Quality Methodology

9

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Abbreviations

KDD Key driver diagram
PDSA Plan-Do-Study-Act

Chapter Objectives

- Utilize the Roadmap for Quality allowing for enhanced communication, collaboration, and coordination among team members and among separate teams that may be working toward an overall goal
- Leverage quality tools to identify a goal and create a high-level plan and individual team plans which will support the overall goal of the improvement project
- Execute effective PDSA cycles with predictions, measurement, and decisions to determine the next steps
- Understand nonrandom variation, common cause variation, and special cause variation
- Understand the steps for successfully implementing change
- Learn strategies to spread and sustain improvements

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Vignette 9.1
According to the 2017 CDC National Center for Health Statistics, nearly 6.2 million children under the age of 18 have asthma [1]. Childhood asthma leads to increased emergency department visits, hospitalizations to acute care and intensive care settings, missed days of school for children, and missed days of work for parents resulting in a significant financial and social burden for patients and families. Evidence demonstrates that early identification and management of asthma, avoidance of asthma triggers, and strict compliance with daily medication regimes create the best possible outcomes for children with this chronic condition. A tertiary, free-standing children's hospital has seen a fairly flat 12-month rolling average in emergency department visits as well as hospital admissions despite a multitude of disconnected teams working to solve the problem within

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their given areas with their current resources. To date, no significant improvements have been demonstrated. What needs to change to create better outcomes for patients with asthma seeking care in this hospital?

Due to the disconnection of asthma teams, quality leaders observed unsuccessful tests of change being inappropriately duplicated, disparate improvement goals, inconsistent application of evidence, and limited quality improvement methodology being used. A newly developed asthma improvement team structure will seek to coordinate, allow for collaboration, and enhance communication of these nine teams. Quality team members are newly assigned to the project to redefine the structure and methodology necessary to drive the success of the teams.

Identifying Improvement Opportunities

Identifying improvement needs in any healthcare organization can happen through a variety of means; examples include Community Health Needs Assessment (Affordable Care Act requirement), failures or risks (regulatory reviews or audits, serious and near miss events of harm, safety event reports, or external performance benchmarks), patient feedback, high-volume care, and organizational priorities (i.e., strategic plan) [2].

Understanding the Process for Improvement

Once improvement opportunities are identified, quality improvement methodology is imperative to achieving successful improvement. People with formal and informal roles in quality improvement will be more effective in leading change through the use of quality tools. The Model for Improvement from the Institute for Healthcare Improvement (IHI) allows teams to identify the scope of work and metrics and continually address the work within the framework of Plan-Do-Study-Act (PDSA) cycles [3]. Below are the key Model for Improvement concepts (see Fig. 4.2, Chap. 4):

1. What are we trying to accomplish? (Aim)
2. How will we know that a change is an improvement? (Measures)
3. What changes can we make that will result in improvement? (Interventions)

Leadership

System-level quality improvement requires teams to interface to solve strategic problems but requires strong leadership. Leaders must identify a strategy to improve that is likely different than small-scale and local quality improvement efforts. In the case vignette described, asthma was deemed a “Transformation Project” (descriptors for high-visibility, crosscutting, major initiatives) and endorsed by the executive team. A transformation project carries several benefits: (1) focus on the “system approach”, (2) commensurate resource allocation, (3) executive sponsorship, (4) engaged stakeholder and steering groups, (5) environment for local team leaders to collaborate, and (6) regular executive and governance review of metrics.

To embark on the asthma transformation journey, a multidisciplinary team assembled to analyze baseline data and created a plan to improve the outcome. Executive leaders deployed quality, analytics, project management, informatics, and operational resources for the team in order to drive system-level improvement through enhanced coordination, collaboration, and communication, all missing elements in the prior overall state. Local teams were identified as inpatient, emergency department, primary care, home healthcare, school health, pulmonary, allergy, a newly formed asthma care management team, and a pediatric intensive care team-a collection of nine teams all working toward the same goal. The newly coordinated asthma structure was designed to extend horizontally across teams and vertically, between frontline and leadership. A new culture was created where individuals recognized their role in reducing the burden of asthma.

With local teams aligned around asthma outcome goals, a clear aim statement was developed. The local teams were asked to standardize the data definitions on the measures for "asthma admission" and "emergency department visit." This early precision around inclusion and exclusion criteria allowed for consistent tracking of data. This organization had an existing asthma registry containing years' worth of patient-level data, allowing for prospective and retrospective data analysis.

The teams started with the Roadmap for Quality (Fig. 9.1) which outlines each step to guide the teams' progression through the improvement journey. Each stage has associated tools to complete tasks and provide learning as the improvement process continues.

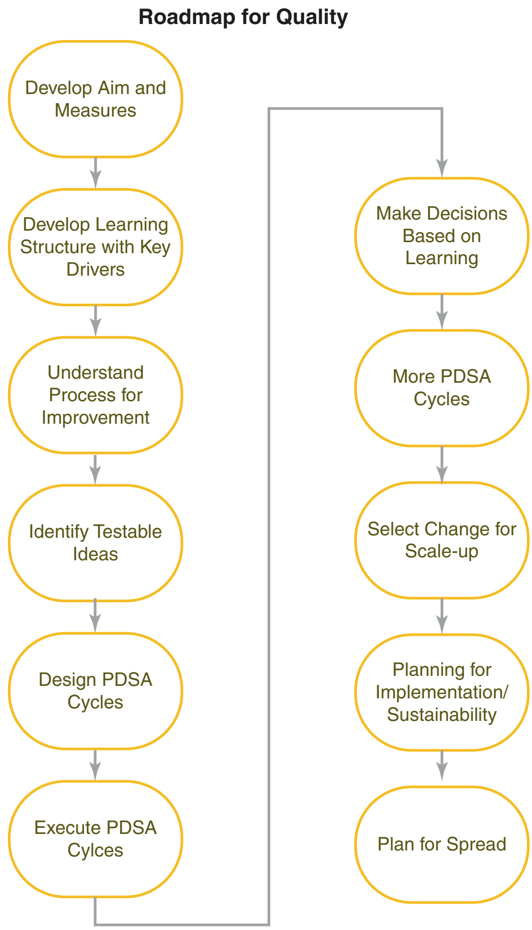


Fig. 9.1 Roadmap for quality

Aim and Measures

Step one in the Model for Improvement requires clarity on "What are we trying to accomplish?" The Roadmap for Quality thus begins with the identification of an aim statement and associated measures. When teams came together and successfully identified an aim inclusive of detailed measurement, the improvement journey commenced.

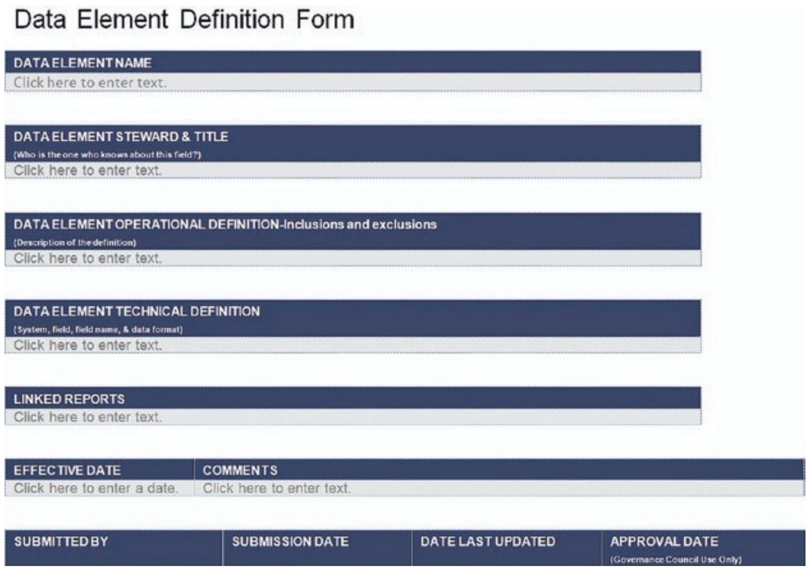
Global aims development precedes specific aims and identifies the direction and intent of the work. A global aim is broad with no measures or timelines included. In this vignette, the Global Aim was:

> We aim to substantially reduce the burden of asthma for our patients, their families, and our community.

