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Special Series — A Primer in Quality Improvement

Implementing Change Ideas, Interpreting Data and Sustaining Change in a Quality Improvement Project

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Key Messages

- A run chart is a simple tool that can be used to track data over time, which is essential when testing ideas for change.
- Four probability-based run chart rules exist for evaluating whether or not improvement is due to chance alone: shift, trend, too few or too many runs and an astronomic point.
- Sustainability should be considered early in the planning process of any quality improvement project.

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ABSTRACT

This article is the third and final installment in our diabetes quality improvement primer series. It summarizes how to interpret real-time data with run charts and highlights 4 key rules that can be applied to understand whether improvement is statistically significant. We also review the importance of outlining a family of measures, including outcome, process and balancing measures. Finally, we discuss strategies for sustaining change.

RÉSUMÉ

Cet article est le troisième et dernier volet de notre série d'abécédaires sur l'amélioration qualitative en matière de diabète. Il résume la façon d'interpréter les données en temps réel à l'aide de diagrammes de progression et met en évidence quatre règles clés pouvant être appliquées pour comprendre si une amélioration est statistiquement significative. Nous examinons également l'importance de définir un ensemble de mesures, y compris des mesures concernant les résultats, le processus et les mesures compensatoires. Enfin, nous discutons de stratégies pour maintenir le changement.

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Introduction

In the first 2 articles of the diabetes quality improvement (QI) primer series (1,2), you were introduced to a client with a missed diabetic foot ulcer, which resulted in the requirement of an urgent below-knee amputation. This critical event served as a platform for assessment of foot-screening processes within your diabetes education program (DEP). It triggered you to perform a baseline gap analysis, during which you found that only 35% of your clients were having annual foot assessments, a number well below the national average. As the clinic manager, you assembled a QI team to engage in a project to improve care gaps. You performed a root-cause analysis using QI diagnostic tools to identify factors leading to low screening rates, and 3 main problems were identified: 1) lack of training in how to perform foot examinations; 2) lack of time to complete the assessments; and 3) no reminder system to trigger awareness of when a foot examination should be performed. You then mapped your change ideas to these problems.

How Can You Tell Whether the Changes Are Resulting in Improvement?

In QI, it is essential to track data over time while testing change ideas. A run chart is an effective way to understand whether change has resulted in improvement. It records the frequency of a quality measure over time and is easy to construct and to interpret (3,4).

The Health Care Data Guide (4) summarizes key steps in the creation of a run chart. An adapted version is summarized here:

1. Identify the measure that will be examined and label it on the y-axis (the vertical axis).
2. Identify the time scale (e.g. days, weeks, months, years) and label it on the x-axis (the horizontal axis).
3. Plot the data points.
4. Connect the dots with straight lines.
5. Add the median line: use the baseline data (i.e. the data prior to the implementation of the improvement plan) to create the median line, freeze it, and extend it forward. In order to apply the run chart rules (outlined below), the median must be created using 10 or more data points (4).
6. Add the target line, a pictorial representation of your aim.
7. Draw arrows and add boxes explaining when change ideas were implemented.

A run chart can be created using pen and paper or may be constructed electronically using Microsoft Excel or a similar program. For those with a special interest, QI macros for Excel, which possesses a special run chart function, can be purchased online (5,6).

Your QI team meets to create a run chart showing the rate of foot screening in the DEP. You plan to track the monthly rate of screening over a 2-year period as your improvement plan is rolled out. Figure 1 shows the completed run chart with your 3 change ideas highlighted by yellow arrows. Data points 1 through 10 represent your baseline data, prior to implementation of change ideas. The y-axis is your outcome measure, the percent of eligible clients who completed foot screening at the previous visit, and your x-axis is the time scale in months. The median line is set at 35%, which was derived from your baseline data. The target line is drawn at 80%, which demarcates the aim you specified at the start of your project and which is described in the first article (1).

Is the Improvement Real?

There are 4 main rules of probability-based testing that may be applied to your run chart to confirm that improvement is not due to chance alone. If 1 of these rules is met, you can conclude that the change you see is significant. It is essential to have 10 or more data points to apply these rules (4,7).

1. Shift: 6 or more points in a row, all above or below the median.
2. Trend: 5 or more points in a row, all in a downward or upward direction.

