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Special Series — A Primer in Quality Improvement

Determining Root Causes and Designing Change Ideas in a Quality Improvement Project

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Key Messages

- Prior to initiating changes, it is important to understand the root causes of a quality problem.
- Change ideas should be directly related to the root causes of a quality problem.
- Change ideas should be iteratively evaluated and improved upon using small-scale plan-do-study-act cycles.

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ABSTRACT

In this second article of our diabetes quality improvement primer series, readers will become familiar with various diagnostic tools used to understand the root causes of a quality problem. We discuss change concepts, and specific change ideas are developed to match the root causes. We review the application of a plan-do-study-act cycle from the Model for Improvement quality improvement framework to test 1 change idea and measure for the intended improvements.

RÉSUMÉ

Dans ce deuxième article de notre série d'introductions sur l'amélioration de la qualité des soins du diabète, les lecteurs se familiariseront avec les divers outils diagnostiques utilisés pour comprendre les causes fondamentales d'un problème de qualité. Nous discutons de concepts de changement et nous élaborons des idées particulières de changement qui s'harmoniseront aux causes fondamentales. Nous passons en revue l'application du cycle penser-démarrer-contrôler-agir du cadre d'amélioration de la qualité « Modèle d'amélioration » pour vérifier 1 idée de changement et la mesure des améliorations visées.

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Introduction

In the first article of this primer series, you were introduced to a client in a diabetes education program (DEP) who underwent an amputation for an infected foot ulcer. It was determined that the patient had been seen a few weeks earlier at the DEP, and no foot screening had been performed. This critical incident leads you, the manager, to embark on a quality improvement (QI) project. Although there are many contributing factors to amputations, timely foot screening is an important component that was not being performed well at your DEP. Baseline chart reviews showed that the rate of annual foot screening was around 35%, well below the national reported rates of 50%. You assembled a QI team consisting of 2 certified diabetes educators (CDEs), a primary care physician, a chiropodist, a patient advocate and 1 clerical staff member. The aim statement is: To increase the percentage of clients with a documented foot examination from 35% to 80% by 2 years from the start of the QI project.

How Do You Identify the Root Causes of a Quality Problem?

Your team convenes a meeting, eager to start piloting some change ideas to improve rates of foot screening within the DEP. However, 1 of the CDEs attended a workshop on the Model for Improvement at the last Diabetes Canada meeting, and she remembers the importance of doing a deeper dive into the root causes of the problem before rushing to implement change ideas. She suggests you start with a fishbone (or Ishikawa) diagram (1). First made popular by Kaoru Ishikawa, a Japanese organizational theorist, the Ishikawa cause-and-effect diagram is used to understand the complex contributing factors to a quality problem. The quality problem is represented by the "head of the fish," or the effect drawn at the far right of the page. The spine of the fish has multiple ribs with various categories or causes. Some of the commonly used categories to clarify quality problems in health care include patient, provider, system, policies and procedures, physical environment/equipment and organizational culture. The team spends some time brainstorming possible causes for their low rate of foot screening and allocating them to categories so as to construct a preliminary Ishikawa diagram (Figure 1).

Once root causes are identified, Pareto charts can help to identify where to focus improvement efforts. Originally used to describe the distribution of wealth in a population, in quality improvement, the Pareto principle dictates that 80% of the problem can be attributable to 20% of the causes (2). To determine the frequency of various contributing causes, the process of interest is observed by using a defect check sheet, simply a list of all the causes, with space to place checks each time that defect is witnessed during the process. As detailed in the first article of this series (How to Begin a Diabetes Quality Improvement Project) (3), the number of times the process needs to be observed depends on the baseline performance. If 10 to 20 charts are audited, then the process should be observed 10 to 20 times to determine the contributing causes. When the process occurs less frequently and would take a significant amount of time to observe, an alternative is to do a group prioritization exercise in which all relevant stakeholders are given 3 votes to identify the contributing causes they think are most frequent and relevant. Because some of the contributing causes are not observable but, rather, need to be reported by the diabetes educators and patients, the QI team opts for a group prioritization exercise. All the causes from the Ishikawa diagram are listed on the wall, and each stakeholder is given 3 sticky notes to vote for what they feel contributes most to low rates of foot screening. Once the frequency of the various causes has been identified, it is plotted as a bar graph, with the x-axis detailing the causes and the left-sided y-axis demonstrating the frequency count. Each contributing cause is added up, creating a cumulative percentage, and a line graph that connects the cumulative percentage (right-sided y-axis) is drawn. At the point where the line graph hits 80%, you can identify the areas on which to focus improvement efforts. Your QI team builds its Pareto chart (Figure 2), which reveals that 80% of the problem appears to be due to 3 root causes: lack of training, lack of time and lack of reminder systems. Identifying these 3 main root causes allows your QI team to focus on improvement efforts to address the main factors for inadequate foot screening within your DEP.

