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INVITED REVIEW

Quality Improvement Feature Series Article 1: Introduction to Quality Improvement

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Quality improvement methods offer a rigorous approach to designing and disseminating improvement efforts. This report is the first in a series to introduce QI methodology, effective data display, and considerations in the review of QI manuscripts.

Keywords. key driver diagram; Pareto principle; quality improvement; run chart; SMART aim.

Nearly 2 decades ago, the Institute of Medicine called attention to the topic of patient safety in the American healthcare system [1]; the committee recommended 6 areas for improvement in providing care that is safe, effective, patient-centered, timely, efficient, and equitable [2]. As clinicians address care gaps in a variety of practice fields, embracing a practical and robust methodology can lead to results that are measurable and sustainable. The objective of this report was to review basic quality improvement (QI) methods to assist clinicians in designing successful studies.

MODEL FOR IMPROVEMENT

The model for improvement is a fundamental concept for healthcare QI efforts (Figure 1). This iterative model emphasizes the difference between making a change and making an improvement, thus distinguishing between a change that resets a process to "normal" versus one with a measurable effect [3].

DEVELOPING AIMS

To create improvement, those who develop potential changes must take into account an overarching goal. This goal can be described as a global aim that answers the question, "What are we ultimately trying to accomplish?" For infection control practitioners, a relevant global aim would be to eliminate hospital-acquired infections.

Often, a global aim includes a clinical outcome that can be influenced by many factors. To progress toward the global aim, the improver should formulate a narrower, measurable aim known as a "SMART aim". The SMART aim relates to the global aim via a unifying theory. For example, a theory for our global aim might be that increasing rates of hand hygiene will lead to less disease transmission to patients and thus reduce rates of hospital-acquired infection.

Thus, increasing rates of hand hygiene would be the target of a narrower aim. The acronym SMART guides the development of an aim that is specific, measurable, achievable, realistic, and timely [3]. Performance toward the SMART aim can be measured on a run chart, which displays data over time. An example SMART aim is to increase appropriate hand hygiene before patient encounters by practitioners from 60% to 80% within 6 months.

To measure progress, practitioners must consider the question, "How will we know a change is an improvement?" The practitioner must have a testable hypothesis to determine whether a change will lead to improvement [3]. For example, a hypothesis for increasing hand-hygiene rates could be that increasing the accessibility of hand sanitizer will lead to increased hand-hygiene rates by providers.

MEASUREMENT

The SMART aim for a project should assist in clearly defining the measures to study. Table 1 displays QI measures to consider [3].

To inform an attainable goal, the baseline, or current status, of the measure of interest must be quantified. Baseline data should be collected for enough time to understand the current system with consideration of context to determine the appropriate time frame. To apply run chart analysis rules, at least 10 data points should be collected to calculate a baseline median [4]. Data points should be collected as frequently as is manageable to monitor for change.

USING OBSERVATION TO INFORM THEORY

Before implementing changes or interventions, observation of the current process is important for understanding a system under study [3]. Observation should align with the defined

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Figure 1. Model for improvement.

measure. For example, observing and measuring the current rate of hand hygiene among practitioners is likely to be more informative than measuring the practitioners' beliefs regarding their hand-hygiene practices.

By observing the system, the improver can create a process map to identify steps in the system [3]. It is important to record the system as it currently exists and not as one believes it to be, because these steps later become targets for intervention. Many improvement specialists favor the simplified failure mode and effects analysis (FMEA) tool (Figure 2) [3]. The FMEA tool displays the process map along with anticipated breakdowns or failures and possible interventions that might improve the success of the individual steps. This diagram can also inform the overall theory for the improvement team. Using the hand-hygiene example, an FMEA can identify limited time for the practitioners as a potential process failure and introducing hand sanitizers as a potential time-saving intervention.

A few key steps in the process might emerge as areas most likely to influence success. These steps inform the "key drivers" for the process to be changed and become the basis for future interventions. A key driver diagram helps the team focus on its theory of change and determine which interventions to test (Figure 3) [3].

The last question in the model for improvement encapsulates the concept of a hypothesis: "What change can we make that will result in an improvement?" This fundamental question asks the practitioner to create a theory that can be tested [3]. Testing is an important step that will determine whether the change results in an improvement.