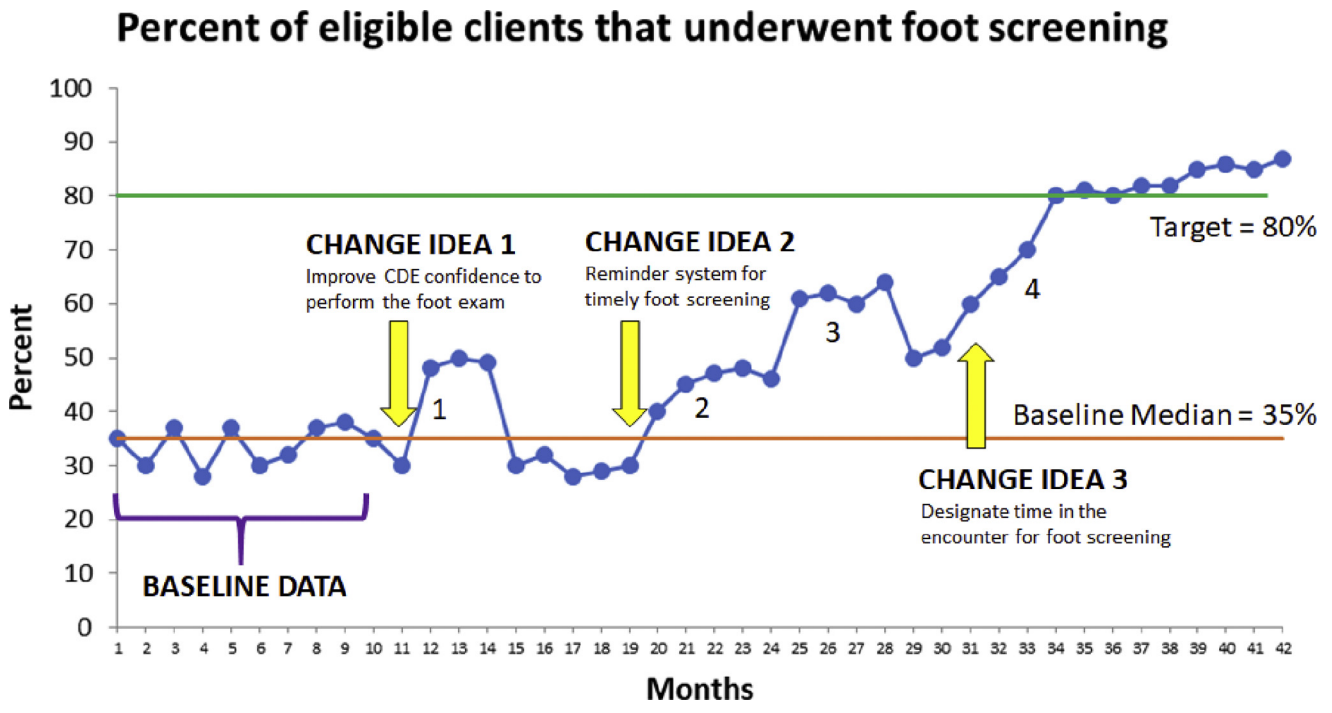

Figure 1. Run chart showing the rate of foot screening in people with diabetes. 1, Initial improvement with regression to the median. 2, Shift in the data set. 3, Steep improvement when paper-based standardized documentation form and reminder system are switched to electronic, with slight dip when consultation rooms ran out of monofilaments, 4, Steady improvement in foot-screening rates after change idea 3 was implemented with trend in data set.

3. Too few or too many runs: a run is a group of points all above or below the median; it does not matter if they all trend in 1 direction. To calculate the number of runs, count the number of times the line crosses the median and add 1. Then review the minimum and maximum number of runs expected, based on the number of data points (4,7,8). You can access the table for assessing whether there are too few or too many runs on the Health Quality Ontario website: http://qualitycompass.hqontario.ca/Documents/EN/Interpreting%20Run%20Charts.pdf. If there are more or fewer runs than specified, this is considered statistically meaningful (i.e. $p<0.05$).
4. Astronomic point: This is a point that is noticeably different from the rest when judged subjectively. Of the 4 rules, this is the only rule that is not probability based.