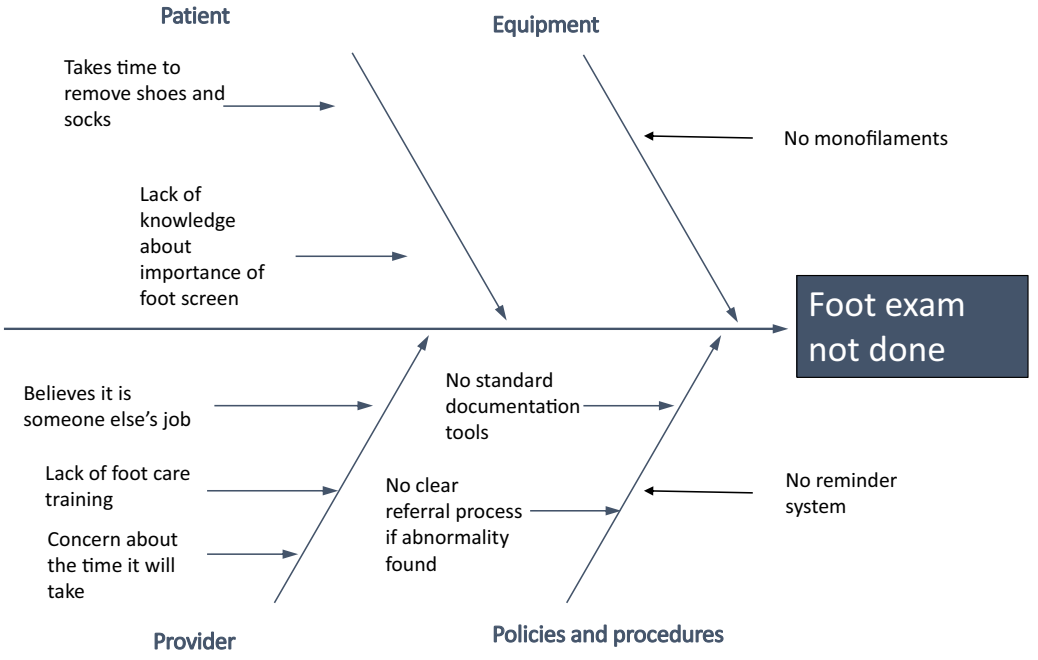


Figure 1. Ishikawa diagram.

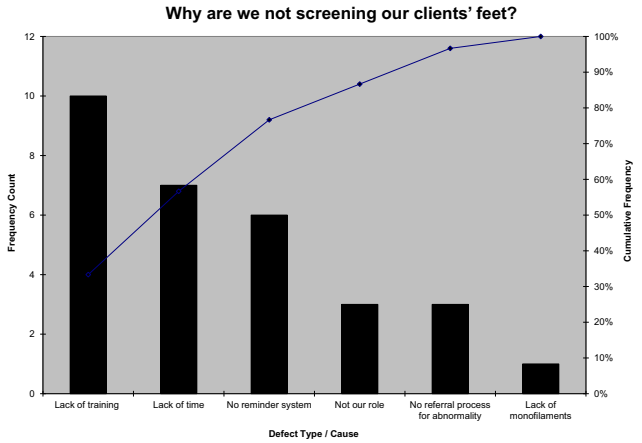


Figure 2. Pareto chart.

