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Ward AdmiSsion of Haematuria: an Observational mUlticentre sTudy (WASHOUT) – study protocol

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ABSTRACT

Introduction Haematuria contributes significantly to emergency urology admissions with over 4 per 1000 annual UK emergency admissions and 10% readmitted within 30 days. However, there is limited focus on optimising inpatient pathways internationally. Existing studies highlight a substantial underlying malignancy rate (32%) in patients presenting with visible haematuria, yet many receive inconsistent care, leading to prolonged hospital stays and increased resource use. A systematic review performed by our research group found no large-scale prospective studies have been performed in this area, and little is known about current practice. This study aims to address these gaps by investigating current management practices and their impact on outcomes, with the goal of informing evidence-based guidelines and improving patient care.

Methods and analysis The Ward AdmiSsion of Haematuria: an Observational mUlticentre sTudy is an international, multicentre prospective observational study designed to describe the management of patients with unplanned admission to hospital with haematuria under the care of the urology team. The study will use a collaborative methodology using the British Urology Researchers in Surgical Training model. This model delivers international multicentre studies by empowering trainees to lead all aspects of multi-centre clinical studies, building research skills cost-effectively while shaping the future urological consultant workforce. Data on demographics, comorbidities, management practices and outcomes will be collected using a standardised case report form and analysed using multilevel linear regression modelling. Primary outcomes include length of stay, while secondary outcomes cover hospitalisation free survival, mortality, readmission rates at 90 days and resource use. The study was launched in January 2024 and will continue follow-up data collection through December 2025. Patient and public involvement (PPI) has been integral to the study design, ensuring that outcomes reflect patient priorities and that the research addresses key areas of concern.

Ethics and dissemination Ethical and regulatory approvals will be obtained as required in each participating region. In the UK, the study is classified as a service evaluation and does not require individual patient consent. Participating sites must obtain local audit department approval. Data will be collected and stored securely, ensuring patient confidentiality. Results will be disseminated through scientific conferences, peer-reviewed publications and patient advocacy groups.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The large international, multicentre prospective study design captures real-world clinical practice, enhancing the generalisability of findings due to the diversity of data.
⇒ Broad inclusion and exclusion criteria ensure the study captures a wide variety of haematuria presentations, enabling comprehensive analysis and robust subgroup analysis.
⇒ The collaborative model of data collection, proven successful in previous studies, ensures high-quality, standardised data and sufficient power through large patient recruitment.
⇒ PPI in the study design ensures that the research addresses relevant clinical outcomes and aligns with patient priorities, increasing the relevance and impact of the findings.
⇒ Limitations include variability in data quality across different sites, the lack of a standardised workup and management pathway, and the observational design, which limits the ability to establish causality.

INTRODUCTION

Emergency haematuria accounts for at least 15% of all urological emergency admissions in the United Kingdom, translating to approximately 4 cases for every 1000 emergency hospital presentations.[1] Up to 10% of these patients are readmitted with the same presentation within 30 days — patients frequently lack a durable treatment response or do not receive definitive diagnosis or management on initial presentation.[2] Despite the prevalence of this presentation, little focus

has been placed on optimising inpatient pathways at a national level and reducing unnecessary resource use.

Findings from the prospective multicentre IDENTIFY study (by the British Urology Researchers in Surgical Training (BURST) research collaborative) of 11 059 patients showed that 32% of patients presenting with visible haematuria had an underlying malignancy.[3] Of the remaining cohort, 40% had benign aetiology (eg, comprising one or more of: urinary tract infections (28%), urolithiasis (25%), prostatic bleeding (37%), radiation cystitis (55%) and trauma (3%)). 28% had no abnormality on investigation. Similar findings were reported by two further authors: a third of the patients presenting as an emergency with haematuria had malignancy, with the rate increasing in patients with clots, while a malignancy rate of 39% was reported in a French study in patients presenting as an emergency with haematuria.[4 5] More advanced bladder tumours are more likely to present as emergencies. In National Cancer Registration and Analysis Service data, the rates of emergency admission for bladder cancer increased from T1 (7%) and T2/3 (16–19%) to T4 (31%).[6] Patients in this cohort are typically elderly and frail, with multiple comorbidities and poor performance status. This cohort of patients has a high all-cause mortality rate, with a 30-day mortality rate of 5% and a 1-year mortality rate of 23%.[2] Severe haematuria is often complicated by concomitant comorbidities such as cardiac failure, renal failure, history of thromboembolic events and use of antiplatelet or anticoagulant medications.[7]

