The Newcastle upon Tyne Hospitals
NHS Foundation Trust

CONFIDENTIAL

ALternatives **T**o prophylactic **A**ntibiotics for the treatment of **R**ecurrent urinary tract infection in women

PARTICIPANT QUESTIONNAIRE

Participant Study Number: ☐☐ - ☐☐☐☐ (Centre - Study ID.) 1

Date of Completion: ☐☐ - ☐☐ - ☐☐☐☐ (D D - M M - Y Y Y Y)

PARTICIPANT QUESTIONNAIRES

18 months

☐

Please return this questionnaire to the ALTAR trial office in the reply paid envelope – no stamp is needed.

Newcastle Clinical Trials Unit
1-4 Claremont Terrace
Newcastle upon Tyne
NE2 4AE

☎ 0191 208 2523

The ALTAR Trial is funded by the National Institute for Health Research's HTA Programme
ALTAR Participant questionnaire 18 month v1.0 07 Apr 2016

10. How easy or difficult is it to plan when you will use the medication each time?

☐1 Extremely Difficult
☐2 Very Difficult
☐3 Difficult
☐4 Somewhat Easy
☐5 Easy
☐6 Very Easy
☐7 Extremely Easy

11. How convenient or inconvenient is it to take the medication as instructed?

☐1 Extremely Inconvenient
☐2 Very Inconvenient
☐3 Inconvenient
☐4 Somewhat Convenient
☐5 Convenient
☐6 Very Convenient
☐7 Extremely Convenient

12. Overall, how confident are you that taking this medication is a good thing for you?

☐1 Not at All Confident
☐2 A Little Confident
☐3 Somewhat Confident
☐4 Very Confident
☐5 Extremely Confident

13. How certain are you that the good things about your medication outweigh the bad things?

☐1 Not at All Certain
☐2 A Little Certain
☐3 Somewhat Certain
☐4 Very Certain
☐5 Extremely Certain

14. Taking all things into account, how satisfied or dissatisfied are you with this medication?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

A. Date of Completion: ☐☐ ☐☐ ☐☐☐☐ [DD/MM/YYYY]

B. Have you experienced any episodes of <u>urinary infection</u> treated with antibiotics during the <u>past three months</u>? Please tick '✓' to indicate yes or no as appropriate for each question.

Yes ☐1 **If yes how many urinary infections (e.g if two: insert 2 in the box)** ☐

No ☐2 **[please go to section C, on page 3]**

For each episode, if you have not done so already, you should complete a separate ALTAR urinary tract infection questionnaire supplied to you.

EPISODE 1

1a. Name of antibiotic treatment taken:		Code for antibiotic **OFFICE USE ONLY** ☐
1b. Date treatment antibiotic started ☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y		1c. Date treatment antibiotic stopped ☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
1d. Urinary tract infection questionnaire completed	Yes ☐1 No ☐2 Don't know ☐3	
1e. Urine specimen sent to ALTAR trial office	Yes ☐1 No ☐2 Don't know ☐3	
1f. Urine specimen given to GP's surgery	Yes ☐1 No ☐2 Don't know ☐3	

EPISODE 2

2a. Name of antibiotic treatment taken:		Code for antibiotic **OFFICE USE ONLY** ☐
2b. Date treatment antibiotic started ☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y		2c. Date treatment antibiotic stopped ☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
2d. Urinary tract infection questionnaire completed	Yes ☐1 No ☐2 Don't know ☐3	
2e. Urine specimen sent to ALTAR trial office	Yes ☐1 No ☐2 Don't know ☐3	
2f. Urine specimen given to GP's surgery	Yes ☐1 No ☐2 Don't know ☐3	

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EPISODE 3

3a. Name of antibiotic treatment taken:		Code for antibiotic **OFFICE USE ONLY**
3b. Date treatment antibiotic started (D D M M Y Y Y Y)	3c. Date treatment antibiotic stopped (D D M M Y Y Y Y)	
3d. Urinary tract infection questionnaire completed	Yes ☐1 No ☐2 Don't know ☐3	
3e. Urine specimen sent to ALTAR trial office	Yes ☐1 No ☐2 Don't know ☐3	
3f. Urine specimen given to GP's surgery	Yes ☐1 No ☐2 Don't know ☐3	

