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Development of the first guideline for the standardization of health technology assessment in traditional Chinese medicine

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ABSTRACT

Health technology assessment (HTA) in the field of traditional Chinese medicine (TCM) is in its infancy, and its development has been relatively slow. The shifting disease burden pattern has driven a growing demand for TCM-HTA to optimize resource allocation, particularly in managing chronic diseases. To promote the development of TCM-HTA, it is important to address current TCM-HTA development issues in a targeted manner and enhance the TCM-HTA system to improve the quality and efficiency of limited health resource utilization. We systematically analyzed HTA methodological guidelines to summarize the development experiences of HTA organizations globally. The imperative development of HTA in the field of TCM should: a. Clarify the types of health technologies used in clinical TCM practice and define the objects of assessment. b. Develop technical specifications for the implementation of HTA in TCM. c. Choose appropriate assessment perspectives and involve patients, guided by their real needs and clinical problems. d. Formulate HTA methods and processes that reflect the characteristics of TCM. e. Establish a multi-level assessment model for teamwork, with a clear division of responsibilities and tasks among different members. This analysis will enable the development of guidelines for implementing HTA in TCM, based on current healthcare policies and the needs of clinical practice. These guidelines include the definition and classification of TCM health technologies, steps for implementing HTA in TCM, assessment domains, the TCM-HTA reporting checklist, and relevant explanations and data sources.

KEYWORDS

health technology assessment, traditional Chinese medicine, guideline, standardization, development experience

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1. Background

Health technology assessment (HTA) uses a multidisciplinary process with explicit methods to determine the value of a health technology at different points during its lifecycle, informing decision-making to promote an equitable, efficient, and high-quality health system.[1,2] A health technology is defined as "an intervention developed to prevent, diagnose, or treat medical conditions, promote health, provide rehabilitation, or organize healthcare delivery."[2] Potential interventions include tests, devices, medicines, vaccines, procedures, programs, or systems. This formal, systematic, and transparent process employs state-of-the-art methods to consider the best available evidence. The value of a health technology may be assessed by examining its intended and unintended consequences compared with the existing alternatives. The dimensions involved can include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural, and legal issues, organizational and environmental aspects, and broader implications for patients, relatives, caregivers, and the population.[3-5] The overall value may vary depending on the perspective taken, such as the stakeholders involved and the context of the decision. HTA implementation spans the entire technology lifecycle, including pre-market, market approval, post-market phases, and the disinvestment of a health technology.[2]

The various types of organizations and structures utilizing HTA range from large institutions to small advisory committees and government secretariats, such as Ministries of Health. HTA is used in many high-income countries as a tool for selecting appropriate pharmaceuticals, clinical procedures, and medical devices for reimbursement, budgeting, insurance programs, and public health interventions.[3,5]

Concerns regarding the inadequate capacity to assess and research the public health, economic, social, legal, and ethical implications of TCM interventions and technologies in mainland China have resulted in insufficient information to guide rational policy, professional decisions, and practices. To raise awareness and encourage the adoption of TCM-HTA in evidence-based decision-making among national policymakers and stakeholders, it is necessary to draw on best practices from the operation, performance, and contributions of research institutes, HTA agencies, and programs. Additionally, developing relevant guidelines for the implementation of TCM-HTA is crucial.

Numerous international and national HTA organizations and institutes exist, including Health Decision Hub (Decide), Health Technology Assessment International (HTAi), HTAsiaLink, the International Network of Agencies for Health Technology Assessment (INAHTA), the European Network for Health Technology Assessment (EUnetHTA), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). National HTA institutions/organizations from 11 countries include the Canadian Agency for

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Drugs and Technologies in Health (CADTH), the National Institute for Health and Care Excellence (NICE), the Institute for Quality and Efficiency in Health Care (IQWiG), the Pharmaceutical Benefits Advisory Committee (PBAC), the Malaysian Health Technology Assessment Section (MaHTAS), and the Health Intervention and Technology Assessment Program (HITAP), *etc.*[6] A total of 41 published HTA method guidelines from 23 countries or international HTA organizations cover HTA implementation steps, evaluation domains, and reporting checklists.[7] The 2015 Global Survey on HTA by the World Health Organization (WHO) reported that most HTAs focused primarily on safety and clinical effectiveness, followed by economic and budgetary considerations, while issues of ethics, equity, and feasibility received little attention.[8,9]

