Development of best practice standards for the clinical management of patients presenting with Malignant Upper Urinary Tract Obstruction

Participant Information Sheet

We are inviting you to participate in our research study. Before you decide, we would like you to understand why the research is being conducted and what it would involve for you. Thank you for reading through this information.

What is the purpose of the study?

In this study, we are aiming to develop consensus-driven standards for the diagnosis, treatment, and ongoing management of patients with malignant upper urinary tract obstruction (MUUTO).

MUUTO is a blockage in the upper part of their urinary tract that some cancer patients can experience. This blockage can occur when cancer presses on or grows into the tubes that carry urine from the kidneys to the bladder. Although it is not known how common MUUTO is, it's often linked to deterioration of the patient's condition. MUUTO can happen in many types of cancer. To help relieve symptoms and possibly improve survival, medical staff may use treatments to relieve the blockage. Procedures such as the insertion of a tube into the kidney (a nephrostomy) or a stent can help improve kidney function, ease pain, and treat infections. Despite its seriousness, there's little clear guidance for medical staff on how best to manage MUUTO. Different medics and hospitals may handle it in different ways, with no agreed standard on when or how to treat it, or which patients would benefit most. This makes it hard for patients and families to make informed choices with their doctors. In order to address this, we plan to distribute a series of anonymous surveys to a panel of medical experts on MUUTO to gather their opinions about how best to manage the condition. It is anticipated that by using this method we will be able to reach agreement on best practices, and create clear, expert-backed guidelines for diagnosing and treating MUUTO. These guidelines will help medical staff to make better, more consistent decisions, and improve care for patients facing this complex condition.

The study will utilize the Delphi methodology, a structured process designed to achieve consensus among experts in the field, and often used in healthcare studies. Service users helped develop the research topic and what research questions should be asked.

By gathering insights from experienced clinicians, we aim to improve clinical care pathways and patient outcomes. Before you decide whether to participate, it is important to understand the purpose of the study, what your involvement will entail, and any potential risks or benefits.

Why have I been invited?

You have been selected as a participant because of your expertise in urology, oncology, radiology, nursing, or palliative care, with relevant experience in managing malignant upper urinary tract obstruction. Your contribution is vital to ensuring the recommendations are evidence-based, practical, and applicable to real-world clinical practice.

What will I have to do if I take part?

We will invite you to complete two online surveys, and attend a final face-to-face meeting. We will use the online survey platform Qualtrics to develop and distribute surveys, over approximately 1-3 rounds:

- **First survey (Round 1/R1):** We will ask you to vote on the importance of statements regarding the management of MUUTO. We will also ask you to provide your perspective on questions about the management of MUUTO where there is uncertainty amongst clinicians. Finally, you will have the opportunity to provide further suggestions for the management of MUUTO that have not been included. This survey will take approximately 15-20 minutes to complete. The survey will remain open for 2 – 3 weeks and reminders will be sent to anyone who has not responded, to ensure timely participation. After the first round, we will collate responses, and statements that have not met the pre-determined consensus thresholds will be progressed to Round 2, along with summary results from R1.
- **Subsequent Rounds:** For Round 2 you will have the opportunity to review anonymised summarized responses from the previous round. Also, we will invite you to consider statements that did not meet consensus criteria in R1, re-evaluate each statement's importance and relevance, and provide feedback where necessary.
- **Final face-to-face meeting:** The final Delphi round will be a virtual face-to-face meeting. At this meeting you will have the opportunity to discuss any statements that have not met consensus criteria in previous rounds or that require further refinement; to ratify statements that met consensus criteria; and to develop recommendations for the way forward.

How long will the study last?

The study will last for approximately 6 months, and your involvement would last for approximately 3 months.

Who is organising this study?

The main sponsor for this study is North Bristol NHS Trust.

Are there any risks or benefits to participation?

There are minimal risks associated with participation. The primary risk is the time commitment required to complete the survey rounds. While there are no direct benefits to you as an individual participant, your insights will contribute to the development of improved clinical guidelines, ultimately enhancing patient care.

Is participation voluntary?

Your participation is entirely voluntary, and you may withdraw at any stage without providing a reason. Withdrawing will not affect your professional standing or any future interactions with the research team. If you withdraw from the study, we will keep and continue to use all your previously collected data. We will, however not collect any further data from you.

How will my data be handled?

Your responses will be treated confidentially and anonymized before analysis. Only members of the research team will have access to your data. Findings from the study may be published in peer-reviewed journals or presented at conferences, but no identifiable information will be disclosed. We may share anonymised information with others in the future. Dating sharing with other researchers is important to ensure that research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making. The Chief Investigator is the data custodian.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, location and email address.
People will use this information to do the research or to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study, unless you have provided consent for this.

International Transfers

Your data will not be shared outside the UK.

What are your choices about how information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by asking one of the research team;
- By sending an email to Helen Williamson (Head of Information Governance) at helen.e.williamson@nbt.nhs.uk, or
- by ringing us on 01174147934

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the study researcher first who will do their best to answer your questions. If you wish to complain formally, you can do this through the National Health Service complaints procedure, using the Patient Advice and Liaison Service (PALS http://www.pals.nhs.uk/). Their contact number is 0117 414 4569. This study does not involve any tests or treatment and it is highly unlikely that you will be harmed during the research. If something does go wrong and this is due to someone's negligence, then you may have grounds for legal action for compensation against the NHS or the trial's sponsor organisation North Bristol NHS Trust. You may have to pay your legal costs. The normal NHS complaints mechanisms will always be available to you.

What will happen to the results of the research study?

The study results will be presented at research meetings, and published in scientific journals. We will also make the results widely available to the public. You will not be identified in any report or publication.

What do I do now?

If you wish to take part, please access the link to an online consent form. After completion of the consent form please proceed to the first survey. Thank you very much for considering taking part in our research.

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