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Clinical practice guidelines for the management of adult patients with neurogenic lower urinary tract dysfunction: a systematic review protocol

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ABSTRACT

Introduction Neurogenic lower urinary tract dysfunction (NLUTD) both threatens the health of affected patients long-term and also has a significantly negative impact on the patients' quality of life. present, many clinical practice guidelines (CPGs) have been developed for NLUTD patients, but these CPGs may confuse healthcare professionals and patients due to their great difference in terms of scope, quality and content. This review aims to identify the CPGs for NLUTD patients published from 2012 to 2022, assess their quality and then analyse them in an integrated manner.

Methods and analysis We will systematically search electronic healthcare databases (English databases including PubMed, EMBASE, OVID, Scopus, Web of Science, Cochrane Library, CINAHL, UpToDate, and Best Practice and Chinese databases including China National Knowledge Infrastructure, Wanfang Database, VIP Periodical Resource Integration Service Platform and SinoMed), online CPG repositories and relevant professional association websites to identify eligible CPGs. The CPGs published in English and Chinese with full texts available within the period from January 2012 to March 2022 will be included in this study. The Appraisal of Guidelines for Research and Evaluation (AGREE) II will be used to assess the quality of included CPGs. According to the predesigned data table, the general characteristics of these CPGs, proposed recommendations and their quality of evidence, strength of recommendation and other information will be extracted. Qualitative thematic analysis will be applied to the extracted recommendations. A summary of the proposed recommendations, their quality of evidence, strength of recommendation and other information will eventually be described in a table. This review is expected to identify knowledge gaps in current CPGs and to identify the areas of the proposed recommendations derived from low-level evidence.

Ethics and dissemination This systematic review does not involve the participation of any subjects, and therefore no ethical approval is required. The findings of this review will be published in a peer-reviewed journal and disseminated via conference presentations.

PROSPERO registration number CRD42022318180

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This review is the first all-around systematic review of clinical practice guidelines (CPGs) for adult patients with neurogenic lower urinary tract dysfunction (NLUTD), which will identify the CPGs that cover a range of issues, such as diagnosis, assessment and management.
⇒ This review will comprehensively and critically integrate the proposed recommendations related to adult patients with NLUTD, involving diagnosis, assessment, conservative therapy, drug management, complication management, surveillance and follow-up and surgical management.
⇒ This systematic review will provide a tabular summary of clear and definite best practice recommendations for NLUTD management.
⇒ One of the limitations of this review is that only the CPGs that were published in English and Chinese will be included.
⇒ Due to the vast amount of information contained in CPGs, condensing them into clear and precise summaries can be a daunting and time-consuming process, and the loss of potentially important information may be unavoidable.

INTRODUCTION

Neurogenic lower urinary tract dysfunction (NLUTD) is defined by the International Continence Society (ICS) as a 'lower urinary tract dysfunction due to disturbance of the neurological control mechanism'.[1] NLUTD can be caused by central or peripheral nervous system lesions involving the physiological regulation of urine storage and/or voiding. Diseases such as spinal cord injury (SCI), stroke, Parkinson's disease and multiple sclerosis that affect the central nervous system can lead to NLUTD. It affects approximately 70%–84% of patients with SCI, 53% of those with stroke, 38%–71% of those with Parkinson's disease and 32%–96% of those

with multiple sclerosis.[2–4] In addition, diseases involving the peripheral nervous system, such as diabetes and postpelvic surgery, can also cause NLUTD.[4] NLUTD both threatens the health of affected patients long-term,[5] and also has a significantly negative impact on the patients' quality of life.[6] It is reported that 46% of the patients with NLUTD suffer from urinary tract infections in China,[7] 20%–80% of them may have ureterectasia, pyelonephritis, hydronephrosis or renal failure[8] and even death may occur in severe cases.[6] Therefore, it is necessary to pay close attention to adopting standardised and scientific management for NLUTD patients to improve their prognosis and clinical outcomes.

