

Investigation, Analysis, and Work Recommendations on the Current Status of Formulation and Revision of Traditional Chinese Medicine Clinical Practice Guidelines (Post-Print)

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Abstract

Background At the end of 2014, the Department of Policy, Regulation and Supervision of the National Administration of Traditional Chinese Medicine launched the formulation and revision of clinical practice guidelines for Traditional Chinese Medicine (TCM), covering 240 TCM clinical practice guideline projects across 13 specialty fields in the TCM domain, with the China Association of Chinese Medicine undertaking this portion of the work.

Objective To understand the current status of formulation and revision of clinical practice guidelines in the field of Traditional Chinese Medicine, analyze existing problems in the project teams' work from a methodological perspective, and provide recommendations, this project team conducted a survey of the China Association of Chinese Medicine' s TCM Clinical Practice Guideline Formulation and Revision Project Teams.

Methods The survey was conducted using electronic questionnaires, covering several aspects including understanding of TCM clinical practice guidelines, guideline formulation and revision processes and workflows, key issues and critical links in guideline formulation and revision, implementation promotion and application of guidelines, and overall investigation of guideline formulation and revision work. The survey period was from June 2020 to December 2020. After completion of the survey, data were compiled and descriptive analysis was performed.

Results A total of 198 valid questionnaires were ultimately collected in this survey. The results indicated that most project teams considered TCM clinical practice guidelines to have important guiding significance in clinical practice,

and most teams emphasized the application of evidence-based methodology during guideline formulation and revision. Meanwhile, various project teams also encountered some problems and difficulties in their formulation and revision work.

Conclusion It is recommended that future work attach greater importance to guideline formulation and revision, with increased financial support; each working group should have methodological experts participate throughout the entire process of TCM clinical practice guideline formulation and revision to control quality; training related to evidence-based medicine and clinical practice guideline development should be increased; the latest technical protocols and methodological processes should be strictly followed; attention should be paid to guideline content quality, promotion and implementation of guidelines, with timely updates; during the guideline formulation and revision process, care should be taken to reflect the characteristics of TCM diagnosis and treatment, with the goal of clinical practicality and applicability, in order to improve the quality of TCM clinical practice guidelines and promote better service of Traditional Chinese Medicine to people's health.

Full Text

Investigation, Analysis, and Recommendations on the Preparation and Revision of Clinical Diagnosis and Treatment Guidelines for Traditional Chinese Medicine

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Abstract

Background: At the end of 2014, the Department of Policies, Regulations, and Supervision of the State Administration of Traditional Chinese Medicine launched a comprehensive project to prepare and revise clinical diagnosis and treatment guidelines for traditional Chinese medicine (TCM), covering 240 guidelines across 13 specialty areas. The China Association of Chinese Medicine was entrusted with implementing this initiative.

Objective: To understand the current status of guideline preparation and revision in TCM, identify methodological challenges faced by project teams, and provide evidence-based recommendations for improvement, our research team conducted a nationwide survey of TCM clinical guideline development groups organized by the China Association of Chinese Medicine.

Methods: An electronic questionnaire was administered from June 2020 to December 2020, covering five domains: understanding of TCM clinical guidelines, guideline development/revision procedures and methodological application, key challenges and critical steps, implementation and promotion, and overall assessment of the guideline development process. Data were compiled and analyzed descriptively.

Results: A total of 198 valid questionnaires were collected. The majority of project teams recognized the significant clinical value of TCM guidelines and emphasized evidence-based methodological approaches. However, substantial challenges were identified, including insufficient high-quality clinical evidence, lack of methodology tools tailored to TCM characteristics, and difficulties in standardizing clinical classification systems.

