# Development Status and Reflections on Applicability Assessment Tools for Clinical Practice Guidelines in China: Postprint

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## Abstract

Background: With the rapid growth in the number of clinical practice guidelines in China, existing applicability evaluation tools have exhibited rapid development. However, issues such as missing evaluation dimensions and a singular target user population persist, making it difficult to meet the urgent needs for guideline applicability evaluation within a medical system where traditional Chinese and Western medicine coexist.

Objective: To systematically evaluate applicability evaluation tools for clinical practice guidelines developed in China, and to provide a reference for the proper selection and application of such tools.

Methods: We systematically searched Chinese and English databases including CNKI, Wanfang Data Knowledge Service Platform, VIP, Chinese Medical Journals Full-Text Database, PubMed, Embase, and Web of Science, as well as the Clinical Practice Guidelines Scientificity, Transparency and Applicability Rating Tools Platform and the Medlive Guidelines Channel, to collect tools suitable for evaluating domestic guidelines. The search timeframe spanned from database inception to April 1, 2024. Two researchers independently extracted and screened the collected data according to corresponding inclusion and exclusion criteria, and performed categorical induction and comparative analysis of the included applicability evaluation tools.

Results: Five complete guideline applicability evaluation tools and three guideline quality evaluation tools containing applicability evaluation items were ultimately included. The target users of all eight guideline applicability evaluation tools were physicians; the evaluation domains primarily included basic information, readability, feasibility, acceptability, overall evaluation, and recommendations. The three traditional Chinese medicine guideline applicability evaluation

tools reflected the diagnostic and treatment characteristics of traditional Chinese medicine in their item settings, but lacked item settings in the accessibility and acceptability domains. General guideline evaluation tools lacked item settings regarding personal recommendations.

Conclusion: Although numerous guideline applicability evaluation tools have been developed domestically, problems such as a singular user population, inconsistent evaluation domains, and long update cycles remain. Users should fully consider the evaluation purpose and domains to select appropriate guideline applicability evaluation tools. Future revisions of applicability evaluation tools could expand the target user population to include patients and guideline developers, and establish update plans to ensure the advancement and effectiveness of the evaluation tools.

## Full Text

# Development Status and Reflections on Applicability Evaluation Tools for Clinical Practice Guidelines in China

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### Abstract

**Background:** With the rapid growth in the number of clinical practice guidelines in China, existing applicability evaluation tools are developing quickly. However, these tools generally suffer from problems such as missing evaluation dimensions and a narrow target user base, making it difficult to meet the urgent need for guideline applicability evaluation within China' s unique medical system where traditional Chinese and Western medicine coexist.

**Objective:** To systematically evaluate applicability evaluation tools for clinical practice guidelines developed in China, and to provide references for the correct selection and application of such tools.

**Methods:** We systematically searched Chinese and English databases including CNKI, Wanfang Data, VIP, Chinese Medical Journals Full-text Database, PubMed, Embase, and Web of Science, as well as the STAR (Scientific, Transparent and Applicable Rankings) platform and the Medlive guideline channel. We collected tools applicable for evaluating domestic guidelines, with the search period extending from database inception to April 1, 2024. Two researchers extracted and screened the collected data according to established inclusion and

exclusion criteria, then classified and performed comparative analysis of the included applicability evaluation tools.

**Results:** We ultimately included five complete guideline applicability evaluation tools and three guideline quality evaluation tools containing applicability evaluation items. The target users of all eight tools were physicians, with evaluation domains primarily covering basic information, readability, feasibility, acceptability, overall evaluation, and recommendations. Three traditional Chinese medicine (TCM) guideline applicability evaluation tools reflected TCM diagnostic and treatment characteristics in their item settings, but lacked items in the domains of availability and acceptability. Universal guideline evaluation tools lacked items for personal recommendations.

**Conclusion:** Although numerous applicability evaluation tools for guidelines have been developed in China, they still face issues such as a single user group, inconsistent evaluation domains, and long update cycles. Users should fully consider the evaluation purpose and domain when selecting appropriate tools. Future revisions of applicability evaluation tools should expand the target user groups to include patients and guideline developers, and establish update plans to ensure the tools remain advanced and effective.