Table 1. Quality Improvement Measures

Measure	Definition	Example
Outcome	Relation of project aim to performance of system under study	Number of hospital-acquired infections acquired over time
Process	Completion of an activity relating to the project	Number of practitioners who wash their hands before and after patient encounters
Balance	Potential way the project might have an unintentional, negative impact on a different part of the system	Employee falls from a hand sanitizer spill

TESTING SMALL AND OFTEN

Instead of designing the perfect experiment with a large sample size and control group, QI testing should be practical [5]. Using the sanitizer-dispenser example, the dispenser could be placed in a patient's room, and the nurse for that patient could be queried about its ease of use. Perhaps the nurse would immediately report that the dispenser should be placed outside of the room so that her hands are clean before she collects supplies. After this feedback, the test can be adjusted and tried on 2 more rooms. This test finds that the dispenser's design is causing spillage onto the floor, which leads to further adjustments. These small tests allow for rapid learning and refinements before testing is ramped up to a larger scale.

The plan-do-study-act (PDSA) testing cycle enables the improver to measure intervention effectiveness. This iterative cycle has 4 phases. The first stage, to plan, determines the objective, identifies the population, and defines the tasks needed for the test. During this stage, the anticipated result should also be predicted. The next stage, do, tests the change and measures the results. The next stage is to study whether the predicted result was correct and, if not, to learn from the results. Last, the act stage includes a choice of 3 options, adopting the tested change if it was successful, adapting the change if slight revisions are needed, and abandoning the change if the test failed [3].

As successful interventions are adopted, they typically are tested on a larger scale and often in different environments (such as another inpatient unit). It is vital to test an intervention sufficiently before implementation, which is defined as permanently introducing the change [3].

DATA COLLECTION AND REVIEW

For QI work with multiple sequential tests, it is important to display data over time. A run chart provides a simple chronological display and can provide important insights.