Clinical practice guidelines (CPGs) are systematically developed statements, aiming to assist practitioners and patients in making decisions on appropriate healthcare for specific clinical circumstances based on the best evidence available.[9] As CPGs have specified the nature, quantity and quality of research evidence, they can be used to improve decision-making, further promote best evidence-based practice by healthcare providers and ultimately improve clinical outcomes for patients.[10 11] Although the number of CPGs for adult patients with NLUTD has increased rapidly in the past decade, the CPGs developed by different organisations vary greatly in terms of scope, quality, content and proposed recommendations. This may be affected by factors such as different development purposes, development processes, organisational personnel and financial resources.[12 13] Jaggi *et al*[13] compared the treatment recommendations for NLUTD patients proposed in CPGs developed by National Institute for Health and Care Excellence (NICE), European Association of Urology (EAU) and International Consultation on Incontinence (ICI), respectively. They found that the recommendations proposed for conservative treatment were consistent, but those for drug management and surgical management differ from each other significantly. Due to their differences, it is difficult for healthcare professionals or patients to identify which recommendations should be followed, hindering them to select standardised healthcare practice. Therefore, a systematic review of CPGs for NLUTD patients may help assess the similarities and differences of the proposed recommendations, and will provide a tabular summary of the proposed recommendations in a clear and concise manner. It is expected that the results will promote the best evidence-based practice by healthcare professionals and ultimately improve clinical outcomes of patients.

Nowadays, more and more scholars have recognised the significance of quality evaluation of CPGs for NLUTD patients, and some efforts have been made in this research field. However, current systematic reviews still have certain limitations. For example, some reviews focused on a single population with NLUTD (only those CPGs for NLUTD patients after SCI were reviewed),[14] or some only dealt with a single aspect of NLUTD management (only CPGs on the assessment and management of NLUTD were reviewed and only the assessment of NLUTD patients and proposed recommendations for urethral catheterisation management were integrated).[15] Bragg *et al*[14] conducted a comprehensive review and quality assessment of the CPGs for the management of NLUTD patients after SCI developed in the period from 2011 to 2018. In their study, they analysed the number of proposed recommendations in those CPGs and recorded 304 proposed recommendations in total. According to their findings, more than half of the proposed recommendations were correlated with assessment, surgery or education, most of the proposed surgical recommendations came from older CPGs and the most recent CPGs highlighted conservative treatment. However, their study only included a single population with NLUTD after SCI and statistically analysed the number of proposed recommendations. They did not integrate such recommendations in a clear and definite summary table. In the latest systematic review published in 2021, the researcher(s) assessed the quality of the CPGs designed for the assessment and management of NLUTD and created a summary table with 20 proposed recommendations under five themes, including NLUTD classification, medical history collection, related examinations, urethral catheterisation recommendations and auxiliary bladder management measures.[15] However, it only included the CPGs for the assessment and management of NLUTD but excluded those for NLUTD patients with other problems. In addition, it did not integrate the proposed recommendations on drug management, surgical management, follow-up management and surveillance and therefore the integration of these recommendations was incomplete.

By reasons of the foregoing, this review aims to make a more comprehensive review of CPGs relating to the management of adult patients with NLUTD published in the past decade to identify, evaluate, integrate and analyse the quality and content of such CPGs. This review will first comprehensively integrate the proposed recommendations in present CPGs relating to the NLUTD management, including NLUTD diagnosis, assessment, behavioural therapy, urethral catheterisation management, drug management, surgical management, surveillance and follow-up, then provide a clear and definite tabular summary of the proposed recommendations for healthcare professionals and patients and finally identify the proposed recommendations with deficiencies and those derived from low-level evidence in current CPGs. In this way, we hope to help the research community to design more studies to fill the gaps in the field in the future.

Aim

This review aims to identify, assess, integrate and analyse the quality and content of the CPGs correlated with the management of adult patients with NLUTD published between January 2012 and March 2022.

Objectives

1. To use AGREE II to assess the quality of the CPGs correlated with adult patients with NLUTD published from January 2012 to March 2022.

