UNIVERSITY OF ALBERTA

Information Sheet

Project Title: The Alberta Vascular Risk Reduction Community Pharmacy Project (R_xEACH)

Principal Investigator(s):

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Dr. Charlotte Jones	University of British Columbia – Southern Medical Program	

Co-Investigator(s):

Dr. Yazid Al Hamarneh	Dept. of Medicine, University of Alberta	(780) 492-9608
Dr. Dunsi Oladele	Alberta Health Services	(780) 860 8499

Background:
Cardiovascular disease (disease of the heart and blood vessels) is one of the leading causes of death in Canada. It also costs the Canadian economy close to $21 billion divided between lost years of patient productivity and healthcare costs. The majority of cardiovascular disease cases (90%) are caused by factors that can be controlled. These factors include high blood pressure, high cholesterol, diabetes (high blood sugar), tobacco smoking, unhealthy diet, obesity, physical inactivity and high alcohol intake. Such factors are very common and not very well controlled. People who have any of these factors would be at risk of having cardiovascular disease. Controlling these factors will bring down the risk of having cardiovascular disease and make the individuals' life better. Pharmacists work with patients and their family doctors to give cardiovascular care. Having a pharmacist involved in cardiovascular care may help patients with cardiovascular disease or at risk of having the disease. Pharmacists are easier to reach and may have more opportunities to educate people about cardiovascular medications. This might lead to better prevention and control of cardiovascular diseases.

Purpose:
You are being asked to participate in a research study to find out if a community pharmacy cardiovascular risk reduction program can help bring down your cardiovascular risk.

Procedure:
If you have an elevated blood pressure, cholesterol, blood sugar, waist circumference or body weight or if you have kidney disease, are physically inactive, have an unhealthy diet, are a smoker or taking medications for any of the previously mentioned conditions, your pharmacist will assess your risk of having a heart attack or a stroke using a computer program. This assessment might require asking you to do some blood tests (for example, cholesterol level, three months sugar control test (HbA1c) 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 with a copy of the test sent to your family doctor. If you are found to be at high risk, you will be asked to take part in the study.

If you agree to take part in the study, you will be randomly put into one of two groups using a computer program. These groups are the Usual Care Group and the Advanced Care Group. You have an equal chance of being put into either group. If you are in the Usual Care Group you will receive the care and services that you would normally be provided by your pharmacist. After 3 months, your pharmacist will see you and you will be offered the Advanced Care at that time.

If you are put into the Advanced Care Group, you will be asked to meet with the pharmacist every 3-4 weeks over a 3 month period. These meetings can be done either in person or over the phone. The first meeting will take 30-45 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, waist circumference, height and weight measurements and talk to you about your cardiovascular risk, medications, diet, physical activity and stop smoking plan (if appropriate). You and your pharmacist (and possibly a pharmacy student) will come up with a plan for how to try to lower your cardiovascular risk. The plan may include medication changes or additions, stop smoking support, healthy diet, and the option to participate in a pedometer-based walking program. Your pharmacist will discuss this plan with your family doctor. You will be asked to do some laboratory tests just before the end of the 3 months of Advanced Care program. These tests may include cholesterol level and three months sugar control test (HbA1c) to find out the effect of the plan on your cardiovascular risk.

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 pharmacists 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 and the Alberta College of Pharmacists.

Possible Benefits:

This pharmacist delivered program may help you to reduce your risk of having a heart disease or stroke by:

- Bringing down your blood pressure
- Bringing down your cholesterol level
- Bringing down your blood sugar
- Making healthier lifestyle options
- Helping you to stop smoking

We hope that this study will also help other patients who are at risk of having a heart disease or stroke. This study will help us understand how pharmacists can help to prevent and manage cardiovascular disease in people.

Your cardiovascular risk 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.

Possible Risks:

Your medications may be changed or altered in dose to help you bring down your cardiovascular risk. These changes and alterations may cause side effects such as dizziness, muscle pain, headaches, and stomach. 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 risks of heart disease and stroke. The pharmacists will work with you and your family physician to help you stop smoking, bring down your blood pressure, cholesterol level, blood sugar and encourage you to take on healthier lifestyle choices in order to become healthier and bring down your risk of having a heart disease or a stroke.

Confidentiality:

The data collected for this study will be kept strictly confidential. It will not be released unless we are asked to do so by law. We will not give out your name outside the research office, which is in a secure area. No information that could identify you will be put 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 the investigators to access the necessary personal health information to do this research study. Specifically, we will obtain from your pharmacist information on the medicines you were prescribed and on some laboratory tests (such as your cholesterol level and three months sugar control test (HbA1c)). By signing the consent form you also give permission to the investigators to access any personally identifiable health information, which is under the custody of other health care professionals as deemed necessary for the conduct of this research. This includes access to health information in the past, as well as in a follow-up period of five years. This might include data held in provincial or national sources such as Alberta Health or the Canadian Institute for Health Information. You are free to withdraw this consent at any time.

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.

Permission to contact for future studies:
We are also asking for consent for the investigators to contact you in the future to tell you about other research studies for which you are eligible. You may decide if you want to participate in a specific study when you are contacted. By consenting to this you are only agreeing to have the investigators contact you to tell you about the study.

Questions or concerns:
If you have any questions/concerns regarding this study please contact Dr. Yazid Al Hamarneh, Dept. of Medicine: (780) 492-9608 or 1-877-876-9888, Dr. Ross Tsuyuki, Dept. of Medicine: (780) 492-8526, Dr. Brenda Hemmelgarn, Dept. of Medicine, University of Calgary (403-944-2745), Dr. Charlotte Jones, University of British Columbia – Southern Medical Program, Dr. Dunsi Oladele, Alberta Health Services: (780) 860 8499.

If you have any concerns about your rights as a study participant, you are encouraged to contact the University of Alberta Research Ethics Office at (780) 492-2615. This office is not connected with the researchers setting up this study.

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CONSENT FORM

The Alberta Vascular Risk Reduction Community Pharmacy Project (RxEACH)

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Dr. Brenda Hemmelgarn 403-944-2745
Dr. Charlotte Jones

Co-Investigators: Dr. Yazid Al Hamarneh 780-492-9608
Dr. Dunsi Oladele 780 (860) 8499

	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