Cover Page - Physician participant Informed Consent

Official Title: Nudging Doctors to Collaborate With Pharmacists to Improve Medication Adherence

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BROWN UNIVERSITY
Program in Public Health, Alpert School of Medicine
and
TUFTS MEDICAL CENTER
Institute for Clinical Research and Health Policy Studies

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

PHARxMOS : Pharmacy Home Reporting Monitoring Outcomes Study

Principal Investigator: Ira B. Wilson, MD, MSc
Co-Investigators: William Rogers, PhD, Emilia Simeonova, PhD, Margaret McConnell, PhD

INTRODUCTION

You are being invited to take part in a research study the purpose of which is to improve the quality of medication management received by patients under your care. The study focuses on improving patients' medication adherence by informing physicians when study patients are late picking up refills for chronic medications, and by providing access to a pharmacist to consult with such patients.

PHARxMOS (Pharmacy Home Adherence Reporting Monitoring Outcomes Study) establishes a Patient-Centered Pharmacy Home, supporting and complementing the work of the New England Quality Care Alliance (NEQCA) to develop Patient-Centered Medical Homes. Improvements to patient care offered by PHARxMOS will potentially benefit physicians as well as patients by improving both clinical outcomes and client retention. It is our intent that these benefits will be realized without disrupting a practice's normal operating procedures, without raising physician operating costs, and without taxing physicians' limited time.

Taking part in this research study is totally your choice. You can decline to participate, or you can withdraw from participation, at any time, for any reason. If you decide not to participate in this study, it will not affect your relationship with New England Quality Care Alliance (NEQCA) or at Tufts Medical Center/Tufts University.

Please read all of the following information carefully. Ask Dr. Wilson, the Principal Investigator, or Dr. Cantor, the Quality Medical Director of NEQCA, to explain any words, terms, or sections that are unclear to you. Please ask any questions that you have about this research study. If you decide to take part in the study, you will be asked to sign an Informed Consent form. Do not sign the consent form unless you understand the information in it and have had your questions answered to your satisfaction.

You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

If you have question about your rights as a research study subject, you can contact Susan Toppin, Assistant Director, in the Research Protections Office at Brown University, either by phone at 401-863-3050, toll-free at 866-309-2095, or via e-mail at Susan_Toppin@brown.edu.

PURPOSE OF STUDY

The goal of this study is to determine whether medication adherence and clinical outcomes are improved by providing physicians with both timely information about patients' failure to refill prescriptions, and access to pharmacists who can call patients in follow up.

WHAT WILL BE DONE

The intervention we propose has a diagnostic component and a therapeutic component. Regarding the diagnostic component, we will send participating physicians a brief email alert when their patient is 10-14 days late picking up a refill for a medication that they are taking for diabetes, hyperlipidemia, or hypertension. We will use the term "non-adherence email alert" below to describe these communications. This is information that you could get for yourself by calling the patients' pharmacy, but in most cases physicians do not have the time and resources to do this. Thus, the study may provide you with information that you would normally not have.

The non-adherence email alert will be sent to the email address of your choosing. It will have no identifying information, and will say only "You have a message from the PHARxMOS Project. Click on this link [hypertext link] to see the message." The link will take you to a secure website. You will need to provide an identification number and a password in order to enter the website. When you are in the secure area of the website, you can click on a note and see the name of the patient, the name of the medication, and the date that it should have been filled. It should take less than 20 seconds to complete the process of gaining access to the secure website and viewing the non-adherence information.

Regarding the therapeutic component, participating physicians will have access to a specially trained study pharmacist (employed by NEQCA, but paid for by the study). The pharmacist can assist you by calling the patient to discuss the late refill, to discuss any medication-related concerns that the patient might have, and to answer any of the patient's questions. Normally, patients can direct questions to retail pharmacists at drug stores, but we believe that a personal phone call from a pharmacist who is working with NEQCA to improve care quality will be a more useful and more effective method to improve mediation adherence.

We will collect administrative and clinical data for up to 60 patients per physician by examining prior pharmacy claims and medical records. The information collected will include data on late refills for chronic medications, demographic data (age and gender), diagnoses that make patients eligible for the study (hypertension, diabetes, and hyperlipidemia), and clinical outcomes related to those diagnoses (blood pressure, hemoglobin A1C, and lipid levels.)

If you consent to participate in this study, you could fall into one of two physician groups – Intervention or Control. Control Physicians will receive no email alerts from the study about non-adherence. Nothing will be required of Control Physicians other than signing this informed consent (which is required for all participating physicians), and giving us permission to review the medical records of up to 60 selected patients.

Intervention Physicians will have eligible patients from their practice randomized into 3 arms: Control Patients, Information Patients, or Intervention Patients.

1. Control Patients. You will not receive any email alerts from the study about non-adherence among Control Patients. You will not even know that these patients are in the control group.

2. Information Patients. For Information Patients, you will receive email alerts from the study about non-adherence, but you will not have access to a study pharmacist. When you log onto the secure website, you will view the patient's name, the medication they were late picking up, and the date they should have picked it up, but that is all. It is up to you to act or not act on this information as you see fit.
3. Intervention Patients. For Intervention Patients, you will receive a non-adherence email alert from the study. You can then connect to the secure website, and view the patient's name, the medication they were late picking up, and the date they should have picked it up. For those patients, the secure note will also contain a link that will allow you to control the initiation of the pharmacist call. You will be able to click or unclick a pharmacist call option as you see fit for the individual patient case.

