Can J Diabetes 43 (2019) 234–240

Contents lists available at ScienceDirect

Canadian Journal of Diabetes

journal homepage: www.canadianjournalofdiabetes.com

Special Series — A Primer in Quality Improvement

Beginning a Diabetes Quality Improvement Project

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Key Messages

- Conducting a baseline gap analysis is essential to clarify the nature and extent of a quality improvement problem prior to implementing changes.
- Understanding the context and engaging the relevant stakeholders can facilitate the success of a quality improvement project.

ARTICLE INFO

Article history:
Received 29 November 2018
Received in revised form
7 February 2019
Accepted 13 February 2019

Keywords:
diabetes
performance improvement
quality improvement
quality of care

Mots clés :
diabète
amélioration de la performance
amélioration de la qualité
qualité des soins

ABSTRACT

There is a large evidence-to-clinical practice gap in diabetes care. Application of quality improvement (QI) strategies can be used to improve gaps in care delivery. In this first of 3 articles in the diabetes QI primer series, we introduce the steps required to plan a QI project by using a case example for improving foot screening of people with diabetes. We review how to select an appropriate QI project, conduct a baseline gap analysis to clarify the QI problem and engage stakeholders to ensure successful implementation. The next 2 articles in the series will focus on root-cause analysis, selection of change ideas to improve care gaps, execution of the QI project using rapid-cycle testing and monitoring to sustain improvement over time.
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RÉSUMÉ

Il existe des lacunes importantes entre les données probantes et la pratique clinique en soins du diabète. Des stratégies d'amélioration de la qualité (AQ) peuvent être appliquées pour améliorer les lacunes dans la prestation des soins. Dans ce 1er article d'une série de 3 de la série d'introductions à l'AQ des soins du diabète, nous présentons les étapes requises pour planifier un projet sur l'AQ à l'aide d'un exemple de cas sur l'amélioration du dépistage du pied diabétique. Nous passons en revue la façon de choisir un projet approprié sur l'AQ, effectuons une analyse initiale des lacunes pour éclaircir le problème de l'AQ et faisons participer les intervenants pour assurer la réussite de la mise en œuvre. Les 2 prochains articles de la série porteront sur l'analyse des causes fondamentales, la sélection des idées de changement pour améliorer les lacunes en matière de soins, l'exécution du projet sur l'AQ à l'aide du processus d'amélioration rapide par cycle et la surveillance pour maintenir l'amélioration dans le temps.
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https://doi.org/10.1016/j.jcjd.2019.02.003

Introduction

Diabetes can result in potentially devastating complications, including adult blindness, amputation and end-stage renal disease (1–3). Optimal management of diabetes can help to prevent or slow the progression of long-term complications (4–6). Despite knowledge dissemination through clinical practice guidelines (7), however, a large evidence-to-clinical-practice gap remains in diabetes care (8,9). Quality improvement (QI) strategies may be used to bridge gaps in clinical care delivery. QI can be broadly defined as real-life changes that will lead to better patient outcomes, better health system performance and better professional development (10). Traditional research, by contrast, is focused primarily on generating new knowledge (11). To engage in QI work, it is essential to have a strong improvement team, a clear evaluation of baseline performance, a good understanding of the scientific evidence so as to apply changes at a local level and to monitor for improvement over time (10).

Many health-care providers may not have adequate training and expertise in the methodology of QI to be able to execute and sustain change. The purpose of this QI primer series is to educate and empower health-care providers to successfully engage in QI efforts. In this first of 3 articles in the diabetes QI primer series, we introduce you to the steps required to start a QI project, using a case example of improving diabetes foot screening (Box 1).

Assembling a quality improvement team

Prior to engaging in a QI project, it is essential that you form a strong improvement team, or working group, consisting of various stakeholders who support the development and implementation of the project. A stakeholder is anyone who has an interest in the project and can influence its success or failure (12). An effective strategy for identifying potential members of your QI team is to brainstorm with interested colleagues and list all the relevant stakeholders who can influence and may be affected by the QI project (13). For this project, you choose to engage in a stakeholder-mapping exercise to identify potential stakeholders for your QI team (Figure 1). You organize all the stakeholders into groups (e.g. patients, various diabetes education program [DEP] providers, etc.) and outline the relationships graphically by using lines or arrows, with the quality problem at the centre of the map. Having a diverse group of stakeholders with varying skill sets and vantage points can support a QI project.

