

HEALTHCARE: A BETTER WAY

THE NEW ERA OF OPPORTUNITY



CHAPTER 6



HealthCatalyst
ignite change

Healthcare: A Better Way

The New Era of Opportunity



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ACKNOWLEDGMENTS

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

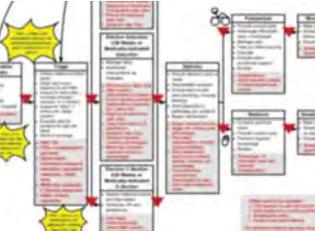
marketing. Leslie has been a joy to work with on this project. Sister Monica Heeran, CSJP, is one of the most supportive and thoughtful leaders I have ever known. Without her vision and willingness to take a risk with a young physician leader, my career would never have been the same. John Hayward has 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

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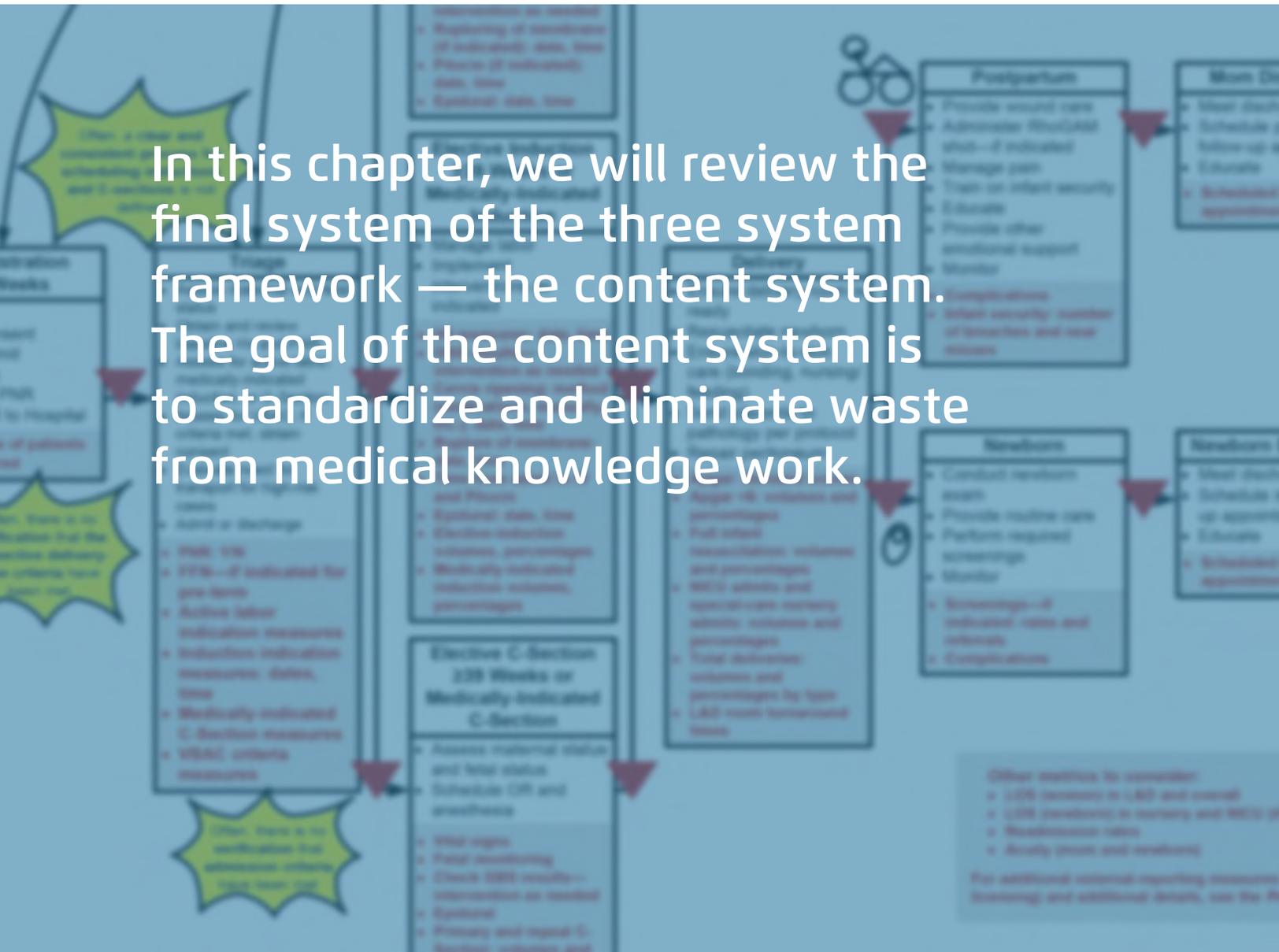
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6 THE CONTENT SYSTEM: STANDARD KNOWLEDGE WORK

In this chapter, we will review the final system of the three system framework — the content system. The goal of the content system is to standardize and eliminate waste from medical knowledge work.



In chapter 4, we discussed the steps an organization can take to strengthen its analytic system in order to make data-driven decisions, and in chapter 5 we reviewed the characteristics of an effective deployment system which is essential to achieve scalable and sustainable quality improvement outcomes. In this chapter, we will review the final system of the three system framework — the content system.

The goal of the content system is to standardize and eliminate waste from medical knowledge work. Medical knowledge work is the process of taking today's best medical knowledge and having it become the standard in every day practice of most clinicians. Currently the process can take as long as 17 to 20 years to occur, as reported by the Agency for Healthcare Research and Quality (AHRQ).⁷² This lag in the application of new knowledge is predominantly an outcome of a weak content system.

By standardizing knowledge assets, such as order sets, intervention criteria, process flow maps and patient safety protocols, an organization can improve the speed at which new medical knowledge becomes everyday practice. This includes a consistent standard method for gathering evidence, evaluating that evidence and integrating it into care delivery.

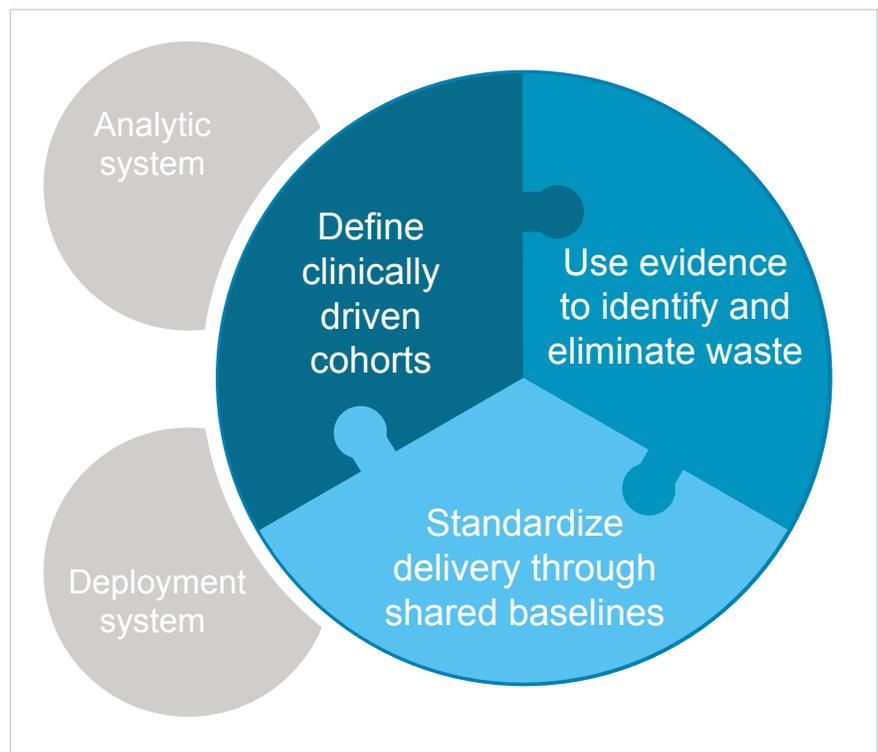


Figure 65: Content system components

An advanced clinical content system can decrease the lag time between the discovery of new knowledge and the standard application of that knowledge into clinical practice. As illustrated in Figure 65, the three major components of the content system include:

- Defining a clinically driven patient cohort
- Using evidence to identify and eliminate waste, and
- Standardizing care through shared baselines

Together, these three components help healthcare systems ignite change by eliminating the non-value added, or wasteful activities, and hard wiring the most current evidenced-based activities into the care process. Consistent with Lean principles, this hard wiring enables clinicians to have an evidence-

based, standardized way of delivering care that also supports deviation from the shared baseline when required for an individual patient. A content system allows organizations to achieve mass customization, where the variation in care is a result of the patient’s condition and not in provider practice. Each of these content system components will be discussed in more detail, starting with the principles behind defining a clinically driven cohort.

By the end of this chapter you will understand how to identify cohorts of patients for quality improvement initiatives, how to use evidence to identify and eliminate waste, and the importance of standardizing care delivery through shared common baselines.

Chapter 6.1 — Defining clinically driven cohorts

A cohort is a group of patients with similar characteristics. There are three types of cohorts — chronic condition cohorts, episodic cohorts and procedural cohorts. A chronic condition cohort includes chronic conditions, such as asthma or diabetes. Episode centric cohorts revolve around a single episode of care like pregnancy that typically lasts nine months. An example of a procedural cohort could be an appendectomy. An appendectomy involves a one-time visit to the hospital and the episode of care requires minimal or no follow-up.

The first step is to identify what type of cohort you are dealing with. The procedural cohorts like appendectomy are reasonably straightforward: either you had an appendectomy or you haven’t. Chronic conditions are more difficult to define since patients tend to go in and out of the cohort. For example, an asthma patient might get her asthma under control and have no further incidents for a year or more. But then, the asthma flares up when the patient gets a cold and develops a cough. It is important to develop the best cohort definition possible for these types of chronic conditions.

An example of defining an asthma cohort is illustrated in Figure 66. In this example, a work group created a simple initial cohort definition for asthma as follows: “All patients with ICD-9 493.XX diagnosis codes in their hospital bills.” The work group chose this initial definition since 493.XX is the ICD-9 hospital billing code

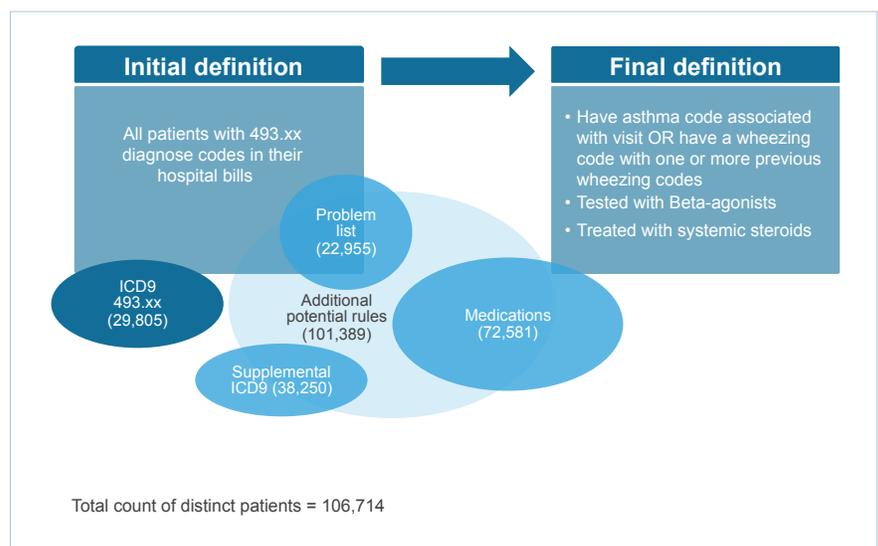


Figure 66: Defining asthma cohort definition
(Click for larger version)

for asthma cases. Using this initial definition, the work group determined there were about 29,000 patients in the cohort.

The number of patients seemed too low. Some of the clinicians said, “Well, you know we don’t always code the condition as asthma. Sometimes we code it as wheezing because we are not sure if it is asthma when the patient initially presents. But many of those cases do turn out to be asthma.” The work group involved in the cohort definition and clinical improvement project started to add some supplemental codes that resulted in an additional 38,000 patients. Then they realized that sometimes asthma was noted on the problem list — even though it wasn’t coded — so they added those patients as well. Finally, they noted that certain medications were only given to asthma patients (e.g., Albuterol) so they added those patients to the asthma cohort. When all of these rules were considered in the inclusion criteria, 101,000 patients were added to the cohort. Some of the patients overlapped with the original group that was coded as asthma patients, but some were new. As this example shows, having a clinically defined cohort versus just a billing or administratively defined cohort is essential in clinical improvement initiatives.

In this example, the healthcare organization ended up with the following definition for the asthma cohort: patients that have an asthma code associated with a visit or have a wheezing code with one or more previous wheezing codes, and patients that are treated with Beta-agonists or with systemic steroids. After going through this iterative process to build the definition of the cohort, the work group was confident the cohort included all the people with asthma in their patient population.

The Health Catalyst Cohort Builder is an example of a discovery application organizations can use in the process of defining a cohort. In many situations today, when clinicians have questions about patient populations, they have to request data from data analysts who often have a lengthy backlog of requests. Even getting simple queries can take a long time. These questions tend to be iterative resulting in numerous emails between the clinician and the data analyst, which can be a time consuming process. Cohort Builder allows people who are not experts at querying databases to construct complex queries using a simple, self-service interface.

Chapter 6.2 — Evidence-based practice, comparative effectiveness research and levels of evidence

Evidence-based practice (EBP)

Is it taking years — rather than weeks — to put the latest medical evidence into practice? For most organizations, the time between medical knowledge discovery and broad adoption by the majority of clinicians is often measured in years. With patients’ health and welfare on the line, everyone agrees these timeframes must change.

A weak clinical content system hinders rapid deployment of new clinical diagnostic and treatment approaches. From a clinical perspective, a clinical content system should consist of standardized knowledge assets, which include evidence-based practice (EBP) guidelines, treatment cascade models, indications for intervention, indications for referral, standing order sets and protocols. The goal of EBP is to systematize how providers decide, for example, when to do surgery and when to order physical therapy.

The most widely used definition of evidence-based practice originated with David Sackett, MD. According to Dr. Sackett, EBP is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”^{91, 92}

EBP is the integration of clinical expertise, patient values and the best research evidence into the decision making process for patient care, as illustrated in Figure 67. Clinical expertise refers to the clinician’s accumulated experience, knowledge and clinical skills. The patient brings his or her own personal preferences and unique concerns, expectations and values. The best research evidence generally originates from clinically relevant research that has been conducted using the best available methodology.⁹³



Figure 67: Components of evidence-based practice

Although research is clearly a key element of the care delivery process, clinicians cannot rely solely on the research in their quest to make the best possible decisions for patients. The best decisions result from fully integrating all three key components into the clinical decision-making process — with the goal of optimizing clinical outcomes, addressing patient preferences and achieving the highest possible quality of life and patient satisfaction.

EBP seeks to assess the strength of the evidence as well as the risks and benefits of diagnostic tests and treatments. By using this assessment, clinicians are better able to predict whether a treatment will do more harm than good. Evidence-based medicine seeks to use the experience of a population of patients reported in research literature to guide decision-making in routine clinical practice.

As illustrated in Figure 68, EBP is a multi-step process that generally begins with the patient encounter, during which the clinician generates questions about the etiology of the symptoms, the utility of diagnostic tests, the effects of various therapies and the prognosis of the illness or injury. A clinician who promotes and is a good practitioner of EBP must: be knowledgeable and experienced; know how to search the literature for evidence; apply a logical reasoning process to evaluate the validity and applicability of the evidence; and combine the evidence with clinical experience and patient preferences to arrive at the most appropriate decisions. The EBP process also implies the clinician will learn from their experience. If good data is collected as a byproduct of the care delivery process, then the data can be used as part of an ongoing effort to continuously improve patient care in pursuit of better outcomes.

