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Evaluation of a Unique and Innovative Diabetes Care Model in Primary Care in Ontario, Canada: A Protocol

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ABSTRACT

Introduction

The growth and complexity of diabetes is exceeding the capacity of family physicians, resulting in the demand for community-based, inter-professional, primary care-led transition clinics. The Primary Care Diabetes Support Program (PCDSP) in London, Ontario is an innovative approach in 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, Patient Study, Provider Study, Complications Study, and a Cost-Effectiveness Study. The project design will define the intervention, support replication at other sites or to 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 analyzed using both qualitative (content analysis, thematic analysis) and quantitative techniques (descriptive statistics, multiple logistic regression).

Ethics and dissemination

We received approval from the research ethics boards at Western University, Lawson Health Research Institute. As well, a privacy review was completed by St. Joseph's Health Care 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.

Strengths and limitations of this study

- The novel, interdisciplinary research team comprised of primary care researchers, scientists, providers, and patients involved at the 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.
- The definition of the study cohorts in the Complications and Cost-Effectiveness Study is limited by the availability and reliability of variables in the linked administrative data sets held at the Institute for Clinical Evaluative Sciences (ICES), with the potential to fall into multiple categories, and if overlap is extensive, we may miss some of the benefits of the program by analyzing each cohort separately.
- 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 endeavors in chronic disease policy and clinical interventions on high-risk individuals during transitions in care.

INTRODUCTION

Diabetes is best managed in primary care, with a regular primary care provider (typically a family physician) supported by an inter-professional team [1-3]. However, because of the increasing complexity in 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 on their own [4-8].

Established in 2007, the Primary Care Diabetes Support Program (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 self-care capacity and 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-centered treatment plans that balance the competing demands of multimorbidity with the individual patient's preferences and capacities [19]. For unattached patients, 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 of care related to social determinants of health [10,11]. Once a treatment plan is developed and patients are stabilized, 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 process of care indicators for diabetes management [20]. The PCDSP involves a team of providers, including individuals with specialized training in diabetes [20-22]. In addition to promoting diabetes self-management typical of diabetes education programs, nurse practitioners and focused-practice family physicians with specialized 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 utilization 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 have not been evaluated.

In this study we will employ a quadruple aim approach to evaluate the health system impacts of the PCDSP. We hypothesize that the PCDSP realizes the quadruple aim compared to usual care; that is, it promotes positive patient and provider experiences, reduced 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 organizational and contextual factors integral to the sustain, 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, Patient Study, Provider Study, Complications Study, and a Cost-effectiveness Study. The project design is intended to define the intervention (to support replication at other sites or to 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 organizational 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, organization, 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 program.

We will ask team members from the PCDSP to identify and provide relevant documents, such as organizational charts, program 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

organizations. Broadly, we will ask participants about the PCDSP program elements using the Extended Chronic Disease model [20] and patient population, funding, organization, and human resources. Specific questions will depend on the participant's position and expertise (e.g. medical director, 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 (e.g., risk factors) or gender (e.g., care-seeking, meal preparation) and provider gender (e.g., part-time work). Interviews will be audio-recorded and transcribed.

Analysis

Using WebDR data, we will examine patients' socio-demographic (age, sex, gender, urban/rural, low income, ethnicity, primary language, private insurance coverage), clinical characteristics (co-morbidities, use of insulin, mobility issues, referral source, provision of a primary care provider), and PCDSP utilization (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 April 1, 2011 and March 31, 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 analyze 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, organization, human resources, and patient population. For each code, we will identify relevant text/figures, document the source, and summarize 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 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 program 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 program models to team members, Case Study interview participants, and PCDSP staff (see integrated knowledge translation [iKT]). Data collection and analysis will be iterative, with an aim to reach general consensus on the PCDSP program model.

Objective 2: Patient Study

Approach

We will conduct semi-structured qualitative interviews with PCDSP patients. We will recruit along a wide range of characteristics (i.e., maximum variation sampling) [28-30], including past and current patients, different genders, referral sources (hospital, self, family doctor), socio-economic status, and immigration status (e.g., refugee, recent immigrant, permanent

resident/citizen). To be included in the study, patients must have visited the PCDSP between April 1, 2011 and March 31, 2023. We anticipate interviewing 20-24 patients, but will continue recruiting until we have sufficient data to interpret the data rigorously (i.e., 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 (e.g., 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 PCDSP. We will also gather relevant data on demographic characteristics (e.g., 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 1 hour, 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 key words/codes, and iteratively develop a robust coding and analysis template, which will then be used to code the transcripts in NVivo 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 summarize participant characteristics.