**Keywords:** Guidelines; Clinical practice; Assessment instruments; Systematic reviews; Applicability; Progress reports

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## Introduction

Clinical practice guidelines (hereinafter referred to as "guidelines" ) serve as guiding documents for medical practice and play an important role in China' s healthcare system [1]. High-quality, practical guidelines can improve clinical practice efficiency, benefit more patients, and enhance healthcare service quality [2]. In recent years, driven by deepening research in guideline methodology and increasing attention from clinical researchers, guidelines in China have not only increased in quantity but also demonstrated improved methodological rigor and quality [3]. However, despite this growth in guideline numbers, the lack of systematic evaluation of clinical applicability has resulted in insufficient promotion and implementation effectiveness. Applicability evaluation of guidelines employs systematic methods and tools to assess the applicability, feasibility, and promotion value of guideline recommendations in real clinical scenarios, thereby measuring guideline quality and expected implementation effects to improve quality and facilitate widespread promotion [4]. Guideline applicability evaluation tools can be used to assess the degree of alignment between guidelines and clinical practice [5], enabling clinicians to understand guideline applicability based on evaluation results and correctly apply guideline recommendations to guide clinical practice.

Many international guideline applicability evaluation tools have been published

[6], providing valuable references for researchers. However, differences in cultural background and healthcare systems make them difficult to apply directly to domestic guidelines, limiting their promotion and use in China. Consequently, domestic scholars and institutions have developed guideline applicability evaluation tools suitable for different fields. Previous studies have preliminarily summarized domestic applicability evaluation tools [7], but have not deeply explored the characteristics and limitations of each tool or systematically reviewed relevant literature. To better promote the development of guideline applicability evaluation in China, facilitate standardized guideline development, popularization, and scientific use, this study conducted a systematic evaluation of domestic guideline applicability evaluation tools to provide references for correctly selecting and applying these tools.

## Methods

**1.2 Search Strategy** We systematically searched Chinese databases (CNKI, Wanfang Data, VIP, Chinese Medical Journals Full-text Database) and English databases (PubMed, Embase, Web of Science), as well as the STAR platform and Medlive guideline channel to collect domestic guideline applicability evaluation tools. The search period extended from database inception to April 1, 2024. Chinese search terms included: guideline, expert consensus, applicability. English search terms included: Guideline, Practice guidelines, Clinical practice guidelines, Experts Consensus, Applicability, and Applicable.

**1.3 Literature Screening and Data Extraction** One researcher extracted information from the collected data, while another researcher verified the extracted information. Disagreements between the two researchers were resolved through discussion among all researchers. We conducted initial screening by obtaining relevant bibliographic records, removing duplicates from the databases, and reading titles and abstracts. After excluding irrelevant literature, we performed secondary screening by reading full texts to determine the final included studies and examined the references of included studies to avoid omissions. We also downloaded supplementary information and supporting materials for included studies to gain comprehensive understanding. Extracted data included: tool developer, publication year, tool name, type of developing institution, tool type, evaluation domains, number of items, and whether quantification was used.

**1.6 Evaluation Methods** We employed descriptive analysis, using characteristic tables and basic condition descriptions to classify and compare the included guideline applicability evaluation tools.

## Results

**2.1 Literature Screening Results** The initial search yielded 8,480 relevant documents. After removing 1,268 duplicate documents, we excluded 7,175 doc-

uments by reading titles and abstracts, and eliminated 29 documents through full-text rescreening, ultimately including 8 documents [8-15]. The literature screening process is detailed in Figure 1 [Figure 1: see original paper].

**2.2 Basic Characteristics of Included Studies** We included eight domestic guideline applicability evaluation tools [8-15]. Three tools were led by domestic scholars [9-11], three were developed by health administrative departments [12-13,15], one by an academic society [8], and one by an academic center [14]. Seven tools were published in journals [9-15], and one was published in documents issued by health administrative departments [8]. The publication years of included tools ranged from 2012 to 2023. The target users of all eight tools included clinicians and third-party evaluation agencies, with one tool also targeting guideline developers [14]. Three tools were applied to TCM guidelines [8-10]; five tools had no application restrictions [11-15]; and six tools quantified item scores [8-9,12-15]. The basic characteristics of the tools are detailed in Table 1 .