What Changes Will Lead to an Improvement?

Through the use of diagnostic tools, including the Ishikawa diagram and Pareto charts, improvement teams can develop a theory about the changes that will be necessary to achieve their aim. The factors or components of a system that influence the achievement of the aim are called *drivers* (4). Drivers can be thought of as the actions needed to tackle the root causes of the quality problem. Primary drivers are those actions that will directly influence the aim, while secondary drivers are required for primary drivers to be successful. The creation of a driver diagram allows for a visual display of this change theory and often identifies the appropriate process measures for monitoring adherence to change ideas. The driver diagram should be visited often during the planning phases of the project. The diagram evolves as change ideas are tested out and refined through plan-do-study-act (PDSA) cycles (more on this later). Box 1 lists some tips for drawing a driver diagram. Figure 3 shows the driver diagram for our project. Note that problems identified through the Ishikawa and Pareto diagrams are all present in the diagram but are now reorganized into positive actions that can help move the team toward achieving its aim.

Box 1. Steps for designing a driver diagram (4)

1. Agree on the project aim (what will be improved, by how much, for whom, by when).
2. Brainstorm all of the system's elements, or drivers, that team members feel are necessary to achieve the aim or are likely to affect it. Don't worry about whether drivers are primary or secondary at this point.
3. Logically group the drivers, and define high-level headers that summarize the groups. The headers will be the primary drivers. The grouped items will be the secondary drivers associated with each primary driver.
4. Check the drivers for duplicates, clarity, missing elements and team consensus.
5. You can now draw connecting arrows showing the cause-and-effect relationships. The effect is the aim at the far left, the primary drivers cause the aim, and the secondary drivers cause the primary drivers. You may have multiple secondary drivers, but they should not lead to more than 1 primary driver.
6. You are now ready to define the interventions or strategies (the "hows") that you will use to have an impact on the various drivers.
7. You can also define project measures for tracking progress, to test and modify your theories for improvement and to monitor for overall project effectiveness.

Tip: Often, when causes in a system are well known, it is easier to first identify the primary drivers and then identify the secondary drivers that are key elements of each primary driver. When the drivers are less defined and the approach is more innovative, brainstorming often works well to help define the drivers.

What Is the Difference Between a Change Idea and Change Concept?

A change idea is an actionable idea for changing a process. A change concept is an overarching notion within which a specific change idea may fall (5). The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (6) identifies 9 main change concepts for improving health care: 1) eliminating waste; 2) improving workflow; 3) optimizing inventory; 4) changing the work environment; 5) enhancing the consumer relationship; 6) managing time; 7) managing variation; 8) designing the system to avoid mistakes; and 9) focusing on a product/service. Improvement teams should assess their root causes and driver diagrams to identify which change concepts are best suited to achieve the drivers.

Your QI team reads about the different change concepts and identifies that changes in the work environment, managing variations and improving workflow will best address the primary drivers of your quality initiative. For each change concept, the team then designs specific change ideas that align with the secondary drivers. In reality, the process of identifying change concepts, designing change ideas and finalizing the driver diagram is a fluid process. The driver diagram will change over time as the change ideas are tested out and refined. Table 1 outlines the root causes, change concepts and change ideas proposed by you and your improvement team.

Changing the work environment

This change concept involves investing resources in improvement, education and cross-training of staff and removing barriers to optimal behaviours. The intent is to give people access to information in order to improve the system. Changing the work environment includes creating a standard operating procedure ensuring that the CDEs understand that foot examinations are within their scope of practice and providing training that will improve CDE confidence and self-efficacy to perform foot screening.

Managing variation

This change concept involves developing operational definitions and standardizing procedures to minimize the chances that something is done incorrectly or is omitted. Introducing a standardized tool and reminder system for foot screening will decrease practice variation and increase foot screening.