Study rigour

To enhance the rigour of our qualitative study, we will prepare interview guides and pre-test 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 description and use illustrative quotes

Objective 3: Provider Study

Approach

We will conduct semi-structured 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 (i.e., maximum variation sampling) [28-30] including different genders, provider type (nurse practitioner, family versus other specialty physician), years of experience, urban/rural, setting (hospital, community-based), payment model (fee-for service, capitation, salary) and practice model (solo, group, team). To be included in the study, providers must have accepted patients from or referred patients to the PCDSP between April 1, 2011 and March 31, 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 (e.g., referrals, consultations, 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 (e.g., 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 (e.g., transition of care, 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 (e.g., model type, community size) to describe study participants. Interviews will take up to one hour, be recorded, and transcribed for analysis.

Analysis and study rigour

We will use the steps described in the Patient Study to analyze the transcripts and to 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 ICES – an arm's length agency authorized 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 April 1, 2011 and March 31, 2023. To be eligible for the study cohort, patients must be diagnosed with type 1 or type 2 diabetes, be 20 years 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 co-morbidity or any acute or chronic complication in the year before index date [i.e., 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 hospitalization or emergency department (ED) visit for hyper- or hypo-glycemia.
2. Had at least one hospitalization or ED visit for skin and soft tissue infection or foot ulcer.
3. Had at least one hospitalization or ED visit for any acute complication (hyper- or hypoglycemia, skin and soft tissue infection, or foot ulcer).
4. Had at least one hospitalization 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 (hospitalization 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 hence are feasible with ICES data holdings (Appendix 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 organization, number of primary care and specialist visits, presence of acute or chronic complications, and ACG® System Aggregated Diagnosis Groups (ADG) and Resource Utilization Bands (RUB) in the year preceding index date.

Data sources

We will link Ontario Health Insurance Plan (OHIP) number, birthdate, postal code (for deterministic linkage), and date of first visit (to identify index date for PCDSP patients) from WebDR to administrative health data at ICES (Appendix Table 2). Once linked, OHIP numbers will be removed and replaced with unique encoded identifiers (ICES key numbers) and analyzed 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 and location-related variables. The Canadian Institute for Health Information Discharge Abstract Database (CIHI-DAD) will be used to identify hospitalizations 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, comorbidities, and to create ADGs and RUBs. The Canadian Organ Replacement Register (CORR) Database will be used to identify chronic diabetes complications related to kidney transplants. The Client Agency Program Enrolment (CAPE) will be used to identify unattached patients, and primary care models. The Immigration, Refugees and Citizenship Canada Permanent Residents Database (CIC) will be used to identify immigration-related variables. The Ontario Marginalization Index (ONMARG) along with RPDB will be used to identify low-income individuals. We will use validated condition-specific cohorts for asthma, CHF, COPD, hypertension, dementia, human immunodeficiency virus (HIV), rheumatoid arthritis, or Crohn's/colitis to identify comorbidities [33-40].

Analysis

All analyses will be conducted using SAS version 9.4 (SAS Institute, Cary, NC). 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, attached to a regular doctor at index, number of comorbid conditions, type of primary care organization, 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 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 mid-point year of proposed cohort), approximately 5% (n=3,915) [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), 2,084 PCDSP and 4,168 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 (6,252 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 hospitalization or ED visit for any acute complication (hyper- or hypoglycemia, skin and soft tissue infection, or foot ulcer) in the follow-up period, and 2) any chronic complication (hospitalization 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 utilization data from OHIP (physician visits), CIHI-DAD (hospitalizations), NACRS (ED visits and day procedures), Ontario Laboratory Information System (OLIS; lab tests), CERNER (lab testing in Southwestern Ontario), and the Ontario Drug Benefit (ODB; prescription drugs) database at ICES. We will gather cost data from Ontario Case Costing Initiative (OCCI), OHIP fee schedule, Ontario Schedule of Lab Tests, and the Ontario drug formulary. Costs 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 utilization and related costs (physician, hospital, and ED visits; day procedures, lab tests, and drug prescriptions) in the PCSDP and usual care group. 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 analyze and interpret findings from each study and disseminate study findings.

ETHICS AND DISSEMINATION

Ethics approval

We have obtained approval from the research ethics boards at Western University and Lawson Health Research Institute. As well, a privacy review was conducted by St. Joseph's Health Care Corporation. 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 where, given the number of PCDSP providers, we will seek explicit consent to identify them.

