How to Measure and Interpret Quality Improvement Data

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Abstract
This article will demonstrate how to conduct a quality improvement project using the change idea generated in “How To Use Quality Improvement Tools in Clinical Practice: How To Diagnose Solutions to a Quality of Care Problem” by Dr. Ziv Harel and colleagues in this Moving Points feature. This change idea involves the introduction of a nurse educator into a CKD clinic with a goal of increasing rates of patients performing dialysis independently at home (home hemodialysis or peritoneal dialysis). Using this example, we will illustrate a Plan–Do–Study–Act (PDSA) cycle in action and highlight the principles of rapid cycle change methodology. We will then discuss the selection of outcome, process, and balancing measures, and the practicalities of collecting these data in the clinic environment. We will also introduce the PDSA worksheet as a practical way to oversee the progress of a quality improvement project. Finally, we will demonstrate how run charts are used to visually illustrate improvement in real time, and how this information can be used to validate achievement, respond appropriately to challenges the project may encounter, and prove the significance of results. This article aims to provide readers with a clear and practical framework upon which to trial their own ideas for quality improvement in the clinical setting.


Clinical Scenario
In the previous article in this Moving Points feature (1), the improvement team performed a root cause analysis to examine, by way of example, reasons why more patients were not dialyzing independently at home. The change idea that this analysis generated was the addition of a nurse educator into the CKD clinic. This change addressed the main causes of limited patient education by the nephrology staff and limited interdisciplinary communication between nephrology staff. Now, the improvement team needs to put this idea into practice and determine if the change is having the impact that was anticipated. Although the improvement team is familiar with Plan–Do–Study–Act (PDSA) methodology, they are unsure exactly how to conduct small tests of change and convey progress to the rest of the improvement team and stakeholders.

In order to do so, the team needs to formulate a plan for how the nurse educator will be introduced into the clinic. The team must decide what parameters of success (or failure) are to be measured and identify a method whereby, in real time, they can tell if this change is having the desired effect and respond appropriately if it is not.

PDSA Cycles and Rapid Cycle Change Methodology
To do this, The Model for Improvement suggests using a series of PDSA cycles in a process called rapid cycle change (2,3). This is an iterative process, whereby one cycle yields results that inform the next, and so on, toward reaching the eventual goal (Figure 1). Rapid cycle change can be thought of as being analogous to building a wall out of bricks rather than pouring a concrete floor. In the case of the wall, each brick’s placement can be examined and used to decide where the next brick should go; this approach is obviously not the case with the concrete floor.

In our example, the correlate would be to put in place a suite of interventions across a health care system in the hope of increasing independent dialysis penetrance, without first trialing these interventions individually and on a small-scale basis. Blindly implementing multiple interventions has the potential for significant expenditure and unintended consequences. The advantage of the rapid cycle change methodology is that it allows us to mitigate risk and sharply reduce expenditures of time and money, while making changes that are less disruptive to our patients and colleagues. We also reduce resistance to change by starting on a small scale and learning from the ideas and processes that work and from those that do not (Figure 1).

Although the overarching aim of our project is to increase independent dialysis rates to 30% for all new dialysis patients across a health care system, we may not achieve this goal through one intervention alone, but rather through a series of interventions tested locally and extrapolated to the broader community. Each PDSA cycle is essentially a graphic representation of the scientific method. The starting point is
Plan

It is useful at the planning stage to create a document that outlines objectives and timelines, and encourages accountability on the part of the improvement team members and stakeholders. The PDSA worksheet is recommended for this purpose by the Institute for Healthcare Improvement (4) (Figure 2).

We begin, therefore, by explicitly stating what the objective of this cycle will be; in this case, to examine the effect of a dialysis nurse educator on rates of new patients being assessed for independent dialysis suitability. Clearly, preliminary work will need to be done to recruit and establish this individual in practice, which will involve considerable stakeholder engagement (5). This step should be reflected in the planning document, along with the improvement team member or members responsible.

