

Development of Clinical Questions and Outcome Indicators for the Guidelines for Diagnosis and Treatment of Childhood Nocturnal Enuresis with Integrated Traditional Chinese and Western Medicine Using a Modified Delphi Method (Post-Print)

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Date: 2025-04-03T00:00:00+00:00

Abstract

Background Childhood enuresis is one of the common clinical renal system diseases. First-line Western medicine treatment for this condition exhibits a high recurrence rate after medication discontinuation and poor patient compliance, whereas Traditional Chinese Medicine (TCM) treatment demonstrates a slow onset of action and lacks standardized therapeutic protocols. Therefore, the complete integration of Chinese and Western medicine to fully leverage their respective therapeutic advantages is of significant importance. Objective

To develop the clinical questions and outcome indicators for the “Guidelines for the Integrated Chinese and Western Medicine Diagnosis and Treatment of Childhood Enuresis”. **Methods** A list of clinical questions and outcome indicators was formulated through literature review, expert interviews, and clinical investigation. Employing the modified Delphi method, two rounds of expert questionnaire surveys and one round of expert panel discussion were conducted from July to November 2024. SPSS 26.0 statistical software was utilized to analyze questionnaire results, with response rate, mean score, standard deviation, coefficient of variation, and Cronbach’s α coefficient serving as quality control evaluation criteria to finalize the clinical questions and outcome indicators included in the guideline. **Results** The first round of questionnaire surveyed 26 experts and medical staff, achieving a response rate of 100% and a Cronbach’s α coefficient of 0.907. Seven experts participated in the second round of expert panel discussion and the third round of expert questionnaire survey, both attaining a response rate of 100% and a Cronbach’s α coefficient of 0.724.

Ultimately, 14 clinical questions and 9 outcome indicators (8 efficacy indicators and 1 safety indicator) were incorporated. The clinical questions primarily encompassed TCM characteristics, TCM intervention modalities (herbal decoction, Chinese patent medicine, acupuncture, moxibustion, tuina, etc.), treatment of recurrence, early intervention, and preventive care and nursing. The 8 efficacy indicators comprised frequency of enuresis, degree of nocturnal awakening, negative emotion indicators, quality of life, sleep quality, TCM syndrome score, recurrence rate, and bladder capacity. The single safety indicator was adverse reaction rate. **Conclusion** The clinical questions and outcome indicators were established through the modified Delphi method, preliminarily forming the structural framework of the guideline and laying a foundation for its subsequent development.

Full Text

Defining Clinical Question and Outcome Indicators in Guidelines for Diagnosis and Treatment of Nocturnal Enuresis in Children with Integrated Traditional Chinese and Western Medicine Based on Modified Delphi Method

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Abstract

Background: Nocturnal enuresis in children is a common renal system disease in clinical practice. First-line Western medical treatments exhibit high recurrence rates after discontinuation and poor patient compliance, while traditional Chinese medicine (TCM) treatments have slow onset and lack standardized protocols. Therefore, complete integration of Chinese and Western medicine to fully leverage their respective therapeutic advantages is of significant importance. **Objective:** To construct clinical questions and outcome indicators for the “Guidelines for Diagnosis and Treatment of Nocturnal Enuresis in Children with Integrated Traditional Chinese and Western Medicine.” **Methods:** An initial list of clinical questions and outcome indicators was developed through literature research, expert interviews, and clinical surveys. Using the modified Delphi method, two rounds of expert questionnaire surveys and one round of expert discussions were completed between July and November 2024. SPSS 26.0 statistical software was used to analyze questionnaire results, with positivity co-