Improving workflow

This change concept involves eliminating wasteful steps in the process, identifying and removing bottlenecks and moving steps in the process closer together. By improving workflow and ease of

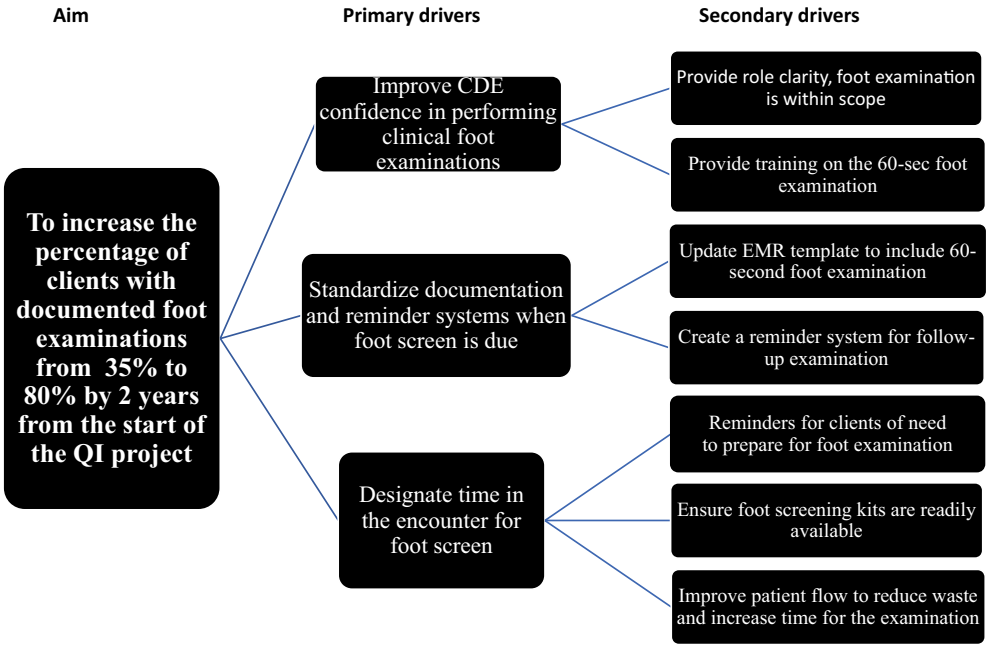


Figure 3. Driver diagram. *CDE*, certified diabetes educator; *EMR*, electronic medical records; *QI*, quality improvement.

conducting foot examinations, there should be more time to perform foot examinations without sacrificing other important aspects of the patient/CDE encounter.

Another important concept when selecting change ideas is to understand the hierarchy of effectiveness of QI interventions (7,8). This is a risk management theory that rates interventions related to human behaviour (e.g. education and training) at the lower end of its scale and technologic interventions (e.g. forcing functions and automation) as higher leverage actions that result in sustainable system change rather than relying on individuals to do the right thing. As an example of a forcing function, highly concentrated insulin (300 u/mL) is not available in a vial so that a double dose cannot be administered in error. This theory recognizes that education and policy changes are necessary but not sufficient to realize sustainable improvements.

How Do You Use PDSA Cycles to Implement and Refine Your Change Ideas?

Change ideas that make up a QI intervention need pilot testing and iterative refinements until the team has confidence that the change idea is having the desired impact. PDSA cycles (6) can be used to test change ideas during rapid-cycle improvement efforts. They may be very small, involving only a few patients on a single day. The team should make a prediction (plan), test that prediction (do), assess the impact (study) and use the results to refine the intervention (act). It is important to understand that 1 QI project is made up of a few change ideas, and each change idea is designed and refined using many rapid PDSA cycles.

Change idea 1: Improve CDE confidence in performing clinical foot examinations

The first change concept your team employs is changing the work environment. The team predicts that by increasing access to information through training and by removing barriers to optimal performance, CDEs' confidence and self-efficacy in performing an examination should improve. The first area of concern identified by the QI team is role clarity; a perceived barrier during the root cause analysis was uncertainty about foot examinations' being within scope of practice for all CDEs, regardless of professional background. You ask the nurse and dietitian to contact their respective professional colleges, and you confirm that, with adequate training, a foot examination is within the scope of any health care provider who is also a certified diabetes educator (9).

