



## Education Article

## Developing TCM clinical practice guidelines: A comparison between traditional Chinese medicine and western medicine



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## ABSTRACT

Clinical practice guidelines in Traditional Chinese Medicine (CPG-TCM) is the recommendation that aims to provide the best service to users by identifying and summarizing the rules of prevention, diagnosis, treatment, rehabilitation, and regression of diseases based on systematic reviews of evidence and balancing the advantages and disadvantages of different interventions for clinical questions of Traditional Chinese Medicine. Over the past 30 years, the concept and methods of evidence-based medicine have had a significant impact on the development of clinical practice guidelines in Western Medicine (CPG-WM), and their standardized guideline development methods are being adapted and used in the development of CPG-TCM. However, the quality of CPG-TCM is far from CPG-WM, and the methodological system for developing CPG-TCM is not yet fully established. Therefore, this study aims to explore the methodological differences between CPG-TCM and CPG-WM and to inform the development of high-quality CPGTCM.

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## 1. Introduction

Referring to the definition of clinical practice guidelines provided by the Institute of Medicine in 2011,<sup>1</sup> clinical practice guidelines in Traditional Chinese Medicine (CPG-TCM) provide recommendations that aim to provide the best service to users by identifying and summarizing the rules of prevention, diagnosis, treatment, rehabilitation, and regression of diseases based on systematic reviews of evidence and balancing the advantages and disadvantages of different interventions for clinical questions of Traditional Chinese Medicine (TCM). The Making Grade the Irresistible Choice (MAGIC) working group first proposed the concept of "the Digital and Trustworthy Evidence Ecosystem" in 2017, and emphasized that guidelines (through the dissemination of tools for analyzing data, writing, and publishing trustworthy guidelines) are an

important way to disseminate evidence to clinical practitioners.<sup>2</sup> Developing CPG-TCM not only helps to standardize the diagnosis and treatment of TCM in clinical settings but also improves the level of disease treatment, optimizes the quality of medical services, strengthens medical management, and promotes the orderly development of TCM toward internationalization.<sup>3,4</sup>

Over the past 30 years, the concept and methods of evidence-based medicine have had a significant impact on the development of clinical practice guidelines in Western Medicine (CPG-WM). The standardized guideline development methods are now being adapted and used in the development of CPG-TCM (see Table 1 for the detailed comparisons of the development process between the CPG-WM and CPG-TCM). Meanwhile, the quality of CPG-TCM is gradually improving, and their methodological quality and reporting quality are far from that of the CPG-WM.<sup>5,6</sup> Although methodological research on the development of CPG-TCM is gaining attention and has resulted in nearly 150 methodological-related studies being published, the methodological system for developing CPG-TCM is not yet fully established, particularly in the areas of patient preferences and values, cost-effectiveness analysis, and updating living guidelines.<sup>7</sup> This paper aims to explore the methodological

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**Table 1**  
Comparisons of the Development Process between the CPG-WM and CPG-TCM.

Steps	CPG-WM	CPG-TCM
Initiation and planning	Clarify the importance and feasibility of guidelines	In addition to the factors to be considered in the CPG-WM, it is also necessary to focus on the topic selection, such as dominant diseases and the dominant stages of disease treatment in TCM
Registration	Practice guideline REgistration for transPAREncy platform (PREPARE)	Same as the CPG-WM, and maybe required to document and register by the competent units
Development of protocol	Refer to the core items of Reporting Items for Practice Guidelines in Healthcare (RIGHT)	Refer to the core items of RIGHT-TCM or RICHT-Acupuncture
Establishment of working group	A multidisciplinary working group composed of Western medicine experts	A multidisciplinary working group dominated by experts in TCM, and may also need to include experts in western medicine
Declaration of the Conflicts of interest	All participants in the development of the guidelines need to declare conflicts of interest, and update and manage them on time	Same as the CPG-WM, and special attention should be paid to declare academic conflicts of interest (such as the school of TCM)
Formulation of the clinical questions	PICO (Population, Interventions, Comparisons, Outcomes) format	PICO or SICO (Symptoms, Interventions, Comparisons, Outcomes)
Retrieving evidence	Mainly based on clinical research or systematic reviews of database retrieval	On the basis of western medicine evidence retrieval, ancient books and ancient materials should be considered
Grading evidence quality	GRADE (Grading of Recommendations Assessment, Development and Evaluation)	GRADE, evidence body of traditional medicine and recommendations for its evidence grading, and the grading criteria for recommendations in clinical guidelines/consensus for TCM
Reporting	RIGHT	RIGHT-Acupuncture, RIGHT-TCM

CPG, clinical practice guidelines; TCM, Traditional Chinese Medicine; WM, Western Medicine.

differences between CPG-TCM and CPG-WM and to inform the development of high-quality CPG-TCM.

2. Initiation and planning of CPG-TCM

Before developing CPG-TCM, it is crucial to plan the guideline development process systematically to ensure scientific guidelines. This planning should cover two main aspects: first, clarifying the importance of CPG-TCM development (including the need, purpose, type, topic, and target population of the guidelines), and second, assessing the feasibility of guidelines development (such as evidence resources, funding, personnel, schedule, publication type, and language). During the topic selection for guideline development, it is necessary to focus on the dominant diseases and the dominant stages of disease treatment in TCM. Meanwhile, it is essential to determine the type of CPG-TCM and choose a standard method to develop guidelines. Nowadays, there are various types of CPGs, including living guidelines, rapid guidelines, and patient guidelines, each with a different purpose and slightly different development methods. Besides the traditional criteria for classifying CPG-WM, CPG-TCM can also be divided into three types: disease-based, symptom-based, and technology-based CPG-TCM.