After your team sets up the run chart and starts plotting points, it is evident that some of the run chart rules are met (Figure 1). Data points 1 through 10 represent your baseline data. The baseline data show a steady state in which none of the run chart rules are met. After change idea 1 at month 11 (improve certified diabetes educator [CDE] confidence in performing the foot examination) has been implemented, you observe initial improvement in the rate of foot screening; however, there is eventual regression toward your baseline performance rate. It is not uncommon to see this type of pattern following the implementation of an education-based change initiative because education-based changes are heavily dependent on human behaviour and are less likely to result in intervention effectiveness (9). In your DEP, you recognize that there was initial enthusiasm for change idea 1. However, it waned over time and was eventually forgotten. In turn, you realize that this type of initiative requires constant attention and repeated educational refreshers in order to be more successful. Therefore, you develop a continuing education program with refresher seminars for all CDEs at 6-month intervals.

After change idea 2 in month 19 (reminder system for timely foot screening) has been implemented, you notice a shift in the data set, with all subsequent data points above the median line. In month 24, your DEP switches to electronic medical records and is able to implement electronic modifications to the initial paper-based system. This results in a dramatic increase in foot screening and an eventual plateau. There is a small dip at month 29, when foot-screening supplies run out in each of the consultation rooms, resulting in screening not being completed. You quickly recognize the problem and solve it by creating a foot-screening box that is placed in each consultation room. A small red flag is attached to the side of each box, and when 3 monofilaments are left in each box, the CDE working in that consultation room raises the flag. A pull system is implemented (10) in which the manager takes on the task of checking the box flags each week. This restores the upward trend in screening toward your aim. At month 31, change idea 3 (designate time in the encounter for foot screening) is implemented and requires multiple plan-do-study-act cycles to reach your aim (summarized in the second article (2)). You achieve your aim of attaining an 80% foot screening rate by month 34, which is 2 years after change idea 1 was implemented.

When reviewing the run chart in its entirety, you do not see evidence of an astronomic point, but there is evidence of too few runs. Your data set has 42 data points; therefore, fewer than 16 runs would be considered too few and more than 28, too many (4,7,8). The line connecting your data points crosses the median line 9 times; therefore, there are only 10 runs on the run chart. The presence of too few runs confirms that the improvement seen is not due to chance alone and is truly significant. It is important to note that if a data point sits directly on the median line, it should not be interpreted as crossing the line (4).

When analyzing data from a QI project, a common pitfall is relying too heavily on pre- and postintervention aggregate data for comparison analyses. For example, if your team had implemented only change idea 1 (improve CDE confidence in performing the foot examination) and had compared the data from months 1 through 10 to months 11 through 14 and stopped collecting data, you may have falsely assumed your intervention had led to sustained improvement. Instead, you were able to learn from your run chart and long-term data collection that, although there was initial improvement, there was regression to the baseline performance from months 15 to 19.

How Do You Know That Improvements Are Due to the Change Ideas You Implemented and Not to Other, Extraneous Factors?

Creating a series of clear measures is an essential part of any QI project. The previous article summarizes the theoretic principles behind outcome, process and balancing measures (1). It is important to design process measures that are directly linked to the implemented change ideas. For example, if none of your CDEs actually completed the training in how to perform the 60-s foot examination, you could not conclude that the first change idea truly contributed to the improvement observed in foot screening (your outcome measure). Balancing measures should also be updated and refined after the change ideas have been clarified, and they should take into account the unintended consequences of the new initiatives. Table 1 highlights process and balancing measures that are linked to each of your 3 change ideas. It is important to note that multiple process and balancing measures can be defined for each change idea. Now that your family of measures has been clearly defined, your project charter (11) is complete (Figure 2).

Like outcome measures, process measures should also have an aim statement and can be tracked over time by using run charts (12). Using change idea 2 (reminder system for timely foot screening) as an example, you decide to track the percent of eligible charts with a 60-s tool completed per week over a 3-month period. You begin by determining the level of performance in this process measure at your DEP after change idea 2 has been implemented, and you set an aim to achieve a level of 90% (Figure 3). You decide that the DEP clinic manager will be responsible for collecting these data. The manager will review all clinic charts for the week, check to see whether the 60-s tool is complete and then calculate a completion percentage. After a 2-month period, you are able to achieve your aim and conclude that the implementation of change idea 2 directly contributed to the overall improvement in the outcome measure. A similar strategy can be applied to each of the process measures defined in Table 1. For each process measure, 1 member of the QI team is selected to be responsible; a timeline for assessment is set, an aim statement is created and a strategy for data collection is established.

How Do You Create an Intervention That Is Sustainable?