Global aims are not specific enough to provide focused improvement targets, so a SMART (*S*pecific, *M*easurable, *A*ttainable, *R*elevant, and *T*ime-bound) aim is established to provide focus. The asthma team arrived at the following SMART aim for inpatient admissions and emergency department visits:

> We will reduce Inpatient Hospitalization rate from 2.7% to < 2.0% (approx. 26% reduction), and ED visit rate from 5.8% to <5.0% (approx. 14% reduction), for all Asthma registry patients by December 31, 2017.

In this vignette and in many successful improvement projects, the use of data analysts to enhance the development of data definitions is beneficial. Clearly defined metrics ensure teams are able to maintain data to follow over time, lessening the risk of mid-project modifications. If done well, data element definitions help the team members understand the common goal and answer the question of "What Are We Trying to Accomplish?" A tool to ensure consistent and repeatable data definitions is helpful (Fig. 9.2).


Data Element Definition Form

DATA ELEMENT NAME
Click here to enter text.

DATA ELEMENT STEWARD & TITLE
(Who is the one who knows about this field?)
Click here to enter text.

DATA ELEMENT OPERATIONAL DEFINITION-Inclusions and exclusions
(Description of the definition)
Click here to enter text.

DATA ELEMENT TECHNICAL DEFINITION
(System, field, field name, & data format)
Click here to enter text.

LINKED REPORTS
Click here to enter text.

EFFECTIVE DATE	COMMENTS
Click here to enter a date.	Click here to enter text.

SUBMITTED BY	SUBMISSION DATE	DATE LAST UPDATED	APPROVAL DATE (Governance Council Use Only)

Fig. 9.2 Data element definition

Vignette 9.2
Nine separate asthma teams worked together developed a system-level key driver diagram (aka Learning Theory). Though committed individuals were doing good work in isolation, the need was clear to develop a unified plan with ideas for common drivers and interventions (testable ideas) that could serve in a crosscutting manner allowing more than one team to benefit from PDSA cycles for overlapping interventions. Some teams had garnered past success with identified interventions which were included in the system-level key driver diagram (Fig. 9.3).

Develop Learning Structure with Key Driver Diagrams

Key driver diagrams (KDDs) connect the aim/outcome, with key drivers and interventions (testable ideas) to create a "Learning Structure," and address the three questions that are part of the Model for Improvement (the Aim, Measures, and Interventions) (Fig. 9.3). Key drivers are big picture items ("what needs to happen") that allow the teams to reach their aim. To identify drivers, the teams use evidence, data, interviews, observations, and discussions. Drivers such as technology, engagement, and education are commonly identified on a variety of clinical improvement projects. Other drivers in this case vignette included asthma care coordination, community engagement, and medication management.

A key driver diagram is a fluid document and should be reviewed continuously and updated as needed. As teams progress through the improvement work, they may discover additional drivers that were not identified initially. Good version control is critical to ensure all improvement teams have the most recent version. The KDD may include color coding to identify work completed, work in progress, or work on hold. Drivers can also be labeled with team identifiers to highlight the areas where teams have the opportunity to collaborate.

In the nine-team example from the vignette, it was crucial to have each team develop local team-level KDD to identify contributions toward the system-level aim. As a result, each of the nine teams completed their own team-level KDD (inpatient team-level KDD, Fig. 9.4). A team-

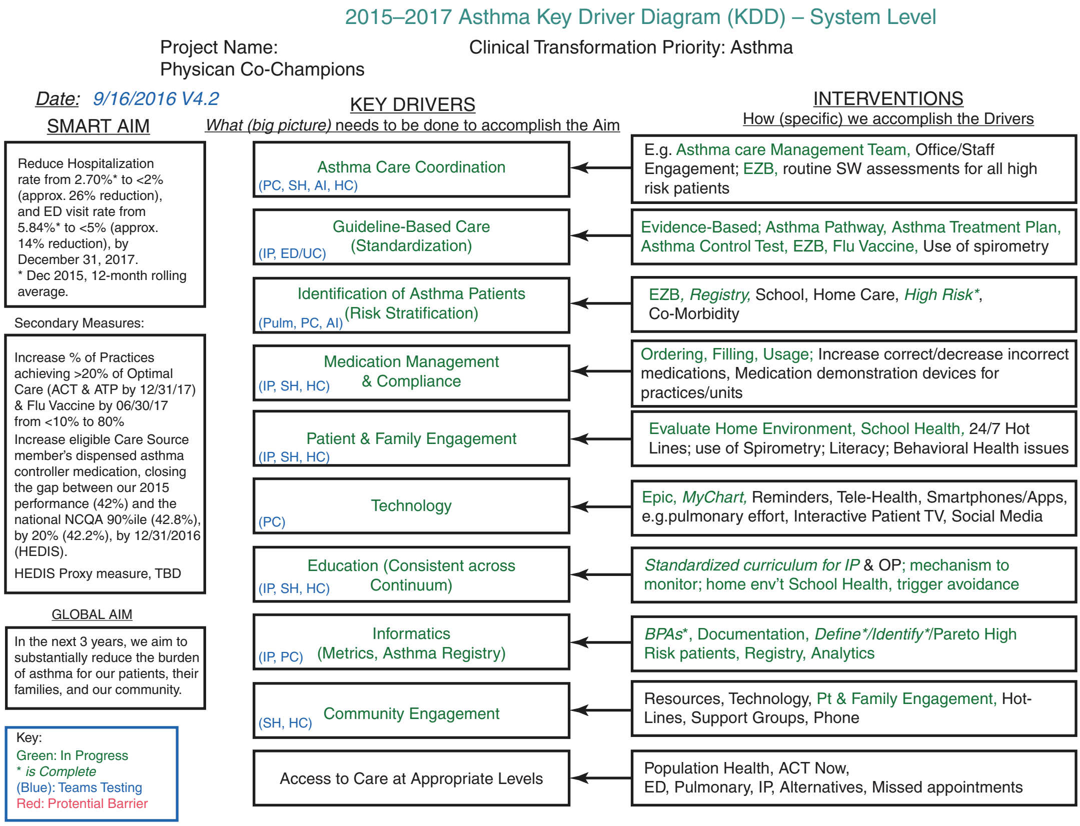


Fig. 9.3 Key driver program

level KDD helps each team focus on work within their control.

Identify Testable Ideas

With a maturing KDD, the intervention column is truly the opportunity to identify "testable" ideas. Said differently, interventions are the "how to" for each key driver. Sources of intervention might be better practice learned from within or outside of an organization, an evidence-based intervention, learnings from PDSA cycles, or even a best guess theory. A tenet of quality improvement is recognizing that many valuable "testable" ideas are generated by frontline providers and caregivers. Frontline staff live in the current process, thus are often the people who encounter and experience the problems and have spent time thinking of possible solutions. Their input must be solicited. In the case vignette regarding inpatient asthma care, frontline staff revealed that they didn't have a good way of remembering and tracking everything they were supposed to accomplish for an asthma patient prior to his/her discharge. Data analysis informed by the frontline observation of the process demonstrated that one important discharge element, the Asthma Treatment Plan, was only updated <10% of the time upon discharge.

