



Project Title: Ward AdmiSsion of Haematuria: an Observational mUlticentre sTudy (WASHOUT)

Study Protocol for Local Approval Applications

Background summary:

Over 25,000 patients are admitted each year in the UK with haematuria (1), contributing to at least 15% of all emergency urology admissions. The incidence is generally reflective of international practice. Approximately 10% of these patients are readmitted with the same presentation within 30 days (2). Management of patients during their initial presentation frequently lacks durable treatment response and definitive management. Despite the prevalence of this presentation, little focus has been placed on optimising inpatient pathways at an international level and reducing unnecessary resource use.

Audit aim

WASHOUT is an international, multicentre prospective service evaluation aiming to describe the management of haematuria emergency/unplanned admissions.

Methods:

Design

We will conduct a service evaluation performed by case note review. The service evaluation will open to registration in January 2024 and data collection and new patient data entry will remain open for a period of 12 months. Case note review will be undertaken by surgeons or members of the direct care team who have access to case notes as part of their clinical role. Once consecutive patients have been identified prospectively on a local key, their details can be added retrospectively to IRB/ethics have approved this service evaluation as a case notes review. Only anonymous (non-identifiable) data will be entered into a secure, approved online database (REDCap) which is securely hosted at University College London.

The audit will be administered by the British Urology Researchers in Surgical Training collaborative (BURST). Data will only be audited after a patient has undergone their usual clinical care. Only data routinely available from case notes is collected and there is no intervention to the patient's usual care.

Inclusion criteria:

Patients will be included consecutively if they are over 18 years of age and admitted to a participating secondary care centre as an emergency with haematuria under the primary or joint care of the urology team.

Exclusion criteria:

- Catheter-related urethral trauma (defined as haematuria immediately after insertion of a urethral catheter, without a preceding history of haematuria prior to this admission, and including traumatic catheter removal by patients).
- Urological trauma (abdominal/pelvic).
- Patients that are in hospital less than 24 hours.

General Methods

Phase 1: Site and surgeon survey

- Audit registration. Each site will complete a registration survey about their normal protocols, practices and organisation of services that are relevant to the audit outcomes.

Phase 2: Prospective data collection

- Sites will then collect data about all consecutive emergency admissions for haematuria until a minimum of 15 patients have been collected within a fixed time period (between one collaborator and supervisor)

Phase 3: Follow up:

- Patients should be followed up for data entry until 90 days from day of discharge of index admission

Minimum participation requirements

15 prospective cases will be the minimum participation requirement for a site, however it is strongly encouraged for sites to submit more records as it will increase the power of analysis for their hospital, allow more authors to be involved from their team and increase the chance of being invited to write manuscripts with the steering committee and therefore be on the main author line of papers. For 15 prospective cases 1 collaborator and a supervising consultant can be recognised as authors. More authors are allowed if more cases are submitted (as outlined in the authorship agreement document). All collaborators meeting the minimum recruitment requirement will receive pubmed indexed collaborative authorship on all papers arising from the study. Author requirements and full site participation requirements are contained in separate documents.

Timeframe

The database will be open for new data entry for 1 year from the time the study begins and for 4 months beyond this to collect follow up. Centres are still eligible to join after commencement of international recruitment. It is hoped that most sites can meet their minimum requirements within 6 months. For these reasons, registration for new centres will be allowed until 1st July 2024.

Data to be collected:

Hospital surveys:

- Hospital type (Academic/ University teaching hospital/ Tertiary referral centre

Or District general/ community hospital) urology service arrangements, staffing and on-call arrangements

- Local pathways for management of emergency haematuria patients

Patient data (non-identifiable):

- Non-identifiable patient demographics
 - Age, sex (male/female), smoking, ASA grade, comorbid status, frailty index, previous urological history
- Details of admission
 - Length of stay, higher dependency unit admission, presentation, vitals status
- Investigations
 - Bloods, imaging including timeline of investigations
- Formal diagnosis
 - Cause of haematuria
- Management
 - Ward based, radiological intervention, surgical intervention with details of procedure performed
 - Date of intervention
 - Medical management including blood transfusion, reversal agents used
- Readmission details (if any)
 - Number of episodes, length of stay during this
- Mortality (if any)
 - Date of death, primary cause of death
- Follow-up
 - Any readmission, any mortality within 90 days of discharge from index admission
 - Diagnosis or cause of unscheduled haematuria if found during follow-up period

Approvals Required for your site to run WASHOUT

This project has been approved as a clinical audit in the UK. As per UK Health Research Authority guidelines, ethical approval is not required in the UK. This is because:

1. No interventions are being carried out on patients - this is an observation of clinical practice (i.e. a process evaluation).
2. Patients undergo their standard care procedures as determined by the clinician.
3. Data is collected after a patient's standard care and procedures.
4. Only anonymised data is collected and uploaded onto a secure database.

Furthermore, the UK confidentiality advisory group (CAG, a division of the national healthcare research authority) have confirmed that the collection and storage of the anonymous data is acceptable without application for approval since the data is non-identifiable.

Each UK site must register the project as an audit locally with their audit department (or equivalent) and hold their local registration number should the WASHOUT audit co-ordinators (BURST) request it for governance purposes. Some institutions may not formally register audits,

in which case written approval (e.g. in an email) from an authorised person confirming that you have permission to carry out the project as a clinical audit at the site is acceptable, or we will ask you to sign a confirmation that you have reviewed your local approval policies and there is no need for a formal approval for an audit.

The study is being coordinated by the BURST collaborative: The BURST Collaborative will run this study (www.bursturology.com). BURST is an award-winning, trainee-led organisation, who work closely with BAUS (British Association of Urological Surgeons) (3).

Lay Summary

WASHOUT is a study on the current management of emergency admissions in hospitals for visible blood in the urine. During this, routinely available data will be collected from records about patient presentation, details of admission, diagnosis and management of the patient during admission and rates of readmission or patient death during the 3 month follow-up period. From this, we will gain an understanding of how we are managing patients with emergency admissions for blood in their urine, and understand if there is variation in how this is performed across the world.

Timelines:

Register centres – 1st January 2024 - 1st July 2024

Enter new patients – 1st January 2024 - 31st December 2024

Complete follow up - Open until 31st March 2025

Analyse data, site feedback - April 2025 - December 2025

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Reference:

1. Hospital Episode Statistics, Hospital Admitted Patient Care Activity. NHS Digital. 2022. <https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics> (accessed January 1, 2022).
2. Pavithran A, Bhatt NR, Banerjee G, Hawizy A. Management of Inpatient Macroscopic Haematuria: A Typical Urology Emergency With a High Mortality. *Urology* 2022;166:22–8.
3. Kasivisvanathan V, Ahmed H, Cashman S, Challacombe B, Emberton M, Gao C, et al. The British Urology Researchers in Surgical Training (BURST) Research Collaborative: an alternative research model for carrying out large scale multi-centre urological studies. *BJU Int* 2018;121. <https://doi.org/10.1111/bju.14040>.