In mainland China, there are only two HTA organizations/institutions: the Department of HTA under the China National Health Development Research Center and the Key Lab of HTA at Fudan University. HTA development has been in its third stage (since 2017), playing an increasingly important role in healthcare decision-making.[10,11] A milestone achievement was the use of HTA to update the National Reimbursement Drug List for the first time in 2017.[10] In 2020, the *Guideline for the Management of Clinical Comprehensive Evaluation of Drugs* was issued to strengthen the use of HTA.[12] Clinical comprehensive evaluation is a unique concept in HTA in China.[13] The guideline encourages multi-stakeholder participation and includes evaluation theme selection, assessment across six domains, and application of evaluation results. These six dimensions cover safety, effectiveness, economy, innovativeness, appropriateness, and accessibility. Following this guideline, a series of drug comprehensive clinical evaluation sub-guidelines have been published, covering various fields such as oncology, cardiovascular diseases, pediatric diseases,[14-16] and Chinese patent medicine (CPM).[17] However, no specific HTA-related guidelines have been developed yet. The further development of HTA in China faces challenges, including insufficient HTA professionals, limited data availability/accessibility, lack of standardized methodology and quality control measures, and barriers to integrating multidimensional assessments into deliberative processes, *etc.*[10] Given the unique diagnostic and therapeutic practices of TCM, the development and standardization of HTA in this field are particularly important. This has led to a three-year project aimed at developing guidelines for implementing HTA in TCM.[18]

2. Brief description of the development process of the guideline

The current guidelines have been released through the Chinese Society of Traditional Chinese Medicine (CSTCM, https://www.cacm.org.cn/2024/10/31/30468/). The guideline was developed following the standardized process of CSTCM guideline development, as shown in Figure 1. At the beginning of the development process, a multidisciplinary team of experts and a working group were established, leading to a comprehensive and systematic literature search, evaluation, and analysis. The guideline development was informed by an in-depth analysis of published guidelines and HTA-related literature from around the world. Following independent dual screening by two investigators, 41 HTA methodological guidelines were included. This process enabled the identification and summarization of assessment domains, assessment outcomes, and reporting standards in HTA implementation. After four rounds of brainstorming, a preliminary framework for TCM-HTA was developed, comprising 11 implementation steps, 10 assessment domains (with 40 criteria and 110 sub-criteria), and 18 items in the reporting checklist. To refine this framework and achieve expert consensus, 13 experts from various fields, including HTA, TCM clinical practice, health economics, and evidence-based medicine, participated in two rounds of a Delphi survey. The project team carefully considered all expert opinions, incorporating modifications with detailed explanations for each item. Two additional rounds of external expert review were conducted to finalize the TCM-HTA guideline. The entire development process adhered to the principles of standardization, openness, transparency, and institutionalization.[19,20] This approach ensured that the guideline for TCM-HTA remains structured, scientific, and rational. Furthermore, a case study was conducted to validate its feasibility.[21]

This guideline defines the categories of health technologies in the TCM field, specifies the steps for implementing HTA, provides a reporting checklist, and suggests data sources.[22] It serves as a technical framework for implementing HTA, targeting national/regional government and health department policymakers, HTA organizations, researchers, manufacturers, physicians, patients, the public, and other stakeholders. It aims to support evidence-based health decision-making in various areas, including clinical practice guidelines, health planning and budgeting, medical technology pricing and negotiation, nursing quality control, the design of health benefit packages,