Typically, multiple interventions are considered and depicted on a KDD. The interventions are commonly prioritized by the ease of testing, the expected impact on change, strategic alignment with other improvement efforts, or any combination of these reasons. Once interventions are considered, they are tested through Plan-Do-Study-Act (PDSA) cycles. Interventions may be connected to one or several drivers. The arrows in Fig. 9.4 indicate where interventions connect to

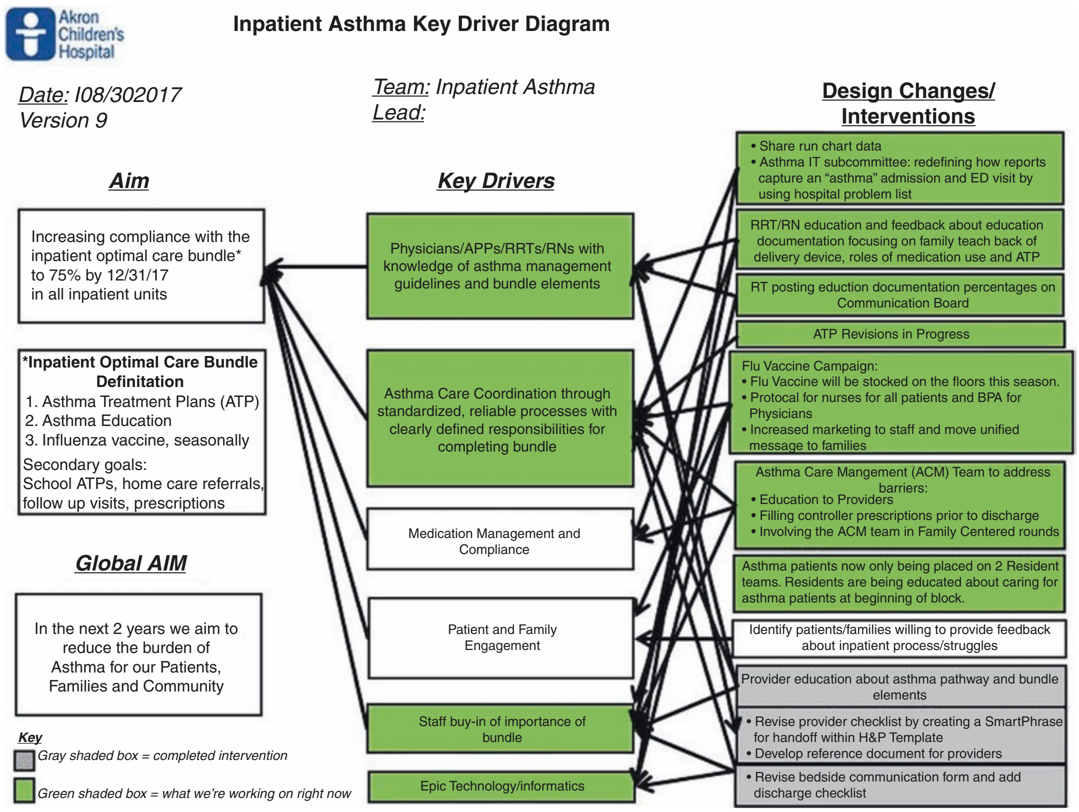


Fig. 9.4 Inpatient key driver program

drivers. Teams should test interventions regularly using PDSA cycles.

Design PDSA Cycles

The use of a standard PDSA cycle template (Fig. 9.5) is highly beneficial as it serves as the historical documentation of the many PDSA cycles the teams will complete over the course of an improvement project [3]. Projects may take years to accomplish during which time the composition of the improvement team may change. The PDSA documents memorialize all tests of change. Often, the PDSA templates inform the sequence of PDSAs, allowing one PDSA to inform the next PDSA.

Those involved in the tests of change should participate in the completion of the PDSA form. The team should agree on a date and a location and identify the people involved in the test. A poorly designed PDSA cycle increases the risk of drawing incorrect conclusions from the results leading to misinformed decisions regarding adoption, adaption, or abandonment of a particular intervention. Measurement of a PDSA impact can be enhanced by an assigned observer who is not directly involved in the test. The team should determine what information would be needed to answer the question the PDSA is designed to answer. Teams should also predict the impact of an intervention, particularly because those interventions with the highest likelihood of achieving improvement may be prioritized for early testing. Much can be learned from a simple test which does not require large numbers of patients, many days of testing, or multiple team members. The majority of the PDSA cycle should be spent in planning.

A well-planned PDSA cycle yields information that informs the team about the subsequent PDSA cycles [4]. PDSAs should start small.

Fig. 9.5 PDSA template form

PDSA WORKSHEET		
Team name	Date of test:	Test completion date:
Overall team/project aim:		
What is the objective of the test?		
What 90 day goal does the change impact?		

PLAN	DO
Briefly describe the test: How will you know that the change is an improvement? What driver does the change impact? What do you predict will happen? Task Plan:	Test the changes: Was the cycle carried out as planned: Y / N Record data and observations: What did you observe that was not part of your plan? **STUDY** Did the results match your predications? Y / N Compare the result of your test to your previous performance: What did you learn?

List the tasks necessary to complete this test (what)?	Person responsible (who)?	When?	Where?
1.			
2.			
3.			
4.			
5.			
6.			

Plan for collection of data:	**ACT** Decide to Adopt, Adapt, or Abandon ☐ Adapt: Improve the change and continue testing the plan. Plan/changes for next test. ☐ Adopt: Select changes to implement on a larger scale. Develop an implementation plan and plan for sustainability. ☐ Abandon: Discard this change and try a different one.

For example, one PDSA cycle for the inpatient asthma team involved adding a bedside paper checklist reminder to review the patient's Asthma Treatment Plan, confirm asthma education completion, and confirm influenza vaccination status. This checklist was the first test of a reminder system that may ultimately become part of the electronic medical record decision support functionality. The data assessing the PDSA "value" would include how often the checklist was completed and how many patients had all three of these bundle elements completed.

Execute PDSA Cycle

This is the "Do" part of the PDSA. Any person involved in the testing, especially frontline staff, should be made aware of the test and clearly understand that the intervention is not a permanent change. The asthma checklist was placed at the bedside of five asthma patients for a 24-hour period. The team was delighted to find that all five patients with asthma had the bundle completed. The team was surprised that parents asked about the checklist and why the bundle items were important for their child. They had not anticipated this reaction from parents, but inspired a parental checklist to inform parents about what should be completed before their child is discharged. This is an example of how a well-planned PDSA could yield data on the desired impact but also facilitate additional learning. The parent and staff partnership creates a shared accountability for bundle completion. This unexpected event during the PDSA cycle would prove to become a future intervention to be added to the KDD.

Make Decisions Based on Learning

Studying the data ("S" of PDSA) qualitatively and quantitatively will assist the team in deciding if (1) the intervention worked as predicted, (2) the intervention enhanced performance, and (3) there were additional learnings. During early PDSA cycles, teams may find the data recorded does not definitively determine the success or failure of the intervention. This revelation affords the team the opportunity to identify additional data needs. Again, small tests of change provide valuable information even if the test resulted in a failure. Teams can gain valuable insight when failures occur and with little financial or human capital expended due to the small-scale testing. Teams can execute many PDSA cycles and learn about the system rather quickly.

The final PDSA step is to "Act." As PDSA cycles are completed, teams determine if the intervention should be adopted, adapted, or abandoned. Adoption simply means the PDSA was successful and the team views the intervention as useful in support of the corresponding key driver. This intervention could be eventually implemented as a permanent change and/or tested more broadly, with more patients, or in different settings. Adapting an intervention indicates the team needs to improve the intervention and retest. Abandon is the decision to drop the intervention because the data reflected no appreciable change, the intervention was too burdensome, or the intervention proved unreliable. This adopt, adapt, abandon conclusion should be noted on PDSA tracking forms and if adopted or abandoned, then noted on the key driver diagram.