EPISODE 4

4a. Name of antibiotic treatment taken:		Code for antibiotic **OFFICE USE ONLY**
4b. Date treatment antibiotic started (D D M M Y Y Y Y)	4c. Date treatment antibiotic stopped (D D M M Y Y Y Y)	
4d. Urinary tract infection questionnaire completed	Yes ☐1 No ☐2 Don't know ☐3	
4e. Urine specimen sent to ALTAR trial office	Yes ☐1 No ☐2 Don't know ☐3	
4f. Urine specimen given to GP's surgery	Yes ☐1 No ☐2 Don't know ☐3	

EPISODE 5

5a. Name of antibiotic treatment taken:		Code for antibiotic **OFFICE USE ONLY**
5b. Date treatment antibiotic started (D D M M Y Y Y Y)	5c. Date treatment antibiotic stopped (D D M M Y Y Y Y)	
5d Urinary tract infection questionnaire completed	Yes ☐1 No ☐2 Don't know ☐3	
5e. Urine specimen sent to ALTAR trial office	Yes ☐1 No ☐2 Don't know ☐3	
5f. Urine specimen given to GP's surgery	Yes ☐1 No ☐2 Don't know ☐3	

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5. How much do the side effects of the medication you take to treat your condition bother you?

☐1 Extremely
☐2 Very much
☐3 Somewhat
☐4 A Little
☐5 Not at All

6. To what extent do the side effects interfere with your physical health and ability to function (e.g., strength, energy levels, etc.)?

☐1 A Great Deal
☐2 Quite a Bit
☐3 Somewhat
☐4 A little Bit
☐5 Not at All

7. To what extent do the side effects interfere with your mental function (e.g., ability to think clearly, stay awake, etc.)?

☐1 A Great Deal
☐2 Quite a Bit
☐3 Somewhat
☐4 Minimally
☐5 Not at All

8. To what degree have medication side effects affected your overall satisfaction with the medication?

☐1 A Great Deal
☐2 Quite a Bit
☐3 Somewhat
☐4 Minimally
☐5 Not at All

9. How easy or difficult is it to use the medication in its current form?

☐1 Extremely Difficult
☐2 Very Difficult
☐3 Difficult
☐4 Somewhat Easy
☐5 Easy
☐6 Very Easy
☐7 Extremely Easy

Australian and UK English TSQM, *version 1.4*

Treatment Satisfaction Questionnaire for Medication

Instructions: Please take some time to think about how satisfied or dissatisfied you are with the medication you are taking in this clinical trial. We are interested in what you think about the effectiveness, side effects, and convenience experienced when using the medication over the last two to three weeks, or since you last used it. For each question, please place one tick next to the response that most closely corresponds to your own experiences.

1. How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

3. How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

4. As a result of taking this medication, do you experience any (even slight) side effects?

☐1 Yes
☐0 No (if No, then please go to Question 9)

C. During the last three months have you made any lifestyle changes or used any 'over-the-counter' home remedies to help prevent urinary tract infection (please tick '✓' to indicate yes or no as appropriate for each question)?

	Lifestyle/home remedy use change	Yes1	No2
1.	Drinking more fluid	☐	☐
2.	Stopping cigarette smoking	☐	☐
3.	Vaginal oestrogen tablet or cream	☐	☐
4.	Cranberry product (juice, capsule or other)	☐	☐
5.	Substances like potassium citrate or sodium bicarbonate to alter the acidity of your urine	☐	☐
6.	Foods or drinks with anti-bacterial properties such as manuka honey or nettle tea	☐	☐
7.	Probiotics such as live yoghurt, 'Actimel', 'Yakult' or 'acidophyllus' and others.	☐	☐

D. Have you taken any courses of antibiotic for <u>any other reason</u> apart from urinary infection during the past three months?