In addition to poor clinical outcomes, patients admitted with haematuria require a higher resource use in terms of nursing and medical input, irrigation requirements, long inpatient stays and high readmission rates. A recent retrospective study (of 56 patients) in Ireland examining resource use associated with radiation cystitis conservatively estimated a cost burden of €23 706 per inpatient stay.[8] Radiation cystitis accounted for 621 inpatient bed days, averaging 11 days per patient. A minority of patients are resource intensive, some being transfusion-dependent with long inpatient stays and multiple procedures. The median length of stay (LoS) for patients admitted with haematuria has increased from 8.5 days to 10 days over the last 5 years.[9] The reason behind this trend is currently unknown. This trend is the reverse of contemporary management goals such as LoS in elective urological surgery (eg, Transurethral Resection of Prostate (TURP)/transurethral resection of bladder tumour (TURBT)), for which a move toward day-case surgery (and same day of surgery discharge) has reduced unnecessary inpatient days in patients with postoperative haematuria.[10]

Components of an effective inpatient haematuria pathway could potentially include specialist urology input at the point of presentation (to perform catheterisation and washout), timely imaging studies, theatre staff competent in supporting endoscopic urology, decisive intervention, consultant involvement in operative management, acceptance of operative risk and the avoidance of deferral to elective lists for definitive management. However, these elements of a haematuria pathway remain to be investigated. It remains unclear which elements of management pathways are associated with best outcomes. There is a need to protocolise inpatient haematuria management in line with recommendations in other areas by Getting it Right First Time national programmes.

A systematic review[11] performed by our research group found that no large-scale prospective studies have been performed in this area, and little is known about current practice. The evidence available comprises small single-centre retrospective audits[2 8] evaluating mortality, readmission and cost burden of this presentation.

There are no evidence-based guideline recommendations on the timing of investigations and interventions for inpatients with haematuria. Consequently, the management of visible haematuria is currently suspected to be highly variable, both nationally and internationally, but further evidence is necessary to substantiate this. Clear guidelines and standardised management pathways may reduce variability in the management of these patients. There is an urgent need to provide good quality evidence in this under-researched area to potentially improve outcomes.

METHODS AND ANALYSIS

Study design and aim

Ward AdmiSsion of Haematuria: an Observational mUlticentre sTudy (WASHOUT) is an international, multicentre prospective observational study aiming to describe the management of patients with unplanned admission to hospital with haematuria.

Objectives

Primary objectives

Describe the clinical outcomes of patients unplanned admission to hospital because of haematuria, including LoS, mortality and readmission rates.

Secondary objectives

- Establish the prevalence of causative diagnoses in patients with unplanned admission to hospital because of haematuria.
- Describe demographics, comorbidities and management of patients with unplanned admission to hospital because of haematuria.
- Identify factors associated with adverse outcomes and/or increased resource use in this population.
- Identify if variation in management and outcomes exists at local, regional and international levels.
- Describe the impact different management pathways have on clinical outcomes (in terms of LoS, health resource utilisation, readmission, 30-day and 90-day mortality rates).
- Provide information to design a future randomised trial, for example, control group outcomes and estimates of intercluster correlations.

Hypothesis

The study hypothesis is that there is significant international and national variation in the diagnostic workup and management of patients requiring admission to hospital with haematuria.

Increased LoS and poor outcomes in terms of mortality and healthcare costs are associated with clinical management practices.

Eligibility

Patient inclusion criteria

Patients will be included consecutively if they are over 18 years of age and have an unplanned admission to a participating secondary or tertiary care centre under the primary or joint care of the urology team due to haematuria (microhaematuria or macrohaematuria/visible or non-visible haematuria).

In the UK, individual consent is not necessary as this study has been considered a service evaluation.

Patient exclusion criteria

We will exclude any patients with trauma as a cause of haematuria (including catheter-related trauma: defined as haematuria immediately after insertion of a urethral catheter without a preceding history of haematuria on this admission including traumatic catheter removal by patients), urological trauma (abdominal/pelvic) as well as patients who are in hospital less than 24 hours. Our study steering group felt this population had several confounders, including inappropriate admissions. Including these patients would mix the study population with patients best served by outpatient investigation and management (for which guidelines currently exist to guide practice).

Site inclusion criteria

Secondary* or tertiary care centre** with a urology-specific unit/team that accepts unplanned admissions anywhere in the world.

*Secondary care centres provide specialist services following referral from primary care, while **tertiary centres offer highly specialised care for complex conditions, often within academic or referral hospitals

Site exclusion criteria

Sites lacking a minimum standard of data quality and completion will be excluded. Sites with no Urology emergency care input would be excluded.

Outcomes

Primary outcome

LoS, measured in calendar days. A basic definition of LoS is the number of days measured as an integer by taking the date of admission in the index hospital admission episode and the date of discharge from the hospital, and calculating the date difference between them. Variations in exact definitions of LoS will be reported. Examples of this include calendar days spent in the emergency department, or excluding days after care of the patient is taken over by another team, or after being medically discharged.