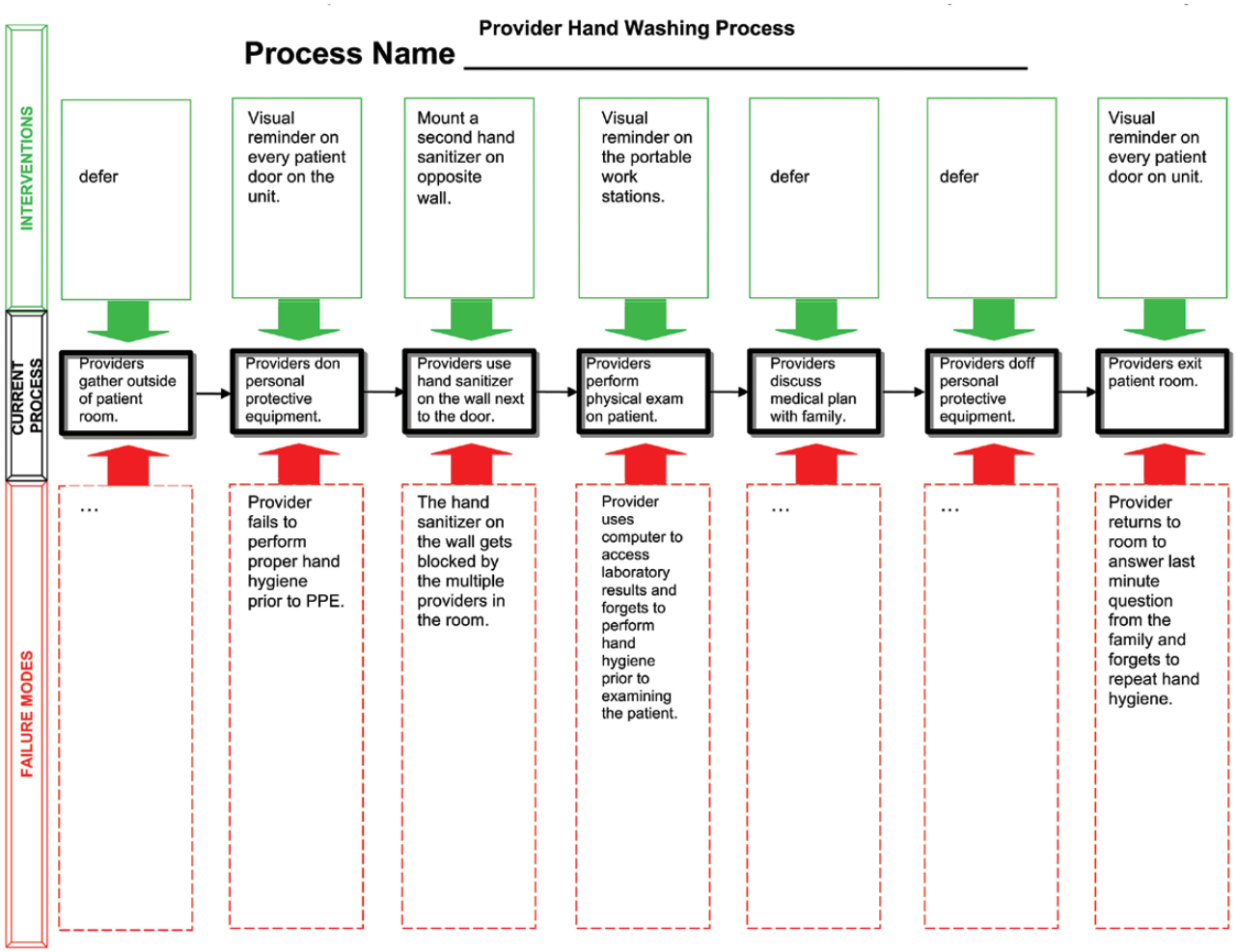

Figure 2. Simplified failure mode and effects analysis (FMEA) tool for hand hygiene. Abbreviation: PPE, personal protection equipment.

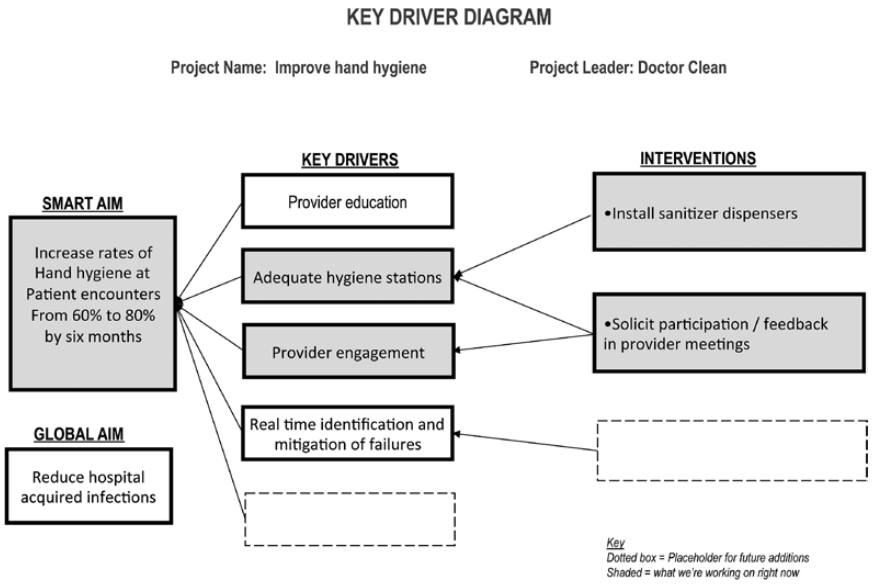

Figure 3. Key driver diagram for project to improve hand-hygiene rates.

