



User Manual

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Primary Investigator:

Cheryl A. Sadowski, B.Sc. (Pharm), Pharm.D., BCGP, FCSHP Professor
Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta

Study Coordinator:

Sarah M. Abu Fadaleh, B.Sc. (Pharm), MSc (Pharm)
Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta

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Study Summary

This project will involve the **case-finding, assessment, and intervention for lower urinary tract symptoms (LUTS) in older adults in the community**. The goal is to **reduce LUTS symptoms while enhancing interprofessional care** with the pharmacist and other community-based team members.

More information can be found on the PILUTS Practice Tool site (<https://www.epicore.ualberta.ca/home/piluts/>), including resources library, guidelines and presentations.

Team and Roles

Principal Investigator: Dr. Cheryl Sadowski

Email: cherylas@ualberta.ca

Study Coordinator: Sarah Abu Fadaleh

Email: abufadal@ualberta.ca

Co-Investigator(s):

Dr. Yazid Al Hamarneh	Faculty of Medicine & Dentistry	(780) 492-9608
Dr. Kathleen Hunter	Faculty of Nursing	(780) 492-8941
Dr. Jane Schulz	Dept. of Obstetrics & Gynecology, University of Alberta	(780) 735-4942
Dr. Ross Tsuyuki	Dept. of Medicine, University of Alberta	(780) 492-8526
Dr. Adrian Wagg	Geriatric Medicine, University of Alberta	(780) 492-5338

Study registration

- You will receive an email from EPICORE to register in the study.
- Each pharmacist will have access on REDCap with a unique username and password.

Log In



Through the support of the Women & Children's Health Research Institute (WCHRI) and in collaboration with the Northern Alberta Clinical Trials and Research Centre (NACTRC), we are pleased to provide you with access to REDCap.

WCHRI was the first Canadian organization to implement REDCap and we continue to promote and support its adoption in research centres across Canada. WCHRI is a partnership between the University of Alberta and Alberta Health Services, with core funding from the Stollery Children's Hospital Foundation (SCHF) and the Alberta Women's Health Foundation (AWHF).

REDCap is licensed by the University of Alberta for internal not-for-profit use only. It is provided free of charge to University of Alberta researchers and their collaborators.

For additional information please refer to our support pages.

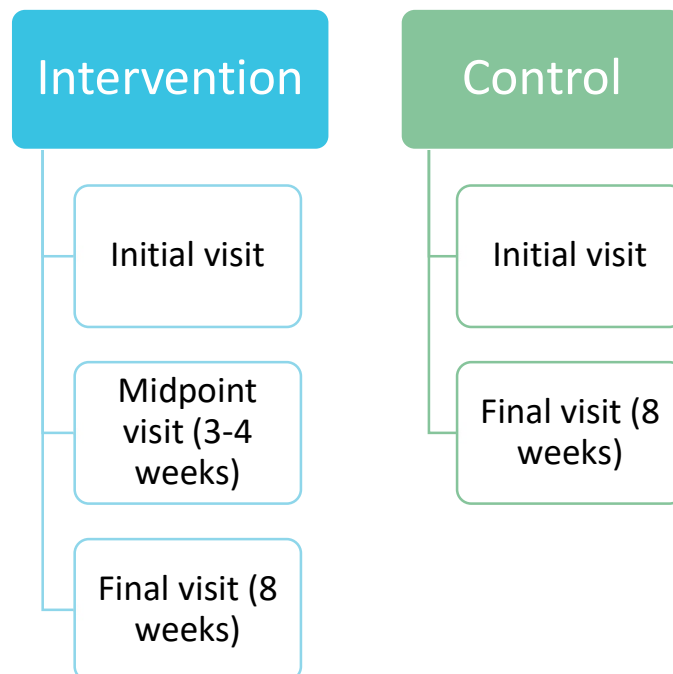
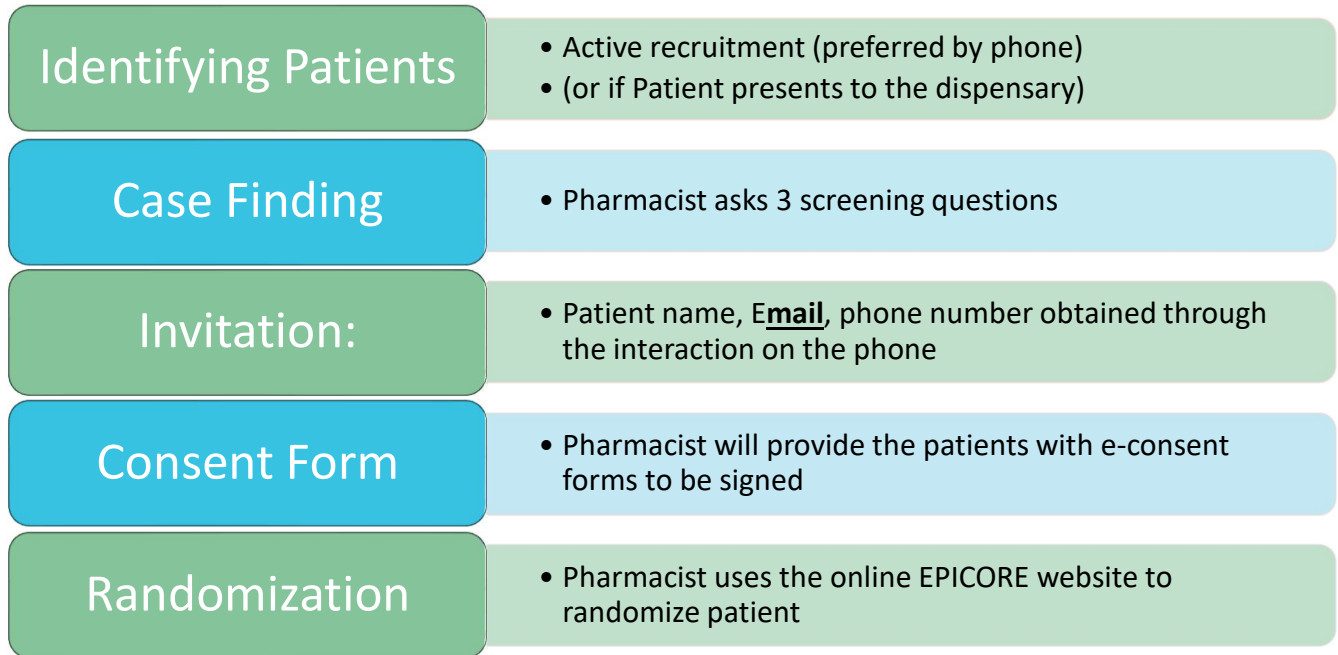
Please log in with your user name and password. If you are having trouble logging in, please contact [the REDCap System Administrator](#).