Knowledge Translation

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 (e.g., interview questions, administrative data variable definitions, etc.). At the second study meeting, we will present initial results and seek feedback on sensitivity analyses and interpretation of results.

Our end-of-grant KT (eKT) goals are to disseminate findings to improve PCDSP operations, inform policy and program discussions, encourage further research, and raise public awareness of study findings with the hopes to promote the spread, scale, and transferability towards 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 policy makers 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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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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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 is exceeding the capacity of family physicians, resulting in the demand for community-based, inter-professional, primary care-led transition clinics. The Primary Care Diabetes Support Program (PCDSP) in London, Ontario is an innovative approach in 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 had received care at the clinic between 2011 and 2023. The project design will define the intervention, support replication at other sites or to 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, thematic analysis) and quantitative techniques (descriptive statistics, multiple logistic regression).

Ethics and dissemination

We received approval from the research ethics boards at Western University (reference ID: 2023-121766; 2023-122326) and Lawson Health Research Institute (reference ID: R-23-202). A privacy review was completed by St. Joseph's Health Care 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 at the 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 (ICES), with the potential to fall into multiple categories, and if overlap is extensive, we may miss some of the benefits of the program 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 inter-professional team [1-3]. However, because of the increasing complexity in 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 on their own [4-8].

Established in 2007, the Primary Care Diabetes Support Program (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 self-care capacity and 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, 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 of 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 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 programs, 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 have 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 to usual care; that is, it promotes positive patient and provider experiences, reduced 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 the sustain, 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 to 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 program.

We will ask team members from the PCDSP to identify and provide relevant documents, such as organisational charts, program 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 program 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 (e.g. medical director, 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 (e.g., risk factors) or gender (e.g., care-seeking, meal preparation) and provider gender (e.g., part-time work). Interviews will be audio-recorded and transcribed.

Analysis

Using WebDR data, we will examine patients' socio-demographic (age, sex, gender, urban/rural, low income, ethnicity, primary language, private insurance coverage), clinical characteristics (co-morbidities, use of insulin, mobility issues, referral source, 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 April 1, 2011 and March 31, 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 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 program 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 program models to team members, case study interview participants, and PCDSP staff (see integrated knowledge translation [iKT]). Data collection and analysis will be iterative, with an aim to reach general consensus on the PCDSP program model.

Objective 2: Patient study

Approach

We will conduct semi-structured qualitative interviews with PCDSP patients. We will recruit along a wide range of characteristics (i.e., maximum variation sampling) [28-30], including past and current patients, different genders, referral sources (hospital, self, family doctor), socio-economic status, and immigration status (e.g., refugee, recent immigrant, permanent

resident/citizen). To be included in the study, patients must have visited the PCDSP between April 1, 2011 and March 31, 2023. We anticipate interviewing 20-24 patients, but will continue recruiting until we have sufficient data to interpret the data rigorously (i.e., 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 (e.g., 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 PCDSP. We will also gather relevant data on demographic characteristics (e.g., 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 1 hour, 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 key words/codes, and iteratively develop a robust coding and analysis template, which will then be used to code the transcripts in NVivo 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 pre-test 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 description and use illustrative quotes.

Objective 3: Provider study

Approach

We will conduct semi-structured 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 (i.e., maximum variation sampling) [28-30] including different genders, provider type (nurse practitioner, family versus other specialty physician), years of experience, urban/rural, setting (hospital, community-based), payment model (fee-for service, capitation, salary) and practice model (solo, group, team). To be included in the study, providers must have accepted patients from or referred patients to the PCDSP between April 1, 2011 and March 31, 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 (e.g., referrals, consultations, 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 (e.g., 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 (e.g., transition of care, 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 (e.g., model type, community size) to describe study participants. Interviews will take up to one hour, 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 to 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 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 April 1, 2011 and March 31, 2023. To be eligible for the study cohort, patients must be diagnosed with type 1 or type 2 diabetes, be 20 years 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 co-morbidity or any acute or chronic complication in the year before index date [i.e., 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 hyper- or hypo-glycemia.
2. Had at least one hospitalisation or ED visit for skin and soft tissue infection or foot ulcer.
3. Had at least one hospitalisation or ED visit for any acute complication (hyper- 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 hence are feasible with ICES data holdings (Appendix 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 Utilization Bands (RUB) in the year preceding index date.