Sustaining improvement is 1 of the trickiest parts of any QI project. It has been estimated that 33% to 70% of projects are not sustained over the long term (13,14). Your team has been able to embed changes through routinization (15), and after 2 years, your change ideas are considered second nature by all CDEs.

The 3 key components that were essential to creating sustained improvement in foot screening at your DEP were: 1) thinking about sustainability early; 2) developing an accountability environment; and 3) capitalizing on the concept of standard work and automation.

Table 1
Quality improvement family of measures

	Change idea	Process measure	Balancing measure
1	*Improve CDE confidence in performing the foot examination* Create a standard operating procedure that foot examinations will be performed by CDEs and conduct staff training in how to perform foot examinations	% of CDEs who feel confident or very confident in performing foot screenings	Number of non-foot-screening training sessions offered over a 1-year period
2	*Reminder system for timely foot screening* Use clinical decision support tool (60-s foot screening tool) and integrate reminder system that prompts the CDE to conduct a foot examination (paper-based vs automated)	% of charts with completed 60-s tool over a 1-week period	Average number of counselling topics covered per consultation (including driving, hypoglycemia, sick-day management, alcohol and exercise) over a 1-week period
3	*Designate time in the encounter for foot screening* Adjust workflow so clients are seated in consultation room with their socks off when the CDE walks into the consultation room and ensure that rooms are adequately stocked with required tools to complete the examination	% of rooms with foot-screening signs visible and foot-screening boxes stocked at weekly intervals	Time in min for CDE to complete consultation

Think about sustainability early

The key to sustaining improvement is thinking about it early. At the outset of your QI project, your team considered the National Health System (NHS) model for sustainability (14). This model asks the QI team to consider 10 factors pivotal to the project's sustainability: process, staff and organization. Each category is divided into 4 sections, and specific, nonarbitrary point scores are assigned to each. The NHS Sustainability Model and Guide, including the scoring system, can be found at https://www.aquanw.nhs.uk/resources/academy/NHS%20Sustainability%20Model.pdf (14). A score of $\geq$55 indicates a high chance of sustained success, whereas a score below this threshold means that a great deal of effort is required to sustain the project. Using your project as an example, the following score values were assigned by your team (14).

Process

1. *Benefits*. Your project score = 8.7. This intervention has a wide range of benefits that extend beyond the client. Work flow is streamlined, and the CDE can perform the foot examination in addition to completing the standard assessment and counselling. There are also downstream benefits for the health-care system; for example, early treatment of osteomyelitis may prevent the requirement and financial cost of an urgent below-knee amputation.
2. *Credibility*. Your project score = 9.1. Leadership engagement existed at the outset of the project and triggered the development of this QI project. Evidence exists in the literature that increasing foot screening can lead to decreased occurrences of amputation (16). All CDEs at your DEP believe in the benefits of foot screening and can describe them.
3. *Adaptability*. Your project score = 3.4. The intervention is built on the premise that CDEs are educated in how to perform a foot examination. If individuals leave the organization, their replacements will require training to ensure that the project continues. The addition of an electronic prompt within the EMR indicating when foot screening is due increases its adaptability and significantly adds to sustainability, even if there are staffing changes.
4. *Effectiveness of monitoring system*. Your project score = 3.3. Although the monitoring system for lower-limb amputations is supported beyond the end of the project through data generated by the regional health network, the rate of monthly foot screening is generated at the DEP by the clinic manager, and it is time consuming. The results are communicated to all members of the DEP through regular meetings and creation of a performance board (Figure 4).

Staff

1. *Staff training*. Your project score = 11.4. Frontline CDEs were involved in the development of the QI plan, and everyone was provided education in how to perform the 60-s foot examination. If gaps are identified in the ability of a CDE to perform the foot examination, the clinic manager recommends that they attend a refresher training session.
2. *Staff behaviours*. Your project score = 11. CDEs' ideas were frequently tested and incorporated into the change initiative. The idea of creating a foot-screening toolbox with a pull-system was the idea of 1 of the registered dietitians in your clinic. All staff members are empowered and believe that the improvement will be sustained.
3. *Senior leadership engagement*. Your project score = 5.7. Senior leadership from the regional health network was supportive of the change intervention but was not involved in the planning or development of the QI plan. As the DEP clinic manager, you were the individual with the most influence over project development.
4. *Clinician leadership*. Your project score = 15. As the leader of the DEP, you are well respected by all CDEs. You worked previously as a diabetes educator within the clinic and are very knowledgeable. You have been effective at ensuring the successful roll-out of the change interventions and have been respectful of all opinions and ideas brought forward at your monthly QI team meetings.