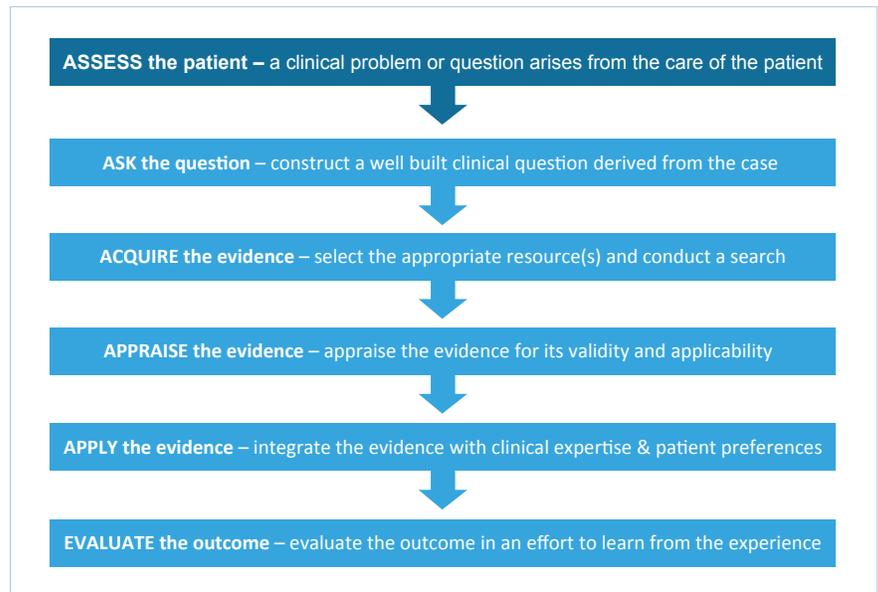


Figure 68: Steps in the evidence-based process
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Comparative effectiveness research

The movement toward EBP and the paucity of evidence for many clinical practices has spawned the field of comparative effectiveness research (CER). An Institute of Medicine (IOM) committee has defined comparative effectiveness research as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of clinical effectiveness research is to assist consumers, clinicians, purchasers and policy makers to make informed decisions that will improve health care at both the individual and population levels.”⁹⁴

An important component of comparative effectiveness research is the concept of pragmatic trials. Clinical trials have been described as either explanatory or pragmatic. Explanatory trials generally measure efficacy — the benefit a treatment produces under ideal conditions, often using carefully defined subjects in a highly controlled care delivery environment. Pragmatic trials measure effectiveness — the benefit the treatment produces in routine clinical practice.

The goal of using an explanatory approach is to further scientific knowledge by recruiting as homogeneous a population as possible. Randomized controlled trials are a form of explanatory trial. By contrast, the design of a pragmatic trial reflects variations between patients that occur in clinical practice and aims to inform treatment choices.⁹⁵

As discussed in chapter 1, Jack Wennberg, MD, and his colleagues at the Dartmouth Institute for Health Policy and Clinical Practice have spent over 40 years documenting the geographic variation in healthcare that patients in the U.S. receive — a phenomenon referred to as practice pattern variation. The Dartmouth researchers concluded: if unwarranted variation were eliminated, the quality of care would increase and healthcare savings of up to 30 percent would be possible — a statistic often repeated in CER.

Several groups have emerged to provide leadership in the area of CER. These include the AHRQ, the IOM and the ECRI Institute. Interested readers can learn more about comparative effectiveness research on their websites. In addition, the IOM has produced an extensive report on comparative effectiveness research.⁹⁴

Understanding levels of evidence

In EBP, it is important to realize that evidence is not the same as proof. The evidence available to clinicians can vary depending on the situation. In some instances, evidence can be so weak it is hardly convincing at all, and in other instances, it can be so strong that no one doubts its correctness. It is therefore important to be able to determine which evidence is the most authoritative. So-called levels of evidence are used for this purpose and specify a hierarchical order for various research designs based on their internal validity.

Internal validity refers to the extent that the results of the underlying research may be biased; it is thus a reference to the degree to which alternative explanations for the outcome are possible. Internal validity is a measure of the strength of the cause-and-effect relationship between an intervention and its outcome. The pure experiment in the form of a randomized controlled trial (RCT) is regarded as the gold standard for documenting internal validity in many disciplines. That is, the study design of RCTs is believed to yield the lowest chance of bias. Non-randomized studies, also referred to as quasi-experimental, observational or correlation studies, are regarded as research designs with lower internal validity. Examples of this type of research design include panel, cohort and case-control studies.

External validity refers to the extent to which the results of a study can be generalized to other situations or populations. Quality improvement trials emphasize external validity, whereas RCTs emphasize internal validity.

The ability to incorporate EBP into clinical care requires a basic understanding of the main research designs underlying the published evidence. Some research designs provide a stronger level of evidence than others based on their inherent characteristics. Systems designed to stratify evidence based on the quality of the evidence have been developed, such as the one developed by the United States Preventive Services Task Force (USPSTF).⁹⁶ The USPSTF is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services. The panel is funded by the U.S. Department of Health and AHRQ.

In creating its recommendations, the USPSTF uses a grading system. The grading system is as follows:

- Grade A: Recommended. There is a high certainty the net benefit is substantial.
- Grade B: Recommended. There is a high certainty the net benefit is moderate, or there is a moderate certainty the net benefit is moderate or substantial.
- Grade C: No recommendation. Clinicians may provide the service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit.
- Grade D: The task force recommends against this service. There is moderate or high certainty the service has no net benefit or the risk of harm outweighs the benefits.
- Grade I: The current evidence is insufficient to assess the balance of benefits and harms.

As illustrated in Figure 69, the USPSTF hierarchy of evidence has often been illustrated as a pyramid. The pyramid is an appropriate shape for this graphic, as it represents the quality of research designs by level as well as the quantity of each study design in the body of published literature (i.e., more low quality evidence exists than high quality evidence).

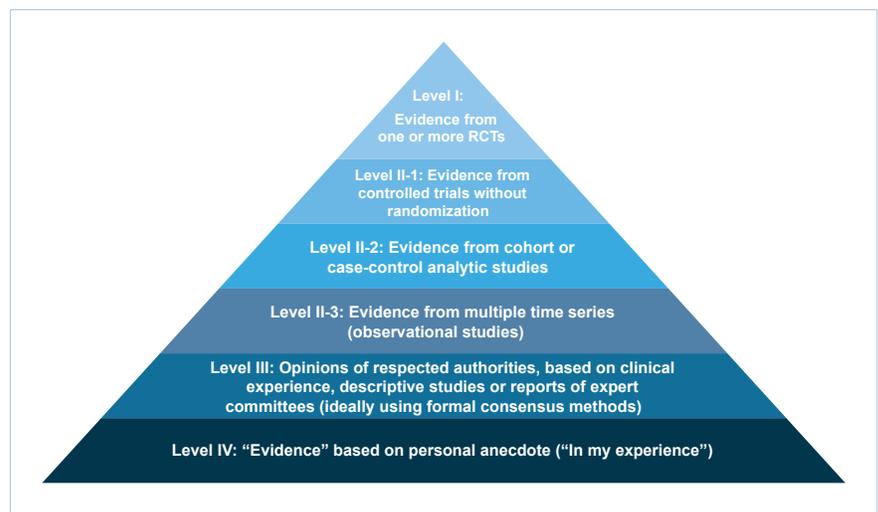


Figure 69: Levels of evidence
(Click for larger version)

The following is a description of each level of evidence:

- Level I: Evidence from one or more RCTs. A randomized controlled trial is an experimental, prospective study in which participants are randomly allocated into an experimental group or a control group and followed over time for the outcomes of interest. Study participants are randomly assigned to ensure that each participant has an equal chance of being assigned to an experimental or control group, thereby reducing potential bias. Outcomes of interest may be death (mortality), a specific disease state (morbidity) or a numerical measurement, such as blood chemistry level. Randomized controlled trials are frequently used to measure the effectiveness of a particular therapy, especially drug therapies.

A systematic review is a summary of the medical literature that uses explicit methods to perform a comprehensive literature search and critical appraisal of individual randomly controlled trials. These composite studies use appropriate statistical techniques to combine valid studies.⁸⁸ Systematic reviews provide the strongest type of evidence, as the authors attempt to find all research on a topic, published and unpublished. The authors then combine the research into a single analysis. Systematic reviews are different than review articles. While systematic reviews are conducted to answer a specific clinical foreground question, review articles provide a broad overview on a topic to answer background questions. Another difference is that the literature search for review articles does not attempt to find all existing knowledge on a topic.

A meta-analysis is a particular type of systematic review that attempts to combine and summarize quantitative data from multiple studies using sophisticated statistical methodologies. Such a strategy strengthens evidence by making the small sample size of individual studies larger, giving the results more statistical power — and therefore, more credibility than the individual studies. Meta-analyses tend not to be comprehensive as only compatible data may be combined into a larger data set.

- Level II-1: Evidence from controlled trials without randomization (quasi-experimental design). Quasi-experimental design is a form of experimental research used extensively in the social sciences and psychology. While many view this approach as unscientific and unreliable, the method has proven useful for measuring social variables. Quasi-experiments resemble quantitative or qualitative experiments, but they lack random allocation of study subjects and proper controls, making good statistical analysis difficult.

- Level II-2: Evidence from cohort or case-control studies. A cohort study is an observational, prospective or retrospective study. A cohort study involves identification of two groups (cohorts) of patients: one that received the exposure of interest, and one that did not. The outcome of interest is measured going forward in time for these cohorts. While at first glance a cohort study may appear similar to a RCT, it differs in one very significant way — the researchers do not assign the exposure or randomize the groups. RCTs are experimental, while cohort studies are observational. Cohort studies may be prospective or retrospective. Retrospective studies involve a major look in the past in an effort to collect information about events that occurred previously. Prospective cohort studies (e.g., the Framingham study) can be extremely time-consuming. It may be necessary to follow a cohort for years or even decades to capture meaningful results. Study participants may no longer be available for follow-up, potentially biasing the results. Retrospective cohort studies, on the other hand, are conducted on data that have already been collected, such as hospital records. A retrospective approach may save time and be less costly.

A case-control study is an observational, retrospective study, which involves identifying patients who have the outcome of interest (cases) and control patients without the same outcome, and looking back to see if they had the exposure of interest. Because retrospective case-control studies rely on people's memories, they are more prone to error. Also, it may be difficult to measure the exact amount of an exposure in the past.

- Level II-3: Evidence from multiple time series with or without intervention. A case series is a descriptive report on a series of patients with an outcome of interest. No control group is involved. Case series provide the weakest evidence of the study types examined so far, since they describe a relatively small number of patients and no experimental manipulation is involved. Case reports are simply descriptive reports of single patients. Despite their limitations, these study designs can be useful. A case series and case reports often are used to introduce practitioners to unusual and rare conditions, or to point out so-called exceptions to the rule. Dramatic results in uncontrolled trials can be regarded as this type of evidence. Case series and case reports are often the basis for future research using stronger evidence study designs.
- Level III: Evidence based on opinions of respected authorities (ideally using formal consensus methods). As long as one appreciates its limitations, the clinical experience, expertise and judgment of respected healthcare professionals can play an important role in evidence-based medicine. In instances where there is not methodologically sound research to answer a clinical question, expert opinion can be valuable

in a clinician's decision-making process, especially when the approach includes agreement among a group of respected authorities using formal consensus methods. In these instances, it becomes extremely important for clinicians to gather baseline data for a process in an effort to assess the outcomes of the process and to determine how the process (and outcome) can be improved over time.

- Level IV: Personal anecdote (“In my experience...”). Although there may be instances where clinicians have little evidence to draw on beyond their individual experience, it should be recognized that this approach is highly prone to bias and often unreliable in producing consistent, best practice outcomes. Unless one's experience is based on some level of evidence, many would argue that this is not evidence at all. In these situations, it becomes extremely important for clinicians to gather baseline data regarding a process in an effort to assess the outcomes of the process, to compare their data with other clinicians involved in the process of care, and to determine how the process and outcome can be improved over time. At a minimum, clinicians owe it to their patients to gather data in these situations to document outcomes as part of a continuous improvement and learning process.

The Oxford Centre for Evidence-Based Medicine has developed a more detailed approach for defining levels of evidence. They use a numbering scheme ranging from 1a, homogenous systematic reviews of RCTs, to 5, expert opinion.⁹⁷ The Oxford system can be especially useful when comparing articles with similar study designs. Equivalent research designs do not necessarily produce results of equal quality.

Though one would prefer to use research studies high on the pyramid, EBP may need to draw on research designs lower in the evidence hierarchy because of a lack of higher quality published evidence. There are instances where only case reports or bench research may exist on a topic. When making evidence-based decisions in clinical care, clinicians should always strive to select the highest level research design available for the specific clinical situation.

While a double-blinded RCT is the optimum form of evidence, as discussed in chapter 2, a minority of clinical practice is based on RCTs. Thus, clinicians frequently are faced with using lower levels of evidence. Sometimes, the only real evidence they have is their own data. As you move down the pyramid, the need to have control of your own data and to use it wisely in continuous improvement projects increases.

Quality improvement versus research

There are numerous definitions for quality improvement. The Rand Corporation has defined quality improvement as “systematic, data-guided activities designed to bring about immediate improvement in the healthcare delivery process.”⁹⁸ Alternatively, the IOM has defined quality improvement as “a systematic pattern of actions that is constantly optimizing the productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product or service in the context of the expectations and needs of customers and users of that product or service.”²⁰ In contrast, traditional research (RCTs) has been defined as “a systematic investigation including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge.”⁹⁹

Not only are traditional research and quality improvement defined differently, but they are governed differently. Quality improvement tends to be governed by entities that focus on quality of care, such as The Joint Commission (TJC), while traditional research is governed by federal regulation and is under Institutional Review Board (IRB) surveillance.

As illustrated in Figure 70, quality improvement studies and traditional research methods (i.e., RCTs) vary in terms of their aims, emphasis and methods. The goal of traditional research is new knowledge, while the goal of quality improvement efforts is better practice. As outlined above, RCTs emphasize internal validity (cause-and-effect

Quality improvement versus research	
Quality improvement studies	Research studies (RCTs)
Aim: better practice	Aim: new knowledge
Emphasizes external validity	Emphasizes internal validity
Methods:	Methods:
Identify best known practice	Establish clinical equipoise
Open loop (systems-level changes)	Closed loop (patient-level changes)
Tests observable (helps spread)	Tests blinded
Stable bias (tolerates “dirty” data)	No bias
Just enough data	All possible data, just in case
Changing hypotheses	Fixed hypotheses
Sequential tests	One large test
Ongoing outcomes tracking	When study ends, data ends

Figure 70: Quality improvement versus research

relationship), whereas quality improvement research emphasizes external validity (can the result be generalized to other situations or people). Different aims imply different methods. Thus, the methods of the two approaches vary as well.

In reality, there is a synergy between these two approaches. Quality improvement studies can actually enhance traditional research. For example, quality improvement can help determine the external validity (generalizability) of a randomized controlled study's findings. In addition, because one continuously measures in quality improvement studies, the likelihood is actually higher that you will eventually pick up the causality errors you might not find in RCTs.