Data sources

We will link Ontario Health Insurance Plan (OHIP) number, birthdate, postal code (for deterministic linkage), and date of first visit (to identify index date for PCDSP patients) from WebDR to administrative health data at ICES (Appendix 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 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, comorbidities, and to create ADGs and RUBs. The Canadian Organ Replacement Register (CORR) Database will be used to identify chronic diabetes complications related to kidney transplants. The Client Agency Program Enrolment (CAPE) will be used to identify unattached patients, and primary care models. The Immigration, Refugees and Citizenship Canada Permanent Residents Database (CIC) will be used to identify immigration-related variables. The Ontario Marginalization Index (ONMARG) along with RPDB will be used to identify low-income individuals. We will use validated condition-specific cohorts for asthma, CHF, COPD, hypertension, dementia, human immunodeficiency virus (HIV), rheumatoid arthritis, or Crohn's/colitis to identify comorbidities [33-40].

Analysis

All analyses will be conducted using SAS version 9.4 (SAS Institute, Cary, NC). 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, attached 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 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 mid-point year of proposed cohort), approximately 5% (n=3,915) [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), 2,084 PCDSP and 4,168 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 (6,252 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 (hyper- 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), Ontario Laboratory Information System (OLIS; lab tests), CERNER (lab testing in Southwestern Ontario), and the Ontario Drug Benefit (ODB; prescription drugs) database at ICES. We will gather cost data from Ontario Case Costing Initiative (OCCI), OHIP fee schedule, Ontario Schedule of Lab Tests, and the Ontario drug formulary. Costs 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 group. 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 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) is 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: 2023-121766; 2023-122326) and Lawson Health Research Institute (reference ID: R-23-202). A privacy review was conducted by St. Joseph's Health Care 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 (e.g., interview questions, administrative data variable definitions, etc.). At the second study meeting, we will present initial results and seek feedback on sensitivity analyses and interpretation of results.

Our end-of-grant KT (eKT) goals are to disseminate findings to improve PCDSP operations, inform policy and program discussions, encourage further research, and raise public awareness of study findings with the hopes to promote the spread, scale, and transferability towards 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 policy makers 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.

Contributors: MM is the lead and corresponding author. Contributions to the manuscript are described using the CRediT taxonomy (Brand et al. (2015), Learned Publishing 28(2)). Writing – Original Draft: MM, RL. Writing – Review and Editing: MM, RL, SH, LH, YHC, JD, MG, EH, BR, SS, LM, SMR. Conceptualisation: MM, SH, LH. Methodology: MM, LH, SH. Supervision: MM, LH. Project Administration: MM, LM. Funding Acquisition: MM, SH, LH, YHC, JD, MG, EH, BR, SS, 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.

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Appendix Table 1

Outcomes

Measure	Data Source(s)	Codes/Definitions
1 Had at least one hospitalization or emergency department (ED) visit for **hyper- or hypoglycemia**, 2006/07–2010/11	• Ontario Diabetes Database (ODD) • Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD) • National Ambulatory Care Reporting System (NACRS)	1. Hospitalization for hyper- or hypoglycemia based on CIHI-DAD records with any of the following ICD-10 codes: E100, E101, E110, E111, E130, E131, E140, E141 (hyperglycemia with coma or acidosis); E15, E160, E161, E162, E1063, E1163, E1363, E1463 (hypoglycemia). Hospitalizations listing the above diagnostic codes were included regardless of whether or not these were specified as being the 'most responsible diagnosis,' as long as the diagnosis was present at the time of admission and not a complication arising during the hospital stay (dxtype = '1' or '1'). Suspected cases were also included. 2. ED visits based on NACRS records with any of the following ICD-10 codes listed as the main reason for coming to the ED (dxtype = 'Main'): E100, E101, E110, E111, E130, E131, E140, E141 (hyperglycemia with coma or acidosis); E15, E160, E161, E162, E1063, E1163, E1363, E1463 (hypoglycemia); R73802, R73812 (blood glucose > 14 mmol/L). Cases of varying severity (any CTAS level) and suspected cases were also included.
2 Had at least one hospitalization or emergency department (ED) visit for **skin and soft tissue infection or foot ulcer**, 2006/07–2010/11	• Ontario Diabetes Database (ODD) • Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD) • National Ambulatory Care Reporting System (NACRS)	1. Hospitalization for skin and soft tissue infection or foot ulcer, based on CIHI-DAD records where any of the following ICD-10 codes were listed as the most responsible diagnosis (dxtype = 'M'): L00–L05, L08, M725, M726, A480, E1051, E1151, E1351, E1451, R02, E1061, E1161, E1361, E1461, E1070, E1071, E1171, E1371, E1471. Suspected cases were also included. 2. ED visits based on NACRS records where any of the following ICD-10 codes were listed as the 'main' reason for coming to the ED (dxtype = 'Main'): L00–L05, L08, M725, M726, A480, E1051, E1151, E1351, E1451, R02, E1061, E1161, E1361, E1461, E1070, E1071, E1171, E1371, E1471. Cases of varying severity (any CTAS level) and suspected cases were also included.
3 Had at least one hospitalization or emergency department (ED) visit for **any acute**	• Ontario Diabetes Database (ODD) • Canadian Institute of Health Information	1. Hospitalization for hyper- or hypoglycemia, skin and soft tissue infection, or foot ulcer, based on CIHI-DAD records with any of the following ICD-10 codes: E100, E101, E110, E111, E130, E131, E140, E141 (hyperglycemia with coma or acidosis); E15, E160, E161, E162, E1063, E1163, E1363, E1463 (hypoglycemia); L00–L05, L08, M725, M726, A480, E1051, E1151, E1351, E1451, R02, E1061, E1161, E1361, E1461, E1070, E1071, E1171, E1371, E1471 (skin or soft tissue infection or foot ulcer);