Once stakeholders have been identified, you need to prioritize their involvement in your QI team because it is not feasible to include all relevant stakeholders. A tool you may consider using to prioritize stakeholders for engagement is a power vs. interest grid (Figure 2). Be sure to consider the positions of the stakeholders within the organization and their abilities to exercise change (power) on the x-axis and their interest in the QI problem on the y-axis. This will help to determine who may have a vested interest in the QI project and allow you to assess their abilities to influence others and mitigate issues (12).

Once you have identified all of your stakeholders, consider who will be part of your core QI team, with specific roles that support your project. Generally, this means forming a multidisciplinary team, especially in this case, because diabetes care is most commonly provided in a team-based environment. It is essential to include front-line workers who are directly invested in the project's success and can help to implement changes at the point of care (14). An integral member of the QI team is a team lead, or a process owner, who will oversee the project and ensure its implementation and day-to-day management. You will also need a QI advisor, an individual with QI expertise, who will act as a resource for the team lead. An executive sponsor also needs to be identified; this should be an influential person who can help remove barriers and may provide resources to facilitate the project. A physician champion, especially for hospital-based QI projects, can support the project and may also provide content expertise. Many QI teams will also include patients, who can provide their own unique perspectives; patients are playing increasingly key roles in setting priorities and identifying gaps in health-care delivery (15).

How do you identify the problem?

In selecting which problems will be the focus of your QI efforts, it is essential to consider the following:

1) Is the problem and its potential solutions under your locus of control? The problems that are chosen for QI efforts are more likely to be successful if they are under your group's direct control. For example, a DEP who wishes to improve rates of obtaining reports back from ophthalmologists and optometrists on their patients' diabetes retinopathy screening results may run into challenges because a DEP will have limited control in influencing the practice patterns of health-care providers who work outside of the DEP.
2) What is the degree of feasibility? In considering feasibility, it is important to assess the amount of restructuring that may be involved and the associated costs necessary to conducting your project. For example, if a QI project relies highly on changing the IT infrastructure system of a hospital in order to collect data, the project may run into significant challenges in execution because the QI team may not be able to influence such large changes in the hospital's IT infrastructure.
3) What is the importance of the problem? It is essential to select QI problems that are important to the stakeholders and can affect patients' outcomes (morbidity and mortality) and/or patients' experiences.
4) What is the frequency and scope of the problem? It is important to understand the frequency and scope of a problem because you can have a larger impact on improving care delivery if the problem occurs often and there is a large gap in care delivery.

Box 1. Case

You are a certified diabetes educator and manager of a community diabetes education program (DEP) in a midsized Canadian city (population of 650,000). Using well-defined medical directives, your team provides care for patients with both type 1 and type 2 diabetes who are referred by primary care physicians, general internists and endocrinologists.

Last month, a patient with type 2 diabetes required a right-foot amputation at your local hospital following an infected diabetic foot ulcer. After review, it was noted that this patient was seen 6 weeks earlier at your DEP, but his feet were not examined during the clinical encounter. Your centre currently has no standardized protocols for diabetes foot screening, though foot screening is within scope of practice of the staff within your DEP.

As a result, your DEP decides to undertake a quality improvement initiative to improve the rate of foot screening.

