Chapter 5
QI Methods and Improvement Science

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Definition of Improvement

On its own, improvement is a difficult term to define. Improvement is most clearly understood when it is defined by characteristics with a positive connotation like faster, easier, more efficient, safer, or less expensive. All of these characteristics have one thing in common—they require change from a current state, the baseline. Thus, improvement is the outcome achieved when a system has undergone some fundamental change for the better. In an ideal state, the effects of the improvement are sustained and have a lasting impact on the system.

Not all changes will lead to improvement. Improvement is driven by the application of knowledge about the current state, the desired state, and the context of the system you are working in. There are a variety of methods by which the quality of patient care can be improved, such as Lean and Six Sigma [1, 2]. The Institute for Healthcare Improvement (IHI) supports a method based on the Model for Improvement. The Model for Improvement, described in Chap. 2, is a framework for applying the following five principles of improvement.

Five guiding principles of improvement [3]:

1. Knowing why you need to improve
2. Having a feedback mechanism to tell you if the improvement is happening
3. Developing an effective change that will result in improvement

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4. Testing a change before attempting to implement broadly
5. Knowing when and how to make the change permanent (implement the change)

We will explore each of these principles in more detail through this chapter using the following example:

> As the quality leader in your oncology division, you would like to improve time to antibiotics (TTA) for oncology patients who present to the emergency department (ED) with fever and concern for infection. You recognize the national benchmark for TTA is 60 minutes or less, and after reviewing your hospital's data over the past year, you find the average TTA in your ED is currently twice that, 120 minutes. In fact, only 25% of immunosuppressed patients with fever receive antibiotics within 60 minutes. Further, in the past 6 months the hospital patient safety team has identified an increase in ICU transfers for oncology patients related to need for initiation of vasoactive medications. The team believes one reason for the clinical deterioration of these patients is delay of initial antibiotics. When the individual patient charts are reviewed, the team finds a number of problems, ranging from port access issues to protocol deviations and communication failures.

The first principle of improvement, knowing why you need to improve, is sometimes referred to as the aim or purpose of the improvement project. The improvement aim of the oncology team above was clear; they first needed to make changes to the processes surrounding TTA to deal with the time delays.

Selection of a Global and Project Aim

Improvement projects should begin by addressing the first question of the Model for Improvement, "What are we trying to accomplish?" This requires development of an aim statement. To be effective, an aim statement should be developed in collaboration with leadership and frontline staff in response to an observed problem [4]. A clearly written aim statement is critical for a successful improvement project and serves several purposes. For example, a clearly written aim statement provides leadership with an understanding of the purpose of your project and therefore promotes leadership buy-in and support. Further, an aim statement will help clarify who should be part of the improvement team. It also reduces variation from the project's original purpose; when stakeholders begin to push different agendas, an aim statement serves as an effective reminder of the project's intended scope. Finally, an aim statement defines the magnitude of the expected improvement and sets an expected timeline for achieving results.

The aim statement may be divided into a global aim, which describes the long-term goals of the process under evaluation, and a project, or specific aim, which is narrow in scope and related to the current team's work. The specific aim for a project, often referred to as a SMART aim, should be specific, measurable, actionable, relevant, and time bound [3]. To do this, the specific aim statement should clearly state the process/system which will be the subject of the work, the desired outcome,

the timeline during which the team will accomplish the work, and the magnitude of change that is expected.

With this information, you write down the following global and specific aim statements for the TTA improvement project:

Global aim: Improve outcomes by providing timely and effective care to immunosuppressed patients with fever.

Specific aim: Increase and maintain the percentage of febrile immunosuppressed (F&I) oncology patients who receive their antibiotics in the ED within 60 minutes from 25% to 90% over the next 12 months.