Chapter 6.3 — Using evidence to identify and eliminate waste

Once the patient cohort is defined, the improvement team is ready to incorporate evidence and start the process of identifying and eliminating waste. While health systems often believe they are unique, in truth they generally are not. The most common clinical and operational problems may be found in all healthcare organizations.

Quality waste relates to process. If a step in a process falls short of expectations or fails, it will often lead to a poor outcome. If one identifies a poor outcome, you either need to fix it or throw it away. Both options cost money. Deming called this re-work. Studies have suggested that quality waste in U.S. hospitals runs between 25 and 40 percent.^{100, 101} In 2013, healthcare expenditures in the United States were \$2.8 trillion. This means between \$700 billion and \$1.2 trillion could be recovered and used for other purposes if waste could be eliminated. Some have suggested that U.S. healthcare does not have a cost problem, but rather a waste problem. These staggering numbers would suggest this may be true. The more the U.S. moves towards payment for quality outcomes and not paying for harm (a form of waste), the less tolerable waste will be in healthcare.

If an organization can eliminate waste, their operations costs will go down and their quality will go up — representing a win-win. Modeled on the quality improvement successes that Japan experienced, most organizations outside of healthcare have learned: if they cannot minimize waste, they simply fail. Organizations unable to operate at peak efficiency are not competitive in the market and cannot succeed. They disappear. The elimination of waste has become a condition for entry into most markets.

Historically, healthcare has been rewarded for creating waste. For example, if we caused post-op wound infections, we have been paid to treat it. We have been paid to do unnecessary surgical or other procedures. We have been paid for excess time a patient spent in the ICU on ventilators. However, this is

changing. An increasing number of never events (i.e., the kinds of mistakes that should never have happened) are not reimbursed, payments for specific diagnoses and treatments are being fixed and there is steady downward pressure on reimbursement. All of these trends and others make clinical and operational quality waste increasingly untenable.

As discussed in chapter 5 and illustrated in Figure 71, a care process can be broken down into a set of decisions and activities. Using the evidence-based practice approach discussed in section 6.2, evidence about the best ways to make these decisions or accomplish certain activities may be found in the medical literature. As clinical teams try to understand how their care delivery varies from provider to provider or from one facility to another facility, they can look at how care decisions are currently made and measure the amount of variation existing in the current process compared to the evidence.

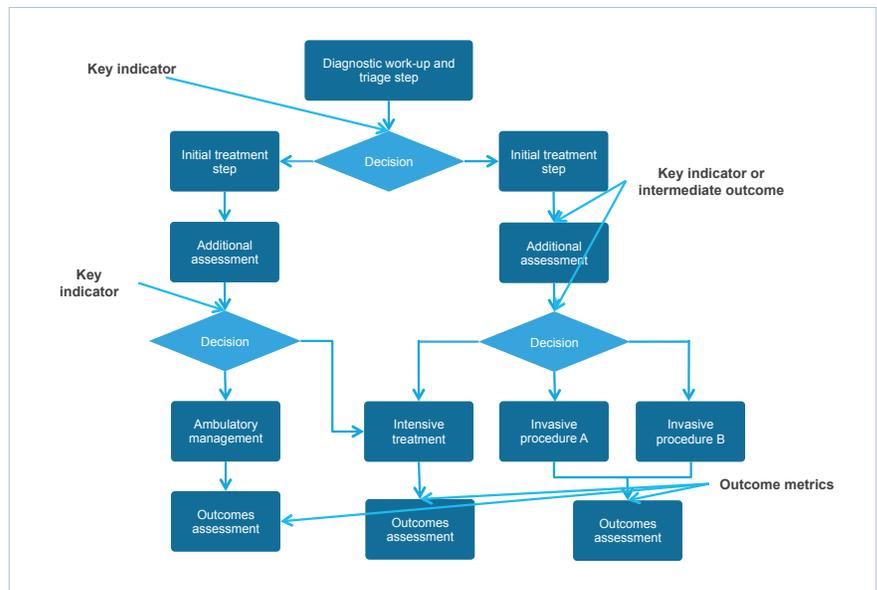


Figure 71: Care process model template
(Click for larger version)

For example, the AHRQ has published detailed guidelines that highlight the dangers of inducing labor before a baby is thirty-nine weeks in gestational age.¹⁰² These guidelines were based on a systematic review of 76 research studies originally published between 1964 and 2007.¹⁰³ Only under certain specific conditions are the risks of early induction overridden because greater risk to the baby or mother exists. Thus, it is useful to measure what percentage of the time clinicians followed this evidence-based guideline by tracking how many times an induction occurred before thirty-nine weeks without an evidence-based reason. Additionally, clinicians can track how many times a poor outcome, such as an emergency C-section, occurred because the evidence was not followed. This helps the team design tools that match actual care delivery to the evidence.

Using this example, the clinical team might design a knowledge asset like a brochure to educate patients about the risks of early induction. The brochure may reduce the number of mothers asking to be induced before thirty-nine weeks. In addition, the order set for inducing labor could require documentation of the evidence-based reason for inducing early.

Categories of waste

Now let's consider the types of waste commonly seen in healthcare. As shown in Figure 72, there are three common categories of quality waste — ordering waste, workflow waste and defect waste.

Figure 73 illustrates how you can map the Lean types of waste to ordering, workflow or defect waste categories.

Ordering waste

Diagnostic tests can be used to illustrate ordering waste. Figure 74 demonstrates that diagnostic tests can be sorted into three categories: diagnostic, contributory and wasteful. Diagnostic tests aid the physician in making care decisions. Contributory tests may help confirm the diagnosis. Wasteful tests are those that are ordered and do not help in diagnosis or those that are overlooked that would aid diagnosis. Of course, wasteful tests should be eliminated. These tests may be done out of habit, by mistake, based on old evidence or because clinicians are not aware of new evidence. Examples of wasteful tests include duplicate tests, tests that are not helpful in establishing the diagnosis and valid diagnostic tests that do not add any additional information.

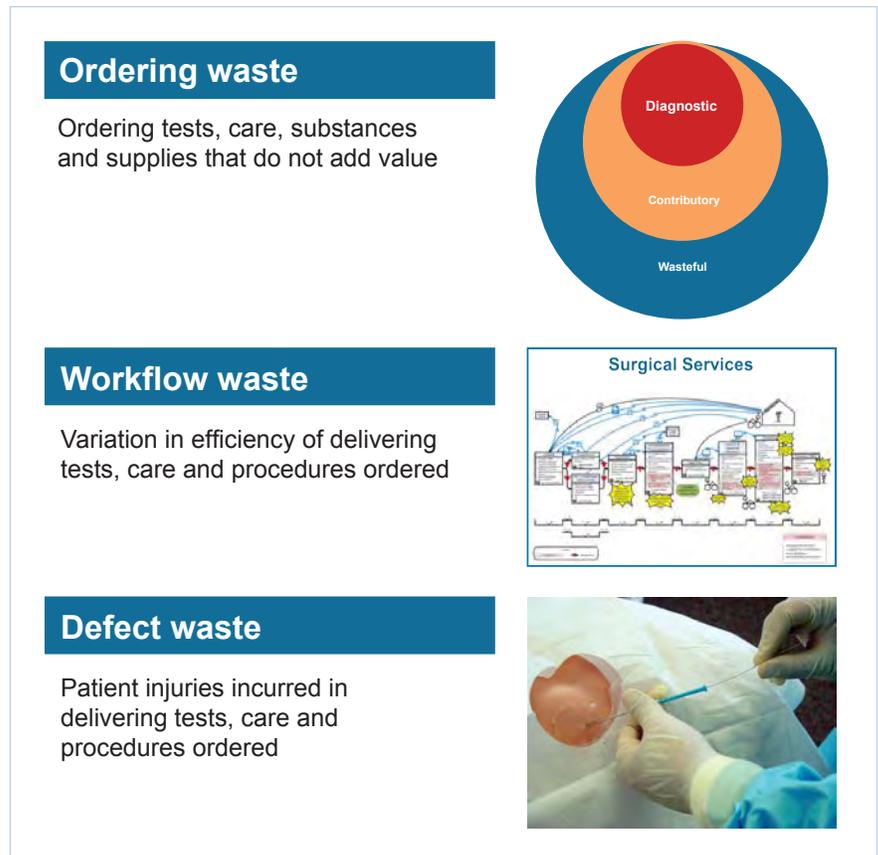


Figure 72: Three forms of waste

Ordering waste	Workflow waste	Defect waste
Over production	Motion	Defects
Inventory	Movement	
Knowledge	Poor processing	
	Waiting	

Figure 73: Categories of waste cross-walked with Lean types of waste

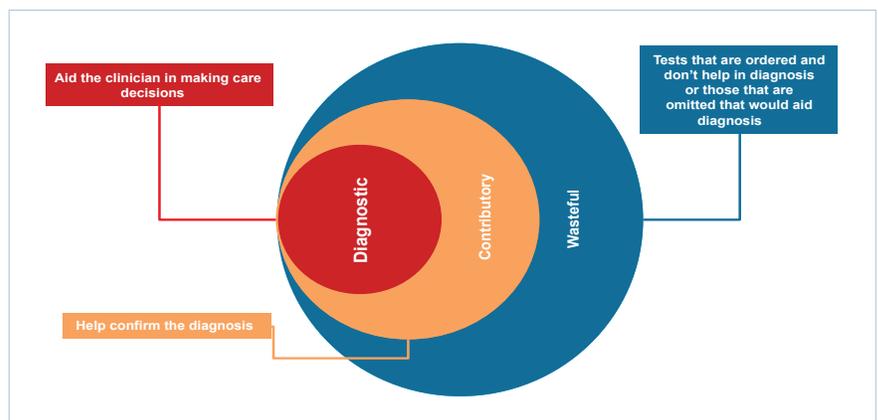


Figure 74: Ordering waste — diagnostic tests
(Click for larger version)

Let's walk through a heart failure example to illustrate ordering waste (Figure 75). It is not uncommon for patients to be treated for suspected heart failure without confirming the diagnosis. However, without confirming the diagnosis, the treatment may not be appropriate. An echocardiogram is a simple, low cost, noninvasive way to measure the ejection fraction (i.e., the percent of the blood pumped out of the heart ventricle with each stroke). A low ejection fraction is a relatively simple way to confirm heart failure. Brain natriuretic peptide (BNP) is released into the blood when the cardiac muscle is stretched in heart failure. A rising BNP is also diagnostic of heart failure. BNP is another simple, low cost, noninvasive test to confirm the diagnosis of heart failure. Other tests, such as chest X-rays (showing an enlarged heart) and arterial blood gases (showing low oxygen levels), contribute to the diagnosis of heart failure, but they are not unique to heart failure. Given their non-specificity, these tests may be considered wasteful. A cardiac ventriculogram (cardiac catheter used to inject radio opaque dye into the heart) can accurately measure stroke volume (an indirect measure of ejection fraction), but it is expensive and invasive. One would be wiser to try to confirm the diagnosis with less costly and less invasive tests like an echocardiogram or measuring BNP levels. Thus, a cardiac ventriculogram could be considered ordering waste.

Another example can be seen in Figure 76, which depicts an analytic application that is evaluating physician habits when writing orders for appendectomy patients. The data reveals that clinically effective tests to order were

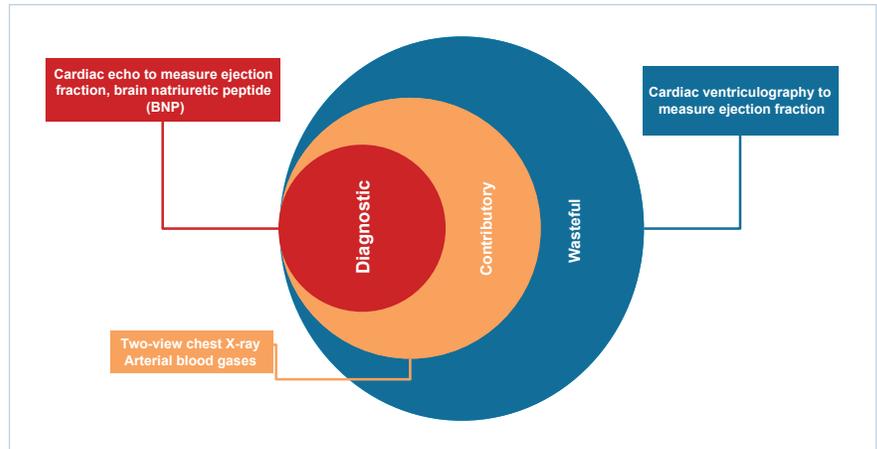


Figure 75: Heart failure ordering waste example
(Click for larger version)

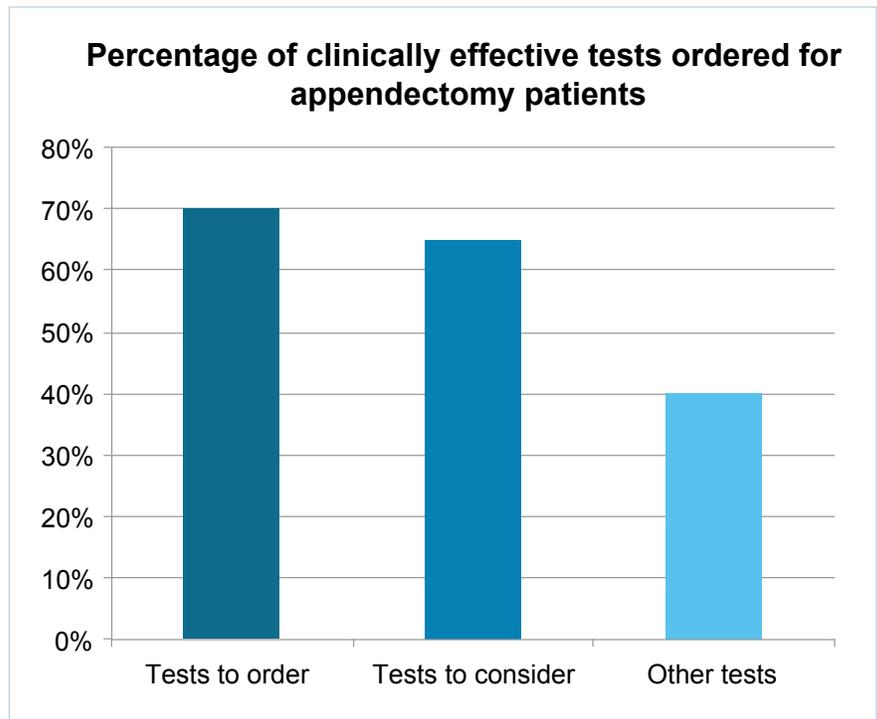


Figure 76: Tests ordered by category example

only ordered, on average, 70 percent of the time. Tests to consider were ordered nearly the same percentage of the time. Other tests were ordered 40 percent of the time. There's a good chance the other tests were wasteful. This analytic application provides the ability to drill down into the data to determine in greater detail what percentage of the time these tests were ordered and under what circumstances. In addition, the order sets that called for specific tests can be viewed. The goal of order sets and workflow modifications should be to make the right thing to do, the easy thing to do.

Workflow waste

Workflow waste differs from ordering waste in that it tends to span departments and often involves inefficiencies in care delivery. Workflow waste occurs either during key value-added steps or in between those steps.

In the chapter on the deployment system, we discussed how to combine Lean with analytics and value stream maps. Value stream maps can help identify workflow waste. By generating knowledge assets such as value stream maps as part of the content system, improvement teams can standardize the value-added steps and eliminate delays.