Username:





Password:

[Forgot your password?](#)

PILUTS Study Process












REDCap online portal

-  **Survey Distribution Tools**
- Get a public survey link or build a participant list for inviting respondents
-  **Scheduling**
- Generate schedules for the calendar using your defined events
-  **Record Status Dashboard**
- View data collection status of all records
-  **Add / Edit Records**
- Create new records or edit/view existing ones







All steps of PILUTS study will be conducted using REDCap online portal.

Displaying: Instrument status only | Lock status only | All status types

Patient Study ID	Baseline			4 Weeks			8 Weeks		
	Screening	Formal Informed Consent	Randomization	Patient Questionnaire	Pharmacist Assessment	Pharmacist Assessment	Patient Questionnaire	Pharmacist Assessment	Patient Satisfaction Questionnaire
1									

Follow the status bar for each step.

Legend for status icons:

-  Incomplete
-  Unverified
-  Complete
-  Incomplete (no data saved) ?
-  Partial Survey Response
-  Completed Survey Response

Follow the legend for status icons on the REDCap portal to make sure each step is **completed** by pharmacist and patient.

PILUTS Steps

1. Enrollment & Consent

- You will explain the study to the interested patients.
- You will collect patient **e-mail**, and **phone number**
- Obtain consent by having the patient sign an electronic consent form through the REDCap online portal.
 - Alternately you can generate a copy and send a link to patients' email address to be signed and submitted.

The screenshot shows a REDCap form with the following fields and options:

- Do you understand who will have access to your study records? (Yes/No radio buttons, reset button)
- Who explained this study to you? (Text input field)
- I agree to take part in this study: (Yes/No radio buttons, reset button)
- Patient Signature (Text input field, Add signature button)
- (Printed Name) (Text input field)
- Date: (Date picker with Today button, D-M-Y format)
- Email address (Text input field)
- Any other means of communication? (Text input field)

Fill in at the pharmacy or while talking with patient on the phone.

Or

The screenshot shows a survey management interface with the following elements:

- Invitation status: (Dropdown menu)
- Survey options: (Dropdown menu)
- Open survey (Green arrow icon)
- Log out + Open survey (Blue arrow icon)
- Compose survey invitation (Envelope icon)
- Survey Access Code and QR Code (QR code icon)
- 3 (Number of invitations)
- CGP, FCSHP, CHE (Text)

Send consent form by email

Note: personalize the email before it is sent to the participant

The screenshot shows a patient status screen with the following elements:

- Baseline (Text)
- Patient Study ID (Text)
- Screening (Text)
- Formal Informed Consent Form (Text)
- Randomization (Text)
- 1 (Text)
- Green circle (Indicator for Screening)
- Green circle (Indicator for Formal Informed Consent Form)
- Red circle (Indicator for Randomization)

The status screen will show you a green color legend once the consent is signed.

2. Randomize

Only when the consent form is signed by the patient, you will do an online randomization for the patient into either CONTROL or INTERVENTION group.

Randomization Data Access Group: [No Assignment] ?

Editing existing Patient Study ID 1

Event Name: **Baseline**

Patient Study ID: 1

Did the patient consent? Yes No reset

* must provide value

If Yes, proceed to randomization

Date/Time of Randomization: Today D-M-Y
(dd/mm/yyyy)

Randomization:

* must provide value

Form Status

Randomizing Patient Study ID "1"

Patient Study ID "1" was randomized for the field "Randomization" and assigned the value "Intervention" (1).

Close

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Patient Study ID	Baseline				4 Weeks	8 Weeks		
	Screening	Formal Informed Consent Form	Randomization	Patient Pharmacist Assessment	Pharmacist Assessment	Patient Pharmacist Questionnaire	Assessment	Patient Satisfaction Questionnaire
1								

The main status screen will show you the green color legend after randomizing the patient.

3. Intervention Group

I. Pharmacists Pre-visit

- Patients will receive an email with the link to the survey.
- Each patient will have a unique activation key to access and complete the survey online
- The survey must be completed by the patient before you conduct your first visit with them.

The screenshot shows a web-based 'Patient Questionnaire' form. At the top, it says 'Patient Questionnaire' and 'Data Access Group: [No Assignment]'. Below that, it indicates 'Invitation status: [email icon]' and 'Survey options'. The form is titled 'Editing existing Patient Study ID 1' and shows 'Event Name: Baseline' and 'Patient Study ID: 1'. The 'Demographics' section includes 'Date of Birth' (with a date picker set to 22-03-2021), 'Sex' (radio buttons for Female and Male), and 'Assessment of symptoms, past treatment' with two questions: 'Have you talked to your doctor about your bladder concerns?' and 'Have you talked to another health professional about your bladder concerns?'. Each question has radio buttons for 'Yes' and 'No' and a 'reset' button. Red asterisks indicate required fields.

- You will be notified by an email once the patient completes the survey.
- You can use the assessment/prompting questions to guide your preparation for the first visit You can use the algorithm or any other resources that help you identify risk factors, conduct the assessment, or think of a plan.

II. Visit 1

- You will arrange a time to call the patient, either by phone, Zoom, or another acceptable interface for the patient
- You can use this visit to gather more information, discuss the responses from the questionnaire, discuss your findings from the patient records, or any other content you feel is relevant to develop a plan.
- You will work with patient to come up with plan to make changes to improve LUTS

Pharmacist Assessment ←

Data Access Group: [No Assignment] ?