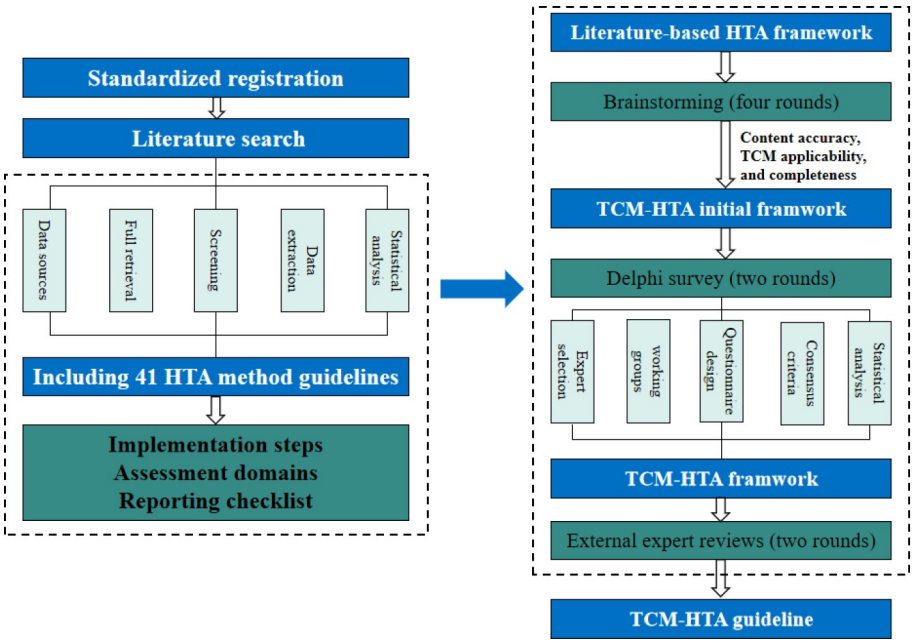

Figure 1 Flow chart of TCM-HTA guideline development

Notes: TCM: traditional Chinese medicine; HTA: health technology assessment.

and public health program protocols. This guideline addresses a critical gap in TCM-HTA implementation methodologies, strengthens the foundational framework of TCM-HTA, and will promote its institutionalization and systematic development in the future.

The current version of the TCM-HTA guideline includes: 10 implementation steps (1 optional and 9 mandatory); 7 assessment domains, covering technical characteristics, safety, effectiveness, economic evaluation, ethical equity, organizational adaptability, and patient and societal considerations; 19 criteria and 37 sub-criteria, including 2 criteria and 5 sub-criteria specific to TCM diagnostic and treatment technologies; 16 items in the reporting checklist.

3. Presentation of the contents of the guideline

The current guideline proposes that TCM-HTA refers to the specific knowledge system and diagnostic and therapeutic methods used in the field of TCM, including Chinese medicines, TCM-appropriate techniques, TCM diagnostic and therapeutic equipment, and TCM diagnostic and treatment protocols, *etc*. In general terms, it encompasses all Chinese medicine technological means used in the prevention, screening, treatment, and rehabilitation of diseases, as well as in the promotion of health and the improvement of quality of life and survival duration. Therefore, this document defines the targets for the assessment of TCM-HTA, including but not limited to the following four major categories: a. Chinese medicine: Chinese medicinal materials, processed herbal slices, CPMs, and TCM preparations; b. TCM-appropriate techniques: acupuncture, tuina, guasha techniques, orthopedic techniques, and methods, *etc*.; c. TCM diagnostic and therapeutic equipment; d. TCM diagnostic and treatment protocols: clinical pathways, clinical practice guidelines.

The 10 steps of HTA implementation for TCM include filing a request to initiate the HTA process, topic selection and prioritization, development of the assessment protocol, implementation of the assessment, drafting the HTA report, reviewing the draft, publishing the HTA report, public participation and publication of the final report, dissemination and application, and monitoring and updating. The dimensions of the assessment of health technologies in this document include seven domains: technical characteristics, safety, effectiveness, economic evaluation, ethical equity, organizational adaptability, and patient and societal considerations, with 19 criteria, and 37 sub-criteria, while incorporating patient preferences. In addition, to promote scientific and standardized reporting of assessment results, which facilitates the dissemination of assessment findings and promotes their application, a checklist for reporting HTA results has been drawn up in this document, including sixteen items. Moreover, this guideline specifically emphasizes the importance of the patient perspective.