**2.3.1 Comparison of Characteristics of Different TCM Guideline Applicability Evaluation Tools** TCM guideline applicability evaluation tools included: (1) the Clinical Application Evaluation Tool for TCM Clinical Diagnosis and Treatment Guidelines published by the China Association of Chinese Medicine in 2012 [8]; (2) the Guideline Clinical Applicability Evaluation Tool developed by Professor Li Hui' s team in 2016 [9]; and (3) the Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines developed by Bai Xue et al. from the Evidence-Based Medicine Center of Beijing University of Chinese Medicine in 2020 [10].

**Basic Information:** Both the TCM Clinical Diagnosis and Treatment Guideline Applicability Questionnaire [8] and the Guideline Clinical Applicability Evaluation Tool [9] require evaluators to fill in basic information, including whether they have used the guideline and their familiarity with it. The Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] does not mention evaluator basic information.

**TCM Characteristic Therapies:** The TCM Clinical Diagnosis and Treatment Guideline Applicability Questionnaire [8] and the Guideline Clinical Applicability Evaluation Tool [9] cover four aspects of TCM characteristics: syndrome differentiation and treatment, prescription and medication, other treatment methods, and lifestyle guidance and prevention. The Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] provides more detailed classification of these contents. For example, the prescription and medication category includes formula source, name, dosage, and decoction methods; other treatment methods include acupuncture, massage, fumigation and washing, application, auricular points, and qigong.

**Item Scoring Quantification:** The TCM Clinical Diagnosis and Treatment Guideline Applicability Questionnaire [8] uses a 4-point scale, where 1 represents

extremely poor and 4 represents extremely good. Compared with a 5-point scale, the 4-point scale lacks a "poor" option, which may introduce certain bias in the evaluation process. The Guideline Clinical Applicability Evaluation Tool [9] uses a 7-point scale with more detailed options and richer scoring, though evaluation speed may be affected. The Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] does not quantify item scores, with options limited to "yes," "no," and "not applicable."

**Guideline Evaluation Recommendations:** The TCM Clinical Diagnosis and Treatment Guideline Applicability Questionnaire [8] does not set specific questions; evaluators provide other modifications and supplementary suggestions for the guideline in text form. The Guideline Clinical Applicability Evaluation Tool [9] sets three multiple-choice questions and one fill-in-the-blank question, covering areas needing improvement in the guideline, most important outcomes to incorporate, guideline evaluation recommendations, and other specific modification opinions. The Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] does not include personal recommendation items. The comparison of characteristics among the three TCM guideline applicability evaluation tools is detailed in Table 2 .

**2.3.2 Comparison of Characteristics of Different Types of Applicability Evaluation Tools** Currently, domestically developed guideline applicability evaluation tools fall into two categories: those applied to TCM guideline applicability evaluation and those without application restrictions (i.e., universal evaluation tools). Three TCM guideline applicability evaluation tools [8-10] are complete guideline applicability evaluation tools. The Chinese Clinical Guideline Evaluation Tool [12], Chinese Medical Clinical Guideline Evaluation Tool [11], and the STAR Tool [14] are guideline quality evaluation tools containing applicability evaluation items. The Guideline Clinical Applicability Evaluation Tool (2.0) [15] and its previous version (1.0) are complete evaluation tools. A comparison of characteristics between the Guideline Clinical Applicability Evaluation Tool (2.0) [15] and TCM guideline applicability evaluation tools [8-10] is detailed in Table 3 .

**Basic Information:** The TCM Clinical Diagnosis and Treatment Guideline Applicability Questionnaire [8] and the Guideline Clinical Applicability Evaluation Tool [9] involve basic information but only include two items: whether the evaluator has used the guideline and their familiarity with it. The Guideline Clinical Applicability Evaluation Tool (2.0) [15] includes 12 basic information items: age, region, education, practice type, professional title, medical institution, institution level, time spent with guidelines, familiarity with guidelines, specialty, years of practice, and conflict of interest declaration. The Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] does not include items in this domain.

**Availability/Accessibility:** Availability primarily includes the ease of obtaining and promoting guidelines. TCM applicability tools [8-10] do not include

items in this domain. The Guideline Clinical Applicability Evaluation Tool (2.0) [15] includes one item in this domain.