The chiropodist on the team offers to provide training, but the CDEs are concerned that his approach to a foot examination will be too thorough for their time constraints. Upon reviewing the literature, the chiropodist identifies 2 standardized tools for performing rapid foot examinations, the Diabetes Canada Guidelines (10) and

Table 1
Root causes, change concepts and change ideas

Root cause	Change concept	Change idea
Lack of training in how to do a foot examination	Changing the work environment	• Create a policy that all CDEs can perform foot screening. • Provide adequate training using education outreach visits.
No reminder system for when to conduct a foot examination	Managing variation	• Use clinical decision support tool: 60-sec foot examination tool • Build automated reminders based on the results of the 60-sec tool.
Lack of time to perform foot examination	Improving workflow	• Adjust workflow so patients are seated in consultation room with their socks off when the CDE walks into the room to start the consultation. • Ensure rooms are adequately stocked with requested tools for completion of the examination.

Table 2
PDSA cycles for change idea 2: Reminder systems for timely foot examinations

PDSA #1	PDSA #2	PDSA #3
CDE staff are tasked with placing a reminder sticker on the chart for when the next foot examination is due.	Pop-up box occurs when a new encounter is opened on the EMR.	The EMR vendor is able to create a push function so that, based on the score of the 60-sec tool, the next time an examination is due, it will automatically appear on the screen when the encounter is open.
Plan (hypothesis): The stickers will alert the clinician to do the foot examination.	Plan: By providing a reminder to the CDEs to check when the next examination should be due and keeping it in the EMR, there should be more consistent completion of the reminder form, and it won't get lost.	Plan: By removing a step in the workflow for busy clinicians, there is less room for human error.
Do: Differently coloured stickers are used to denote when the next examination is due.	Do: A pop-up box alerts the team member to select when the next screen is due after completing the 60-sec tool.	Do: As above.
Study: Some CDEs forget to the place the sticker on; it is not always in a consistent place in the chart and sometimes falls off.	Study: There is an improvement, but it is not a fully automated reminder system because the clinician still needs to tick a box, and when people are busy it can be skipped.	Study: The reminder system works seamlessly within the work flow, with the remaining barrier being time within the encounter to complete the examination when patients may have competing priorities.
Act: The team contacts the electronic medical records vendor to create a pop-up box that will prompt the CDE to check when the next examination is due.	Act: See PDSA #3.	Act: The next change idea will focus on designating time within the encounter for foot examinations.

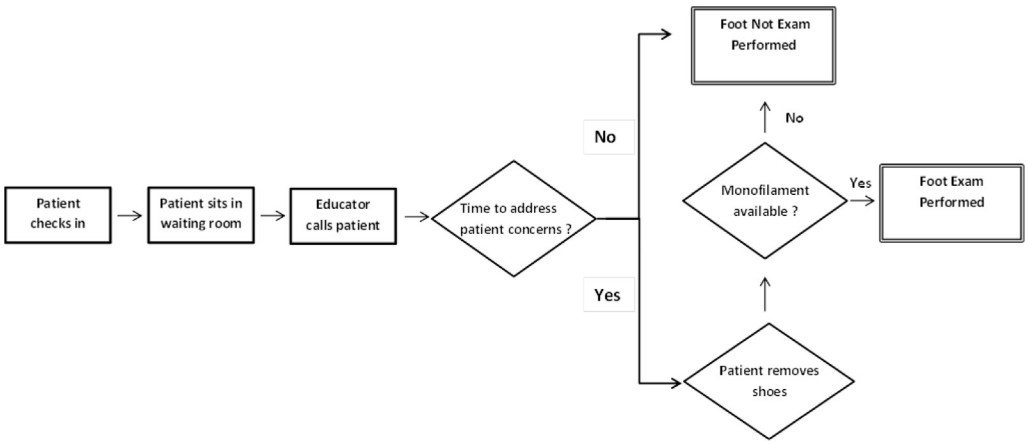
CDE, Certified diabetes educator; *EMR*, electronic medical records; *PDSA*, plan-do-study-act.

the 60-sec tool for foot screening (11). The team reviews both tools and chooses the 60-sec tool, which includes both patient-reported and objective findings and creates a risk-stratification score that directs the clinician when to make a specialty referral and how often to repeat the examination.