Figure 77 is an example of a value stream map for an inpatient surgery workflow. The yellow bursts represent waste in the process. The first burst indicates there is tremendous variability in preparing for the surgical cases. The process is nonstandard because each provider has his or her own preference for what to include in the surgical tray. The improvement team could help eliminate this waste by implementing standard surgical preference cards. In this case the intervention would be to standardize the surgeon preference cards.

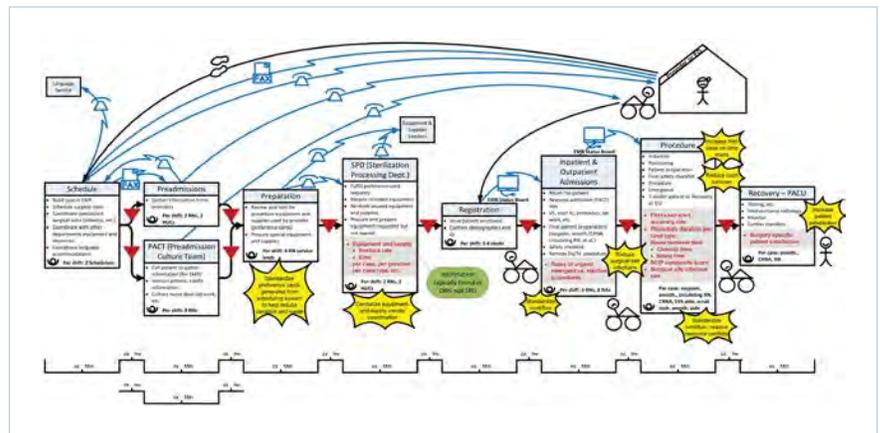


Figure 77: Sample value stream map for inpatient surgery
(Click for larger version)

The other bursts identify an opportunity to standardize the room turnover workflow. The team might create a room turnover checklist that organizes the steps and indicates the typical length of time each step should take. In each of these instances, improvement teams would look to analytics to examine the process and help track adoption of the new standard.

Figure 78 demonstrates another operating workflow example. Each bar in the graphic shows the total OR turnover time for the hospital, with the most recent turnover stats shown on the bottom of the graph. The colored segments in each bar represent different stages of the process. For example, the blue segments show the lag between the patient's departure from the OR and the cleanup crew's arrival.

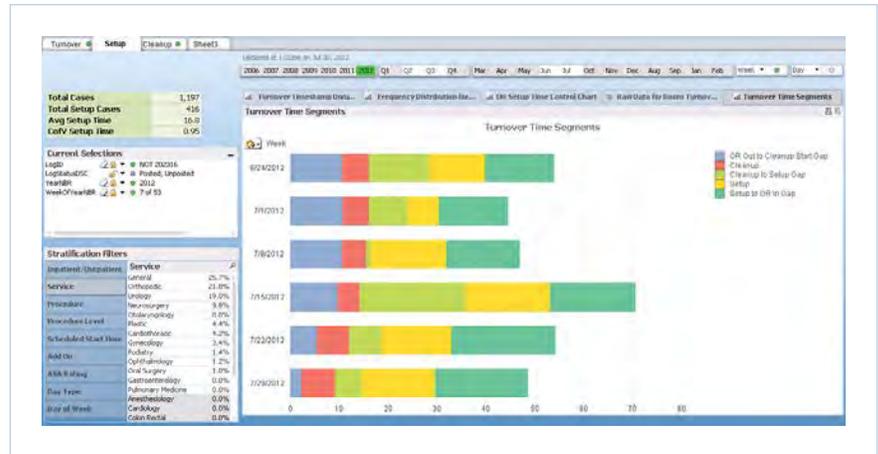


Figure 78: Operating room workflow
(Click for larger version)

When provided with detailed data about the process, team members are equipped to quickly identify where workflow waste exists and to design counter measures to eliminate the waste. Over time, improvement teams can track whether the counter measures are having the intended impact.

Defect waste

Defect waste represents the third category of waste. Defect waste consists of preventable outcomes that consume additional resources. This includes things like pressure ulcers, transfusion reactions, patient falls and hospital acquired infections.

Most healthcare systems have an incident tracking system, but incident tracking only accounts for incidents that are severe enough for the clinician to fill out an incident report. Incident tracking does not capture all the near misses or instances that are almost bad enough to be tracked.

Figure 79 shows a pressure injury prevention example. Any patient who is going to be admitted to a certain unit of the hospital for more than a couple hours should be assessed for risk of a pressure injury. For

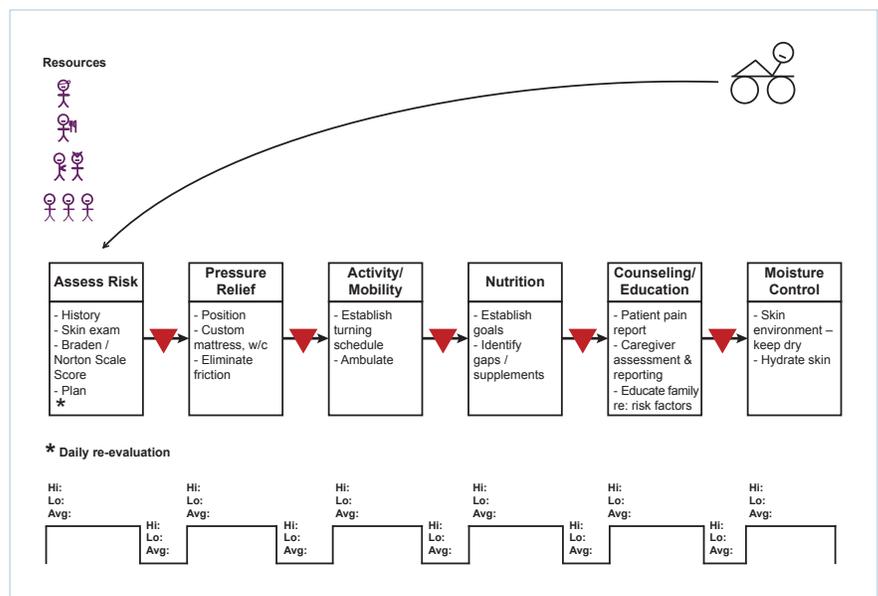


Figure 79: Pressure injury prevention
(Click for larger version)

patients deemed at risk, various pressure relief interventions should be used: a special mattress, specific activities, nutrition, etc. As long as clinicians check 100 percent of patients, they can make sure the patients who need special provisions receive them and that other patients do not. Clinicians can use an analytic application to examine historical trends to help inform them of the types of workflow changes or knowledge assets that may need to be implemented. Then they apply the principles of the content system to create several tools to reduce the incidence of pressure ulcers.

It is very important that waste reduction be systematic, not limited to a specific department and that a consistent approach be used across clinical programs. As shown in Figure 80, to accomplish this improvement teams should keep strengthening the three systems and revisiting important questions.

Strong analytics are used to uncover and provide information on the three kinds of waste. The data is unlocked, data gathering is automated and the data is used to reveal the highest priorities and define the necessary cohorts of patients. This can be used to build dashboards with actionable metrics that allow an organization to change behaviors.

Strong deployment is used to implement and sustain less wasteful practices. Permanent teams integrating clinicians and technical experts are established. These teams will engage in Agile, iterative work processes involving high levels of communication. Lean principles are combined with analytics so improvement teams can uncover root causes and sustain gains.

Finally, strong content is used to hone and improve clinical practices. Advanced medical knowledge within your organization or knowledge that is discovered in another organization is used to establish a new standard within weeks, instead of years. Going forward, these practices should be continually improved upon. In combination, all three of these systems — analytic, deployment and content — can ignite change.

	Ordering	Workflow	Defect
Analytic system	Are we following clinical effectiveness guidelines?	Are we delivering the care efficiently?	Are we delivering the care safely?
Deployment system	Clinical program	Clinical support service	Clinical support service
Content system	What should be done?	How can it be done efficiently?	How can it be done safely?

Figure 80: Sample questions to improve your 3 systems

Viewing healthcare waste from society's perspective

The categories of waste described above relate to the treatment of individual patients. There is another type of waste that relates to populations and societies as a whole.

In chapter 2, we discussed Donabedian's concept of the maximalist and optimalist approach illustrated in Figure 81.

Instead of thinking of the care of one patient at a time, imagine that you are tasked with care delivery to a population and you have a finite (limited) number of resources. Given the direction of healthcare economics, this is not a stretch. In fact, this reality is currently unfolding in healthcare. Because of many competing demands, it is unlikely that more money will be allocated to clinical care delivery. We have to spend the resources we are currently given in a better, more efficient manner.

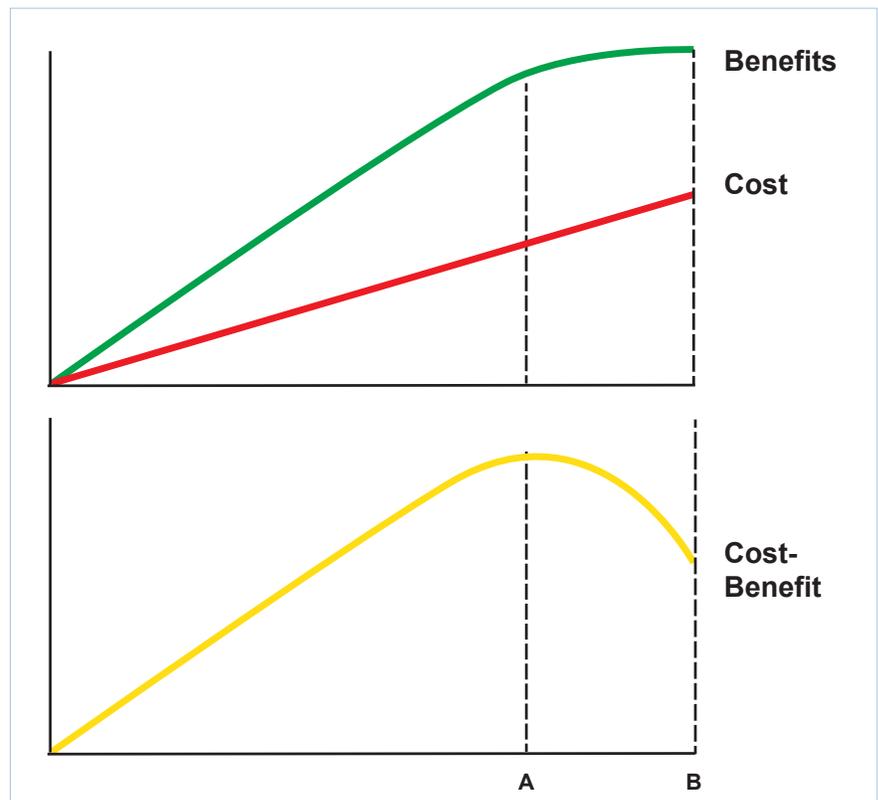


Figure 81: Useful additions to care

In such a situation, you are likely going to want to pay attention to the cost-benefit curve. This is the slope of the green line divided by the slope of the red line in the Figure 81. 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 yellow graph). Donabedian called this an optimalist approach because an optimalist seeks maximum benefit across a population. If you are going to spend more treatment money, you would prefer to find a patient located before point A where the slope of the curve is still going up, indicating the patient will get more benefit than a patient beyond point A. The difference is focusing on the whole (i.e., the population) rather than solely on an individual patient.

Donabedian's whole purpose was to talk about the ethics of patient care from a different perspective (i.e., the population as opposed to an individual patient). If you are talking about a population, you have a responsibility to ask patients as a group how much healthcare they want to buy, at what cost and what benefit.

Donabedian argued this was not a decision for clinicians to make. Instead, it was the decision of the population of patients (i.e., society). The obligation of clinicians in this circumstance is to help society understand the trade-offs. We have a professional responsibility to do this. Ethically, it is our responsibility to inform society. It is society's ethical responsibility to decide how much to spend and where to spend it.

It is unethical to tolerate any kind of waste in healthcare delivery. As a caring clinician, executive or administrator, we have a professional responsibility to think not only about the patient in front of us, but all patients. It is becoming increasingly clear that resources are finite. Every time we waste resources on one patient, we deny resources to other patients. As respected professionals, we have an ethical responsibility to think of all patients. It is important that clinicians and administrators see this need and get out in front of it. Nature abhors a vacuum. If we do not deal with this reality, someone else will and that would not necessarily be a good thing from society's perspective. At a minimum, we need to play a participatory leadership role because we have the expertise and knowledge to do so. This is a tough standard, and it is not easy, but it is a role we must play. This is what the pioneers like Sir William Osler were willing to do over a century ago. They provided this type of leadership. It is now time for clinical and operational leaders in our generation to do the same. We are living on borrowed time. Healthcare is approaching the zero hour.

Chapter 6.4 — Standardizing care delivery through practice protocols and shared baselines

Next, we need to turn our attention to the steps a healthcare organization can take to establish a standard process using shared baselines that are reflected in practice protocols. As an initial step, let's discuss the role of practice protocols in evidence-based medicine.

The role of practice protocols in evidence-based medicine

As healthcare transforms, the traditional craft of medicine is being supplanted with a more profession-based approach for the reasons outlined in chapter 3. The idea that every physician, nurse or administrator is a personal expert, relying solely on his or her personal commitment to excellence is no longer acceptable. We are moving from medicine practice as individual heroism to medicine as a team sport.

David Eddy, MD, was the first to suggest that the core assumption of the craft of medicine is untenable.¹⁰⁴ Under the craft of medicine, the idea was that when a physician faced a patient, by some fundamentally human process called the art of medicine or clinical judgment, the physician would synthesize all of the important information about the patient, relevant

research and experiences with previous patients to determine the best course of action.

Over the last thirty years, however, it has become apparent that the published evidence for most of what we do in clinical care is limited. Over the same period of time, clinical care has become increasingly and overwhelmingly complex.

As illustrated in Figure 82, these trends coupled with widespread variations in beliefs and human limitations in the face of complexity has led to well documented clinical uncertainty, massive variation in care and unacceptable levels of inappropriate care.

The movement toward evidence-based medicine has led to a growing acceptance of practice protocols in clinical care. Practice protocols are an important part of a profession-based practice. They support an environment of professional accountability where groups of physicians and other professionals manage similar patients in similar settings, discuss best patient care practices, inform their decisions based on the medical literature and expert opinion, and use credible data to assess their performance and outcomes.

Developing a shared common baseline

Every health system and hospital needs a more systematic approach to learning about evidence, to get the evidence integrated quickly and efficiently into the normal work processes, and to avoid the “if it wasn’t invented here, we have to reinvent it” mentality. Sometimes physicians will call this cookie-cutter medicine. However, for the simple or common standard clinical cases, all clinicians should want to provide care in a standard way because it allows for the creation of shared common baselines and supports improvement efforts. This allows well-trained clinicians to focus on the more complex cases that are the roughly 20 percent of outlier cases where their judgment and expertise are most important. For the more simple cases, standardized processes work just fine.