Editing existing Patient Study ID 1

Event Name: **Baseline** ←

Patient Study ID 1

Process

Visit location By phone
 By zoom
 By other
* must provide value reset

Describe your intervention/activity during the visit

Information/Education/Counseling provided
 Caffeine reduction or change in intake
 Alcohol reduction

III. Visit 1 follow-up

- Implement the shared plan which may include:
 - Providing resources or educating the patient
 - Informing the family physician that the patient is enrolled and you are developing a plan (you can use the template on the webpage)
 - Writing specialist referrals (e.g., physiotherapy for pelvic floor assessment)
 - Ordering laboratory testing
 - Adapting medication (e.g., amendment/deprescribe/start)
 - Other interventions or activities as appropriate

IV. Midpoint visit (3-4 Weeks)

- Visit set up with patient by Zoom, phone, or appropriate platform
- Review the shared plan from Visit 1
- Reassess the plan based on patient feedback and progress
- Provide educational reinforcement, respond to patient inquiries.
- Implement new strategies if needed

Pharmacist Assessment ←

Data Access Group: [No Assignment] ?

Editing existing Patient Study ID 1

Event Name: **4 Weeks** ←

Patient Study ID 1

Process

Visit location By phone
 By zoom
 By other
* must provide value reset

Describe your intervention/activity during the visit

V. Final visit

- Patients will fill the questionnaire and you will be notified by email once completed

Editing existing Patient Study ID 1

Event Name: 8 Weeks

Patient Study ID 1

Patient Perception of Bladder Condition (PPBC)

Which of the following statements describes your bladder condition best at the moment?

* must provide value

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder conditions causes me some minor problems
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

reset

PPBC Score View equation

Bladder Self-Assessment Questionnaire (BSAQ)

- Pharmacists will arrange a time to call the patient, (either by phone, Zoom, or other acceptable interface for the patient) to close the study with patients by thanking them for participation.

Editing existing Patient Study ID 1

Event Name: 8 Weeks

Patient Study ID 1

Process

Visit location By phone By zoom By other

* must provide value

reset

Summary Provided to Patient

Questions from patient: (describe)

Expand

Patient thanked for participating

Expand

4. Control Group

I. Pharmacist pre-visit

- The patients will receive an email to enroll in the study
- The patient will complete a questionnaire then an email will be sent to you.
- You should review the questionnaire to ensure it is completed but you will **not** be conducting any assessment or intervention for a CONTROL patient.

The screenshot shows a REDCap form titled "Editing existing Patient Study ID 2". The form is divided into several sections:

- Event Name:** Baseline
- Patient Study ID:** 2
- Demographics:**
 - Date of Birth:** A text input field with a calendar icon and a "Today" button. A red asterisk indicates it is required.
 - Sex:** Radio buttons for "Female" and "Male". A red asterisk indicates it is required.
- Patient Perception of Bladder Condition (PPBC):**
 - Which of the following statements describes your bladder condition best at the moment?** A radio button question with five options:
 - My bladder condition does not cause me any problems at all.
 - My bladder condition causes me some very minor problems.
 - My bladder conditions causes me some minor problems
 - My bladder condition causes me (some) moderate problems.
 - My bladder condition causes me severe problems.
 - My bladder condition causes me many severe problems.
 - PPBC Score:** A text input field with a "View equation" link.
- Bladder Self-Assessment Questionnaire (BSAQ):** A section header.

II. Visit 1

- Acknowledge the patient for completing the questionnaires.
- Email the patient the healthy aging brochure that is built into the REDCap database

The screenshot shows a REDCap form titled "Pharmacist Assessment". The form is divided into several sections:

- Event Name:** Baseline
- Patient Study ID:** 2
- Process:** A large blue section header.
- Visit location:** Radio buttons for "By phone", "By zoom", and "By other". A red asterisk indicates it is required.
- Healthy Aging Information:** A large blue section header.
- Brochures/counseling provided:** Checkboxes for "Healthy Aging" and "Other". A red asterisk indicates it is required.
- Feasibility:** A large blue section header.
- Time assessment started:** A text input field.

- Control group patients do NOT have a follow up visit at week 4, and the portal will not be activated for this option.

Pharmacist Assessment Data Access Group: [No Assignment] ?

Editing existing Patient Study ID 2

Event Name: **4 Weeks** ←

Patient Study ID: 2

This is a control patient. You do not need to complete this form

Form Status

Complete? Incomplete ▾

III. Final visit

- Patients will complete the questionnaire and you will be notified by email once completed
- Arrange a time to call the patient, (preferably by phone, but you can also use Zoom, or other acceptable interface for the patient) to close the study with patients by thanking them for participation.

Editing existing Patient Study ID 2

Event Name: **8 Weeks**

Patient Study ID: 2

Process

Visit location reset
 * must provide value
 By phone
 By zoom
 By other

Summary Provided to Patient

Questions from patient: (describe) Expand

Patient thanked for participating Expand

Important note:

After every visit, both for the control & intervention groups, pharmacists are asked to answer feasibility questions (check pharmacists forms below on page 15 and following, under Feasibility)

Feasibility

Time assessment started
* must provide value
22:15 Now H:M

Time patient interaction completed
* must provide value
22:15 Now H:M

Total time with patient
* must provide value
0 minutes View equation

Total time for documentation
* must provide value
minutes

Total time reviewing records (e.g. Netcare)
* must provide value
minutes

Total time communicating with physician or other health care

At the completion of the study the patient will complete the Patient Satisfaction Questionnaire. This will be sent to the patient by EPICORE. This information will be compiled and shared with you after the study is completed.

Editing existing Patient Study ID 1

Event Name: 8 Weeks

Patient Study ID 1

General Satisfaction

	Strongly agree	Agree	Uncertain	Disagree	Strongly agree
I am totally satisfied with my visit to this pharmacist * must provide value	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Some things about my consultation with this pharmacist could have been better * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am not completely satisfied with my visit to the pharmacist * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

reset

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Pharmacists' forms

1. Intervention group

I. Initial visit

Initial Visit – Intervention

Patient Study ID:
Patient questionnaire completed on: ____/____/____ dd mm yyyy
Pharmacist review completed on: ____/____/____ dd mm yyyy

Stage 1 - Process

- 1. Visit location
 - By phone
 - By Zoom
 - By Other _____

Stage 2 – Describe your intervention/activity during the visit

- 2. Information/Education/Counseling provided
 - Non-pharmacologic intervention
 - Caffeine reduction or change in intake
 - Alcohol reduction
 - Fluid reduction
 - Fluid increase
 - PFME/T
 - Scheduled toileting
 - Weight loss
 - Other
 - Describe

- Medication changes
describe
- Other
Describe
- Labwork ordered
describe
- Referrals
 - ER
Describe
 - Family physician
Describe
 - Medical specialist or specialty clinic
Describe
 - Physiotherapist
Describe
 - Dietician
Describe
 - Other
Describe

Stage 3 – Feasibility

3. Duration:

Time of assessment started: ____:____

Time patient interaction completed: ____:____

Total time with patient: ____ minutes

Total time for documentation: ____ min.