efficient, mean score, standard deviation, coefficient of variation, and Cronbach's α coefficient serving as quality control evaluation criteria to finalize the clinical questions and outcome indicators included in the guidelines. **Results:** The first round questionnaire involved 26 experts and medical staff, with a positivity coefficient of 100% and Cronbach's α of 0.907. Seven experts participated in the second round expert meeting and third round questionnaire survey, both achieving a positivity coefficient of 100% and Cronbach's α of 0.724. Ultimately, 14 clinical questions and 9 outcome indicators were included (8 efficacy indicators and 1 safety indicator). Clinical questions primarily involved TCM characteristics, TCM intervention methods (herbal decoctions, patent medicines, acupuncture, moxibustion, massage, etc.), relapse treatment, early intervention, and preventive care. The 8 efficacy indicators were: frequency of enuresis episodes, degree of nocturnal awakening, negative emotion indicators, quality of life, sleep quality, TCM syndrome scores, relapse rate, and bladder capacity. The safety indicator was adverse reaction rate. **Conclusion:** Clinical questions and outcome indicators were identified through the modified Delphi method, initially forming the structural framework of the guidelines and establishing a foundation for subsequent guideline development.

Keywords: Enuresis; Nocturnal enuresis in children; Integrated traditional Chinese and Western medicine; Clinical questions; Outcome indicators; Modified Delphi method; Guidelines

Nocturnal enuresis in children refers to involuntary nocturnal urination occurring at least twice per week on average for three consecutive months in children aged 5 years or older. It is a common renal system disease during childhood and adolescence, with a prevalence rate as high as 4.8%, and 1.1% of cases persist beyond age 16, significantly impacting children's quality of life and psychosomatic development [?]. Current Western medical treatment for pediatric nocturnal enuresis primarily consists of desmopressin tablets and enuresis alarms [?], which act rapidly and demonstrate good efficacy in reducing nocturnal enuresis frequency. TCM treatment protocols, mainly comprising internal herbal medicine and external TCM therapies, have proven effective in promoting nocturnal awakening, increasing bladder capacity, and reducing relapse rates. However, complete integration of Chinese and Western medicine has not yet been achieved, and evidence-based medical support remains lacking.

In response to the current state of diagnosis and treatment for pediatric nocturnal enuresis, the "Guidelines for Diagnosis and Treatment of Nocturnal Enuresis in Children with Integrated Traditional Chinese and Western Medicine" (hereinafter referred to as the Guidelines) was initiated by the First Affiliated Hospital of Henan University of Chinese Medicine. The project is supported by the 2023 China Association of Chinese Medicine Group Standard (20230902-BZ-CACM) and has been registered on the International Practice Guidelines Registry Platform (Registration No.: PREPARE-2023CN347). This article summarizes the collection and determination process of clinical questions and outcome

indicators for this project to guide further development and advancement of the Guidelines.

1.1 Collection and Development of Clinical Questions and Outcome Indicators

Based on preliminary literature research, qualitative interviews with six experts, and patient surveys, an initial list of clinical questions and outcome indicators was established. The research team conducted comprehensive literature searches using search terms including “enuresis,” “nocturnal enuresis,” “bedwetting,” “integrated traditional Chinese and Western medicine,” “children,” “Nocturnal Enuresis,” “Traditional Chinese and Western Medicine,” and “Children” across CNKI, Wanfang Data, VIP, SinoMed, PubMed, Embase, and Cochrane Library databases from inception to December 2023. Population, intervention, efficacy, and other information were extracted from the literature to identify preliminary clinical questions and outcome indicators. Expert interviews and patient surveys were subsequently conducted to further expand the clinical questions. After streamlining and merging, the initial list was structured according to the PICO (Population, Intervention, Comparison, Outcome) framework. The preliminary list of clinical questions and outcome indicators is presented in Table 1 and Table 2 .

1.2 Formation of the Expert Panel for Clinical Questions and Outcome Indicators

The guideline consensus expert panel consisted of 26 experts, including 16 TCM clinical experts, 9 Western medicine clinical experts, and 1 methodology expert. All experts had over 10 years of professional experience and held associate senior or higher professional titles. Panel members represented 14 provinces and municipalities across China, ensuring broad geographical distribution to maximize solicitation of recommendations for optimizing and expanding clinical questions and outcome indicators.