Analysis of the Existing Process

Prior to attempting any improvement project, a thorough analysis of the existing process should be undertaken. All stakeholders, which may include but are not limited to physicians, nurses, patient services, ancillary staff, administrators, patients and their families, consultants, and external supports, should be included [5]. Representatives from this group then create a comprehensive operational map of the flow of the process from the first to the last step. If the process map is created properly, potential areas of operational failure, both those that currently exist, and potential future areas of weakness can be identified more easily. These can be described in a healthcare failure mode and effect analysis (HFMEA). First used in engineering, the failure modes and effects analysis (FMEA) uses a proactive approach to identify vulnerabilities in a system or product to prevent failures [6]. The HFMEA expands the engineering approach to a more comprehensive, systematic approach that can be applied to healthcare operations to improve processes and hopefully prevent safety failures [6]. This is particularly relevant in healthcare where the product is the process itself [7].

You assemble a quality improvement (QI) team that includes key stakeholders in oncology and emergency medicine (physicians, nurse practitioners, nurses, clerical staff, clinic managers) as well as a few interested oncology patients and families. You review the aim statements with the team and develop an HFMEA for the process (Fig. 5.1). The QI team then pictographically represents potential failures as a Pareto chart which shows a cumulative histogram of failures from the direct observation period. (Fig. 5.2)

The next step is to create a process map. To start, key stakeholders meet and discuss the process from start to finish. They then observe the process "in action." When the group meets again, depending on the improvement theory the team has chosen to implement, they create a map of the process. Process maps help clarify complex processes by showing decisions, events, wait times, and delays in care. The process map helps draw a picture of how a process works and serves as a base that can be used as the team transforms the currently existing process.

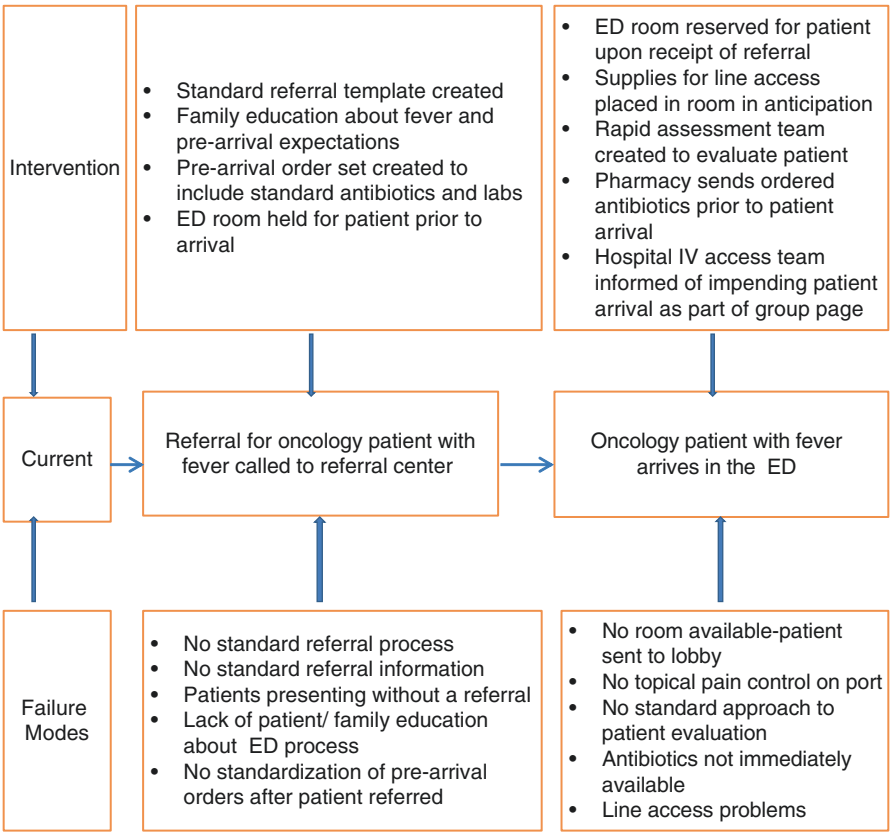

Fig. 5.1 Healthcare failure modes and effects analysis (HFMEA) for time to antibiotics for oncology patients who present to the emergency department with fever

Steps to Create a Process Map

It is important to have representatives of all the roles involved in the process that participate in the creation of the process map. Start with a high-level process map which will contain the various steps that are imperative to the process (Fig. 5.3). After the high-level process map is finished, a detailed process map should be completed. The detailed process map includes decisions as well as all subprocesses (Fig. 5.4). After completing the process maps, the team should validate them with other individuals.

