HEALTHCARE: A BETTER WAY
THE NEW ERA OF OPPORTUNITY

CHAPTER 4

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Healthcare: A Better Way

The New Era of Opportunity
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 Rimmischn, 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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An overview of the three-system framework for improving and sustaining clinical effectiveness, reducing waste and improving patient safety was discussed in chapter 3. Now we will review the analytic system.
This discussion will focus on unlocking your data and the importance of a good measurement system. By the end of this chapter, you should be able to describe different data models (including their strengths and weaknesses in healthcare), know how to use Pareto analysis to prioritize improvement opportunities, and discover patterns in the data to ignite meaningful, scalable and sustainable change.

Arguably, healthcare is the most data-intense industry in the world. Clinicians cannot deliver and sustain high-quality, safe care without information that is readily available. Measurement is the basis for assessing and sustaining potential improvements in healthcare quality. Deming once said, “In God we trust, all others must bring data.” In order to know whether a change is an improvement, an analytic system is absolutely essential. Key performance measures allow improvement teams to assess care against past performance (shared common baselines), evidence-based clinical guidelines and nationally recognized standards. As Lord Kelvin said, “If you cannot measure it, you cannot improve it.” In an improvement effort, you always need some form of objective measure to demonstrate how well things are working.

Analytics have to do with how we make data accessible for use, how we use data, how we measure work, how we prioritize improvement opportunities and how we monitor improvement efforts over time. The three components of an analytic system are shown in Figure 23. First, an organization needs to effectively unlock their data. Second, an organization needs to broadly distribute the data to individuals across the organization and teach them how to access and use the data — so-called self-serve analytics, versus the current report-queue mentality where one requests and waits for a report to be built that may or may not meet their needs. And, third, improvement teams need to discover patterns in the data so they can target areas for improvement, and ignite meaningful and sustainable change. We’ll discuss each of these components in turn, starting with unlocking data.
Chapter 4.1 — Unlocking and appropriately using data

Two ways of using data: accountability versus learning

Few would argue that data is necessary to drive improvement. However, it is equally important to understand at the outset of an improvement initiative how data should be used to optimize the likelihood that clinicians will engage in improvement efforts.

New knowledge and a migration to a profession-based model of care require a move from the traditional judgment-based model to a learning-based model. A judgment-based approach focuses on the person, while a learning-based model focuses on continuous improvement.

A judgment-based approach tends to make most people defensive and creates resistance to learning. Therefore, it will likely impede continuous improvement. Based on the philosophy that the best defense is a good offense, the accused will often counterattack in an attempt to shift the blame elsewhere. In an attempt to kill the messenger, they may challenge the veracity of the accuser, the validity of the analytic system, the accuracy of the data, the legitimacy of the analytical methods and the accuracy of the evaluation. They will also often question the competence and motives of those conducting the assessment. This is a classic example of the cycle of fear described by Scherkenbach and illustrated in Figure 24. The behaviors described in the cycle of fear occur because the majority of situations where errors occur are the result of a flawed system rather than a failure by an individual.

Brent James, MD, of Intermountain Healthcare, Don Berwick, MD — the founder of the Institute for Healthcare Improvement (IHI) and former administrator of the Centers for Medicare and Medicaid Services (CMS) — and Molly Coye, MD, chief innovation officer at UCLA, defined two ways of using data to get results.
As illustrated in Figure 25, you can use data to hold people accountable or to measure improvement and encourage learning.

Every organization needs to gather some data that encourages accountability, but the overall focus should be on learning, not accountability or judgment.

The focus you choose will determine what you do to improve your numbers. Deming identified three ways to get a better number:

- The first is to improve the system. To do this, you have to change your processes and add value at the front line.
- The second is to suboptimize. You focus on improving the area being measured, often at the expense of other areas.
- The third is to game the numbers. You manipulate the data to make the numbers look better. In healthcare, this is often accomplished by eliminating troublesome subpopulations from the cohort of patients.

A learning approach focuses on the process and the system. This is a bottoms-up approach centered on the idea that people can study a flawed process and improve it over time. A profession-based model allows and encourages people to continuously learn and improve. It involves them in the solution. Thus, a profession-based approach is essential to fostering a culture of continuous improvement in healthcare.

Organizations that focus on learning are more likely to improve their processes and systems. Organizations that focus on accountability are more likely to suboptimize or game the numbers.

What makes healthcare data unique?

There are several characteristics of healthcare data that make it unique. First of all, healthcare delivery and healthcare organizations are both diverse and complex. As a result, healthcare data tends to reside in multiple places and formats (e.g., text, numeric, paper, digital, pictures, videos, multimedia, etc.). Some healthcare data is structured, while other types of data are unstructured. Even in situations where clinicians should be putting data in a structured field,
they may not be, resulting in the need to manually extract the data — a time-consuming and costly process. Oftentimes, healthcare data is described using inconsistent or variable definitions. For example, one group of clinicians may define a cohort of asthmatic patients differently than another group of clinicians. Healthcare also tends to generate very large volumes of data. The amount of new healthcare knowledge is massive and expanding on an almost daily basis. This means evidence is constantly changing. Regulatory and reporting requirements also continue to increase and evolve. Finally, for both care delivery and improvement efforts, clinicians need to get to patient-level detail.

The best way to make healthcare data accessible

A healthcare enterprise data warehouse (EDW) is the core of an analytical infrastructure. Given its complexity and quantity, it is important that healthcare data be readily accessible electronically and that the design of the EDW is maximally adaptable to support the dynamic and unique nature of the healthcare environment.

EDWs are described using conceptual data models. Different data models have been developed to meet various analytic requirements. A data model can be thought of as a diagram or flowchart that illustrates the relationships between data and data sources. The data model demonstrates the specific entities, attributes and relationships involved in a business or enterprise. The data model serves as the basis that IT professionals use to create the physical data model. The characteristics of the data model matter because of the complex and dynamic nature of healthcare data and the healthcare environment. Various types of data models and how they relate to healthcare are described below.

Data model types

There are several approaches to unlocking data in healthcare. One approach is the enterprise data model. In this model, an organization creates a perfect model of the data, representing all the concepts and relationships that need to be defined. They then map the different source transactional systems into that model, as shown in Figure 26.

This model works well in some industries — such as banking and retail — that have minimal variability in their
data and where concepts and definitions are relatively static. Unfortunately, this highly organized model cannot be delivered incrementally, it takes a long time to create and it can be expensive. The extract, transform and load (ETL) routines used to move data into the model are complex. Finally, because of the characteristics of healthcare data — including constant, evidence-based care updates — you have to continuously redesign the model to make new data fit. Some healthcare systems have spent years on this approach and still have not been able to move any data into the model. This model has had limited success in healthcare, although it has been very successful in other industries.

Another approach to unlocking data is the dimensional data model, as illustrated in Figure 27. With this model, an organization builds an analytic data mart for a particular area — such as heart failure — gathers the data it needs directly from the source systems and maps it to different areas.

This model is easy to start. However, it grows very quickly, as do the data streams, until several redundant streams exist. This creates a challenge for those trying to maintain the model. If one underlying source system changes, they have to change each extraction routine that uses that particular source. Additionally, it often doesn’t have underlying patient-level detail. If a metric in a summary mart is unfavorable, you are unable to drill to the patient level to determine the reasons why.

