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Implementation and evaluation of a pharmacist-led diabetes care pathway in Alberta community pharmacies (D-PATH)

PROTOCOL AND STATISTICAL ANALYSIS PLAN

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Implementation and evaluation of a pharmacist-led diabetes care pathway in Alberta community pharmacies (D-PATH)

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Background:

As of 2024, 8% of Albertans are living with diagnosed diabetes and this number increases to 9% when cases of undiagnosed type 2 diabetes are included[1]. Certain populations are at a higher risk of developing type 2 diabetes including those of African, Arab, Asian, Hispanic, Indigenous, or South Asian descent[1]; these ethnicities represent approximately 30% of the population of Alberta. In addition, individuals who are older, or who have a lower level of income or education, or who are physically inactive, or who are living with overweight, or obesity increases the risk of type 2 diabetes[1].

Diabetes complications are associated with premature death and can reduce lifespan by 5 to 15 years[1,2]. Diabetes contributes to 30% of strokes, 40% of heart attacks, 50% of kidney failure requiring dialysis, 70% of all non-traumatic leg and foot amputations, and is the leading cause of blindness[2]. Unfortunately, less than half of patients with Type 2 diabetes reach ideal glycemic targets[3] and only 13% of Canadians with diabetes achieve the composite triple target of glycemic, blood pressure and lipid control[4]. In 2024, the direct cost of diabetes to the Alberta Health Care System was $556 million[1]. Therefore, there is a need for new and innovative ways to tackle one of Canada's major public health issues.

There are numerous guidelines and tools to guide the treatment of diabetes and reduce the risk of diabetes-related complications, however these interventions have been slowly adopted[4]. There are multiple factors that have led to a high degree of clinical inertia with difficulty achieving timely intensification of hyperglycemic medications in relatively uncomplicated patients; these include a multitude of priority issues and increasing demands on limited healthcare resources[4]. In addition, through a scoping review of the literature, it was identified that pharmacists often lacked confidence in prescribing[5].

Clinical decision support (CDS) is defined as an electronic tool that supports clinical decision-making that can incorporate patient specific considerations; this assists the clinician in providing guideline-based treatment recommendations[6] and improve guideline concordance[7]. In a trial evaluating CDS in diabetes, hemoglobin A1c (HbA1c) was significantly improved[8]. Another study showed that CDS added value and improved risk control in diabetes care[9]. Overall, CDS can improve drug therapy appropriateness, reduce medical errors, and integrate non-pharmacological management such as lifestyle changes[7,10].

Pharmacists are frontline primary healthcare providers who practice in the heart of their communities. They see patients with chronic conditions more frequently than any other healthcare provider[11,12]. There is robust evidence that pharmacists improve patients' diabetes management[13]. Various studies have shown that pharmacists effectively improve glycemic control and overall diabetes care in patients[13-15].

While there is strong evidence for the impact of pharmacist care in diabetes management, implementation of this evidence is lacking. Such lack of implementation, combined with the family physician crisis in Canada[16], highlights the need for creative

implementation initiatives.

Shared decision-making is the engagement of patients and clinicians in making health decisions jointly, encouraging patient involvement in care decisions[17]. Shared decision-making incorporates domains such as the patients' values, lifestyle, and background. Studies have demonstrated that shared decision-making improves patient outcomes, reduces healthcare utilization, patients' disease knowledge, and satisfaction of care[17-19], however, has not yet been explored in the context of pharmacist care.

Pharmacist primary care clinics are new initiatives that are aiming to improve patients' access to care in many areas, including chronic disease management[20]. While anecdotal findings reported that these clinics are successful[21], there has been no formal evaluation of their services. With the increased prevalence of diabetes, pharmacists are the most accessible healthcare provider to support patients with diabetes within community pharmacies and pharmacist primary care clinics. This is an opportunity to implement and evaluate a clinical decision support tool and a shared decision-making tool for pharmacists in clinic and non-clinic settings in managing diabetes.