Secondary outcomes

- For those without a previously known cause of haematuria: time to definitive diagnosis, defined as the number of days between original presentation and final diagnosis.
- Length of time required to be in hospital, measured as an integer by taking the date of admission in the index hospital admission episode and the date of discharge from the hospital or the date deemed medically fit for discharge (whichever is first), and calculating the date difference between them.
- 90-day mortality rate measured as the proportion of patients who died from the day of admission to the 90-day follow-up period.
- 90-day readmission rate, measured as the proportion of patients who were readmitted to the hospital with the same issue in 90 days after the date of discharge.
- Number of days alive and out of hospital at 90 days, a composite outcome of mortality and number of days readmitted in hospital subtracted from 90.
- Hospitalisation free survival at 90 days, calculated as length of stay at the initial admission (as a negative integer), the number of days alive and out of hospital in the 90 days after discharge, whether the patient was readmitted, and whether the patient died during follow-up.
- Resource use, including inpatient days and investigations and procedures that the patient underwent during the admission and in the 90-day follow-up period.
- The study will also assess current pathways that exist in hospitals, including acute care pathways and specific pathways for the management of haematuria. Details will be obtained through a questionnaire distributed to each participating site.

Subgroup analysis

- Plan to report outcomes of the study for the following diagnostic subgroups:
  - Radiation cystitis.
  - Urological malignancy (including pre-existing and new diagnoses).
  - Unknown diagnosis at presentation.

Study setting

This study will take place in urological secondary and tertiary care centres internationally. The study will be conducted in centres that agree to participate in the study and meet the study's inclusion criteria.

Study dates

Hospital site registration began in January 2024, with patient enrolment starting in February and was initially planned to end by December 2024. In response to collaborator feedback, the study has been extended, with data

entry open until June 2025 and follow-up continuing through December 2025.

Study delivery

The study will use the BURST collaborative model, which has been previously applied to observational studies globally.[1 2] This model delivers international multicentre studies by empowering trainees to lead all aspects of multicentre clinical studies, building research skills cost-effectively while shaping the future urological consultant workforce. This collaboration has a previous track record of successful recruiting to similar study designs, resulting in reporting of important patient outcomes, especially in the realm of haematuria care. For example, In theIDENTIFY (Investigation and detection of urological neoplasia in patients referred with suspected urinary tract cancer) was a study focussing on outpatient haematuria, which recruited 11 029 patients in multicentre observational design, resulting in the production of a risk calculator for the workup of patients with haematuria in outpatient clinics.[3] RESECT (Transurethral REsection and Single instillation intra-vesical chemotherapy Evaluation in bladder Cancer Treatment) was a study focussing on elective care of bladder cancer patients undergoing TURBT in an observational, international, multicentre design with an embedded cluster randomised trial of audit, feedback and education. This study recruited 19 500 cases.[13] The BURST collaborative hence possesses the necessary experience, expertise and support to successfully deliver a study such as WASHOUT. The design of the current study has been supported by input from the Centre for Healthcare Randomised Trials (ie, The Urology Foundation (TUF) trials unit), who will be involved in designing and conducting the next study, which we anticipate will be an implementation randomised controlled trial.

Recruitment

Patients will be recruited consecutively. The recruitment target for this study is based pragmatically on the prevalence of inpatient haematuria. Target recruitment per participating site is 15 patients across a 12-month period from 70 centres. The cumulative recruitment target from all sites is 1050 patients. We want to recruit as many participants as possible during the 12-month period. The sample size is also based on the anticipated wide variation of practice and the heterogeneous nature of the presentation in terms of patient demographics and the underlying cause of the haematuria ranging from benign causes to malignant urological conditions.[1 2]

This sample size is also adequately powered to detect a meaningful difference in LoS (defined as at least 1 day by study authors) using ANOVA (Analysis of Variance) to analyse any binary variable (spanning both clinicopathological features and management factors). This 1-day difference in LoS is based on a calculated sample size of 1054 patients, obtaining a power of 0.90 with a significance level of 0.05 and taking an SD of LoS as 5 days obtained from original data of a retrospective review covering this study population.[2]

Data collection

Participating sites will complete a registration survey describing their institution and urological practice (subspecialities and consultants, on-call rota and support) and if any local protocols or defined criteria for referral/admission exist (online supplemental appendix 2).