A new approach to data modeling that Health Catalyst uses to address healthcare’s unique data needs is the Late-Binding™ Data Warehouse (Figure 28). The advantages of the late binding approach are
that it is generally faster to launch, it is easier and less expensive to maintain, and most importantly, it provides maximum adaptability for clinicians who are involved in improving care in the highly dynamic healthcare environment.

In the late binding model, one brings data into the warehouse in a raw format that keeps the same structure and feel of the underlying transactional system. This quick copy can be done in a few weeks, unlike the enterprise model, which can take years to develop. The structure stays the same, which enables analysts familiar with the transactional system to recognize the data structure in the warehouse. Naming and data type standards are applied to make it easier for analysis, but minimal transformation occurs.

In the late binding platform one can connect disparate data with a common linkable vocabulary. For example, identifiers for patients, providers and facilities can be linked across different data source systems such as an electronic health record (EHR) or claims (source marts), and one patient can be viewed across the entire system. From there, you can build marts focused on a particular clinical area such as diabetes (subject area marts). This can be done quickly because you are not going back to the individual source systems. You already have all the data in the late binding data warehouse. If an underlying source changes, you update one extraction routine instead of multiple streams. The result is just-in-time data binding. Rather than trying to define everything up front, you bind the data later, when you are trying to solve an actual clinical or operational problem. Finally, you can build graphical data visualizations atop the subject area marts, so it’s easier to interpret the data and identify trends and patterns.

Data binding and why it matters

Data binding is a technique in which raw data elements are mapped to conceptual definitions. One of the keys to the data model developed by Health Catalyst is binding the data late (i.e., when clinicians are trying to solve a problem). But that doesn’t mean you always wait until the end. Data that is stable, like vocabulary terms and patient and provider identifiers, can be bound early. Data that is likely to change should be bound later. For example, length of stay (LOS) in a hospital may sound straightforward on paper, but surgeons might define LOS as point of incision to discharge from the post-anesthesia care unit (PACU), and cardiologists might define it as emergency department (ED) arrival to discharge. Because the LOS definition will change for different use cases, you will want to bind it later.
Figure 29 shows points where you can bind data.

- The earliest you can bind data is when you are moving it from transactional systems into the warehouse and then during the ETL process (points 1 and 2 in Figure 29). It is best to bind only low-volatile rules and vocabularies at these first points.

- You can also bind data in the target data source model they land in or when moving it to customized data marts (points 3 and 4).

- You can bind somewhat volatile data in the customized data mart — this is still considered late binding (point 5).

- The last place you can bind data is in the visualization layer for rules and vocabulary that are likely to change. Once you establish definitions, the data can be locked down (points 3, 4 or 5).

A late binding data warehouse has several advantages, including:

- The process is driven by business and clinical needs instead of architectural design.

- It is less expensive to develop because it can be built in stages.

- The late binding approach provides both atomic- and summary-level information, so you are not bombarded with data, yet you can find specifics when you need them.

- It is flexible and allows an organization to build other structures on top of it, if desired.

- It is very quick and easy to develop and deploy source and subject area data marts, so an organization can start using and benefiting from it sooner.

- It becomes a great source of analytic information for different departments.
The structure aligns with governance or data stewardship, so different departments can access different source marts because they are the stewards of that data.

It improves an organization’s information about the data (i.e., metadata) by tracking how often it is refreshed, where it came from, who’s in charge of that data and so on.

It is noteworthy that the late binding data warehouse is the approach that has most consistently worked in healthcare to unlock data and drive improved results.

**Automating data distribution**

Once the data is unlocked, an organization can automate the broad distribution of the information. Ideally, the data is distributed electronically to enable clinicians to effectively and efficiently view the information they need in as close to real time as possible.

Today, in most healthcare delivery organizations, the distribution work falls primarily to analysts or clinicians, who encounter many challenges. First, they must understand what types of data are needed. Before they can locate and compile that data, they have to wait for IT to run reports or queries. Only then can they start interpreting data and distributing it to the right people. Obviously, understanding the need and interpreting data are two value-add tasks. But at many healthcare organizations at least 80 percent of the analyst’s or clinician’s time is spent gathering or waiting for data instead of analyzing information.

There are several examples of non-value-added tasks. If the person preparing the report doesn’t get all the necessary data, he or she has to do chart abstraction, where one pulls up the patient’s record and manually types the missing data into an Excel spreadsheet or another data collection file system. This is sometimes called sneaker ETL because the analyst spends a lot of time walking from one system to another to enter data. When you reach the stage where you want to provide others access to the data (i.e., the distribution/provisioning stage), the new data are typically integrated into another Excel spreadsheet (spreadsheet data marts or spreadmarts), but they aren’t tied back to the source information. The person creating the report might have built clever macros to grab this data, but if they leave the organization, they also take the knowledge about how the macros work, and the people left behind can only hope the data imports correctly. Spreadmarts are volatile — they are not standardized, they are not predictable and they are often not secure.
Automation can help solve these problems, as illustrated in Figure 30. An organization can easily eliminate unused or obsolete reports and standardize data capture as part of the workflow during or just after key events. Instead of sending reports, an organization can encourage front-line workers to explore data themselves by collecting data in the EDW, standardizing common definitions and automating information distribution. Finally, an organization can use rollup instead of summary data by gathering patient-level detail and using it as a starting point for summaries. This allows end-users to drill down and answer “why” questions that might otherwise go unanswered.

By automating data capture, data distribution (provisioning) and data analysis, an organization can encourage self-exploration. It is best if healthcare can get away from a report factory mentality where an end-user sends in a data request and waits a couple of weeks or longer for the results. If an end-user wants the request moved up the list, they need to cajole the IT person to do them a favor — and hope the data is right when they get it back. Often, the end-user has forgotten the question they originally asked because it takes so long to get the report. By getting rid of this report factory mentality, and making tools that the end-user can use available, the end-user can explore their own data and ask and answer their own questions.

Some organizations feel as though they have automated their data because they have created dashboards. When mandated from the top, dashboards can create fire drills that steal clinicians’ time and attention. They often do not match the front-line clinical needs or workflow and overemphasize a single outcome metric while neglecting far more important process metrics. Executives do need information, but ideally, problems should be attacked at the clinical level, using metrics designed at the frontline. Rather than a one-off request for a single outcome metric, the executive team may want to track a department’s progress toward achieving a set of core objectives that have been defined by the department to help improve outcomes.
Chapter 4.2 — Prioritizing improvement opportunities

Once an organization’s data is unlocked and readily available, the next step in the improvement journey is to decide where to focus improvement efforts. Every organization has limited resources. Their goal is to get the greatest benefit from the resources they invest in improvement efforts. Therefore, they need to determine which investments will provide the greatest benefit: improving care for the largest number of patients, streamlining operations to the greatest extent possible and lowering costs. Taking this approach will help organizations achieve their highest value.

The Anatomy of Healthcare Delivery — a conceptual framework for organizing healthcare

Anyone involved in healthcare delivery knows it is complex. Traditionally, healthcare has used clinical service lines to categorize clinical care. While clinical service lines may be useful, they are generally not comprehensive enough to capture all clinical care. A clinical service line model tends to be acute care-centric, and it does not adequately describe the details of any given care delivery process (e.g., what the decision points are, how decisions are made or who makes them). In short, the traditional clinical service line model does not provide us with the level of detail and the depth of understanding necessary to organize our thinking and manage the process of care most effectively. Thus, the need for a conceptual framework that supports our ability to do this.

