

Quality Assessment of Traditional Chinese Medicine Clinical Practice Guidelines/Consensus: Post-print Based on Two Guideline Appraisal Tools

Authors: Guo Jiao, Zhang Gaojing, Liu Xincan, Liu Xincan

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Abstract

Background Clinical practice guidelines can standardize clinicians' diagnostic and therapeutic behaviors and provide appropriate recommendations and references for patients. In recent years, the number of clinical practice guidelines in China has demonstrated an upward trend; however, the quality of Traditional Chinese Medicine (TCM) guidelines/consensus documents (hereinafter referred to as guidelines) is variable. Although existing studies have employed guideline evaluation tools to assess guidelines, research specifically evaluating TCM guidelines remains relatively scarce.

Objective To evaluate selected TCM clinical practice guidelines using two guideline evaluation tools and to analyze the critical dimensions influencing the quality of TCM clinical practice guidelines.

Methods TCM clinical practice guidelines for common and frequently occurring diseases in gastroenterology, pediatrics, orthopedics, and gynecology, as indexed in CNKI, Wanfang Data Knowledge Service Platform, VIP Database, and Chinese Biomedical Literature Database, were retrieved. The search period spanned from November 1, 2023, to June 30, 2024. Two clinicians from each specialty were selected to negotiate and each choose two guidelines. Data were collected regarding the publishing journal, publishing institution/organization, tools utilized for evidence grading and recommendation strength, number of references, number of authors, number of development experts, whether the guideline was an updated version, evaluation results from the Chinese Clinical Practice Guideline Evaluation System (AGREE-China), evaluation results from the Quality Evaluation Recommendation Checklist for TCM Clinical Practice Guidelines, and time required for guideline evaluation.

Results Among the eight guidelines included in the evaluation, six received strong recommendations following AGREE-China assessment, whereas only three guidelines achieved reporting rates exceeding 50% when evaluated using the Quality Evaluation Recommendation Checklist for TCM Clinical Practice Guidelines. Regarding evaluation time expenditure, the median time required for AGREE-China evaluation was 22 minutes; the median time required for the Quality Evaluation Recommendation Checklist for TCM Clinical Practice Guidelines was 18.75 minutes.

Conclusion Although AGREE-China identified six high-quality guidelines, this tool lacks evaluation of TCM-specific content and entails relatively lengthy evaluation times. While the Quality Evaluation Recommendation Checklist for TCM Clinical Practice Guidelines has incorporated TCM evaluation components and reduced time consumption, only three guidelines achieved reporting rates above 50%, and the evaluation results lack quantification and are not intuitively presented, thus still presenting practical inconveniences for clinical application.

Full Text

Quality Evaluation of TCM Clinical Practice Guidelines/Consensus: Based on Two Guideline Evaluation Tools

Authors: GUO Jiao¹, ZHANG Gaojing², LIU Xincan^{1*}

Affiliations: 1. National Regional TCM (Cardiovascular) Diagnosis and Treatment Center, the First Affiliated Hospital of Henan University of Chinese Medicine, Zhengzhou 450000, China 2. The First Clinical Medical College of Henan University of Chinese Medicine, Zhengzhou 450000, China

*Corresponding author: LIU Xincan, Chief physician; E-mail: liu.xin.can@126.com

Abstract

Background: Clinical practice guidelines can regulate clinicians' diagnostic and treatment behaviors and provide appropriate suggestions and references for patients. In recent years, the number of clinical practice guidelines in China has been increasing, but the quality of TCM guidelines/consensus (hereinafter referred to as guidelines) is highly variable. While some studies have applied guideline evaluation tools, research specifically evaluating TCM guidelines remains limited.

Objective: To evaluate selected TCM clinical practice guidelines using two guideline evaluation tools and analyze the key dimensions influencing the quality of TCM clinical practice guidelines.

Methods: We searched CNKI, Wanfang, VIP, and SinoMed databases for TCM clinical practice guidelines for common and frequently occurring diseases

in gastroenterology, pediatrics, orthopedics, and gynecology published between November 1, 2023, and June 30, 2024. Two clinicians from each specialty negotiated to select two guidelines each. We collected data on publication journals, issuing institutions/groups, tools used for evidence grading and recommendation strength, number of references, number of authors, number of formulation experts, whether they were updated guidelines, AGREE-China evaluation results, TCM clinical practice guideline quality evaluation checklist results, and evaluation time required.