More PDSA Cycles

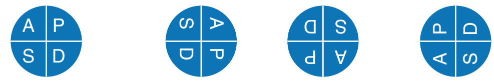
When interventions require adaptions, additional PDSA cycles should be planned and completed as methodically as prior PDSA cycles. Concurrent PDSA cycles can be completed by leveraging multiple teams in different areas, though careful planning must be made not to deploy too many PDSAs simultaneously to affect the same key driver. If there is improvement noted while there are multiple simultaneous PDSAs, it may be unclear which intervention yielded the improvement. The inpatient asthma team conducted the "Checklist" PDSA cycle in one acute care unit and tested "filling controller medications before discharge" in another acute care unit.

Select Change for Scale-Up

When interventions are successful in the small-scale test of change, the team should plan to expand the intervention testing. These tests can be documented and memorialized using a PDSA ramp summary (Fig. 9.6). If the intervention is not successful under altered conditions, be sure to evaluate an adaption to the intervention and conduct another PDSA. Consider if the adaption may negatively affect the areas where the testing was initially completed. If the intervention proves to be successful when scaled up, the intervention is ready for broad adoption.

Plan for Implementation and Sustainability

If interventions are to be implemented, corresponding changes need to happen to successfully implement the intervention. Policies, guidelines, education, and Standard Work Instructions may need to be updated to ensure the intervention is made permanent. Testing for a day or a week could be well tolerated, even a temporary ramp-



		Cycle 1	Cycle 2	Cycle 3	Cycle 4
Document BEFORE test	Test Description:				
	Test Population:				
	Location of test:				
	Date/Time (From – To):				
	Prediction:				
	Action taken:				
Document AFTER test	Test Results:				
	Action – Adapt, Adopt, Abandon				

Fig. 9.6 PDSA ramp summary

up of tests could be absorbed and fulfilled reliably. However, large-scale and more permanent implementation and sustainably can only exist when the intervention becomes the new normal. The asthma bundle checklist education was delivered to the inpatient staff on all acute care units, and an electronic health record bundle checklist was built. Policies were updated to include information defining the standard work for the bundle checklist completion.

Sustaining the observed gains is an essential component of improvement work. Using tactics like hardwiring interventions helps guarantee the successful implementation of the interventions even when the focus is turned to other improvement projects [5]. Collecting and reviewing data regularly helps to detect when an intervention begins to fail. If the data identify the intervention as being used regularly, the data collection frequency and sample size may be reduced [5]. Assigning a group or person to monitor the data over time will ensure early recognition of a change in the data.

Spread

Spreading the work to other relevant areas will include the same considerations as when implementing the work in a single area. Policies, guideline, tools, and Standard Work Instructions may need to be altered to support the new interventions. Determine what other areas would benefit from the intervention(s), engage the leaders from those areas to share the success of the interventions, and make the case for the change [6]. There is value in sharing the data and a story of how the intervention has led to improvement, as this may accelerate change adoption in new areas. It is important to identify other organizational activity that may conflict with the spread of the team's work and plan the pace and direction of the spread accordingly.

Data

Learning from data during the course of an improvement project is essential. Data are collected, analyzed, and acted upon prior to the kickoff of the project, for the duration of active improvement (PDSA) and during the sustain phase where intermittent monitoring ensures continued success of the improvement.

Data collected prior to the commencement of improvement work identifies the prevalence and significance of the problem and can be used to breakdown a problem categorically (Pareto chart) [7]. A Pareto chart focuses the direction and priorities of the improvement work. Pre-improvement data will create the baseline measure of the outcome or process being targeted for improvement. By presenting pre-improvement data in the context of organizational strategy, the need for specific improvement work can be made more compelling.

Data collected during the improvement work should clearly align with the desired outcome of the work. Occasionally, direct measurement may not be possible, requiring a proxy measure to be carefully selected. A proxy measure will allow for change to be detected rapidly, but with a strong correlation between the interventions and the outcome. Data collected during active improvement will assist teams with decision-making relevant to success or failure of interventions, determine next steps, and may identify problems that were not initially apparent. Data should first be collected and displayed using a simple run chart and progress to more sophisticated means using appropriate control charts (often referred to as a Statistical Process Control Chart or Shewhart chart).

Post-implementation data should be monitored to track the effectiveness of the interventions on the desired outcome/process metric. These data can be measured with a sustain phase plan. The burden of data monitoring should be reduced during the sustainability phase of any project and should be measured using a control chart (Shewhart chart) so that processes moving out of "control" can be easily identified.

Types of Quality Improvement Measures

There are a number of strategies to categorize quality improvement measures. Avedis Donabedian succinctly categorized measures in three ways: structure, process, and outcome [8]. Others have considered a fourth category for quality improvement measures, a balancing measure.

Structural measures include those measures that represent the physical space and equipment used to deliver care or manage a process. Some think of these as measures of the environment – and are clearly distinct from process, outcome, and balancing measures. This is occasionally binary, meaning it either exists or it does not, and for that reason is often easier to measure. It is believed that structural measures are often foundational to the ability for subsequent process or outcome measures to be achieved. For example, a structural measure in our asthma vignette may be the availability of a care manager position for asthma patients. This role either exists or doesn't and doesn't address how care management occurs, how the care manager is contacted, or even how frequently/infrequently patients use the emergency department or are compliant with home medications when contacted by the care manager.

Process measures generally represent one or more specific steps of a process that are thought to possibly lead to a particular desired outcome. Most outcomes are derived from a structure that supports success and the multiple processes that each contribute collectively to an outcome. Some have used the analogy of a ladder to Donabedian's structure, process, and outcome measures. The ground that the ladder is seated on is the structural measure, and the rungs of the ladder serve as individual process measures, each contributing to the journey to the top of the ladder, which is the desired outcome. The inpatient asthma team studied and tested the administration of the influenza vaccine to patients admitted to the hospital as a process measure – asking if they were able to reliably administer the vaccine.

Thirdly, outcome measures represent the state of the patient or population of patients and what is important. It may demonstrate overall system-level performance for patients or the financial picture associated with the improvement. Said differently, an outcome measure is the actual thing that we want to change or improve in the end. In our asthma examples, the outcome measures are emergency department (ED) visits and inpatient hospital admissions. The idea of avoiding either situation is important to the patient (and his/her family).

Lastly, balancing measures are considered to ensure an improvement in one area is not negatively impacting another area. It may be difficult to identify balancing measures, and the impact may be realized in a clinical metric or an administrative/financial metric. While trying to reduce inpatient admissions, the emergency department may keep asthma patients in the emergency department longer or send more of them home when an admission would possibly have been wiser. Therefore, admissions decrease, but ED length-of-stay (LOS), ED revisits, and patient satisfaction could each be negatively impacted. It is difficult, often times, to capture all potential balancing measures, but great thought should be given to try and ensure the breadth of balancing measures are captured.

Features of a Good Measure

Data considerations and metric determinations start with the aim statement. Useful metrics ensure buy-in for the improvement project [9]. When selecting the aim or goal, consider the following features of a useful metric:

1. *Understandable* – The metric is defined in such a way that it conveys, at a glance, what it is measuring and how it is derived. When creating a data definition for the metric, keep the metric clean and simple to understand without multiple exceptions that potentially add unnecessary complexity to the metric and the data collection process. Test out a metric by trying to explain it to someone outside the improvement team.
2. *Credible* – Credible is offering reasonable grounds for being believed. The credibility of a metric can be increased by staying consistent, using the best evidence, citing definitions from outside organizations, or simply having an understandable metric.
3. *Comparable* – Being able to compare a metric across time periods, groups of users, national benchmarks, or competitors allows the improvement team or sponsor to understand the metric performance.
4. *Actionable* – This is by far the most important criterion for a metric requiring consideration of what will be done differently based on changes in the number. If the improvement leader or team has little potential to influence change, then the improvement project should be either abandoned, turned over to a team that has the ability to influence, or enlist a sponsor with span of control to champion the change.
5. *Aligned* – To assess if a metric is aligned, it would be useful to ask, "How does the metric relate to other metrics in the hospital and the hospital's overall objectives?" Improvement should be tied to strategy, whether organizational, departmental, or local.
6. *Accessible* – To assess if a metric is accessible, consider the following:
   - Where are the data available?
   - Are the data collected manually?
   - How much manipulation do the data need in order to be in the desired format?
   - How many calculations does the metric involve?
   - How many people have to touch the metric?