This section focuses on a framework that lays out the process of healthcare delivery and provides context for a discussion about quality improvement opportunities. The framework accounts for population-based improvements in utilization as well as improvements in prevention, encounters or cases.

As healthcare increasingly focuses on producing value — higher quality and safer care at the lowest possible cost — there will be a shift in emphasis toward managing care across the continuum. There will be a need to efficiently and effectively conceptualize and manage care from the home to the clinic, urgent care unit, emergency department, special procedure unit or hospital. As the pressure grows to manage care more effectively, there will be an increasing emphasis on post-acute care in order to reduce hospital lengths of stay or bypass the acute care admission altogether. Examples of post-acute care environments may include the home, clinic, home healthcare, skilled nursing facilities and hospice, as shown in Figure 31.

Figure 31: Population Health Management — paradigm shift
As healthcare transformation unfolds, a paradigm shift is taking place from an acute care-centric model of patient care to a focus on the continuum of care and a shift toward population-centric management. Some of this is being driven by federal government programs such as the Patient Protection and Affordable Care Act or the commercial emulation of value-based reimbursement in various forms that promote shared accountability for the risk and the reward of taking care of patients.

**Conceptualizing the flow of care**

The first step in understanding clinical care is to understand the flow of care when patients interact with the delivery system. The Anatomy of Healthcare Delivery framework developed by David A. Burton, MD, and shown in Figure 32, demonstrates the potential pathways patients can go through in their interactions with the delivery system. This is a conceptual framework that enables us to organize our thinking about the care delivery process and to focus our attention on key processes and decision-making points. The degree to which an organization standardizes their approach in each of the knowledge asset categories (indicated by the blue and light blue boxes shown in Figure 32) will impact the degree of variation in care delivery.

As seen at the top of Figure 32, patients may present with symptoms or they may be seeking screening or preventive care. If they have symptoms, or there are positive findings identified in the process of screening, patients enter into a diagnostic workup. Once a provisional diagnosis is established, patients are triaged to a treatment venue (e.g., clinic, acute medical or invasive) based on decisions that are driven more by subjective considerations than objective data. The goal should be to triage the patient to the care venue that best matches delivery system resources to the patient’s needs in a manner that optimizes the balance between quality, safety and cost (e.g., ambulatory, acute medical or invasive).

Condition-specific care guidelines and implementation protocols can be developed for each of the boxes in the flow of care. Health maintenance and preventive guidelines are applied to patients who neither have symptoms of disease nor show positive results after screening. These guidelines, which

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**Figure 32: Population health management — Anatomy of Healthcare Delivery**

(Click for larger version)
extend to the patient’s home, help keep those who are healthy in a state of good health for as long as possible.

Knowledge assets focused on the care processes are employed in the management of preventive, ambulatory, acute medical, invasive and post-acute care. Treatment and monitoring algorithms are used to care for patients in ambulatory clinics. If they have a positive diagnosis, a sequence of events is launched. For example, treatment of a diabetic usually starts with diet and exercise. If these initial efforts do not achieve treatment goals, the next step is to prescribe a single oral agent for type 2 diabetes, followed by addition of a second oral agent if treatment goals are not reached, and so on down to basic insulin therapy if oral agents do not work.

If after a defined period of time treatment such as that outlined above for type 2 diabetes fails to meet the established aim, the patient may be referred to a chronic disease subspecialty clinic where more intensive treatment algorithms are employed.

Some patients for whom adequate care is not possible in a clinic environment, or who are sick enough to be triaged directly to the acute medical or invasive venues of care, receive care in one of these acute care venues. These types of patients are triaged to specific care units within these venues based on their condition and acuity. Admission order sets for these patients regulate their care during the initial phase of their treatment.

As treatment progresses on an acute medical unit, supplementary orders govern care in accordance with evidence-based guidelines for administration of blood products, pharmaceuticals or fluid and electrolyte replacement.

For the invasive care units, there are pre-procedure order sets that include clinical supply chain management processes such as the utilization of prosthetic devices (e.g., hip or knee replacement), stents, synthetic grafts, devices to regulate heart rhythm or neurostimulators.

For patients admitted directly to acute medical care units, the various order sets translate into bedside care practice guidelines, including risk assessments and intervention protocols to prevent patient injury, protocols designed to deliver standard evidence-based care for the patient’s condition, and ultimately transfer and discharge protocols. Similarly, for patients who undergo treatment in invasive care units, there are care practice guidelines such as “timeouts” and sponge and instrument counts to prevent wrong site surgeries and retained foreign bodies. After a procedure is completed in one of the invasive care units, post-anesthesia care is initiated, based on post-procedure order sets.

As the patient enters post-acute care, there are order sets for facilities such as skilled nursing facilities, inpatient rehabilitation facilities, home health and hospice, as well as standardized follow-up instructions as the patient eventually returns home. Standardized steps and treatments are employed in each venue of care.
In addition to the treatment cascades outlined above, which apply within an episode or case of care, there are complementary criteria or algorithms that determine what tests should be ordered based on diagnostic findings, as shown in Figure 32. For example, once a provisional diagnosis is established, specific triage criteria are used. An example of this is the CURB-65 criteria for community-acquired pneumonia. Documenting how many of the risk factors are present helps the clinician decide whether it is safe to treat in the ambulatory environment or whether the patient needs to be admitted to a med-surg general acute care unit or to an intensive care unit.

In the clinic care setting, the treatment and monitoring algorithms lead to indications for referral if the care process does not achieve established goals and target values. For example, a diabetic who is treated in accordance with the standardized steps of the algorithm but does not achieve the target hemoglobin A1c level within a defined time window meets indications for referral to an endocrinologist. Another example of indications for referral would be a child with acute otitis media that, after recurrent infections, progresses into serous otitis media, with complicating speech retardation and/or hearing loss. Such a child needs to be referred to an ear, nose and throat (ENT) specialist for evaluation and possible myringotomy and placement of tympanostomy tubes.

Similarly, patients who are referred to an invasive physician (i.e., interventional medical or surgical subspecialist) either during the acute phase of their illness or after failing to respond appropriately to clinic care treatment and monitoring algorithms, should also meet indications for intervention before an invasive procedure is undertaken.

A Clinical Integration hierarchy — care process families and clinical programs

Now that we have examined how patients flow through the care delivery system and its critical decision points, we can use the information to create a logical framework to help us organize a Clinical Integration hierarchy to help us think about clinical care delivery. This hierarchy applies along the continuum of care delivery, from the home and clinic, to the outpatient and inpatients venues of acute care, and thence to the post-acute care venues.

The most granular level of the hierarchy is the care process. Figure 33 shows examples of ischemic heart disease care processes (e.g., hyperlipidemia, coronary atherosclerosis, AMI, PCI, CABG and cardiac rehab). These care processes...
belong to the next level of the hierarchy, the ischemic heart disease care process family.

Ischemic heart disease and its care process family siblings of heart failure, heart rhythm disorders and vascular disorders make up the cardiovascular clinical program, which is an example of the next level of the hierarchy. These care process families make up the vast majority of clinical conditions in the cardiovascular domain, as illustrated in Figure 34.

The cardiovascular clinical program is one of several major clinical domains, as shown in Figure 35. Clinical programs are organized based on physician specialists and other clinicians who share management of care processes and who are responsible for the ordering of care for patients. Either they work on things together, or one team’s output is another team’s input (e.g., OB-GYN subspecialists and neonatologists). Each of these domains or clinical programs consists of a group of care process families.