2. To comprehensively integrate the proposed recommendations related to the management of adult patients with NLUTD in the CPGs published from January 2012 to March 2022, mainly including NLUTD diagnosis, assessment, conservative management (behavioural therapy and urethral catheterisation management), drug management, complication management, surveillance and follow-up, surgical management and develop a tabular summary.

METHODS AND ANALYSIS

Protocol and registration

This review protocol[16] will be conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols (PRISMA-P).[17] The PRISMA-P checklist is available as an online supplement (online supplemental appendix 1). The results of the systematic review will also be reported according to the PRISMA statement.[18] This review is expected to start in January 2023 and is expected to end in August 2023.

Eligibility criteria

Guided by the PICAR framework (Population and Clinical Indications, Interventions, Comparators, Attributes of Eligible guidelines, Recommendation characteristics),[19] we identified eligibility criteria for CPGs in this review.

Population and clinical indications

The population of interest for this review will be CPGs for the adult patients with NLUTD.

Interventions and comparators

For the purposes of this systematic review, our 'Interventions' are various forms of NLUTD management, namely CPGs that cover a wide range of issues related to NLUTD management (eg, diagnosis, assessment, treatment, management, monitoring and follow-up) will be included. This systematic review does not involve 'comparators'.

Attributes of eligible guidelines

We will include CPGs that have been developed by relevant professional organisations for the adult patients with NLUTD from January 2012 to March 2022. The included CPGs must be identified as guidelines by the authors and comply with the definition of guidelines in AGREE II 'a CPG is a systematically developed statement designed to help health professionals and patients make appropriate decisions about specific clinical situations".[20] The publication language is English or Chinese, with no restrictions on the region of publication and access to the full text. For revised or updated guidelines, the updated version will be included if it is a content update; if it is a content supplement, both guidelines will be included.

Recommendation characteristics

This review is interested in the recommendations related to the management of NLUTD, mainly in the areas of diagnosis, evaluation, conservative management (behavioural therapy and catheterisation management), pharmacological management, management of complications, monitoring and follow-up and surgical management of NLUTD. We will extract relevant recommendations that address these elements. However, we will only extract recommendations that describe the quality of evidence and the strength of recommendation.

We will exclude the following:

1. The CPGs apply only to one pharmacological approach, surgical approach or assessment approach for NLUTD (eg, Botulinum toxin A in NLUTD and urodynamic monitoring guidelines).
2. Non-evidence-based guidelines (non-evidence-based guidelines can be operationally defined as guidelines with 'no quality of evidence and strength of recommendation').
3. Guidelines that do not use systematic methods to depict the certainty in the evidence and the strength of recommendation.
4. Directly translated guidelines, guideline interpretations, guideline excerpts, or guideline evaluations.
5. Normative documents or manuals.

Search strategy

A systematic search of the following databases will be conducted independently by two reviewers (CZ, FH or XW) to identify CPGs related to NLUTD, including the following:

- medical electronic databases: covering nine English databases (PubMed, EMBASE, OVID, Scopus, Web of Science, Cochrane Library, CINAHL, UpToDate and Best Practice) and four Chinese databases (China National Knowledge Infrastructure, Wanfang Database, VIP Periodical Resource Integration Service Platform and SinoMed).
- online guideline repositories: National Guidelines Clearinghouse (NGC), Guidelines International Network (GIN), New Zealand Guidelines Group (NZGG), Registered Nurses' Association of Ontario (RNAO), the Australian National Health and Medical Research Council (NHMRC), Queensland Coding Committee (QCC), Scottish Intercollegiate Guidelines Network (SIGN), NICE, Canadian Medical Association Clinical Practice Guidelines Infobase (CMA Infobase), Royal Australian College of General Practitioners (RACGP), ClinicalKey for Nursing and Medlive.
- urological association websites: ICS, American Urological Association (AUA), British Association of Urological Surgeons (BAUS), EAU, Canadian Urological Association (CUA), ICI and the Chinese Urological Association (CUA).