Conclusion: We recommend: (1) increased institutional support and funding for guideline development; (2) mandatory involvement of methodological experts throughout the entire development process; (3) expanded training in evidence-based medicine and guideline methodology; (4) strict adherence to updated technical protocols and methodological workflows; (5) enhanced focus on content quality, dissemination, and timely updates; and (6) preservation of TCM diagnostic and therapeutic characteristics with emphasis on clinical practicality and applicability. These measures will improve the quality of TCM clinical guidelines and enhance their contribution to public health.

Keywords: Clinical guidelines; Traditional Chinese medicine; Guideline preparation and revision; Methodology

1 Current Status and Background

Clinical practice guidelines (CPGs) constitute a critical component of healthcare standardization, serving as authoritative documents that guide medical practice and significantly improve healthcare quality [1-2]. Evidence-based guidelines sys-

tematically incorporate clinical evidence following methodological principles of evidence-based medicine to formulate recommendations [3]. Currently, evidence-based guideline development has become the international mainstream approach and consensus [4]. As a pivotal element in TCM standardization, the preparation and revision of evidence-based TCM clinical guidelines have been ongoing for many years.

At the end of 2014, the Department of Policies, Regulations, and Supervision of the State Administration of Traditional Chinese Medicine initiated a large-scale guideline preparation and revision project, encompassing 240 TCM clinical guidelines across 13 specialty areas (140 revisions and 100 new guidelines) [5]. The potential benefits of these guidelines depend directly on their quality. This massive undertaking necessitated enhanced quality assurance mechanisms. Simultaneously, TCM guideline development faces significant challenges, including scarcity of high-quality clinical evidence, lack of methodology tools suited to TCM characteristics, and incomplete evaluation systems for TCM therapeutic efficacy.

To investigate the actual implementation process of guideline development teams, particularly to understand their genuine perspectives and identify practical problems, our team conducted this questionnaire survey based on the summary work of TCM clinical guideline preparation and revision organized by the China Association of Chinese Medicine. This survey aims to uncover the authentic status of guideline development, identify existing problems, and provide robust data support and directional guidance for subsequent workflow construction, methodological control, and quality optimization, thereby enhancing the scientific rigor and stability of TCM guideline development while improving methodological quality and clinical applicability.

2 Methods

2.1 Survey Participants and Timeline

The survey targeted TCM clinical guideline development project teams organized by the China Association of Chinese Medicine, with each team submitting one questionnaire representing collective opinions. The survey was conducted from June 2020 to December 2020.

2.2 Survey Methodology

An electronic questionnaire was distributed via the Questionnaire Star platform through official communications from the China Association of Chinese Medicine to all project teams, with responses collected online.

2.3 Questionnaire Design

The semi-structured questionnaire covered five domains: (1) understanding of TCM clinical guidelines, (2) guideline development/revision procedures and

methodological application, (3) key challenges and critical steps, (4) implementation and promotion, and (5) overall assessment. The questionnaire comprised [text appears incomplete in original].

2.4 Data Analysis

Microsoft Office Excel 2019 was used for data management. Two independent researchers compiled and analyzed the survey results using descriptive statistics.

3 Results

3.1 Participant Characteristics

A total of 198 guideline development project teams participated in the survey. All respondents were members of TCM clinical guideline development teams organized by the China Association of Chinese Medicine, with content requiring review by the entire team. The frequency distribution of participating teams across disciplines is shown in [Figure 1: see original paper], with the majority from internal medicine specialties.

3.2 Understanding of TCM Clinical Guidelines

Regarding overall perceptions, 74.24% of teams considered TCM clinical guidelines very important for clinical practice, 95.96% believed guidelines could effectively guide clinical activities, and 93.43% reported using guidelines as important references in clinical decision-making. However, 94.45% of teams acknowledged the need for more TCM guidelines, citing limited coverage and suboptimal clinical application as current challenges.