Total time reviewing records (e.g. Netcare): ____ min.

Total time communicating with physician or other health care professionals: ____ min.

Other time required: ____ min.

TOTAL time for subject: ____ minutes

4. Challenges noted: (describe)

Patient

Describe

Algorithm – assessment

Describe

Algorithm – intervention

Describe

Documentation

Describe

Study form/questionnaire

Describe

Other

Describe

If you have any other comments, please enter them here:

Pharmacists' forms

1. Intervention group

II. Midpoint visit

Interim Visit – Intervention

Patient Study ID:

Form completed on: ____/____/____

dd mm yyyy

Stage 1 - Process

1. Visit location

By phone

By Zoom

By Other _____

Stage 2 – Describe your activity/intervention during this follow-up visit

Choose what additional and/or amendments intervention(s) have you done during the second visit

2. Reviewed/reaffirmed original plan with patient

New activities this visit include:

3. Information/Education/Counseling provided

Non-pharmacologic intervention

Caffeine reduction or change in intake

Alcohol reduction

Fluid reduction

Fluid increase

PFME/T

Scheduled toileting

Weight loss

Other

Describe

Medication changes

describe

Other

Describe

- Labwork ordered
describe
- Referrals
 - ER
Describe
 - Family physician
Describe
 - Medical specialist or specialty clinic
Describe
 - Physiotherapist
Describe
 - Dietician
Describe
 - Other
Describe

Stage 3 – Feasibility (Pharmacist to complete)

4. Duration:

Time of assessment started: ____:____

Time patient interaction completed: ____:____

Total time with patient: ____ minutes

Total time for documentation: ____ min.

Total time reviewing records (e.g. Netcare): ____ min.

Total time communicating with physician or other health care professionals: ____ min.

Other time required: ____ min.

TOTAL time for subject: ____ minutes

5. Challenges noted: (describe)

6.

- Patient
Describe
- Algorithm – assessment
Describe
- Algorithm – intervention
Describe
- Documentation

Describe

Study form/questionnaire

Describe

Other

Describe

If you have any other comments, please enter them here:

Pharmacists' forms

1. Intervention group

III. Last visit

Final Visit

Patient Study ID:

dd mm yyyy

Pharmacist closing call completed on: ____/____/____

dd mm yyyy

Stage 1 - Process

1. Visit location

- By phone
 By Zoom
 By Other _____

Stage 2 – Summary Provided to Patient

1. Questions from patient: (describe)
2. Patient thanked for participating ...
3. Other interaction with patient (describe)

Stage 3 – Feasibility (Pharmacist to complete)

4. Duration:

Time of assessment started: ____:____

Time patient interaction completed: ____:____

Total time with patient: ____ minutes

Total time for documentation: ____ min.

Total time reviewing records (e.g. Netcare): ____ min.

Total time communicating with physician or other health care professionals: ____ min.

Other time required: ____ min.

TOTAL time for subject: ____ minutes

5. Challenges noted: (describe)

Patient

Describe

Algorithm – assessment

Describe

Algorithm – intervention

Describe

Documentation

Describe

Study form/questionnaire

Describe

Other

Describe

If you have any other comments you would like to share with the researchers, please enter them here:

Pharmacists' forms

2. Control group

I. Initial visit

Initial Visit – Control

Patient Study ID:

Form completed on: ____/____/____
 dd mm yyyy

Stage 1 - Process

1. Visit location
 By phone
 By Zoom
 By Other _____

Stage 2 – Healthy Aging Information

2. Brochures/counseling provided:
 Healthy Aging
 Other

Stage 3 – Feasibility (Pharmacist to complete)

3. Duration:

Time of assessment started: ____:____

Time patient interaction completed: ____:____

Total time with patient: ____ minutes

Total time for documentation: ____ min.

Total time reviewing records (e.g. Netcare): ____ min.

Total time communicating with physician or other health care professionals: ____ min.

Other time required: ____ min.

TOTAL time for subject: ____ minutes

4. Challenges noted: (describe)

- Patient
Describe
- Algorithm – assessment
Describe
- Algorithm – intervention
Describe
- Documentation
Describe
- Study form/questionnaire
Describe
- Other
Describe

If you have any other comments, please enter them here:

Pharmacists' forms

2. Control group

II. Last visit

Final Visit

Patient Study ID:
dd mm yyyy
Pharmacist closing call completed on: ____/____/____
dd mm yyyy

Stage 1 - Process

1. Visit location

- By phone
 By Zoom
 By Other _____

Stage 2 – Summary Provided to Patient

2. Questions from patient: (describe)
3. Patient thanked for participating ...
4. Other interaction with patient (describe)

Stage 3 – Feasibility (Pharmacist to complete)

5. Duration:

Time of assessment started: __:__

Time patient interaction completed: __:__

Total time with patient: ____ minutes

Total time for documentation: ____ min.

Total time reviewing records (e.g. Netcare): ____ min.

Total time communicating with physician or other health care professionals: ____ min.

Other time required: ____ min.

TOTAL time for subject: ____ minutes

6. Challenges noted: (describe)

- Patient
Describe
- Algorithm – assessment
Describe
- Algorithm – intervention
Describe
- Documentation
Describe
- Study form/questionnaire
Describe
- Other
Describe

If you have any other comments you would like to share with the researchers, please enter them here:

Participants Questionnaire

1. Intervention group

I. Female patients – Initial visit

Initial Visit – Intervention

Patient Study ID:
Form completed on: ___/___/____ dd mm yyyy

Stage 1 - Demographics

7. What is your date of birth: ___/___/____
 dd mm yyyy

8. Sex: Female Male

Stage 2–Assessment of Symptoms, Past Treatment

9. Have you talked to your doctor about your bladder concerns?

Yes

No

10. Have you seen a bladder, incontinence, or urology specialist for your bladder concerns?

Yes

No

11. Have you talked to another health professional about your bladder concerns?

Yes

No

Who did you speak to?