Variation

To understand changes in the data and what those changes mean, improvement teams need to understand what random and nonrandom variation, as well as common cause and special cause variation [7]. When run charts are used to display data, random and nonrandom variation differentiates change that occurs randomly or change that is distinct. For control charts, variation is considered common cause if it represents the ebb and flow of a process that is unchanged, whereas special cause variation indicates the improvement work has either positively or even negatively impacted the measure. Recognizing variation characteristics that signify change in the data alerts the team to explore the reason for the change.

There are two main types of variation in any systems: intended and unintended variation. Intended variation is an important part of effective, patient-centered healthcare. It is similar to the concept of variety – one size does not fit all. It is often called purposeful, planned, guided, or considered. It is acceptable to both the healthcare consumer and those who work within the delivery system. Unintended variation is due to changes introduced into healthcare structure or process that are not purposeful, planned, or guided. This type of variation creates inefficiencies, waste, rework, ineffective care, errors, and injuries. Most healthcare improvement projects focus on reduction of these unwanted variations as they are unwelcomed by the consumer and those within the delivery system.

A basic premise of improvement work is the idea that variation is a measure of quality and variation has one of two causes: common cause or special cause. Knowing the source of variation and identifying the nature of variation is a critical quality improvement skill. Common cause variations are those causes inherent in the process over time that affect everyone working in the process and affect all outcomes of the process. Conversely, special causes are not part of the process all the time or do not affect everyone but arise because of specific circumstances or interventions.

This premise and understanding of the causes of variation become important as data are collected, and the team determines the next steps in the work. Leaders and teams must be vigilant in not unduly reacting to common cause variations but certainly need to be poised to react to special cause variation. Teams should be able to clearly understand what their data are telling them, so they are able to convey the improvement story and make decisions about the next steps in the work. Some basic descriptive statistical analysis review may be necessary. Understanding the type and distribution of the data will allow the team to determine how to best summarize, present, and analyze data during all phases of the improvement project.

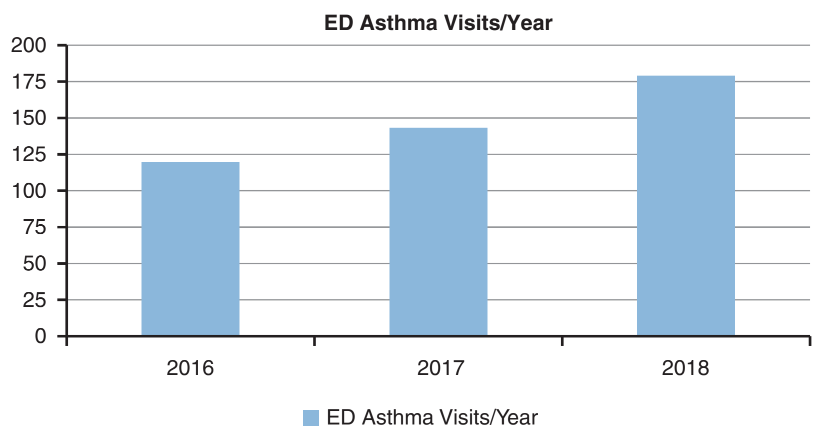
More Considerations for Data and Measurement

Identifying the process or outcome to be measured will help frame the baseline data so that it is in alignment with the aim statement. This numerical baseline data can be easily represented in a histogram (a chart that relates the frequency of one variable on the Y-axis, over time, on the X-axis). (See Key Point Box 9.1) The chart below (Fig. 9.7) reflects the rising frequency of ED asthma visits as a count per year and is not adjusted as a comparison to all patients with asthma or all emergency department visit reasons.

Key Point Box 9.1
A histogram is a graphical representation using bars to depict the frequency of continuous variables as they fall into a given range. The height of each bar indicates how many fall into each category range.

Numerical data can also be divided into categories related to the frequency of problem types for process failure and is best visualized in a Pareto chart. A Pareto chart contains discrete X-axis bars representing the frequency of each problem and the Y-axis depicts the % of the failures attributed to each problem. Generally, a line

Fig. 9.7 Asthma ED visits/year



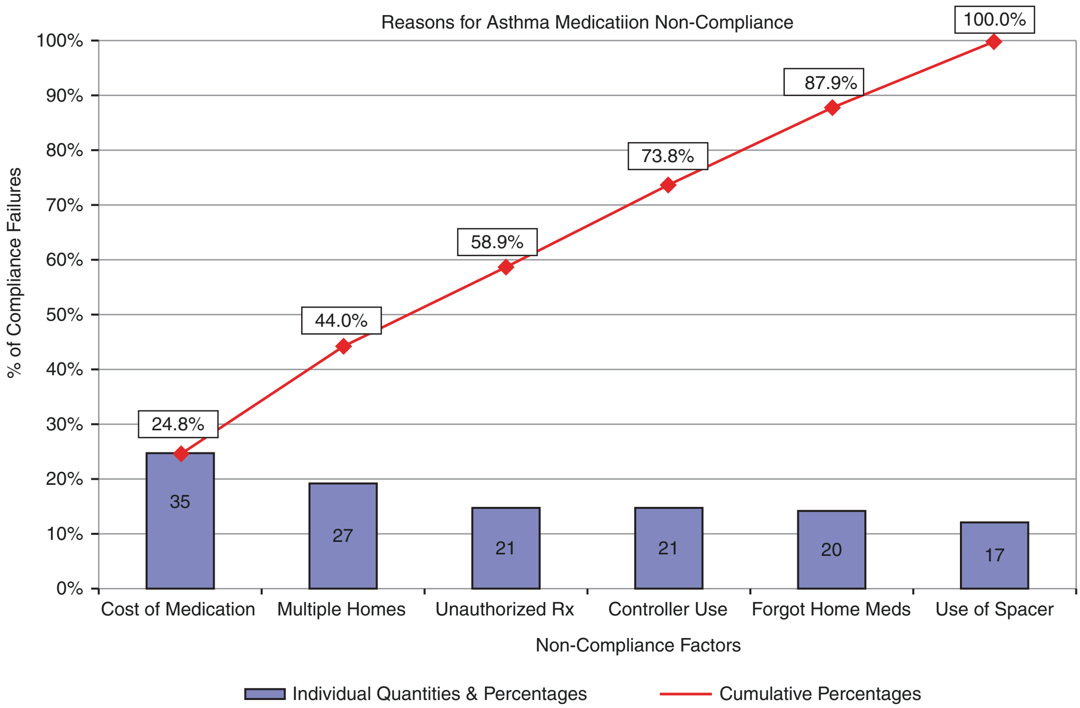


Fig. 9.8 Reasons for asthma medication noncompliance

is generated depicting a cumulative frequency from left to right on the chart. A Pareto chart helps identify problems may be causing more failures and may guide intervention testing (PDSAs). In Fig. 9.8, the reasons patients with asthma are not compliant with their prescribed medications are identified by category and frequency. This information was collected through a patient questionnaire, and the data were entered to generate the Pareto chart. The information was shared among the teams with each team being charged to identify potential interventions they wanted to test using the Plan-Do-Study-Act cycle. These interventions were included in the key driver diagram.

Data Display

Quality improvement data (both pre-improvement data and PDSA data) can be plotted using a run chart [7]. A run chart can plot a count or rate (Numerator over Denominator) across time using points connected by lines. This type of visual chart reflects a basic understanding of the data in comparison to a standard grouping (histogram), is a quick and easy way to begin the tracking of data, and allows for a clear picture of the performance of the process or outcome. Interventions tested through the PDSA cycle may impact the process/outcome and change to the performance of the system, which can be seen in the asthma ED visit rate run chart. In the case of the asthma patients, data are plotted as the number of ED asthma visits as a numerator over the number of patients in the hospital's asthma registry (denominator) per month. The "n" represents the number of patients in the asthma registry for that month. The time series of the run chart should be displayed on the X-axis and the rate on the Y-axis.