Yes1	No2 [please go to Section E]
☐	☐

If yes, how many infections : ☐ **(e.g. if two: insert 2 in the box)**

If **yes**, please now fill in the boxes for each episode.

Episode 1:

a. Name of treatment antibiotic taken:	b. Date antibiotic treatment started:	c. Date treatment antibiotic stopped:	d. Reason for antibiotic [type of infection]:
	D D M M Y Y Y Y	D D M M Y Y Y Y	
OFFICE USE ONLY ☐			**OFFICE USE ONLY** ☐

Episode 2:

e. Name of treatment antibiotic taken:	f. Date antibiotic treatment started:	g. Date treatment antibiotic stopped:	h. Reason for antibiotic [type of infection]:
	D D M M Y Y Y Y	D D M M Y Y Y Y	
OFFICE USE ONLY ☐			**OFFICE USE ONLY** ☐

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Episode 3:

i. Name of treatment antibiotic taken:	j. Date antibiotic treatment started:	k. Date treatment antibiotic stopped:	l. Reason for antibiotic [type of infection]:
	D D M M Y Y Y Y	D D M M Y Y Y Y	
OFFICE USE ONLY			**OFFICE USE ONLY**

Episode 4:

m. Name of treatment antibiotic taken:	n. Date antibiotic treatment started:	o. Date treatment antibiotic stopped:	p. Reason for antibiotic [type of infection]:
	D D M M Y Y Y Y	D D M M Y Y Y Y	
OFFICE USE ONLY			**OFFICE USE ONLY**

Episode 5:

q. Name of treatment antibiotic taken:	r. Date antibiotic treatment started:	s. Date treatment antibiotic stopped:	t. Reason for antibiotic [type of infection]:
	D D M M Y Y Y Y	D D M M Y Y Y Y	
OFFICE USE ONLY			**OFFICE USE ONLY**

E. Did you experience any of the following health problems while you were taking treatment courses of antibiotics for <u>any reason</u> [excluding the once daily prophylactic antibiotic for UTI] during the last three months and did you have to stop taking the antibiotic because of the problem? For each question please tick '✓' to indicate yes or no as appropriate). **Please fill in a separate table for each antibiotic that you had problems with.**

Problem with antibiotic 1:		**Code - OFFICE USE ONLY***
1a.	**Name of antibiotic:**	
1b.	**Reason for taking antibiotic:**	

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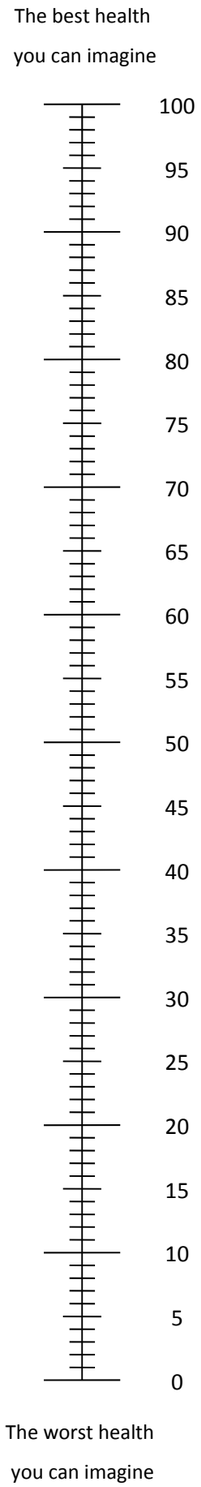
- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

Action: Did you……

Problem whilst taking antibiotics: Did you experience any of the following?				**Stop taking the antibiotic**		**Change to a different antibiotic**	
		Yes₁	**No₂**	**Yes₁**	**No₂**	**Yes₁**	**No₂**
1c.	Skin rash	☐	☐	☐	☐	☐	☐
1d.	Feeling sick (nauseated)	☐	☐	☐	☐	☐	☐
1e.	Being sick (vomiting)	☐	☐	☐	☐	☐	☐
1f.	Looser or more frequent bowel movements (diarrhoea)	☐	☐	☐	☐	☐	☐
1g.	Thrush (candidal fungal infection) in the vagina	☐	☐	☐	☐	☐	☐
1h.	Thrush (candidal fungal infection) in the mouth	☐	☐	☐	☐	☐	☐
1i.	Other: please describe side effect(s) in the space below						