Results: Among the eight evaluated guidelines, six were strongly recommended after AGREE-China evaluation, while only three guidelines had more than half of the items reported after evaluation using the TCM clinical practice guideline quality evaluation checklist. In terms of time consumption, the median time required for AGREE-China evaluation was 22 minutes, while the median time for the TCM clinical practice guideline quality evaluation checklist was 18.75 minutes.

Conclusion: Although AGREE-China identified six high-quality guidelines, this tool lacks evaluation of TCM-specific content and requires relatively long evaluation time. While the TCM clinical practice guideline quality evaluation checklist includes TCM evaluation content and reduces time consumption, only three guideline reports exceeded half of the items, and the evaluation results lack quantification and are not intuitive, making clinical use inconvenient.

Keywords: Traditional Chinese medicine therapy; Integrated traditional Chinese and Western medicine therapy; Guidebook; Consensus; AGREE-China; List of suggestions for quality evaluation of TCM clinical practice guidelines

1.1 Work Group

The evaluation working group consisted of experts in gastroenterology, pediatrics, orthopedics, and gynecology from traditional Chinese medicine and integrated traditional Chinese and Western medicine backgrounds, with master's degrees or higher and certain work experience (associate senior professional titles or above). Two experts from each specialty participated in the guideline evaluation. The data compilation working group comprised two professionals from other clinical specialties responsible for literature retrieval, data collection, and organization.

1.2 Inclusion and Exclusion Criteria

Inclusion criteria: TCM clinical practice guidelines publicly published in journals, conferences, or websites between November 1, 2023, and June 30, 2024; guidelines targeting common and frequently occurring diseases in gastroenterology, pediatrics, orthopedics, and gynecology; guidelines whose target population

includes patients in gastroenterology, pediatrics, orthopedics, and gynecology-related fields.

Exclusion criteria: Non-Chinese language; guideline interpretations; inability to obtain full text; guidelines for rare diseases or non-frequent diseases that do not involve treatment aspects.

1.3 Literature Search Strategy

We searched CNKI, Wanfang, VIP, and SinoMed databases for TCM diagnosis and treatment guidelines for common and frequently occurring diseases in gastroenterology, pediatrics, orthopedics, and gynecology published between November 1, 2023, and June 30, 2024. Chinese search terms included: digestion, liver disease, spleen-stomach, children, bone, joint, spine, female, traditional Chinese medicine, integrated Chinese and Western medicine, guideline, consensus, etc. The search was conducted independently by two researchers and verified. Two evaluators from each specialty negotiated to determine the final guidelines for evaluation. Taking CNKI and orthopedics specialty literature as examples, the specific search strategy was:

#1 Chinese Title = guideline
#2 Chinese Title = clinical practice guideline
#3 Chinese Title = expert consensus
#4 Chinese Title = consensus
#5 Chinese Title = expert opinion
#6 Chinese Title = standard
#7 #1 OR #2 OR #3 OR #4 OR #5 OR #6
#8 Chinese Subject Headings = musculoskeletal diseases
#9 Chinese Title = bone
#10 Chinese Title = joint
#11 Chinese Title = spine
#12 #8 OR #9 OR #10 OR #11
#13 Chinese Title = traditional Chinese medicine
#14 Chinese Title = integrated Chinese and Western medicine
#15 #13 OR #14
#16 #7 AND #12 AND #15

1.4 Literature Screening and Data Extraction

After initial screening by two researchers, the literature was reviewed by two evaluators from the relevant specialties who negotiated to determine the final included studies. During literature screening, titles and abstracts were first read to exclude irrelevant literature, followed by full-text reading to determine final inclusion. Data extraction included: guideline name, main formulation institution, number of references, number of authors, number of expert panel members, whether it was an updated version, evidence grading standards, etc.

