

Information Sheet

Project Title: Outcomes of Urinary Tract Infection Management by Pharmacists (RxOUTMAP)

Principal Investigator(s):

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Co-Investigator(s):

Dr. Nathan Beahm Dept. of Medicine, University of Alberta (780) 492-3454

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Background:

Urinary tract infection (UTI) is a common infection, estimated to affect about 12% of women each year, with 50% of women experiencing a UTI by 32 years of age. UTIs produce symptoms that may be unpleasant and distressing for patients and have the potential to lead to complications. They are also commonly misdiagnosed and treated inappropriately, resulting in unnecessary antibiotic use and increased potential for side effects. Unnecessary antibiotic use also puts patients at increased risk of developing resistant bacteria, which can be problematic later. Because bacterial resistance is on the rise, we have to be careful with when and how we use antibiotics. Pharmacists are accessible and highly knowledgeable healthcare providers who are able to take on a larger role in the management of medical conditions, including UTIs, and they have a unique skill set which can be useful to ensure that antibiotics are being used appropriately.

Purpose:

You are being asked to participate in a research study to assess the impact that community pharmacists can have on the management of UTIs.

Procedures:

If you agree to participate in this study and you have signed the attached consent form, your pharmacist will start by asking you some questions and accessing your electronic health record to get some background information, as well as to screen for study eligibility and to assess for appropriateness of treatment.

If you do not already have a prescription for an antibiotic from another healthcare provider, your pharmacist will prescribe one for you if you meet certain criteria. If you do already have a prescription for an antibiotic from another healthcare provider, your pharmacist will assess the appropriateness of the prescription and work with you to potentially change it to make it more appropriate, if necessary. If the prescription from another healthcare provider was found to be for asymptomatic bacteria in your urine, your pharmacist will work with you to either discontinue the antibiotic or just put it on file. Your pharmacist will be sure to explain everything to you so that you understand the reasons for any changes and so that you know what to expect. All pharmacist assessments and treatment plans will be communicated to your family physician. If your pharmacist identifies any complicating factors that require a physician's assessment, you will be referred to your physician.

The study will consist of an initial visit and a 2-week follow-up for patients meeting criteria. At the 2-week follow-up, your pharmacist will ask you some questions to see how your treatment went and assess if any further action is needed. Additional follow-ups (before or after 2 weeks) are also allowed, if necessary, and these would be for instances such as if your symptoms do not improve after 3 days or if you think you are experiencing a side effect to treatment. The follow-ups may be in person or via a phone call with your pharmacist, whichever is preferable to you. The initial visit will usually take no longer than 15-20 minutes and the 2-week follow-up will usually take no longer than 10-15 minutes. You will also be asked to complete a short survey after the initial visit. This survey will be emailed to you, should take no longer than 5 minutes to complete, and will be completely confidential. We are planning to include 750 patients from approximately 40 different pharmacies in New Brunswick for this study.

Possible Benefits:

There may or may not be a benefit to you in taking part in this study. One potential benefit, for patients who do not already have a prescription for an antibiotic from another healthcare provider, is timely access to care with your pharmacist, which will hopefully result in a speedier improvement of symptoms for you. For patients who already have a prescription for an antibiotic from another healthcare provider, a potential benefit will be having a pharmacist assess to ensure appropriateness and minimize the risk of unintended effects and the selection of resistant bacteria. We hope that this study will benefit others by helping us to understand how pharmacists can help to manage UTIs.

Possible Risks:

Taking antibiotics could have unintended effects, such as stomach upset and diarrhea, as well as other potential side effects, depending on the specific antibiotic. They may also contribute to antibiotic resistance. There is also a chance that you may not achieve resolution of your symptoms.

Confidentiality:

The information 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 pharmacy, which is in a secure area, besides in confidential communications with your physician. 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. It can, however, be removed from the analysis up to immediately prior to the analysis being performed. The 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 your pharmacist to access the necessary personal health information, including your electronic health records, from other health care professionals (like your family physician) for the conduct of this research study.

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 that may affect your decision to continue in the study, we will inform you as soon as possible.

Alternative Treatment

You do not have to participate in this study to receive antibiotics. Antibiotics can be prescribed for you by a physician and, in certain circumstances, by a pharmacist.

Reimbursement of Expenses

You will not be paid for participating in this study. The cost of your pharmacist assessing and prescribing for you will be covered by the study and not charged to you. The cost of the antibiotics themselves that you may receive will not be covered by the study, so your usual medication coverage still applies.

Questions or concerns:

If you have any questions or concern regarding this study, please contact Dr. Nathan Beahm: (780) 492-3454 or 1-877-876-9888 (toll free); or Dr. Daniel Smyth: (506) 857-5670.

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 or the Horizon Health Network Research Ethics Office at (506) 648-6094. These offices are not connected with the researchers setting up this study.

CONSENT FORM

Outcomes of Urinary Tract Infection Management by Pharmacists (RxOUTMAP)

Principal Investigator: Dr. Daniel Smyth 506-857-5670
Co-Investigators: Dr. Nathan Beahm 780-492-3454
 Dr. Ross Tsuyuki 780-492-8526

	<u>Yes</u>	<u>No</u>
Do you understand that you have been asked to be in a research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you read and received a copy of the attached Information Sheet?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the benefits and risks involved in taking part in this research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had an opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>
Has the issue of confidentiality been explained to you?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand who will have access to your records, including personally identifiable health information?	<input type="checkbox"/>	<input type="checkbox"/>
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name _____	<input type="checkbox"/>	<input type="checkbox"/>
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