**Readability:** This domain primarily includes the completeness and rationality of guideline structure and content, and the clarity of language expression. All tools [8-10,15] include items in this domain.

**Feasibility:** Feasibility primarily includes clinical application characteristics, flexibility, technical level, coordination and compatibility, and factors promoting or hindering guideline application. All tools [8-10,15] include items in this domain. The Guideline Clinical Applicability Evaluation Tool (2.0) [15] sets five sub-items under the question "Are there barriers to implementing this guideline in your medical institution?" to detail specific factors causing implementation difficulties.

**Acceptability:** Acceptability primarily includes the degree of alignment between the guideline and user willingness. TCM tools [8-10] do not include items in this domain. The Guideline Clinical Applicability Evaluation Tool (2.0) [15] includes three items in this domain.

**Overall Evaluation:** This primarily represents the evaluator' s overall impression of the guideline and most directly reflects their attitude toward it. Only the Guideline Clinical Applicability Evaluation Tool (2.0) [15] and the Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] include items in this domain.

**Recommendations:** This primarily includes the evaluator' s suggestions and supplements regarding guideline issues. Except for the Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10], the other three evaluation tools [8-9,15] include items in this domain.

## Discussion

Guideline applicability reflects the degree of alignment between guidelines and clinical practice, as well as the promotion and applicability of guideline recommendations in clinical settings [5]. Guideline applicability evaluation requires appropriate evaluation tools, and different tools may yield different results when evaluating the same guideline. Therefore, selecting an appropriate evaluation tool is the first step to accurately assess guideline quality and implementation effectiveness. Among the eight guideline applicability evaluation tools included in this study, six tools [8-9,12-15] have been used in guideline applicability evaluations [16-21] and have demonstrated good reliability and validity [22-23], gaining certain recognition in China' s guideline evaluation field. However, each tool has its own focus and characteristics, requiring targeted selection based on guideline type during application.

In this study, TCM guideline evaluation tools differ from other evaluation tools by adding TCM-specific content such as TCM characteristic therapies, better reflecting TCM diagnostic and treatment features. However, whether they are

suitable for all TCM guidelines remains subject to further discussion and improvement.

The ultimate purpose of guidelines is to serve clinical practice through users [24]. Typical target users include clinicians, guideline developers, and patients. Guideline applicability evaluation tools targeting guideline developers can alert developers to potential, correctable defects before formal promotion and application [6]. Tools targeting patients can objectively reflect patients' clinical needs, provide timely feedback to guideline developers, and facilitate reasonable revisions in guideline updates to ensure patients receive optimal medical services. However, current evaluation tools only target clinicians and third-party evaluation agencies, lacking tools for patients as a target user group, which may require further improvement.

Although guideline applicability evaluation tools cover various domains, they inevitably omit some items. Personal recommendation items can fill these gaps and facilitate guideline revision work.

Traditional Chinese medicine, as a unique traditional medicine in China, has made tremendous contributions to people' s health. TCM standardization is an important pathway to promote TCM modernization, scientification, and internationalization [26]. The development of TCM guidelines, as a core component of TCM standardization, still has some deficiencies, such as lack of high-quality evidence, non-standardized development processes, and insufficient promotion, which restrict the quality improvement and application of TCM guidelines. Evaluation of TCM guidelines is an important part of the guideline development process and can provide references for TCM guideline promotion, application, and revision [27].

In actual guideline evaluation work, evaluation results may vary significantly depending on evaluator characteristics (e.g., education, professional title, region, years of practice, medical institution) [13]. Among the eight tools included in this study, only four evaluation tools [8-9,13,15] included items for evaluator information, which may lead to bias in evaluation results due to differences in reviewer backgrounds. Future tools should include evaluator information sections and establish scoring correction mechanisms to improve horizontal comparability of evaluation results.

Regarding availability/accessibility, high availability is a prerequisite for guideline application in clinical practice. Four tools [9,11-12,14] in this study included items in this domain. As of 2024, the STAR platform shows that the number of domestic guidelines has exceeded 2,700, but a considerable portion has not been effectively promoted, resulting in low clinical usage rates. Therefore, all evaluation tools should include relevant items.