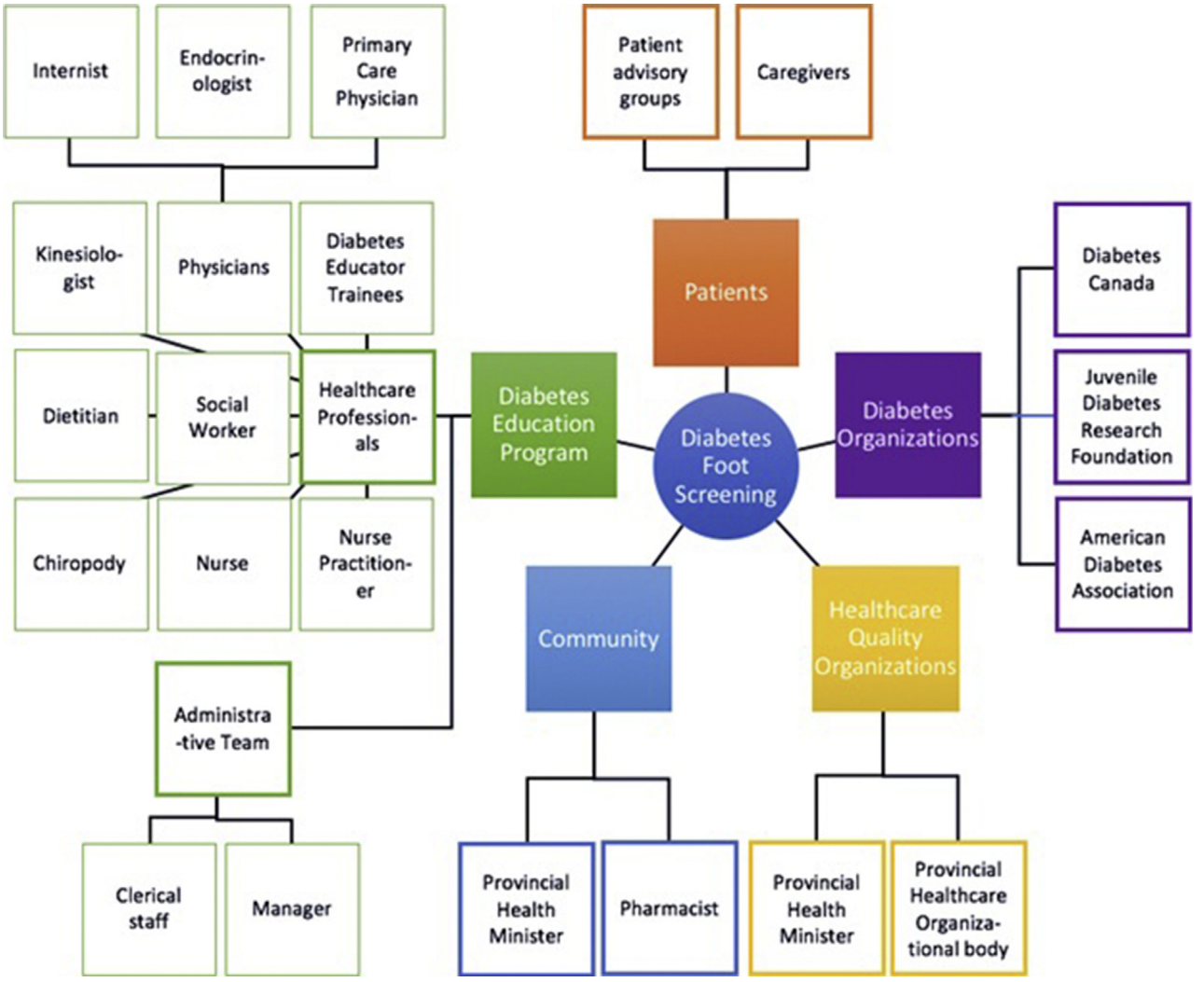

Figure 1. Stakeholder map for foot screening in patients with diabetes.

Your QI team decides that improving diabetes foot screening is an important topic to address, with significant potential to improve care delivery. Foot screening is considered within the scope of care of providers at your DEP and, overall, is a highly feasible project requiring limited restructuring.

What is the importance of understanding scientific literature?

A literature review will help you to assess the scientific evidence concerning the importance of your QI problem. After completing your review, you might note that foot screening for