A run chart should optimally have the following elements:

- Labels along both axes with a clear description of the measurement (%, days, weeks, minutes)
- Equal X- and Y-axis tick marks
- Title which clearly and simplistically describes what is being plotted

- Arrow showing the desired direction of change that is an improvement
- Appropriate scale
- Identified and labeled goal
- Annotations
- Line drawn to show the median of the data

The scale should be appropriate for both the current range of data being displayed and what future data may need to be plotted. When the scale is small compared to the range of the data set, improvement can be difficult to detect; conversely, when the scale is too large, the data may appear to have significant gains or losses, when in fact, this is simply a product of an inappropriate scale. Most of the current data should fall in the middle of the chart, so variation in either direction becomes apparent.

Any observer of the chart should be able to quickly understand what is being measured and if the performance is improving or declining. The chart should also display the goal of the project so teams can demonstrate what the final target is and how close the team is to accomplishing the goal set out in the Aim statement (Fig. 9.9). Teams should become accustomed to regularly annotating the chart to reflect PDSA cycles, unusual situations (i.e., abnormally low or high denominators), or any other notes that may not be remembered as the work progresses. Use the first 10–12 data points to calculate the median (the number in the middle of the data set) and plot the median on the run chart parallel to the X-axis. The median can be extended across the chart to reflect the original baseline or may shift when a system change is identified according to run chart rules, as improvement happens. The centerline in a run chart is the median value. If baseline data are not available, use the first 10–12 data points available once the data collection is possible as early improvement planning will not likely affect the early data measurement points. Run chart rules related to the median allow for the detection of changes resulting from the testing of interventions [10].

There are several run chart rules for nonrandom variation; the descriptions below are intended to give the reader a primer on nonrandom variation and are not exhaustive or all-inclusive of the rules [7]. These probability rules indicate a nonrandom change in the system and alert the team that the process or outcome has changed – sometimes for the better or potentially for the worse. These rules are based on successive data points and their relationship to the median. These rules do not indicate if the process is stable or "in control," only that some intervention(s) has probably caused the observable change and the change is not random. Instances of nonrandom variation in data should

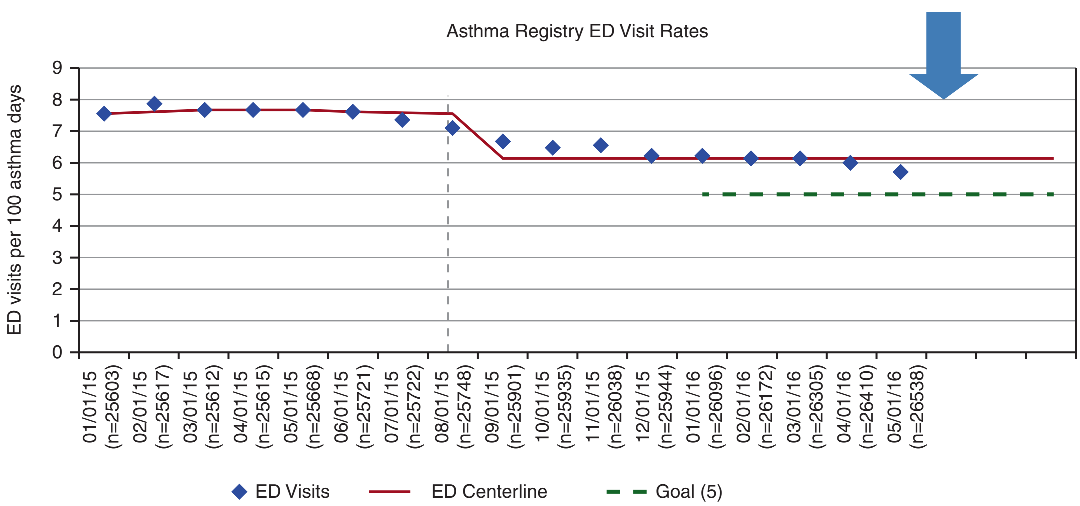


Fig. 9.9 Asthma registry ED visit rates

be investigated, prompting the formulation of a theory as to why the change occurred and annotated on the run chart. Run chart medians can be shifted or recalculated based on data changes identified within the grouping of nonrandom variation in data as long as none of the data points were also used to establish the baseline median.

Run chart rules depicting nonrandom variation [10]:

1. Shift – Six or more consecutive points all above or all below the median (Fig. 9.10)
2. Trend – Five or more consecutive points all going up or all going down (Fig. 9.11)
3. Runs – Alternating points in a "zigzag" pattern (Fig. 9.12)
4. Astronomical point – A point that is obviously and blatantly significantly different from all of the other data points

When run chart data do not meet these nonrandom variation rules, any data changes can be considered normal or random variation. When data has been collected past the baseline stage and results in 10–12 additional data points, teams may consider abandoning a run chart in favor of one of the many types of control charts (Shewhart charts) in order to create a clearer picture of the nature of the data.

Control Charts (Shewhart Charts)

Control charts are similar to run charts in that they too plot data over time. Control charts differ from run charts in that they can identify the process as being "in or out of control" or the stability of the process and the ability of the process to function predictably. Control charts accomplish this predictability through the use of statistical process control to determine the stability of the system. Predictable processes follow a known pattern, and predictions are made based on that pattern, depicting clearly common cause or special cause variation. In statistics, that pattern is known as distribution. Knowing the distribution of the data allows for an expected outcome. For a stable, predictable process, 99.7% of the data points will fall within three standard deviations (+ or −) from the mean of the data. Each standard deviation away from the mean is used to identify variation from the average performance (mean). Once a data point falls outside of the third deviation, the process is no longer predictable and that point is identified as an outlier (a type of special cause variation). Because data falls outside the limits 0.3% of the time, it would be highly unlikely that a data point outside the control limits would be attributed to common cause variation.