Objectives

Primary objective:

A) To determine the effect of a pharmacist-led diabetes care pathway (please see the intervention section for the description) on participants' glycemic control in individuals with poorly controlled type 2 diabetes and,

Secondary objectives:

1. To utilize the EPI·R_xISK™ calculated score to evaluate change in cardiac risk.

2. The yield of each enrollment approach (please see enrollment approaches description below).

3. Determine the effect of a diabetes care pathway for pharmacists on patient satisfaction of pharmacist care in patients with type 2 diabetes.
    - Assessed via change in diabetes treatment satisfaction questionnaire standard (DTSQs) from baseline to 6 months (end of study) in both groups
    - Assessed via change in diabetes treatment satisfaction questionnaire-change (DTSQc) at 6 months (end of study)

4. To determine the impact of a diabetes care pathway for pharmacists on diabetes guideline concordance in the management of diabetes in patients with type 2 diabetes.
    - Change in blood pressure
    - Change in low-density lipoprotein cholesterol (LDL-c)
    - Number of patients receiving influenza and pneumococcal vaccination

    - Number of patients who completed annual foot exams, eye exams, kidney function screening to reduce risk of diabetes-related complications.
    - Number of patients who received of sick-day education
    - Number of patients who have appropriate vascular protection in place at baseline vs end of study.
5. To determine the types of interventions provided by the pharmacists, such as education on lifestyle factors (tobacco cessation, diet, exercise), prescribing or changing the dose of medications, education on new or changed medications, education on adherence to medications and/or lifestyle recommendations.
6. To determine the percentage of individuals who attended their scheduled laboratory assessments.
7. To determine the yield of each enrollment approach.
8. To determine whether the type of pharmacy (clinic or non-clinic) affects study outcomes.
9. To determine the extent to which shared decision making was achieved in the intervention as measured by the validated Shared Decision Making 9-item Questionnaire (SDM-Q-9) tool.

Methods:

Study design: Randomized control trial with the patient as the unit of randomization.

Setting: Community pharmacies in Alberta

Population:

Inclusion criteria:

- Individuals aged 18 years or older.
- Individuals with type 2 diabetes.
    - Further assessed to rule out latent autoimmune diabetes in adults (LADA) or maturity onset diabetes of the young (MODY) by asking patients:
        - "Do you have diabetes that does not require the use of insulin, or did not require the ongoing consistent use of insulin immediately after diagnosis for more than 6 months after diagnosis"
        - "Did you develop diabetes as a result of damage to the pancreas such as acute/chronic pancreatitis, or pancreatic surgery?"
- Individuals with type 2 diabetes not reaching HbA1c target of ≤7.0%

Exclusion criteria:

- Individuals with type 1 diabetes, gestational diabetes, or other forms of diabetes that are not type 2 diabetes.
- Pregnant individuals.
- Individuals at their HbA1c target (HbA1c ≤7.0%) or those with a limited life expectancy, frailty, or lack hypoglycemic awareness (i.e., those with an A1c target >7.0%).

- Individuals unable to provide consent or who are unwilling to attend follow-up visits.

Enrollment/Recruitment:

Community Pharmacies:

Pharmacies will be recruited through Epidemiology Coordinating and Research (EPICORE) Centre's R_xCELLENCE Network, Alberta College of Pharmacy, and Alberta Pharmacists' Association in Alberta. Participating pharmacists must have their additional prescribing authorization (APA) from the Alberta College of Pharmacy and agree with the intervention and control groups protocol. Pharmacists may be certified diabetes educators (CDE) with the Canadian Diabetes Educator Board; however, this is not required.

Participants:

1. Self-referral:
   Participant Recruitment Posters will be displayed in participating community pharmacies. If patients are interested, they can speak to their pharmacist for further information and enroll in the study.

2. In-pharmacy enrollment:
   a. Opportunistic: Pharmacists will approach potential participants who report having type 2 diabetes, regardless of their reason for visiting the pharmacy (e.g. a patient visiting for hypertension management, or a patient visiting for a urinary tract infection who, upon review of history, fits the inclusion criteria).
   b. Case finding activities: Use of pharmacy dispensing software (e.g. Kroll) to identify patients currently dispensed antihyperglycemic medications at their pharmacy.