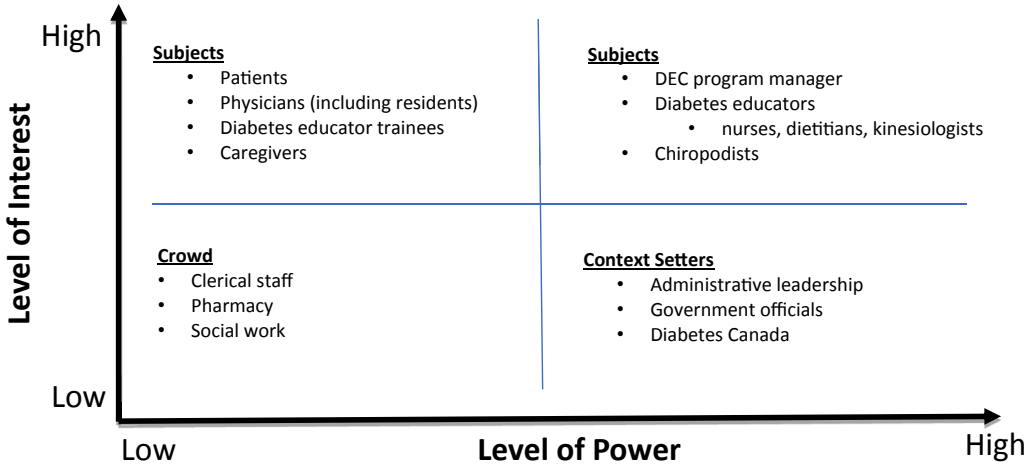

Figure 2. Power vs. interest grid for diabetes foot-screening project. The x-axis represents stakeholders' levels of power in the system you are trying to change, while the y-axis represents their levels of interest in the problem and its solutions. *DEC,* diabetes education program.

those with diabetes can identify people at risk for developing foot ulcers and is also an integral upstream preventive strategy that can decrease the risk for foot infections, wounds and amputations (16). Canadians with diabetes are approximately 20 times more likely to be hospitalized for nontraumatic lower-limb amputations than those without diabetes (17). You learn that up to 85% of diabetes-related foot amputations can be prevented, supporting the benefits of screening for diabetes-related foot complications (7). As per the Diabetes Canada 2018 recommendations, "Healthcare providers should perform foot examinations to identify people with diabetes at risk for ulcers and lower-extremity amputation at least annually and at more frequent intervals in high-risk people" (7).

What is involved in outlining the scope of a problem?

Prior to engaging in a QI project, it is essential to determine whether there is a true problem in the local environment. The team might recognize that there are many contributing factors to lower-limb amputations related to diabetes, but timely foot screening is an important preventive component that can be identified through the literature review. Your team has determined that foot screening is within the scope of practice of the staff at the DEP. Although the patient in the case example did not have his feet examined, you do not know whether that was a systematic problem within your DEP or if it was an isolated lapse in care delivery. To address this, you decide that a baseline gap analysis of local practice will have to be performed. A chart review of practice patterns and/or a patient survey may be conducted to quantify the gap. For the purpose of this article, we focus on conducting a baseline retrospective chart review of local performance to determine the degree of care gap in diabetes foot screening at your DEP.

Prior to conducting a retrospective chart review of patients within your DEP, the first task is to understand the appropriate policies of your institution to ensure that you have the appropriate approval to review charts and that your team understands the ethical issues regarding patient confidentiality. Many centres now have separate expedited ethical oversight processes for QI projects that do not require a full research ethics board review (18–20).

Second, you must establish a sampling strategy with clear inclusion and exclusion criteria and operational definitions of your variable of interest. For example, your team needs to define what qualifies as appropriate foot screening assessment so there is a consistent method to determine whether "adequate screening" has been performed when charts are reviewed. Multiple diabetes foot screening assessments could be performed, but your QI team decides that their operational definition of adequate foot screening includes monofilament testing (21), a comment on the general appearance of the patients' feet and palpation of pedal pulses, all completed within the past 15 months.

To avoid sampling bias with nonrandom sampling during a chart review, it is important to define a sampling strategy, such as examining consecutive charts, every tenth chart or all charts during a specific time period. Another important factor, particularly for a small chart-sampling audit, is to ensure the completeness of data collection to capture adequate data quality. Your QI team decides to examine consecutive charts of patients with type 1 or type 2 diabetes seen in your DEP within the past month and to exclude patients with gestational diabetes.

Third, it is important to determine the sample size for your chart review (Box 2). For chart reviews, small sample sizes of 5 to 20 patients may be sufficient or, alternatively, you can choose to review a sample of 10% of eligible charts (22). Excessive samples sizes can delay the initiation of a QI project, waste resources and pose a significant barrier to feasibility. Another approach to determining an adequate sample size is to have an estimated benchmark for the target of the measure of interest, which may be determined from the literature or a stretch goal. The literature suggests that only 51% of Canadians with diabetes receive yearly diabetes foot screening assessments (16), but your team decides on a target foot screening rate of 80%, based on internal goals.

