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Evaluation of a unique and innovative diabetes care model in primary care in Ontario, Canada: protocol for a multiple-methods study with a convergent parallel design

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ABSTRACT

Introduction The growth and complexity of diabetes are exceeding the capacity of family physicians, resulting in the demand for community-based, interprofessional, primary care-led transition clinics. The Primary Care Diabetes Support Programme (PCDSP) in London, Ontario, is an innovative approach to diabetes care for high-risk populations, such as medically or socially complex and unattached patients. In this study, we will employ a quadruple-aim approach to evaluate the health system impacts of the PCDSP.

Methods and analysis We will use multiple methods through a convergent parallel design in this project across five unique studies: a case study, a patient study, a provider study, a complications study and a cost-effectiveness study. The project will be conducted in a dedicated stand-alone clinic specialising in chronic disease management, specifically focusing on diabetes care. Participants will include clinic staff, administrators, family physicians, specialists and patients with type 1 or type 2 diabetes who received care at the clinic between 2011 and 2023. The project design will define the intervention, support replication at other sites or for other chronic diseases and address each of the quadruple aims and equity. Following the execution of the five individual studies, we will build a business case by integrating the results. Data will be analysed using both qualitative (content analysis and thematic analysis) and quantitative techniques (descriptive statistics and multiple logistic regression).

Ethics and dissemination We received approval from the research ethics boards at Western University (reference ID: 2023–1 21 766; 2023–1 22 326) and Lawson Health Research Institute (reference ID: R-23–202). A privacy review was completed by St. Joseph's Healthcare Corporation. The findings will be shared among PCDSP staff and patients, stakeholders, academic researchers and the public through stakeholder sessions, conferences, peer-reviewed publications, infographics, posters, media interviews, social media and online discussions. For the patient and provider study, all participants will be asked to provide consent and are free to withdraw from the study, without penalty, until the data are combined. Participants will not be identified in any report or presentation except in the case study, for which, given the number of PCDSP providers, we will seek explicit consent to identify them.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The novel, interdisciplinary research team comprised of primary care researchers, scientists, providers and patients involved in the Primary Care Diabetes Support Programme (PCDSP) allows for expertise in carrying out this project and the support of sustainability, scale and spread of the PCDSP.
⇒ The design of the project allows for the integration of the five individual studies while also evaluating distinct aspects of the PCDSP operations.
⇒ We foresee that the PCDSP promotes positive patient and provider experiences and is a cost-effective approach to reducing acute and chronic diabetic complications, which will aid in future endeavours in chronic disease policy and clinical interventions on high-risk individuals during transitions in care.
⇒ The patient and provider studies may suffer from social desirability bias if patients and providers are hesitant to speak of negative experiences with the PCDSP; additionally, these studies may suffer from selection bias if only participants with positive experiences volunteer for interviews.
⇒ The definition of the study cohorts in the complications and cost-effectiveness studies is limited by the availability and reliability of variables in the linked administrative data sets held at the Institute for Clinical Evaluative Sciences, with the potential to fall into multiple categories, and if the overlap is extensive, we may miss some of the benefits of the programme by analysing each cohort separately.

INTRODUCTION

Diabetes is best managed in primary care, with a regular primary care provider (typically a family physician) supported by an

interprofessional team.[1–3] However, because of the increasing complexity of diabetes management, the care needs of patients with diabetes may exceed the capacity for the skills and knowledge of their family physicians to adequately address them on their own.[4–8]

Established in 2007, the Primary Care Diabetes Support Programme (PCDSP) in London, Ontario, is an innovative, award-winning[9] approach to managing transitions in diabetes care for high-risk populations such as medically complex, unattached and socially complex patients.[10] Medically complex patients are individuals with diabetes who are treated with insulin—considered a high-risk medication—or who have any comorbidity.[6 11–13] Unattached patients do not have a regular primary care provider and consequently lack continuity of care and have poorer access to care.[12–15] Socially complex patients experience a range of social conditions (including low and unstable income, poor housing, social isolation, poor literacy, poor proficiency in English and/or recent immigration)[2 13–18] that negatively impact their self-care capacity and the self-resources needed to adopt and sustain diabetes-related treatment and lifestyle changes. If a patient has a primary care provider, the PCDSP works in collaboration with them to develop person-centred treatment plans that balance the competing demands of multimorbidity with the individual patient's preferences and capacities.[19] For unattached patients, the PCDSP coordinates care until the PCDSP can find a family physician or nurse practitioner willing to accept the patient. In addition to active medical management, the PCDSP promotes patients' self-management skills and addresses barriers to care related to social determinants of health.[10 11] Once a treatment plan is developed and patients are stabilised, PCDSP negotiates responsibility for the ongoing management of the patient's diabetes care with the regular primary care provider.