	complication (hyper- or hypoglycemia, skin and soft tissue infection, or foot ulcer), 2006/07–2010/11	Discharge Abstract Database (CIHI-DAD) • National Ambulatory Care Reporting System (NACRS)	specified as being the 'most responsible diagnosis' (dxtype = 'M') or, for hyper- or hypoglycaemia, as being a preadmission comorbidity (dxtype = '1'). For all outcomes, suspected cases were also included. 2. ED visits for hyper- or hypoglycemia, skin and soft tissue infection or foot ulcer, based on NACRS records with any of the following ICD-10 codes listed as the 'main reason for coming to the ED (dxtype = 'Main'): E100, E101, E110, E111, E130, E131, E140, E141 (hyperglycemia with coma or acidosis); E15, E160, E161, E162, E1063, E1163, E1363, E1463 (hypoglycemia); R73802, R73812 (blood glucose > 14 mmol/L); L00–L05, L08, M725, M726, A480, E1051, E1151, E1351, E1451, R02, E1061, E1161, E1361, E1461, E1070, E1071, E1171, E1371, E1471 (skin and soft tissue infection or foot ulcer). Cases of varying severity (any CTAS level) and suspected cases were also included.
4	Had at least one hospitalization for a **cardiovascular condition**, 2006/07–2010/11	• Ontario Diabetes Database (ODD) • Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD)	1. Hospitalization for acute myocardial infarction (AMI): based on CIHI-DAD records with most responsible diagnosis of AMI (ICD-10 codes I21 and I22, dxtype = 'Main'); or 2. Hospitalization for stroke: based on CIHI-DAD records with the most responsible diagnosis of stroke (ICD code = I61, I63, I64, dxtype = 'Main'); or 3. Hospitalization for congestive heart failure (CHF): based on CIHI-DAD records with most responsible diagnosis of CHF (ICD-10 code I50; dxtype = 'Main'); or 4. Hospitalization for unstable angina (UA): based on CIHI-DAD records with most responsible diagnosis of UA (ICD-10 code I20; dxtype = 'Main'); or 5. Hospitalization for transient ischemic attack (TIA) based on CIHI-DAD records with most responsible diagnosis of TIA (ICD-10 codes G450, G453, G458, G459; dxtype = 'Main').
5	Had at least one hospitalization for a **lower extremity amputation**, 2006/07–2010/11	• Ontario Diabetes Database (ODD) • Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD)	Hospitalization with any of the following Canadian Classification of Interventions (CCI) procedure codes in CIHI-DAD: 1VC93, 1VG93, 1VQ93, 1WA93, 1WE93, 1WI93, 1WJ93, 1WK93, 1WL93, 1WM93, 1WN93. These procedure codes were not included if they occurred in the setting of cancer or major trauma (identified by the following ICD-10 diagnostic codes if present on the same admission: C40.2, C40.3, C46.1, C47.2, C49.2, D16.2, D16.3, D21.2, S72–S79, S82–S89, S97–S99, T02.3, T02.5–T02.9, T03.3–T03.9, T04.3–T04.9, T05.3–T05.9, T07, T13.2– T13.9, T14.2–T14.9).
6	Had received **chronic dialysis or kidney transplantation**, 2006/07–2010/11	• Ontario Diabetes Database (ODD)	1. Chronic dialysis – any of the following: a) Chronic dialysis record in CORR; or b) Chronic dialysis, defined as dialysis for a minimum duration of 90 days, based on OHIP claims with any of the following fee codes: R849, G323, G326, G330, G331, G332, G333, G860, G861