Clinical support services deliver care ordered by clinical program physicians

Once care is ordered by clinical program physicians, clinical support services are responsible for delivering care to patients. Clinical support services, as illustrated in Figure 36, include diagnostic, therapeutic, clinic care, acute
medical and invasive clinical support services. The vertical clinical programs order the care and are responsible for defining the evidence-based, scientific flow of the care. The horizontal clinical support services implement the care that is ordered and are responsible for defining a safe and efficient workflow.

Patient injury prevention is an integral element of the workflow because patient injury really should be viewed as a defect in the implementation of optimal care. Figure 37 shows which value stream protocols each department should use to help prevent patient injuries.

In order to prioritize improvement projects relating to the ordering of care and its implementation, we need to be able to measure the relative size and variability of the three levels of the Clinical Integration hierarchy. This requires linking each level of the hierarchy to some quantitative metric, such as cost. This is done by mapping the clinical processes of care to administrative codes such as ICD-9-CM, diagnostic and procedure codes such as CPT-4 codes, and APR-DRGs. Figure 38 is a conceptual diagram that illustrates the use of a cardiovascular example using ICD-9-CM and CPT-4 codes. The ICD-9-CM codes are being supplanted by ICD-10-CM codes. ICD-10 will offer even more advantages because it can explain clinical conditions in far greater detail.

Medicare recently published nationwide data for the benefit
of those developing innovation proposals. Using these data, one can group care by venue. Figure 39 illustrates the nationwide dollars of care based on venue: clinic care, outpatient, inpatient, skilled nursing facility, inpatient rehabilitation facility, home health and hospice. This helps us understand the relative contribution of each of the venues of care to the total Medicare expenditures nationwide.

Key Process Analysis (KPA) — prioritizing the opportunity for variation improvement

The Anatomy of Healthcare Delivery framework helps clinicians and others understand the flow of patient care. It also provides a useful model for organizing the complex care delivery process and determining where to focus care improvement resources to achieve the greatest possible impact in terms of value. We will now turn our attention to a discussion of how we can use the Anatomy of Healthcare Delivery framework to prioritize improvement efforts.

The key variables in prioritization are resource consumption (larger processes offer greater opportunity) and variability. Once care process families are mapped to costs, relative resource consumption can be identified and ranked, as shown in Figure 40.

Each of the blue dots represents one of those care process families, such as arthritis, pregnancy, lower gastrointestinal disorders and so on. The red dots represent the cumulative total of the blue dots. If you focus on the first 10 blue dots, the cumulative total is over 40 percent. This analysis looks at direct variable costs because they represent the costs over which providers have the most control. Extending out to 32 processes, we reach a point of about 80 percent of total resource consumption. In addition to highlighting costs, this approach provides
a reasonably good surrogate for the risk to the patient. For example, the higher the resource consumption, the more likely the patient is in an intensive and costly care environment such as the ICU. Both because of patient benefit and cost reduction opportunities, it is reasonable to assume that focusing on these 32 processes would yield the greatest benefit. Organizations would likely not be wise to invest money into processes on the far right of the grid because the benefit is less likely to outweigh the costs. If an organization is doing this, it may be prudent to refocus their improvement efforts on high-priority areas that offer a potentially greater return on investment.

One of the challenges that can be encountered when applying quality measures to different care process families is that many things cannot be compared, and hospitals lack clinical data that can be used to prioritize their problems. Instead of using clinical data they do not have, healthcare organizations can substitute financial data. This works surprisingly well because complicated, expensive care often entails greater risk to the patient. Additionally, financial variation often reveals clinical variation.

If the cost of care for the same type of patient varies greatly between two physicians at the same facility, the physicians are probably using different clinical practices. By standardizing on evidence-based practice, clinicians can improve outcomes and reduce costs. Financial data can be used to prioritize clinical initiatives, but it should not be used to confront physicians about cost. Improvement in cost outcomes should be a by-product of the standardization and improvement of clinical practices and not an end in itself.

To prioritize the allocation of development resources, you want to combine and rank objective data criteria and subjective criteria, such as organizational readiness. Then, assess different care process families against those criteria as shown in Figure 41.

Pregnancy ranks first in case count and total LOS hours in Figure 41. Each delivery LOS is relatively short, but the number of deliveries makes pregnancy the top bed occupier. Pregnancy is only seventh in total charges because, on average, a labor and delivery event costs much less than a trauma or heart failure event. Infectious disease has the greatest variation in cost, which makes it an area of high opportunity as well.

<table>
<thead>
<tr>
<th>Care process family</th>
<th>Case count rank</th>
<th>LOS hours (capacity) rank</th>
<th>Total charges rank</th>
<th>Total direct cost rank</th>
<th>Total direct cost opportunity rank</th>
<th>Organizational readiness (1 to 10) 1 = most ready</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma</td>
<td>9</td>
<td>2</td>
<td>2</td>
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Figure 41: Prioritization criteria and ranking
Chapter 4.3 — Discovering patterns in the data

We have gotten to a point where the data is readily accessible, and we have established a logical way to focus our efforts on the greatest areas of opportunity to maximize the return on our investments in quality improvement. The next step is to start identifying patterns in the data with the goal of measuring and sustaining improvements in care. Patterns in the data are often driven by variations. These include variations in clinician performance, data capture, data collection, processes, resource consumption and outcomes.

Before we discuss patterns in the data, it is important to touch on two important topics. First, we need to understand variations: types of variation, which variations matter and which do not, how we measure variation and how we monitor variation over time. As a part of this discussion we will review statistical process control (SPC), the most important quality improvement tool for identifying and monitoring variation. Second, we need to understand how to use data in quality improvement to maximize clinician engagement and outcomes. We will discuss each of these in turn and then go on to patterns in the data that help guide improvement efforts.

Understanding variation in healthcare

We live in the information age, and much of the information that bombards us every day comes in the form of numbers. In order to effectively use numerical information in decision making, however, we must be able to analyze, interpret and assimilate it. Unfortunately, few of us are taught how to make sense of numerical data. This is even true in the high-powered education that most clinicians receive. Arguably, clinicians work in the most information-intense industry in the world, yet they generally have not been taught the basics of analyzing and interpreting the volumes of data they encounter on a daily basis.

To understand information, it is important to grasp the concept of variation. Variation has been defined as a deviation from the norm, like the variation of colors in nature. A variation from an accepted standard can be important. For example, a variation in an electrocardiogram (EKG) tracing can tell a provider that a heart attack might be imminent. Not all variation is bad, of course. There are wide variations in people’s appearance, for example. But these trait differences make each person unique.

It is important to understand that variation exists in virtually all processes we encounter in work and in our daily lives. For example, people vary in looks, intelligence, how they learn, how they perform tasks, how they respond to
events and how they perceive quality. In addition, the response of any given individual to a situation or process can vary over time.

Organizations are collections of people, and organizations can likewise vary as they respond to situations. Financial outcomes vary from company to company in the same industry and from quarter to quarter in the same company. Success rates for the same clinical procedure vary from physician group to physician group and from hospital to hospital. In addition, success rates for the same clinical procedure can vary for an individual physician group or hospital over time.

Clinicians constantly make decisions based on their interpretation of variations in information they encounter as they care for patients. Is it time for a patient to have a thorough clinical workup? Is a patient's condition improving, or should an alternative treatment be considered? Are the outcomes of the diabetics in my panel improving based on the treatment plan? Are we saving lives?