1.5 Quality Evaluation

We used AGREE-China and the TCM clinical practice guideline quality evaluation checklist to evaluate the included guidelines. Before formal evaluation, two additional guidelines were selected for pre-evaluation using AGREE-China. SPSS 20.0 statistical software was used for intraclass correlation coefficient (ICC) consistency testing. If $ICC > 0.80$, indicating good consistency, independent evaluation could begin. AGREE-China comprises 5 domains with 15 items, each scored 0-5 (5 = fully compliant, 0 = not compliant at all), with weight coefficients of 0.5-2.0. Higher scores indicate higher quality. Domain score rate = (sum of evaluator scores for the domain / maximum possible score sum) $\times 100\%$; maximum possible score = 5 points \times item weight coefficient \times number of evaluators \times number of domain items. After calculating the total score according to weights, the average value was taken as the guideline's score. The TCM clinical practice guideline quality evaluation checklist contains 22 items with judgment criteria of "yes," "no," or "not applicable." If all were judged as "yes," it indicated the guideline formulation process was scientifically rigorous. If judged as "no," it indicated areas needing correction. Results were presented as reporting ratios.

2.1 Literature Screening Process and Results

Initially, 68 relevant articles were identified. After hierarchical screening, eight guidelines were finally included [Figure 1: see original paper].

2.2 Basic Characteristics of Included Literature

The basic characteristics of the eight included guidelines are shown in Table 1. Among them, four guidelines (50%) were issued by the China Association of Chinese Medicine, two (25%) by the Chinese Association of Integrative Medicine, and two (25%) jointly by the China Association of Chinese Medicine, Chinese Medical Association, and Chinese Association of Integrative Medicine. Regarding evidence grading and recommendation strength, four guidelines (50%) used the GRADE system, two (25%) used the Evidence Body-Based TCM Clinical Evidence Grading Standard Recommendation and Nominal Group Technique, and two (25%) used unclear evidence grading standards. Only three guidelines (37.5%) had update plans. The number of authors ranged from 2 to 27 (median: 8), the number of formulation experts ranged from 6 to 168 (median: 61), and the number of references ranged from 29 to 130 (median: 41).

2.3 AGREE-China Evaluation Results

The AGREE-China evaluation results for the eight included guidelines are shown in Table 2. (1) **Scientificity/Rigor:** This domain contains 8 items with average scores of (4.25 ± 0.68) , (4.81 ± 0.40) , (3.25 ± 1.61) , (4.00 ± 1.59) , (3.44 ± 1.55) , (3.75 ± 1.24) , (3.56 ± 1.03) , and (2.00 ± 0.82) .

points. All included guidelines reported conflict of interest statements. In summary, among the eight guidelines, six were strongly recommended, two were weakly recommended, and none were not recommended.

2.4 Consistency of Evaluation Results

Before evaluation, two additional guidelines were selected for pre-evaluation using AGREE-China. SPSS 20.0 statistical software was used for ICC consistency testing. The ICC values across all domains for the two guidelines evaluated by eight evaluators using AGREE-China were all >0.80 , indicating good consistency (Table 3).

2.5 TCM Clinical Practice Guideline Quality Evaluation Checklist Results

After evaluation and discussion by researchers, the results are shown in Table 4. The checklist contains 22 items, but only three guidelines had more than half of the items reported. Items with low reporting rates were mainly distributed in items 4-10 and 15, such as literature search, inclusion/exclusion criteria, literature screening, detailed description of the process for forming recommendations, etc.

2.6 Time Required for Both Guideline Evaluation Tools

A comprehensive analysis of the time used by evaluators for guideline evaluation is shown in Table 5. The AGREE-China evaluation required 10-35 minutes (median: 22 minutes), while the TCM clinical practice guideline quality evaluation checklist required 10-30 minutes (median: 18.75 minutes).