In creating a practice protocol, clinicians select a high priority care process, generate an evidence-based best practice guideline and appropriately blend the guideline into the flow of clinical work (e.g., staffing, supplies, physical

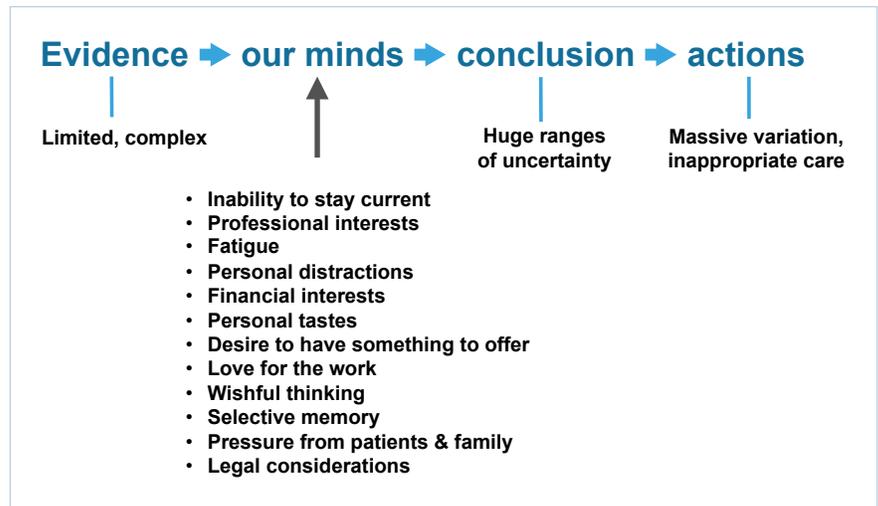


Figure 82: The craft of medicine is no longer tenable

layout, information flow, and training) as illustrated in Figure 83.

The first step to evidence integration is to select a high-priority care process that has high variation as defined by analytical tools like Health Catalyst’s Key Process Analysis application — the tool that was illustrated in chapter 4.

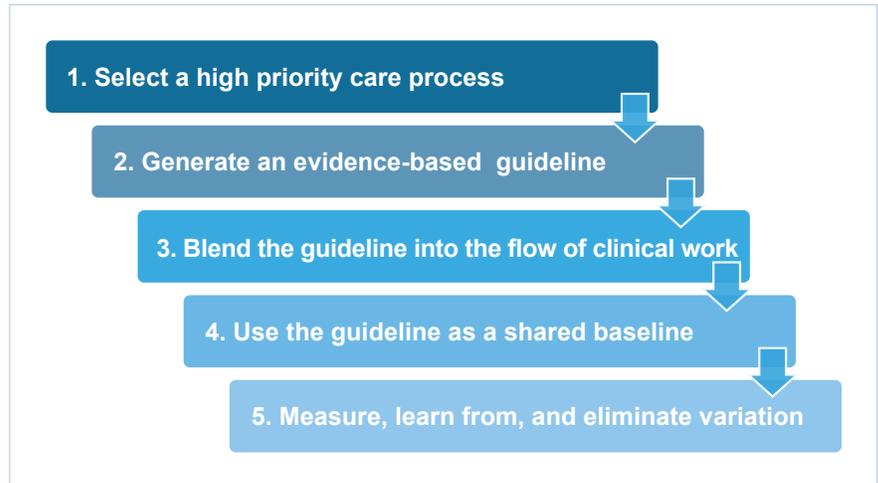


Figure 83: Shared baseline solution

From there, an improvement team can generate an evidence-based guideline and blend it into the workflow. This could involve standardizing diagnostic algorithms, order sets, intervention criteria, supplies, department layouts, and patient and provider education materials. The improvement team will also design the best way to measure utilization of the guideline.

Then, they will use the guideline as part of a standard protocol using a shared baseline. A shared common baseline requires that a protocol be standard. That is, all care providers involved in any given care process must use a standard protocol. Without using a standard protocol, it is impossible to develop a meaningful shared common baseline. A shared common baseline is essential in defining baseline performance for a care process and in allowing care providers to know if future enhancements to a process represent an improvement.

In a standard protocol-based care environment, clinicians can vary care based on individual patient needs and desires. Once again, this is a key element of Lean production — so-called mass customization. That is, front-line clinicians are able to address complexity and drive out waste using standardized processes while also providing room to adapt to individual customer needs. This allows caregivers to focus on a relatively narrow band defined by a patient’s individuality where their expertise and experience really make a difference. The protocol standardizes the mundane work so that it happens automatically, using a measurement system to assure it is happening consistently and correctly, while allowing the caregiver to use their intellect where it is needed most — the roughly 20 percent of care that needs to be modified to match the needs or characteristics of an individual patient. When clinicians do vary from a standard protocol, the reason for varying should be captured, so everyone can learn from it.

Once a protocol is implemented, clinicians can measure outcomes and learn from their experience. Teams of clinicians involved in a given care process can manage cycles of measurement and learning, repeating the process until variation is eliminated. Specifically, improvement teams want to eliminate variation caused by different healthcare professionals yet retain variation arising from different patient conditions.

Evidence-based protocols and shared baselines actually make care easier. When properly integrated into workflow, protocols have been shown to help physicians become substantially more productive. With good protocols in place, physicians do not need to worry about details that do not require their intellect. Those details happen automatically. The standardized protocol assures these details get done reliably every time. This yields more time for clinicians to see patients and generate additional value for patients. However, it is important to remember protocols need to be continuously improved as new published evidence becomes available and as care teams learn more about the care they deliver.

Protocols can also be a very effective training tool (as they have been for a long time) — think of the Washington Manual that medical students and residents have used for decades. It is filled with standard protocols. These published tools had at least one drawback — they lacked a shared common baseline to determine how well you were doing and the ability to thoughtfully measure as you implemented changes to see if they were making a difference. A well designed EHR and enterprise data warehouse (EDW) creates the ability to collect the data you need to understand and improve protocols over time.

A growing body of evidence suggests that a profession-based practice using standard protocols has many advantages. It produces better outcomes for patients. It eliminates waste, reduces costs and increases available resources for patient care. It puts caring professionals back in control of care delivery where they belong. It is the foundation for useful shared electronic data.

Chapter 6.5 — Tools to help accelerate waste identification and elimination

Now that we have learned how to define clinically driven cohorts, how to use evidence to identify and eliminate waste and how to standardize care delivery through shared common baselines, let's consider what tools are necessary to accelerate waste identification and elimination.

EHRs and analytical tools

When an organization or a nation tries to implement value on a broad scale (i.e., safe, high-quality care, at the lowest possible cost), it requires

ready access to good data. This, in turn, requires the broad implementation of EHRs. It also requires you to think of an EHR in terms of its ability to build care management capability. The EHR needs to be a foundation for building and supporting care management. It is also necessary to collect the data required to determine shared common baselines and to document improvement as processes are improved over time.

Just as in the case of protocols, standardization is important when implementing an EHR. When you tailor any enterprise information technology system (e.g., EHR, finance, human resources, patient satisfaction, etc.), an organization can lose its advantages if a non-standard approach is taken with the system — especially when it is time to upgrade to a new version of the system with new capabilities. If the EHR has been heavily customized, it will cost the organization more and be more difficult to implement the new version of the system. In addition, if data is entered in an EHR in a non-standard manner, it impacts data integrity in the EDW.

Healthcare organizations need an EDW and other elements of an effective analytical platform that supports selective information tracking required for mass customization. Using one healthcare analytic vendor as an example, Health Catalyst offers three suites of tools, and each suite supports identifying and eliminating waste in each of the three categories: ordering, workflow and defects. These tools are shown in Figure 84.

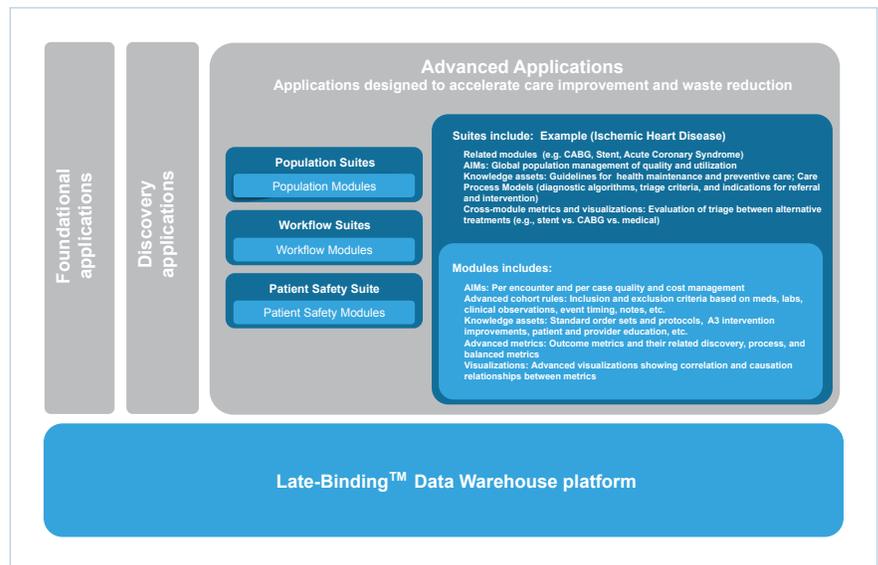


Figure 84: Health Catalyst Advanced Applications
(Click for larger version)

Population suites help improvement teams manage clinical processes and determine the types of care being ordered. Workflow suites help manage the efficiency of care delivery within departments. Patient safety suites support the safe delivery of care. Within the application suites, clinical work process modules exist. For example, a population suite for ischemic heart disease would have modules for each of the clinical work processes within that care process family, such as open-heart surgery, stents and angina.

Tools to model, measure and monitor processes

As reviewed in chapter 3, a process is a series of actions or steps that are taken in order to achieve a particular goal or outcome. A system is generally made up of a collection of interlinked processes that collectively allow an organization to achieve its goals on behalf of customers. Process modeling is an activity whereby those who understand a process create a representation of the process using a variety of graphical tools. The goal of process modeling is generally to create a reasonable representation of a given process in an effort to eliminate unnecessary steps (waste) and optimize specific desired outcomes.

In order to understand any clinical process, care providers need to use the basic process improvement and team tools used in any other industry. These tools are simple and easy to use. They are used to help describe and organize a process, and to focus process improvement efforts. The most commonly used process improvement tools are:

- Flow (conceptual flow, decision flow) charts
- Value stream mapping
- Cause and effect (Ishikawa, fishbone) diagrams
- Tally sheets
- Pareto charts
- Statistical process control (SPC) and statistical process control charts

Flow charts

Flow charts are easy-to-understand diagrams showing how steps in a process fit together. This makes them useful tools for communicating how processes work, and for clearly documenting how a particular job is done and how a particular outcome is achieved. The act of mapping a process out in flow chart format helps teams clarify their understanding of a given process and helps them think about where the process can be streamlined or improved.

A flow chart can be used to:

- Define and analyze processes
- Build a step-by-step picture of the process for analysis, discussion and communication
- Define, standardize or identify areas for improvement in a process

By conveying the information about a process in a step-by-step flow chart, teams can then concentrate more intently on each individual step in the process as well as the overall process.

The types of flow charts and the types of symbols used in flow charts are summarized in Figure 85.

The following graphics demonstrate two examples of flow charts from healthcare improvement projects — Figure 86 depicts the discharge process from a rehab unit and Figure 87 illustrates an adverse drug event (ADE) detection process.

Value stream mapping

Value stream mapping is a Lean tool that employs a flow diagram documenting in high detail every step of a process. Many Lean practitioners see value stream mapping as the fundamental tool to identify waste, reduce process cycle times and implement process improvement. A value stream map is often the key tool used in Lean improvement efforts.

Value stream mapping can help improvement teams map, visualize, understand the flow of patients, materials, information and decisions in a process. The “value stream” is all of the actions required to complete a particular process. The goal of value steam mapping is to identify improvements that can be made to reduce waste (e.g., patient wait times), improve cycle times (e.g., OR turn around) and identify and implement process improvements.

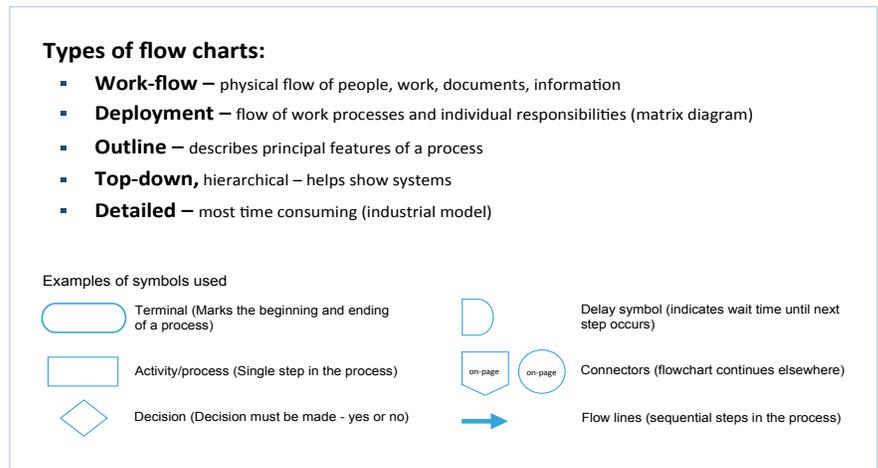


Figure 85: Types of flow charts and flow chart symbols
(Click for larger version)

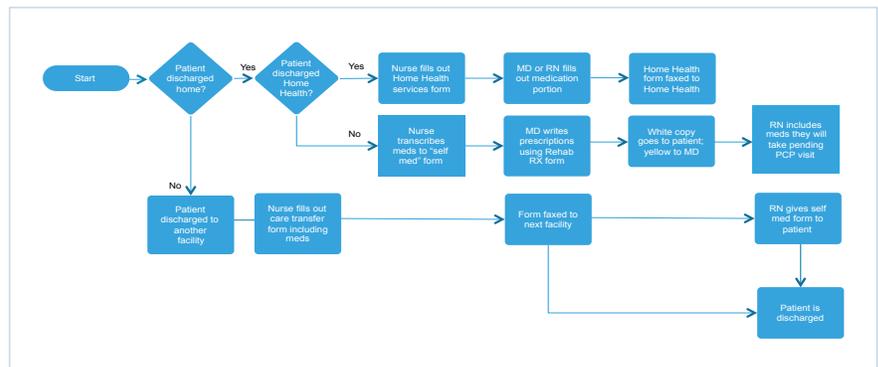


Figure 86: Rehab discharge process
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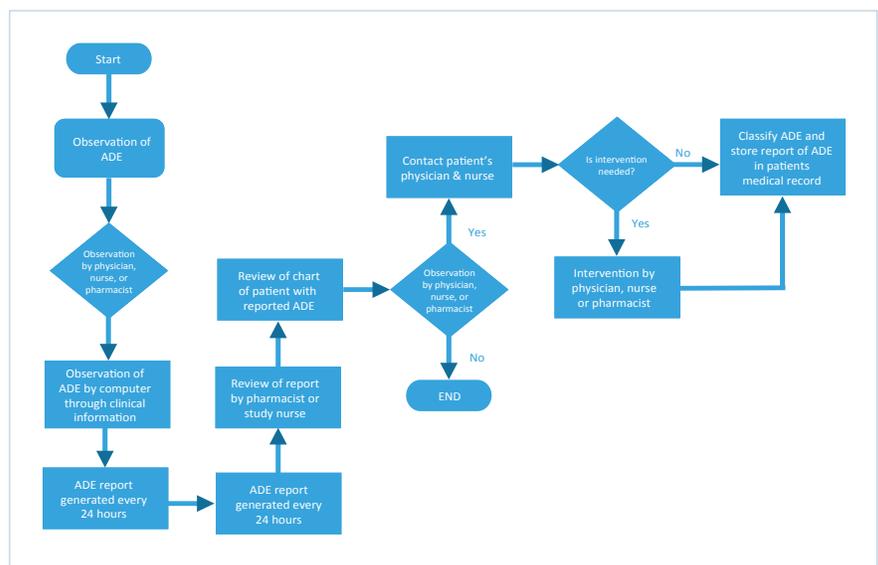


Figure 87: Detection of adverse drug events process
(Click for larger version)

To accurately map a process, it is important to obtain high-quality, reliable data about the flow of information and the time spent at (or between) steps. Accurately timing process steps and using multi-departmental teams is essential to obtain a true picture of what's going on in any process.

