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Faculty of Medicine
Department of Medicine

# EmPhAsIS:
# Empowering Pharmacists in Asthma management through Interactive SMS

## Subject Information & Consent form

## *Study Information*

**Title:**

**EmPhAsIS**: **Em**powering **Ph**armacists in **As**thma management through **I**nteractive **S**MS

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## Introduction

You are being invited to take part in this research study because you have been diagnosed with asthma, prescribed inhaled corticosteroids (ICS) and are 14 years or older. The following information will describe the research and your role in the study. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits and risks.

Please ask the study investigator or your study pharmacist to explain any part of this study that is not clear to you. You may keep this consent form to review at your leisure or ask for advice from others before signing. You may take the time you need to decide whether you want to sign the consent form and participate in the study. After signing this informed consent, you may keep a copy of the signed and dated form for your own records.

## Voluntary participation

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves.

If you wish to participate, please sign the last page of two consent forms .Give one copy to the study pharmacist and keep one copy for your records. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision. Signing this consent form will in no way limit your legal rights against the sponsor, investigators, or anyone else.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled to or are presently receiving.

Please take time to read the following information carefully and to discuss it with your family or friends before you decide.

## Who is conducting the study?

The Collaboration for Outcome Research and Evaluation (CORE) and the Faculty of Pharmaceutical Sciences is conducting this study in collaboration with the Faculty of Medicine at UBC. The research is funded by the Canadian Institutes of Health Research (CIHR) and the College of Pharmacists of British Columbia (CPBC).

## Background

Asthma is a chronic inflammatory disease of the airways, causing symptoms of shortness of breath, tightness in the chest, coughing, and wheezing. About 3 million Canadians suffer from asthma and it affects individuals of all ages.

The cause of asthma is not known, and currently there is no cure. There are effective and inexpensive treatments, that when taken properly or as prescribed, can help patients live symptom-free lives. However, adherence (taking medications properly or as prescribed) to asthma treatment is very poor and leads to avoidable adverse medical outcomes, high healthcare costs, and reduced quality of life.

There is great potential for improving the quality of care for asthma in the community by increasing the role of community pharmacists in asthma management and using an accessible communication technology: SMS: short message service which means text messages.

We are hoping to recruit a total of 370 participants (185 for "intervention group" and 185 in the "usual care group" these groups are explained below) from 74 pharmacies in British Columbia over a period of 12 months.

**Purpose of the study**

The purpose of this study is to assess whether a pharmacist-initiated intervention (which means that it is the pharmacist who will start the process of care) that includes education and monthly text messages to ask patients how they are managing their asthma medication will help improve adherence to the medication as well as care for asthma.

**Who can participate in the study?**

You may be eligible to participate in this study if you:

- have been diagnosed with asthma
- prescribed inhaled corticosteroids (ICS)
- are 14 years or older
- have a cell-phone with ability to send/receive text messages
- reside in BC and planning to reside in BC for the next 12 months
- have been registered with the medical services plan (MSP, the provincial insurer of medically-required services) in the past 12 months.
- speak and read English

**Who should not participate in the study?**

You should not participate in this study if you:

- are currently participating in another clinical study related to asthma

**What does the study involve?**

A total of 370 individuals, from 74 pharmacies in British Columbia, who meet the eligibility criteria, will be asked to take part in this study. Half of the individuals will be chosen to partake in the "Intervention" group and the other half in the "Usual care" group. You will be chosen to be in either group by randomization, which is like a flip of a coin so that there is an equal chance of being in either group.

*Overall design of the study*

If you agree to take part in this study, the procedures and visits you can expect will include the following:

*Intervention (EmPhAsIS) Group*

If you are in this group, you will receive the EmPhAsIS intervention which consists of three components: a) education, b) monthly text messages to see how you are doing with your asthma medications, and c) follow-up telephone calls with your pharmacist if you are having challenges with taking your asthma medication.

a) **Education about asthma** : Your pharmacist will discuss your asthma medications, check that you are using your inhaler properly, and provide you with education about asthma.

b) **Monthly text messages to see how you are doing with your asthma medications**: Every first Monday of the month, you will receive a text message asking how you are following your asthma medication plan. You will be asked to respond to this question. If you do not respond to a text message, you will be sent a another text message the following day. If we do not receive a response, then your pharmacist will contact you via telephone to ask about how you are doing.

c) **Follow-up telephone calls with your pharmacist if you are having challenges with adhering to asthma medication:** Your answers to the text messages will let us know whether you are experiencing any challenges with your asthma medications. If you are experiencing challenges, then your pharmacist will contact you via telephone. The pharmacist will ask you additional questions regarding your challenges to see how she/he may help. The pharmacist may provide you education and resources over the telephone or if you mutually agree, you may come visit the pharmacy where the pharmacist may review your asthma medications and your inhaler technique. If the pharmacist deems that you are experiencing uncontrolled asthma, then he/she will recommend a physician visit.
As part of the intervention group, you will also be asked to complete short questionnaires about how you are doing with your asthma during the study, over the telephone by the research team. You will receive a telephone call at the begininng of the study (month 0), at month 6 and at month 12 at the end of the study. It usually takes a total of 10 minutes to complete these questionnaires. Being in the intervention group may take between 3 to 5 hours of your time over the 12 month period of the study.