The study will compare several different ways to offer physicians choices to involve a pharmacist in patients' care. Physicians will be blinded to the nature of these choices because knowledge of these choices might change physicians' responses.

The pharmacist will report back to you with the results of the consultation after contact has been made. If patient contact is made, the pharmacist will fill out a standardized consultation form describing the conversation. Pharmacists will be expected to exercise clinical judgment, and will call you if they feel a patient needs to been seen quickly, as in the case of the onset of new chest pain. If after 2 weeks of trying the pharmacist has not made contact with the patient, they will let you know that contact was not made.

All eligible patients will be sent a letter describing the study. Those who do not want their physician to see data about medication refills will be encouraged not to participate. Patients will be able to decline or "opt out" by simply returning a pre-addressed, stamped postcard. Those who opt out will not be contacted by the study pharmacist, and you will not receive any information about their adherence.

To understand if and how you responded to the information provided about patients' medication adherence, we will follow and track your use of the secure website.

The study is being funded by the National Institutes of Health. We hope to study 8,700 patients using this protocol (2,970 intervention patients, and 5,730 control patients).

PROCEDURES TO BE FOLLOWED

If you are randomized into the Intervention group, approximately 45 of your patients will be followed for non-adherence: 30 Intervention Patients, and 15 Information Patients. Additionally, there will be 15 Control Patients will participate, but neither you nor they will know that they are "controls." You can expect to receive, on average, 1 email alert every 3 days over the course of the 6-9 months (the active phase of the study). The only involvement of participating physicians that will be needed after the 6-9 month active phase of the study is to give us permission to review the medical records of participating patients, which will occur 12-18 months after the start of the active phase.

RISKS

Patients of Control Physicians will simply have the adherence of their patients observed using administrative data. Thus for Control Physicians there should be neither risk nor benefit.

Intervention Physicians will be receiving information about patients who are late picking up refills. It is possible that a physician might perceive some legal liability as a result of having information but not acting appropriately on it. Because the data in question is information about adherence with chronic medications for diabetes, hyperlipidemia, and hypertension, we do not believe that this is a "high exposure" situation, but this is at least in theory possible. Another risk for Intervention Physicians is related to the potential hassle or annoyance involved with receiving study email alerts about non-adherence, and the time it could take to follow up. We believe that the time spent in receiving email non-adherence alerts, connecting to the secure website, and reviewing refill information will be minimal.

A final risk is the loss of confidentiality related to how you chose to respond to patients' adherence information. This information, like all study data, will be kept confidential except as required by law, stored in a secure location, and used only to assess the efficacy of the proposed intervention.

BENEFITS

Many physicians will consider it a benefit to learn about potential non-adherence with chronic medications. In addition, many physicians will consider it a benefit to have no-cost and convenient access to a pharmacist to consult with patients about medication management issues. It may also be considered a benefit that the pharmacist will complete a consultation report that will be sent to the physician.

Another type of benefit relates to the fact that many of these patients (approximately 50%) will have HMO Blue. The care of these patients falls under the BCBS Alternative Quality Contract, and there is currently a very aggressive pay-for-performance program in place that focuses in part on the management of patients with diabetes, hypertension, and hyperlipidemia. Thus, higher quality medication management of patients with these problems may hold out the prospect of improved financial outcomes for your practice.

Finally, improved medication management may improve your patients' health outcomes.

WHOM TO CONTACT

Please contact the study Principal Investigator, Dr. Ira Wilson, if you have any questions about this study.

Ira B. Wilson, MD, MSc

Office phone: 401-863-9736
Cell phone: 617-680-3116

Physicians who have questions about their rights as research participants can also contact Susan Toppin, Assistant Director, in the Research Protections Office at Brown University, either by phone at 401-863-3050, toll-free at 866-309-2095, or via e-mail at Susan_Toppin@brown.edu.

PRIVACY AND CONFIDENTIALITY

If you agree to take part in this research study, your personal information will not be given to anyone unless we get your permission in writing. We will make every effort to keep your information private, but it cannot be totally guaranteed. Certain government agencies such as the Office for Human Research Protections and the National Institutes of Health (the sponsor of this project), and the Institutional Review

Boards of Brown University, Tufts Medical Center, and Tufts University, may check records that identify you. This might include your practice's medical or research records and the informed consent form you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

PARTICIPANT'S STATEMENT

I have read this consent form and have discussed it with Dr. Wilson or Dr. Cantor. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

I understand that my participation is voluntary. I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue participation in this study at any time, I will be free to do so.

If I have any questions about the study, I may contact the Principal Investigator, Dr. Ira Wilson, at 401-863-9736 (office) or 617-680-3116 (cell).

If I have any questions concerning my rights as a research subject in this study, I may contact Susan Toppin, Assistant Director, in the Research Protections Office at Brown University, either by phone at 401-863-3050, toll-free at 866-309-2095, or via e-mail at Susan_Toppin@brown.edu,

I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the U.S. Food and Drug Administration which regulates investigational drug/device studies, and the National Institutes of Health (the study sponsor).

_____	_____	_____
Date	Participant's Signature	Participant's Printed Name

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____	_____
Date	Principal Investigator or Representative's Signature

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