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DUTY: The Diagnosis of Urinary Tract Infection in Young Children Study

We would like to invite you and your child to take part in a research study. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if anything is unclear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

The Study is called **DUTY: The Diagnosis of Urinary Tract Infection in Young Children**. We want to improve the way doctors and nurses find out if a child has a urine infection. Doctors could then start the right treatment earlier for those who need it, and avoid unnecessary treatment for those who don't.

Bladder or urinary infections in children are common. In rare cases, these infections may lead to future medical problems which could be prevented by early treatment. This is a particular problem in children under the age of five because their kidneys are more prone to damage from infections. It can be difficult to diagnose if a child has a urine infection as the symptoms are often the same as those for other illnesses. Additionally young children cannot tell us what is wrong.

We do know that urine infection is more common in children who are already unwell but we don't know how common or which children are at greatest risk. So it is important that for this study we check the urine of nearly all children under the age of five who are seeing the doctor because they are not well, even if there seems to be another reason for the illness. We also want to see whether using a simple test on the urine, completed in the doctor's surgery, can detect infection.

Why have my child and I been invited?

Because your child is younger than 5 years old and is unwell, and/or you have noticed a change in their urine or the way they are passing urine. We hope to include 6,000 children with similar symptoms. Asking you to help with this research does not mean we believe your child has a urine infection. We are simply checking the urine and gathering information that might not otherwise have been collected.

Do we have to take part?

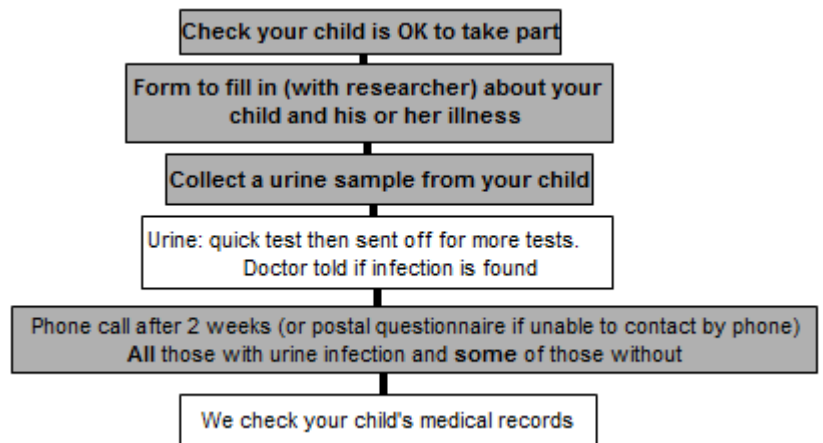
No. It is up to you whether or not you want your child to take part. Deciding not to take part will not affect the standard of care you or your child receives now or in the future.

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

You and your child can leave the study at any time, without giving a reason. This will not affect the standard of care your family receives now or in the future. If you do decide to leave the study, we will use information collected up to that time but will not collect any more. Any urine samples not needed for your child's care, and which can still be identified as your child's can be destroyed if you wish.

If we take part, what will happen to my child?

This shows the stages of the study. Only the grey boxes are those where we need your time.



A Research Nurse/Research Officer or your doctor will ask you about the symptoms your child has and will check your child's temperature, breathing rate and heart rate. The doctor will decide in the normal way how to treat your child.

In addition, you will then be helped to obtain a urine sample from your child. You will be given a sterile pot to collect the sample or a pad to put in your child's nappy, and you will be shown how to do this. We will try to obtain a urine sample before you leave the surgery, although in some cases we may need to ask you to collect a sample at your home and drop the sample off later.

Taking part in the study may mean spending between 15 and 30 minutes longer in the surgery for the Research Nurse/Officer to ask about symptoms and to collect the urine sample. In most cases the Research Nurse/Officer will see you while you are waiting to see the doctor so you won't be delayed at all. If you are delayed and it is more convenient for you, the Research Nurse/Officer may be able to visit you at home later in the day.

What happens next?

The urine sample will be tested with a test strip in the surgery, and sent to the usual hospital laboratory. If your child is found to have a urine infection, s/he will be treated by your doctor or nurse according to local and nationally agreed care plans. Treatment and further tests will only be performed if your doctor or nurse, or a hospital specialist, feels your child needs them. They will not be performed as part of this research study.

At the laboratory the urine sample will be tested, to see if an infection is present. These tests are often part of normal clinical practice for ill children, although they are not necessarily performed on all ill children. The results will be sent to your doctor who will decide about any further treatment, and will be available to the research team.

If there is enough urine, a sample will be sent to a laboratory at Cardiff University for research into the germs that cause urinary infections. If that sample shows a urine infection when the routine NHS sample did not, we will tell your child's doctor. Although these tests may not directly benefit your child, they will improve our understanding of urine infections in children, and help with the diagnosis and treatment of this problem in the future. Your child's urine may be stored for these additional tests.