*Usual Care (Control) Group*
If you are in this group, your pharmacist will discuss your asthma medications, check that you are using your inhaler properly, and provide you with education about asthma.

As part of the usual care group, you will also be asked to complete short questionnaires about how you are doing with your asthma during the study, over the telephone by the research team. You will receive a telephone call at the begininng of the study (month 0), at month 6 and at month 12 at the end of the study. It usually takes a total of 10 minutes to complete these questionnaires. Being in the usual care group will take a total of approximately 2 to 3 hours of your time over the 12 month period of the study.

At the end of the one year in the usual care group, you will be offered to receive the automated SMS-based monthly assessment of adherence text messages for the next 12 months if you wish to. You will receive regular care from your pharmacist during this time. We will not be collecting questionnaire data. Only the administrative data, as described below, will continue to be analyzed.

*Personal and Medical Information:*

Using a specific study form, the study pharmacist will collect and provide your personal and medical information (BC care card number, name and date of birth) to the researchers. This information will be kept confidential in a secure area at the pharmacy and at UBC and will be used only for the purpose of linkage. (Linkage is a way to connect your information collected during the study to the data that has already been collected by the organizations listed below.)

The researchers will then use a secured process to submit this information to Population Data BC, a trusted multi-university organization dedicated to data access, protection and privacy of research data. Population Data BC will use this information to link the data collected in this study to data from PharmaNet (prescription medications), Ministry of Health (physician visits, hospitalizations and other health services information), Vital Statistics (deaths) and Statistic Canada (income-related information); for 12 months before your entry in this study and 12 months after or until date of withdrawal. Once linked, your personal information will be de-identified and kept in a confidential area at all times. The linkage of this data allows researchers to study the effects of the intervention. The information will be held in accordance with strict government security standards and Population Data BC will not use your information in any way other than as authorized by this consent form.

The study pharmacist will also print and provide the research team the list of medications that you have been given in the past 12 months. This will be used for research purposes only.

A letter of courtesy will be sent to the physicians who practice in the community where pharmacists are taking part of the study to inform them about the research.

## What are your responsibilities?

If you are part of the intervention group, your responsibilities as a participant are to reply to the text messages and complete telephone questionnaires regarding your physical and emotional health. If you are part of the usual care group, your responsibilities as a participant are to complete telephone questionnaires regarding your physical and emotional health.

## What are the possible harms of participating in this study?

No new treatment or health intervention is being experienced in this study. We do not anticipate that you will have any possible harm if participating in this study.

## What are the benefits of participating in this study?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study. If you decide to participate in this research study, the information obtained during this research study may be scientifically useful and may benefit future patients with asthma. This study may lead to an improvement to the health care system by implementation of a program using text messages to improve adherence to asthma medications. This study, if proved to be feasible and effective, is expected to decrease the burden of illness on patients, save resources being used to treat asthma, and improve the quality care for asthma overall. There is a

possibility that you may not benefit from taking part in this study in terms of any improvement in your asthma.

**What are the alternatives to participation?**

Should you choose not to participate in this study, you can discuss with your pharmacist about how you can improve your medication adherence or you can contact your family physician.

**What happens if you wish to withdraw your consent to participate?**

You may withdraw from this study at any time without providing any explanation of your reasons for doing so, and you are not required to submit a request for withdrawal in writing. If you decide to enter the study and then withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. However, all data collected about you during your enrolment in the study will be retained for analysis. By law, these data cannot be destroyed for 7 years after the study is completed.

**What are the costs of participating?**

Each participant will receive an honorarium in the amount of $25.

**How will my taking part in this study be kept confidential?**

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law. All the data collected in this study will be stored at UBC and all linked data will be stored at Population Data BC. These data will be kept for 7 years after the completion of the study. At the end of the above time period all information records will be destroyed in accordance with current government standards. The Government of British Columbia or Research Ethics Board may also direct that the information records be destroyed before the retention date.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study pharmacist.

**Contact numbers for further questions and expressing your concerns about your rights as a subject**

If you have any questions or desire further information about this study before or during participation, including the collection of personal information or how your information will be handled you can contact Dr. Mary De Vera at 604-827-2138 or the Research Coordinator at: 604-827-1567 .

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

*After the study is finished*

You may not be able to receive the study intervention after your participation in the study is completed. There are several possible reasons for this, some of which are:

- The intervention may not turn out to be effective or safe.
- The intervention may not be approved for use in Canada.
- The intervention even if approved in Canada, may not be available free of charge.

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## CONSENT STATEMENT

- I have read and understood the information in this consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary. I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I agree to have my identifying information (BC care card number, name, date of birth) linked to administrative health databases to study the effect of the program. Once linked, my information will be de-identified and kept in a confidential area at all times. ,
- I authorize access to my health records as described in this consent form
- I authorize my pharmacist to print or/and review, my medication profile that lists all the medication that I have been given in the past 12 months.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I will receive a signed and dated copy of this consent form for my own records.
- I, _____ (please print your name), hereby grant my consent to participate in this study.

| _____ | _____ | _____ |
|---|---|---|
| Participant's Signature | Printed name | Date |

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Person obtaining consent | Printed name | Study Role | Date |

Future Contact: If you wish to be contacted for future studies please let us know by ticking the box:

☐ Yes, I wish to be contacted to participate in future studies.