At that time, potential interventions are reviewed and a first series of trials are planned based on improvement theory. Theories are grand (global and general), big (concepts that can be applied across projects), and small (pragmatic and applicable

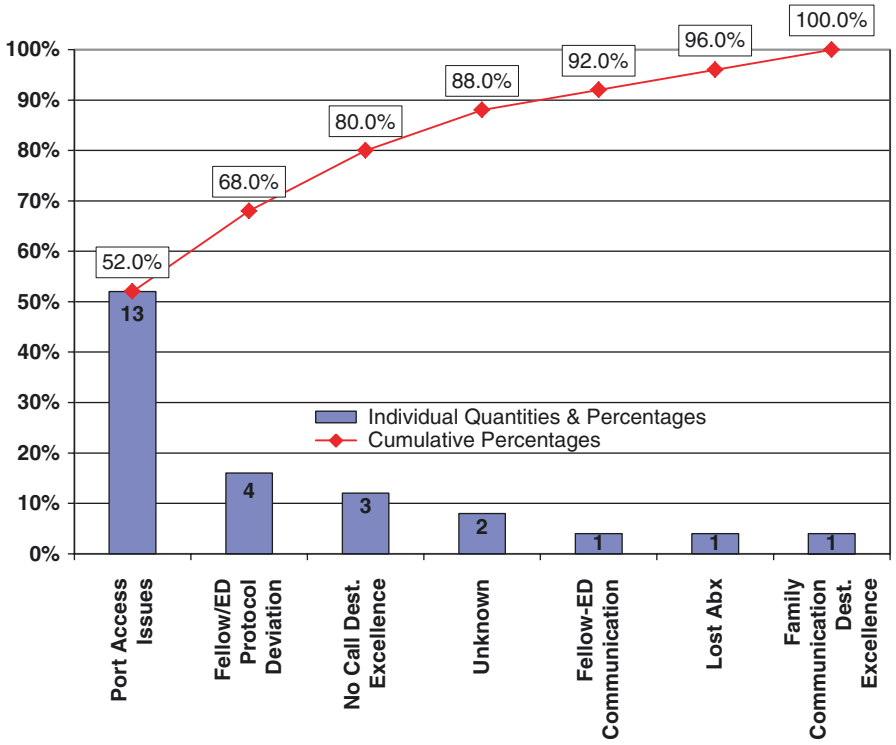

Fig. 5.2 Pareto chart: Oncology patients who did not receive antibiotics within 60 min of arrival in the ED

Fig. 5.3 High-level process map

to a specific improvement) [8]. After the failures are identified and the Pareto chart created, the team can identify barriers to improvement, develop key drivers, and plan the first improvement intervention. On the other hand, if the project is focusing on Lean methodology and eliminating waste, the observation period will identify process steps that are valuable to the patient (value added) and those that may be necessary but are non-value added [9].