You audit 20 continuous charts of patients with diabetes seen in the past month and find that only 7 patients (35%) have had adequate foot screening. Although 20 charts may seem like too small a sample size from which to draw useful conclusions, they may be sufficient when local performance (35%) falls well below

Box 2. Determine sample size for chart review

You audit 20 continuous charts of patients with diabetes who have been seen in the past month and find only 7 charts (35%) that indicate adequate foot screening. Your team sets a benchmark target of performing foot screening at least 80% of the time. You want to see whether you need to sample more patients or whether the 20 charts reviewed provide a sufficient sample size based on your audit result.

You can use the confidence interval (CI) calculation for a proportion in 1 sample to determine whether you need more charts. You can do this calculation yourself by using the formula below, or you can use a free online calculator such as http://vassarstats.net (23). The 95% CI is a commonly used statistical measure of the precision of study results, which means that if the study was repeated several times, 95% of the time the true value would be within that calculated range. The quality improvement team calculates the 95% CI for their sample of 20 patient charts using the following calculation for the CI:

$$\left(\hat{p} - 1.96\sqrt{\hat{p}\left(1-\hat{p}\right)\Big/ n},\ \hat{p} + 1.96\sqrt{\hat{p}\left(1-\hat{p}\right)\Big/ n}\right).$$

The sample size is denoted by n (in this case n=20 charts), and we denote the proportion of the number of successes as $\hat{p}$ (called *p-hat*), which is computed by taking the ratio of the number of successes in the sample to the sample size. The success in this sample is 7 (in this case, $\hat{p}$=7/20 charts with adequate foot screening). Based on the audit result, we have calculated the 95% CI for several sample sizes in the table below.

Sample size	Audit result	95% confidence interval
10	35%	5%–65%
20	35%	15%–56%
40	35%	20%–50%
80	35%	25%–45%
160	35%	27%–42%

Our audit of 20 charts has a 95% CI that extends from 15% to 56%. In other words, 95% of the time we can be confident that the true result of the audit would be between 15% and 56%. Given our target of 80% falls outside of the 95% CI even at a sample size of 20, we can be fairly confident that our audit sample size is sufficient. In fact, even if we had audited 10 charts, we are unlikely to meet the target of 80%, and additional sampling is not required. The narrower the width of the CI, the higher the confidence level and the larger the sample size required (22,24,25). When observed performance comes close to the desired target, larger sample sizes are required.

the performance target (80%). Etchells et al (24) outline a strategy to determine the size of the sample for your baseline analysis based on your observed gap (system performance) and your target for QI projects.

Fourth, use an audit tool to collect the data. This may be in paper form or a row on a spreadsheet. To protect patient confidentiality, names should not be included on review forms. You may choose to tabulate the data in aggregate form or over time to understand the gravity of your QI problem and share it with your colleagues in a summarized format. You may then use the baseline as a comparator, once you have implemented your QI project, to see whether your changes have made a difference. You may be able to leverage existing data in your medical records.

What is the importance of understanding contextual factors?

Contextual factors can support or hinder the implementation and success of QI efforts (26). It is integral to understand factors of influence at different levels of context within the microsystem, mesosystem and macrosystem (27,28). At the microsystem level, which refers to the clinical team level, the characteristics of the individual DEP may include organizational features, such as size, teamwork, knowledge, leadership and QI culture. In your microsystem, you have a dedicated QI team, but the team lacks QI expertise. The mesosystem refers to the larger organization level that encompasses the microsystem, such as data and information systems, knowledge and training. It can include a regional health network that supports the development of standards and training for diabetes education programs. The macrosystem refers to the health system level, external to the organization, that involves health-care systems, financial incentives, geographic factors and regulatory mechanisms that may influence QI projects. The macrosystem for your DEP includes the accreditation body and provincial health bodies. In your case, the Provincial Ministry of Health's Department of Performance within the macrosystem has flagged a disproportionately high incidence of diabetes-related foot infections and amputations within the Regional Health Network (the mesosystem) where your DEP resides. They have, thus, provided funding to conduct the QI project, which will facilitate the QI efforts of the team.

QI Strategy: Framework for Improvement Efforts

Once you have established your QI team and identified a gap in care delivery, it is important to use an improvement model to frame your project. To engage in performance improvement, your team uses a commonly used QI framework, the Model for Improvement (Figure 3), to guide their QI efforts. Other QI frameworks that can be used are Six Sigma and Lean methodologies (29,30). The Model for Improvement is a useful QI framework that can be applied to many problems without the need for advanced training.