Regarding the data sources and analysis for assessment, these can include various published clinical studies, ancient Chinese medical books, clinical practice guidelines, notification documents issued by the national government, databases of the national drug administration, the national adverse drug reaction monitoring system, public service platforms, medical databases, and information provided by manufacturing companies. A scientific and standardized evidence synthesis and analysis was carried out using a combination of qualitative and quantitative methods to provide evidence-based references for health decision-making.

The quality control of the assessment process presents one of the primary challenges in HTA implementation, mainly reflected in the following aspects. First, data sources should be retrieved comprehensively and adequately, and the information should be open, transparent, and accessible to ensure the quality of the evidence base. Second, a professional team should be established, and the composition of the expert committee should be strictly screened for conflicts of interest. The quality control of the consensus process should align with current HTA deliberative process norms.[23,24] The composition of the assessment team and the implementation process should be guided and supervised by the professional committee to guarantee the professionalism and standardization of the assessment process. Third, the quality of evidence and data should be evaluated using well-recognized tools, such as the Cochrane risk-of-bias tool for randomized trials (RoB 2.0) and A Measurement Tool to Assess Systematic Reviews (AMSTAR), *etc*.

The characteristics of the TCM-HTA guideline are primarily reflected in the assessment targets, evaluation content, and evidence sources. Unlike international health technology classifications—such as tests, devices, pharmaceuticals, vaccines, procedures, programs, or systems—the evaluation targets of TCM-HTA include herbal medicine, TCM-appropriate techniques, TCM diagnostic and therapeutic equipment, and TCM diagnostic and treatment protocols. Among these, herbal formulas exhibit complex compositions of medicinal ingredients with unique mechanisms of action and principles of application. Characteristic TCM therapies, such as acupuncture and tuina (Chinese therapeutic massage), fall under specialized TCM medical practices. Treatment protocols are rooted in the principle of "pattern differentiation and treatment" and emphasize the integration of the "four diagnostic methods"—observation, auscultation-olfaction, inquiry, and palpation. Consequently, the evaluation domains have been contextualized for TCM-specific applications. For instance, herbal medicines require clarification of formula composition, applicable pattern types, and the inclusion of animal-derived ingredients to align with patient values. Target diseases must specify TCM pattern classifications and corresponding clinical manifestations. Economic evaluations of acupuncture and tuina should account for service fees, acupoint selection, treatment duration, and cycle requirements. Additionally, the assessment prioritizes patients' subjective experiences, integrating patient feedback across evaluation domains to mitigate practitioner subjectivity inherent in TCM's experiential medicine approach. This emphasizes the actual risks and benefits of treatments for patients, thereby enhancing the efficiency of TCM clinical application and patient satisfaction. Regarding evidence sources, ancient TCM texts serve as critical repositories of TCM knowledge and are equally vital as modern clinical research evidence. In cases where clinical literature or real-world evidence is lacking, evaluations may draw on historical clinical experience and textual evidence from classical TCM works, tracing their origins and historical evolution to inform assessments.

Compared to the *Guideline for the Management of Clinical Comprehensive Evaluation of Drugs*, this TCM-HTA guideline extends beyond pharmaceutical evaluation. While the two guidelines share strong similarities in fundamental principles—both aiming to support decision-making and advocating for multi-stakeholder participation—their frameworks diverge in scope and structure. For implementation procedures, the TCM-HTA guideline encompasses 10 implementation steps, aligning with the three fundamental stages outlined in the drug evaluation guideline. Regarding assessment domains, the TCM-HTA guideline evaluates seven dimensions: technical characteristics, safety, effectiveness, economic evaluation, ethical equity, organizational adaptability, and patient and societal considerations. Compared to the six dimensions in the drug evaluation guideline, including innovativeness, appropriateness, and accessibility, the TCM-HTA guideline incorporates additional evaluations in ethics, organizational adaptability, and patient perspectives. Furthermore, it integrates assessments of innovativeness, appropriateness, and accessibility—key dimensions from the drug evaluation guideline—into its evaluations of technical characteristics and patient-society interactions. The TCM-HTA guideline categorizes assessment domains into generic indicators, applicable across domains, and domain-specific indicators, tailored to TCM diagnostic and therapeutic equipment and protocols. This classification results in a distinct distribution of evaluation criteria compared to that offered by the drug evaluation guideline. Overall, the TCM-HTA guideline adopts a broader assessment scope, particularly emphasizing patient-centered perspectives to reflect the holistic and individualized nature of TCM.