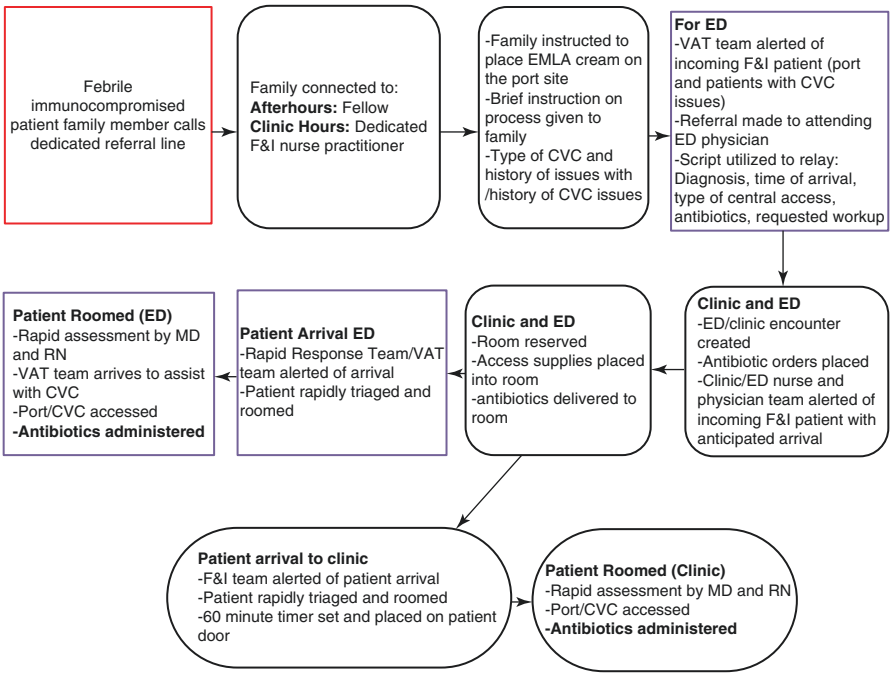

Fig. 5.4 Detailed process map

Identification of Barriers

Inevitably, the people involved in an improvement team are enthusiastic, optimistic, and invested in the success of the new process. Unfortunately, this can cause them to overlook potential barriers to success. During the analysis of the existing process, it is essential that the members of the group honestly evaluate potential pitfalls that may be associated with changing the process in an attempt to improve. This starts by looking at the existing culture and infrastructure theoretically then directly observing the providers. Once the barriers are identified, they further inform the key drivers, described below:

After further consideration and honest discussions, the QI team identified the following potential barriers to improving TTA:

1. A culture that was resistant to standardizing patient care
2. Staff entropy
3. Comfort with silos of care and a lack of collegiality between services
4. Family expectations that did not align with standards of care
5. Acceptance of failure as a part of business as usual

Honesty is essential when identifying impediments to process improvement. It is human nature to believe that fault lies elsewhere—another person, another service,

and another team within the hospital—but for any process to succeed, the silos must be razed and staff engaged. Obstacles are best removed when the staff as a whole perceives themselves to be part of the team as opposed to drafted soldiers being forced into labor; indeed, in those situations, the staff simply becomes another hurdle to overcome in the path of improvement.

Barriers can also be divided into organizational and personal. Though quality improvement is a growing field, some organizations simply do not have the infrastructure or the financial resources to undertake a large-scale quality improvement project [10]. Some organizations are ineffective at communicating the underlying vision of the quality improvement; hence, leadership does not attain support for the process at the grassroots level. Even if employees are ready to undertake quality improvement, sometimes leadership does not understand how to empower frontline providers, so these individuals are not ready to accept the responsibility for the process [11]. Individually, barriers include resistance to standardizing care (i.e., disdain for "cookbook medicine"), personal biases about patients, the organization and leadership, and limitations in skill [11].

Identification of Key Drivers

A driver diagram is a tool for building a testable hypothesis. It illustrates the structures, processes, and norms that may need to change in order for the system to operate at a new, improved level. Similar to conceptual models, a well-designed driver diagram clarifies the theory behind an improvement project and informs the strategy for achieving the aim (outcome). Driver diagrams also provide a framework for measurement, inform evaluation, and allow for comparison of projects across different organizations and researchers.

When creating a driver diagram, the aim statement (desired outcome) is traditionally located on the far left; everything to the right of the aim statement depicts a theory about what must change and how it must change to achieve the desired outcome. The items to the right of the aim statement are known as key drivers. Generally speaking, key drivers are the elements present in a system that must be considered as leverage points when developing a plan for change. Key drivers may be further broken down into primary and secondary drivers.

Primary drivers are high-level elements in the system that must change to accomplish the outcome of interest. These include the structures (physical space, equipment, technology), processes (workflow, protocols), and operating norms (culture, organizational psychology) that define the system in its current state [12]. Depending on the scope of the improvement project, secondary drivers may also be relevant. Secondary drivers are more specific, actionable items within the system that can be acted upon when introducing change.

