UNIVERSITY OF ALBERTA

Information Sheet

Outcomes of Diabetes Management by Pharmacists: The RxING Prospective Registry

Principal Investigator(s):

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Background:
Diabetes (blood sugar) control in many patients with diabetes mellitus is poor (or not at the recommended target of less than 7%). Poorly controlled diabetes can cause other problems and lower quality of life. Diabetes control is very important so that patients will not suffer from any other medical conditions, such as heart attack, stroke and kidney failure and will enjoy their lives. Diabetes can be treated by lifestyle changes, oral diabetes medicines or insulin. Pharmacists frequently work with patients and their family doctor to provide diabetes care. Having a pharmacist involved in diabetes care may help people with diabetes because they are highly accessible and may have more opportunities to educate people about diabetes medications. This might lead to better blood sugar control.

Purpose:
You are being asked to participate in a research study to assess the impact of pharmacist management on your blood sugar control.

Procedures:
If you have diabetes and have at least one of the following: elevated blood pressure, elevated blood sugar, elevated cholesterol or consume tobacco products, you will be asked to take part in the study. If you agree to take part in the study your pharmacist will do a comprehensive medication review, assess your blood pressure, cholesterol, blood sugar control and tobacco consumption status. This assessment might require asking you to do some blood tests [for example cholesterol level, three months' sugar control test (hemoglobin A1c)] in the laboratory; if you have not done the tests in the last three months. The pharmacist will give you a laboratory requisition form to do the tests without any extra cost to you and a copy of the test will be sent to your family doctor.

As part of being in the study, you will be asked to meet with your pharmacist regularly (minimum frequency would be at 3 and 6 months. You may meet with the pharmacist more frequently if he/she deemed it clinically important). These meetings will usually last 10-20 minutes and can occur in person or over the phone. During these meetings, your pharmacist will access your lab test results and conduct an assessment that may include blood pressure, waist circumference, height and weight measurements and talk to you about your medications, diet, physical activity and tobacco cessation plan (if appropriate). You and your pharmacist will come up with a plan for how to try to lower your blood sugar, blood pressure, cholesterol and/or tobacco cessation (as appropriate). The plan may include medication changes or additions, tobacco cessation support and healthy diet. Your pharmacist will discuss this plan with your family doctor. You will be asked to do some laboratory tests just before the 3 and 6 months' marks. These tests may include cholesterol level and 3 months' sugar control test (HbA1c) to find out the effect of pharmacist management.

During this study, you will have close follow-up with both your pharmacist and your family doctor. Your family doctor will receive a letter from the pharmacist to let him/her know that you agreed to participate in this study. The letter will also contain detailed information of what the study is about. The pharmacist will let your family doctor know about the results of all the tests taken and any changes in your medications. Also, information about the study would be in the newsletter of Alberta Medical Association, College of Physicians and Surgeons of Alberta, the Alberta College of Pharmacists and the Alberta Pharmacists Association.

As part of being in this study, you will also be asked to complete some surveys. You will receive two surveys at the start of the study. At the end of the study you will be given two more surveys. Each survey should take no longer than 15 minutes to complete. You may complete the survey in your pharmacy and place it in a sealed envelope or do it at home and mail it in. All surveys will come with a pre-paid postage envelope so they may be mailed with no cost to you.

Possible Benefits:
This pharmacist delivered program may help you to:

- Bring down your blood sugar
- Bring down your blood pressure
- Bring down your cholesterol level
- Quit tobacco
- Make healthier lifestyle options

We hope that this study will also help other patients with diabetes. This study will help us understand how pharmacists can help in diabetes management and assist in preventing its complications.

Possible Risks:
Your medications may be changed or altered in dose to help you bring down your blood sugar, blood pressure and/or cholesterol levels. These changes and alterations may cause side effects such as dizziness, muscle pain, headaches, and stomach pain. Increasing the drugs doses or frequency may increase the cost of your treatment if you do not have health insurance (private or governmental). Also, you would be asked to do some laboratory tests, those tests will require a blood sample, obtaining this sample may be painful.

Your pharmacist will help you to understand your medical condition. The pharmacists will work with you and your family physician to help you quit tobacco, bring down your blood pressure, cholesterol level, blood sugar and encourage you to take on healthier lifestyle choices in order to become healthier.

Your blood sugar, blood pressure and/or cholesterol levels may not be brought down even by the end of the study.

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

Confidentiality:
The data collected for this study will be kept strictly confidential. It will not be released unless we are required to do so by law. Your name will not be revealed outside the research office, which is in a secure area. No information that could identify you will be included in any report published from the study. The University of Alberta requires us to keep data from the study for five years. Even if you withdraw from the study, your data will not be destroyed. The Health Research Ethics Board has authorized us to use the data for this study only. Any future use of the data requires additional ethics approval.

By signing the consent form you give permission to study staff to access the necessary personal information from other health care professionals (like your family doctor). Specifically, we will obtain from your pharmacist information on your prescribed medications and laboratory test results.

Voluntary Participation

You do not have to take part in the study at all, and you can quit at any time. If you decide not to participate in the study or if it is stopped at any time, the quality of your care will not be affected. If we find anything out, which may affect your decision to continue in the study we will inform you as soon as possible.

Reimbursement of Expenses

You will not be paid for participating in this study.

Contact Names and Telephone Numbers

If you have any concerns about any aspect of this study, you are encouraged to contact the University of Alberta Health Research Ethics Board at (780) 492-2615. This office is not connected with the researchers setting up this study. You may also contact Dr. Ross Tsuyuki, Dept. of Medicine: (780) 492-8526 or Dr. Yazid Al Hamarneh, Dept. of Medicine: (780) 492-9608 or 1-877-876-9888.

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CONSENT FORM

Outcomes of Diabetes Management by Pharmacists: The RxING Prospective Registry

Principal Investigators: Dr. Ross Tsuyuki 780-492-8526

Dr. Yazid Al Hamarneh 780-492-9608

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your records, including personally identifiable health information?	☐	☐
Do you agree to allow the investigators to contact you about future studies?	☐	☐

Who explained this study to you? _____

I agree to take part in this study: YES ☐ NO ☐

Signature _____

(Printed Name) _____

Date:_____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Person Obtaining Consent _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT