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

Pharmacist Guide for Usual Care Pharmacies

To receive project assistance

If after reading this guide you have any additional questions, or you require some assistance during the course of the study, please contact:
The Research Coordinator at: 604-827-1567

Email: emphasis.core@ubc.ca FAX: 604-827-4014

Emphasis Study Website: emphasis.core.ubc.ca

Vancouver, 20 January 2015

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1. Introduction

Congratulations on being one of the pharmacies selected as a partner in the **Em**powering **Ph**armacists in **As**thma management through **I**nteractive **S**MS **(EmPhAsIS)** study. This pharmacist guide contains the information you need as a partner in helping conduct the study. Please take a moment to review its contents. If you have any questions regarding the **EmPhAsIS** study or our organization, please feel free to contact us at any time.

2. About the Research Team and Organisation

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

Principal Investigator

Mary De Vera, Ph.D.
Faculty of Pharmaceutical Sciences, UBC
mdevera@mail.ubc.ca

Co-Investigators:

Mohsen Sadatsafavi, MD, PhD
Faculty of Medicine, Medicine, UBC

Larry Lynd, BSP, PhD
Faculty of Pharmaceutical Sciences, UBC

Carlo Marra, PharmD, PhD
School of Pharmacy Memorial University

Mark FitzGerald, MD, FRCPC
Faculty of Medicine, Medicine, UBC

Richard Lester, MD,
Faculty of Medicine, UBC

Penelope Brasher, PhD
Vancouver Coastal Health Research Institute

Nicole Tsao, BSc Pharm, MSc Pharm.,
Faculty of Pharmaceutical Sciences, UBC

Parkash Ragsdale, BSc. Pharm.
Faculty of Pharmaceutical Sciences, UBC

3. About the EmPhAsIS Study

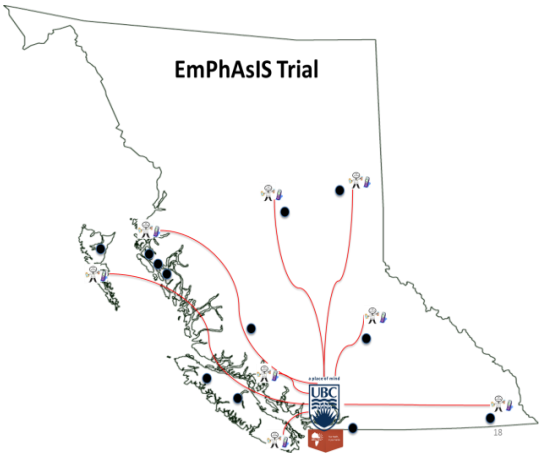
Asthma is a chronic inflammatory disease of the airways, which is characterized by recurrent, but reversible, episodes of shortness of breath, tightness of the chest, coughing, and wheezing. About 3 million Canadians suffer from asthma and it affects individuals of all ages and imposes a significant burden to the patient and the health care system. The cause of asthma is not known, and currently there is no cure. Although there are effective and inexpensive treatments, adherence (continuing taking asthma medication as prescribed) to asthma treatment is amongst the lowest among chronic diseases, causing avoidable adverse medical outcomes, costs, and reduced quality of life.

Pharmacists are ideally suited to impact medication adherence given their training, skills, and frequent contact with patients – up to eight times more than doctors. Given this context, there is great potential for improving the quality of outpatient care in asthma using a model of care that enhances the role of community **pharmacists** while supporting the practice with an accessible communication technology: **text messages**.

Patients across BC are eligible for **EmPhAsIS** study if they are 14 years old or older, have been diagnosed by a doctor as having asthma and who fill a prescription for inhaled corticosteroids (ICS).

The **EmPhAsIS** study is a 1-year pragmatic cluster randomized controlled study of an innovative intervention targeting medication adherence in participants with asthma. There are three pillars to the **EmPhAsIS** intervention:

- Participant education delivered by **pharmacists**
- Monthly **text messages** to assess and monitor adherence, centralized and coordinated at UBC
- Follow-up with participants who are non-adherent (or having challenges with medication taking) by **pharmacists**



Our **objective** in the **EmPhAsIS** study is to answer the following questions regarding the **EmPhAsIS** intervention:

- Does the **EmPhAsIS** intervention improve adherence to asthma medications?
- Does the **EmPhAsIS** intervention improve outcomes of asthma participants?
- Is the **EmPhAsIS** intervention cost-effective?

4. Study Pharmacies

As this is a cluster RCT, it is pharmacies that will be randomized to either **EmPhAsIS** intervention group or usual care group. The study team used a random number generator to create randomization blocks of pharmacies for this study. Please note that while pharmacists and participants cannot be blinded to whether or not they are receiving the intervention, members of the research team will be blinded, ensuring the objectivity and rigor of the study.