4. Discussion

To the best of our knowledge, this is the first Chinese guideline on the implementation of HTA, and its guiding value is not limited to TCM. In general, the current guideline is not only applicable to the four major categories of TCM technologies but is also universally compatible and can be flexibly applied to the assessment of various health technologies. In this guideline, we

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have fully considered the specificity of various health technologies in the field of Chinese medicine. For example, TCM classic books serve as primary carriers of Chinese medicine knowledge and are one of the most important sources of evidence for TCM, on par with modern clinical research. Furthermore, based on this guideline, we conducted two empirical studies on TCM-HTA: one evaluating a CPM for the treatment of childhood tic disorders and the other assessing acupuncture for the treatment of secondary dysmenorrhea.[21,25] This current version of the guideline inevitably has some limitations. Regarding assessment domains, the TCM-HTA guideline serves as a general framework without specific methods or outcomes for particular diseases or technologies. In the future, assessment domains can be further refined for certain types of health technologies based on actual needs.

The WHO estimates that 20%–40% of all healthcare expenditure is wasted due to the inappropriate use of medicines, inefficient resource allocation, and weaknesses in essential functions.[26] Governments must increase investment in essential health services to meet the needs of their populations and ensure that limited resources are used to their maximum benefit.[27] HTA can inform the creation of an essential medicines list and a health benefits package for universal health coverage (UHC).[28] Establishing a sustainable and locally relevant TCM-HTA mechanism for priority setting can support progress toward UHC. However, some shortcomings in TCM UHC policy design persist, such as an excessive focus on strengthening administrative regulatory measures while neglecting the use of incentive mechanisms, such as providing effective methods and pathways.[29] Evidence-driven decision-making will shape the development of healthcare systems for decades to come, making it essential to ensure that these decisions are sustainable and based on the best available evidence. This highlights the importance of standardizing the TCM-HTA.

Therefore, the TCM-HTA guideline was developed to support those interested in engaging in HTA in the field of TCM by providing guidance on selecting a sustainable and locally relevant HTA framework for priority setting within the healthcare system. While the guideline is primarily intended for practitioners with HTA knowledge and decision-makers, it remains accessible to related stakeholders. Target users can further develop implementation standards from specific perspectives, such as hospitals or particular TCM technologies, based on this guideline.

However, there may also be barriers to the implementation of this guideline. In China, HTA has little influence on and integration within health policy. The policy-making process involving HTA is disorganized and fragmented, and its contribution to policy-making remains minimal.[5] To enhance the dissemination of this guideline, a professional team should be established. The guideline can be promoted in several ways. First, the guideline development team could organize training lectures to explain its content and the details of its development. Second, dissemination can be facilitated through multimedia tools, including online communication platforms such as WeChat and posts on the official website of the China Association of Chinese Medicine. Third, the guideline can be promoted through scholarly communication, including participation in academic conferences, oral presentations, or posters. Fourth, interpretations of the guideline can be published in academic articles. Finally, the application of the guideline can be encouraged through targeted outreach, such as unsolicited invitations and feedback collection via questionnaire surveys.

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Author Contribution Statement

Xue Wu: Investigation, resources, and writing – original draft. **Jian-ping Liu:** Investigation, project administration, supervision, and writing – review and editing. **Xing Liao:** Conceptualization, funding acquisition, supervision, and writing – review and editing.

Declaration of Competing Interest

Prof. Jian-ping Liu and Prof. Xing Liao are the Editor-in-Chief and Associate Editor-in-Chief of *Evidence-Based Chinese Medicine and Technology Assessment*, respectively, but they are not involved in the peer review or decision of this article. The other contributing author reports no conflicts of interest in this work.

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