The PCDSP incorporates key components of the Extended Chronic Care Model, which has been shown to improve the process of care indicators for diabetes management.[20] The PCDSP involves a team of providers, including individuals with specialised training in diabetes.[20–22] In addition to promoting diabetes self-management typical of diabetes education programmes, nurse practitioners and focused-practice family physicians with specialised training in diabetes management provide active medical management and a social services worker addresses the social determinants of health.[11 23] The team-based approach is supported by WebDR, a built-for-purpose electronic medical record developed for diabetes outpatient clinics that also serves as a researchable database.[11 24]

Unlike evaluations of diabetes interventions that focus on biological markers,[21 25] this project examines the impact of the PCDSP on diabetes complications, which are not only associated with increased health service utilisation and costs[7 26] but also with reduced patient satisfaction[27] and quality of life.[19] While routine quality improvement data demonstrate that the PCDSP improves blood glucose levels and other clinical indicators associated with better diabetes outcomes,[11] its broader impact on patient and provider experiences, diabetes complications and health system costs has not been evaluated.

In this study, we will employ a quadruple-aim approach to evaluate the health system impacts of the PCDSP. We hypothesise that the PCDSP realises the quadruple aim compared with usual care; that is, it promotes positive patient and provider experiences, reduces acute and chronic diabetic complications and is cost-effective.

Objectives

The goal of this project is to evaluate the PCDSP and find evidence to support its sustainability, scale and spread. The research objectives are:

1. Describe the key programmatic elements of the PCDSP and the key organisational and contextual factors integral to its sustainability, scale and spread.
2. Explore the impact of the PCDSP on patient experiences and quality of life.
3. Explore the impact of the PCDSP on comprehensive family physicians.
4. Compare the likelihood of having acute and chronic diabetes-related complications among PCDSP versus usual care patients.
5. Assess the cost per prevented complication per patient-year of PCDSP versus usual care.

METHODS AND ANALYSIS

Overall study design

This multiple-methods project uses a convergent parallel design,[28] consisting of five studies: a case study, a patient study, a provider study, a complications study and a cost-effectiveness study. The project design is intended to define the intervention (to support replication at other sites or for other chronic diseases, if warranted) and address each of the quadruple aims.

Objective 1: case study

Approach

We will use documents, qualitative interviews and WebDR data to describe the key programmatic elements of the PCDSP and the key organisational and contextual factors integral to its sustainability, scale and spread. Specifically, we will describe the PCDSP's programmatic elements using the Extended Chronic Disease model,[20] as well as its funding, organisation, human resources and patient population. The PCDSP is a stand-alone clinic with dedicated staff, space, administration and relatively distinct budget envelopes, facilitating our ability to delineate the elements of the programme.

We will ask team members from the PCDSP to identify and provide relevant documents, such as organisational charts, programme logic models, quarterly practice audits, budgets and financial reports, job descriptions, annual reports, standard operating procedures and educational and operational materials, from 2011 to 2023.

Using content analysis,[29] we will create an initial description of the PCDSP. We will then conduct interviews with the PCDSP staff and, if applicable, administrators from relevant local organisations. Broadly, we will ask participants about the PCDSP programme elements using the Extended Chronic Disease model[20] and patient population, funding, organisation and human resources. Specific questions will depend on the participant's position and expertise (eg, medical director or administrator). We will also gather data related to patient and provider sex and gender differences related to care. For example, tailoring clinical services to account for patients' sex (eg, risk factors) or gender (eg, care-seeking and meal preparation) and provider gender (eg, part-time work). Interviews will be audio-recorded and transcribed.

Analysis

Using WebDR data, we will examine patients' sociodemographic (age, sex, gender, urban/rural, low income, ethnicity, primary language and private insurance coverage), clinical characteristics (comorbidities, use of insulin, mobility issues, referral source and provision of a primary care provider) and PCDSP utilisation (number of encounters and nature of provider/services [physician, nursing, social services, wound care, etc]). We will examine data from all patients seen in the PCDSP between 1 April 2011 and 31 March 2023. Using descriptive statistics, we will describe the PCDSP patients by patient group (medically complex, unattached, socially complex and episodes of care [number and nature of visits]). Analyses will be conducted for the sample as a whole and by sex, and, if data are available, by gender.