The decisions we make are often based on whether we think the variation we observe is indicative of a true change or simply a random variation. Making this distinction between random variation and assignable cause variation (i.e., variation due to an identifiable cause instead of random events) is critically important in patient care. It is not possible to be a good clinician without knowing the difference.

There are numerous examples of how clinicians interpret patterns in variation as they practice clinical care every day. For three months in a row, the HgbA1c values in our panel of diabetic patients are higher than expected. Do the data indicate a trend that requires a change in how we are managing diabetes? What action should we take? A physician experiences some unexpected outcomes. As the chair of the clinical department, are these outcomes random variations, or should we intervene? Who needs special assistance and who should be left alone? The number of adverse events in a hospital is higher than last year’s average for two months in a row. Should we respond with special programs, or is this simply a chance event?

It is important for clinicians to understand some of the basic concepts needed to accurately interpret variation. They must be able to determine whether the patterns of variation that are observed are indicative of a trend or simply a random variation similar to others observed in the past. Recognizing this distinction is essential to minimizing losses that can result from misinterpreting a pattern. These losses can include blaming people for problems that are beyond their control, spending money on interventions that
are not necessary, wasting time looking for explanations of trends that do not matter and taking actions when it would have been better to do nothing.

Understanding systems and processes

In order to understand variation, it is helpful to appreciate the concepts of processes and systems. In his study of process in the 1920s, Walter Shewhart defined a process as a set of linked steps, often but not necessarily sequential, that are designed to cause some set of outcomes to occur, to transform inputs into outputs, to generate useful information and to add value.\(^75\) Inputs to a process can include supplies, information or people. Outcomes from a process can include services, products or people.

A system has been defined as “an independent group of items, people or processes with a common purpose.”\(^76\) In this context, healthcare can be viewed as a complex system comprising thousands of interrelated processes.

Performance indicators for any process or system can be identified and measured. These performance indicators are referred to as quality characteristics. In clinical care, quality characteristics include rates of harm (e.g., adverse drug events, falls, retained foreign bodies, wrong site surgery, hospital acquired infections, handoff errors, etc.) and outcome measures (i.e., clinical outcomes, functional outcomes, satisfaction rates, access to care, rates of waste and cost outcomes).

Quality characteristics will vary over time or by location. Analysis of variation in quality characteristics is used as a basis for taking action on the process or system. Deciding whether to act on variations in data depends on differentiating between variations that are inherently part of the process or system (so-called random or common cause variation) and those that are not part of the process or system (so-called assignable — or special cause — variation).

The output of a process can be graphed as a frequency distribution. A frequency distribution is a graphical representation of values of one or more variables sampled from a process, as seen in Figure 42. A frequency distribution tracks the performance of

Performance indicators for any process or system can be identified and measured. These performance indicators are referred to as quality characteristics.

Figure 42: A frequency distribution
a process across a group of observations or measurements. It shows the number of times (y-axis — count, rate, proportion) each possible value occurred (x-axis). While it is not possible to exactly predict any single future observation for the process, the frequency distribution gives a range within which nearly all of the process’s future measures are likely to fall. Stated another way, how a process behaved in the past is a reasonable predictor of how it will behave in the future.

Process capability is defined as the degree to which a process meets specifications. A specification explicitly states an acceptable range for a measurable performance or outcome parameter. This is usually expressed as the proportion of all measured points that fall within a specification range. A defect is a process output that does not meet specifications (i.e., an output that falls outside of the specification range).

The specification range is generally defined by control limits. Control limits represent action or decision thresholds. They generally are measured in units of standard deviations and are often referred to by the term “sigma scores.” Six Sigma represents about 3 to 4 defects per million (six standard deviations from the mean). Five Sigma is about 5 to 6 defects per 100,000 (five standard deviations from the mean). Four Sigma is about 3 to 4 defects per 10,000 (four standard deviations from the mean). Three Sigma is about 4 to 5 defects per 1,000 (three standard deviations from the mean). Two Sigma is 4 to 5 defects per 100 (two standard deviations from the mean). One Sigma is about 30 to 40 defects per 100 (one standard deviation from the mean). Over time, you can build a graph of how often a process results in an output (outcome) that falls within specifications. Given this, you can measure the defect rate. This tells you how well a process works.

In frequency distributions, the parameters that drive the specification limits are the centerline and the spread. The centerline is the vertical line on a control chart that represents the average for a process. The spread is bounded by the control limits for the process. These parameters explain how the random component of a process behaved in the past.

Figure 43 demonstrates a frequency distribution with the control limits set at 2.33 standard deviations from the mean such that 99 percent of the measurements are...
deemed acceptable and 1 percent of the measurements are deemed to be outside of specifications — that is, a 1 percent defect rate (0.5 percent of the defects below specifications and 0.5 percent of the defects above specifications).

Specification ranges are commonly used in healthcare. For example, specification ranges are often set based on a balance between an appropriate therapeutic range to avoid a clinical consequence and the need to minimize complications from the treatment. Coumadin anticoagulation is an example of this. Figure 44 demonstrates the range of coagulation that has been determined to be ideal for avoiding the most common complications of blood clots while also minimizing the risk of bleeding.

For any given population of patients on Coumadin, one can plot their Coumadin values in a frequency distribution. If the control limits are drawn narrowly, more patients will fall outside the ideal therapeutic range and risk the consequence of clots. If the control limits are defined over a broader range, more patients will avoid the risk of clots, but they will also face a higher risk of bleeding. For this reason, the majority of control limits in healthcare are drawn at three standard deviations from the mean (Three Sigma).

### Condition

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<tr>
<td>Valve Replacement</td>
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Figure 44: Ideal range of coagulation for avoiding complications

**SPC and SPC control charts**

A picture is worth a thousand words. This is a fundamental concept for quality improvement experts. Research has shown that the human eye can interpret patterns in graphical displays of data far better than in tables of numbers. Rather than relying on confusing data tables, it is best to make a picture of the data and let the picture do the talking.

Plotting data over time offers insights and maximizes the learning from any data collected by revealing patterns and improvement opportunities. In quality improvement, SPC and SPC charts are key tools for providing pictures of data that can allow decision-makers to quickly determine whether variations are a likely or unlikely part of a process. If they are deemed to be unlikely, intervention may be necessary.
Shewhart, the physicist and statistician credited with initially pioneering SPC in managing processes, was initially presented with the challenge of improving and maintaining quality in the manufacture of telephone components. His approach to statistics was fundamentally different from many of his contemporaries. He adopted a strong operational focus, placing particular emphasis on understanding, measuring and improving processes. This led him to focus on using statistical methods that would allow him to better understand, analyze and measure variation in a process.

Shewhart studied Taylor-style mass production to better understand how processes worked. He recognized that the world we live in tends to follow physical laws. He also saw that complex processes tended to result in variable outputs. Shewhart then turned his attention to developing a deeper understanding of variation. Where did variation come from? What caused it?

Shewhart recognized that sources of variation at any point in a process can be one of two types: common (normal or chance) sources of variation and assignable sources of variation, as seen in Figure 45.

Most complex processes have many sources of variation. Most of these sources are minor and can be ignored. Such random variation represents the sum of many small variations arising from real, yet small causes that are inherent in any complex process or system. Random variation tends to follow the laws of probability. That is, it behaves as a statistically random function. Because random variation represents the sum of many small causes, it cannot be traced back to a root cause. Instead, it is a physical attribute of the process. It represents appropriate variation. Different processes have different levels of random variation. While random variation is an important part of measuring and monitoring a process, it is not useful in setting improvement goals for a process.