Next, it is important to clearly define the details of the proposed change and its implementation as part of the planning process. Using our example, we would need to consider the following: What percentage of CKD stage 4 patients will be seen by the nurse educator? What information will the education session include? What is the referral process? Will we need to design a referral tool or checklist? How will the nurse educator communicate back to the team? How will we evaluate patient and staff satisfaction? Outlining these details in advance of implementing the change will standardize the intervention and data collection components of the PDSA cycle. This will ultimately improve the quality of the change intervention process and improve generalizability.

The next phase of planning is to make a prediction about the effect we expect our change to have. This is a key component of rapid cycle change methodology. Comparing our prediction with what actually transpires and studying the reasons why a change did or did not produce the desired result fuels the next PDSA cycle along the process toward our goal.

Once we have made a prediction, we are now ready to decide what to measure. As mentioned in Dr. Silver’s article in this Moving Points feature (5), quality improvement metrics may be thought of in terms of outcome measures, process measures, and balancing measures (6) (Table 1). Outcome measures occur at the level of the patient. Here, the outcome measure of interest would be the patient dialyzing independently at home within, for example, 6 months of dialysis initiation.

Process measures relate to provision of the appropriate services and are an indicator that a health care system is working efficiently. In this case, assessment for suitability for independent dialysis would be a process measure. Similar to a prospective research project in which data on mortality may not be immediately forthcoming, in quality improvement work, the outcome measure often occurs far downstream from the process measure. A process measure is a better short-term indicator of whether a system is working as intended because it is directly within our control and may often be measured in a more time-sensitive manner. The choice of process measure should be directly linked to the outcome measure. This connection may be evidence based; for example, angiotensin-converting enzyme inhibitor prescription (process) and progression of diabetic nephropathy (outcome). In this case, root cause analysis suggests that by assessing patients for independent dialysis and educating them regarding its benefits (process), actual numbers of patients on independent dialysis will increase to the desired level (outcome).

Whenever changes are being made to a system it is crucial to record balancing measures, which track the unintended consequences of our intervention. If we intend to add another team member to a nephrology clinic setting, we must consider what effects this change could have on personal dynamics. Clinics may be longer in duration, which may adversely affect physician satisfaction. Individual visits being longer or more frequent may adversely affect patients financially through transportation costs and time off work. Anticipating, understanding, and accounting for these factors will allow us to ultimately construct a health care delivery system more robust in meeting the needs of our patients and ensuring the participation of staff.

When selecting measures, convenience of data collection should be considered. The readiness with which data can be captured may impact on the success of the improvement project. For example, are measures already being recorded electronically which can easily be extracted and tracked by the team to guide the improvement initiative? A related point is that it is crucial to have baseline data before initiating an improvement project because otherwise it is impossible to ascertain that a problem exists or that an improvement has occurred. Finally, as in this example, where we are tracking the rate of dialysis patients receiving a home-based treatment, it is vital that we can accurately determine the size of the total dialysis population (the denominator), as well as the numbers receiving dialysis at home (the numerator).
In this first PDSA cycle, we will, therefore, be testing our prediction that introducing a nurse educator into an outpatient CKD clinic will increase the number of new referrals being assessed for suitability for home dialysis. We will be tracking the percentage of patients referred to the clinic who are assessed by the nurse educator as the process measure. We will be monitoring patient and clinic staff satisfaction as balancing measures.

The “do” phase is where we will test our prediction in the real-world setting. In this phase, implementation of the change (introduction of the nurse educator to the outpatient CKD clinic) is carried out according to the details outlined during the planning phase. The PDSA worksheet is used throughout the “doing” phase to clarify who will do what and encourage accountability (Figure 2). In addition to collecting data on the measures of interest, we should also have some method (team meetings, suggestion box, bulletin board, etc.) whereby those involved in the work can express qualitative feedback. Feedback may prove invaluable in understanding why the intervention did or did not work. If feedback from the clinic staff and patients is overwhelmingly positive, we have good reason to believe this that this change should be continued and further developed. On the other hand, addressing negative qualitative data allows us to adjust the current process toward one, which will be more effective in achieving our goals.

