whenever feasible, you will want to select the highest statistical power possible when analyzing data.

Choosing the appropriate SPC chart

Once different data types are understood, you can look at the different types of statistical process control charts applicable to each data type, as shown in Figure 110. Because interval data are not commonly seen in healthcare improvement projects, the control charts used for this type of data will not be discussed.

The p chart

The p chart ("proportion" chart) is the most common type of control chart in healthcare. It is typically used to look at variation within binary attributes data where there are two possible outcomes (e.g., a defect is present or it is not, a condition is present or it is not). It is used in situations where the sample size is relatively small.

Because the sub-group size can vary, a p chart often shows a proportion of nonconforming observations rather than the actual count. P charts show how the process changes over time. The process attribute (or characteristic) is always described in a binary manner — male/female, yes/no, pass/fail, alive/dead, etc. Because it is possible to set almost anything up as a
proportion, you can often analyze data in this binary form. Examples include the proportion of patients in a specific DRG category, entering a specific hospital, of a particular ethnicity, with a particular infection, developing skin ulcers, or with essentially any complication (other than very rare complications, in which case the g chart is used — see the discussion below). In each case, the proportion represents a “yes/no” situation (either this condition exists or it does not) and is therefore binary.

This type of data generates a binomial frequency distribution, as displayed in Figure 111. A binomial distribution looks like a bell-shaped curve (e.g., like a normal distribution). It can get misleading if the distribution is distorted or “skewed” as it nears its binary limits, 0 or 1. This is more likely to happen when the mean proportion and sample size are small. In this circumstance, a Poisson distribution (c chart) may be more appropriate (see discussion of Poisson distributions and c charts below).

There are four properties that indicate a binomial distribution:

1. There are “n” repeated trials or samplings (e.g., a fixed number of observations).
2. All trials are identical and independent.
3. The probability of success is the same for each observation.
4. Each trial has exactly two possible outcomes, “success” and “failure” — that is, it is binary.

The larger the sample size, the more a binomial distribution will approach a true normal distribution. This type of distribution will generate an SPC chart called an X-bar chart (see discussion of Gaussian distributions below).

The g chart

Most of the other types of SPC charts are uncommonly used in healthcare. The g chart is an exception.
Rare events inherently occur in all kinds of processes. In hospitals, there are adverse drug events, unusual post-operative infections, patient falls, ventilator-associated pneumonias, mortality from community-acquired pneumonia, and other rare, adverse events that cause prolonged hospital stays, result in poor outcomes and increase healthcare costs.

Because rare events occur at very low rates, traditional control charts like the p chart are typically not as effective at detecting changes in the event rates in a timely manner. In these situations, the probability that a given event will occur is so low, considerably larger sample sizes are required to create a p chart and abide by the typical rules governing this type of statistical analysis. In addition to the difficult task of collecting more data, this requires the improvement team to wait far longer to detect a significant shift in the process.

The trouble is that when you are considering very rare events, the statistical power depends more on the actual event rate than on your total sample size (“n”). The effective power depends on the number of events.

The g chart is a statistical process control chart developed by James Benneyan to monitor the number of events between rarely occurring errors or nonconforming incidents in healthcare. The g chart creates a picture of a process over time. Each point represents the number of observed units between occurrences of a relatively rare event. For example, deep mediastinal infections following open heart surgery are very rare (incidence of less than 1 percent). If an improvement team focuses on tracking the number of mediastinal infections, it will take them many years of experience to collect enough cases to have a statistically valid sample. This is also true of other rare events, such as contaminated needle sticks, instances of ventilator associated pneumonia, etc.

To develop a g chart, the team can count and plot the number of non-infection cases occurring between infection cases. This effectively increases the sample size and creates a statistically valid way of analyzing the process. This type of data are summarized with a mean. The “g” in g chart stands for geometric, since data relating to events between occurrences is represented by a geometric distribution, as portrayed in Figure 112.
The g chart helps to display this data in traditional control chart form. Specific formulas for g chart control limits are used with this type of data.

Figure 113 is an example of a g chart illustrating the time between infections in patients receiving total hip replacement. Note the improvement in performance resulting from a change in process (new type of hip prosthesis used).

Figure 114 is an example of a g chart illustrating the time between MRSA infections on a hospital ward as a result of implementing a hand hygiene protocol.

The c chart

It is not uncommon in healthcare to encounter discrete ratio data in the form of “number of per.” Examples include number of children per family, number of tests per patient, number of patients per hour, number of patients through a unit per day, number of blood stream infections per 1,000 central line days and so forth. Data of this type follows a Poisson distribution, as illustrated in Figure 115. When you encounter “number of counts per” data, it always suggests a Poisson distribution.

A Poisson frequency distribution has only one parameter, the mean. With a Poisson distribution, the mean equals the standard deviation.

The control chart that corresponds to a Poisson distribution is the c chart (a “count per unit” chart). If the data are expressed as a proportion, the output is called a u chart (a “unit per proportion” chart). Like other control charts, flipping a Poisson distribution on its side and plotting observations over time will generate a c chart or u chart.
The X-bar chart

Continuous ratio data are the fourth type of data commonly encountered in healthcare. Continuous ratio data are summarized by the mean and standard deviation. This type of data almost always yields a normal (Gaussian or bell-shaped) distribution. If it is a near perfect normal distribution, the chart that works with it is called an X-bar chart.