Because random variation is a physical attribute of a process, Shewhart recognized that the only way one can reduce random variation is to identify a new process that yields a better outcome and a new level of random variation. That is, a process that is superior to the original process. Managing random variation in this manner requires the use of the plan, do, study, act (PDSA) cycle.
The other type of variation Shewhart observed was special cause variation (later called “assignable variation” by Deming). Assignable variation represents variation that arises from a single cause that is not attributable to the process. Therefore, assignable variation can be identified, traced to a root cause and eliminated (or implemented if it improves the outcome of the process). Unwanted assignable variation represents inappropriate variation.

Identifying these two types of variation is important in quality improvement. If the dominant (assignable) sources of variation are identified, improvement teams can focus their attention on them. Improvement teams can track the assignable variation to its root cause. Once the root causes of the assignable variation sources are known, the team can eliminate them if they are found to contribute to less than optimal outcomes. Once an assignable cause of variation is removed, the process is said to be stable. Alternatively, if an assignable cause of variation represents an improvement, improvement teams can retain and exploit it in a new, stable process. When a process is stable, its variation should remain within a known set of limits. This stability will persist until another assignable source of variation is introduced.

Shewhart pioneered the use of SPC in managing and controlling processes and developed the control chart as a tool to use in differentiating random variation from assignable variation. SPC uses statistical methods to observe the performance of a process in order to predict significant variations that may result in a substandard outcome.

Creating SPC charts

As mentioned above, a frequency distribution provides a range within which nearly all of a process’s future measures are likely to fall. That is, how a process behaved in the past is a reasonable predictor of how it will behave in the future.

Using this knowledge, Shewhart developed the concept of a control chart. Flipping a frequency distribution curve on its side and plotting individual observations from a process over time is the first step in creating a control chart. Each time you plot a point, you are really saying to yourself, “Is it reasonable that the random nature of this process could be producing this new measured result?” Adding the upper and lower control limits defines the specification range of the process and allows one to differentiate random cause variation from assignable

Figure 46: Statistical process control chart
variation. Adding these elements results in an SPC chart, as shown in Figure 46.

A control chart is made up of several elements. The title briefly describes the information displayed in the chart. The y-axis shows the scale of the measurement for variables (numeric) data or the count (frequency) or percentage of occurrence of an event for attribute data. The x-axis displays the chronological order in which the data were collected.

In healthcare, control limits are generally set at a distance of Three Sigma above and Three Sigma below the centerline. They indicate variation from the centerline and are calculated by using the actual values plotted on the control chart graphs. The centerline is drawn at the average, or mean, value of all the plotted data. The centerline generally denotes the expected outcome or output of a given process. Thus, the centerline can also be said to represent the process capability of a process. If a process is improved, one can expect the centerline — and, therefore, the process capability — to move closer to the ideal or optimal outcome for the process.

Applying SPC charts

SPC charts are useful for monitoring process variation over time, differentiating between assignable cause and random cause variation, identifying and eliminating unwanted assignable variation, and assessing the effectiveness of changes on improving a process, as shown in Figure 47.

Figure 47 displays a key goal of a control chart — achieving and maintaining process stability. Process stability is defined as a state in which a process has displayed a certain degree of consistency in the past and is expected to continue to do so in the future. This consistency is characterized by a stream of data falling within control limits that are generally based on plus or minus three standard deviations (Three Sigma) of the centerline. Less stringent control limits (closer to the centerline) can result in misinterpreting random cause variation as assignable cause variation. Control limits represent the limits of variation that should be expected from
a process in a state of statistical control. When a process is in statistical control, any variation is the result of random causes that affect the entire process in a similar way.

As outlined above, control charts typically include data from a process plotted over time, with a centerline representing the median and upper and lower control limits that are typically set at three standard deviations from the mean (Three Sigma). When data points appear within the control limits, the process is exhibiting random variation and therefore is considered to be in statistical control, or stable.

On the other hand, control charts can also be used to identify assignable causes of variation. There are several guidelines that indicate when a signal of assignable cause variation has occurred on a control chart. The foremost rule is that a data point appears outside the control limits. Since the control limits are usually set at three standard deviations from the mean, one can state that for a process that is producing normally distributed data, the probability of a measurement appearing outside the control limits (upper or lower limit) is about 4 or 5 out of 1,000.

Several other rules have also been promoted to help identify assignable cause variation based on patterns of data points occurring within the control limits. While there is disagreement about some of the guidelines, three rules are widely recommended:

- A run of eight (some prefer seven) or more points on one side of the centerline.
- Two out of three consecutive points appearing beyond two standard deviations on the same side of the centerline (i.e., two-thirds of the way toward the control limits).
- A run of eight (some prefer seven) or more points all trending up or down.

Tampering

One of the most important concepts that came out of Shewhart’s work was the concept of tampering. Tampering occurs when a manager uses techniques for managing assignable variation to deal with random variation. If you tamper, you effectively broaden the frequency distribution and increase the defect rate of a process. Tampering always increases the amount of variation and increases the defect rate. Avoiding tampering is particularly important in healthcare because it can worsen patient outcomes and lead to harm.
In a classic article published in “Medical Care” in 1991, Dr. Berwick used a clinical example to illustrate the risks of tampering:

Brian was a year-old patient admitted to the hospital with possible osteomyelitis. It was only “possible” because, although the clinical picture and a bone scan in an outlying hospital were consistent with the diagnosis, no organism had been recovered from Brian’s bloodstream. Antibiotic therapy had been started on an empirical basis, but Brian had continued to spike fevers for a week after treatment began. He was transferred for further evaluation. The clinical question of greatest importance was this: Did Brian, indeed, have osteomyelitis, with an organism sensitive to the current antibiotic or was a different process operating, perhaps osteomyelitis with a resistant organism or maybe another disease, such as lymphoma?

The diagnostic strategy included careful observation. Over the next 14 days, Brian was, indeed, observed, and among the observations made were measurements of his temperatures. During that period, his antibiotic regimen was changed three times, he underwent multiple imaging tests, and had both a bone biopsy and a bone marrow biopsy. During those 14 days, Brian had 100 separate temperature measurements recorded in his chart. Those 100 measurements appeared, in fact, on 22 separate pages of nursing notes.

Show this list to Walter Shewhart, and he would feel quite at home. A measurement system exists, which reports on an important process variable and is placed at the disposal of “operators” (in Shewhart’s language) who are to make adjustments based on the measurement. In a manufacturing process, the adjustments would involve dials and levers; here they involve modifications of antibiotics and testing strategies.

When Shewhart studied systems like this at Bell Telephone Laboratories, he discovered that the information was not being used very well. The “operators” of the gauges and machines in fact varied greatly in the ways in which they responded to the information. They varied among themselves, and even a single decision maker varied over time in his or her own apparent rules of action. Operators often overreacted, making adjustments in settings in response to variation that, through the lens of Shewhart’s statistical understanding, was simply random. In over adjusting, they produced more variation than they started with. They actually made the system less reliable, instead of more reliable, an effect that Deming was later to call ‘tampering’ but that Shewhart simply called ‘errors of Type I.’
Managers, too, tampered. Unable to understand the underlying causes of the variation they saw, managers changed systems in response to variations that were merely random or not caused by the system in the first place, thereby adding complexity but doing no good. Systems got more and more complex, costs rose, and quality suffered.

