2025

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

INFORMED CONSENT FORM

DATE: OCTOBER 2, 2025

PARTICIPANT CONSENT FORM

Title of Study: Evaluation of pharmacist-led diabetes care pathway in Alberta community pharmacies.

Principal Investigator:

Dr. Ross Tsuyuki
Professor of Medicine (Cardiology)
Faculty of Medicine and Dentistry
University of Alberta
Edmonton, AB
rtsuyuki@ualberta.ca

Co-investigator(s):

Dr. Stephanie Gysel
Post-doctoral fellow
Faculty of Medicine and Dentistry
University of Alberta
Edmonton, AB
sgysel@ualberta.ca

Dr. Dave Campbell
Associate Professor
University of Calgary
Cumming School of Medicine
Calgary, AB
dcampbel@ucalgary.ca

You are being invited to take part in a research study. Before you take part, a member of the study team is available to explain the project and you are free to ask any questions about anything you do not understand. You will be given a copy of this form for your records.

Why am I being asked to take part in this research study?

You are being invited to take part in this research project because you have type 2 diabetes and have not reached your target hemoglobin A1C – your target for blood sugar control. This may place you at higher-than-normal risk for diabetes-related complications.

Type 2 diabetes is a condition in which your body cannot make enough insulin (a hormone that helps control the amount of glucose or sugar in your blood) or does not properly use the insulin it makes. Type 2 diabetes is caused by several different risk factors and accounts for 90% of diabetes cases in Canada. Controlling type 2 diabetes will reduce your risk of diabetes-related complications and may improve your overall health.

This research project is testing 2 different programs to improve your diabetes control and reduce your risk of diabetes-related complications. It will involve working with a pharmacist to see if there is a change to your diabetes control.

This form contains information about the study. Before you read it, a member of the study team will explain the study to you in detail. You are free to ask questions about anything you do not understand. You will be given a copy of this form for your records.

What is the reason for doing the study?

The purpose of this research project is to find out if a community pharmacy-led program can help improve your diabetes control and reduce your risk of diabetes-related complications.

What will I be asked to do?

You will be asked to participate in a research project designed to compare programs aimed to improve your diabetes control and reduce your risk of diabetes-related complications.

Sometimes, we do not know which program is better. To find out, we need to compare the different programs. We will randomly assign you to receive one of two programs. The results will then be compared to see if one program is better.

If you agree to participate in this research project, you will be asked to sign the Consent Form at the end of this form.

If you fit the criteria for the research project and agree to participate in it, you will be randomly put into one of two groups. These groups are the Group A and Group B. You will have an equal chance of being put into either group.

If you are in Group A, you will be asked to meet with the pharmacist every 3 months over a six-month period. These meetings will be done in-person or over the phone. The first meeting will take up to 60 minutes, and the follow-up meetings will take 10-20 minutes. During these meetings, your pharmacist (and possibly a pharmacy student) will conduct an assessment that may include blood pressure, height and weight measurements, and will talk to you about your type 2 diabetes, medications, diet, physical activity, and other health conditions.

At the first visit, the pharmacist will help you work out if your type 2 diabetes is controlled by gathering some initial information and reviewing your laboratory tests with you. The pharmacist will then refer you to see your family doctor. If you don’t have a family doctor, your pharmacist will help you find the closest walk-in family doctor office and refer you to review your diabetes control with them. You will see the pharmacist or speak with them over the phone in 3-months’ time to receive information about dietary and lifestyle measures for diabetes. Prior to six-months, you will be asked to do some laboratory tests, and the pharmacist (and possibly a pharmacy student) will conduct an assessment that may include blood pressure, height and weight measurements, and will talk to you about your type 2 diabetes, medications, diet,

physical activity, and other health conditions. At the end of the six-month research project period, everyone in Group A will be offered the same program offered to people in Group B.

If you are in Group B, you will be asked to meet with the pharmacist every six weeks over a six-month period. These meetings will be done in person or over the phone. At least one of the meetings with the pharmacist will need to be in person. The first meeting will take up to 60 minutes, and the follow-up meetings will take 10-20 minutes. During these meetings, your pharmacist (and possibly a pharmacy student) will conduct an assessment that may include blood pressure, height and weight measurements, and will talk to you about your type 2 diabetes, medications, diet, physical activity and tobacco cessation plan (if appropriate). You and your pharmacist (and possibly a pharmacy student) will come up with a plan for how to control your diabetes and lower your risk of diabetes-related complications. The plan may include medication changes or additions, tobacco cessation support, and a healthy diet. Your pharmacist will discuss this plan with your family doctor. You will be asked to do some laboratory tests at 3 months and just before the end of the 6 months of the program. These tests may include a blood sugar control test (A1C), cholesterol level, and tests to assess your liver and kidneys to find out the effect of the program on your diabetes control and risk of diabetes-related complications.

During this study, you will have close follow-up with both your pharmacist and your family physician. Your family physician will receive a letter from the pharmacist to let them know that you agreed to participate in this study. The letter will also contain detailed information of what the study is about. The pharmacists will let your family physician know about the results of all the tests taken and any changes in your medications.

Laboratory tests with blood and urine samples, are needed in group A and B of this study. These tests will be done at licensed and registered laboratories by Alberta Health Services. The pharmacists in this study will not collect your sample. These laboratories will use their approved and standard procedures to handle, store and examine the samples. The laboratory services will store samples and data in a secure, private, and confidential manner. The research team has no impact or influence on how these laboratory samples are stored and/or handled.