We will use content analysis[29] to analyse the qualitative document and interview data, as well as summary data from the WebDR data analysis and financial data. Codes will capture the programmatic elements, funding, organisation, human resources and patient population. For each code, we will identify relevant text/figures, document the source and summarise the data. This data will be used to produce a description of the PCDSP. We will seek out additional data (documents, interviews and WebDR data) until the data can no longer provide new information.

Study rigour

To enhance the rigour of our analysis, we will keep an audit trail (detailed records of the data collection procedures, sources and analyses; preliminary analyses and draft programme models; and notes on discussions of model development, disagreements and resolutions). We will triangulate across sources (documents, interviews and WebDR data). We will validate our models by presenting draft programme models to team members, case study interview participants and PCDSP staff (see integrated knowledge translation [iKT]). Data collection and analysis will be iterative, with the aim of reaching a general consensus on the PCDSP programme model.

Objective 2: patient study

Approach

We will conduct semistructured qualitative interviews with PCDSP patients. We will recruit along a wide range of characteristics (ie, maximum variation sampling),[28–30] including past and current patients, different genders, referral sources (hospital, self and family doctor), socioeconomic status and immigration status (eg, refugee, recent immigrant and permanent resident/citizen). To be included in the study, patients must have visited the PCDSP between 1 April 2011 and 31 March 2023. We anticipate interviewing 20–24 patients but will continue recruiting until we have sufficient data to interpret the data rigorously (ie, data saturation).[29 30]

Staff from the clinic will identify eligible participants using WebDR, which includes data on the characteristics of interest in our maximum variation sampling. Clinic staff will then contact patients (by email or in person) and ask them to contact the study research assistant if they are interested in learning more about the study. The research assistant will provide interested patients with additional study information, obtain consent and schedule and conduct interviews. To provide a token of appreciation for participation, we will provide a $50 gift certificate to each patient participant. Clinic staff will not know which patients have contacted the research assistant or participated in an interview. Interviews will be conducted in English by video conference, telephone or in person at the Centre for Studies in Family Medicine, based on patient preferences. With patient consent, family members or caregivers can also participate in the interview.

Qualitative interviews

In the interview, we will ask patients to describe (1) the circumstances leading to their care from the PCDSP; (2) the nature of their care from the PCDSP; (3) the impact of the PCDSP on their health, self-management of diabetes, broader determinants of health (eg, housing, employment, income, etc) and quality of life; (4) how the PCDSP fits in with their current care or care provider and (5) how they perceive their sex and/or gender have influenced the PCDSP care or the impacts of care from the PCDSP. We will also gather relevant data on demographic characteristics (eg, gender, age, date and length of care under the PCDSP), indicators of medical and social complexity and regular physician attachment to describe study participants. Interviews will take up to an hour and will be recorded and transcribed for analysis.

Analysis

Using a thematic analysis approach,[29] at least two members of the research team will independently read each transcript to identify keywords and codes and iteratively develop a robust coding and analysis template, which will then be used to code the transcripts in NVivo V.14.[29 30] Through various iterations of the coding process, we will move from more descriptive to more analytic codes, developing broader conceptual themes. Research assistants

will code all transcripts with the final coding template. We will compare across sex and gender to identify any potential sex and/or gender-based differences. Descriptive statistics will summarise participant characteristics.

Study rigour

To enhance the rigour of our qualitative study, we will prepare interview guides and pretest questions, document interviewing and transcription protocols, use experienced interviewers and member-check with the participants during interviews.[28–30] We will keep detailed records of the interviews (transcripts and audio recordings), field notes, drafts of the coding template and coding disagreements and their resolutions. We will look for negative cases and encourage and document self-reflection among all members of the research team. We will provide thick descriptions and use illustrative quotes.

Objective 3: provider study

Approach

We will conduct semistructured qualitative interviews with family physicians (or nurse practitioners) and other specialists who interact with the PCDSP. We will recruit along a wide range of characteristics (ie, maximum variation sampling),[28–30] including different genders, provider types (nurse practitioner and family versus other specialty physician), years of experience, urban/rural, setting (hospital-based, community-based), payment model (fee-for-service, capitation and salary) and practice model (solo, group and team). To be included in the study, providers must have accepted patients from or referred patients to the PCDSP between 1 April 2011 and 31 March 2023. We anticipate interviewing 20–24 providers but will continue recruiting until we reach data saturation.[28–30]

Staff from the clinic will identify eligible providers through WebDR. Clinic staff will send a group email or fax to each provider, inviting them to contact the study research assistant to learn more about the study. The research assistant will provide interested providers with additional study information, obtain consent and schedule and conduct interviews. To encourage participation, we will provide a $50 gift certificate to each participant. Clinic staff will not know which providers contacted the research assistant or participated in an interview. Interviews will be conducted by telephone or in person at the Centre for Studies in Family Medicine based on participant preferences.

