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Ali I, Wong F, et al.

BMJ Open Methenamine hippurate for the management and prophylaxis of recurrent urinary tract infections: a scoping review protocol

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ABSTRACT

Introduction Recurrent urinary tract infections (rUTIs) are typically treated using antibiotics. Given the growing issue of antimicrobial resistance, non-antibiotic management options for rUTIs have faced a recent resurgence in popularity. Methenamine hippurate is a urinary antiseptic used as a non-antibiotic prophylactic measure in those with rUTIs. The results of a recent randomised controlled trial showed methenamine hippurate to perform on par with antibiotic prophylaxis in adult women with rUTIs. However, little is known about the efficacy of methenamine hippurate in vulnerable patient populations, such as children, the elderly, patients with indwelling catheters and those with renal tract abnormalities. Moreover, an up-to-date, comprehensive evaluation of the entirety of the literature surrounding methenamine hippurate has yet to be carried out. As such, key trends within the literature, such as common side effects and specific avenues for future research, are difficult to determine. Therefore, we developed the methodology for a scoping review to map the entirety of the existing evidence base for methenamine hippurate.

Methods and analysis The protocol for this scoping review was developed in accordance with the framework set out by Arksey and O'Malley. We will search MEDLINE, Embase, Scopus, the Cochrane Central Register of Controlled Trials and ProQuest Dissertation and Theses from inception until August 2024, with no language restrictions applied. Studies including patients of any age and sex receiving methenamine hippurate treatment, either as a primary or adjunct treatment for rUTIs, will be eligible for inclusion. Interventional studies, such as randomised controlled trials and their protocols, nonrandomised clinical trials, cohort studies, case-control studies and observational studies of any design, will be included. Grey literature, systematic reviews and qualitative studies will also be included. Two independent reviewers blinded to each other's decisions will assess the eligibility of articles at each stage using the Covidence review platform. After the relevant data from each study has been extracted, we will report the results of our scoping review using descriptive summary statistics and a narrative thematic analysis.

Ethics and dissemination Due to the nature of the present study, ethical approval was not required for this

STRENGTHS AND LIMITATIONS OF THIS STUDY

- \Rightarrow The methodology for this scoping review was developed in accordance with the frameworks set out by Arksey and O'Malley in 2005 and further expanded on by Levac et al in 2010 and the Joanna Briggs Institute in 2021.
- \Rightarrow In order to capture the full breadth of the evidence base, we developed database-specific search strategies and did not restrict our searches to any particular language or time period.
- \Rightarrow We will not assess the weight (by conducting a meta-analysis, for example) of the identified evidence, as this falls outside of the purview of a scoping review.

scoping review. The final manuscript of this scoping review will be published in an international, peer-reviewed journal and the findings of the review presented in relevant national and international conferences.

INTRODUCTION

Protected by copyright, including for uses related to text and data mining, Al training, Urinary tract infections (UTIs) are one of the most common forms of bacterial infection worldwide.¹ UTIs can be classified as affecting the upper or lower urinary tract.² Lower <u>0</u> UTIs in female patients can be classified as uncomplicated, provided they occur in the absence of comorbidities or renal tract abnormalities.² Lower UTIs in every other patient population, irrespective of existing comor-bidities, are considered to be complicated.³ bidities, are considered to be complicated.³ Upper UTIs, regardless of the population in which they occur, are always considered to be complicated.² Approximately 50%–60% of all women will experience a UTI in their lifetime.⁴ A recurrent UTI (rUTI) is defined as two or more UTIs in a 6-month period or three or more UTIs within 1 year.⁵ Whilst the true prevalence is difficult to determine, it is thought that 20%-30% of women with a UTI will experience a recurrence.⁶ In addition to

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impairments in quality of life for an individual, rUTIs also exert a significant psychological burden on a patient as well as an economic burden on the broader healthcare system.⁶ The role of antibiotics in rUTI management is prominent; acute treatment of each recurrence with antibiotics and prophylactic low-dose daily antibiotic suppression are both common mainstays of treatment.¹ However, given the ever-developing issue of antimicrobial resistance,⁷ there is a growing interest in non-antibiotic management options for rUTIs.