We will use medical subject heading terms combined with free-text words related to NLUTD and CPGs in our search strategy and personalise the search to improve comprehensiveness and specificity of search results

Box 1 Sample search strategy for PubMed

#1 'Urinary Bladder, Neurogenic'[(Mesh])
#2 ((((((((((((((((((((((((Neurogenic Urinary Bladder[Title/Abstract]) OR (Bladder, Neurogenic[Title/Abstract])) OR (Neurogenic Bladder[Title/Abstract])) OR (Urinary Bladder Neurogenic Dysfunction[Title/Abstract])) OR (Neurogenic Dysfunction of the Urinary Bladder[Title/Abstract])) OR (Neurogenic Urinary Bladder Disorder[Title/Abstract])) OR (Neuropathic Bladder[Title/Abstract])) OR (Urinary Bladder Disorder, Neurogenic[Title/Abstract])) OR (Bladder Disorder, Neurogenic[Title/Abstract])) OR (Neurogenic Bladder Disorders[Title/Abstract])) OR (Neurogenic Bladder Disorder[Title/Abstract])) OR (Urinary Bladder Neurogenesis[Title/Abstract])) OR (Neurogenesis, Urinary Bladder[Title/Abstract])) OR (Bladder Neurogenesis[Title/Abstract])) OR (Neurogenesis, Bladder[Title/Abstract])) OR (Neurogenic Urinary Bladder, Atonic[Title/Abstract])) OR (Neurogenic Bladder, Atonic[Title/Abstract])) OR (Atonic Neurogenic Bladder[Title/Abstract])) OR (Neurogenic Urinary Bladder, Spastic[Title/Abstract])) OR (Neurogenic Bladder, Spastic[Title/Abstract])) OR (Spastic Neurogenic Bladder[Title/Abstract])) OR (Neurogenic Urinary Bladder, Uninhibited[Title/Abstract])) OR (Neurogenic Bladder, Uninhibited[Title/Abstract])) OR (Uninhibited Neurogenic Bladder[Title/Abstract])) OR (Neurogenic lower urinary tract dysfunction[Title/Abstract])) OR (Neurogenic urethra[Title/Abstract])) OR (Neurogenic urinary incontinence[Title/Abstract])
#3 #1 or #2
#4 'Practice Guideline' [(Publication Type])
#5 ((((((((((((((((Clinical Practice Guideline[Title/Abstract]) OR (Clinical Guidelines[Title/Abstract])) OR (guide[Title/Abstract])) OR (guideline[Title/Abstract])) OR (guidance[Title/Abstract])) OR (best practice guideline[Title/Abstract])) OR (recommended practice[Title/Abstract])) OR (evidence-based[Title/Abstract])) OR (recommendation[Title/Abstract])) OR (recommendations[Title/Abstract])) OR (consensus[Title/Abstract])) OR (statement[Title/Abstract])) OR (best practice[Title/Abstract])
#6 #4 or #5
#7 #3 and #6
MeSH, medical subject heading.

according to the characteristics of different databases. The sample search strategy for PubMed is shown in box 1. The search strategies for all databases are detailed in online supplemental appendix 2.

Guideline selection

The search results for medical electronic databases will be imported into NoteExpress V.3.5 reference manager, and duplicate documents will be deleted by the manager's automatic deduplication function. The screening will be done independently by two reviewers (YJH and YW). The first step is to screen the literature titles and abstracts based on the eligibility criteria. When the abstracts could not be determined, they will proceed to the second step, which is to review the full text to determine the inclusion. When conflicts of opinions arise, a third reviewer (LC) will be consulted to minimise the risk of selection bias. Disagreements will be resolved through discussion.

Results from searches of online guideline repositories and urological association websites will be screened by two reviewers (CZ and FH) independently by title (if abstracts not available), and the titles of potentially eligible literatures will be recorded. A full-text reading will then be performed independently to determine the inclusion by two reviewers (YJH and YW). Any disagreements will be consulted with a third reviewer (LC), and consensus will be reached through discussion.

For the excluded literatures during the full-text review, the reason for the exclusion will be reported, and the screening process will be presented in a PRISMA flow diagram (figure 1).