Qualitative interviews

In the interview, we will ask providers to describe: (1) the nature of their interactions with the PCDSP (eg, referrals, consultations and accepting unattached patients); (2) the nature of services provided to patients by the PCDSP; (3) the impact of the PCDSP on patients' health, self-management of diabetes, broader determinants of health (eg, housing, employment, income, etc) and quality of life; (4) the impact of the PCDSP on the provider's own practice and management of patients with diabetes (eg, transition of care and continuity of care) and (5) their perception of how sex and/or gender (patients' and their own) have influenced the interactions with or impacts of the PCDSP. We will also gather relevant demographic and practice data (eg, model type and community size) to describe study participants. Interviews will take up to an hour and will be recorded and transcribed for analysis.

Analysis and study rigour

We will use the steps described in the patient study to analyse the transcripts and promote rigour.

Objective 4: complications study

Approach

We will conduct a retrospective cohort study linking data from WebDR to the linked administrative data sets held at the Institute for Clinical Evaluative Sciences (ICES)—an arm's length agency authorised under Ontario's Personal Health Information Protection Act—to examine acute and chronic complications among patients who received PCDSP care versus usual care. We will use the WebDR research database to identify patients who received care from the PCDSP between 1 April 2011 and 31 March 2023. To be eligible for the study cohort, patients must be diagnosed with type 1 or type 2 diabetes, be 20 years of age or older at baseline and live in the Southwest Local Health Integration Network (SWLHIN) region. We will exclude patients who become pregnant during the study period (because they are referred to a specialist for care). We will conduct separate analyses on three cohorts: (1) medically complex (defined as having one or more comorbidity or any acute or chronic complication in the year before the index date [ie, date of first visit to the PCDSP]); (2) unattached (defined as not rostered to a primary care provider) and (3) socially complex (defined as being from the lowest income quintile or an immigrant).

Outcomes and covariates

In each of the three cohorts, we will examine seven dichotomous (yes/no) outcomes related to acute and chronic complications:

1. Had at least one hospitalisation or emergency department (ED) visit for hyperglycaemia or hypoglycaemia.
2. Had at least one hospitalisation or ED visit for a skin and soft tissue infection or foot ulcer.
3. Had at least one hospitalisation or ED visit for any acute complication (hyperglycaemia or hypoglycaemia, skin and soft tissue infection or foot ulcer).
4. Had at least one hospitalisation for a cardiovascular condition (myocardial infarction, stroke, coronary artery bypass graft or percutaneous coronary intervention).
5. Had a lower extremity amputation.
6. Had dialysis or kidney transplantation for end-stage chronic kidney disease.
7. Had any chronic complication (hospitalisation for a cardiovascular condition, lower extremity amputation or end-stage renal disease).

These outcomes were previously used in an ICES study to describe the burden of diabetes in Ontario and are hence feasible with ICES data holdings (online supplemental table 1).[31] When not used as inclusion/exclusion criteria, covariates will include patient and community variables: age, sex, rurality of community (using Rural Index of Ontario score), years since diagnosis, income quintile, immigrant status (non-immigrant, immigrated less than 10 years, immigrated more than 10 years), attached to a regular doctor at index date, number of comorbid conditions, type of primary care organisation, number of primary care and specialist visits, presence of acute or chronic complications and ACG System Aggregated Diagnosis Groups (ADG) and Resource Utilisation Bands (RUB) in the year preceding index date.

Data sources

We will link the Ontario Health Insurance Plan (OHIP) number, birthdate, postal code (for deterministic linkage) and date of first visit (to identify the index date for PCDSP patients) from WebDR to administrative health data at ICES (online supplemental table 2). Once linked, OHIP numbers will be removed and replaced with unique encoded identifiers (ICES key numbers) and analysed at ICES. The WebDR data file will also include variables that identify patients in each cohort so that we can assess case ascertainment when using ICES data.

