TOUCAN

TOUCAN: pla**T**form f**O**r **U**ti diagnosti**C** ev**A**luatio**N**

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

The TOUCAN study is testing new devices that, hopefully, will quickly tell a GP whether a patient has a urinary tract infection (UTI) – something which is not currently possible. Some of these new devices may also pinpoint which antibiotics may be best suited to treat your infection. To make sure that the devices give reliable information, we will compare the results with those from established tests that can only be done in a specialised laboratory.

Why have I been invited to take part?

You have been invited because it is suspected that you have a UTI and are able to provide a urine sample. We are inviting people who were assigned female at birth to take part, including pregnant women.

Do I have to take part?

No, your participation is completely voluntary.

What will happen to me if I decide to take part?

If you are interested in taking part in this study you will be asked to provide a midstream urine sample into a sterile bottle (if possible **enough to fill a container like the one pictured (30ml or 2 tablespoons**). To collect a midstream urine sample, please pass the first portion of your urine into the toilet and collect the next part in the pot. We may ask you to provide a fresh urine sample because some of the devices we're testing only work with fresh urine. The same sample can be used by your doctor to decide how best to treat your suspected UTI, as part of standard care. The remaining urine will be used by our research team to test new UTI diagnostic devices - Point of Care Tests (POCT). Point of Care Tests are tests which can be performed in the GP practice by practice staff and offer a result to the GP within 40 minutes, so if this study can show that they are accurate they could improve the way UTI's are diagnosed. You will be asked to fill in a short questionnaire (either online or on paper) with some basic information including your age and ethnicity, the time the sample was taken, your

UTI symptoms and if you have taken any antibiotics in the last 7 days. This should only take a few minutes.

Our study team will also collect relevant information from your medical notes today, including what antibiotics you were prescribed, if any.

What are the possible benefits and disadvantages/risks of taking part?

Taking part in the study will take up a small amount of your time. You will not personally benefit from taking part, but your participation should help us understand whether these new rapid tests, (which can be done while a patient waits in the GP surgery), work as well as current laboratory tests. The hope is that, if these tests do work well enough to be used in GP surgeries, future patients will be diagnosed faster and receive the most appropriate antibiotic for their UTI.

Will my taking part in the study be kept confidential?

Absolutely! A code and your age, not your name, is used to link your sample, test results and clinical information together. Your name and other identifiable personal information will be stored in the GP practice. We will not store any data from which you can be identified outside of your GP practice.

Responsible members of the University of Oxford may be given access to the study data for monitoring and/or audit of the study, to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

There is no reimbursement for taking part. The study has been designed to be as convenient as possible.

What will happen to the samples I give?

Your urine sample will be used by your medical team to carry out the usual tests/observations as part of your standard care, to ensure you receive the most appropriate treatment. Any remaining sample will be used for our research study. We may ask you to provide a fresh urine sample for our research study, because some of the devices we're testing only work with fresh urine. Up to four tests will be performed directly in the surgery. The first is the widely used dipstick test which involves dipping a specially treated paper strip into a sample of your urine. The paper changes colour if your urine contains certain substances indicating that you have a bacterial UTI. The dipstick test result will be written in your medical notes. Then we will use up to three new devices under investigation to test your urine in addition. The results from these devices under investigation will not be used by your GP or practice nurse to decide on your treatment, as we still need to check how well they work in comparison to an established test done in a specialised laboratory.

The remainder of your sample will be posted to a Cardiff reference laboratory, part of Public Health Wales. Your sample will be assigned a study code and labelled with this code, your age and the date you joined the study. The laboratory will perform routine tests aiming to find out if there are bacteria in your urine which are causing your symptoms, and which antibiotic treatment should work best.

The study team will also keep samples of any bacteria grown for further testing aimed at improving UTI diagnosis.

The laboratory's routine test results will be compared with those from the new devices to see how well they work. These results won't be shared with your GP or nurse, nor will they be used to direct your treatment, because we will not be able to identify you to do this. Once the reference laboratory tests are completed, any remaining samples will be destroyed according to local laboratory guidelines.

What will happen to my data?

UK data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is '*a task in the public interest*.' The University of Oxford, based in the United Kingdom as sponsor is the data controller and is responsible for looking after your information and using it properly.

Responsible members of the University of Oxford may be given access to the study data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

We will be using information from you, your medical records, your urine sample and any prescription details from your GP appointment in order to undertake this study, and will use the minimum personally-identifiable information possible. Relevant sections of your medical notes will be reviewed by authorised members of staff at your GP practice. Only data relevant to the research study will be recorded. Your name will only be stored by your GP practice in order to identify your medical notes, to store your consent form, to add the dipstick test results, and to get prescription details from this appointment. Your local study team will keep identifiable information about you from the study for up to 3 months after the study has finished. A copy of the consent form will be in your medical notes for as long as those medical notes are held by the practice. None of your identifiable data will be accessible outside your GP practice. Responsible members of the University of Oxford and staff outside of your GP practice review the study data (including your consent form) for study monitoring purposes, such as to make sure that your consent was in place for your participation in the study.

The central laboratory run by Public Health Wales will combine your study code with the results of the specialised culture tests they run. The companies who have created the new devices may also be given data about your sample tested on their device, but they will not be given any data about you. Neither Public Health Wales nor device manufacturers will receive your name or any other identifiable information about you from this study. Fully anonymised data for the results of the specialised culture test and data about your sample tested on the devices may also be shared with Nesta Longitude Prize, an important collaborator with this study. For more information, please visit: https://longitudeprize.org/

Data protection regulations provide you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be

limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting toucan@phc.ox.ac.uk.

What will happen if I don't want to carry on with the study?

Your participation in this study is entirely voluntary. However, as we will not store data that will identify you, it will not be possible for you to withdraw from the study later. This means that data already collected about you and your urine sample will continue to be used. If you don't want to take part in the study, please let a member of the study team know and please do not complete the study questionnaire.

What will happen to the results of this study?

A report of the study results will be completed for the funding body (see below for details). Results will also be published in scientific journals, presented at scientific conferences, and published on the Oxford University departmental website. It will not be possible to identify you in any report, publication or presentation. If you would like to receive copies of any publications that arise from this study, please contact the study team.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the study team on toucan@phc.ox.ac.uk or 01865 617 854. You may contact the University of Oxford Research Governance Ethics and Assurance (RGEA) office on 01865 616480, or to contact the head of RGEA, email rgea.complaints@admin.ox.ac.uk.

How have patients and the public been involved in this study?

Patient focus groups helped develop the research topic and gave feedback on the study design and this information sheet. You can find out more information on taking part in a research study on the following website:
https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.htm

Who is organising and funding the study?

The study is being funded by the National Institute for Health and Care Research School of Primary Care Research and NHS England. The trial is being run by the Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London - Central Research Ethics Committee.

Further information and contact details:

Please contact the study team using the following contact details:

Email: toucan@phc.ox.ac.uk

Telephone: 01865 617 854

Thank you for considering taking part.