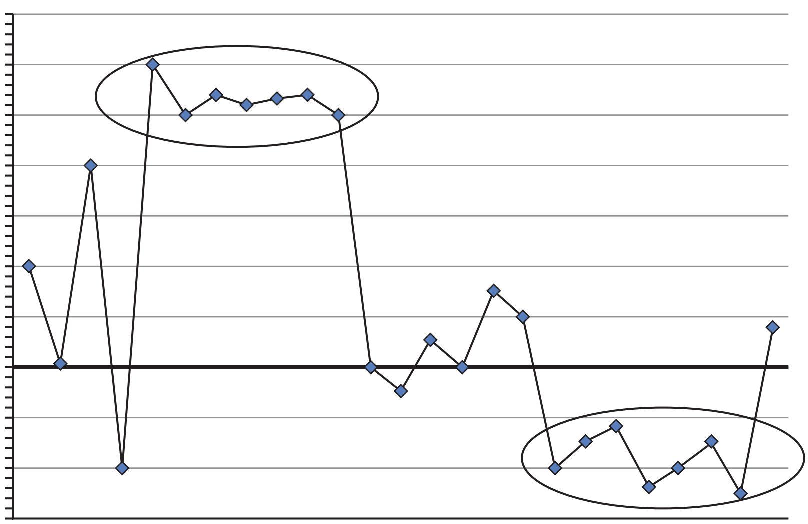


Fig. 9.10 Six points above/below the mean

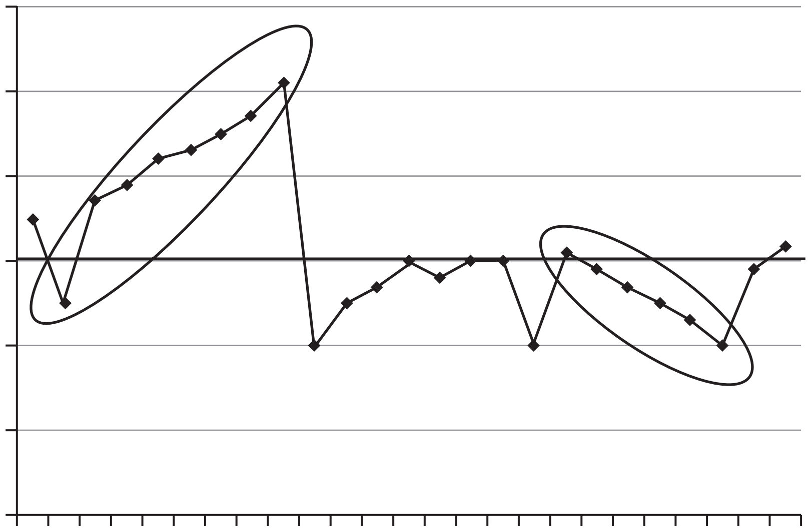


Fig. 9.11 Trend five or more points

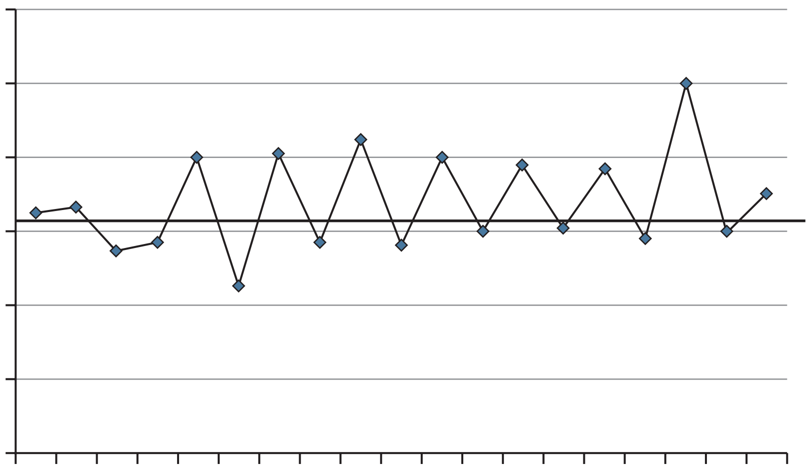


Fig. 9.12 Alternating points zigzag pattern

Data within the control limits could still be identified as special cause if they meet the definition for data that differs from the normal distribution. If the goal of the improvement work is to raise or lower an average, data patterns will exist inside the expected distribution that signals a change which indicates the interventions are moving the data toward the goal (new average). These rules are discussed after some basic understanding of control charts is established.

The anatomy of a control chart is as follows (Fig. 9.13):

- There are an upper control limit (UCL) and a lower control limit (LCL).
- Typically, the upper (UCL) and lower (LCL) control limits are ±3 standard deviations from the mean.
- The centerline is the actual process mean (average).

Figure 9.14 represents a normal distribution of data. If this familiar distribution is rotated to the side, a control chart becomes more understandable. There are many available templates that allow a user to enter a time series, title, and

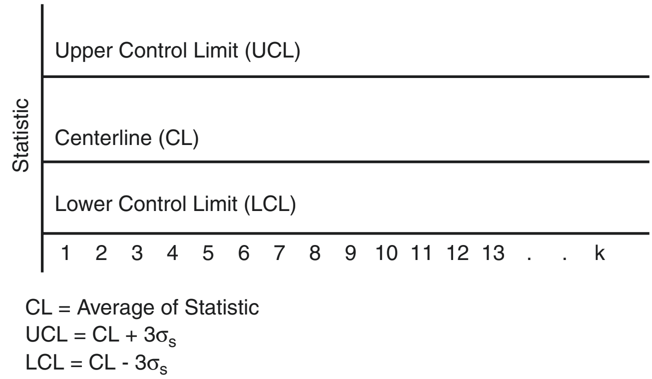


Fig. 9.13 Anatomy of control chart

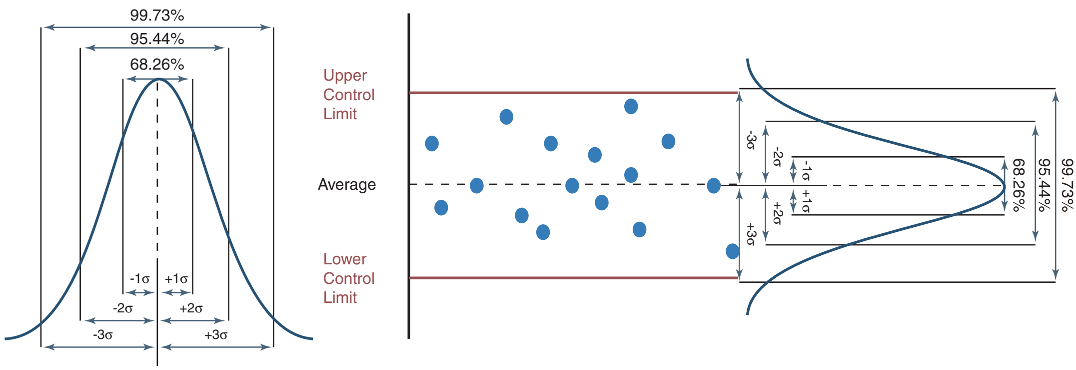


Fig. 9.14 Control chart bell curve

accompanying data to ultimately generate a control chart. Creating control charts through manual computation is not overly challenging but will require the use of some additional resources.

The type of control chart used to display data depends on the type of data being used. The decision tree in Fig. 9.15 is helpful when choosing a control chart. Continuous vs. attribute data is the initial bifurcation in the decision tree. Continuous data are data that have a broad range of values that could be anywhere within a range of data. Common examples of continuous data are body weight or time in seconds. Attribute data, on the other hand, is more discrete and usually can only take a limited set of values. For example, attribute data may be either in range or out of range.

Identifying Special Cause Variation

Points that fall outside the control limits are indicative of special cause variation and require investigation. Other special cause rules also indicate a change to the process with the data points remaining within the control limits. The system may be performing within control, but not where the team has set the goal. The following special cause rules help to identify such changes as the interventions are tested through the PDSA cycle and are used to answer the improvement question related to “Is the change an improvement?” Most importantly, these rules allow teams to determine the need to react to the data and make changes or if the data is demonstrating normal variation and do not require mediation.

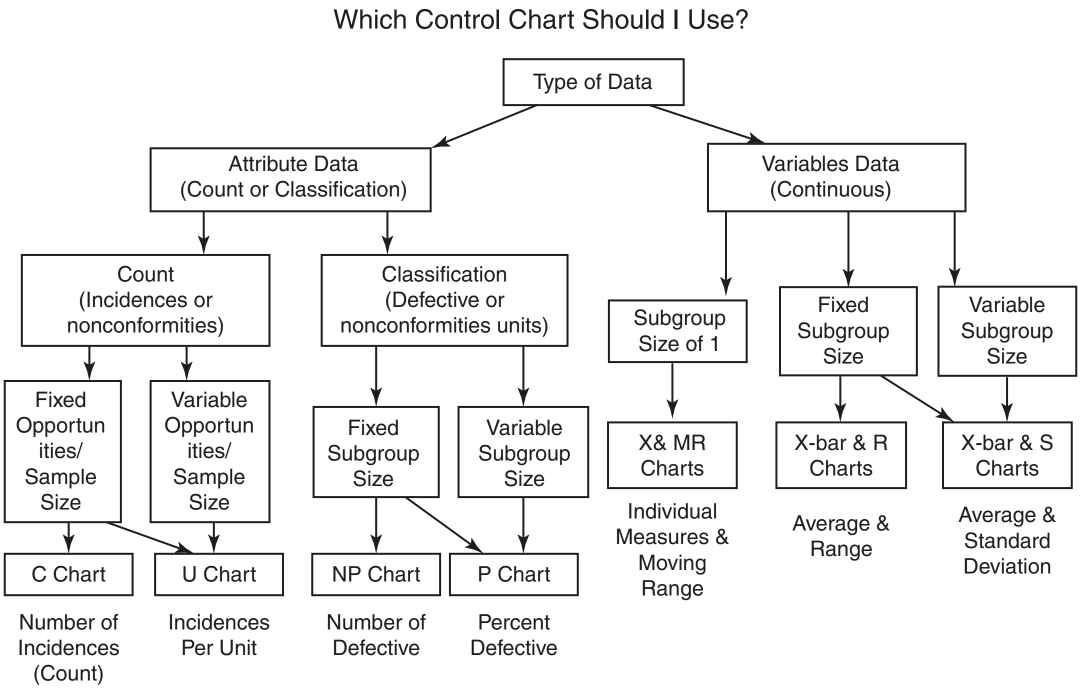


Fig. 9.15 Control chart decision tree

The rules governing special cause variation for control charts are as follows [7]:

1. Eight or more consecutive points above or below the centerline (Fig. 9.16)
2. Six or more points increasing or decreasing (Fig. 9.17)
3. Two out of three consecutive points near an upper or lower control limit (Fig. 9.18)
4. Fifteen consecutive points near the centerline (Fig. 9.19)
5. A single data point outside of the control limits (Fig. 9.20)

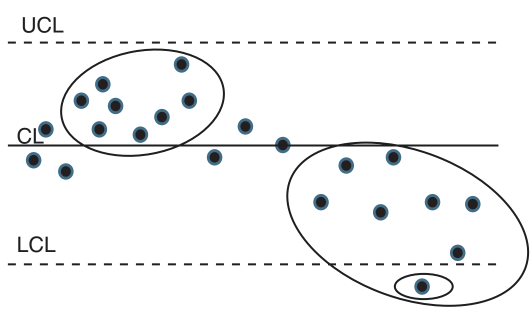


Fig. 9.16 Eight or more consecutive points above or below the centerline

Don't Get Lost in Data

Quality improvement in healthcare is a moral imperative. Each and every patient deserves high-quality care. As such, improvement teams must never allow the measurement and nuances of healthcare data to negate the fact that the data often represent real people or processes that

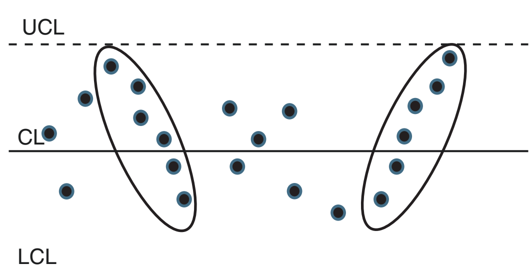


Fig. 9.17 Six or more points increasing or decreasing

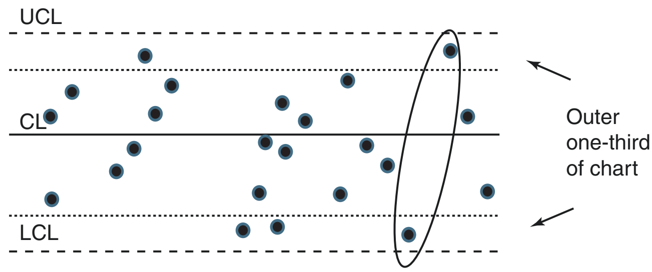


Fig. 9.18 Two out of three consecutive points near outer third of control limit

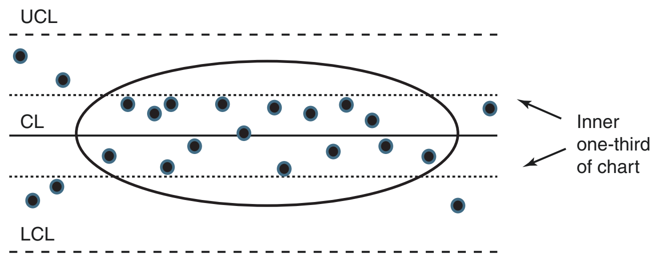


Fig. 9.19 15 consecutive points close to centerline

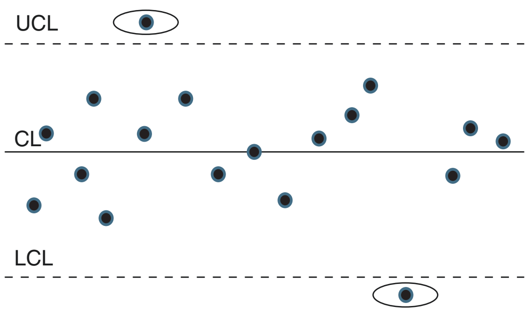


Fig. 9.20 Single data point outside of the control limits

affect people. Goals and ongoing measurements often contain language about percent reductions or increases, dollar costs, failures, and special causes. Inspiring improvement requires leaders to be sure to equate numerical measures back to the people impacted by the care delivered every day. A better practice is to consider phrasing goals in terms of the number of patients, so this notion is not forgotten as teams move forward in their work. This understanding will serve as a motivator for continuous improvement.

Editors' Comments

Each and every chapter in this textbook is important; each and every chapter is value-add for the novice as well as experienced improvement scientists. This chapter serves as a primer for the novice or casual quality improvement scientists and forward thinking and directional for those that are more advanced in their improvement journey. Using the case vignettes, the authors masterfully navigate the quality improvement process using methodologies as their framework. We sincerely appreciate the authors demonstrating specific strategies that they have employed in their organization (e.g., “data element definition form”). These concrete examples are invaluable for organizations that want to use this chapter as a foundation to build upon or advance their quality improvement journey.

The core of improvement science is using a roadmap in an iterative manner. The authors thoroughly explain key driver diagrams and eloquently link these to the iterative tests of change. Again, we are most appreciative of the demonstrations of how they actually implement and operationalize these tools in their respective organizations.

We are inundated by payers, the government regulations, and the public with requests for more and measures. The end of the chapter nicely builds on the need to have pertinent and solid measures with how to best use data. It is not expected that this chapter is completely thorough; indeed, the Editors refer the reader to Lloyd Provost and Sandra Murray's definitive and expansive textbook on data for quality improvement [7]. However, the authors of this chapter demonstrate the value of data, how to be wary of data, and how to best use data to create measures that matter.

Each and every chapter in this textbook is a value-add. This chapter is crucial. We strategically placed this as the ninth chapter so that the improvement scientist is primed at this point of their reading journey to become committed to the quality improvement methodologies as outlined in this chapter.

Chapter Review Questions

1. True or False – The three basic elements that constitute the framework of a key driver diagram are: Aim Statement, Drivers, and Interventions?

   Answer: True
2. Multiple Choice – What does "SMART" stand for when discussing a "SMART" Aim (goal)?
   A. Specific, Measurable, Attainable, Relevant, and Time-bound
   B. Standard, Measurable, Articulate, Range, Testable
   C. Standard, Mindful, Attributable, Relevant, and Testable
   D. Statistical, Meaningful, Attainable, Real, Tangible

   Answer: A
3. Why is it important to make a prediction about a PDSA cycle?

   Answer: Making a prediction about the success of an intervention, before the testing, establishes a level of confidence in the intervention affecting the process or outcome and assists the team in determining the testing priority of the interventions. By comparing the actual results to the predictions, shared learning can occur.
4. True or False – Special cause variation should be investigated because this type of variation is unexpected and don't exist in the system all the time.

   Answer: True
5. Which of the following should be included on any type of run chart or control chart?
   A. Labels on the axes and the chart
   B. An arrow describing the desired change of direction
   C. A clear and equivalent time series and tick marks appropriate for the data set
   D. All of the above

   Answer: D

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