A member of the research team will telephone you about two weeks from now to ask how your child is and what treatment (if any) s/he has received. As we need to understand the costs to families and the NHS of these infections, we will ask about what you have spent looking after your child. You will not have to answer all of the questions if you don't want to. The person calling you will deliberately not know if your child has an infection or not, to prevent them from changing the way they ask you questions. We will only be contacting parents of children who

have a urinary infection AND an equal number of parents whose children did not have urinary infections. A call from us does not necessarily mean that your child has an infection. If we do not manage to contact you by telephone we will send you a questionnaire in the post with a prepaid return envelope.

If your child is still unwell or you are worried about your child you should contact your doctor in the normal way.

Researchers will check your child's medical notes for the results of the urine and any other routine NHS tests your child has needed. This may include GP out of hours, Accident & Emergency and hospital notes as well as GP notes.

Why do you want to look at my child's medical records?

We are asking to look at your child's medical records in order to see if there is any difference between children with urine infections and those without, in terms of medical care in the 12 months before today's illness and further medical care, including further infections and other illnesses for up to 12 months from today.

What are the possible disadvantages and risks of taking part?

Taking part will mean that we take up a little of your time asking certain questions about your child's illness, and in taking a urine sample. The way in which we are taking urine samples is safe and does not cause discomfort. We will not take any blood as part of this study.

What are the possible benefits of taking part?

There may be no direct benefit to your child taking part, but if your child is found to have an infection, treatment can be given. Improving the understanding, diagnosis and management of urinary infections may benefit your own child or other children in the future.

What if there is a problem?

We want to know about any concern you have about how you or your child has been treated during the study, or possible harm you may have suffered.

If you have a concern about any aspect of this study, you can speak to the researchers at Cardiff University who will do their best to answer your questions (contact the local Study Manager, details below).

We would like you to tell Cardiff University about any harm you may have suffered as part of this study so that an investigation can be conducted by the Study Manager/Chief Investigator.

If you remain unhappy and wish to complain formally, you can do this by contacting the Study Manager at the University of Bristol who are sponsors of the study (details below).

Contact for Formal Complaints procedure at the University of Bristol:

Harriet Downing, DUTY Study Manager, University of Bristol, School of Social and Community Medicine, 39 Whatley Road, Bristol, BS8 2PS Tel: 0117 331 3811; e-mail: harriet.downing@bristol.ac.uk.

In the unlikely event that something does go wrong and you or your child are harmed during the research and this is due to our negligence, you may have grounds for a legal action for compensation against the University of Bristol. The normal National Health Service complaints mechanisms will also be available to you.

Will my taking part in this study be kept confidential?

Yes. All information collected about your child during the research will be kept strictly confidential in accordance with the Data Protection Act. Study data stored at the University will be kept separate from personal information (names and addresses). Only authorised staff on the research team or from regulatory authorities, who check the quality of the research, will be given access to the data. Once the study is complete, identifiable information and contact details will be destroyed. Records which cannot be linked to you or your child in any way will be kept securely for 15 years in line with University of Bristol policies.

Your doctor is involved in helping us with this research, and will be aware of your child's involvement in the study. If you are taking part in a clinic that is not your usual doctor's surgery, your doctor will be informed about your participation.

What if relevant new information becomes available?

Sometimes we get new information about the condition being studied. If this happens, we will inform your doctor, who will tell you and discuss with you whether you and your child should continue with the study. If you decide not to, this will not affect the care of you or your child in any way. If the study is stopped for any other reason, we will tell you and the care of your child by the doctor will continue as normal.

What will happen to any samples I give?

Any of the child's urine which is not used as described already will be stored securely for further research into urine infections. Names and addresses will be removed from all urine samples stored for research purposes. Research Ethics Committee approval will be sought for any further research on these urine samples.

Will any genetic tests be done?

No. We will not be doing any tests on human DNA.

What will happen to the results of the research study?

A report of the research results will be completed and submitted to the National Institute of Health Research (NIHR), part of the Department of Health, who is funding the study. Results will also be published in scientific journals and presented at scientific conferences. Once the research study is completed, we will send a summary to your doctor to display in the waiting room. Your child will not be identified in any report, publication or presentation; all results will be completely anonymous. If you would like a report of the research findings, these will be available by contacting the local Study Manager (see below).

Who is organising and funding the research?

This study is being organised by the Department of Primary Care and Public Health, Cardiff University and the Department of Community Based Medicine, University of Bristol. It is funded by the Department of Health.

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 your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Southmead Research Ethics Committee, Southmead Hospital, Bristol.

Contact for Further Information:

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THANK YOU FOR CONSIDERING TAKING PART IN THE STUDY.