Those who meet the inclusion criteria will be asked if they would like to participate in the study. Those who agree to participate will be given a participant information sheet and given the opportunity to ask the study investigator any questions. Patients will then be asked to sign the study's informed consent form. Once the signed consent form is obtained, the patient will be enrolled in the study.

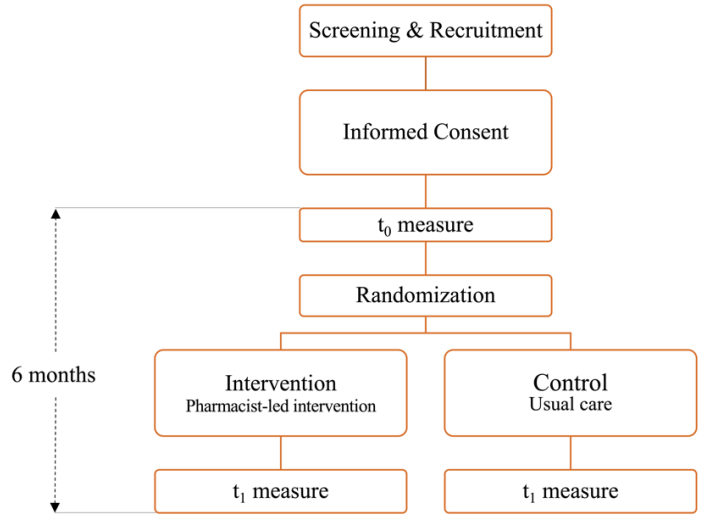

Figure 1. Study Flow Diagram

Randomization:

- Individual patients will be the unit of randomization.
- Study participants will be randomized on a 1:1 ratio to the intervention or control groups (Figure 1) using a variable blocked randomization.
- Randomization will be stratified by pharmacy site and the presence of a CDE certified pharmacist.
- Randomization will be conducted using a centralized randomization service by EPICORE to ensure allocation concealment.

Blinding:

Due to the nature of the intervention, blinding of the participants to treatment allocation will not be possible.

Study Interventions:

Baseline questionnaire:
All patients who consent to participate in the study will complete a baseline questionnaire prior to randomization (see appendix 1).

Intervention Group:
Participants in the intervention arm will receive the care using a shared decision-making pharmacist care pathway approach designed to guide type 2 diabetes management to achieve target A1C levels and reduce the risk of diabetes-related complications. The pharmacist care pathway is modelled after the Canadian Diabetes Association Guidelines[22]. This pathway (tool) will be built into a computer web-based program and include step-by-step, algorithm-guided patient assessment to achieve target A1C levels and reduce the risk of diabetes-related complications. This tool will also calculate the participant's estimated CV risk using the EPI·R_xISK™ calculator.

The participant and pharmacist will be guided by the care pathway to review the participant's current type 2 diabetes management and diabetes-related complication risk factors and engage in shared decision-making to guide further management of diabetes. The care pathway will suggest individualized follow-up plans, guideline-driven targets (e.g., A1C or blood pressure or serum lipid concentration targets) and treatments (including lifestyle modifications and medications). The pharmacist and participant will be prompted to reach an agreed diabetes management plan and book a follow-up appointment in 6-weeks' time.

The individualized diabetes management plan will be provided to the participant (hard and/or soft copy) and used to guide the care provided by the pharmacist to the participant. With the participant's consent, correspondence (hard and/or soft copy) detailing the diabetes management plan will be sent to the participant's family physician or nurse practitioner. Follow-up appointments will continue every six weeks for six months. The study intervention has been co-designed with key stakeholders (including practicing pharmacists, diabetes specialists, and patients with lived experience).