Usual Care (Control) Group

You are receiving this guide because your pharmacy has been <u>randomly</u> assigned to provide the <u>usual care</u> intervention. Please note your group number is:

Group No.

As part of the **EmPhAsIS** usual care group, participants that you will recruit will receive the following:

- Participant education delivered by **pharmacists**
- **PLEASE KEEP YOUR RANDOMISATION STATUS CONFIDENTIAL**

Usual Care (Control) Group

Pharmacies that are assigned to provide usual care, will provide the following to their recruited participants: a) participant education delivered by pharmacists. It is imperative that the study can distinguish between the impact of the intervention itself than the necessary training that pharmacists and participants receive upon recruitment in the study (regardless of group assignment).

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

Intervention (EmPhAsIS) Group

For your information, the following are the components of the EmPhAsIS intervention that will be provided by pharmacies randomized to this group.

a) Participant education delivered by pharmacists:

One component of the **EmPhAsIS** intervention highlights the role of pharmacists as educators in their patients' health. The pharmacist will discuss participants' individual treatments, educate the participant on the chronic, episodic nature of asthma, provide instruction on inhaler technique, and emphasize the importance of continuous controller therapy and medication adherence.

Note that this is the same as what you will provide as part of the usual care group. The reason for this is that it is imperative that the study can distinguish between the impact of the intervention itself than the necessary training that pharmacists and participants receive upon recruitment in the study (regardless of group assignment).

b) Monthly text messages to assess and monitor adherence, centralized and coordinated at UBC

A principal component of the **EmPhAsIS** intervention is monthly text messages by which participants are asked to text their level of agreement with the following statement by keying in the corresponding number:

"I follow my asthma medication plan"

1	2	3	4	5	6
Agree completed	*Agree mostly*	*Agree somewhat*	*Disagree somewhat*	*Disagree mostly*	*Disagree completely*

This statement and corresponding responses represent the first item of the Adult Asthma Adherence Questionnaire™ (AAAQ). The AAAQ is made up of five statements (questions) and was developed specifically as a screening diagnostic tool for adherence among asthma patients by care providers and as well as for eliciting potential adherence barriers. The first question is a general adherence monitoring question, and questions 2-5 determine specific barriers to adherence among low-adherent individuals (forgetting, no need, adverse effects, and costs).

Pharmacists will not have to send messages themselves and all sending and receiving of text messages will be coordinated and centralized at UBC. If a participant does not respond to a scheduled monthly text assessment (or responds in error), then they will be sent a follow-up text message the following day. If a participant does not respond, then the recruiting pharmacy will be notified by login in the Emphasis Website to initiate a pharmacist follow-up telephone call.

c) Follow-up with participants who are non-adherent (or having challenges with medication taking) by pharmacists

Follow-ups and counselling will be done according the participant responses.

5. Study Participants

Inclusion Criteria

Participants presenting at your pharmacy who meet the following criteria are eligible to participate in the **EmPhAsIS** study:

- ✓ 14 years of age or older
- ✓ provide an affirmative to the question: *"have you ever been diagnosed by a doctor as having asthma?"*
- ✓ fill a prescription for an inhaled corticosteroid (incident or prevalent; either as monotherapy or in combination inhaler with long-acting beta-agonists)
- ✓ possess a cell-phone with ability to send/receive text messages
- ✓ reside in BC and planning to reside in BC for the next 12 months
- ✓ registered with the BC Medical Services Plan for the past 12 months and planning to remain registered for the next 12 months
- ✓ currently not participating in another research study related to their asthma
- ✓ does not have communication difficulties such as inability to communicate in English,or significant impairment in vision, hearing, or speech
- ✓ consent to participate in the study

Exclusion Criteria

- ☒ Inability to speak and write English

6. Responsibilities for Usual Care Group

Pharmacist' Responsibilities

BEFORE STUDY IS LAUNCHED

1. Ensure all pharmacists, pharmacy technicians, and pharmacy students at the pharmacy are informed of the decision to participate.

2. Review the contents of the study binder.

3. Display the laminated counter card and advertisement poster. A special clinic day might help encourage recruitment

4. Fax the letter of courtesy provided in the study package to family physicians who practice your community to inform them about our research study.

DURING THE STUDY

5. Recruit and discuss the **EmPhAsIS** study with potential participant(s).

6. Work directly with the participant to complete the *Pharmacist Screening Form* to determine whether they are eligible.

