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Development of guidelines for treating patients with cancer-related blockages in the upper urinary tract

Submission date 06/06/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 25/06/2025	**Overall study status** Ongoing	
Last Edited 20/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Some cancer patients develop a blockage in the upper part of their urinary tract, known as malignant upper urinary tract obstruction (MUUTO). 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. This might include placing a tube directly into the kidney (called a nephrostomy) or inserting a stent into the urine tube if possible. These procedures 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. To address this, this study plans to distribute a series of surveys to a panel of medical experts on MUUTO to gather their opinions about how best to manage the condition. It is anticipated that using this method will enable agreement to be reached on best practices and inform the creation of clear, expertbacked 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.

Who can participate?

Medical experts who represent professional groups involved in direct patient care that would benefit from clinical practice standards and are employed in a UK NHS institution.

What does the study involve?

The study will begin by reaching out to medical experts with experience in the management of MUUTO to inform them about the study and invite their participation in the development of best practice guidelines. Interested experts will provide informed consent by completing an online consent form. Following consent, participants will receive a survey covering all key aspects of MUUTO management. They will be asked to indicate their level of agreement with

various proposed management strategies. Once all responses are received, the data will be analysed to determine the level of agreement among experts. For items where there is significant disagreement, the statements will be revised and included in a second-round survey. This modified survey will be distributed to the same group of clinicians for further input. Upon receiving the second-round responses, the final analysis will be conducted to identify the management recommendations with the highest level of expert agreement. These preliminary guidelines will then be discussed and ratified during a final face-to-face meeting involving the research team and participating medical experts.

What are the possible benefits and risks of participating?
Research participants will have the opportunity to contribute to the development of much-needed best practice standards for the clinical management of MUUTO. It is anticipated that this will benefit patients and also clinicians, through the reduction of clinical variability and enhancing patient outcomes. Moreover, standardising best practice in all aspects of MUUTO management will potentially minimise unnecessary interventions and hospital admissions, thereby saving clinician time and resources.

Risks to participating will be minimal. Completion of each survey and attendance at a final meeting will involve time and inconvenience to busy clinicians who have competing priorities. The survey will be carefully designed and piloted to minimise time spent on completion and inconvenience to clinicians.

Where is the study run from?
Bristol Urological Institute, Southmead Hospital, UK

When is the study starting and how long is it expected to run for?
May 2025 to October 2025

Who is funding the study?
North Bristol NHS Trust, UK

Who is the main contact?
Mr Jonathan Aning, Jonathan.Aning@nbt.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
357641

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Development of best practice standards for the clinical management of patients presenting with malignant upper urinary tract obstruction. A Delphi study

Study objectives
To develop best practice standards for the diagnosis, treatment, and follow-up care of patients with malignant upper urinary tract obstruction (MUUTO), a condition with currently variable management and lacking standardised clinical guidelines.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/06/2025, HRA and Health and Care Research Wales (HCRW) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; HCRW.approvals@wales.nhs.uk), ref: 25/PR/0825

Study design
Qualitative research using Delphi methodology design

Primary study design
Observational

Secondary study design
Delphi study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Clinical guidelines for the management of malignant upper urinary tract obstruction (MUUTO), in cancer patients.

Interventions
Development of guidelines for treating patients with cancer-related blockages in the upper urinary tract.

Key elements of intervention:
1. Method:
A Delphi consensus process will be used. This involves a series of structured surveys and a final consensus meeting with a panel of multidisciplinary clinical experts.

2. Participants:
~40 clinical experts across the UK, including professionals in urology, oncology, radiology, palliative care, and specialist nursing.

3. Duration: Each participant will be expected to be part of the study for a maximum of 3 months.

4. Process:
Round 1: Online survey with statements rated on a 5-point Likert scale. Experts may also suggest new items. The survey will take 15-20 minutes to complete.
Round 2: Participants receive anonymised feedback from Round 1 and re-rate statements. The survey will take 15-20 minutes to complete.
Round 3: A final face-to-face consensus meeting to discuss unresolved areas and finalise recommendations. The meeting will last approximately 3 hours.

5. Content of Surveys:
Thematic blocks such as:
Pathway to admission
Disease prognosis
Timing and type of intervention (e.g., stenting, nephrostomy)
Palliative care decisions

6. Data Collection Tool:
Qualtrics online survey platform is hosted on a secure NHS server.

7. Follow-up: None required.

Intervention Type
Other

Primary outcome measure
Best practice guidelines for the management of MUUTO using an online survey, over two rounds at months 1 and 2, and a final face-to-face meeting at month 3.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date
01/05/2025

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Can represent professional groups involved in direct patient care and would benefit from clinical practice standards
2. Employed in a United Kingdom NHS institution
3. Willing to complete the surveys

Participant type(s)
Health professional

Age group
Mixed

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Not considered to be an expert in the field
2. Not directly involved in patient care
3. Not employed in a United Kingdom NHS institution

Date of first enrolment
01/07/2025

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Bristol Urological Institute
Biomed Centre
Southmead Hospital
Southmead Road, Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research & Development
North Bristol NHS Trust,
Learning & Research (Level 3),
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BS10 5NB
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Sponsor type
Hospital/treatment centre

Website
https://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Bristol NHS Trust

Alternative Name(s)
NBT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/10/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	23/05/2025	20/06/2025	No	Yes