Ideally, a driver diagram should be constructed by working closely with subject matter experts who work directly with the system of interest; they will know the

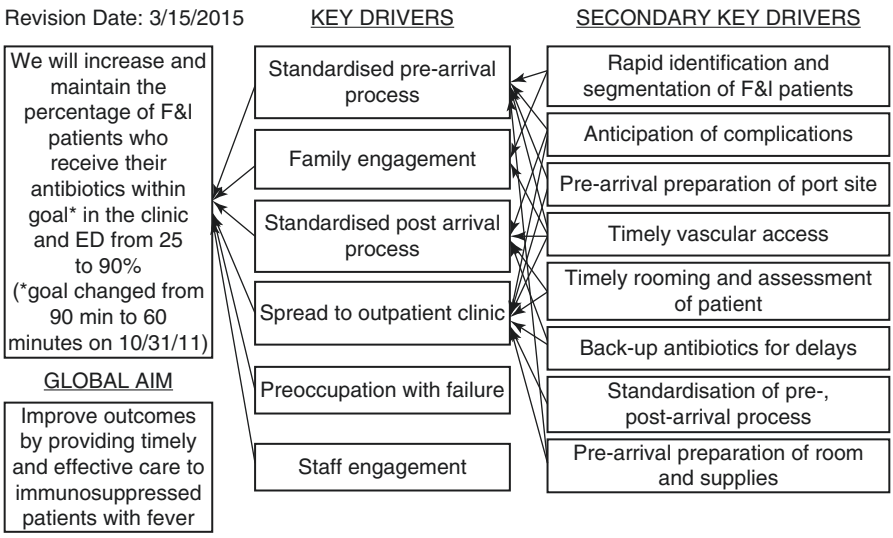

Fig. 5.5 Driver diagram: Improving time to antibiotics in febrile oncology patients

system best and will likely be able to provide a high-yield list of key drivers. The following steps may then be followed to create a driver diagram:

1. Write out the global aim and SMART aim statements for your improvement project.
2. List all key leverage points or "drivers" in your system that will require change to achieve your aim.
3. Logically group drivers and identify high-level primary drivers (structure/process/culture) and more specific, actionable elements (secondary drivers).
4. Draw connecting arrows to show causal relationships.

The QI team identified key drivers related to structures (spread to the outpatient clinic), processes (standardized pre-arrival and post-arrival processes), and operating norms (family and staff engagement, preoccupation with failure). Further, the team was able to identify secondary drivers such as pre-arrival preparation of port sites, timely rooming and assessment of patients, and availability of back up antibiotics for delays. These drivers were organized into a driver diagram for your improvement project. (Fig. 5.5)

Root Cause Analysis and Understanding of Failures

Root cause analysis (RCA) is a structured method used to analyze failures and serious events and is utilized as an error analysis tool in healthcare. RCA helps identify underlying problems that increase the likelihood of errors utilizing a systems approach to identify both active errors (errors occurring at the point of interface between humans and a complex system) and latent errors (the hidden problems within healthcare systems that contribute to adverse events).

Plan-Do-Study-Act

In order to effectively create solutions in quality improvement, study the effects and determine if the process change versus any of a number of potential confounders created the improvement; a quality improvement team must use a systematic approach. The most commonly adopted in quality improvement is a variation of the "Deming Wheel" or the "Plan-Do-Study-Act" (PDSA) approach [11]. In the PDSA model, during the **P**lan, a hypothesis is generated; while "**D**oing," data is collected; the data is **S**tudied; this data creates the foundation for future **A**ctions [14]. These are also called "PDSA ramps" as each phase builds on the previous to become more comprehensive. As each PDSA cycle is looking to show a specific and causal improvement, often only one or two subjects are included in the initial test ramp to establish a baseline; as additional cycles are undertaken, more subjects can be included [4, 14]. Additionally, in the interest of time and resources, while in the initial phase with small groups of subjects, multiple PDSA cycles can be run in parallel then aggregated to create the next PDSA ramp using the data collected. It is important, however, to note each of these interventions on a run chart so those analyzing or attempting to recreate the process can do so accurately [4]. Once all ramps are complete, interventions that fall into similar categories can be grouped for ease of data reporting, but the discrete data should be maintained for integrity, so anyone who wants to recreate the process can do so.