7. If eligible, enrol participant into the study according to the Step-By-Step Guide in Section 7.

8. Deliver the Emphasis Usual care according to the Step-by-Step Guide in Section 7.

AT THE END OF THE STUDY

1. Print the 12-month medication history for participants you recruited

2. At the end of the one year in the usual care group, the participant in this group will be offered to receive the automated SMS-based monthly assessment of adherence for the next 12 months if they wish to. They will receive regular care from their pharmacist during this time. We will not be collecting questionnaire data. Only the administrative data will continue to be analysed.

Participant's Responsibilities

1. Provide answers to the pharmacist for the *Pharmacist Screening Intervention Form*.

2. Read the *Subject Information and Consent Form* and if agreed to the conditions mentioned sign the consent form (Two copies*)*.

3. Complete the *Contact Information Form*.

4. Fill out the *Baseline Demographics* form.

5. Have a functioning cell phone and check text messages (those assigned to the **EmPhAsIS** intervention group only)

6. Answer the questionnaires by telephone as per the study protocol (Baseline, 6 and 12months)

7. Arrange a follow-up call or visit with pharmacist if required (those assigned to the **EmPhAsIS** intervention group)

Research Personnel Responsibilities

1. Provide support throughout the duration of the study (e.g. questions, training, feedback)

2. Send the study binder to partner pharmacies

3. Ensure monthly automated text is functional (for Intervention group only)

4. Conduct follow-up phone calls and questionnaires as per the study protocol (0 [baseline], 6, and 12 months)

5. Communicate with pharmacist when appropriate

6. Complete all data collection and analysis

7. Conduct knowledge translation activities including communicating study findings to partner pharmacies

7. Step-by-Step Guide to Conducting the EmPhAsIS Study for Usual Care Group

A) At Start of the Study

Step A1: <u>Approaching potential participants</u>

Based on our prior experiences with conducting research studies at community pharmacies, there are several ways that individuals can become informed about a research study:

- Information through study advertisements including posters, shelf-talkers, and bag stuffers
- Information through special clinic days (e.g., an asthma clinic day) held at the pharmacy

With these information sources, participants mainly identify their interest in the study and then approach you for more information.

Step A2: <u>Explaining the EmPhAsIS study to potential participants</u>

Study ethics require that the pharmacist is ultimately responsible for the explanation of the study to the participant. The explanation about the **EmPhAsIS** study should be given in the following, standardized way, using the suggested script:

- <u>Introduction</u>

  "Are you interested in participating in a research study offered through UBC that is investigating medication adherence in asthma and text messaging?"

- <u>Pharmacy participation:</u>

  "Our pharmacy is a partner in this research, along with other pharmacies throughout BC."

- <u>Purpose of the study</u>

  "The purpose of the research is to evaluate whether pharmacist education combined with monthly text messages to monitor medication taking will help improve adherence to asthma medications and the care of patients with asthma."

- <u>What the study involves</u>

  "If you agree, you will be randomly, (which is like a flip of a coin so that there is an equal chance of being in either group) assigned to either receive the pharmacist and texting intervention or no intervention. The study team at UBC will then follow-up with you via telephone questionnaires to see how you are you doing at month 0, 6 months, and 12 months after.

- What do participants receive for participating

  "You will be provided with an honorarium of $25 for participating in the study, regardless of whether you receive the pharmacist and texting intervention or no intervention. This is to offset any expenses, for example - sending and receiving texts – that you may incur as part of your participation. If we determine that you are eligible to participate and if you consent to participate, then we will enrol you and send your information to UBC who will provide you with the honorarium."

- Voluntary nature of participation

  "Your participation is voluntary and in no way affects any care that you will receive. If you agree to participate but then have a change of heart, then you are free to leave the study at any time without having to provide a reason.

- Importance of participants

  "Your assistance and participation in this study is greatly appreciated."

After explaining the study with the participant according, one of three scenarios will likely result:

1. The participant agrees to complete the *Pharmacist Screening Form*
   - start completing the *Pharmacist Screening Form*

2. The participant declines to complete the *Pharmacist Screening Form*
   - the participant is excluded; this will have to be noted in the study log

3. The participant does not speak or read English or is cognitively impaired
   - the participant is excluded; this will have to be noted in the study log

Step A3: Completing the Pharmacist Screening Form

If the participant agrees to go to this step, please ask the participant the questions on the *Pharmacist Screening Form*. **It is important that the pharmacist ask all the questions, rather than asking the participant to fill in this form, since an objective observer is needed to determine the participant's eligibility.**

From the participant's responses to the screening form, you should be able to determine whether or not the participant is eligible (in both cases, fill in the study log!)