Quality assessment

Instrument

AGREE II is an internationally recognised, validated and rigorous tool,[20] which will be used to evaluate the quality of CPGs.[21 22] The translated and validated Chinese version of AGREE II will be used for quality appraisal.[23] The instrument includes six domains with a total of 23 items, namely (1) scope and purpose (items 1–3); (2) stakeholder involvement (items 4–6); (3) rigour of development (items 7–14); (4) clarity of presentation (items 15–17); (5) applicability (items 18–21) and (6) editorial independence (items 22–23). Each item is scored on a 7-point Likert scale, where 7 points represents 'strongly agree' and 1 point means 'strongly disagree'. Additionally, each CPG will also be given an overall assessment score. That is, each CPG will have two groups of scores, one for the domain score and one for the overall score. AGREE II Score Sheet is available as an online supplement (online supplemental appendix 3).

Appraisal and training

The guideline evaluation team consists of six reviewers, including four quality reviewers (CZ, YJH, FH and YW), one clinical nursing expert (WZC) and one methodologist (LC). All quality reviewers must learn the AGREE II user manual in detail and complete the online training course on the My AGREE PLUS platform. Before the formal appraisal, two guidelines will be selected and independently prescored by four reviewers. After the scoring, a meeting will be held among the reviewers to analyse the items one by one to ensure that the four quality reviewers have basically the same understanding of all items and follow uniform evaluation standards. Then, they will independently conduct formal quality appraisal for included CPGs. Items with greater disagreement during the evaluation process will be discussed with the methodologist (LC) or the clinical nursing expert (WZC).

Scoring

The score for each domain is the sum of the scores of all items in such domain. The final score for each domain of each guideline is expressed as a standardised percentage. The calculation formula of the standardised percentage is: (actual score−lowest possible score) / (highest possible score−lowest possible score) × 100%. Among them, the calculation formula of the highest possible score is: (the number of raters) × (the number of items) × 7. The calculation formula of the lowest possible score is: (the number of raters) × (the number of items) × 1. The higher the