12. Which technique have you tried to improve your bladder concerns, and was this effective?
(select all the techniques that you tried)

Did you change the amount of fluid you drink? Effective Yes No
Please describe how you changed this.

Did you make changes to your diet? Effective Yes No
Please describe the changes you made

Did you try Scheduled toileting Effective Yes No
Describe

Did you record your bladder diary Effective Yes No
Describe

Have you done pelvic floor muscle training (sometimes referred to as “Kegels”) Effective Yes No
Describe

Have you used a Pessary Effective Yes No
Describe

Have you used a catheter Effective Yes No
Describe

Have you used absorbable pads/briefs/diapers Effective Yes No
If you currently use pads or brief, how many do you use each day?

Were you prescribed Medications or did you make any changes to your medications Effective Yes No
Describe

Other Effective Yes No
Describe

Stage 3–Bladder Scales

Patient Perception of Bladder Condition (PPBC)

Which of the following statements describes your bladder condition best at the moment? Please mark X in one box only.

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder conditions causes me some minor problems
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

Bladder Self-Assessment Questionnaire (BSAQ)

For each question score 0-3

0 = not at all 1 = a little 2 – moderately 3 – a great deal

1. Is it difficult to hold urine when you get the urge to go?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

2. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

3. Do you have a problem with going to the toilet too often during the day?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

4. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

5. Do you have to wake up from sleep at night to pass urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

6. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

7. Do you leak urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

8. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

Stage 4–Assessment of Urinary Symptoms

Urinary symptoms

Many people experience urinary symptoms some of the time. We are trying to find out how many people experience urinary symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS

Stage 4b – Assessment - Female

2. How often do you pass urine during the day?

- one to six times
- seven to eight times
- nine to ten times
- eleven to twelve times
- thirteen times or more

3. During the night, how many times do you have to get up to urinate, on average?

- none
- one
- two
- three
- four or more

4. Do you have a sudden need to rush to the toilet to urinate?

- never
- occasionally
- sometimes
- most of the time
- all of the time

5. Does urine leak before you can get to the toilet?

- never
- occasionally
- sometimes
- most of the time
- all of the time

6. Do you have pain in your bladder?

- never
- occasionally
- sometimes
- most of the time
- all of the time

7. How often do you leak urine?

- never
- once or less per week
- two to three times per week
- once per day
- several times per day

8. Does urine leak when you are physically active, exert yourself, cough or sneeze?

- never
- occasionally
- sometimes
- most of the time
- all of the time

9. Do you ever leak for no obvious reason and without feeling that you want to go?

- never
- occasionally
- sometimes
- most of the time
- all of the time

10. How much urinary leakage occurs?

- no leakage
- drops/pants damp
- dribble pants/wet
- floods, soaking through to outer clothing
- floods, running down legs or on to floor

11. Is there a delay before you can start to urinate?

- never
- occasionally
- sometimes
- most of the time
- all of the time

12. Do you have to strain to start urinating?

- never
- occasionally
- sometimes
- most of the time
- all of the time

13. Do you stop and start more than once while you urinate?

- never
- occasionally
- sometimes
- most of the time
- all of the time

14. Do you leak urine when you are asleep?

- never
- occasionally
- sometimes
- most of the time
- all of the time

15. Would you say that the strength of your urinary stream is...

- not reduced
- reduced a little
- quite reduced
- reduced a great deal
- no stream

16. Have you ever blocked up completely so that you could not urinate at all and had to have a catheter passed to drain the bladder

- no
- yes, once
- yes, twice
- yes, more than twice

17. Do you have a burning feeling when you urinate?

- never
- occasionally
- sometimes
- most of the time
- all of the time

18. How often do you feel that your bladder has not emptied properly after you have urinated?

- never
- occasionally
- sometimes
- most of the time
- all of the time

19. Can you stop the flow of urine if you try while you are urinating?

- yes, easily
- yes, with difficulty
- no, cannot stop it flowing

Stage 5—General health

Please check all of the following that you have experienced or have been told you have been diagnosed with:

Diabetes:	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Stroke	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Dementia	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Depression	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Spinal cord injury	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Constipation	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Urinary tract infections	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Difficulty walking	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

Other conditions you would like the pharmacist to know about:

Stage 6—Lifestyle

On a typical day, how many servings or glasses do you have of the following:

- Water: _____
- Caffeinated tea or coffee
- Caffeinated cola or caffeinated soft drinks
- Caffeine-free soft drinks
- Milk
- Juice
- Other

How many servings of alcohol do you drink each day: (a serving is 1 bottle or can of beer, 1 glass of wine (150 mL or 5 ounces), or 1 shot of spirits/hard liquor (30 mL or 1 ounce)):

Stage 7–Comments

If you have any other comments, please enter them here:

1. Intervention group

I. Male patients – Initial visit

Initial Visit – Intervention

Date you are completing this form: ____/____/____
dd mm yyyy

Stage 1 - Demographics

13. What is your date of birth: ____/____/____
dd mm yyyy

14. Sex: Female Male

Stage 2–Assessment of Symptoms, Past Treatment

15. Have you talked to your doctor about your bladder concerns?

- Yes
 No

16. Have you seen a bladder, incontinence, or urology specialist for your bladder concerns?

- Yes
 No

17. Have you talked to another health professional about your bladder concerns?

- Yes
 No

Who did you speak to?

18. Which technique have you tried to improve your bladder concerns, and was this effective?
(select all the techniques that you tried)

Did you change the amount of fluid you drink? Effective Yes No
Please describe how you changed this.

Did you make changes to your diet? Effective Yes No
Please describe the changes you made

Did you try Scheduled toileting
Describe Effective Yes No

Did you record your bladder diary
Describe Effective Yes No

Have you done pelvic floor muscle training (sometimes referred to as “Kegels”)
Describe Effective Yes No

Have you used a catheter
Describe Effective Yes No

Have you used absorbable pads/briefs/diapers
If you currently use pads or briefs, how many do you use each day? Effective Yes No

Were you prescribed Medications or did you make any changes to your medications
Describe Effective Yes No

Other
Describe Effective Yes No

Stage 3–Bladder Scales

Patient Perception of Bladder Condition (PPBC)

Which of the following statements describes your bladder condition best at the moment? Please mark X in one box only.