Participants in group A and B may be required to go to the lab before the start of the study. For individuals in group A, you will need to go to the lab at the end of the study period in 6 months. For individuals in group B, you will need to go to the lab at 3-months and at the end of the study period in 6 months. The amount of blood to be collected at each laboratory visit is approximately 10mL. The amount of urine to be collected at each laboratory visit is approximately 60mL.

What are the risks and discomforts?

You may be prescribed new medications or have changes made to your existing medications to help improve your type 2 diabetes control and reduce your risk of diabetes-related complications. These changes and alterations may cause side effects. For example, if you are prescribed or have an increase in your dose of medicines for blood sugar levels, you may

experience dizziness or shakiness. If you are prescribed blood pressure medicine or if doses of your blood pressure medicine are increased, you may experience temporary dizziness or light-headedness. If you are prescribed medicines for your cholesterol levels, you may experience nausea, stomach discomfort, or muscle pain. In most people, the medicines that are prescribed are well tolerated and side effects are uncommon. If you experience any side effects from your medicines, your pharmacist will help you manage your side effects and if necessary, switch your medicines to alternatives that are most tolerable. Increasing the dose or frequency of your medications may increase the cost of your treatment if you do not have health insurance (private or governmental).

If you are in Group A of the study, you will be referred to a walk-in-clinic for further care if you do not have a regular primary care provider (family doctor or nurse practitioner). Walk-in clinics do not generally have an established relationship with their patients and may only provide acute care. This type of medical practice may not be ideal for the increased care you may need for the management of chronic health conditions, like diabetes.

Also, you will be asked to do some blood and urine tests as part of this study. You may experience pain or discomfort, and a rare risk of infection if a sample needs to be obtained from you. Blood and urine tests will be performed at a local blood testing facility and will be performed by trained phlebotomists.

It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant. If we find out anything new during the course of this research which may change your willingness to be in the study, we will tell you about these findings.

What are the benefits to me?

There may be no direct benefit to you in participating in this study.

Participation in the pharmacist delivered program may help you to have a better understanding of how to manage your diabetes and risk of diabetes-related complications:

- Bringing down your blood sugar level
- Bringing down your blood pressure
- Bringing down your cholesterol level
- Making healthier diet and lifestyle choices
- Helping you to quit tobacco use

We hope that this study will also help other patients improve their type 2 diabetes control and reduce their risk of diabetes-related complications. This study will help us understand how pharmacists can help to improve diabetes control and risk of diabetes-related complications in people.

Your diabetes control and risk of diabetes-related complications may not be reduced by the end of the study.

You will also continue to receive care from your family doctor for all your medical conditions.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that you are entitled to. You do not have to answer any questions you are uncomfortable with in the research questionnaires.

To withdraw from the study please contact Dr. Stephanie Gysel at sgysel@ualberta.ca. Even if you remain in the research study, you may choose to withdraw some or all of your responses by contacting Dr. Stephanie Gysel at sgysel@ualberta.ca by June 1, 2026. We are unable to remove your answers after that time because the data has been anonymized, and the study paper will be written.

Will I be paid to be in the research?

You will not be paid for participating in this study.

What happens if I am injured because of this research?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form, you are not giving up any of your legal rights or releasing the researcher(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

Will my information be kept private?

During this study we will do everything we can to make sure that all information you provide is kept private. No information relating to this study that includes your name will be released outside of the researcher's office or published by the researchers unless you give us your express permission. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private

During research studies it is important that the data we get is accurate. For this reason, your data, including your name, may be looked at by people from the Research Ethics Board.

As a part of this study, we require information on your demographics such as your full postal code and date of birth to accurately compare the characteristics between Group A and Group B, and its generalizability to the broader population.

For pharmacists to deliver the diabetes management program, they will collect information including your name, health care number, and members of your health care team to communicate any changes made to your care (e.g. to your family doctor). We will also collect

your contact information including your telephone and email address to send you information about your health care (as a part of standard practice) and reminders about your follow-up appointments with the pharmacist.

Once data collection is complete, all your identifiers will be removed and replaced with a non-identifiable unique patient code. The study principal investigators will retain a master list that links your identifiers with de-identified data. This master list will be kept on a cloud-based, password protected platform that is accessible by the study principal investigators only.

After the study is done, we will still need to securely store your data that was collected as part of the study. Your 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 locked office.

Once all the data analyses are completed, data will be sent to the following secured storage facility: Iron Mountain Canada Corporation 14410 121 A Ave. Edmonton, T5L 4L2. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

What if I have questions?

Your questions can be answered by a member of the study team; you are not obligated to ask your pharmacist questions about participating in the study. You can directly contact a member of the study team if you wish to discuss the study further prior to deciding to participate. You may contact Dr. Stephanie Gysel at sgysel@ualberta.ca if you have questions about the research now or later.

If you have any questions regarding your rights as a research participant, you may contact the University of Alberta Research Ethics Office at ethics@ualberta.ca or (780)492-2615 and quote Ethics ID Pro00145395. This office is independent of the researchers.

The study is being sponsored by Shoppers Drug Mart. The Institution and Principal Investigator are getting money from the study sponsor to cover the costs of doing this study. You are entitled to request any details concerning this compensation from the Principal Investigator.

How do I indicate my agreement to be in this study?

By signing below, you understand:

- That you have read the above information and have had anything that you do not understand explained to you to your satisfaction.
- That you will be taking part in a research study.
- That you may freely leave the research study at any time.
- That you do not waive your legal rights by being in the study
- That the legal and professional obligations of the researchers and involved institutions are not changed by your taking part in this study.

SIGNATURE OF STUDY PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

A copy of this consent form has been given to you to keep for your records and reference.