We will use the Ontario Diabetes Database (ODD) to identify the control sample. The ODD includes all individuals in the province with type 1 and type 2 diabetes identified since 1991 using a validated algorithm.[32] The Registered Persons Database (RPDB) includes data on all Ontarians insured by the OHIP and will be used for demographic-related and location-related variables. The Canadian Institute for Health Information Discharge Abstract Database (CIHI-DAD) will be used to identify hospitalisations related to acute and chronic diabetes complications and to create ADGs and RUBs. The National Ambulatory Care Reporting System (NACRS) will be used to identify emergency department visits related to acute and chronic diabetes complications, ADGs and RUBs. The OHIP database will be used to identify data on physician visits related to diabetes complications and comorbidities and to create ADGs and RUBs. The Canadian Organ Replacement Register Database will be used to identify chronic diabetes complications related to kidney transplants. The Client Agency Programme Enrollment will be used to identify unattached patients and primary care models. The Immigration, Refugees and Citizenship Canada Permanent Residents Database will be used to identify immigration-related variables. The Ontario Marginalisation Index, along with the RPDB, will be used to identify low-income individuals. We will use validated condition-specific cohorts for asthma, congestive heart failure, chronic obstructive pulmonary disease, hypertension, dementia, HIV, rheumatoid arthritis or Crohn's disease/colitis to identify comorbidities.[33–40]

Analysis

All analyses will be conducted using SAS V.9.4 (SAS Institute, Cary, North Carolina, USA). To account for potential bias in referral to PCDSP, in each cohort, we will use propensity scores to match PCDSP patients to usual care (non-PCDSP) patients.[41] We will use multiple logistic regression to identify the predictors of having PCDSP care (yes/no). When not used as inclusion/exclusion criteria, potential predictors include age, sex, rurality of community, years since diagnosis, income quintile, immigrant status, attachment to a regular doctor at index, number of comorbid conditions, type of primary care organisation, number of primary care and specialist visits in baseline year, presence of acute or chronic complications in baseline year and ACGs and RUBs in baseline year. The first PCDSP visit will be used as the index date and the preceding year will be used as baseline. We will use Pearson r correlation and variance inflation factor to assess multi-collinearity between variables a priori. Each PCDSP patient will be matched to two usual care patients.[41]

For each cohort, we will describe the characteristics of the sample by total number of unique patients and patient-year. We will use univariable and multivariable logistic regression to examine the relationship between each predictor and each outcome. We will stratify by sex and repeat analysis. Potential covariates will be the variables listed above that are neither used to define each cohort nor create the propensity score. Potential sensitivity analyses will assess the impact of using different combinations of variables to identify medically and socially complex individuals. To assess the robustness of the results,[41] we will also repeat the analysis by matching PCDSP and usual care patients by age, sex and diagnosis date.[19]

Sample size

In 2015 (approximate midpoint year of the proposed cohort), approximately 5% (n=3915)[11] of the 78 290 patients with diabetes in the SWLHIN region[31] were seen by the PCDSP. Using the rarer of the two summary outcomes (any chronic complication: 2.24% of prevalent cases per year)[31] and a conservative estimate of the smallest cohort group (socially complex=5.5% of all patients with diabetes[31]; 215 PCDSP patients in 2015), 2084 PCDSP and 4168 usual care (based on 1:2 match) patient-years are needed to detect a 1% difference in the outcome with 80% power at α=0.05.[42] Therefore, roughly 10 years of data are needed. The sample size (6252 patient-years) will allow us to include all proposed covariates, based on the custom of one covariate per 20 cases.[43]

Objective 5: cost-effectiveness study

Approach

The cost-effectiveness study will build upon the findings of the PCDSP case study and the complications study. From the health system (payer) perspective, we will assess the costs per prevented acute and chronic complications per patient-year in each cohort (medically complex,

unattached and socially complex patients with diabetes). The two outcomes are (1) any hospitalisation or ED visit for any acute complication (hyperglycaemia or hypoglycaemia, skin and soft tissue infection or foot ulcer) in the follow-up period and (2) any chronic complication (hospitalisation for a cardiovascular condition, lower extremity amputation or end-stage renal disease). We will examine direct costs only; indirect costs, capital costs and costs borne by patients will not be included, which are in line with recommendations used by Health Quality Ontario.[44] Costs for usual care will include all physician services, hospital services, ED services, lab tests and drugs.