Participants' treatment regimen may be adapted by initiating new prescriptions medications or adjusting the dosage or frequency of prescription medications or ordering laboratory tests. All the aforementioned activities are within the scope of practice for pharmacists in Alberta (https://www.pharmacists.ca/advocacy/scope-of-practice/). As such, pharmacists can perform them as part of the routine care they are providing to their patients. Changes to participants' treatment regimen made by the pharmacist will be communicated to the participant's family physician or nurse practitioner.

The pharmacist will provide the following to all the participants randomized to the intervention group:

- Patient assessment
    - Weight
    - Height
    - Social history (self-reported)
    - Lifestyle (self-reported)
    - Blood pressure (measured according to Hypertension Canada Guidelines[23])
- Lab assessment:
    - As part of routine care the pharmacist will check the most recent laboratory test results for A1C, lipid profile, kidney and liver function through the provincial electronic health record.
    - A1C will be at baseline, 3 and 6-months' time.
    - Lipid profile, kidney and liver function will be assessed at baseline and 6-months' time.
- Individualized A1C target.
    - Using Canadian Diabetes Association tool.
- Individualized CV risk calculation and education about this risk

    - Using EPI·R_xISK™ (https://www.epicore.ualberta.ca/epirxisk/)
        - The calculator will demonstrate the participants' individualized cardiovascular risk, the contribution of each risk factor to the overall risk and the impact of controlling these factors on the overall CV risk. It is based on validated risk assessment equations (Framingham[24], UKPDS[25] and SMART[26]) and was evaluated in the largest CV risk reduction randomized controlled trial in a community pharmacy setting[27].
- Adherence assessment
- Treatment initiation/adjustment:
    - Prescription adaptation
    - Prescribing as appropriate to meet the treatment targets according to the most recent Canadian guidelines or evidence-based literature for diabetes management and vascular protection.
    - Lifestyle and medication education
    - Assessing vaccination status for pneumococcal and influenza immunizations.
    - Screen for completion of diabetes-related complications required monitoring to ensure annual foot exam, necessary eye exams, and renal function are completed.
- Regular follow-up
    - Follow-up on a six-week basis for six months.

As a professional courtesy and as a part of standard professional practice, the pharmacist will inform the participant's family doctor and all members of the participant's health care team (such as their cardiologist, nephrologist, physiotherapist etc.) of the participant's involvement in the study. The pharmacist will inform the participant's health care team of all updates to their medicines and health care plan. Members of the participant's health care team will have the opportunity to express any comments regarding the participant's health plan and may communicate directly with the pharmacist to discuss the most appropriate treatment plan for the participant.

If the patient experiences any adverse reactions, the pharmacist will exercise clinical judgement to manage the adverse reactions if it is within their scope to do so and if required, will refer the patient to see their family physician or nurse practitioner or to the nearest emergency room as clinically appropriate. This does not deviate from standard practice as pharmacists in Alberta possess the scope to diagnose, prescribe, and manage medication regimens including the management of potential adverse reactions to medications.

At the completion of the intervention period, participants will be given a certificate of completion and a summary of their diabetes management plan.

Control:
The control group will involve facilitated relay of information to participants' family physician or nurse practitioner. Participants in the control group will have their

pharmacist collect information informing the patient's current diabetes control. Participants will then be given a letter that contains their A1C value, and they will be advised to present it to their family physician or nurse practitioner. No specific suggestions for diabetes management will be detailed in the letter. In the case where the patient does not have a family physician or nurse practitioner, they will be referred to a physician walk-in clinic. Note, this may result in confounding of the control group. A follow-up appointment will be booked for all participants in the control group at 3-months to discuss dietary and lifestyle interventions in the management of type 2 diabetes to maintain participant interest in the study and again at 6-months' time for a final visit.

During the 6-month follow-up appointment, participants will have their diabetes management reassessed. At the end of the study period (after the 6-month follow-up appointment), all the participants in the control group will be offered to receive care using the shared decision-making pharmacist care pathway approach designed to guide the type 2 diabetes management process (received by participants in the intervention arm).