One such non-antibiotic management option for rUTIs is methenamine hippurate. Preparations of methenamine, a cyclic hydrocarbon, have been utilised as a urinary antiseptic for decades.⁸⁹ In the environment of acidic urine, a salt preparation of methenamine degrades to form ammonia and formaldehvde; the latter is thought to act as a bacteriostatic agent by inhibiting bacterial cell division.¹⁰ Methenamine hippurate is often thought to have gone overlooked by most clinicians,¹¹ with most guidelines providing no strong recommendation regarding the use of methenamine hippurate for long-term rUTI prevention in women.¹² Nonetheless, methenamine hippurate is widely prescribed in some Scandinavian countries,¹³ particularly in Norway.¹⁴ Following the resolution of a 4-month drug shortage of methenamine hippurate in Norway, the number of prescriptions for methenamine hippurate rose as prescriptions for UTI antibiotics fell sharply.¹⁵

Recently, methenamine hippurate has faced a resurgence in popularity. The ALTAR non-inferiority randomised controlled trial (RCT) found methenamine hippurate to be equivalent to antibiotic therapy at reducing the incidence of rUTIs in a large cohort of adult women.¹³ Two recent systematic reviews of the literature, similarly focused on adult women with uncomplicated rUTIs, identified that methenamine hippurate performed on par with antibiotic prophylaxis.^{16 17} Recent reviews, both systematic reviews and those looking broadly at non-antibiotic treatments for rUTIS,^{8 9} have not investigated the efficacy of methenamine hippurate in vulnerable patient populations. rUTIs are a common problem in the elderly, and diagnosis and management can prove to be challenging in the presence of multiple comorbidities, contraindications to antibiotic treatment and the increased risk of Clostridium difficile infections due to prolonged antibiotic use.¹⁸⁻²⁰ Indeed, elderly women are particularly vulnerable to UTIs, with the prevalence of UTIs being almost threefold higher in this population.⁵ In children, long-term infection of the urinary tract can have, although rare, negative consequences on kidney function in later life,²¹ and long-term prophylactic antibiotic regimens are typically not recommended.²² Moreover, patients with indwelling catheters are at greater risk for developing catheter-related UTIs.^{23 24} It is unclear to what extent the literature has evaluated methenamine hippurate's viability in these vulnerable patient subgroups.

In the existing literature, a Cochrane review of RCTs last updated in 2012 did identify a number of studies

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of a scoping review²⁸: identifying the research questions, identifying relevant studies, study selection and reporting the data. This scoping review protocol was prospectively registered on the Open Science Framework (OSF) (https://doi.org/10.17605/OSF.IO/NWMB8).

METHODS

This protocol was written in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews checklist $(PRISMA-ScR)^{36}$ (online supplemental file 1).

Research questions

As outlined by Arksey and O'Malley,²⁸ the first stage of conducting a scoping review involves identifying the pertinent research questions. Based on our understanding of the current evidence surrounding methenamine hippurate as a management option for rUTIs, we developed the following research questions that our scoping review seeks to address:

- 1. In what patient populations has the efficacy of methenamine hippurate already been investigated, and, conversely, in what patient demographics is there a lack of research into the efficacy of methenamine hippurate for the management of rUTIs?
- 2. How effective is methenamine hippurate in managing rUTIs in these patients (as defined by each study's endpoints), and does its efficacy vary between different patient populations?
- 3. In what manner is methenamine hippurate evaluated? That is, as a standalone prophylactic measure, an adjunct to antibiotic treatment or alongside other nonantibiotic treatments for rUTIs?
- 4. What dosage of and over what time course is methenamine hippurate commonly given in the extant literature, and does this vary between studies?
- 5. What are the commonly reported side effects of methenamine hippurate?
- 6. What are the geographical and temporal trends in research investigating the efficacy of methenamine hippurate? In other words, is methenamine hippurate evidently more popular in certain countries, and is there a reason for this?

Search strategy

In order to identify potentially eligible studies for inclusion in our scoping review, we will conduct a systematic search of five databases: MEDLINE, Embase, Scopus, the Cochrane Central Register of Controlled Trials (CENTRAL) and ProQuest Dissertation and Theses Global. A thorough search strategy for each database was developed using key terms identified from our research questions and Medical Subject Heading (MeSH) terms and was adapted to suit each database accordingly using the appropriate Boolean operators, database-specific MeSH terms and database-specific syntax (online supplemental file 2, table S1). Key terms included but were not

limited to 'methenamine hippurate', 'recurrent urinary tract infections', 'rUTIs' and 'urinary tract infections'. The polyglot search translator was used to aid the process of constructing the search strategy. Databases will be searched from inception up until 10 August 2024, and no language filters will be applied. Prior to the final analysis, the searches will be re-run up until the present day, and any additional studies meeting the eligibility criteria will be included. In addition to database searching, citations of relevant articles will be manually exported otected and included within the screening process. For studies not given in the English language, a suitable translated version will be sought, either from the authors themselves or using Google's inbuilt translation software.