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder conditions causes me some minor problems

- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

Bladder Self-Assessment Questionnaire (BSAQ)

For each question score 0-3

0 = not at all 1 = a little 2 – moderately 3 – a great deal

9. Is it difficult to hold urine when you get the urge to go?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

10. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

11. Do you have a problem with going to the toilet too often during the day?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

12. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

13. Do you have to wake up from sleep at night to pass urine?

- 0 = not at all
- 1 = a little
- 2 – moderately

3 – a great deal

14. How much does this bother you?

0 = not at all

1 = a little

2 – moderately

3 – a great deal

15. Do you leak urine?

0 = not at all

1 = a little

2 – moderately

3 – a great deal

16. How much does this bother you?

0 = not at all

1 = a little

2 – moderately

3 – a great deal

International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS:

5. How often do you leak urine?

Never - 0

About once a week or less often -1

Two or three times a week -2

- one to six times -0
- seven to eight times -1
- nine to ten times -2
- eleven to twelve times -3
- thirteen times or more -4

3. During the night, how many times do you have to get up to urinate, on average?

- none -0
- one -1
- two -2
- three -3
- four or more -4

4. Do you have a sudden need to rush to the toilet to urinate?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

5. Does urine leak before you can get to the toilet?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

6. Do you have pain in your bladder?

- never -0
- occasionally -1
- sometimes -2

- most of the time -3
- all of the time -4

7. Does urine leak when you cough or sneeze?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

8. Do you ever leak for no obvious reason and without feeling that you want to go?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

9. Is there a delay before you can start to urinate?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

10. Do you have to strain to start urinating?

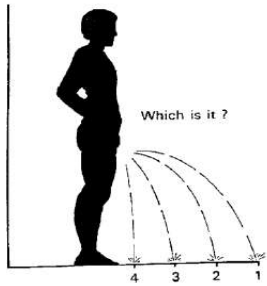
- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

11. Do you have to strain to continue urinating?

- never -0
- occasionally -1
- sometimes -2

- most of the time -3
- all of the time -4

12. Would you say that the strength of your urinary stream is...



- normal -0
- occasionally reduced -1
- sometimes reduced -2
- reduced most of the time -3
- reduced all of the time -4

13. Do you think you have always had a weak stream?

- (from Peeling, 1989)
- yes -1
 - no -0

14. Would you say that the strength of your urinary stream is... *(please ring one number)*

- 4
- 3
- 2
- 1

15. Do you stop and start more than once while you urinate?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

16. Do you have a burning feeling when you urinate?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

17. How often do you feel that your bladder has not emptied properly after you have urinated?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

18. Does your urine stream end with a dribble?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

19. How often have you had a slight wetting of your pants a few minutes after you had finished urinating and had dressed yourself?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

20. Do you leak urine when you are asleep?

- never -0

- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

21. If you leak urine during the day, do you have to change your clothes or wear pads?

- no, urine does not leak -0
- yes, change underpants -1
- yes, change clothes -2
- I wear pads -3

22. Do you have to urinate again (within 15 minutes) after you thought you had finished urinating?

- never -0
- occasionally -1
- sometimes -2
- most of the time -3
- all of the time -4

23. Have you ever blocked up completely so that you could not urinate at all and had to have a catheter passed to drain the bladder

- no -0
- yes, once -1
- yes, twice -2
- yes, more than once -3

Stage 5—General health

Please check all of the following that you have experienced or have been told you have been diagnosed with:

- | | | | | |
|--------------------------|-----|--------------------------|----|--------------------------|
| Diabetes: | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Stroke | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Dementia | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Depression | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Spinal cord injury | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Constipation | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Urinary tract infections | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Difficulty walking | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

Other conditions you would like the pharmacist to know about:

Stage 6–Lifestyle

On a typical day, how many servings or glasses do you have of the following:

- Water: _____
- Caffeinated tea or coffee
- Caffeinated cola or caffeinated soft drinks
- Caffeine-free soft drinks
- Milk
- Juice
- Other

How many servings of alcohol do you drink each day? (a serving is 1 bottle or can of beer, 1 glass of wine (150 mL or 5 ounces), or 1 shot of spirits/hard liquor (30 mL or 1 ounce)):

RESPONSE: Drop down for 0.5, 1, 1.5, etc.

Stage 7 –Comments

If you have any other comments, please enter them here:

1. Intervention group

II. Patients – Final visit

Final Visit – Intervention

Patient Study ID:

Form completed on: ____/____/____
 dd mm yyyy

Stage 1 – Review of the plan

1. I have made the following changes:

- Lifestyle changes
- Caffeine reduction or change in intake
- Alcohol reduction
- Fluid reduction
- Fluid increase
- Pelvic floor muscle exercises or therapy (Kegels)
- Scheduled toileting
- Other

Describe

- Medication changes

Describe

- Have you used absorbable pads/briefs/diapers Effective Yes No

If you currently use pads or briefs, how many do you use each day?

- Other

Describe

Stage 2 – Questions/Concerns

I have the following concerns about my bladder symptoms:

I have the following concerns about the plan:

Other:

Stage 3 – Questionnaires

Bladder Questions

Patient Perception of Bladder Condition (PPBC)

Which of the following statements describes your bladder condition best at the moment? Please mark X in one box only.

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder conditions causes me some minor problems
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

Bladder Self-Assessment Questionnaire (BSAQ)

For each question score 0-3

0 = not at all 1 = a little 2 – moderately 3 – a great deal

1. Is it difficult to hold urine when you get the urge to go?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

2. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

3. Do you have a problem with going to the toilet too often during the day?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

4. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

5. Do you have to wake up from sleep at night to pass urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

6. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

7. Do you leak urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

8. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS:

1. How often do you leak urine?

- Never - 0
- About once a week or less often -1
- Two or three times a week -2
- About once a day -3
- Several times a day -4
- All the time -5

Participants Questionnaire

2. Control group

I. Initial visit

Initial Visit – Control

Patient Study ID:

Patient questionnaire completed on: ____/____/____

dd mm yyyy

Pharmacist review completed on: ____/____/____

dd mm yyyy

Stage 1 - Demographics

19. Date of birth: ___/___/___
 dd mm yyy

20. Sex: Female Male

Stage 2 – Questionnaires

Bladder Questions

How many absorbable pads/briefs/diapers do you use each day?

