

What is the DUTY study?



The DUTY study (Diagnosis of Urinary Tract Infection in Young Children) aims to develop a clinical rule to help identify, in young children (<5yrs) presenting acutely unwell to primary care, those in whom a urine sample should and needn't be obtained as part of the diagnostic pathway.

This is important because:

1. UTI in young children has been associated with long-term complications including renal scarring, renal failure and hypertension. Early recognition and treatment is thought to reduce this risk. But UTI in young children is often missed because the symptoms are non-specific.
2. Preliminary data from an ongoing primary care study suggest that around 2% of children <5 presenting to primary care with any acute illness may have a UTI. Evidence suggests that we currently miss around 50% of UTIs, though this figure could be higher.
3. NICE have recently published a guideline concerning UTI in children. This emphasises prompt diagnosis and treatment of UTI in children, and promotes a high level of suspicion, with increased urine sampling in young children with non-specific symptoms.
4. We want to find out the best way to diagnose a UTI in children less than 5 years of age, specifically which children should be targeted for urine testing, and to determine the added value of point-of-care urine dipstick testing.

About the study

DUTY is a large multicentre study funded by the National Institute of Health Research (NIHR) Health Technology Assessment Programme. The study has ethical approval (Southmead REC - ref: 09/H0102/64) and is sponsored by the University of Bristol.

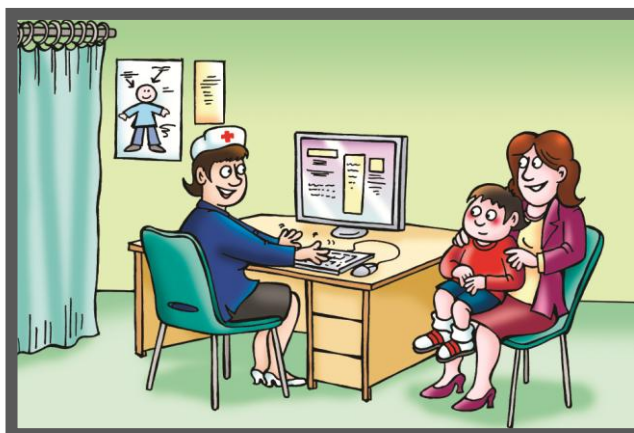
Each of the study's four research centres (Bristol, Cardiff, Southampton and London) are being directed by leading academics and together are aiming to

recruit 6,000 acutely unwell children aged under 5 years.

DUTY Recruitment Targets

From the Bristol centre, we aim to recruit 1,500 children from up to 40 primary care sites centres within the city of Bristol and the surrounding area over the period of the study (1 May 2010 to 30 April 2012). Experience from a previous studies shows that most primary care sites are able to recruit 50-100 children in a year.

What does recruiting to the DUTY study entail?



DUTY is an observational study. Children's care should be managed in the normal way according to locally and nationally agreed guidelines. Other than collecting a urine sample, we will not be asking practices to change their clinical management of children; children will not be randomised, will not receive additional/experimental medication and there are no blood tests. The DUTY team will work with practices to tailor recruitment in order to minimise the burden on the practice.

Children will have a urine sample taken using a non-invasive method and a record of their presenting symptoms will be made on a Case Report Form (CRF).

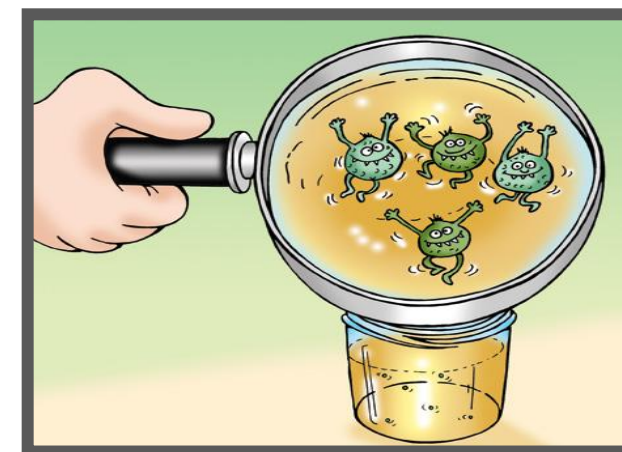
The responsible clinician will be required to perform a standard clinical examination and document their findings on the CRF, and also record planned and actual management of the child pre and post receiving the urine dipstick results.