Does this sound like a modern hospital or not? What are the rules of action that allow a group of six house officers and five consultants to adjust antibiotic dosages based on a stream of 101 temperature measurements? Based upon what statistical theory do they work? Are the changes in management, e.g., hold the antibiotics, start the antibiotics, change the antibiotics, draw a new culture, biopsy the bone, biopsy the marrow, fight the fever with acetaminophen, observe the fever without acetaminophen, systematic interventions on meaningful variations clearly interpreted; or do the clinicians, too, tamper by misinterpreting the signals as noise or the noise as signals? How much of the effort that is poured into the patient, how much of the money, would Shewhart show to be waste, waste that is exactly equivalent to waste the machine tool operator makes when, standing before his or her gauges, he or she adjusts lever after lever in response to meaningless, random, common cause variation?

How much tampering of this exact kind, the kind Shewhart noticed and set about to help others notice, eats into the day-to-day work of clinical management in medical care? No one really knows. The cost could be enormous. Clinicians, flooded today with the results of measurement upon measurement, undoubtedly face serious risks of misunderstanding variation in what is being measured.

Think about the ramifications. How do clinicians measure and respond clinically based on that measurement? The list is endless. Measure prothrombin times and change anticoagulants. Measure oxygen tensions and change respirator settings. Measure fever and change antibiotics. Measure blood pressure and change antihypertensive. Measure leukocytes and change chemotherapies. Measure pain and change analgesia. Measure electrolytes and change IV fluids. Measure and change, measure and change.

In fact, the process of managing data in health care has not changed much at all, even as the volume and complexity of those data have grown by orders of magnitude during this century.

Physicians need not be frightened of trying to master an understanding of variation in these terms.\(^{81}\)
Using SPC and control charts to better understand variation and to more effectively manage processes is foundational to effective quality improvement in any industry, including healthcare. In this regard, Shewhart’s pioneering work and its subsequent application to quality improvement by Deming has proven revolutionary in our ability to understand variation and improve processes. We owe a great deal of gratitude to Shewhart for his revolutionary ideas. In the same article, Dr. Berwick recognized Shewhart’s contribution as follows:

Walter Shewhart was a student of, above all, causes. He believed that results in complex systems did not just happen but were the consequences of lawful relationships; maybe it was because he was a physicist that he chose to interpret production that way. He believed that, properly analyzed, experience in real causal systems could teach a great deal about those systems, and he devoted much of his professional career to developing methods through which the study of variation in measured results could teach the observer about the causal systems that led to those results. If he had been a physician, he would have been called an applied epidemiologist, or a clinical researcher — and a master at it.81

Now that we have reviewed variation and how it applies to quality improvement, we will turn our attention to a conversation about how we use data in quality improvement to maximize clinician engagement and outcomes. For those who would like to learn more about variation and statistical process control, please read Appendix B.

A thoughtful approach to improvement — focus on better care, not people

Once the care process families are prioritized, an organization can focus its attention on improving them. This starts with how to appropriately use data in quality improvement.

How do we measure outcomes? How do we determine which are good outcomes and which are not? This brings us back to the concept of variation. A good outcome is generally viewed as one that represents the optimal outcome for a given process. That is, it represents best practice in the eyes of reasonable clinicians. Once we have determined the ideal outcome, the performance of clinicians can be plotted on a frequency distribution. Using the frequency distribution, we can then determine which outcomes represent reasonable, or random, variations from the norm and which represent assignable cause variations, or so-called outliers.
In Figure 48, the x-axis shows variability in outcomes for a clinical process, with poor outcomes on the left and excellent outcomes on the right for a care process family. The y-axis on each grid shows the number of cases for each outcome. When you see the first grid your initial reaction might be to target only the cases with poor outcomes. That is, focus on the outcomes that deviate far enough from the norm that they are deemed unacceptable. This is called punishing the outliers, or cutting off the tail. When you use this approach, the outliers usually improve barely enough to meet the new minimum standard. Meanwhile, the acceptable outcomes — which constitute most of a hospital’s cases — do not budge.

The goal of quality improvement is to move everyone in the direction of continuously better care. That is, to move the centerline of the outcome frequency distribution and the entire bell-shaped curve toward an improved outcome. By definition, this approach will automatically identify any outliers (bad apples), but the focus is primarily on improving everyone’s performance rather than focusing on those few bad apples. Outliers will either learn to improve or self-select out by demonstrating unwillingness to improve.

Thus, a more effective approach to improving a care process family is to narrow the curve (i.e., narrow the spread of the frequency distribution) and
move all cases closer to better outcomes, as seen in Figure 49. In order to achieve high-quality outcomes and reduce waste, one needs to focus on eliminating inappropriate variation (focus on processes) and documenting continuous improvement (focus on outcomes). This is illustrated in Figure 49 by a narrowing of the distribution of the curve (eliminating inappropriate variation) and the entire curve shifting to the right (improving outcomes).

Instead of focusing on the outliers, improvement teams identify evidence-based shared baselines and use them to reduce variation in all cases — a tactic known as inlier management. Inlier management improves outcomes across the board, producing a much greater overall impact.

Positive reinforcement has been demonstrated to be far more effective with people than a negative, judgmental approach. This is particularly true of clinicians, who generally pride themselves in being the best they can be for patients. While good data may demonstrate that some of them may be misguided in assessing the quality of the care they give, they still want to be the best they can be and are more likely to respond to a collaborative process that engages them in a continuous improvement journey. Even if physicians initially question the data, as they often will, it is okay. The very fact that they are questioning the data means the focus is on a data-driven assessment of the quality of care. Either the data will be proven wrong, in which case the data can

![Figure 49: Approach to improvement — focus on better care](image-url)
be corrected, or the data will be proven correct, in which case reasonable clinicians will seek to improve.

Bringing it all together — finding meaningful patterns in the data

Now that we understand how to measure, differentiate and monitor different types of variation, as well as how data is best used in quality improvement, we can turn our attention to using data to identify meaningful patterns.

Figure 50 shows that frequency distributions can help an organization choose which care process families to focus on. Care process families that consume more resources and have more variability, such as those in quadrant 1, should be addressed first. Quadrant 2 shows care process families with high resource consumption but less variability than quadrant 1. Because the potential yield is lower, a network will want to avoid focusing on care process families where fewer resources are consumed, whether or not they have ample variation in outcomes, like those in quadrant 3, or minimal variation, like those in quadrant 4.

Figure 51 illustrates one way of visualizing how care process families consume resources. This graph shows resources consumed on the x-axis and internal variation in cost on the y-axis. Remember that variability in cost often indicates clinical opportunity. The size of each bubble reflects the number of cases in that care process family. When we overlay our priority
boxes, we can see which care processes to work on first. In this example, septicemia ranks very high in both resources consumed and internal variation. It also has a high case count. This makes it a great target for improvement efforts.

Another data set to examine is variation by provider. Any time there is a wide variation in provider care, we have a high potential for standardization and cost savings. As one drills down to the physician level, significant variation in the cost of treating these patients by physician is apparent. In Figure 52 each bubble represents a different provider handling a specific set of labor and delivery patients. The size of the bubble represents the number of cases for that physician. The grid shows significant cost variation among physicians treating cases of the same severity. This probably occurs because they use different clinical approaches. If the physicians used a standardized, evidence-based process, all of the bubbles at the same severity level would be stacked on top of each other.