3.3 Guideline Development Procedures and Methodological Application

In terms of development procedures, 99.49% of teams followed the technical protocols and methodologies issued by the China Association of Chinese Medicine, though only 31.82% had methodological experts involved throughout the entire process. Regarding methodological familiarity, 58.59% reported thorough understanding, 40.4% partial understanding, and 1.01% limited or no understanding. Methodological expert participation was reported by 99.4% of teams, with 56.06% having full-process involvement and 43.43% partial involvement.

Notably, despite methodological expert participation, 10.61% of teams reported that literature searching, evidence evaluation, and expert consensus meetings were not conducted or led by professional methodological teams. Concerning updates in methodological knowledge, 81.82% actively followed new developments and participated in training, while 15.66% cited heavy clinical workloads as preventing them from staying current.

3.4 Key Challenges and Critical Steps

[Figure 1: see original paper] illustrates the primary difficulties identified in TCM guideline development: insufficient high-quality clinical research evidence (89.39%), lack of methodology tools suited to TCM characteristics (70.2%), difficulty in standardizing clinical classification systems (66.16%), and absence of standardized criteria for herbal formula selection and dosage (60.61%).

Regarding clinical questions addressed during guideline development, lack of literature evidence represented a major challenge. Over half of the teams reported that more than 30% of clinical questions lacked supporting literature evidence [Figure 2: see original paper], confirming that insufficient high-quality evidence remains a critical obstacle. Additionally, the scarcity of methodology tools tailored to TCM characteristics significantly impacts guideline development quality.

The survey revealed that 88.89% of teams believed TCM guideline quality evaluation should employ tools specifically designed with TCM characteristics to ensure relevance, while 8.08% considered international standards acceptable to facilitate clinical application.

3.5 Implementation and Promotion

Regarding whether promotion met expectations, 71.3% of teams reported satisfactory implementation with good clinical guidance, 26.77% believed promotion needed strengthening, and only 2% considered implementation far below expectations requiring substantial improvement.

Clinicians identified major barriers to guideline application as: inadequate promotion (87.37%), lack of consensus (33.33%), discordance between recommendations and clinical reality (19.7%), questionable credibility of recommendations (15.66%), and insufficient authority of guideline developers (15.15%).

3.6 Overall Assessment of Guideline Development

The vast majority (96.97%) of teams reported investing substantial human, material, and financial resources. Notably, 70.2% spent over two years on drafting, with 74.25% devoting five months or more to literature review and preliminary preparation.

4 Discussion and Recommendations

Since the 2014 TCM standardization initiative, participating institutions and project teams have accumulated considerable practical experience. Based on this survey and our work in TCM standardization, we offer the following recommendations:

4.1.1 Emphasize Evidence-Based Methodology While Strengthening Expert Involvement

As authoritative clinical guidance documents, guideline quality directly correlates with rigorous development procedures and methodologies. TCM clinical guidelines, as a form of group standard, require standardized procedures. The China Association of Chinese Medicine drafted the “Technical Requirements for Preparation and Revision of TCM Clinical Guidelines” to regulate development processes. Consequently, most teams emphasized methodological rigor and followed updated technical requirements, with developers’ methodological understanding gradually deepening through evidence-based medicine application. However, although most teams had methodological experts, only 56.06% had full-process involvement, indicating substantial room for improvement.

Previous experience demonstrates that methodological expert involvement significantly impacts guideline quality. *The Lancet* published “Clinical Experts or Methodologists to Write Clinical Guidelines?” [6], highlighting limitations when either party works alone: clinicians lack time and skills for evidence retrieval and evaluation, while methodologists can assist in evidence synthesis and mitigate commercial influence [7], but may lack clinical specialty knowledge.

Additionally, teams reported that methodology training remains limited, primarily consisting of lectures and experience sharing. Teams called for enhanced training on specific operational methods and practical applications. Current training lacks hands-on exercises, targeted content, and timely updates, while teams often encounter difficulties and questions only during actual development.