An example of a value stream map was shown in the workflow waste discussion (Figure 77). Another example is shown in Figure 88.

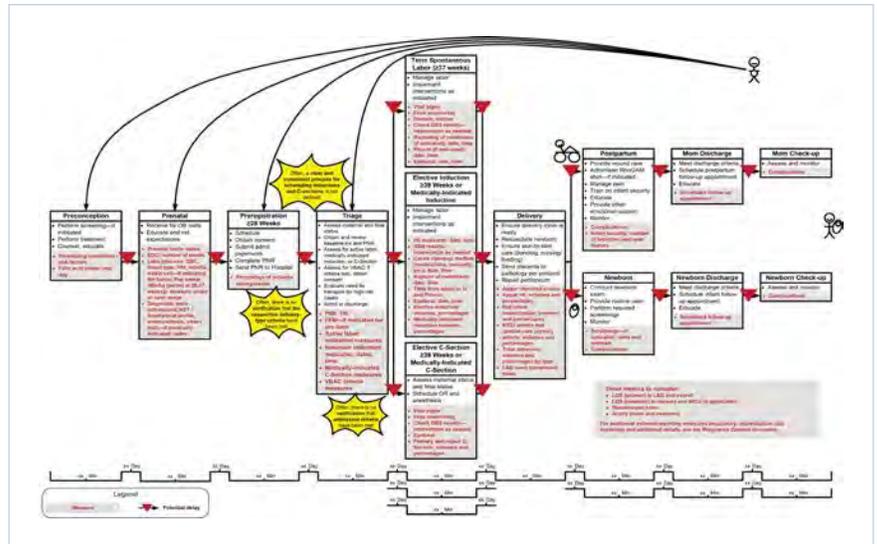


Figure 88: Sample pregnancy value stream map
(Click for larger version)

Cause and effect (Ishikawa, fishbone) diagrams

Once a high level process has been mapped, a performance improvement team often needs to discuss the potential causes of a defect in one or more of the process steps. A cause and effect (Ishikawa, fishbone) diagram has traditionally been used to highlight potential causes.

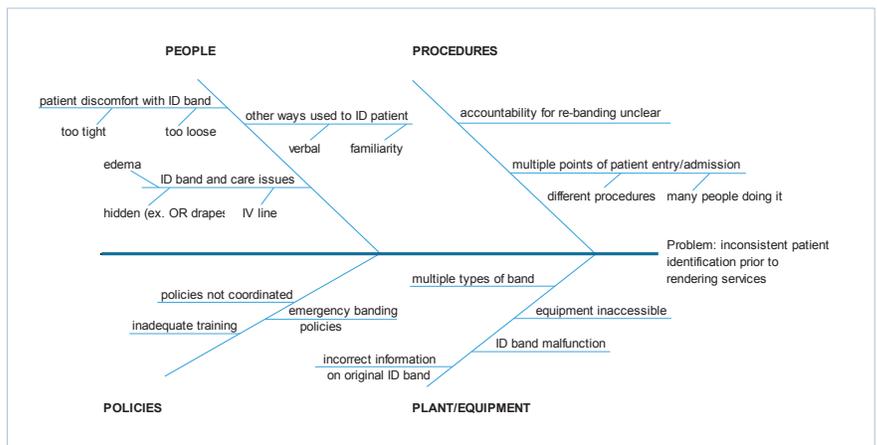


Figure 89: Sample patient identification fishbone diagram
(Click for larger version)

A cause and effect diagram is a graphical tool that enables the visualization of causal relationships between variables in a process. The so-called fishbone diagram can be used to structure a brainstorming session by sorting inputs or causes into useful categories — two examples are shown in Figures 89 and 90. Causes are typically arranged according to their level of importance

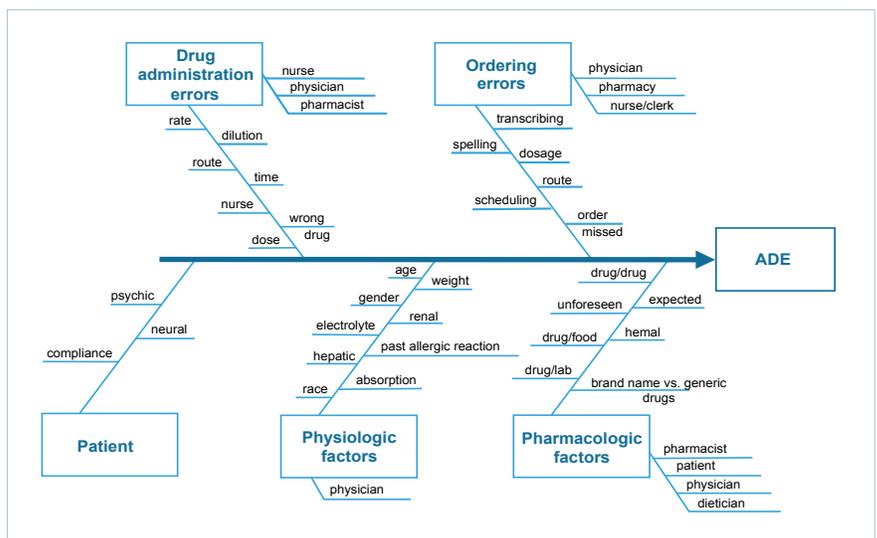


Figure 90: Sample adverse drug effects fishbone diagram
(Click for larger version)

or detail, resulting in a depiction of relationships and a hierarchy of events. The diagram can help search for root causes, identify areas where there may be problems, compare the relative importance of different causes, uncover bottlenecks in a process, identify why a process is not working and discover areas for improvement.

Tally sheets

The tally sheet is a simple and effective tool that is often useful in quality improvement projects. It is a convenient tool for both qualitative and quantitative data gathering and analysis. It is commonly used to collect data on quality problems and to determine the frequency of events. It is a good first step in understanding the nature of the problem as it provides a uniform data collection tool. The tally sheet can be very useful to help distinguish opinions from facts.

Using a tally sheet is appropriate when the data can be observed and collected repeatedly by either the same person or in the same location. It is also an effective tool when collecting data on frequency and identifying patterns of events, problems, defects, and defect location and for identifying defect causes.

For example, the tally sheet is useful for understanding the reasons patients are arriving late for appointments, causes for delays in getting the lab results back, etc. It is also useful in determining frequency of occurrence, such as number of people in line for blood tests at 6:00 a.m., 6:15 a.m., etc., to understand staffing needs. Tally sheets can also be useful in clinical quality improvement projects. Figure 91 is an example of a simple tally sheet used in a laboratory improvement project.

<u>Reason</u>	<u>Frequency</u>	<u>Comments</u>
Label mismatch	//	
Label missing	/	
Incorrect label	///	
Wrong color	/// /	Green ///
Damaged label	/	Blue /
Other	//	

Figure 91: Tally sheet example

Pareto charts

The Pareto principle was discussed in chapter 4. The value of the Pareto principle is that it reminds you to focus on the most important causes of poor quality in a process — the so-called vital few — as opposed to the less important causes — the useful many, as portrayed in Figure 92.

The Pareto distribution is a probability distribution that is used in the description of many observable phenomena. An example of a typical healthcare Pareto distribution is illustrated in Figure 93. It shows the causes of ADEs at a regional medical center. The top five causes of adverse drug events produce 80 percent of the ADEs reported at this medical center.

The Pareto principle also applies to the resources consumed by care processes. That is, the top 20 percent of care processes typically consume 80 percent of resources making them a key target for improvement efforts, as shown in Figure 94.

Statistical process control (SPC) charts

Improvement occurs over time. Therefore, determining if improvement has actually happened and if it is lasting requires observing results over time. Run charts are graphs of data over time. They

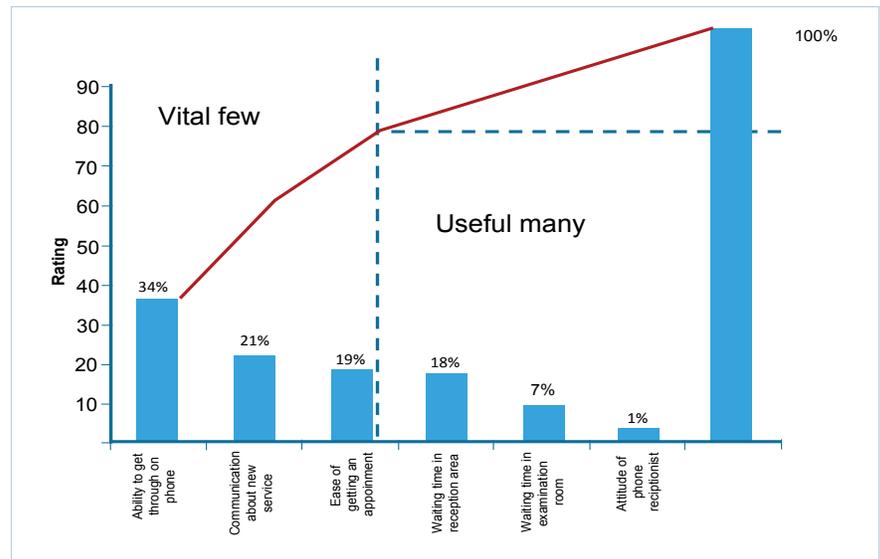


Figure 92: Pareto analysis — family practice patient survey
(Click for larger version)

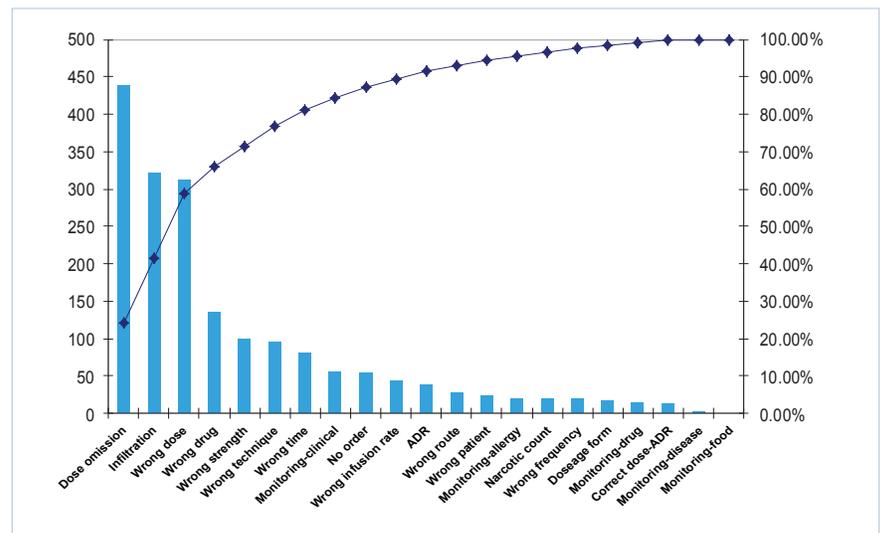


Figure 93: Pareto distribution — 2007 reported ADE types
(Click for larger version)

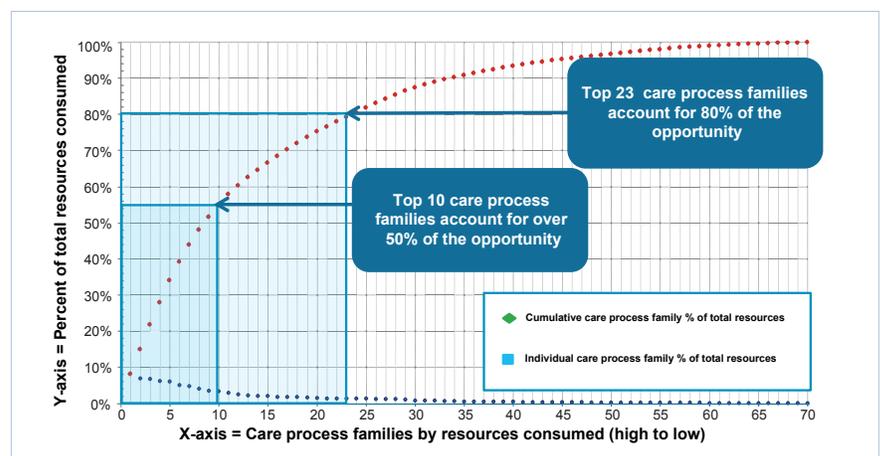


Figure 94: Key Process Analysis
(Click for larger version)

represent one of the most important quality improvement tools for assessing the effectiveness of a change.

As discussed in chapter 4, statistical process control (SPC) is a quality improvement method, which is applied in order to monitor and control a process. Monitoring and controlling the process can help ensure a process operates at its full potential, thus achieving the best possible outcomes with a minimal amount (if not an elimination) of waste. Statistical process control can generally be applied to any process where the output can be measured. Control charts are the primary method of displaying statistical process control results.

The derivation and use of statistical process control and statistical process control charts in quality improvement was discussed in considerable detail in chapter 4.3. The reader is referred to that chapter for further information regarding statistical process control charts.

The Institute for Healthcare Improvement (IHI) model for improvement

IHI recommends the use of the IOM Model for Improvement as a framework to guide improvement work. The Model for Improvement is a simple, yet effective tool for accelerating improvement. Illustrated in Figure 95, the model uses a Plan-Do-Study-Act (PDSA) cycle.

The PDSA cycle can be repeated many times in the continuous improvement process, as shown in Figure 96.