Patient Perception of Bladder Condition (PPBC)

Which of the following statements describes your bladder condition best at the moment? Please mark X in one box only.

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder conditions causes me some minor problems
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

Bladder Self-Assessment Questionnaire (B-SAQ)

For each question score 0-3

0 = not at all 1 = a little 2 – moderately 3 – a great deal

1. Is it difficult to hold urine when you get the urge to go?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

2. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

3. Do you have a problem with going to the toilet too often during the day?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

4. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

5. Do you have to wake up from sleep at night to pass urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

6. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

7. Do you leak urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

8. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

Stage 3 – Comments

If you have any other comments, please enter them here:

Participants Questionnaire

2. Control group

II. Final visit

Final Visit – Control

Patient Study ID:

Patient questionnaire completed on: ____/____/____
dd mm yyyy

Pharmacist review completed on: ____/____/____
dd mm yyyy

Stage 1 – Questionnaires

Bladder Questions

How many absorbable pads/briefs/diapers do you use each day?

Patient Perception of Bladder Condition (PPBC)

Which of the following statements describes your bladder condition best at the moment? Please mark X in one box only.

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder conditions causes me some minor problems
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

Bladder Self-Assessment Questionnaire (B-SAQ)

For each question score 0-3

0 = not at all

1 = a little

2 – moderately

3 – a great deal

1. Is it difficult to hold urine when you get the urge to go?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

2. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

3. Do you have a problem with going to the toilet too often during the day?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

4. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

5. Do you have to wake up from sleep at night to pass urine?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

6. How much does this bother you?

- 0 = not at all
- 1 = a little
- 2 – moderately
- 3 – a great deal

4. When does urine leak?

- Never – urine does not leak
- Leaks before you can get to the toilet
- Leaks when you cough or sneeze
- Leaks when you are asleep
- Leaks when you are physically active/exercising
- Leaks when you have finished urinating and are dressed
- Leaks for no obvious reason
- Leaks all the time

Stage 2 – Comments

If you have any other comments, please enter them here:

REB Forms

Information letter

Information Sheet

Project Title:

A Quality Improvement Project to Address lower urinary tract symptoms (LUTS) by pharmacists in the community

Principal Investigator:

Dr. Cheryl Sadowski	Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta	(780) 492-5078
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Co-Investigator(s):

Dr. Yazid Al Hamarneh	Faculty of Medicine & Dentistry	(780) 492-9608
Dr. Kathleen Hunter	Faculty of Nursing	(780) 492-8941
Dr. Jane Schulz	Dept. of Obstetrics & Gynecology, University of Alberta	(780) 735-4942
Dr. Ross Tsuyuki	Dept. of Medicine, University of Alberta	(780) 492-8526
Dr. Adrian Wagg	Geriatric Medicine, University of Alberta	(780) 492-5338

Background:

Lower urinary tract symptoms occur more commonly in older adults. These symptoms can include incontinence, having to rush to the bathroom, or other urination problems. These symptoms can cause embarrassment, infections, and skin damage. It can also be costly to purchase pads or medications. Unfortunately, many people suffer with these symptoms but never discuss their concerns with a health professional. Fortunately, pharmacists in the community are available to older adults for health and medication concerns. Pharmacists are able to ask about issues like urinary symptoms, and can help seniors adopt some changes, or become more aware of available resources.

Purpose:

You are being asked to participate in a research study to find out if meeting with a pharmacist to discuss urinary symptoms can improve your symptoms. We therefore need to ask you some questions, and check your health records for any care you have received or will receive for your bladder.

Procedure:

1. If you participate you are agreeing to:
 - a. Be in one of two study groups. This will be decided by chance (rolling of dice) so that you cannot pick the group you are in. The groups will each have a different process.
 - b. Complete some questions online about your health and urinary symptoms.
 - c. Meet with the pharmacist by phone or through video conferencing (e.g. Zoom), to discuss your urinary symptoms.
 - d. Depending on the study group you are in, you will talk with the pharmacist by phone (or Zoom) in 3-4 weeks, and again at 6-8 weeks. In the other group, you will only have to meet with the pharmacist at 6-8 weeks.
 - e. Having information from your health records reviewed for urinary issues, and pharmacy records reviewed for medication issues.
 - f. Complete a satisfaction questionnaire at the end of the study.

The initial questionnaire will take 10-15 minutes to complete, and the discussion with the pharmacist could take 10-20 minutes.

The final questionnaire at the end of the study will take less than 10 minutes to complete.

After the study is over you can request all the information that the other study group received.

Possible Benefits:

You may have improvement in your urinary symptoms.

Possible Risks:

The study takes some time for the consultation with the pharmacist. There may be some changes suggested to improve your symptoms, and these may require some changes in your health regimen. When talking about urinary symptoms some people may be embarrassed or uncomfortable. If you want to take a break or stop talking about those issues the pharmacist will not continue with the discussion or questionnaire.

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. Your name will not be recorded. 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. If you withdraw from the study, you can ask that your data be removed from the study. 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 this consent form you are saying it is okay for the study team to collect, use and disclose information about you from your personal health records as described above.* The investigator or their study staff may need to look at your personal health records or at those kept by other health care providers that you may have seen in the past (e.g. your pharmacist). Any personal health information that we get from these records will be only what is needed for the study. During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the University of Alberta if the study is Investigator Initiated. By signing this consent form you are saying it is okay for the study team to collect, use and disclose information about you from your personal health records as described above. After the study is done, we will still need to securely store your health data that was collected as part of the study. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study. The data will become part of a data repository kept at the University of Alberta.

Voluntary Participation:

You do not have to take part in the study at all, and you can quit at any time. You do not have to answer any questions that you do not want to. 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. Cheryl Sadowski, Faculty of Pharmacy & Pharmaceutical Sciences: (780) 492-5078

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.