Organization

1. *Fit within the organization's strategic aims and culture*. Your project score = 3.5. Improving the rate of foot screening to prevent lower-limb amputation is a strategic aim for the regional health network. Prior to the development of this project, the DEP had not participated in a QI project and, therefore, successful sustainability has not yet been observed at the local level.
2. *Infrastructure for sustainability*. Your project score = 9.7. Training and resources support the new system. DEP policies and procedures have been updated to mandate foot screening as part of the CDEs' responsibilities.

Title: Improving foot screening	**Scope/boundaries**: Foot screening within the DEP
Team: **Executive sponsor**: diabetes program manager, regional health network **Team lead/process owner**: DEP manager **Team members**: certified diabetes educator, chiropodist, primary care physician, clerical staff, client advocate	**Problem statement/reason for improvement**: Our regional health network has a higher rate of amputations than other networks in the province. There are many contributing factors to amputations, but timely foot screening is an important component that is not done well at our DEP. Baseline chart reviews reveal that the rate of annual foot screening is approximately 35%, which is below the national reported rates of 50%.
Aim statement: To increase the percentage of clients with documented foot examinations from 35% to 80% by 2 years from the start of the QI project	**Measures**: Outcome and balancing: **Outcome**: % of eligible clients who had a documented foot examination at their last appointment **Balancing**: 1. Number of non-foot-screening-related training sessions offered over a 1-year period 2. Average number of counselling topics covered per consultation (including driving, hypoglycemia, sick-day management, alcohol and exercise) over a 1-week period 3. Time in min for CDE to complete consultation

Root causes of the problem:	**Change ideas**:	**Process measures**:
1. Lack of training in how to do foot examinations	Change work environment: Policy that all CDEs can perform foot examinations Educational outreach visits from chiropodist to train CDEs on 60-s tool	% of CDEs who feel confident or very confident in performing foot screenings
2. No reminder system for when to conduct a foot examination	Manage variation: Clinical decision support and automated reminders built into EMR based on 60-s foot tool	% of charts with completed 60-s foot examination forms over a 1-week period
3. Lack of time to perform foot examination	Improve workflow: Signage for client signs, foot examination first, replenish foot-screening boxes	% of rooms with foot-screening signs visible and foot-screening boxes stocked over a 1-week period

Anticipated barriers and mitigation strategies: 1. Lack of monetary resources to provide training sessions to CDEs • Mitigation strategy: Regional health network to provide funding for educational sessions with chiropody outreach 2. Long delay to set up reminder system and clinical-decision support tool in EMR • Mitigation strategy: Engage EMR vendor early to adapt EMR; start off by using a paper-based system. 3. Lack of support and time for data collection • Mitigation strategy: Regional health network to highlight foot screening as a priority and support clinic manager in data collection and interpretation	**Anticipated timeline/key milestones**: Change idea 1: • First education class = month 11 Change idea 2: • Paper-based 60-s tool and sticky-note reminder system to be rolled-out = month 19 • EMR 60-s tool and automated reminder system = month 24 Change idea 3: • Signs prepared for client education and assessment performed at start of consultation = month 31 Spread of project to local DEPs: • Champions from DEP to assist in spread of initiative to 2 other DEPs in the regional health network = 1 year after aim achieved
Resources required: 1. Chiropodist to teach foot examination (time and physical location within DEP) 2. Paper and sticky-notes for paper-based reminder system 3. EMR vendor to incorporate 60-s tool and reminder system into EMR 4. Paper signs and stickers for educational signs 5. Monofilaments and container for each foot-screening box 6. Time for manager to create signs and to monitor foot-screening boxes at weekly intervals 7. Time for DEP QI team to attend monthly meetings 8. Time for manager to collect data on measures 9. Support from regional health network for data interpretation and display	**Signatures**: Executive sponsor: _____ Process owner: _____

Figure 2. Completed project charter. *CDE,* certified diabetes educator, *DEP,* diabetes education program; *EMR,* electronic medical records; *QI,* quality improvement. *Note:* See reference (11).