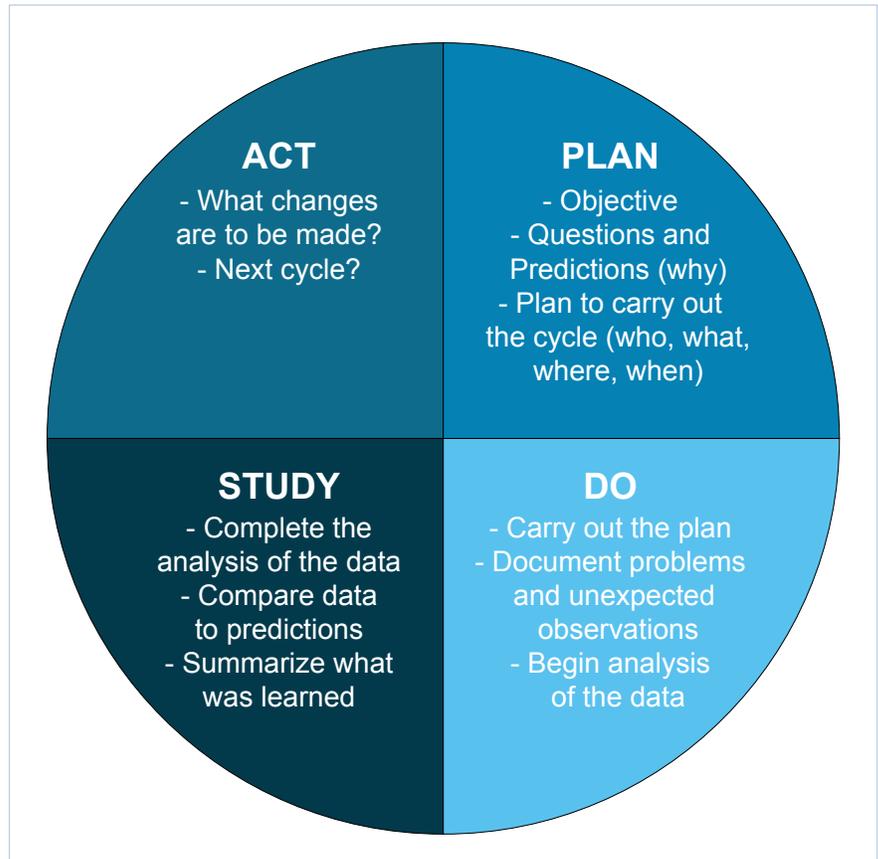


Figure 95: The PDSA rapid improvement cycle

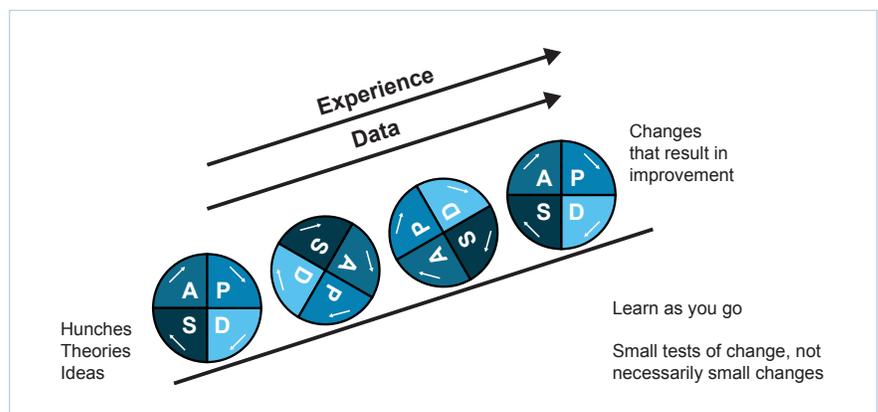


Figure 96: Repeated use of the PDSA cycle

The IHI Model for Improvement involves several logical steps, including forming the right improvement team, setting aims, establishing measurable goals, selecting and testing changes (improvements) for a process, implementing changes and spreading improvements. The reader is encouraged to review the IHI's recommendations in detail.⁹²

An example of applying quality improvement methods to healthcare: Intermountain Healthcare

Under the visionary leadership of Brent James, MD, and David Burton, MD, Intermountain Healthcare has a well-deserved reputation as a world leader in the application of quality improvement concepts and methods in pursuit of clinical and operational excellence. As a result of their focus on quality improvement, Intermountain Healthcare hospitals and clinics are routinely recognized as among the best in the country in terms of their quality, safety and cost outcomes.

Intermountain Healthcare has invested extensively in programs to educate and engage their clinical and operational leaders in continuous quality improvement. These investments in people have proven to be remarkably successful. As a part of the educational programs, each course participant is required to do an improvement project in order to graduate. The purpose of the project is to provide hands-on experience in quality improvement, to produce real results and to provide a practical way to learn what works. As a guide, Dr. James has students/teams use Juran's model of the Diagnostic Journey, the Remedial Journey and Holding the Gains, as shown in Figure 97.

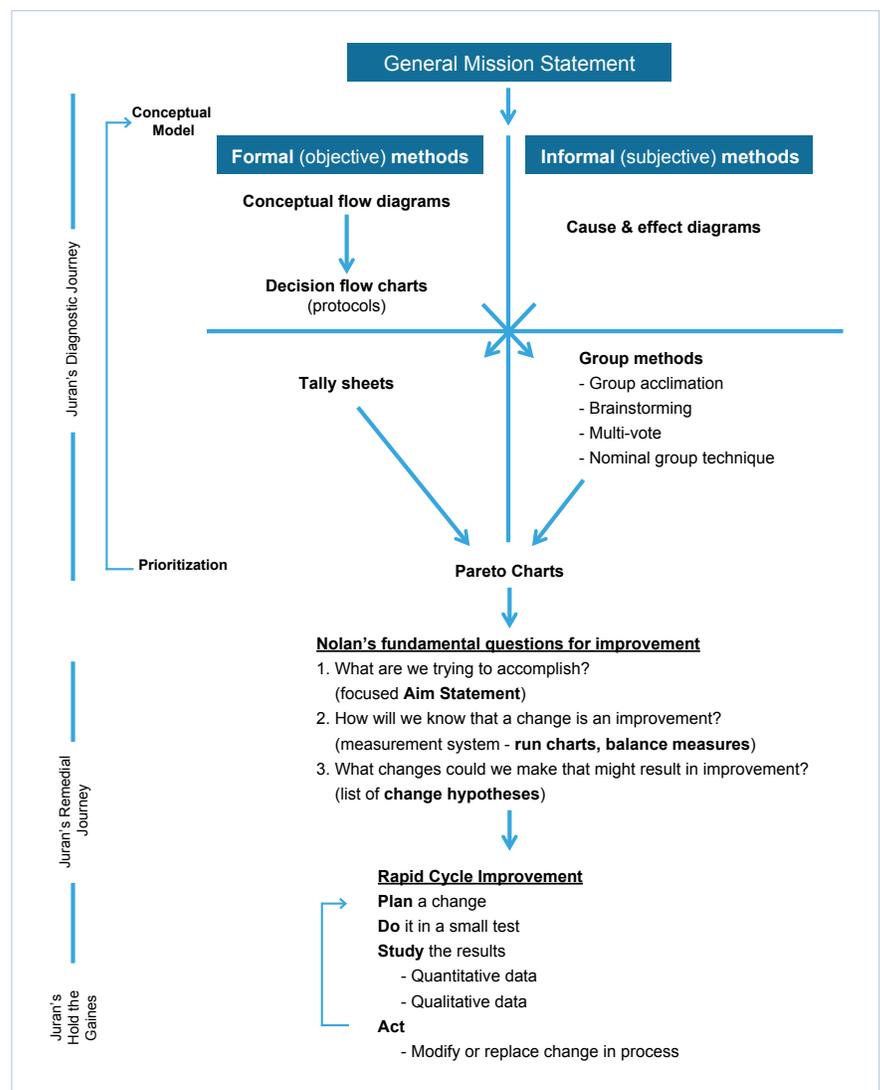


Figure 97: Modeling processes
(Click for larger version)

The Juran Diagnostic Journey goes from the initial analysis of the evidence (symptoms) of the quality problem and ends with the determination of the cause or causes of the problem. The journey includes activities common to all improvement projects.

- Analyze the evidence (symptoms) of the quality problem
- Formulate theories regarding the cause or causes of the problem
- Test the theories

During this stage of the quality improvement journey, teams have a variety of tools at their disposal, including conceptual diagrams, decision flow diagrams, cause and effect diagrams, tally sheets, group methods and Pareto charts. By taking a logical and informed approach using these tools, the quality improvement team will eventually establish the real cause or causes of the quality problem or defect. At that point, the diagnostic journey is over, and the remedial journey begins.

The Juran Remedial Journey begins with the identified known cause or causes for a quality problem or defect and ends with an effective remedy in place. The activities of the project team at this stage include:

- Identify alternative solutions
- Take action to remedy the problem
- Deal with any resistance to change
- Establish controls to hold the gains

A key step in both the IHI Model for Improvement and the Intermountain Healthcare approach is the development of an effective Aim Statement. Aim Statements are specific, measurable, time sensitive, written statements of what a quality improvement team will be focusing on as they strive to improve a process. A good Aim Statement will help keep an improvement project focused and on course.

In general, an Aim Statement should include a few key elements that seek to answer three questions (adapted from The Foundation for Improvement by Thomas W. Nolan, et al.):

- 1 What is the improvement team trying to accomplish?
- 2 Who is the specific target population?
- 3 What changes can we make that will result in an improvement?

The aim should be as concise as possible and be outcomes focused. It is not uncommon for a team to test and refine an Aim Statement in an effort to make it as concise and focused as possible.

A good Aim Statement sets stretch goals. Whether an improvement team hits the goal is less important than whether they advance learning and improve outcomes. The team should measure performance by how much they improve care, not whether they hit any given stretch goal. If the team fails, it should fail in the direction of improvement.

Once the Aim Statement is in place, the identified solutions are implemented and refined as a part of a rapid cycle improvement process using one or more PDSA cycles. In applying the remedy, it is important to recognize that this often means change and change can result in resistance. Thus, the Juran model stresses the importance of dealing with the resistance to change.

See chapter 5 for examples of Aim Statements.

In conclusion

At this point, we have discussed in detail the three systems care delivery organizations need to adopt in order to excel. Organizations need a strong analytic system to standardize measurement work, a strong deployment system to standardize organizational work and a strong content system to standardize knowledge work. Together, these three systems can help an organization improve clinical effectiveness, reduce waste and ensure patient safety.

What happens if an organization strengthens only one of its three systems? If an organization focuses only on analytics, they become information system centric. They end up strengthening the information request queue without ever putting the data to work. If deployment is the main focus, an organization becomes organization centric. Clinicians stop attending meetings because solid evidence and actionable measures are lacking. And if content takes the front seat, an organization finds itself in a research centric model with great academic ideas, but no data to support them and no one willing to deploy.

If even one of the systems is weak, an organization is left with an incomplete plan. Without analytics, an organization can become Lean centric. Quick improvements are made but you will have trouble measuring them as the projects pile up and the improvements are not sustained. Without deployment, an organization ends up with a lot of small, isolated science projects that never get rolled out across facilities. And without content, an organization has what could be referred to as paved cow paths. You have automated — and solidified — processes that have not been refined.

Only by strengthening all three systems can you deliver evidence-based care and drive scalable, sustainable improvements in cost and quality. It is in the confluence of these three systems that enables an organization to ignite change.

As one implements change in the clinical realm, it is important to emphasize once again that care providers are motivated by their professional values. The vast majority of clinicians are aligned by their shared professional values. Most clinicians want to do the best thing for the patients they serve and they have a strong desire to be the best they can be in that service. While money is important, it is also important to align improvement efforts with professional values. Tapping this innate desire of clinicians to be the best they can be is a key element of success in continuous improvement. It can be key to overcoming cultural resistance to change in clinical care. And, it is fundamentally important to transform healthcare.

We will now turn our attention in part three to see what success looks like for organizations that successfully apply the concepts, tools and methods reviewed in this section, as well as the future of healthcare analytics and associated technologies.

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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.^{148, 149}

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, hierarchical 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,

Comparison of organizational system characteristics	
Complex adaptive systems	Traditional systems
Are living organisms	Are machines
Are unpredictable	Are controlling and predictable
Are adaptive, flexible, creative	Are rigid, self-preserving
Tap creativity	Control behavior
Embrace complexity	Find comfort in control
Evolve continuously	Recycle

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 105.¹⁵⁰ 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.

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

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.¹⁵¹ 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.¹⁵² 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."¹⁵³ 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.¹⁵⁴ 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 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.

Categorical data		Numerical data	
Nominal	Ordinal	Discrete	Continuous
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.	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.	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.	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.

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.

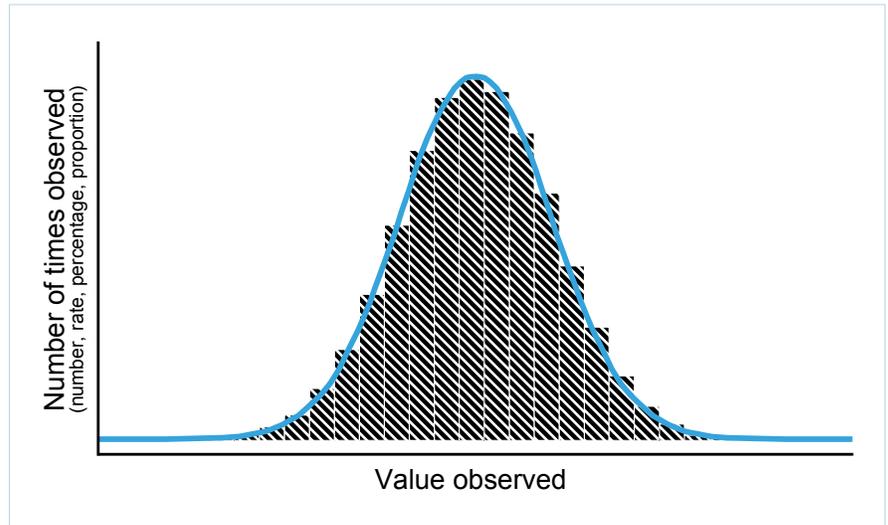


Figure 108: Parametric frequency distribution

Parametric and nonparametric distribution characteristics		
	Parametric	Nonparametric
Assumed distribution	Normal	Any
Assumed variance	Homogenous	Any
Typical data type	Ratio or interval	Nominal or ordinal
Data set relations	Independent	Any
Usual central measure	Mean	Median
Benefits	Can draw more conclusions	Simplicity: less affected by outliers

Figure 109: Parametric and nonparametric distribution characteristics

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

Types of SPC charts commonly used in healthcare			
Data type	Measurement example	Frequency distribution	SPC chart
Attribution (nominal or ordinal) – in binary form (a common situation in healthcare improvement projects)	Acute Myocardial Infarction (AMI) mortality: <ul style="list-style-type: none"> Numerator: AMI patients discharged with the state of “expire” Denominator: all AMI patient discharges 	Binomial distribution	Use the p chart — “proportion chart” for small sample sizes where $np \geq 5$ Where n = sample size and p = mean proportion
Discrete ratio data – “number of per unit” data	Number of primary bloodstream infections (PBIs) per 1,000 central line days: <ul style="list-style-type: none"> Numerator: number of PBIs Denominator: total number of days a central line is in place for all patients having central lines 	Poisson distribution	Use the c chart — “count per unit chart,” or a u chart — “counts per proportion chart”
Discrete ratio data – data in the form of “number of between” events	Mortality from community acquired pneumonia (CAP): <ul style="list-style-type: none"> Numerator: CAP patients discharged with the state of “expire” Denominator: number of non-deaths from CAP between each CAP death 	Geometric distribution	Use the g chart
Continuous ratio data	Mean: (average) time to initial antibiotic administration: <ul style="list-style-type: none"> Numerator: sum of each patient’s number of minutes between time of physician’s order to initial antibiotic administration time Denominator: total number of patients receiving initial antibiotic dose 	Gaussian (normal) distribution	Use the X-bar and s chart for “mean and standard deviation chart” with sample size parameter set to “1”

Figure 110: Types of SPC charts
(Click for larger version)

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.

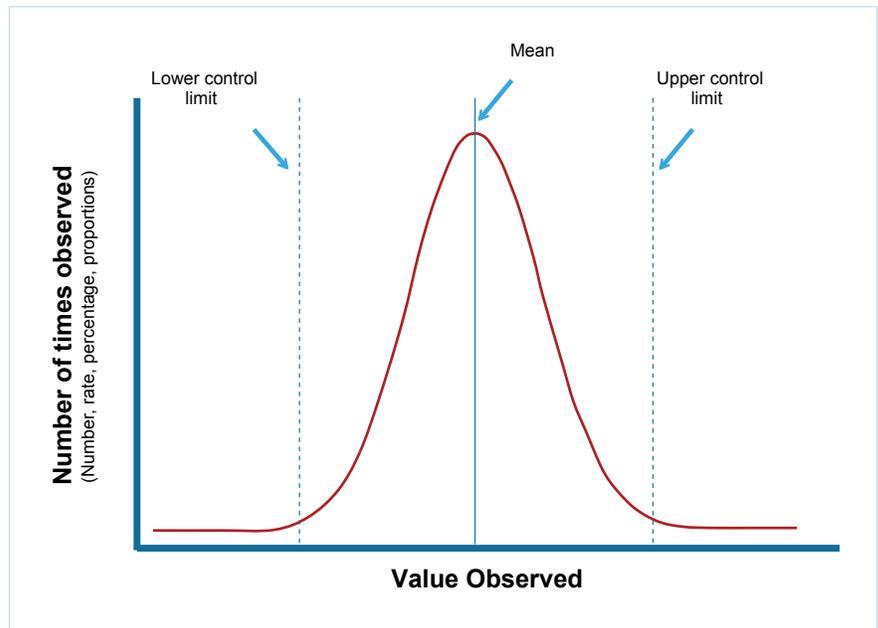


Figure 111: Binominal frequency distribution
(Click for larger version)

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.