Outcomes

The primary outcome is the difference in change in A1C from baseline to the end of the study (at six months) between the intervention and control groups.

The secondary outcomes are:

- difference in change in estimated CV risk (calculated using the EPI·R_xISK™ calculator) from baseline to the end of the study (at six months) between the intervention and control groups.
- The difference in change in individual factors contributing to diabetes-related complications from baseline to the end of the study between the intervention and control groups including:
    - Change in blood pressure
    - Change in low-density lipoprotein cholesterol (LDL-c)
    - Number of patients receiving influenza and pneumococcal vaccination
    - Number of patients who completed annual foot exams, eye exams, kidney function screening
    - Number of patients who have appropriate vascular protection in place at baseline vs end of study
- Types of interventions provided by the pharmacists, such as education on lifestyle factors (tobacco cessation, diet, exercise), prescribing or changing the dose of medications, education on new or changed medications, education on adherence to medications and/or lifestyle recommendations.
- The percentage of individuals who attended their scheduled laboratory assessments.
- The percentage of individuals who use continuous glycose monitoring devices as part of their type 2 diabetes management.
- The yield of each enrollment approach.
- Where the type of pharmacy (clinic or non-clinic) affects study outcomes.

- Patient satisfaction as measured by the diabetes treatment satisfaction questionnaire standard and change.
- Extent to which shared decision making was achieved in the intervention as measured by the validated Shared Decision Making 9-item Questionnaire (SDM-Q-9) tool.

Reimbursement
Pharmacies will be offered an honorarium for their time recruiting participants into the study and completing intervention or control processes. Pharmacies will be offered an honorarium of $150 per intervention participant and $50 per control participant when that participant completes the 6-month follow-up period. Honorariums will be offered to the pharmacy site quarterly.

Data collection:

Data related to patient demographics and the study outcomes will be collected. A summary of the variables and time points that will be collected is shown in Table 1. Please see appendix 1 for further information collected in the baseline questionnaire. Data related to patient demographics and the study outcomes will be collected as part of routine standard care.

Table 1 Data Collection Form

Variable	**Timepoint**		
	Baseline	3-month Follow-up	6-month Follow-up
Demographics (age, sex, gender, postal code, phone number, email address, home language, ethnicity, immigration status, name and contact information [telephone number, fax number] of family physician or nurse practitioner)	X		
Socioeconomic status (employment status, education level, financial barriers, food insecurity)	X		X
Clinical information (duration of diabetes, family history, smoking status, insurance coverage for prescriptions, comorbidities, medications, vaccination history)	X		X
Laboratory Measurements (A1C, serum creatinine, estimated glomerular filtration rate (eGFR), Albumin/Creatinine ratio, LDL, HDL, triglycerides, ALT, AST, platelets	X	X (A1C intervention group)	X
Vital signs: Blood pressure, heart rate	X		X

Biometrics: height, weight, BMI	X		X
Type of community pharmacy (clinic or non-clinic)	X		
DTSQs	X		X
DTSQc			X
SDM-Q-9			X

Baseline data will be collected as a part of the web-based study tool. For individuals in the intervention group, the tool will then be used to formulate a diabetes management plan for the patient using shared decision making. The web-based tool will be administered by pharmacists in community pharmacies. Data at the 3- and 6-month follow up will be collected as a part of the same web-based tool for participants. Therefore, participants will not be contacted to complete any additional questionnaires or data collection sheets outside of community pharmacy visits.

Sample size:
Using the information from Wagner et al[15] and the following assumptions: a mean (SD) of difference in change in HbA1c from baseline to 6 months of 0.6 (SD: 2.35) for control and 1.96 (SD: 2.21) for intervention and α of 0.05, we calculated 90% power to detect a mean of minimum clinically significant change of effect size 0.2630, the sample size of 520 patients was calculated. The sample size was inflated to 600 (300 in each group) by 15% to account for possible losses to follow-up and missing data issues. The sample size calculation was calculated by an independent T-test using G.Power3.1.