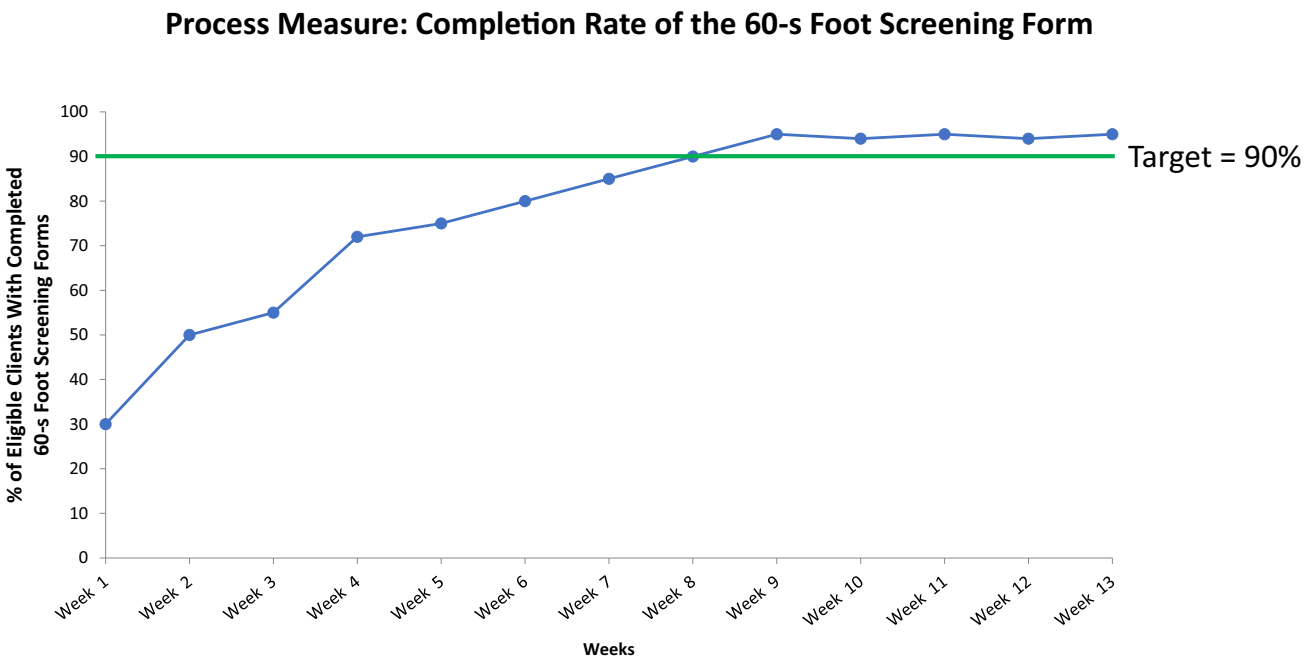

Figure 3. Run chart showing the completion rate of the 60-s tool.

Overall, your team calculates a score for your project of 80.8, which indicates a high level of certainty that your QI plan will be sustainable over the long term. If your score had been lower than 55, you would have adapted your plan in order to position yourselves for success at the outset of the project.

Create an environment of accountability

Individual accountability is required for the long-term success of any project. This can be achieved in 2 main ways:

1. *Make the process visible*. Performance boards are commonly used in QI work. Their main goal is to communicate the quality problem, goal and outcome to all staff (17). When creating a performance board, there are 5 main questions that should be considered and answered in the affirmative: 1) Is it simple? 2) Can I see it easily? 3) Are outcome and process measures displayed? 4) Can I tell from a glance whether we are improving? 5) Is it actionable? This means that if a problem is identified, is it clear that a plan has been created to remedy the situation (18,19)? Typically, performance boards are updated at regular intervals by senior leadership. They should always include the aim, the run-chart and the plan for future activities.
Figure 4 demonstrates the performance board created by your team for foot screening. As the manager of your DEP, you take on the responsibility of updating the performance board at monthly time intervals. The performance board is placed in a high-traffic area, where all staff can easily see the information,