Data sources

We will gather health service utilisation data from OHIP (physician visits), CIHI-DAD (hospitalisations), NACRS (ED visits and day procedures), the Ontario Laboratory Information System (lab tests), CERNER (lab testing in Southwestern Ontario) and the Ontario Drug Benefit (prescription drugs) database at ICES. We will gather cost data from the Ontario Case Costing Initiative, the OHIP fee schedule, the Ontario Schedule of Lab Tests and the Ontario drug formulary. Cost data for PCDSP that are not included in usual care will be based on the financial data collected in the PCDSP case study. Costs will be adjusted for inflation and discounted at 5%.[45]

Analysis

For each patient cohort, we will first describe health service utilisation and related costs (physician, hospital and ED visits; day procedures, lab tests and drug prescriptions) in the PCSDP and usual care groups. We will compare PCDSP and usual care patients for each outcome. Given that PCDSP patients also receive usual care, the analysis will calculate incremental costs per outcome.[45] We will carry out separate analyses for males and females.

We will estimate the cost-effectiveness of the clinic as a whole by weighting a theoretical sample of patients by the relative proportion of medically complex, unattached and socially complex patients seen per year in the PCDSP. These proportions will be based on the analysis of WebDR data in the PCDSP case study. We will carry out sensitivity analyses to assess the implications of changing the overall size (patient population) and relative proportion of each cohort in the patient population. These analyses will estimate the total number of complications prevented and costs saved under scenarios of clinic size and patient population composition.

Patient and public involvement

The research team includes three patient partners from the PCDSP, as well as a family member of a diabetes patient. They have helped develop study methods and data collection instruments and will help analyse and interpret findings from each study and disseminate study findings.

Current study status

At the time of writing (May 2024), we have completed the data cleaning of the WebDR data that will be used in the case, complications and cost-effectiveness studies. Recruitment and data collection for the patient study (Objective 2) are underway. We are also in the initial stages of carrying out recruitment for the provider study (Objective 3). The remaining objectives of the study will occur consecutively, with an estimated completion date of 2026 for the full project.

ETHICS AND DISSEMINATION

Ethics

We have obtained approval from the research ethics boards at Western University (reference ID: 2023–1 21 766; 2023–1 22 326) and Lawson Health Research Institute (reference ID: R-23–202). A privacy review was conducted by St. Joseph's Healthcare Corporation. For the patient and provider studies, all participants will be asked to provide consent and are free to withdraw from the study, without penalty, until the data are combined. Participants will not be identified in any report or presentation except in the case study, for which, given the number of PCDSP providers, we will seek explicit consent to identify them.

Knowledge translation and dissemination

As part of our ongoing iKT plan, we will meet with PCDSP staff at least twice during each study. At the first study meeting, we will review and invite feedback on the goals of each study and data collection tools and methods (eg, interview questions, administrative data variable definitions, etc). At the second study meeting, we will present initial results and seek feedback on sensitivity analyses and interpretations of the results.

Our end-of-grant KT (eKT) goals are to disseminate findings to improve PCDSP operations, inform policy and programme discussions, encourage further research and raise public awareness of study findings with the hopes of promoting the spread, scale and transferability of other chronic diseases. We will share our findings with the staff from the PCDSP to inform and improve ongoing clinic operations. We will conduct a series of stakeholder sessions with policymakers and present a business case to demonstrate that investment in upstream, primary care-based approaches to diabetes management will create downstream health system savings. To reach academic researchers and other knowledge users, we will present at regional, national and international conferences and prepare articles for publication in peer-reviewed open-access journals. To reach PCDSP patients, we will prepare infographics, posters and other materials that will be developed in consultation with PCDSP staff and patient/family member representatives on the team. To reach the public, we will write op-eds, prepare infographics, conduct media interviews, participate in online discussions and use social media.

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Contributors MM is the lead and corresponding author and the guarantor. Contributions to the manuscript are described using the CRediT taxonomy (Brand et al. (2015), Learned Publishing 28(2)). Writing the original draft: MM and RL. Writing the review and editing: MM, RL, SH, LH, YHC, JRD, MEG, EH, BR, SLS, LM and SMR. Conceptualisation: MM, SH and LH. Methodology: MM, LH and SH. Supervision: MM and LH. Project administration: MM and LM. Funding acquisition: MM, SH, LH, YHC, JD, MEG, EH, BR, SLS and LM. All authors have read and approved the final manuscript.

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Competing interests SH, EH and SMR developed and work at the PCDSP and are clinician partners and knowledge users of the project. While they will help recruit participants, facilitate access to data and help interpret findings to mitigate competing interests, they have a limited role in data collection and analysis of the data. All other authors declare no competing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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