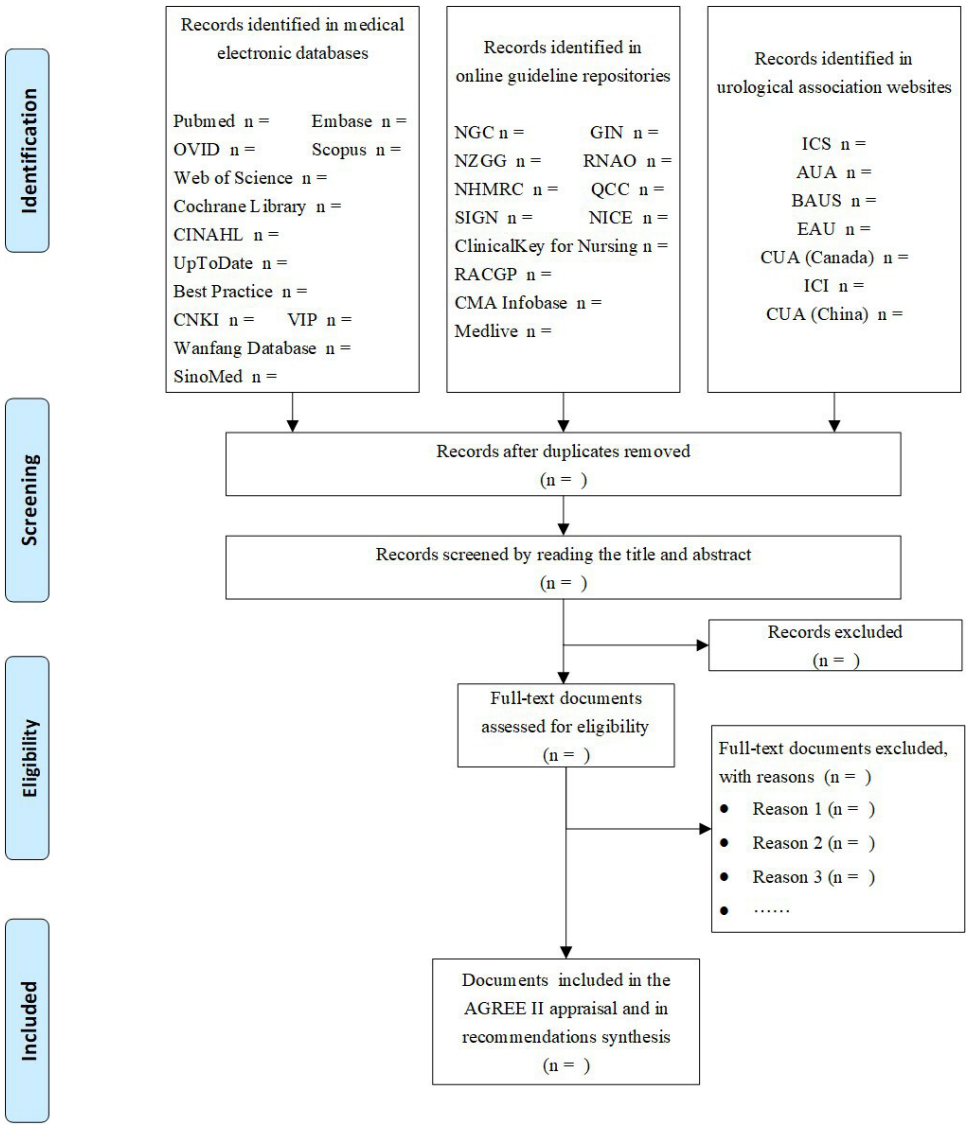

Figure 1 : Flow diagram for screening process.

standardised percentage score, the better the methodological quality of the guideline.

Interpreting domain scores

The AGREE developers do not set fixed cut-offs for high-quality or low-quality guidelines, but recommend that evaluators set their own criteria based on the context of their appraisal project.[24] In this project, we decide to set cut-off values based on a quality appraisal project of CPGs related to intermittent catheterisation by Li and his colleagues.[25] If the scores in all six domains are ≥60%, the guideline is rated as grade A. In other words, the guideline can be directly recommended without changing. If the number of domains with scores ≥30% is ≥3, but there are domains with scores <60%, the guideline is rated as grade B. That means the guideline needs to be revised and improved to varying degrees. If the number of domains with scores <30% is ≥3, the guideline is rated as grade C. It will not be recommended due to the poor quality of the guideline development method or evidence.

Interpreting the overall guideline scores

The overall score for the guideline will also be carefully recorded as supplementary data to the guideline quality assessment, but its score will not contribute anything to the final assessment of whether the guideline is of high or low quality.

Data management and analysis of quality scores

After the evaluation is completed, all the quality evaluation data of the four reviewers will be loaded into Excel 2019, and the final scores of included CPGs will be calculated according to the above scoring method of the AGREE II tool. The consistency of evaluation results among the four reviewers will be calculated by intraclass correlation coefficient (ICC) using IBM SPSS V.23.0. Based on the 95% CI of the ICC estimate, ICC values greater than 0.90, between 0.75 and 0.9, between 0.5 and 0.75 and less than 0.5 are indicative of excellent, good, moderate and poor reliability, respectively.[26]

Data extraction

General characteristics extraction

Data will be extracted independently according to a predesigned data spreadsheet by two reviewers (CZ and YJH) who are proficient in English literacy and have some clinical experience in NLUTD management. If necessary, we will contact the guidline developers to confirm any questions. The following characteristics for each included guideline will be extracted: guideline title, first author, year of publication or update, country, guideline language, publishing institution, target users, type and scope of the guideline, number of references, the method for assessing the quality of evidence and the grading system for determining the strength of recommendations. Before the formal extraction, the datasheet will be used to pre-extract the two included guidelines in order to improve and revise the data spreadsheet in a timely manner.