1.3 Modified Delphi Method Implementation

Between July and November 2024, two rounds of expert questionnaire surveys and one round of expert discussions were completed to finalize the clinical questions and outcome indicators for inclusion in the Guidelines. Clinical questions were scored using a 5-point Likert scale [?], with scores ranging from 1 to 5 points to rate the importance of each preliminary clinical question (1 = “very unimportant, i.e., unnecessary for inclusion in the Guidelines” to 5 = “very important, i.e., essential for inclusion in the Guidelines”). Outcome indicators were scored on a 9-point scale based on “importance level” [?], with scores from 1 to 9 representing increasing importance (7-9 = “critical outcome,” 4-6 = “important outcome,” 1-3 = “general outcome”). To overcome the limitation of traditional Delphi methods where consensus on controversial issues is difficult to achieve without face-to-face discussion, the research team employed

a modified Delphi method [?] combining online meetings with questionnaires. This approach organized thorough discussions after the first round of questionnaire surveys, with the guideline core group providing detailed introductions to the project background, significance, and clinical question development process while presenting aggregated results from the previous round to identify issues lacking consensus and supplementary questions raised by experts.

Survey quality was evaluated through four aspects: expert positivity coefficient, coefficient of variation (CV), authority coefficient (Cr), and questionnaire reliability. The expert positivity coefficient assessed experts' attention and participation in the research, with 60% considered valid [?]. The CV reflected the degree of coordination among experts regarding the importance evaluation of clinical questions, where smaller CV values indicated less variation and higher consensus ($CV = \text{standard deviation} / \text{mean score}$). Expert authority was quantified by Cr, comprising judgment criteria (Ca) and familiarity level (Cs), calculated as $Cr = (Ca + Cs)/2$, with $Cr \geq 0.7$ considered a good indicator. Questionnaire reliability was assessed using Cronbach's α , with $\alpha \geq 0.7$ indicating good reliability and high consistency [?].

1.3.1 First Round Delphi Questionnaire Survey: The first round employed a semi-open format combined with scoring, including: (1) purpose and instructions for completing the questionnaire; (2) basic expert information (name, gender, education, institution, years of practice, professional title); and (3) importance scoring of clinical questions and outcome indicators. Clinical questions used the 5-point Likert scale, while outcome indicators used the 9-point importance scale. The first-round inclusion criteria required both an average score ≥ 4 and $CV \leq 30\%$ for retention [?, ?].

1.3.2 Second Round Expert Meeting: Based on first-round screening criteria and expert recommendations, clinical questions and outcome indicators were revised, supplemented issues were compiled and merged, and main discussion topics for the expert meeting were extracted. Experts who provided supplementary opinions received targeted interviews before the meeting, followed by literature review. Meeting participants included authoritative experts in the field and those capable of providing constructive feedback.

1.3.3 Third Round Delphi Questionnaire Survey: During the second round expert meeting, participants engaged in thorough discussions on controversial and supplementary clinical questions and outcome indicators. The third-round questionnaire was subsequently refined based on discussion outcomes and distributed to meeting participants for importance scoring.

2.1 Summary of Questionnaire Results

Through literature review, expert qualitative interviews, and patient preference surveys, the research team initially listed 13 clinical questions and 9 outcome indicators. After expert interviews refined the descriptions to enrich content coverage, the preliminary list included 13 clinical questions and 9 outcome in-

dicators (8 efficacy indicators and 1 safety indicator). The first round questionnaire achieved consensus on 11 clinical questions and 5 outcome indicators, with 2 clinical questions and 1 efficacy outcome indicator added as supplements. After further literature review of issues requiring discussion and supplementation, the list for the second round expert meeting included 4 clinical questions and 5 efficacy outcome indicators. Following the second round meeting, questions and indicators were again supplemented and revised, resulting in 15 clinical questions and 10 outcome indicators entering the third round questionnaire. After scoring via Questionnaire Star, 2 clinical questions and 1 efficacy indicator were eliminated, yielding final totals of 13 clinical questions and 9 outcome indicators (8 efficacy indicators and 1 safety indicator). The data and process from each stage are summarized in Figure 1 [Figure 1: see original paper].

2.2 Basic Information

A total of 26 guideline expert panel members participated in the first round semi-open Delphi questionnaire survey. Among them, 17 (65.4%) specialized in pediatric TCM and 9 (34.6%) in pediatric Western medicine. Experts were from 20 tertiary Grade A pediatric or general hospitals across regions including Beijing, Shanghai, Fujian, Zhejiang, Henan, Shandong, Liaoning, and Yunnan. Twenty-four experts (92.3%) held master's degrees or higher, all 26 (100.0%) had over 10 years of work experience, and 24 (92.3%) held senior professional titles. The expert panel selection was representative, demonstrating both geographical diversity and authoritative expertise.