Analytical plan:
Participant demographics and clinical information will be reported using basic frequency (percentage), means (standard deviation) and median (inter quartile range) as appropriate.

The change in A1C and EPI·R_xISK™ score will be analyzed using independent t-test. Regression analysis will be performed to adjust for the clinic effect. Missing data will be imputed using a last value carried forward approach. Patient satisfaction, the yield of each enrollment approach, and the types of interventions provided by the pharmacists will be analyzed using descriptive statistics while the change in blood pressure, LDL, renal, and hepatic function will be analyzed using independent t-tests. Change in tobacco use will be analyzed using chi-square test. Mixed-effects models will be used to evaluate associations between A1C and participant characteristics. Data analysts will be blinded to participants allocation.

Data security and storage:
Participant data will be collected and stored securely in a password protected, cloud-based data management system managed by the EPICORE Centre at the University of Alberta. Any hard-copy data will be kept at the EPICORE Centre in a locked cabinet and office. Once all data analysis is completed, data will be sent to the following secured storage facility: Iron Mountain Canada Corporation 14410 121A Ave, Edmonton, AB T5L 4L2. Data collected will be stored for 5 years following completion of the study.

Ethics:
This study will be conducted in compliance with the protocol and the principles of Good Clinical Practice (GCP). Ethics will be obtained from the University of Alberta Health Research Ethics Board.

Participants will be followed up by their pharmacists once every 6 weeks which may be more often than the usual care, however we are identifying patients with uncontrolled diabetes that once identified will need to be aggressively followed to ensure they meet their appropriate targets. We are proactively identifying patients and are, hopefully, modifying their current diabetes management earlier to prevent long term diabetes-related complications. This might cause patient anxiety. In addition, participants will be asked to seek laboratory testing and may experience minor pain or discomfort, or a rare risk of infection related to blood sample collection. Blood and urine tests will be performed at a local blood testing facility and will be performed by trained phlebotomists. In the case that any anxiety or discomfort is caused, participants will be given clear information to contact the study investigators or their health care provider for support. However, any anxiety and risks/discomfort associated with extra lab testing should be mitigated by reducing participants' long-term health risks due to type 2 diabetes. Participants will be informed during the consent procedure that these extra laboratory tests will occur, so that they can consider that prior to consenting in the study. Also, quality of life for participants in different groups will be compared to assess the effect of the intervention on the participants. In addition, pharmacists will help participants to understand the risks of heart disease and stroke.

All participants will be free to withdraw at any time. Data from participants who withdraw from the study will be included until the point of withdrawal.

Knowledge Mobilization:

The study findings and feedback from participants will be used to adapt the intervention to community pharmacies in other Canadian jurisdictions using implementation spread and scale principles (e.g., assessing and addressing readiness, fit, and sustainability).

What this study adds:

This is an opportunity to widely implement and evaluate a clinical decision and shared decision-making tool for community pharmacists managing type 2 diabetes. This study will identify patients with poorly controlled type 2 diabetes and provide appropriate diabetes management to improve outcomes aligned with Canadian Guidelines.

Research dissemination:

The results of this study will be disseminated through scientific conference presentations, meetings with key stakeholders, and peer-reviewed publications.

Partners:

- Shoppers Drug Mart: The project will be conducted at Shoppers Drug Mart's Pharmacy Care Clinics.
- Other community pharmacies will be invited to participate (i.e., non-Shoppers Drug Mart sites)
- EPICORE: EPICORE will provide all the data management and statistical support services for the project.

Training:

Training will be based on the guideline-informed assessment and treatment algorithm described in the intervention section. Training materials will be developed by the research team and provided at face-to-face/virtual meetings with the pharmacists. Additional online training will be developed using the most up-to-date Canadian Guidelines or evidence-based literature. Those materials will be available online and will include the following:

- Case finding
- EPI·R_xISK™ score calculation
- Diabetes treatment and management
- Chronic kidney disease treatment and management
- Hypertension treatment and management
- Cholesterol treatment and management
- Diabetes treatment and management
- Cessation of tobacco use

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