Data will be collected prospectively on consecutive patients requiring emergency admission over a 12-month period. Non-identifiable patient data will be collected by individual investigators using the REDCap (Research Electronic Data Capture) electronic data capture tool. Data will be collected prospectively by the participating centres using a standardised case report form (CRF). The CRF will include data on demographics, medical history, aetiology of haematuria, LoS, investigations, interventions, complications, health resource utilisation, readmissions and 30-day and 90-day mortality rates. Data will also be collected on interventions (if any) including ward management, surgical, radiological and any other interventions or adjunct treatments. Data collected is information recorded as part of clinical assessment, thereby allowing local sites to qualify as a process evaluation in the UK setting. Further details are available in online supplemental appendices 1 and 2.

Data will be entered into a secure online University College of London (UCL) REDCap database. All data collected will be kept confidential and anonymous. Each participating centre will be assigned a unique identifier code, and no personal identifying information will be collected from the patient or managing surgeon. Where available, standardised clinical data models will be used to structure data collection. We will ensure each site is registered with the relevant local audit department that they are undertaking an evaluation of current practice.

Data analysis

We will describe the cohort demographic and clinical variables at baseline, using descriptive statistics.

We will use multilevel linear regression modelling to analyse the primary outcome LoS to understand the variation across centres, extending this to model the association between LoS and factors such as age, gender, comorbidities and management practices. Missing data will be handled using multiple imputation and pattern mixture models. Secondary outcomes will be analysed similarly using the appropriate multilevel generalised linear model for the distribution of the outcome.

Descriptive resource use information will be presented according to standard categories, and standard unit costs (NHS Reference Costs) applied where appropriate to provide information on costs of the observed patient diagnostic and therapeutic pathways.

Patients who do not complete the follow-up period

Participants with a follow-up duration of less than 90 days will be retained in the analysis. Outcomes, including length of stay (LoS), readmission, and mortality, will be evaluated for the follow-up period available. Resource use will be included if entered in the 15 days prior to 90-day follow-up or any point after.

Ethics and dissemination

Before beginning the study, ethical and local regulatory approval as required in each respective region will be obtained in accordance with applicable guidelines. In the UK, the Health Research Authority and the National Research Ethics Service advised that this study was exempt from ethical approval. The letter supporting this is attached as online supplemental appendix 3. Each participating UK site will require approval from its local audit department and/or research and development office. The international sites will be provided with study documentation to apply for local ethics approval.

Once the study is complete, the results will be presented at international scientific conferences in the field of urology, published in peer-reviewed journals, and shared with patient advocacy groups via Urology charities, including TUF, the European Association of Urology patient office and our PPI panel. We are committed to ensuring that all collaborators who make significant contributions to the study will be listed as collaborative authors on PubMed-indexed papers resulting from the study as per the BURST authorship policy used in previous BURST projects.[9] We will communicate findings to leading associations, including NICE (National Institute for Health and Care Excellence) and EAU (European Association of Urology). We will also disseminate research findings using different (social) media platforms.

Quality control

An independent quality control team will thoroughly check all data submitted to ensure accuracy and completeness. Incomplete or outlier data will be identified, and investigators will be contacted to address any issues.

Patient public involvement

A total of 10 patients who have been admitted with haematuria were identified by directly contacting patients admitted to the hospital with this condition, marketing through social media and patient focus groups, as well as charities. Anyone with a personal experience of blood in their urine requiring hospital admission or a relative or friend of a patient suffering from this condition was eligible as a patient representative. Public representatives could include lay members of the public with an interest in patient improvement research. Ethics was not necessary as this was deemed as involvement work and feedback on study design was collected rather than any study data. They were invited to a virtual meeting on Zoom to explore outcomes of interest, aspects of care that they deem important and identify areas of satisfaction or dissatisfaction within the management pathway. The PPI panel was remunerated for their time and input.

During the first PPI group meeting, a BURST committee member introduced the study, providing an overview of its objectives and expected outcomes. The meeting was coordinated by a PPI facilitator based in the UCL. Participants shared their personal experiences with haematuria, discussing symptoms, diagnosis and the impact on their lives. Patients were briefed on the study's objectives, design and research methods, seeking their input on study parameters via an open discussion during the meeting and via a 10-item questionnaire sent via email. Patients and researchers reviewed the potential benefits and risks of the study, highlighting any concerns or suggestions.

The focus group agreed that:

- The study is both valuable and they would prefer a standardised pathway for haematuria management following emergency hospital admission.
- No concerns were expressed regarding the study.
- The study primary and secondary outcomes (eg, length of hospital admission, 30-day and 3-month mortality rate, readmission rate and resource utilisation) are important to patients.
- Care should be taken to create a standardised pathway which includes a prompt management of the patients when presenting symptoms of clot retention in the emergency department or in the community (eg, by promoting fast-track to specialty or access to adequate points of care).
- As a result of PPI involvement, changes have been made to the CRF on aspects of ward management as patients felt this was important. Specifically, they expressed that getting prompt access to catheterisation, washouts and irrigation was important.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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