This type of distribution has more than one parameter. X-bar charts generally have two parallel charts, one for the mean and one for the standard deviation (the two parameters that summarize continuous ratio data). In this format, these are called X-bar and s charts. With an X-bar chart, you typically plot every observation.

What if nothing fits?

There are instances when the data observed in a situation does not easily fit one of the above scenarios. In such situations, the improvement team faces four possible solutions.

1. Transform the data. Many healthcare variables do not meet the assumptions of parametric statistical tests. That is, they are not normally distributed, the variances are not homogenous, or both. These frequency distributions frequently are “skewed” — that is, they have a tail, as portrayed in Figure 116. In this type of skewed

![Figure 115: Poisson frequency distribution](image1)

![Figure 116: Skewed frequency distribution](image2)
distribution, a normal distribution simply does not fit. To “transform” the data, you can perform a mathematical operation on each observation and then use the transformed numbers in a statistical test. If you are going to use one of these transform methods, you need to have a fairly high degree of certainty that your collected data represents a true, clean process (i.e., not a combination of different processes mixed together).

In these situations, there are several types of mathematical transformations you can perform on the data, including:

- **Log transforms.** This is the most common method for transforming data. You plot the logarithm of each of the data points in the data set. This creates a new frequency distribution that is often a bell-shaped curve, or at least it is less skewed than the initial frequency distribution. When this happens, you can apply parametric tools (e.g., X bar S chart). As a result, patterns in the data become more identifiable and interpretable. Even though you have performed a statistical test on the transformed data, it is not a good idea to report the means, standard errors, or similar results of transformed units. Instead, you need to “back transform” the results by doing the opposite of the mathematical function that was initially used in the data transformation. In a log transformation, a back transform is done by raising 10 to the power of the calculated mean of the logarithmic distribution. The upper and lower control limits, and the individual data points, can be similarly back transformed. While it is good to understand this technique conceptually, it is not necessary to understand the mathematics involved. Suffice it to say that the process has been shown to be mathematically legitimate. Taking this approach does not result in any loss of statistical power.

- **Power transforms.** If a log transform does not work, a “root” or “power” transform can be done. This is generally the third square root of your X’s, the fifth square root of your X’s, or the seventh square root of your X’s. Once again, this process can often transform skewed results into a more normal distribution, allowing you to apply parametric tools. Once these tools have been applied, you need to back transform the data, mean and control limits in a fashion similar to that mentioned under log transforms above. Taking this approach does not result in any loss of statistical power.

- **Use severity of illness transforms.** Technically, severity of illness adjustments can be viewed as a type of transformation. Severity of illness adjustments attempt to eliminate variation arising from differences among patients by breaking a cohort of patients into a series of sub-groups that are relatively homogenous in terms of severity based on a particular measurement parameter (e.g.,
cost per case or risk of mortality). If you break a skewed distribution of patients into severity of illness categories in this fashion, it is not uncommon to find the skewed distribution is actually composed of a series of normal distributions — a normal distribution for each category of severity in the cohort of patients under observation, as seen in Figure 117. You can then do the analysis on each subset of parametric distributions. Once this is done, they can be mathematically rolled back together. You do not lose any statistical power with this approach.

- Linear, cyclic, or nonlinear transforms. There are a variety of other mathematical transformations that can be performed on unusual frequency distributions to enable the application of parametric techniques. A detailed discussion of these methods is beyond the scope of this discussion.

2 Use Shewhart’s method of addressing a non-homogenous sample. Whenever possible, Shewhart sought to convert a data sample into a dataset that would generate a normal distribution to which parametric methods could be applied. In a non-homogenous population, as illustrated in Figure 118, you can randomly draw patients in small groups out of the
total non-homogenous population and create frequency distributions for each of these random groups. If you do this a large number of times (or more accurately, get a computer to do it a large number of times), you can plot averages of small groups of observed values. This generally results in a normal distribution to which you can apply parametric techniques, as shown in Figure 119. Using this approach maintains statistical power. This is an example of the so-called central limit theorem.

3 Use some other known frequency distribution. There are many of these, but most are very esoteric and not pertinent to healthcare except for highly unusual situations.

4 Use a non-parametric control chart — an XmR control chart. The problem with this approach is that you will lose a lot of statistical power. XmR charts provide the lowest level of statistical power. As a result, this is a choice of last resort.

For those involved in clinical and operational improvement, it is not necessary to understand the complicated mathematics behind these methods. You can always get a statistician or a computer to do the computations. However, it is important to understand the rules and techniques at a conceptual level in order to make the appropriate directional decisions when you encounter datasets that require the application of these methods.

There are a number of sources that provide a more detailed discussion of the different types of frequency distributions and their associated SPC charts, as well as their respective uses in healthcare. The interested reader can consult these other sources for additional information.157, 158, 159
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