Identification of eligible studies

by copyright. Identified studies will be assessed for eligibility using the Population, Concept and Context framework set out by Arksey and O'Malley²⁸ and the Joanna Briggs Institute.²⁹ With respect to the population, we will include studies investigating patients with rUTIs, with the strict definition of rUTI being defined by each study individually. Owing to the broad nature of our scoping review, we will uses include studies investigating both adult (>16 years old) and paediatric (<16 years old) patients with both complicated and uncomplicated rUTIs receiving methenamine hippurate for UTI prophylaxis (ie, long term). We will also include studies where methenamine hippurate is õ used as an adjunct (eg, alongside conventional antibie otics) or as a control arm. As methodology is likely to be heterogeneous between studies, we have no specific exclusion criteria relating to a comparator; this may be a placebo, conventional antibiotic suppression or no treatment at all. Studies investigating methenamine hippurate for UTI prophylaxis, for example, following surgery or in those with long-term catheters (irrespective of whether ≥ these patients have a history of rUTIs or not) will also be included. We will exclude studies conducted exclusively in vitro and in non-human participants. Studies in which ĝ patients are given methenamine hippurate for any indication other than rUTI management or UTI prophylaxis will be similarly excluded.

With regard to the context, we will include studies conducted in any healthcare or community setting. We will also include grey literature (in the form of conference abstracts) and systematic reviews of the literature (irrespective of whether a subsequent meta-analysis was undertaken). In order to capture the full breadth of the $\mathbf{\hat{G}}$ evidence base, qualitative studies investigating patient or **g** clinician perspectives on methenamine hippurate will also be included. Narrative literature reviews, case reports and case series with fewer than five patients and research letters containing no novel research will be excluded. The full details of the inclusion and exclusion criteria are provided in table 1.

Retrieved articles from each database will be exported and uploaded to Covidence, a digital platform built to facilitate and streamline the process of carrying out systematic

	Inclusion criteria	Exclusion criteria
Population	 Male, female and paediatric patients with recurrent urinary tract infections (rUTIs). Male, female and paediatric patients at higher risk for UTIs (eg, postoperatively, or with indwelling or long-term catheters) who are eligible for UTI prophylaxis. 	Studies conducted in non-human participants (eg, in vivo research) and in vitro research.
Concept	 Patients given methenamine hippurate for the management of rUTIs. Patients at higher risk for UTIs (such as those with long-term catheters, or postoperatively) receiving methenamine hippurate for UTI prophylaxis. We will include studies that use methenamine hippurate as a control arm or as an adjunct medication (alongside, eg, conventional antibiotic prophylactic therapy). 	 Studies involving patients given methenamine hippurate for any indication other than rUTIs (eg, exclusively asymptomatic bacteriuria) or UTI prophylaxis. Studies that focus exclusively on other non-antibiotic treatments for rUTIs, for example, cranberry products or D-mannose not used alongside methenamine hippurate.
Context	 Studies conducted in primary (eg, patients in the community), secondary (eg, hospitalised patients) and tertiary care (eg, specialist centres) settings will be included. Studies conducted in ambulatory care settings, pharmacies and nursing homes will also be included. Studies must report an outcome measure related to rUTIs; this includes but is not limited to the frequency, duration, the growth of drug-resistant bacteria and adverse side effects. Qualitative studies exclusively investigating personal views or satisfaction with a treatment regimen of methenamine hippurate, from either the patient or provider perspective. Systematic reviews of the literature regarding methenamine hippurate. 	Narrative (ie, lacking systematic review methodology, including formal database searching and prospective registration in the PROSPERO database) reviews of the literature surrounding methenamine hippurate.
Study type	 Randomised controlled trials (RCTs). Protocols for ongoing RCTs. Cohort studies. Case-control studies. Observational studies. Non-RCTs. Protocols for planned or ongoing trials/studies Qualitative studies. Systematic reviews (with or without accompanying meta- analyses) of the literature. Conference abstracts. 	 In vitro studies. Case reports and case series <5 patients. Letters, editorials and short communications. Narrative (ie, non-systematic) reviews of the literatures. Rapid reviews.

reviews.³⁷ First, duplicate articles will be removed. Remaining articles will undergo title and abstract screening as per the eligibility criteria (table 1). This will be undertaken by two independent reviewers (AC, IA, FW, PN) who will be blinded to each other's decisions. A disagreement between reviewers will be resolved either via a third independent reviewer or by discussion among researchers. Included articles will then undergo full-text screening by two independent reviewers, again blinded to each other's decisions, with conflicts resolved by discussion among reviewers or, if this is unsuccessful, by a third reviewer. At the full-text review stage, the specific reason for exclusion will be recorded. The details of the screening process will be reported using a PRISMA flowchart.²⁹

Charting the data

Data will be extracted from each included study using a data extraction form. This data extraction form contains key information regarding each study and was developed in line with our PCC framework. This includes but is not limited to information regarding the nature of the study design, the year of publication, whether patients were randomly assigned to a treatment or not, the characteristics of the included patients, the dosage and time course of

methenamine hippurate treatment, UTI frequency pre- and post-intervention, outcome measures used and reported side effects (table 2). Data from included qualitative studies and systematic reviews will be extracted using separate data extraction forms (online supplemental file 2, table S2, S3 respectively) owing to their distinct methodology.