4.1.2 Apply AGREE II for Methodological Quality Evaluation While Addressing TCM Specificity

With increasing guideline numbers, clinicians require tools to assess quality and credibility. The internationally recognized AGREE II instrument (2010) [8] comprises six domains with 23 items, recommending evaluation by four or more assessors for objectivity. In this project, most teams emphasized quality evaluation and adopted AGREE II. Early attention to quality evaluation helps standardize workflows, preempt potential problems, and improve guideline quality.

However, TCM guidelines present unique challenges in development and clinical application, including: standardizing syndrome differentiation, flexible herbal formula usage and dosage, application of classical medical literature, and difficulties for Western medicine practitioners. Many teams advocated for quality evaluation systems specifically designed for TCM characteristics, incorporating syndrome-based treatment and clinical validation. Researchers have already initiated work on TCM guideline applicability evaluation and specialized quality assessment systems [9], which developers should monitor closely.

4.1.3 Insufficient Attention to Guideline Dissemination and Implementation

Some developers consider guideline completion as the project endpoint, paying inadequate attention to subsequent dissemination and implementation, resulting in low awareness among target clinicians, poor clinical application, and implementation difficulties. This also hinders subsequent updates and improvements. Guidelines must be applied in clinical practice to guide decision-making, protect patient rights, and address patient needs. Without adequate promotion, guidelines cannot fulfill their clinical value.

4.2.1 Prioritize Guideline Development with Increased Funding and Enhanced Transparency

This survey reveals considerable room for improvement. Although China's guideline publications have increased annually over the past two decades, industry emphasis and application breadth lag behind developed countries. Stable national or public funding remains insufficient. One survey showed that only 27.17% of Chinese clinical guidelines published in 2018 reported funding sources, primarily from the National Natural Science Foundation and national key R&D programs [10]. Funding shortages may create potential conflicts of interest and hinder project implementation. Additionally, over 80% of Chinese guideline developers have not scientifically declared or managed conflicts of interest, reducing transparency.

We recommend that authorities prioritize TCM guideline development by: (1) providing policy support and including standardization work in professional title evaluation to increase clinician engagement; (2) establishing special funds for TCM standardization with long-term support; (3) encouraging establishment of public welfare funds to attract social capital; and (4) mandating robust conflict-of-interest declaration and management mechanisms to enhance independence and transparency.

4.2.2 Ensure Full-Process Involvement of Methodological Experts

International guideline organizations including WHO, SIGN, and NICE recommend multidisciplinary working groups to ensure reliability, implementability, and representativeness [11]. The China Association of Chinese Medicine's "Technical Requirements for Preparation and Revision of TCM Clinical Guidelines (Trial)" [12] specifies that working groups should include not only clinical professionals (physicians, nurses, pharmacists, rehabilitation therapists) but also methodological experts, clinical epidemiologists, medical literature specialists, statisticians, and health economists. Inappropriate methodology may produce unreliable or erroneous recommendations, misleading clinical decisions [13]. Rigor is a crucial quality indicator [14], making methodological expert involvement essential for quality assurance.

Our survey found that while over 95% of projects had methodological experts,

full-process participation rates were insufficient. Key steps including PICO question formulation, guideline retrieval and evaluation, systematic review conduct and reporting, and GRADE evidence grading require high-level methodological skills. TCM guidelines present unique methodological complexities, and China currently has few evidence-based methodology specialists in TCM, with limited proportions of clinical experts and young medical staff proficient in these methods. Therefore, full-process methodological expert participation is vital for ensuring rigor, objectivity, and scientific validity of TCM guidelines. We strongly recommend enhanced methodologist involvement in future TCM guideline development.