Looking at each step individually:

Plan

During the planning phase, several questions must be asked. Done properly, the answers obtained from the first PDSA cycle will generate questions for the next PDSA, so asking relevant and answerable questions for the first ramp is integral to the success of the project. These include [4]:

- The objective
- Key drivers to be tested
- How to measure the impact (for this PDSA may not be the final project measure)
- Predictions

> One of the key drivers your team identified in trying to improve TTA was to standardize the pre-arrival process. This involved multiple steps, so a PDSA was created for one of the steps, the pre-arrival referral, which was a secondary driver of the key driver of interest, standardization of the pre-arrival process. The objective was to evaluate if creating a standard referral page and template in the electronic medical record would improve standardization of information available to providers. The process owners hypothesized that physicians in the ED who input patient referrals would be more compliant with referral standardization after creation of an accessible template than before. Referrals for oncology patients with fever who presented to the emergency department were analyzed before and after the intervention to determine if the intervention was successful [13].

Do

Doing the test involves the following [4]:

- Do the test.
- Collect data and feedback.
- Make note of unexpected outcomes so these can be incorporated in planning for the next cycle.

> The referral template was introduced to providers at a staff meeting. Additionally, the process owners spoke to individual providers and were in the ED during the initial phases of the PDSA ramp. The template included a pre-populated check list that automatically pulled data like diagnosis, last clinic weight, and allergies about the patient from the existing medical record. The physician would then only have to answer a few questions including antibiotic of choice, time of arrival and type of access. During the initial phase, there were several free text questions asked. Process owners measured compliance with use of the template. They also spoke with all the stakeholders in the referral process to reveal any barriers to success [13].

Study

Studying the test requires analyzing both the test itself and the data collected [4]:

- Was the test done as planned?
- Was the test feasible and reasonable in the existing system?
- Was the hypothesis upheld or disproven?

> The QI team assessed whether the referral template was used during the proposed testing period and surveyed providers about the ease of use, effect on work flow, and content. They then analyzed whether the providers working during the test period in fact used the available template and whether this referral increased standardization of information available to providers [13].

Act

Learnings from the test are used to either adapt the test process and create the next PDSA ramp, to adopt the new process if it was successful, or to abandon the process altogether if the test was unsuccessful and the data showed the hypothesis was unfounded [4]. Abandoning an idea should not be considered a failure but rather an example of the PDSA process working as wasting time on unsuccessful ramps in a desire to prove an unfounded hypothesis is a waste of resources and energy that could be spent on creating a new PDSA cycle.

> The initial test on the oncology referral template demonstrated that providers were in fact willing to use a standard process for referral for a select population; however, they found the template itself difficult to find in the electronic medical record and the information within the template too extensive. As a result, subsequent PDSA ramps focused initially on making the template easier to access in the medical record then on improving the content. The current iteration is the result of several improvement cycles with small volumes of patients [13].

Ultimately, while there are many ways to trial new quality improvement ideas, the PDSA format allows for small trials with a few subjects at a time and mirrors traditional research methodology that most providers are familiar with. It also encourages a stepwise approach and rapid abandonment of an unsuccessful process, hopefully saving time and resources. As a result, even small practices can trial the PDSA format.

Testing (Adapt or Abandon)

After testing a potential improvement, the team must decide whether to adopt, adapt, or abandon the new process. While the testing team often has a personal investment in showing that the new process was successful, it is important to avoid personal bias when deciding whether to implement the improvement on a widespread basis or not.

Most hospital systems have processes already in place that are amenable to small, initial tests of change and PDSAs that focus on the improvement team's SMART aim. By using existing systems and personnel, the team has a better chance to convince staff and administration that the PDSA is worthwhile and will not unnecessarily strain the existing infrastructure. If the small test is successful, ensuing PDSAs can be more ambitious. All tests are temporary, and by making preliminary endeavors small and manageable, the team can learn what works best in the existing hospital system and with the current staff. Hopefully, this will also increase buy-in for future testing.

If the test does not show any improvement or if the risk/benefit ratio is not favorable, the team should not be hesitant to abandon an improvement trial. Admitting failure and moving onto another test of change demonstrates an understanding of the underlying PDSA process and shows both peers and administration that the team is open-minded and willing to continually consider the consequences of all actions.