2.3 Clinical Question Screening Process

Consensus was achieved on 13 clinical questions for inclusion in subsequent research, with specific items, mean scores, and CV values presented in Table 3. The first round Delphi survey reached consensus on 11 clinical questions, while 2 questions failed to meet inclusion criteria for mean score and CV, thus proceeding to the second round expert discussion: "For children with enuresis, how do the efficacy and safety of dietary therapy alone or combined with Western medicine compare with conventional Western medicine treatment?" and "Should children with enuresis under 5 years old receive early intervention?" Two additional clinical questions were supplemented by experts: "For children with enuresis, how do the efficacy and safety of patent Chinese medicine alone or combined with Western medicine compare with conventional Western medicine treatment?" and "How should children with recurrent enuresis be managed?" Therefore, the expert meeting focused on discussing these 4 clinical questions. Regarding the question on early intervention for children under 5 years, although domestic and international guidelines use age 5 as the threshold for enuresis [?, ?, ?], the 2018 "TCM Pediatric Clinical Diagnosis and Treatment Guidelines: Pediatric Enuresis (Revised)" [?] uses age 3 as the threshold, emphasizing the importance of early intervention. Consequently, most experts recommended clarifying "under 5 years" to "children aged 3-5 years," as research indicates

that children with severe enuresis symptoms before age 5 are likely to continue experiencing enuresis after age 5 [?].

2.4 Outcome Indicator Screening Process

Based on the 13 clinical questions, a total of 9 outcome indicators were ultimately included (8 efficacy indicators and 1 safety indicator), with specific items, mean scores, and CV values presented in Table 4. According to mean scores and CV values, 5 outcome indicators achieved consensus in the first round, while 4 efficacy indicators proceeded to the second round expert meeting: sleep quality, quality of life, negative emotion indicators, and antidiuretic hormone levels. One additional efficacy indicator—bladder capacity—was supplemented from literature. During the meeting, most experts emphasized that due to the high relapse rate of enuresis and its adverse impact on children's physical and mental health, assessment of quality of life and negative emotion indicators is particularly important during treatment, with psychological therapy provided when necessary. After the third round questionnaire, one outcome indicator (efficacy indicator) with a score <4 was eliminated: antidiuretic hormone levels. The final efficacy indicators included frequency of enuresis episodes, degree of nocturnal awakening, negative emotion indicators, quality of life, sleep quality, TCM syndrome scores, relapse rate, and bladder capacity. The safety indicator was adverse reaction rate. All outcome indicators are universal measures.

2.5 Quality Control

The first round questionnaire was distributed to 26 experts, with 26 valid responses returned, achieving an expert positivity coefficient of 100% and demonstrating good participation enthusiasm. Cronbach's α was 0.907, indicating excellent questionnaire reliability. The third round questionnaire was scored by meeting participants after the expert discussion, with 100% valid response rate and an expert positivity coefficient of 100%. The expert authority coefficient (Cr) was 1.08 (Ca=1.18, Cs=0.97), indicating high expert authority. Cronbach's α was 0.724, suggesting reliable questionnaire consistency.

The modified Delphi method integrates the nominal group technique with traditional Delphi approaches, incorporating both independent questionnaire completion and expert discussion with voting. This resolves the limitation of traditional Delphi methods in achieving consensus on controversial issues, enabling more efficient and scientific consensus formation. In recent years, this approach has been widely applied in developing evidence-based TCM guidelines and collecting clinical questions [?, ?].

