



Participant Information Leaflet

To help patients, doctors and other health professionals make decisions about treatments, we need evidence about what works best. Treatments are developed and tested by researchers to make sure they work and are safe. To do this researchers need to look at the effects those treatments have on patients. Researchers do this by measuring an 'outcome'.

In this research we are interested in identifying the most important outcomes in trials looking at the effectiveness of interventions for the treatment of uncomplicated Urinary Tract Infection (UTI) in adults.

By joining this effort, you can influence which outcomes should be reported in clinical trials researching the effectiveness of treatment interventions for uncomplicated UTI and thereby have an impact on the quality of future research, and ultimately the care of people experiencing a UTI.

What is the purpose of this study?

A UTI, sometimes known as cystitis, is a very common infection, which is usually caused by bacteria getting into the bladder. It is estimated that UTIs result in 8.6 million health care visits and cost the health care system millions of euro per year. If you have a UTI, you may feel the need to go to the toilet more often, or experience pain when you pass urine. Many patients visit their GP for treatment.

There are lots of trials investigating whether various treatment interventions for UTI work i.e., do they improve outcomes. A treatment intervention is defined as 'anything that aims to make a change to someone's health. For example, providing a counselling service, giving a drug, or giving people information and training are all described as interventions'.

A major problem we are facing more and more is that researchers across trials are not measuring the same outcomes. This makes it difficult for us to compare the effectiveness of treatment interventions between trials to improve our health care and make treatment decisions easier. We know it would be impossible to measure everything; so this study wants to find out what outcomes are most important from the perspective of a variety of stakeholders and therefore should always be measured.

Therefore, **we are developing a core outcome set for the effectiveness of treatment interventions for uncomplicated UTI in adults.** This will allow findings across studies to be compared and combined easily.

This project is guided by the COMET initiative (www.comet-initiative.org), which supports the development and implementation of Core Outcome Sets (COS). COS are agreed standardised sets of outcomes that represent the minimum that should be studied and reported in all clinical trials of a specific condition, and are also suitable for use in clinical audit or research other than randomised trials.

Who should take part?

We are inviting the following stakeholders to take part in the study:

- People who have experienced a UTI or cared for someone experiencing a UTI;
- Health professionals involved in the care of someone with a UTI;
- People with an interest in UTI treatment research;
- Policy Makers

What we are asking you to do?

We would like you to take **three online surveys**. In each survey, we will provide a list of possible outcomes related to the treatment of UTI and ask you to rate the importance of each outcome on a scale.

The outcomes come from a systematic review of outcomes that have been used before in studies of UTI treatment. You will also have an opportunity to add additional outcomes that have not been listed but that you consider important.

The surveys will take approximately 20-30 minutes to complete. **It is really important that you complete all three surveys when you receive them.** You will only be able to complete round two if you have completed round one. The same applies to round three. The repetition process of three surveys is necessary, as it helps to build agreement on the most important outcomes across all of the stakeholder groups that are taking part in the survey.

Following these three surveys, a preliminary list of outcomes will be brought to a face-to-face meeting, attended by key stakeholders, and a final list of outcomes for inclusion in the COS will be agreed. It is important to note that for the moment, we are considering what outcomes are to be included in the

COS (what we measure). We will decide later on how best to measure those core outcomes (how we measure).

Please be aware that this first round needs to be completed by Thursday, 26th November 2020.

Additional Study Information

Responses to this survey are voluntary and confidential. The website system where the survey is available is security protected, and only researchers with study passwords and user-IDs will be able to see it.

Although there are no direct benefits to you from taking part, you will have contributed to an important international effort to standardise outcomes in UTI treatment intervention research. Through this project, you can influence which outcomes should be reported in future research on UTI treatment.

The study is being conducted by a group of researchers from NUI Galway. The members of the Project Team are; Professor Declan Devane, Dr Claire Beecher, Dr Sinead Duane, Dr Akke Vellinga, Dr Patricia Healy, Professor Andrew Smith, Professor Martin Cormican, Professor Micheal Moore, Professor Paul Little, Ms Carmel Geoghegan and Professor Andrew Murphy. This project is funded by the Health Research Board (Ireland).

You do not have to take part in this survey if you don't want to. But we really hope that you do take part and that you can complete all three rounds. However, you can leave the survey at any time. By participating, you are certifying that you are over the age of 18.

If you have questions regarding this study or its procedures, please feel free to email the research coordinator below.

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