If the participant turns out to be not eligible for this study, file the completed screening form in the study binder provided for this purpose. (Up-date study log)

If the participant is indeed eligible, fax the completed *Pharmacist Screening Intervention* form to the researchers and file it in the study binder provided for this purpose. (Up-date study log)

IF ELIGIBLE:

Step A4: Distributing and signing the Subject Information & Consent Form
Ask the participant to carefully read the participant information and consent form. Please be prepared to answer potential questions or refer them to our study team.

If the participant agrees to the conditions mentioned in the participant information, he/she is required to sign two study's consent forms. You should review the consent with the participant.

You can be the person obtaining consent if no other person has done so. Give a signed copy *of* the dated consent to participant. Keep the other signed copy and file in a secure place

Step A5: Assigning Study ID # and Informing the participant of their assignment
Assign the next unique Study ID# for the participant and stick the corresponding label on all the documents related to this participant, you may now inform the participant that they have been assigned to the **USUAL CARE Group**.

It is only after the participant has returned the *Consent Form that* you may inform him/her about his/her group assignment. It is also essential that you keep your randomization status confidential.

Step A6: Completing the Contact Information and Demographics Forms
If the participant is eligible for the study, a *Contact Information* and *Demographics* forms should be completed. The *Contact Information* form contains two parts: one for participant information and the other part for pharmacy information. The pharmacist is required to fill in the pharmacy section and should check that the participant has completed the form correctly. After this is done, the participant is given the participant package, containing the participant information and consent form.

Step A7: Providing education about asthma
Because this is a pragmatic (e.g. "real-world") study, we do not want to interfere with the way you care for your patients. We encourage our partner pharmacists to provide the medication education to participants according to your own practice.

Step A8: Informing the participant of the next steps
Inform the participant that he/she will be contacted by the coordinator within the next 48 hour after being included in the study to complete the study questionnaires.

Step A10: Give participant package

The participant is given the participant package, containing their copy of the signed consent form and congratulation letter.

Step A9: Faxing study materials to the study research team

Please submit the following documents to study researchers by fax:

Fax to: 604-827-4014 Attention to: Dr Mary De Vera

☐ *Pharmacist Screening Form*

☐ *Contact Information Form*

☐ *Demographic Form*

☐ *Signed page of the Consent Form*

B) During the Study

Since participants are receiving usual care, they will not receive any intervention over the 1 year duration of the study.

C) At the End of the Study

Step C1: Printing a Participant's Medication Profile

Once a participant has been followed to the 1 year point of the study, we will notify you.

For this participant, please print a medication profile that lists all of their medications over the past 12 months. Please fax this to the research team.

Step C2: Offer the monthly text messages

At the end of the one year in the usual care group, the participant in this group will be offered to receive the automated SMS-based monthly assessment of adherence for the next 12 months if they wish to. They will receive regular care from their pharmacist during this time. We will not be collecting questionnaire data. Only the administrative data will continue to be analyzed.

Step C3: Sending research data

We will collect study binders at the end of the study. We will make arrangements with individual pharmacies regarding pick-up (if in the Greater Vancouver area) or mailing. If mailing, all original research data will be picked up via a secure delivery services and directed to:

Dr Mary De Vera
University of British Columbia
Faculty of Pharmaceutical Sciences
2405 Wesbrook Mall, Vancouver, BC, V6T 1Z3

8. Research Tips

Tips for Successfully Recruiting Participants

While it is important to be truthful and thorough in providing your participants with the background information pertaining to this study, an overly technical presentation can cause participants to become overwhelmed or nervous. Below are some tips that may help you approach participants regarding the study.

- Stay calm: If you look or act nervous while discussing the study with them, your participants will most certainly pick up on this and will likely be reluctant to get involved

- Keep it short: Each participant will be provided with an informed consent that contains all of the required information; focus your verbal explanation on the pertinent points.

- Rehearse: It is natural to be a little awkward or nervous the first few times that you use the script. Practice your approach on your co-workers, friends or family prior to the study. This will allow you to become comfortable and confident with the study description.

9. Targets and Timeline

Targets

In order to be able to determine the impact of the **EmPhAsIS** intervention on adherence and participant outcomes, we need to have 370 asthma participants complete the study. That is 185 participants who will receive the **EmPhAsIS** intervention and 185 participants who will receive usual care.

As a pharmacy partner, we are asking for you to recruit and enroll a **minimum of 8 asthma participants**.

Timeline

Our anticipated overall timeline for the **EmPhAsIS** study is 3 years according to the following:

Year	Target and Milestones
1	Complete recruitment and enrollment of asthma patients at partner pharmacies
2	Complete follow-up of participants (text messages, follow-ups, data collection)
3	Complete data collection, analysis, and writing of study results

Please do not hesitate to contact us if you have any questions or concern at:

604-827-1567

We greatly appreciate your interest and support!

Thank you