Up to this point, we have been talking mostly about clinical variation, but this alone does not account for all of the internal variation in cost. Variation in the data system — how clinicians define things, how they collect data and how they code activities — also contributes to variation. We may not be defining a care process the same way or collecting the data in the same way. This represents something that needs to be fixed in the name of data quality assurance.

Furthermore, variation will exist in operational processes just as it does in clinical processes. This type of variation will also impact costs. Organizations have the opportunity to identify and reduce variation in all areas. Assignable variation of any type — true differences in the way care is delivered by the providers or how operational processes are managed by staff — represent opportunities for standardizing care and operations to reduce variation from provider to provider and from department to department. Invariably, a reduction in variation has a desirable by-product of reducing costs.

Once we have unlocked an organization’s data and made it readily accessible, prioritized the data to determine where to focus improvements...
and identified meaningful patterns in the data, we are in a better position to ignite change.

This completes the overview of the analytic system and its key components: unlocking the data, automating the distribution of data and discovering patterns in the data. Now that we’ve discussed the importance of measurement and the benefits of a strong analytic system, it is time to consider the deployment system. In the next chapter, we will discuss the organizational work that allows organizations to capitalize on the data they have unlocked, automated and begun to use in the analytic system. We will learn about team structures, roles, fingerprinting, implementation and other elements of effective deployment in chapter 5.
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Dr. John Haughom is a healthcare executive with proven expertise in technology-enabled innovation, development of results-oriented strategic plans, leading multifaceted organization-wide change and directing complex operations. He has a proven record of turning vision into effective strategies and successfully implementing initiatives resulting in value including higher quality and safer care at the lowest possible cost. His broad knowledge of healthcare and emerging healthcare technologies is coupled with his recognized leadership abilities. Dr. Haughom’s passion is engaging peer clinicians in creating the new era in healthcare.

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Mr. Burton is a co-founder of Health Catalyst and former president of the company. He brings 20 years of process improvement and IT experience to the company. Mr. Burton was a member of the team that led Intermountain’s nationally recognized improvements in quality of care delivery and reductions in cost. He has taught courses in the Toyota Production System, Agile Software Development, and Key Process Analysis. He currently teaches courses at Catalyst University and at the Advanced Training Program in Healthcare Delivery Improvement. Mr. Burton holds an MBA and a Bachelor of Science in Computer Science from BYU.

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Ms. Rimmasch has over 28 years of experience in bedside care, as well as clinical and operational healthcare management. Prior to joining Health Catalyst, Ms. Rimmasch was an Assistant Vice President at Intermountain responsible for Clinical Services and was integral in promoting integration of Clinical Operations across hospitals, ambulatory settings and managed care plans. Prior to her role in Clinical Services, she served as the Clinical Operations Director and Vice-Chair of Intermountain’s Cardiovascular and Intensive Medicine Clinical Programs. Ms. Rimmasch holds a Master of Science in Adult Physiology from the University of Utah and a Bachelor of Science in Nursing from BYU.
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Prior to his work in the healthcare industry, Dale Sanders worked for 14 years in the military, national intelligence and manufacturing sectors, specializing in analytics and decision support. In addition to his role at Health Catalyst, Dale served as the senior technology advisor and CIO for the National Health System in the Cayman Islands. Previously, he was CIO of Northwestern University Medical Center and regional director of Medical Informatics at Intermountain, where he served in a number of capacities, including chief architect of Intermountain’s enterprise data warehouse. He is a founder of the Healthcare Data Warehousing Association. He holds Bachelor of Science degrees in Chemistry and Biology from Fort Lewis College and is a graduate of the U.S. Air Force Information Systems Engineering Program.

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Prior to joining Health Catalyst, Leslie held positions as a Nurse Informaticist, Director of Biomedical Engineering, Clinical Engineer for Kaiser Permanente-Northern Region and as a Pediatric ICU nurse. Ms. Falk also worked with Hewlett-Packard in several clinical, marketing, sales and support leadership roles. She holds a Master of Science degree in Community Counseling from Seattle Pacific University as well as an MBA and Bachelor of Science in Engineering from the University of Nevada, Las Vegas. Ms. Falk is also a certified Project Management Professional (PMP), Lean Green Belt and Information Privacy Professional (CIPP/CIPP IT).

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Mr. Horstmeier brings 25 years of Fortune 500 and small business operations and general management experience to Health Catalyst. He co-founded HB Ventures and filled senior executive roles at HB Ventures portfolio companies. Within Hewlett-Packard, Mr. Horstmeier launched and grew three different businesses, including co-founding HP's commercial e-commerce business which later expanded to include the management of the data systems and infrastructure for marketing operations across the company. As Vice President of HP.com, Paul headed up a 700-person organization that received nearly every industry award for quality and innovation during his tenure. Mr. Horstmeier holds an MBA and a Bachelor of Science in Computer Science from BYU.

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Dan Burton serves as CEO of Health Catalyst, a healthcare data warehousing and analytics company. He became involved with Health Catalyst when it was a three-person startup. Mr. Burton is also the co-founder of HB Ventures, the first investor in Health Catalyst. Prior to Health Catalyst and HB Ventures, Mr. Burton led the Corporate Strategy Group at Micron Technology (NASDAQ: MU). He also spent eight years with Hewlett-Packard (NYSE: HPQ) in strategy and marketing management roles. Before joining HP he was an associate consultant with the Boston Consulting Group, where he advised healthcare systems and technology companies. Mr. Burton holds an MBA with high distinction from Harvard University, where he was elected a George F. Baker Scholar, and a Bachelor of Science in economics, magna cum laude, from BYU.
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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, hierarchal relationships and rules.

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

The growing interest in complexity theory

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

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

**Complexity theory and organizations**

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

| 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.

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

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

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

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

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

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

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

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

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

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

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APPENDIX B: UNDERSTANDING DATA TYPES IN HEALTHCARE

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

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

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

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

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

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

Figure 107: Data types
Categorical (attribute) data

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

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

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

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

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

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

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

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

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

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

**Parametric and nonparametric distributions**

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

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

The characteristics of parametric and nonparametric distributions are shown in Figure 109.
Statistical resolution or power refers to how well a statistical test can detect differences. Power is determined by data type (i.e., ratio data exceeds interval data, which exceeds ordinal data, which exceeds nominal data). Parametric distributions give better power and resolution than nonparametric distributions, but they make assumptions about the underlying frequency distribution that may or may not be true. This is why you have to understand the data type you are observing and be sure you know what the most likely distribution is for that data. Whenever feasible, you will want to select the highest statistical power possible when analyzing data.

Choosing the appropriate SPC chart

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

The p chart

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

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

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

There are four properties that indicate a binomial distribution:

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

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

The g chart

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

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

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

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

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

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

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

The c chart

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

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

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

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

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

What if nothing fits?

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

1. Transform the data.
   Many healthcare variables do not meet the assumptions of parametric statistical tests. That is, they are not normally distributed, the variances are not homogenous, or both. These frequency distributions frequently are “skewed” — that is, they have a tail, as portrayed in Figure 116. In this type of skewed
distribution, a normal distribution simply does not fit. To “transform” the data, you can perform a mathematical operation on each observation and then use the transformed numbers in a statistical test. If you are going to use one of these transform methods, you need to have a fairly high degree of certainty that your collected data represents a true, clean process (i.e., not a combination of different processes mixed together).

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

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

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

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

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

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

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

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

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

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

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