THIS INFORMATION SHEET MUST BE GIVEN TO THE RESEARCH PARTICIPANT

REB Forms/ Consent Form

CONSENT

Title of Study: A Quality Improvement Project to Address lower urinary tract symptoms (LUTS) by pharmacists in the community

Principal Investigator(s): Cheryl Sadowski
Professor, Faculty of Pharmacy & Pharmaceutical Sciences
University of Alberta

Phone Number: (780) 492-5078

Co-Investigators:

Yazid Al Hamarneh, Faculty of Medicine & Dentistry, University of Alberta

Ross Tsuyuki, Faculty of Medicine & Dentistry, University of Alberta

Adrian Wagg, Faculty of Medicine & Dentistry, University of Alberta

Kathleen Hunter, Faculty of Nursing, University of Alberta

Jane Schulz, Faculty of Medicine & Dentistry, University of Alberta

Consent of Participant

	Yes	No
Do you understand that you have been asked to be in a research study?		
Have you received and read 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 the study?		
Do you understand that you are free to refuse to participate in the study and that you may withdraw from the study at any time? You do not have to give a reason and it will not affect your care.		
Have you received an explanation of confidentiality of information?		
Do you understand who will have access to your records, including personally identifiable health information?		
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 here: _____		
Do you agree to be contacted by the study investigators in the future?		

Signatures

This study was explained to me by the following person:

Researcher's Name

I agree to take part in this study.

Name of Patient

Signature

Date

MD Information letter

A Project to Address lower urinary tract symptoms (LUTS) by pharmacists in the community

To: _____

Fax Number: _____

From: _____

Date: _____

Dear Colleague,

Re: Patient enrollment in the community-based **Management of LUTS by Pharmacists project**.

Mr/Ms/Mrs was identified as having LUTS including the following symptoms:

As you know, LUTS affect approximately 50% of older adults and can result in isolation, skin breakdown, and UTI's, among other complications. In addition to the financial cost, seniors also experience stigma, and may suffer in silence for many years.

This study was designed to engage community pharmacists to consult with older adults who have purchased absorbable products or who would like to talk about LUTS at the time of prescription pick-up. The intervention is based upon the LUTS Guide and Algorithm for Pharmacists, and will include the following:

1. Review the patient's medication profile, history, and medical conditions (e.g. through patient interview, Netcare documentation)
2. Review the patient's lifestyle habits that can impact bladder health (e.g. fluid intake, caffeine consumption)
3. Review the patient's bladder habits (e.g. frequency of toileting)
4. Provide education regarding lifestyle and behaviours that can impact bladder function
5. Provide education regarding medications that can impact bladder function
6. Discuss a plan with the patient for addressing any modifiable factors
7. Complete patient questionnaire regarding bladder symptoms, bother, and control
8. At 4 weeks have an interim meeting with the pharmacist to determine if the plan is working
9. At 8 weeks complete the plan and repeat the questionnaires

You will be provided with a written notification (sent by fax) of all assessments (including laboratory) for the patient and all changes in his/her management in this study.

Please see the attached study summary for more information.

It is important to emphasize that this pharmacist-assisted study is meant to provide additional care and improve accessibility -it is not intended to replace the rest of the health care team. The pharmacist will continue to work collaboratively with you and the patient to achieve goals over this 8 week period. You will be kept in the loop.

Please note that pharmacists, as a separate regulated health profession, are legally responsible for their own actions. They will take responsibility for any recommendations, tests, or prescriptions they provide. Pharmacists will refer the patient to you as required.

You are receiving this letter because the patient has identified you as being the most responsible primary care physician. We know, however, that sometimes that is not the case. Should you not consider yourself the most responsible physician for this patient's care, please let us know as soon as you can.

Thank you for your cooperation in this study. By working with you and the patient, we believe we can help optimize health outcomes for patients with LUTS.

If you have any questions regarding this specific patient, please contact the pharmacist

..... (Pharmacist name), at

If you have any queries or concerns about the study, please do not hesitate to contact any of the study investigators listed below.

Dr. Cheryl A. Sadowski, Professor, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta, (780) 492-5078

Dr. Yazid Al Hamarneh, EPICORE Centre/COMPRIS, Department of Medicine, University of Alberta, 780-492-9608

Dr. Ross Tsuyuki, Professor of Medicine (Cardiology) and Director, EPICORE Centre/COMPRIS, Department of Medicine, University of Alberta, 780-492-8526

Adrian Wagg, Professor of Medicine (Geriatrics), and Director, Division of Geriatric Medicine, University of Alberta, 780-492-5338

Kathleen Hunter, Professor, Faculty of Nursing, University of Alberta, (780) 492-8941

Jane Schulz, Professor of Medicine (Obstetrics and Gynaecology), (780) 780 735 4942

A Project to Address lower urinary tract symptoms (LUTS) by pharmacists in the community

Background/Rationale: Lower urinary tract symptoms (LUTS) is one of the most common geriatric syndromes, leading to stigma, isolation, urinary tract infections, and skin breakdown. Despite the numerous guidelines, medications, and other evidence-based interventions, LUTS remains under recognized and undertreated.

Community pharmacists are well positioned to identify patients with LUTS, as most older adults obtain medications regularly, and may purchase absorbable products at the pharmacy. The efficacy of pharmacists' intervention in chronic disease has been well demonstrated in the literature.

Primary objective: To determine the effect of a community based identification and intervention program in patients with LUTS on bladder symptoms and bother.

Study design: Randomized controlled trial with the patient as the unit of randomization

Sample size: 100 older adults

Intervention: The pharmacist will complete a review of participants which will include a medication, medical, and bladder history, review of labwork (Netcare), and bladder and lifestyle habits. The plan will be developed with the patient.

Follow-up: Patients will be followed up by the pharmacist at 4 weeks and again at 8 weeks to provide ongoing care and monitor their progress.

Control: Patients receive usual care with no specific intervention for 8 weeks. At the end of the 8 weeks the patients will be crossed over to receive the intervention described above.

Primary outcome: The primary outcome is difference of the Patient Perception of Bladder Condition (PPBC) score from baseline to 8 weeks. The PPBC is a single-item question that the patient answers on a scale of 1-6.

What this study adds:

- This is the first community based study involving pharmacists for management of LUTS.
- It utilizes an already available: community pharmacists, their expanded scope of practice and remuneration system already in place.
- We will use an innovative method in the community to capture patients with LUTS.
- We will pay unique attention to case finding, essential in chronic disease management – without good case finding, interventions are worthless.