Recommendations extraction

In accordance with the study objective of this review, the study team will conduct a comprehensive extraction of recommendations related to NLUTD management, including recommendations for diagnosis, assessment, conservative management (behavioural therapy and catheterisation management), pharmaceutical management, management of complications, monitoring and follow-up, self-management, education and information and surgical management of NLUTD. We will only extract recommendations that clearly describe the quality of evidence and the strength of recommendation. Because the grading system for the level of evidence on which different guidelines are based may differ, we will harmonise the grading scheme of evidence across guidelines to facilitate the process of data synthesis.

All extractions and coding will be performed independently in NVivo V.12.0 software by two reviewers (CZ and YJH). Prior to the formal extraction, two reviewers independently pre-extracted the two included guidelines to refine the relevant categories of the extracted content and standardise the extraction criteria. They then performed the formal extraction and coding independently, and compared the results in the end. In the case of any disagreement, a third reviewer (LC or WZC) will be consulted and agreement will be reached through discussion.

Synthesis of recommendations

After the recommendations are extracted and cross-checked, the recommendations will be integrated according to the following integration principles, specifically: (a) for recommendations with the same or similar content, clear, concise and independent entries will be selected; (b) for recommendations with complementary content, they will be combined according to logical relationships; (c) for conflicting recommendations, we will give priority to evidence-based, high-quality evidenced recommendations, and new publications and trace the sources of different recommendations to find the reasons of the conflicts (d) if a recommendation involves multiple aspects, it will be split.[27]

To ensure the scientific nature of the evidence synthesis process, it will be completed independently by two reviewers (CZ and YJH), and the results will be checked against each other on completion. In case of disagreement, a third reviewer (LC) will be consulted for a ruling.

Data management and presentation

Data on the general characteristics of the included CPGs will be collated into an Excel 2019 spreadsheet and submitted to the results section. Recommendations will be coded in NVivo V.12.0 software using thematic analysis. Ultimately, a summary of the recommendations and their quality of evidence, strength of recommendation and other information will be presented in a narrative format in the table.

PATIENT and public involvement

No patients will be involved in this review. All data will be collected from medical electronic databases and related professional websites.

Ethics and dissemination

This review protocol does not involve any patient participation and does not require ethical approval. The results of this research will be published in a peer-reviewed journal and disseminated through conference presentations and more.

DISCUSSION

To the best of our knowledge, this review is the first all-around systematic review of CPGs for adult patients with NLUTD. Our proposed systematic review will comprehensively identify and assess the quality of CPGs for the management of adult patients with NLUTD published between January 2012 and March 2022 (the last 10 years), and we will also fully integrate the proposed recommendations correlated with the management of adult patients with NLUTD. This review will provide a clear and definite summary table of the proposed recommendations for best practice from current CPGs, and will elaborate them by category, mainly covering NLUTD diagnosis, assessment, behavioural therapy, urethral catheterisation management, drug management, complication management, surveillance and follow-up management, surgical management and other aspects, which both help to promote evidence-based practice by healthcare professionals, and also help to improve patients' capability of active management and participation in decision-making, and ultimately improve patients' prognosis. In addition, this review will identify the proposed recommendations with deficiencies and those derived from low-level evidence in current CPGs, to clarify the knowledge gaps regarding the current NLUTD management, which will indicate a direction for developing more rigorous, reliable

and scientific CPGs in the future, and lay a foundation for the research community to design more targeted studies in the future to fill the gaps in the field.

The strength of this systematic review is that it covers a wide range in terms of content and is not limited to a single population with NLUTD or a single aspect of the management of NLUTD patients. Instead, this review is an exhaustive, comprehensive systematic review covering all aspects of the management of NLUTD patients and is also the first all-around review. A limitation of this review is that we only include CPGs that published in English and Chinese.

Contributors LC and WZC devised the study. CZ and YJH drafted the protocol. CZ, XW and FH designed inclusion/exclusion criteria and search resources and strategies. YJH and YW designed the evaluation strategy for each included guide. All authors provided critical feedback, helped shape the research and draft manuscript. All authors read and agreed the final version of the manuscript. All authors are the guarantors of the review.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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