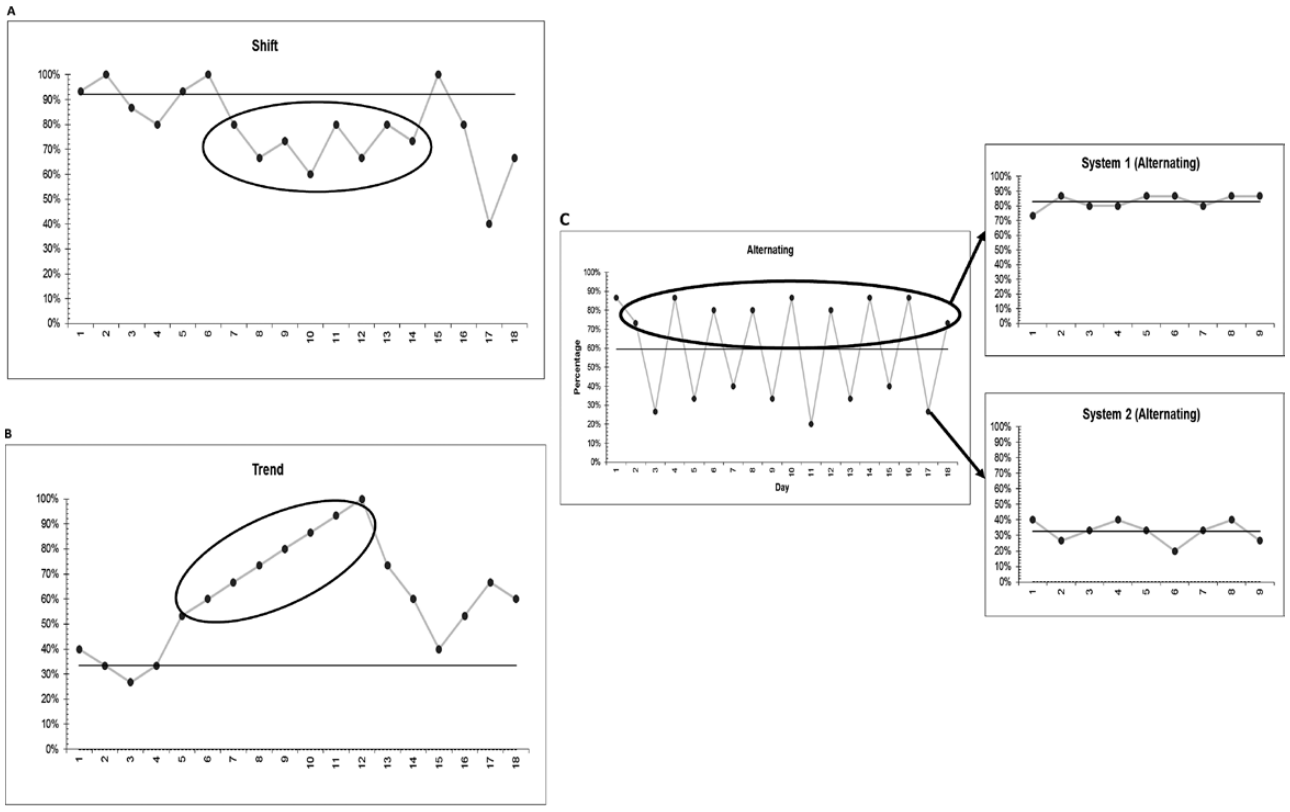

Figure 4. Run chart rules for identifying special cause. (A) The first rule is a shift in which 8 or more points are above the centerline. Points that lay directly on the centerline are not included. (B) The next rule is a trend in which 6 or more points are all trending upward or downward. (C) The last rule applies to an alternating pattern of upward and downward movement, which can be seen for at least 14 points, which might suggest that 2 systems are at work and that it might be best to separate the data into 2 run charts.

Run charts display time on the x-axis and the outcome of interest on the y-axis. The centerline is the median of the data points. The goal line indicates the goal that the team hopes to achieve [6].

The improver should plot initial baseline data on the run chart to measure how the system performs before changes are made. Once the baseline is established, interventions can be introduced and the run chart monitored for "special cause variation," which indicates that the system has likely experienced a change as a result of the implemented intervention [6]. Special cause variation differs from common cause variation, which is the natural variability seen in a stable process.

Identifying special cause on a run chart occurs via 3 different rules, which are shown in Figure 4. These rules are based on statistical probability that the change is not a result of chance.

Each of these rules indicates that modifying the centerline is appropriate. If no intentional intervention triggered these changes, then other unidentified special causes should be considered. If none are found, there should be no change in the centerline [6].

It is important to consider the reasons for failures within the system at baseline and throughout the intervention period. For the hand-hygiene example, it is imperative to understand why providers are not washing their hands. To find the cause, that provider's reason for not washing his or her hands should be documented each time. Then, failure data can be compiled to determine which factors are most prominent. A chart that is useful for studying failure data is called a Pareto chart (Figure 5). The Pareto chart is guided by the Pareto principle, which holds that 80% of failures typically are caused by 20% of the failure modes [5]. By

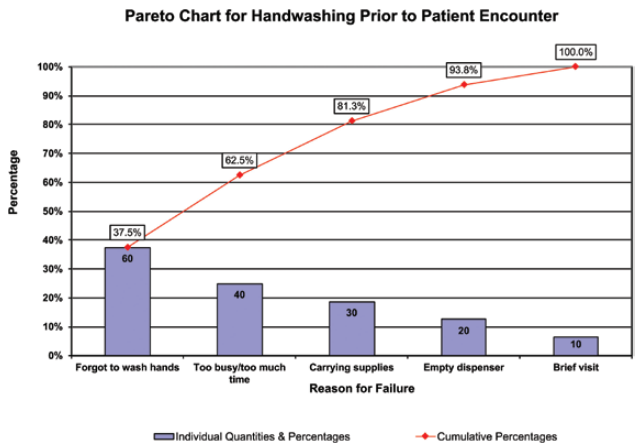

Figure 5. Pareto chart for identifying frequency of failures.

focusing on the top failure reasons as the focus for interventions, improvement efforts can be maximized for the greatest effect. Figure 5 shows that more than 80% of the hand-hygiene failures were caused by forgetfulness or lack of time; thus, targeting these 2 reasons with interventions is likely to have the biggest effect.

CONCLUSION

This article introduces the reader to important concepts in QI, including the importance of an underlying theory, development of appropriate measures, plotting data over time, and how to test interventions. Using the methods discussed here, a practitioner can undertake a QI effort that will produce measurable and sustainable benefits and be worthy of dissemination. Squire 2.0 guidelines are available to assist in the writing of an excellent quality report [7]. For the more advanced improver, additional articles in this series will address approaches to displaying and analyzing QI data, writing a QI study report for publication, and advanced study designs.

Notes

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