To improve the effectiveness of training as a QI intervention, the team looks to the literature concerning educational outreach or academic detailing. A 2007 Cochrane systematic review of more than 60 studies assessing the impact of educational outreach on improvement in clinical practice showed modest but significant improvement in the desired outcomes (median risk difference of 5.6%, IQR 3.0% to 9.0%) (12). An important component of the educational outreach visits is that they occur over time and provide specific feedback on performance. The team plans 2 different training sessions focusing on the 60-sec tool; they include practicing on volunteer patients as well as twice-yearly educational outreach sessions with the chiropodist.

Change idea 2: Reminder system for timely foot screening

By selecting a structured tool that includes clinical decision support (CDS) to guide foot assessments and by designing a



Steps to process mapping
1. Gather a team that considers the perspective of all stakeholders, including patients/clients.
2. Define where the process starts and ends:
   - Start=client checks into the clinic
   - End=foot examination is completed.
3. Use sticky notes to write down each step in the process.
4. Use rectangular boxes for linear steps.
5. Use diamonds for decision points in the process.
6. Discuss various scenarios as a team, and rearrange the steps until the most frequent current step process is mapped.
   - Focus on the current state , *not* the ideal state.
7. Reflect on steps that don't add value and see if they can be removed.

Figure 4. Process map.

Box 2. PDSA cycles for change idea 3: Designate time in the encounter for foot screening

PDSA #1	PDSA #2	PDSA #3	PDSA #4
Front desk admin puts patients in room and reminds them to remove their shoes.	Front desk directs patients to open room; a sign on the wall reminds patients to take off their shoes.	Add a sign on the floor and 1 on each wall.	Signage changes to say, "If you are overdue for a foot examination, we will do this first today."
Plan (hypothesis): If patients are already in room, more time can be spent on clinical care.	Plan: Patients will take off shoes before CDE enters the room, which will also prompt CDE to remember to do examination.	Plan: More signage should remind patients to remove their shoes.	Plan: Spending 2 min at the beginning of the encounter will be easier than cutting the patient off at the end.
Do: Admin directs patients to the room and reminds them to remove their shoes.	Do: As above.	Do: As above.	Do: As above.
Study: Admin is not available to check patients out, and some leave without booking follow-up appointments.	Study: Many patients don't see the sign.	Study: About 80% of patients take off their shoes, but as soon as CDE walks in they want to talk about their concerns, so there is still not enough time for the examination.	Study: 70% of patients got foot examinations. Monofilaments hadn't been refilled in the rooms of those who did not.
Act: Team feels this is not a sustainable change.	Act: See PDSA #3.	Act: See PDSA #4.	Act: Create a refill system so when the last monofilament is used, a sticker is sent back to the front desk with the patient.

reminder system for when the next foot examination is due, you are using the change concept called *managing variation*. The 60-sec tool is a paper-based structured tool that generates a risk score; it includes CDS with specific recommendations for screening intervals and referrals to a foot specialist based on the risk score. CDS has been defined as a process for enhancing health-related decisions and actions, point-of-care prompts that integrate patient information, and clinical evidence (13). CDS encompasses a variety of tools, including alerts and reminders for patients and providers, clinical guidelines, order sets and documentation templates, all aimed at managing variation in health care and improving compliance with best practices (14). A systematic review of 28 studies showed that computer reminders as a QI intervention had a modest but statistically significant impact on adherence to guideline-based recommendations. Using the best outcome from each study, Shojania et al (15) found that the median improvement was 5.6% (IQR 2.0% to 19.2%).

Like CDS, automated reminders have been shown to help improve adherence to evidence-based guidelines in diabetes care (16). PDSA cycles can be more difficult when dealing with information technology solutions because the programming is outside the control of the improvement team. It is often a good idea to pilot a low-tech version of a reminder system prior to investing time and resources into a high-tech version; Table 2 shows the PDSA cycles used to refine and improve the reminder system. It is important to note how small each PDSA cycle is; each change idea in a QI project can be made up of many PDSA cycles that build upon each other to optimize that change idea. The PDSA cycles are used to ensure that each change idea has its intended impact and is implemented in a sustainable way without creating unintended consequences.