4.2.3 Expand Training in Evidence-Based Medicine and Guideline Methodology

Evidence-based medicine knowledge and skills are prerequisites for understanding guidelines and essential tools for developers. The three pillars of evidence-based medicine—clinical expertise, patient values, and best available evidence [15]—require continuous learning, particularly regarding “best available evidence.” Due to regional healthcare disparities, economic development levels, and medical education models, lack of evidence-based medicine knowledge remains widespread in China. Training is insufficient for both grassroots clinicians and guideline developers: (1) Grassroots clinicians need practical skills in guideline acquisition, application, and clinical decision-making, but face limited learning channels, high costs, and time constraints, particularly in economically underdeveloped regions; (2) For guideline developers, available training is limited, variable in quality, and lacks depth and coverage, making it difficult to find targeted, high-quality, flexible training programs.

The situation is even more challenging in TCM. We recommend that: (1) medical institutions increase training investment and collaborate with guideline developers to provide public training for grassroots clinicians; and (2) institutions and research organizations actively develop high-quality, regularly updated training programs using innovative formats such as online teaching, hands-on exercises, roundtable discussions, and case studies to strengthen evidence-based medicine capacity in TCM and improve guideline quality.

4.2.4 Strictly Follow Updated Technical Protocols and Methodological Workflows

High-quality guidelines require rigorous technical methods and workflows. Developers must recognize methodology’s importance and strictly follow updated protocols without cutting corners. Given TCM’s unique characteristics, appropriate standards and tools should be selected. For instance, renowned physicians’ clinical experiences and case records accumulated over thousands of years represent repeatedly validated knowledge, yet are classified as low-level evidence in current evaluation systems. Balancing this historical evidence against modern research requires careful consideration. Issues such as standardizing clinical clas-

sification systems, herbal inclusion criteria, and dosage determination demand flexible approaches that prioritize clinical needs and improved decision-making. Simultaneously, we should develop methodology tools with TCM characteristics and share excellent methods and unique experiences among TCM guideline teams.

4.2.5 Focus on Content Quality, Dissemination, and Timely Updates

High-quality guidelines require rigorous development methods and standardized reporting, but fundamentally depend on reliable, accurate content. While AGREE II evaluates methodological quality and RIGHT for TCM [17] provides reporting standards, tools specifically evaluating whether TCM content improves clinical decision-making and patient outcomes are urgently needed. Therefore, working groups should prioritize content quality, conduct application surveys, consider user feedback, and ensure timely updates. Specifically, content should be scientifically rigorous while ensuring readability, practicality, and clinical operability.

Concurrently, guideline dissemination requires attention. Publication through journals, online platforms, and open-access websites improves accessibility. Post-publication promotion through targeted teaching in hospitals and primary care institutions, coupled with feedback collection, is essential. Continuous monitoring of latest research and timely updates ensures guidelines remain current.

4.2.6 Reflect TCM Characteristics with Focus on Clinical Practicality

Guidelines aim to provide optimal recommendations for clinical decision-making. TCM and Western medicine each have distinct advantages and limitations. TCM guidelines following Western formats lose their value and reduce flexibility in syndrome differentiation and treatment modification. TCM guideline development should incorporate characteristic elements including syndrome-based treatment [18], classical formulas, Chinese patent medicines, characteristic therapies, preventive medicine, rehabilitation, and health preservation, reflecting the holistic theoretical framework [19]. However, guidelines must not simply copy textbooks or classical literature. They should comprehensively consider clinical practicality, ease of use, efficacy, and safety, aiming for clinical applicability and utility.

TCM standardization is fundamental, strategic, and comprehensive, crucial for guiding and supporting TCM development. As a vital component, TCM clinical guidelines improve clinical practice, facilitate transformation of group standards to industry and national standards, and support high-quality TCM industry development. Over the years, continuous guideline development efforts have demanded substantial time and energy from organizations and project teams. Addressing methodological, procedural, and communication challenges promptly and effectively is key to further improvement.

Despite ongoing challenges in enhancing methodological quality, developing

TCM-specific tools, improving technical protocols, and evaluating clinical applicability, TCM standardization and guideline development face a promising future. With steady progress in feedback and improvement mechanisms, these efforts will provide crucial technical support for TCM inheritance and innovation.

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