Study Documentation

Practitioners will be able to complete the study CRF online (preferential) however a paper version will be made available for those who are unable to undertake this data collection method. Our study documentation has been streamlined for ease of completion.

Urine Results

The results of the urine sample will be processed by each practice's usual NHS laboratory and results sent back using the usual channels. Each practice would remain responsible for communicating positive culture results to their patients. The DUTY study team will follow up all children with positive culture results, and an equal number of children with negative results, to establish symptom duration and resource use at 14 days.



If enough urine is available, a second "research" sample will be sent to the Cardiff University Microbiology Laboratory. We will inform you if this "research" sample shows a UTI when the NHS sample does not.

Recruitment Options

Practices may choose to get involved in the study in one of two ways:

Option 1: DUTY Nurse Supported Recruitment

This model of recruitment involves us sending a Research Nurse/Clinical Studies Officer to your practice. If you agree to help us recruit patients, we will pay £60 for every child recruited by the Research Nurse/Clinical Studies Officer with a completed case report form and urine sample.

Option 2: Autonomous Recruitment

If your own practice staff/Research Nurse takes on the responsibility to recruit, consent children, and complete all study recruitment procedures, we will pay £100 for every child recruited.

Time Implications

The recruitment process for the Practice/Research Nurses will take between 20-40 minutes per child depending on the timing of follow-up. The study will require approximately 5 minutes of the GP's time within the consultation and an additional 2 minutes on receipt of the urine dipstick results. Children with positive culture results will also need to be followed up.

Resources provided by the study

We will provide equipment for urine collection as well as urine dipsticks. A Consultant Paediatric Nephrologist will be available for any clinical advice arising from study involvement.

Start date & duration of study

We will start to recruit children into the study as of May 2010 from small number of GP practices. Additional practices will be brought "on-line" incrementally on a rolling programme. This will help us facilitate adequate site set-up and support as well as to ensure that our two

Option 1 DUTY Nurses have adequate time to devote to recruitment, training and support within each practice.

Children will continue to be recruited into the study until the end of April 2012. The results of the study will be disseminated after December 2012.

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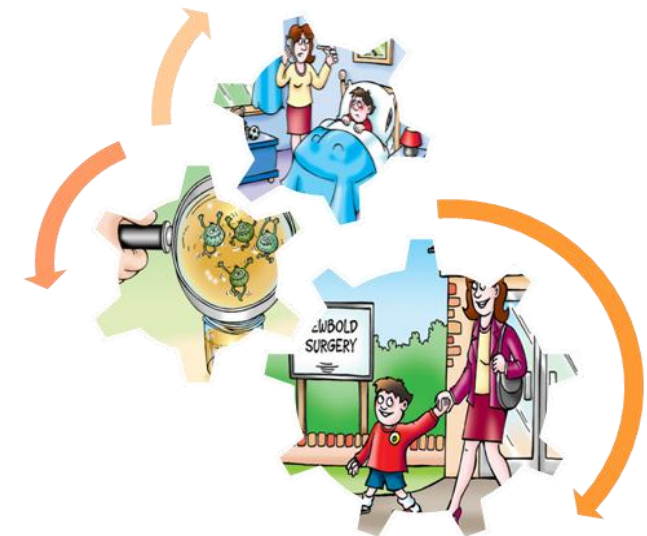
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Introducing The DUTY Study

Diagnostics of **U**rinary **T**ract
infection in **Y**oung children



Information for Primary Health Care Sites