In the real-world practice of a rapid cycle change initiative, the analysis of results actually occurs contemporaneously with the “doing” part of the project. As such,

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome measure</td>
<td>Clinically relevant, patient-level outcomes</td>
<td>Patient performing dialysis independently at home</td>
</tr>
<tr>
<td>Process measure</td>
<td>Indicators of health system performance</td>
<td>Patient assessed for home dialysis suitability</td>
</tr>
<tr>
<td>Balancing measure</td>
<td>Markers of unintended consequences</td>
<td>Patient satisfaction with clinic visit</td>
</tr>
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Figure 2. | PDSA worksheet for testing change, as suggested by The Institute for Healthcare Improvement.
it is critical to be able to view and interpret data in real time. A run chart is a useful tool in accomplishing this (7). This section will deal with how to construct, interpret, and use run charts for improvement initiatives.

Statistical inference tests, with which we may be more familiar in health care (e.g., chi-squared test, t test, etc.), typically rely on comparing data between two or more groups, aiming to infer something about the larger population. In the context of an intervention, the traditional approach would be to compare two groups—one undergoing standard care (or receiving a placebo) and the other undergoing an intervention or receiving a new therapy. In quality improvement work, this approach cannot provide a real-time visual and does not allow us to establish temporally whether an improvement is due to an intervention or whether this improvement is being sustained.

A run chart maps the frequency of a quality measure’s occurrence on the y-axis against a unit of time on the x-axis. In rapid cycle change PDSA cycles, this unit of time is short, typically daily or weekly. By constructing a run chart and illustrating the points in time that an intervention occurred, we can establish whether the intervention is exerting an effect on the outcome in question. A run chart also allows us to depict a nominal target level, which provides a visual motivator for the improvement team. By using the points on the chart to construct a median line (defined as the number in the middle of the data set when the data are ordered from the highest to the lowest) and applying simple probability rules, we can determine whether the observed changes are likely related to the intervention or whether they may be due to chance.

Figure 3 shows an example of a run chart for our project in which the process measure “percentage of patients being assessed for independent dialysis suitability” forms the y-axis and the x-axis is time divided into weeks. Note the median line as well as the target adherence with the process measure.

Run charts used to guide rapid cycle change initiatives should not be confused with statistical process control charts which are used to detect aberrations in an already stable process (8). Statistical process control charts can also be used for quality improvement work, and usually include control limits that are plotted three SDs from the mean or median to detect variation in performance. A complete discussion of statistical process control charts is beyond the scope of this current series, but several
resources exist to support improvement teams in their application (9,10).

In order to interpret the run chart, we first need to understand the four rules of run charts (7). The four rules are explained here and shown graphically in Figure 4, A–D. All of the rules require there to be ten or more points before they may be reliably applied.

**Shift**

The chance of a point lying on one side or another of the median is, by definition, 1 in 2. The chance of two consecutive points being on a given side is 1 in 2×1 in 2 (1 in 4) and so on. By this logic, if six consecutive points are on one side of the median, the chance of this happening are 1 in 64, or 0.015%. This is highly unlikely to have occurred by chance and far surpasses the conventionally applied probability ($P$-) value of 0.05 for determining statistical significance. In calculating shifts, a point that falls on the median should be ignored; it neither adds to nor breaks the shift. It is worth noting that the convention of six points on one side of the line is arbitrary in the same way as the $P$-value is. It simply provides a certain level of confidence, in this case 1 in 64, that the outcome is not occurring by chance. If a higher or lower degree of confidence is required, more or fewer points may be required (10).

**Trend**

By the same rules of probability, if five or more consecutive points are either ascending or descending, this is unlikely to be occurring by chance (8). If two points are the same, only one is counted and this does not add to or break a trend. Again, more points may be desirable based on the level of confidence needed.

**Runs**

If a process is proceeding in a random fashion, the graph generated by joining the points should cross the median line with a predictable regularity. The exact number of crossings can be determined from published charts based on a $<5\%$ probability of being due to random occurrence (7,11). Either too few or too many crossings of the midline imply that something other than chance is governing the process.

**Astronomical Point**

Whereas the previous three rules depend on objective measures of probability, the astronomical point is subjective. Essentially, it is a point on the graph that a casual observer would notice to be blatantly different from all other points on the graph. By convention, the astronomical point is not usually included in calculating the median. If an astronomical data point is present, an improvement team should try to determine what occurred differently at this point in time.