Change idea 3: Designate time in the encounter for foot screening

In health care, there are many steps in a process which, though they seem important, may not be critical to achieving the final goal. The process of identifying and eliminating wasteful or non-value-added steps within a process is known as Lean process improvement. Lean process improvement was initially used to improve production on the Toyota Car Company assembly lines in Japan (17) and is aligned with the change concept of improving workflow.

Your improvement team decides to try applying a Lean approach to create more time for foot screening, without lengthening the time of each appointment, by eliminating wasteful steps. The first step in determining "waste" is to construct a process map. A process map can be a useful tool for identifying root causes of quality problem areas for improvement. Figure 4 outlines the steps to successful process mapping and shows the process map designed by the DEP project team.

The process map identifies that the time the patient spends checking in and then sitting in the waiting room are not adding value to the desired outcome. Your team decides to try some very rapid tests of change. Over the course of 1 week, you are able to improve your workflow and create more time in the encounter to focus on a foot examination. Box 2 outlines these rapid PDSA cycles.

Conclusions

In this second installment of the diabetes QI improvement primer series, we have reviewed the diagnostic tools that can be helpful in identifying root causes of a QI problem and how a driver diagram can help to organize the root causes into a theory for improvement. Change concepts can be applied to the primary drivers and can act as a framework for designing change ideas. Change ideas should be focused on improving the secondary drivers and should be piloted using small-scale PDSA cycles to ensure that the change is leading to the desired outcome. As the project evolves, the project charter is continually updated (Figure 5). In the final article in this series, the reader will learn how to monitor for improvement using a family of measures for monitoring change over time and how to sustain and spread improvements (18).

<table>
<tr><td colspan="2">Title: Improving Foot Screening</td><td colspan="2">Scope/Boundaries: Foot screening within the Diabetes Education Program (DEP)</td></tr>
<tr><td colspan="2">Team
Executive Sponsor: Diabetes Program Manager, Regional Health Network
Team Lead/Process Owner: DEP manager
Team Members: Certified diabetes educators, chiropodist, primary care physician, clerical staff, client advocate</td><td colspan="2">Problem Statement/Reason for Improvement:
Our regional health network has a higher rate of amputations than other networks in the province. While there are many contributing factors to amputations, timely foot screening is an important component that is not done well at our DEP. Baseline chart reviews reveal the rate of annual foot screening is approximately 35%, which is below the national reported rates of 50%</td></tr>
<tr><td colspan="2">Aim Statement: To increase the percentage of clients with a documented foot exam from 35% to 80% by 2 years from the start of the QI project.</td><td colspan="2">Measures – Outcome and Balancing
Outcome: % of eligible clients who have a documented foot examination at their last appointment
Balancing: To be determined</td></tr>
<tr><td>Root Causes of the Problem:</td><td colspan="2">Change Ideas:</td><td>Process Measures:</td></tr>
<tr><td>Lack of training on how to do foot examination</td><td colspan="2">Change work environment: Policy that all CDEs can perform foot exam. Educational outreach visits from chiropodist to train CDEs on 60-second tool.</td><td>To be determined</td></tr>
<tr><td>No reminder system for when to conduct a foot examination</td><td colspan="2">Manage variation: Clinical decision support and automated reminders built into EMR based on 60-second tool.</td><td>To be determined</td></tr>
<tr><td>Lack of time to perform foot examination</td><td colspan="2">Improve workflow: Signage for clients, foot exam first, replenish foot screening boxes.</td><td>To be determined</td></tr>
<tr><td colspan="2">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
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 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</td><td colspan="2">Anticipated timeline/key milestones:
To be determined</td></tr>
<tr><td colspan="2">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-second tool and reminder system into EMR
4. Paper signs and stickers for educational signs
5. Monofilaments and container for each examination room
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</td><td colspan="2">Signatures:

Executive Sponsor: _____

Process Owner: _____</td></tr>
</table>

Figure 5. Project charter (work in progress). Used with permission from Paula Blackstein-Hirsch, 2018.

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Author Disclosures

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Author Contributions

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

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