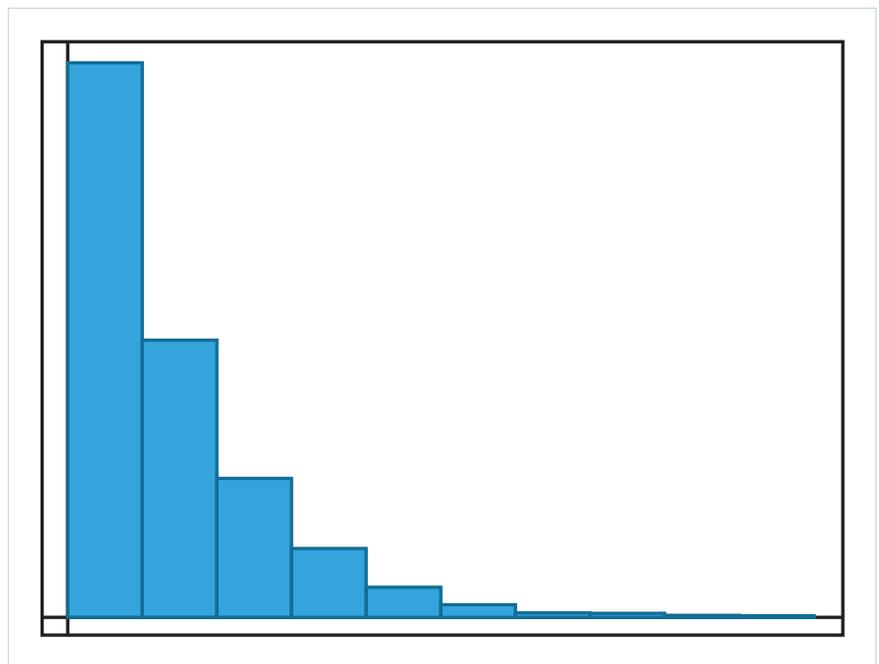


Figure 112: Geometric distribution

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.

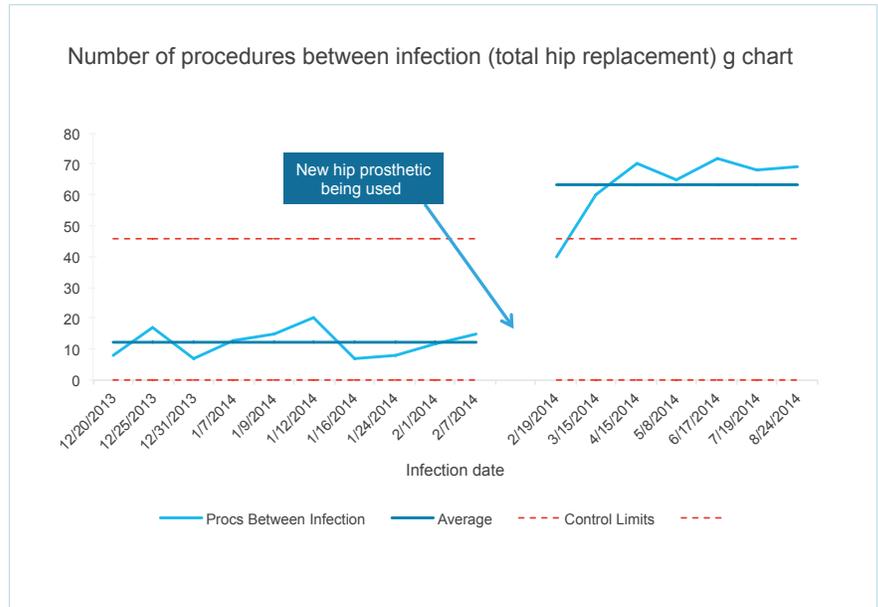


Figure 113: g chart example — number of procedures between infections (Click for larger version)

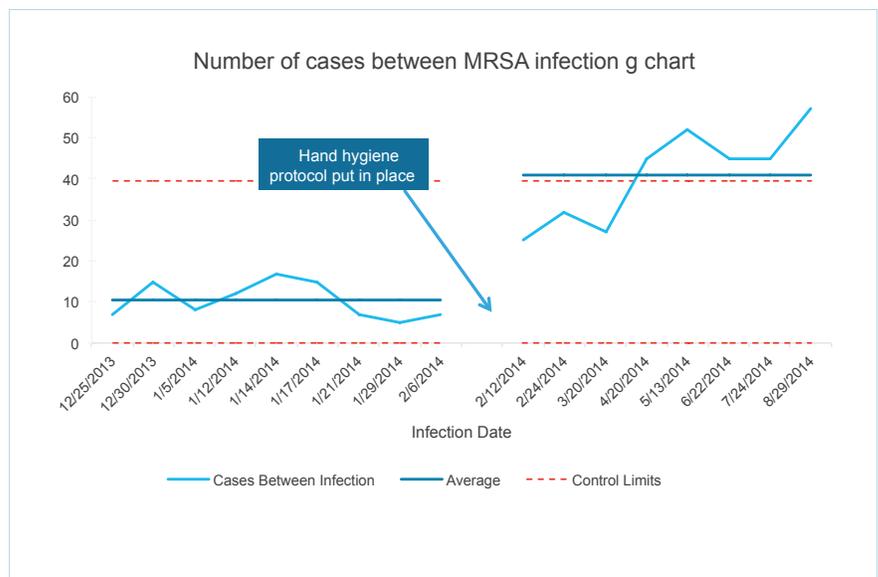


Figure 114: g chart example — MRSA infection (Click for larger version)

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.

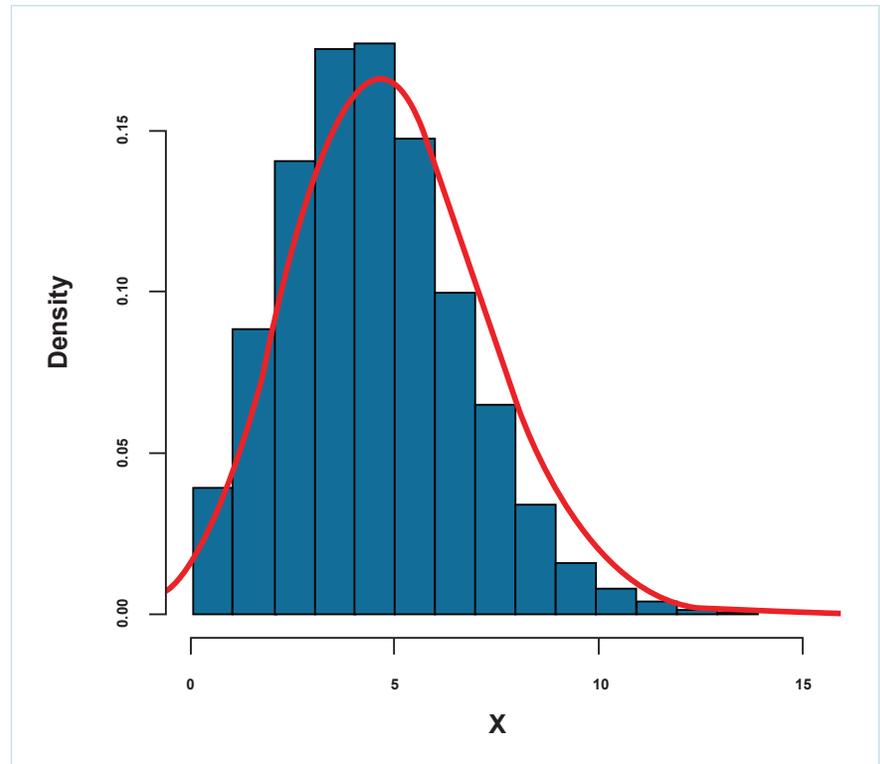


Figure 115: Poisson frequency distribution

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

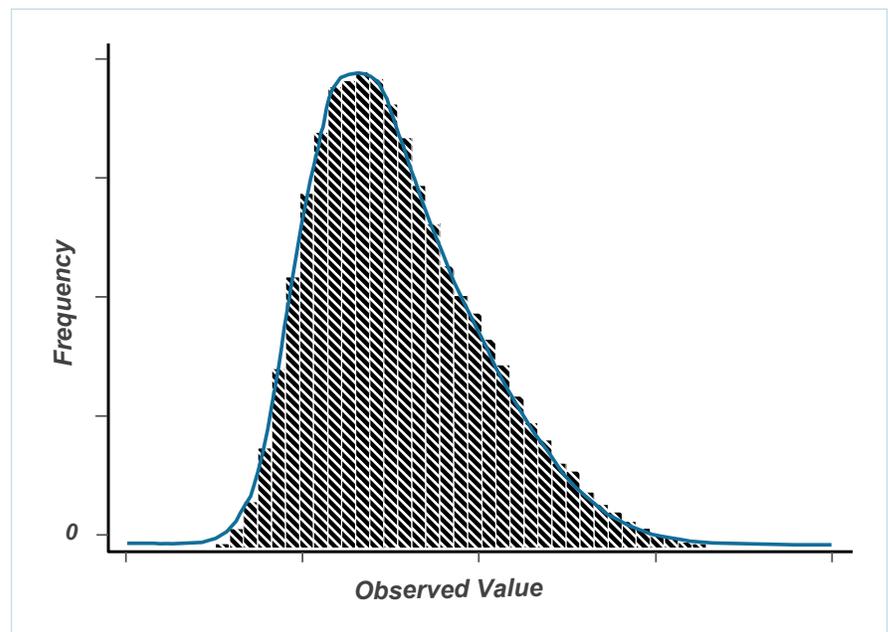


Figure 116: Skewed frequency distribution

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., \bar{X} 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.

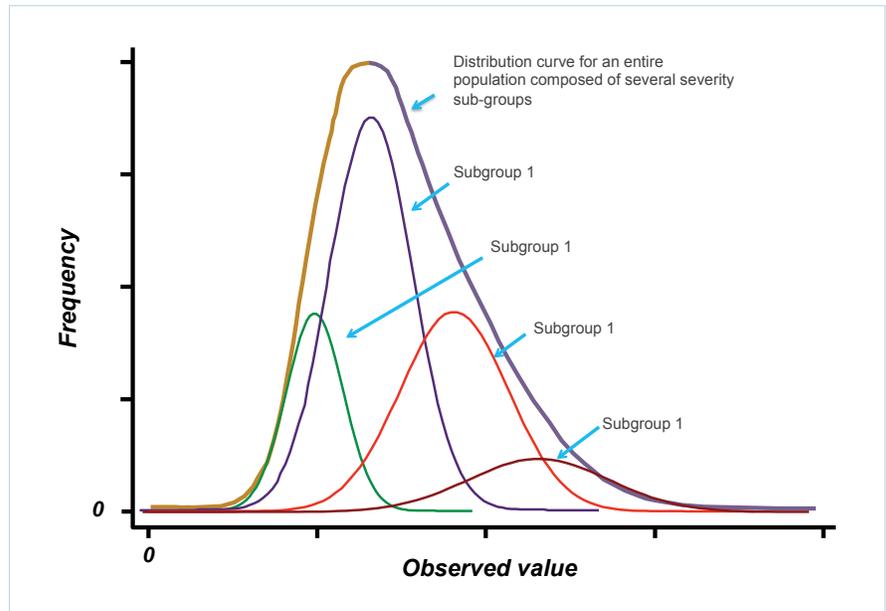


Figure 117: Parametric distributions based on severity
(Click for larger version)

- ▶ 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

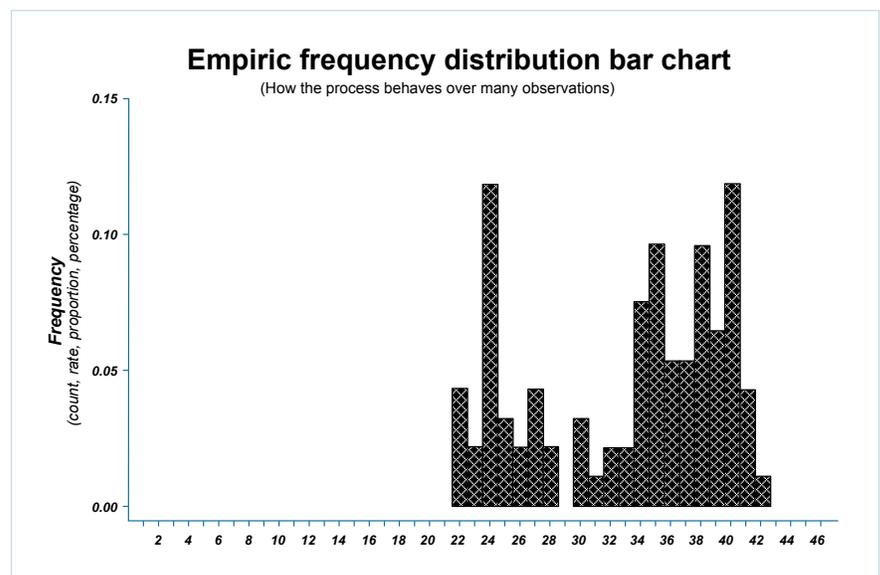


Figure 118: Shewhart's method for non-homogenous samples
(Click for larger version)

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.

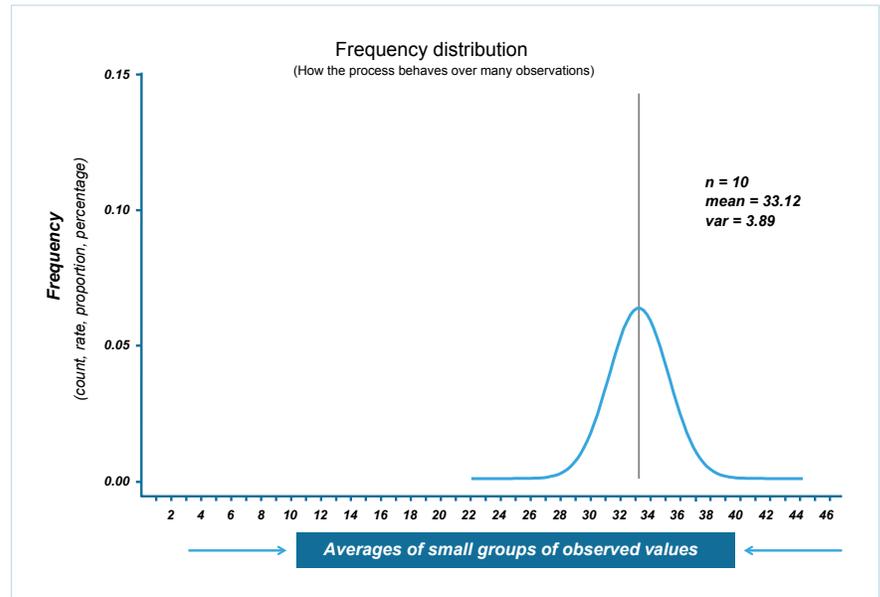


Figure 119: Shewhart's method for non-homogenous frequency distribution (Click for larger version)

- 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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