Acceptability represents the degree of agreement between evaluators and guideline recommendations. Currently, only the Guideline Clinical Applicability Evaluation Tool (1.0) and (2.0) [13,15] include items in this domain. Due to TCM' s emphasis on syndrome differentiation and treatment and differences in per-

sonal clinical experience, understanding and perceptions of the same disease often vary. Therefore, even when TCM guidelines are developed through standardized, rigorous, and transparent processes, their recommendations are more difficult to achieve high acceptance compared to other guidelines. How to improve the acceptability of TCM guidelines warrants serious consideration.

Regarding item scoring quantification, two tools [10-11] did not include scoring. The Recommendations Checklist for Applicability Evaluation of TCM Clinical Practice Guidelines [10] does not provide specific evaluations but rather allows guideline developers to make targeted modifications based on physicians' evaluation results, so items in this tool are not quantified. The Guideline Clinical Applicability Evaluation Tool (1.0) and (2.0) [13,15] and AGREE-China [12] all use a 5-point scale. The TCM Clinical Diagnosis and Treatment Guideline Applicability Questionnaire [8] and the Guideline Clinical Applicability Evaluation Tool [9] use a 4-point scale. Compared with 7-point or 10-point scales, evaluators can more easily assign accurate meaning to each score when using a 5-point Likert scale [25]. The STAR Tool [14] combines item weighting with item scoring, which is more objective and accurate.

Regarding personal recommendations, only four tools [8-9,13,15] include this domain. Although guideline applicability evaluation tools cover various domains, they inevitably omit some items. Personal recommendation items can fill these gaps and facilitate guideline revision work.

Currently, although the number of domestic guideline applicability evaluation tools is increasing, they still face several problems. TCM evaluation tools, while having characteristic dimensions such as TCM therapies, still need improvement in domains like availability/accessibility, acceptability, and overall evaluation. Universal evaluation tools, despite their broad application range, may affect result accuracy due to lack of personalized recommendations and TCM elements. Some evaluation tools lacking basic information dimensions may affect horizontal comparability of results. Most evaluation tools do not mention update plans, which may affect their advancement and timeliness.

In summary, guideline applicability evaluation can promote guideline quality improvement and implementation to a certain extent, but the following areas need improvement: (1) Current domestic guideline applicability evaluation tools primarily target clinicians or third-party evaluation agencies, lacking participation from guideline developers, patients, and other groups, which may introduce bias in evaluation results; (2) Different evaluation tools contain different domains, with some only including usability/feasibility evaluation while lacking personal recommendations and accessibility; (3) Evaluation of TCM guidelines remains challenging, as universal tools lack TCM elements, and the item quantification settings of TCM evaluation tools need further improvement; (4) Most evaluation tools lack clear update plans, with only one guideline applicability evaluation tool having undergone version updates in China.

To address these issues, future development and revision of guideline evaluation

tools could proceed as follows: (1) Tool item settings should fully consider application scenarios and needs of user groups including guideline developers and patients to reduce evaluation bias; (2) Evaluation domains should include basic information, availability/accessibility, readability, overall evaluation, and other content to ensure comprehensive evaluation; (3) Universal evaluation tools should add TCM elements to improve suitability for TCM guidelines; TCM evaluation tools should fully consider the characteristics and advantages of TCM diagnosis and treatment, learn from universal tool development, set reasonable item quantification and evaluation domains to promote implementation and promotion of TCM guidelines; (4) Establish update plans for evaluation tools, and timely supplement, delete, and improve items in older versions based on practical application to ensure the tools remain advanced and effective.

## Limitations

This study searched common Chinese and English databases such as CNKI and PubMed, as well as common platforms like the Medlive guideline channel. However, some guideline applicability evaluation tools may not be indexed in these databases and platforms but may only be accessible through other channels such as official websites of relevant academic organizations, which may introduce selection bias.

## Author Contributions

ZANG Danyang was responsible for conceptualization, manuscript writing, and revision; YANG Shuguang and XU Lili were responsible for literature collection, organization, and information extraction; YU Xueqing was responsible for quality control and manuscript review; ZANG Danyang and YU Xueqing had overall responsibility for the article and supervision; all authors confirmed the final manuscript.

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