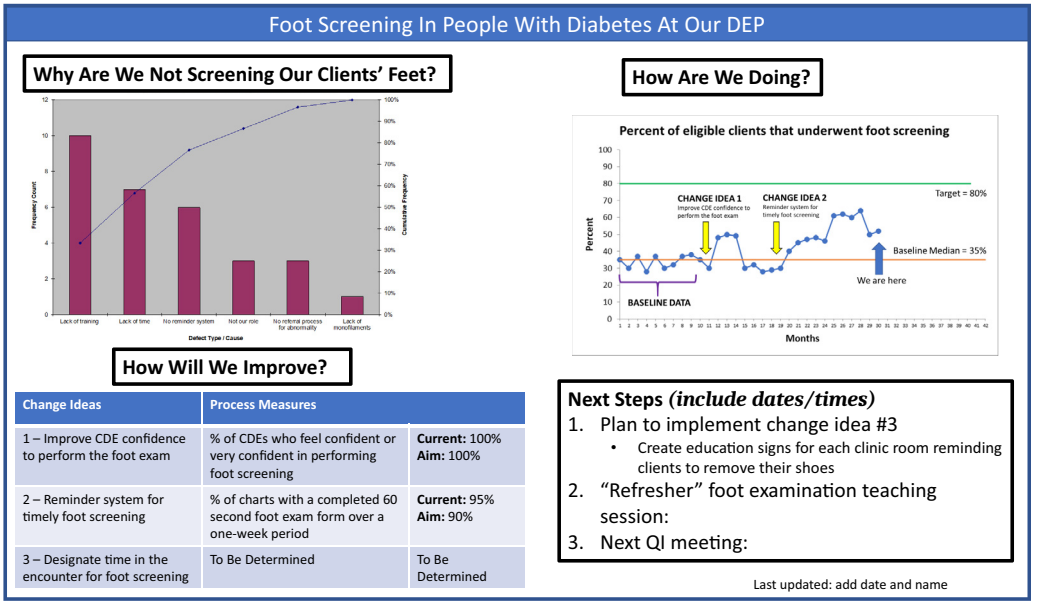

Figure 4. Performance board. *DEP*, diabetes education program; *QI*, quality improvement.

which allows them to keep score of progress. A culture of transparency is created, enabling all staff to take ownership of the project and ensure sustainability.

2. *Team huddles*. Huddles are regular staff meetings that are designed to review the progress of a QI project (20). The 4 main components of a huddle are: 1) report on commitments made at the last meeting; 2) review the performance board; 3) brainstorm reasons for performance results; and 4) make personal and team commitments for the future. Step 4 is essential for creating an environment based on accountability (19).
   At your DEP, you decide that huddles will be held at monthly intervals, will run for 15 min and will take place in front of the performance board. At your first meeting, the team establishes rules for the upcoming meetings (e.g. no cell phone use during the huddle). You follow the standardized 4-step scheme, as detailed above. As the manager, you update the run-chart data before the meeting and 1 of the CDEs takes on the responsibility of documenting the next steps that are decided during each meeting. You are able to develop all of your change ideas during these huddles and, eventually, fine-tune them through multiple plan-do-study-act cycles.

Capitalize on the concept of standard work, and automate when possible

Standard work is a Lean principle, in which the main tenet is to minimize waste (18,21); it involves reducing process steps to a series of value-added activities that occur in a specific sequence (10). At your DEP, change idea 3 (designate time in the encounter for foot screening) was aimed at streamlining the foot-screening process so as to ensure that all client encounters are consistent and timely; this in itself is a technique for sustainment.

The automation of the 60-s documentation form and reminder system is also a strategy for embedding change into the standard workflow and making it sustainable. As previously mentioned, the hierarchy for intervention effectiveness shows that automation is a strategy that is ranked as being more likely to lead to real and sustained change (9).

What Are the Next Steps?

Your QI project has proven to be feasible at a single community DEP and has been sustainable over an 8-month period. You will continue data collection to assess whether your intervention is sustainable over a prolonged period of time.

Given the success of your intervention, you intend to disseminate your initiative to other DEPs within your regional health network. Members of your team will assist in the local adaptation of the initiative by these institutions. Rates of diabetic foot ulcers, as a distal outcome measure, will be closely monitored within your network, with the expectation that these rates will eventually decline.

Conclusions

We hope that this primer series has provided you with a general approach for developing, implementing, measuring and sustaining a QI initiative. This methodology can be used to tackle a wide range of quality problems and can be applied to both large- and small-scale projects. If you are interested in further expanding your QI knowledge, you could consider completing 1 of the online courses offered by the Institute of Healthcare Improvement or Health Quality Ontario (22,23).

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Author Contributions

JG conceived, designed and drafted the manuscript; IJH, GM and PS contributed to the conception and editing of the manuscript. All authors read and approved the final manuscript.

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