Applying these rules to our quality improvement project, we note the following (Figure 3).

(1) No tangible initial improvement was seen on the initial introduction of the nurse educator into clinic. PDSA cycles helped determine that the failure of this step was...
related to insufficient time being allowed to facilitate a consultation with the nurse. This qualitative feedback allowed appointments to be appropriately lengthened and patients were sent reminders that the first clinic visits would take 2 hours rather than the usually allotted 45 minutes. These changes were tested in subsequent PDSA cycles.

(2) After this amendment to the process, there was a statistically significant “trend” (at least five points in the same direction) upwards in the percentage of patients being assessed.

(3) This improvement is transiently sustained.

(4) There is then a significant downward “trend” back toward preintervention levels. The improvement team reviews these results, and the consensus is that the decrease is because the nephrology physician group has decided that all patients with CKD stage ≥4 will be seen in the CKD clinic. Extra physicians and residents have been enlisted, but the single nurse educator is overwhelmed. It should be noted that the observed decrease in assessment rates is as a result of the team’s decision to track the percentage of patients being assessed rather than the overall number of assessments. Here, a change in the denominator resulted in a fall in the rates of assessment rather than merely stagnation had numbers assessed been used as the process measure.

(5) At the end of the run chart, we see another nonsignificant trend upwards following the recruitment of a second nurse educator.

We also note that the line crosses the median on only three occasions; indicative that something other than chance is governing the observed variation (11). Finally, we observe the powerful visual cue given by annotating a run chart with PDSA cycles and changes. This helps a team to visualize the temporal relationship between their intervention and improvement.

Act

In the “act” phase we must decide whether to keep the change, modify it, or discard it, and then plan for the next change and next PDSA cycle, with a new prediction. As will now be apparent, the process of testing the effect of the nurse educator on independent dialysis assessments was more complex than might have been envisaged and actually required several PDSA cycles. This iterative process is characteristic of quality improvement work and of rapid cycle change methodology, and illustrates the importance of ground-level qualitative feedback, real-time data collection, and why “the people who do the work must change the work.”

The next hurdle is to build upon this success. Here, we have deliberately chosen a process measure because it allowed us to rapidly see the effects of our intervention. Whether this process measure indeed translates into the desired 30% of new patients dialyzing independently at home by 6 months of dialysis initiation will depend on the rigor of our root cause analysis and again highlights how vital this preliminary work is (1). This expected improvement in the patient-level outcome measure needs to be verified over the longer term, by constructing another run chart documenting dialysis modality at 6 months after initiation (the outcome measure). If independent dialysis numbers do not, in fact, increase, this may suggest a failing in the root cause analysis or factors in the local environment that are impacting success (12).

Scenario Resolution

The quality improvement team has taken the change idea of an independent dialysis nurse educator attending the dialysis clinic and tested it in a real-world clinic environment. Several PDSA cycles were necessary to achieve the predicted effect. The first PDSA cycle failed, suggesting a need to make organizational changes to patient flow through the clinic. The second PDSA cycle saw a sharp increase in the number of patients being assessed, but was not sustained due to extrinsic factors. The final cycle saw a second nurse educator appointed with resultant increases in patient assessment for independent dialysis. Throughout all of the PDSA cycles, data were tracked on run charts for the improvement team and stakeholders to visualize and interpret. These run charts indicated that once patient assessments for independent dialysis reached target levels, an upward trend was subsequently observed in the proportion of patients dialyzing independently at home. This result supports the findings of the root cause analysis and change idea exercises that a nurse educator was a key component in the independent dialysis process.

What Are the Next Steps?

Now that we have learned how to test and identify improvements to the independent dialysis process, we need to be able to sustain any positive changes. As we have already seen in Figure 3, maintaining an initial improvement is challenging. Achieving success with PDSA requires a dedication to the iterative rapid cycle change process, which may lead to “change fatigue” among stakeholders. Departure from this methodology may lead to eventual failure of an improvement initiative (13). The next paper in this Moving Points feature will describe some tools to help teams hold their quality improvement gains for the long term, as well as review factors in the local environment that contribute to quality improvement success.

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Disclosures

None.

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