Code - OFFICE USE ONLY ☐

Problem with antibiotic 2

2a. Name of antibiotic: ☐ **Code - OFFICE USE ONLY** ☐

2b. Reason for taking antibiotic: ☐ ☐

Action: Did you……

Problem whilst taking antibiotics: Did you experience any of the following?				**Stop taking the antibiotic**		**Change to a different antibiotic**	
		Yes₁	**No₂**	**Yes₁**	**No₂**	**Yes₁**	**No₂**
2c.	Skin rash	☐	☐	☐	☐	☐	☐
2d.	Feeling sick (nauseated)	☐	☐	☐	☐	☐	☐
2e.	Being sick (vomiting)	☐	☐	☐	☐	☐	☐
2f.	Looser or more frequent bowel movements (diarrhoea)	☐	☐	☐	☐	☐	☐
2g.	Thrush (candidal fungal infection) in the vagina	☐	☐	☐	☐	☐	☐
2h.	Thrush (candidal fungal infection) in the mouth	☐	☐	☐	☐	☐	☐
2i.	Other: please describe side effect(s) in the space below						

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		Action: Did you……					
Problem whilst taking antibiotics: Did you experience any of the following?				**Stop taking the antibiotic**		**Change to a different antibiotic**	
		Yes₁	**No₂**	**Yes₁**	**No₂**	**Yes₁**	**No₂**

Code - OFFICE USE ONLY	

Problem with antibiotic 3

			Code - OFFICE USE ONLY*
3a.	**Name of antibiotic:**		
3b.	**Reason for taking antibiotic:**		

		Action: Did you……					
Problem whilst taking antibiotics: Did you experience any of the following?				**Stop taking the antibiotic**		**Change to a different antibiotic**	
		Yes₁	**No₂**	**Yes₁**	**No₂**	**Yes₁**	**No₂**
3c.	Skin rash	☐	☐	☐	☐	☐	☐
3d.	Feeling sick (nauseated)	☐	☐	☐	☐	☐	☐
3e.	Being sick (vomiting)	☐	☐	☐	☐	☐	☐
3f.	Looser or more frequent bowel movements (diarrhoea)	☐	☐	☐	☐	☐	☐
3g.	Thrush (candidal fungal infection) in the vagina	☐	☐	☐	☐	☐	☐
3h.	Thrush (candidal fungal infection) in the mouth	☐	☐	☐	☐	☐	☐
3i.	Other: please describe side effect(s) in the space below						

Code - OFFICE USE ONLY	

F. Finally just a checklist of the other things we would like you to do at this point. For each please tick '✓' yes or no according to whether you have completed them.

11a. If Yes, please indicate what type of health care you have paid for in the past 6 months and what was the cost of this health care to you.

What heath care have you paid for?	**What was the cost of this health care?**
1._____	£ ☐☐☐☐☐.☐☐p
2._____	£ ☐☐☐☐☐.☐☐p
3._____	£ ☐☐☐☐☐.☐☐p

Date of completion:

If you wish to provide any further information, please do so below.

Thank-you for taking the time to complete this questionnaire.

7a. If Yes, approximately how many consultations in total did you have with a nurse at your home in the last 6 months?

Enter number of consultations you had with a nurse at your home ☐☐ **Go to Q8**

8. In the last 6 months have you had any **telephone consultations** with a health care professional?

Yes ☐ 1 **If Yes, go to 8a**

No ☐ 2 **If No, go to Q9**

8a. If Yes, please indicate what health care professional provided this telephone consultation and approximately how many telephone consultations in total you have had in the past 6 months. Please tick as many as apply.