3.1 Guideline Development Group Should be Multidisciplinary

Both evaluation tools require that guideline development groups be multidisciplinary, preferably including clinical epidemiology and evidence-based medicine experts. However, among the eight evaluated guidelines, only three had methodological experts involved. As TCM gradually modernizes and globalizes, more TCM guidelines are being produced. To gain international recognition, guideline quality—especially methodological quality—must be improved. Therefore, guideline development should initially involve comprehensive, detailed, and systematic investigation and screening of clinical questions, ultimately presented in the “PICO” format (Patient/Population, Intervention, Comparison, Outcome). Among the eight guidelines in this study, only two described the clinical question screening process, and two described literature search, but none provided clear literature screening flowcharts or lists of excluded literature. Additionally, attention should be paid to the selection of “O” (outcome) indicators. “How to construct a clinical research and evaluation system that conforms to TCM

characteristics based on traditional medical diagnosis and treatment models” is considered one of the major scientific questions and engineering challenges in TCM for 2023. To address this challenge, constructing outcome indicators and evaluation systems that reflect TCM’s characteristic advantages is crucial. With the introduction and localization exploration of core outcome sets for traditional Chinese medicine (COS-TCM), most COS-TCM research quality has improved, but issues remain, such as unclear language description of outcome indicators, unclear target populations, unmentioned or improperly handled missing data, and unreported protocol modifications.

3.3 Providing Evidence Summary Tables and Regular Updates

Evidence summary tables not only summarize results for each outcome but also provide detailed records of judgments made by guideline developers when evaluating evidence quality, helping to transparentize summary of findings tables. However, none of the eight guidelines in this study mentioned such tables. Additionally, as evidence continues to accumulate and improve, guidelines should be updated regularly, but only three guidelines in this study provided update plans.

3.4 Formation of Recommendations

Recommendations are the core component of clinical practice guidelines. Methods for forming recommendations include Delphi method, nominal group technique, consensus development conference, and modified Delphi method. Guidelines should clearly describe the recommendation formation process and how to handle controversies. Evidence provides the foundation for recommendation formation, but other factors must also be considered during the recommendation development process, such as risks and generalizability of interventions, patient preferences and values, and cost-effectiveness. Among the eight guidelines in this study, six described consensus methods but none provided relevant attachments such as survey questionnaires or meeting minutes, and only one guideline considered economic issues—other guidelines did not consider factors beyond evidence quality.

3.5 External Review

External review refers to pre-publication evaluation of guidelines and their recommendations by experts outside the development group or other stakeholders. External review mainly assesses the applicability, feasibility, and scientificity of recommendations and the guideline itself. External reviewers should include experts outside the guideline development group and other stakeholders. To ensure review quality, external reviewers must also submit conflict of interest declarations. External reviewers can provide feedback through various methods, with form completion being the most common. The external review process should also be reported in the full guideline text. Among the eight guidelines

in this study, only two provided information about external reviewers, but did not detail the methods of their participation.

3.6 Limitations of This Study

This study only included guidelines published between November 1, 2023, and June 30, 2024, representing a relatively narrow time window. We evaluated only two guidelines from each of four different specialties to understand the evaluation effectiveness of these two tools across different specialties. The two guidelines for each specialty were determined through negotiation between two evaluators from that specialty, which may have introduced selection bias. This study only used AGREE-China and the TCM clinical practice guideline quality evaluation checklist, without applying other tools such as AGREE II, STAR, or RIGHT, which also limits the study's findings.

In summary, this study analyzed the effectiveness of AGREE-China and the TCM clinical practice guideline quality evaluation checklist in evaluating TCM clinical practice guidelines. We found that both tools have issues with time consumption and clinical usability. AGREE-China lacks evaluation of TCM-specific content such as TCM disease names, syndromes, interventions, and outcome indicators with TCM characteristics. While the TCM clinical practice guideline quality evaluation checklist includes TCM evaluation content, it only evaluates methodological quality, and its results cannot be quantified. Therefore, when constructing a TCM clinical practice guideline evaluation system, we should consider: first, evaluating guideline scientificity, effectiveness, economics, and transparency, with effectiveness focusing on TCM content evaluation, which may improve the quality of guidelines for TCM-advantaged diseases; second, presenting evaluation results in a more intuitive quantitative format; third, evaluation items should be as simple as possible, and the tool should be as convenient as possible, since guideline users are clinicians—developing the evaluation system as a mini-program, scale, or software may greatly facilitate clinical work.

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