This data extraction tool will be implemented into Covidence and initially piloted by two authors (AC, PN) on five included studies to internally assess its validity prior to the commencement of data extraction, in line with recommendations from Levac et alin 2010.³⁵ If needed, the data extraction fields will be expanded on or edited by the senior authors. Once this is complete, data extraction will be undertaken by one reviewer for each study (AC, IA, FW, PN) with a second independent author checking the extracted data against the original study. The data extraction process will be iterative and collaborative,³⁵ with any disagreements or difficulty in extracting heterogeneous data being resolved through discussion and consideration between the authors. In addition to extracting data from each study, we will also assess the quality of included trials and observational studies. This will be conducted in duplicate for each study (AC, IA, FW, PN),

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Category	Data extraction fields	
Study characteristics	 Study citation Year of publication Country of origin Study design Treatment allocation randomisation (Y/N) Protocol for an ongoing study (Y/N) 	
Participant characteristics	 Control group characteristics (if applicable) Intervention group characteristics UTI aetiology control group (if applicable) UTI aetiology intervention group Control group sample size Intervention group sample size Follow-up time 	
Methenamine hippurate regimen	 Control group medication details (including dosage, adjunct therapy, time course) Intervention group methenamine hippurate details (including dosage, adjunct therapy, time course) 	
Outcomes	 UTI aetiology control group (if applicable) UTI aetiology intervention group Control group sample size Intervention group sample size Follow-up time Control group medication details (including dosage, adjunct therapy, time course) Intervention group methenamine hippurate details (including dosage, adjunct therapy, time course) Outcome measure(s) utilised Control group UTI frequency pre-intervention Intervention group UTI frequency pre-intervention Control group UTI frequency post intervention Intervention group UTI frequency post intervention Side effects reported (Y/N) Details of reported minor side effects Minor side effects (individual and overall rate) Severe side effects (individual and overall rate) 	
Side effects	 Side effects reported (Y/N) Details of reported minor side effects Details of reported severe side effects Minor side effects (individual and overall rate) Severe side effects (individual and overall rate) 	
UTI, urinary tract infection.		

with any disagreements being resolved by consensus among reviewers. For RCTs, the Cochrane Risk of Bias 2 tool will be used.³⁸ For non-randomised trials, the Risk of Bias in nonrandomised studies - of interventions (ROBINS-I) tool will be utilised.³⁹

Collating, summarising and reporting the results

After charting the data, reporting the results of a scoping review is separated into three phases:³⁵ 1) descriptive numerical summary analysis and qualitative thematic analysis, 2) reporting the results in line with the research questions and 3) Discussion of the future implications of the findings of the scoping review.

First, the extracted data will be exported as a CSV file to undergo further analysis. Data analysis will be undertaken using a combination of R⁴⁰ and Microsoft Excel. Initially, study characteristics will be grouped together (eg, methodological approach, patient characteristics, methenamine hippurate regimen, reported outcomes), tabularised and presented in the final manuscript. Where possible, we will calculate and present simple descriptive summary statistics (eg, the proportion of patients reporting side effects of methenamine hippurate across studies). We will use the extracted data to construct evidence maps and simple descriptive figures that will holistically outline the key trends and patterns within the extant literature surrounding methenamine hippurate. Depending on the nature and intrinsic heterogeneity of the extracted evidence, we may construct bar charts, line graphs, word clouds, network diagrams and conceptual frameworks, all popular methods of data visualisation within

scoping reviews.⁴¹ Qualitative thematic analysis will also be undertaken. Key themes between studies will be identified by discussion among the reviewers, and these will be grouped in accordance with the research questions of our scoping review. These themes will be addressed in a narrative manner in the final manuscript, and their implications for future research will be addressed accordingly.

ETHICS AND DISSEMINATION

Due to the nature of the present study, ethical approval was not required for this scoping review. The final manuscript of this scoping review will be published in an international, peerreviewed journal, and the findings of the review presented in relevant national and international conferences.

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