The Model for Improvement framework starts with 3 questions, and the fourth element describes a cycle for testing change ideas or innovations (31).

The first question is: What are we trying to achieve (28)? The answer to this is an aim statement, which helps to focus the project's goals. It is important to have an aim statement that is specific, measureable and attainable and has a realistic and clear target and time frame (31,32). Your QI team aims to increase the percentage of patients who have documented foot examinations from 35% to 80% by 2 years from the date of the start of the project. The target of the aim statement may be based on local stretch goals or set via benchmarking from the literature or other DEP sites.

The second question in the Model for Improvement framework is: How do we know a change is an improvement? This focuses on

Figure 3. Model for Improvement Quality Improvement Framework. (Reproduced with permission from Langley GJ, Moen RD, Nolan KM, Nolan TW, Norman CL, Provost LP. The improvement guide: A practical approach to enhancing organizational performance, 2nd ed. San Francisco, California, United States: Jossey-Bass, 2009.)

measuring the collected data and generally involves a family of measures, which include the following:

1) Outcome measures: these evaluate the effect of the health system on patients (e.g. percentage of eligible patients with documented foot examinations).
2) Process measures: these evaluate the components of the process that make up your health system and can also include components to assess the fidelity of implementation of your ideas for change. They can be further defined when you have selected change ideas that address your root causes (e.g. percentage of eligible rooms that had monofilament testing tools to perform foot examinations).
3) Balancing measures: monitors of unintended consequences of changes to a health system. For example, by improving foot screening, we may inadvertently increase the visit length to the clinic or decrease staff satisfaction by increasing the workload of the providers.

It is important to keep the measures manageable (3 to 8 measures, usually more process than outcome measures), and they must be simple to collect without a great deal of restructuring to determine whether the changes have improved the health system.

The third question is: What changes can we make that will result in an improvement? We will devote the next article in this primer to change idea (solution) development and mapping it to the root causes of the quality problem.

The fourth element of the Model of Improvement is to test a change in the real work setting. The plan-do-study-act cycle is shorthand for testing a change by planning it, trying it, observing

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 educators, chiropodist, primary care physician, clerical staff, patient advocate		**Problem statement/reason for improvement**: Our regional health network has a higher rate of amputations than other networks in the province. Although 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%.
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 have had documented foot examinations at their last appointment **Balancing**: to be determined
Root causes of the problem:	**Change ideas**:	**Process measures**:
To be determined		
Anticipated barriers and mitigation strategies: 1. Lack of monetary resources • Mitigation strategy: Regional health net work to provide funding 2. Lack of support and time for data collection • Mitigation strategy: Regional health network to support manager in data collection and interpretation.		**Anticipated timeline/key milestones**: • To be determined
Resources required: To be determined		**Signatures**: Executive sponsor: _____ Process owner: _____

Figure 4. Project charter template. Adapted and used with permission from Paula Blackstein-Hirsch. *DEP*, diabetes education program; *QI*, quality improvement.

the results and acting on what is learned (33). This will also be addressed in the next article of this primer series.

Organization of Your QI Project

One way to organize your QI project at the outset is to develop a Project Charter (34), which helps to document your aim, your team members and the scope of the project, and it may be used to focus your QI project and to ensure that everyone on the team has the same goals (Figure 4). This is a fluid document, and with each sequential article in this primer series, we will add to this template as we move through the process.

Next steps in conducting the QI project

The QI team has been formed and has determined that there is a large gap in diabetes foot screening at the DEP. The next steps will be to do a root-cause analysis of the problem and decide on change ideas that will target these root causes (35). The data will then be measured over time to monitor for improvement (36).

Acknowledgments

The authors thank the Quality, Education and Safety Committee at the Banting and Best Diabetes Centre and Husayn Marani from the Women's College Hospital Institute for Health System Solutions and Virtual Care for supporting the coordination of the submission process of the manuscript.

Funding

The authors acknowledge the Banting and Best Diabetes Centre for funding this project.

Author Disclosures

IJH reports personal fees from Dexcom and Novo Nordisk. GM, DW, LC, JG, RW, LS and PS have no conflicts of interest to disclose.

Author Contributions

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

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