Health Care Professional	**Yes** 1	✓ **No** 2	**Number of consultations**
GP	☐	☐	☐☐
Hospital Doctor	☐	☐	☐☐
Nurse	☐	☐	☐☐
Other health professional	☐	☐	☐☐

If Other please provide details _____

9. In the last 6 months have you had any **out-of-hours consultations** with a health care professional?

Yes ☐ 1 **If Yes, go to Q10a**

No ☐ 2 **If No, go to Q11**

10a. If Yes, please indicate what health care professional provided this out-of-hours consultation and approximately how many out-of-hours-consultations in total you have had in the past 6 months. Please tick as many as apply.

Health Care Professional	**Yes** 1	✓ **No** 2	**Number of consultations**
GP	☐	☐	☐☐
Hospital Doctor	☐	☐	☐☐
Nurse	☐	☐	☐☐
Other health professional	☐	☐	☐☐

If Other please provide details _____

11. In the past 6 months have you paid for any private health care and/or personal care?

Yes ☐ 1 **If Yes, go to Q11a**

No ☐ 2 **If No, please continue to the end of the questionnaire**

Trial Task	**Completed**		**Sent back to trial office**	
	Yes	**No**	**Yes**	**No**
Asymptomatic urine specimen sent to trial office	☐	☐	☐	☐
Perineal swab sent to trial office (6, 12 and 18 months only)	☐	☐	☐	☐

Thank you very much for completing all your trial tasks. Please don't hesitate to contact your local research team if you have any further questions or need to clarify anything.

Health Service Utilisation Questionnaire - ALTAR

Please complete this questionnaire with details of your treatment over the last 6 months. These questions ask about visits to hospital and your GP. Please tick the appropriate boxes and answer the questions where required.

1. In the last 6 months, have you been admitted to hospital as an inpatient (stayed in hospital overnight or longer)?

Yes ☐ 1 **If Yes, go to Q1a**

No ☐ 2 **If No, go to Q2**

1a. If Yes, approximately how many nights in total did you spend in hospital in the last 6 months?

Enter number of nights that you stayed in hospital ☐☐ **Go to Q2**

2. In the last 6 months, have you had any hospital outpatient appointments (did not stay overnight)?

Yes ☐ 1 **If Yes, go to Q2a**

No ☐ 2 **If No, go to Q3**

2a. If Yes, approximately how many outpatient appointments in total did you have in the last 6 months?

Enter number of times you attended hospital as an outpatient

☐☐ **Go to Q3**

3. In the last 6 months, have you had to attend the A&E/casualty department but were not admitted overnight?

Yes ☐ 1 **If Yes, go to Q3a**

No ☐ 2 **If No, go to Q4**

3a. If Yes, approximately how many times in total did you attend the A&E/casualty department in the last 6 months?

Enter number of times you attended the A&E/casualty department ☐☐ **Go to Q4**

4. In the last 6 months, have you had any consultations with a **GP at their practice**?

Yes ☐ 1 **If Yes, go to Q4a**

No ☐ 2 **If No, go to Q5**

4a. If Yes, approximately how many consultations in total did you have with a GP at their practice in the last 6 months?

Enter number of consultations you had with a GP at their practice ☐☐ **Go to Q5**

5. In the last 6 months, have you had any consultations with a **GP at your home**?

Yes ☐ 1 **If Yes, go to Q5a**

No ☐ 2 **If No, go to Q6**

5a. If Yes, approximately how many consultations in total did you have with a GP at your home in the last 6 months?

Enter number of consultations you had with a GP at your home ☐☐ **Go to Q6**

6. In the last 6 months, have you had any consultations with a **practice nurse at their practice**?

Yes ☐ 1 **If Yes, go to Q6a**

No ☐ 2 **If No, go to Q7**

6a. If Yes, approximately how many consultations in total did you have with a practice nurse at their practice in the last 6 months?

Enter number of consultations you had with a practice nurse at their practice ☐☐ **Go to Q7**

7. In the last 6 months, have you had any consultations with a **nurse at your home**? (E.G. district nurse, specialist nurse, etc.)

Yes ☐ 1 **If Yes, go to Q7a**

No ☐ 2 **If No, go to Q8**