10. What if there is a problem?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this trial, you should contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG (email: ctrg@admin.ox.ac.uk). The University has arrangements in place to provide for any harm arising from the participation in any trial for which the University is the Research Sponsor.

11.What will happen to the information that is recorded about me when the research study stops?

We will ask for your consent to hold your contact details securely in order to contact you about future relevant research at the University of Oxford. There is no obligation to agree to this. If you do not consent, we will destroy any personal information we hold about you after the end of the study. Data which does not identify you will be stored by the study team and may be used in future research projects.

12. What will happen to the results of the research study?

We will publish the results so that scientists and doctors know which method for collecting urine samples led to the least contamination and was the most acceptable to patients. We will send you a copy of the results of the study via email if you provide us with an email address. We will also provide your GP practice with a copy for them to display. You will not be personally identifiable in any publication.

13. Who is organising and funding the research?

The researchers are from the University of Oxford. The funding for this research comes from the NIHR Research for Patient Benefit (RfPB) programme.

14. Who has reviewed the study?

The study was reviewed by the NRES Committee East of England - Cambridge East

15. Do you have any further questions or concerns?

If you want to discuss the study please contact Sarah Tearne, CONDUCT Trial Manager, by email (conduct@phc.ox.ac.uk) or telephone (01865 617958)

If you have any queries or complaints or if you would like to speak to someone independent of the trial please contact the Patient Advice and Liaison service (PALs) on 01865 221473.

Thank you for taking the time to read this information leaflet

PATIENT INFORMATION SHEET

CONDUCT

The CONDUCT study

You are being asked to take part in a research study. Before you decide if you want to participate or not, it is important for you to understand why the research is being done and what it will involve. This leaflet aims to tell you about the purpose of this study and what will happen to you if you decide to take part.

Please ask us if there is anything that is not clear or if you would like more information.

CONDUCT Study Office:
Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Oxford OX2 6GG

Phone: 01865 617958

REC number: 16/EE/0200

1. What is the purpose of the study?

When women contact their GP because they think they might have a urine infection, the GP will often send a urine sample to the laboratory to see if any bacteria can be grown. However, up to a third of these samples can be contaminated with bacteria from the skin or stool. Contaminated samples cannot tell the GP or patient whether the urine is infected or which antibiotics would be best to treat it.

We want to see if two different urine collection devices, which aim to reduce the rates of contamination, really work. We will compare the samples produced using urine collection devices to samples produced in the normal way to see if they reduce the amount of contamination. We want to find out what patients think about using these devices and whether they can reduce the costs to the NHS.

We also want to see what types of bacteria are present in samples that are contaminated by analysing them using new genetic techniques. Finally we will ask your surgery to look at your medical records for some aspects of your past care, including any previous urine infections and which antibiotics you have been prescribed by your GP in the past, to see if this has an impact on whether the bacteria we find in the urine are resistant to antibiotics.

2. Why have I been invited?

You have contacted your GP practice with symptoms that suggest you might have a urine infection.

3. Do I have to take part?

No. You are free to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision not to take part or to withdraw will not affect the standard of care you receive from your healthcare team.

4. What will happen to me if I agree to take part?

- Your GP will check if you are eligible which will include screening your medical records and you will sign a consent form.
- You will then be randomly assigned (that is like tossing a coin) to one of the three methods for collecting your urine sample; you will receive either one of 2 plastic funnel shaped devices to use to collect your urine or a standard plastic pot.
- After you have given your sample back to the GP, they will do a quick test straight away. The urine sample will be sent to the lab for further analysis. You will not hear the result of this analysis unless your GP decides they need to know it.
- We will ask you to fill in a questionnaire about yourself and how you are feeling now before you leave the surgery and also to complete a questionnaire regarding your health over the next two weeks, for example to note down when your symptoms improved, and whether you needed to contact your own GP, A and E, or the Out-of-Hours GP for your symptoms.
- We will telephone you 2 weeks from now to ask you what you wrote in this questionnaire.
- Depending on what your urine sample shows, the trial team may access the results of any urine samples your GP has sent for analysis in the past or in the year following the study, and may ask your GP surgery to review your medical records.
- If you indicate that you are happy for us to contact you, you may be invited to take part in a more in-depth telephone discussion of your experience using a urine collection device. If you are, you will receive a separate information sheet with details of what would be involved before you make a decision.

5. What will happen to my urine sample?

We will use genetic techniques to find out more information about the bacteria in your urine sample. Sometimes these techniques might pick up some of your own DNA, but our computer system automatically deletes any human DNA it detects and does not analyse this. The samples will be stored anonymously and further biochemical and microbiological tests related to urine infection may be performed on them. Some of the samples may be sent with no associated personal details to a research and development UK commercial company, Mologic Ltd, who will conduct analysis to help them develop a new test for better diagnosing UTIs. Information about your age, UTI history and renal tract abnormalities will be shared but you cannot be identified by this information.

6. What are the possible disadvantages and risks of taking part?

We do not anticipate any risks from the study.

7. What are the possible benefits of taking part?

There are no direct benefits to you of taking part. This study may benefit women who have urine infections in the future by giving clear advice to patients and doctors on the best way to collect a urine sample.

8.Will my taking part in this study be kept confidential?

Yes, all information collected about you during the research will be kept strictly confidential in accordance with the Data Protection Act. Only the research team will have access to the data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

9.What if I do not want to take part and/or do not want to carry on with the study once I have started?

If you do not want to take part in the research you can withdraw at any time without affecting your care and we will not contact you again. Information collected up to your withdrawal will be kept. Please contact the study team using the contact details provided at the end of this information sheet.

continued overleaf...