Implementation (Adopt)

If the improvement team is fortunate enough to find that the test of change created a positive change in the tested environment, the members of the team can choose to adopt the new process. To adopt a new process, the team should first discuss the process with the providers who will be responsible for implementing the change in

the clinical environment to ensure acceptance. Once this is done, widespread education can begin. Once the newly adopted process is an established part of the clinical routine, it can be used as a starting point for the next PDSA.

Pitfalls of PDSA Cycles

While the PDSA cycle is not a traditional hypothesis-driven method for research, sloppy methodology can still result in inaccurate improvement testing and, as a result, an unpleasant or even dangerous clinical environment. As a result, it is important to follow rigorous methods when doing improvement testing. First, prior to starting the PDSA cycle, the team should have a clear aim and prediction in mind about the test cycle. The members should write down the aim and the method of the PDSA and review these with the team both before and after testing. While it is acceptable for a PDSA cycle to be small and involve only a few subjects, it should not be so small that the data collected is unreliable or biased, especially if the results are skewed in favor of the results the team desires. Finally, the test should be run a few different times in a few different but appropriate clinical environments to ensure that the outcome is accurate prior to implementation.

> When your testing group implemented the fever, immune compromise order set and tested for the first time, there was an ice storm. As a result, the emergency department had record low volumes and only one oncology patient presented during the week of testing He received his antibiotics in 20 minutes. The team was ecstatic and ready to change the system entirely. Two weeks later, after school had restarted, the clinic had a flood so all oncology patients were referred to the ED and ED census was at a record high, 10 oncology patients were seen in the ED and 3 did not receive antibiotics within sixty minutes.

PDSA Ramp

Small tests are rarely stand alone; therefore, you should start to prepare the next test based upon your predictions. Often a change idea will go through multiple PDSA cycles as data is collected (this is called a PDSA ramp); large-scale tests of changes may require multiple concurrent PDSA ramps before implementation.

Large-scale implementation is viewed in quality improvement as a series or "ramp" of PDSAs, each one larger or under different conditions. When you have evidence that an idea is reliable in one area, further tests and ramps can be spread to the new environment.

Sustainability

Once a QI process has been tested and modified through a robust PDSA ramp, and successfully implemented, it is imperative that infrastructure is in place to sustain improvement. There are several key components of sustainability, described below.

Supportive Management Structure

In order to support sustainability, the division's leadership must consider the process a high priority, devoting regular attention, creating accountability systems for improvement, and recognizing successes.

Structures to "Foolproof" Change

To further support sustainability, the organization should build structures that make it difficult—if not impossible—for providers of care to revert to old ways of doing things. For example, clear documentation of the process in the form of guidelines, job aids, and training materials may reduce variability and prevent drift from the improved state. In addition, tools such as checklists, prepackaged "kits" or carts of materials needed for the intervention, and technology to support sustained implementation of the intervention may be developed and employed.

Robust, Transparent Feedback Systems

As much of the organization as possible should be aware of performance on key indicators, reviewing information generated by a measurement system, comparing it to clear standards set by management, and taking part in improvements devised in response.

Formal Capacity-Building Programs

Once an organization has been successful in developing, implementing, and sustaining improvements, it is important to develop formal capacity-building programs. Such programs promote growth of the improvement efforts and also ensure that future generations of providers maintain and sustain the work that has already been implemented.

Finally, while less tangible than the components of sustainability described above, perhaps one of the most important factors resulting in sustainability is the culture of the division or organization. In an ideal state, the culture should be one that supports change and is willing to work to sustain improvements. This culture of improvement is most easily attained when key stakeholders have been engaged from the start and there is a shared sense of the systems to be improved.

Conclusion

Improvement is driven by the application of knowledge about the current state, the desired state, and the context of the system you are working in. Setting clear aims

and using tools such as process maps and driver diagrams early in your improvement work will establish a foundation and rationale for your efforts and will inform the selection of changes you test. Testing changes through multiple Plan-Do-Study-Act cycles will enable further refinement prior to formal implementation and spread. Finally, developing infrastructure and culture to sustain improvements over time is of key importance.

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