		• Ontario Health Insurance Plan (OHIP) Database • Canadian Organ Replacement Register (CORR) Database • Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD) • Trillium Gift of Life Network (TGLN) Database	G862, G863, G864, G865, G866. Duration = last date [minus] first date [minus] any gaps > 21 days. 2. Kidney transplantation – any of the following: a) Record in TGLN database; b) OHIP claim including fee code for kidney transplantation: E769, E771, S434 or S435; or c) Procedure codes from CIHI-DAD: Canadian Classification of Procedures (CCP) code V42.0 (prior to April 1, 2002) or Canadian Classification of Interventions (CCI) code Z940 (from April 1, 2002 onwards).
7	Had at least one **chronic complication** (hospitalization for a cardiovascular condition, lower extremity amputation or end-stage renal disease), 2006/07–2010/11	• Ontario Diabetes Database (ODD) • Ontario Health Insurance Plan (OHIP) Database • Canadian Organ Replacement Register (CORR) Database • Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD)	1. Hospitalization for a cardiovascular condition; 2. Lower extremity amputation; or 3. End-stage renal disease, defined as chronic dialysis or kidney transplantation, using the same definitions as in measures 6, 7 and 8 listed above

	• Trillium Gift of Life Network (TGLN) Database

*Death records were used to verify that all individuals captured in the Registered Persons Database were alive on the index date before including them in the population denominators. LHIN = Local Health Integration Network

Appendix Table 2

Summary of data sources and proposed use in complications study and cost effectiveness study

Data Source(s)	Description and Proposed Use
WebDR	EMR data from Primary Care Diabetes Support Program Exposure or exposure definition
Ontario Diabetes Database (ODD)	ICES-validated diabetes cohort Cohort creation
Registered Persons Database (RPDB)	Database of OHIP eligible Ontarians Cohort creation Predictor/cofactor/covariate Cohort stratification
Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD)	Database of hospitalizations Cohort creation Outcome or outcome definition
National Ambulatory Care Reporting System (NACRS)	Database of emergency department, outpatient visits Cohort creation Outcome or outcome definition
Ontario Health Insurance Plan (OHIP) Database	Database of physician visits Cohort creation Outcome or outcome definition
Canadian Organ Replacement Register (CORR) Database	Database of organ transplants Cohort creation Outcome or outcome definition
Trillium Gift of Life Network (TGLN) Database	Database of organ transplants Cohort creation Outcome or outcome definition
Client Agency Program Enrolment (CAPE)	Database of patient enrolment to primary care providers Cohort creation Predictor/cofactor/covariate
Immigration, Refugees and Citizenship Canada Permanent Residents Database (CIC)	Cohort creation Predictor/cofactor/covariate
Ontario Marginalization Index (ONMARG)	Database of patient enrolment to primary care providers Cohort creation Predictor/cofactor/covariate
Ontario Asthma dataset (ASTHMA)	ICES-validated asthma cohort Predictor/cofactor/covariate
Congestive Heart Failure (CHF)	ICES-validated congestive heart failure cohort Predictor/cofactor/covariate
Chronic Obstructive Pulmonary Disease (COPD)	ICES-validated chronic obstructive pulmonary disease cohort Predictor/cofactor/covariate
Ontario Hypertension dataset HYPER	ICES-validated hypertension cohort Predictor/cofactor/covariate
Ontario Dementia Database (DEMENTIA)	ICES-validated dementia cohort Predictor/cofactor/covariate
Ontario HIV Database (HIV)	ICES-validated HIV cohort Predictor/cofactor/covariate

Ontario Rheumatoid Arthritis Database (ORAD)	ICES-validated rheumatoid arthritis cohort Predictor/cofactor/covariate
Ontario Crohn's and Colitis Cohort dataset (OCCC)	ICES-validated Chron's and Colitis cohort Predictor/cofactor/covariate
Ontario Case Costing initiative (OCCI)	Costs Outcome or outcome definition
Ontario Laboratory Information System (OLIS)	Lab tests Outcome or outcome definition
Laboratory Data from South-western Ontario hospitals (CERNER)	Lab tests Outcome or outcome definition
Ontario Drug Benefit (ODB)	Prescription drugs for 65+ year old Outcome or outcome definition