The consultation rate for pediatric nocturnal enuresis in clinical practice is only 14%, as parents often believe the condition will resolve spontaneously or because children and parents have difficulty describing symptoms, resulting in poor treatment compliance [?]. Similar findings are reported internationally, with a U.S. anonymous study indicating that only 55% of parents seek medi-

cal care for children with enuresis [?]. However, enuresis significantly impacts children' s quality of life, with 35.9% of affected children reporting decreased quality of life that progressively worsens with age [?]. Therefore, this study focused not only on literature screening and expert interviews but also conducted interviews with enuresis patients and their parents to understand their concerns, clinical questions of interest, and experiences with integrated Chinese and Western medicine treatment. As the patients are minors, parents prioritize safety in treatment selection. Regarding the high recurrence rate of pediatric nocturnal enuresis, parents expect effective integrated treatment to reduce relapse rates and improve cure rates. Based on these considerations, the clinical questions developed in the preliminary work are more instructive, and the outcome indicators are more representative, resulting in better expert coordination during questionnaire surveys and ultimately yielding 13 clinical questions requiring recommendations or explanations in the Guidelines and 9 outcome indicators (8 efficacy and 1 safety).

Feedback from the second round questionnaire and first round expert meeting revealed that experts were most concerned with how to effectively integrate Chinese and Western medicine in clinical practice to reduce relapse rates and improve children' s quality of life. Key TCM interventions of interest included syndrome-based herbal medicine, patent medicines, and application of appropriate TCM techniques such as acupuncture, moxibustion, and massage. Due to the high relapse rate of this condition, management of recurrent cases also became a priority. Additionally, children with severe enuresis symptoms before age 5 show substantially increased likelihood of developing enuresis after age 5 [?]. Therefore, providing clear evidence-based protocols for how to manage and intervene in children aged 3-5 years to effectively reduce disease onset or post-illness relapse is essential.

Previous guidelines have reported on TCM syndrome differentiation and medication, Western medicine treatment protocols, and preventive care for pediatric enuresis, but no evidence-based guidelines currently exist for integrated Chinese and Western medicine treatment of this condition [?, ?]. The clinical questions and outcome indicators for this guideline were developed through comprehensive stages and methods, including literature review, expert interviews, extensive surveys, and patient preferences, ensuring that selected questions and indicators were carefully chosen after thorough discussion, providing a solid foundation for subsequent guideline development.

The selected experts were experienced physicians in pediatric TCM and Western medicine fields, representative in number and appropriately authoritative with geographical distribution, providing crucial reliable support for Delphi results. Additionally, methodology experts were included in the panel to provide evidence-based guidance for guideline development. Patient and parent perspectives were also considered, ensuring guideline development was based on multidisciplinary collaboration and incorporated input from specific stakeholder groups. Although the third round questionnaire had limited sample size, par-

icipating experts demonstrated good authority, and data quality was reliable. The modified Delphi consensus conference provided more in-depth discussion of clinical questions and outcome indicators that failed to achieve consensus in the first round questionnaire. In subsequent guideline development work, conditions should be actively created to organize adequate expert discussions to provide stronger support for guideline content and recommendation formulation.

In summary, the final clinical questions encompass disease diagnosis, integrated Chinese and Western medicine treatment protocols, early intervention measures, post-relapse treatment, and preventive care. These address not only clinical diagnosis and treatment but also recurrent cases and at-risk children eligible for early intervention, expanding the guideline scope and enhancing comprehensiveness. Outcome indicators focus not only on clinical symptom improvement such as nocturnal enuresis frequency, TCM syndrome scores, degree of nocturnal awakening, and bladder capacity, but also emphasize the importance of timely assessment of children's quality of life and mental health. This study employed the modified Delphi method to construct the basic framework of the guidelines, forming authoritative and credible clinical questions and outcome indicators that establish a foundation for subsequent guideline content and recommendation development.

Author Contributions: LIU Xiaoyu was responsible for research implementation, data analysis, and manuscript writing. ZHU Rongxin was responsible for methodological design and manuscript review. ZHANG Bo was responsible for process oversight and supervision. SU Hang was responsible for process oversight and manuscript review. REN Xianqing was responsible for final revision and overall accountability for the manuscript.

Conflict of Interest: The authors declare no conflict of interest.

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(Received: February 11, 2025; Revised: March 17, 2025)

(Editor: KANG Yanhui)

Note: Figure translations are in progress. See original paper for figures.

Source: ChinaXiv – Machine translation. Verify with original.