3. Registration of CPG-TCM

The registration of guidelines involves recording essential information, such as the title, purpose, developers, development methods, and conflicts of interest, through a public registration platform before the guidelines are developed and made available to the public to promote the scientific and transparent development of guidelines, avoid duplication of guidelines, update the progress of guidelines on time, and promote the implementation and dissemination of guidelines.<sup>8</sup> Registering CPG-TCM not only strengthens collaboration among different development organizations, but also better reflects the preferences and values of patients and the public, and promotes the dissemination and implementation of CPG-TCM.

The current global comprehensive practice guideline registration platform is the Practice guideline REgistration for transPAREncy platform (PREPARE, <http://www.guidelines-registry.org>), which is both a registration and information access platform for

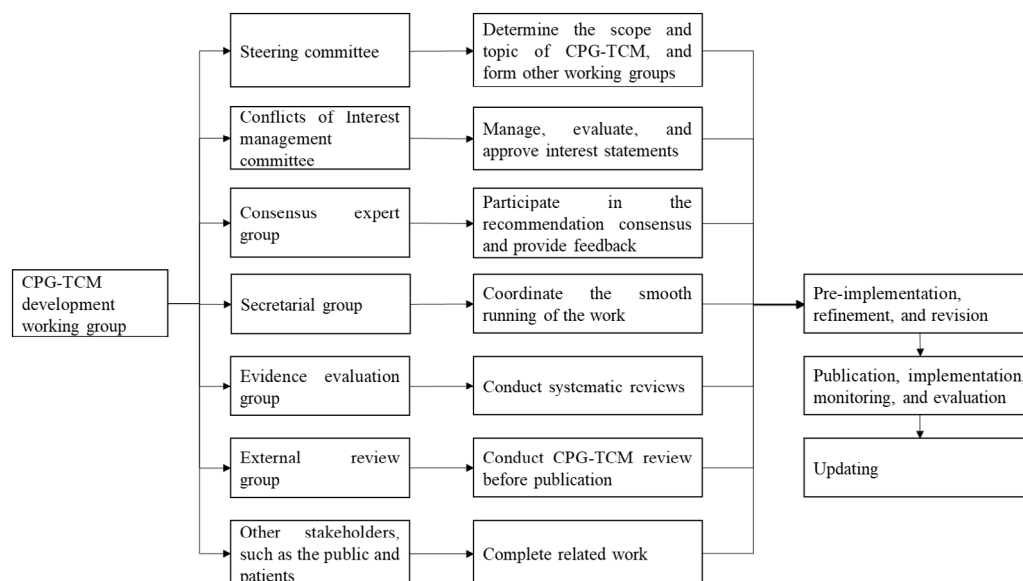
guideline developers and a communication platform for stakeholders such as clinicians, guideline development methodologists, patients, and the public. PREPARE aims to promote scientific and transparent guideline development, facilitate collaboration among guideline developers, and avoid duplication of guideline development and wasteful research.<sup>9</sup> When registering guidelines on the PREPARE platform, there is a guideline type for CPG-TCM, which can quickly help registrants select the guideline type and also help users quickly find registered CPG-TCM. As of January 1, 2023, a total of 179 CPG-TCM were registered on the PREPARE, accounting for 14.0% of the overall guideline registrations.<sup>8</sup>

4. Development of a protocol for CPG-TCM

A guideline protocol is a crucial document that outlines the plan or steps to be taken in developing a guideline, as well as the methods that will be used. The protocol serves to ensure the smooth running of the guideline development, including the overall purpose and specific goals, timeline, task schedule, important processes, and methods (e.g., the establishment of a guideline working group, selection of guideline types and topics, evidence retrieval and evaluation, and consensus methods for recommendations). The reasons for developing a guideline protocol include: (1) to ensure the development of high-quality guidelines; (2) to sort out the differences and connections between the developed guidelines and the currently available or planned guidelines; (3) to ensure that the guideline development process is efficient and smooth; (4) to enhance the accountability of the guideline working group; and (5) to facilitate the guideline development process and the integrity of the final guidelines. The CPG-TCM protocol can refer to some of the core items of RIGHT-TCM<sup>10</sup> and RIGHT-Acupuncture<sup>11</sup> and should be titled as a protocol. When publishing a guideline, it should be indicated whether the guideline has previously developed a protocol, how to access the details of the protocol, and which steps or contents have been changed or followed strictly as expected in the protocol.

5. Establishment of a working group for the CPG-TCM

The responsibility of the guideline working group (GWG) is carried out throughout the entire process of guideline development,



**Fig. 1.** Workflow of the CPG-TCM Working group. CPG, clinical practice guidelines; TCM, Traditional Chinese Medicine.

and usually, the GWG should be established before the formal development of the guideline. The GWG should include a steering committee, conflicts of interest management committee, a consensus expert group, a secretarial group, an evidence evaluation group, and an external review group. The composition of each group should ensure the complementarity of members' skills, expertise, values, and other perceptions to eliminate potential bias. The representativeness of the GWG should also be ensured by considering the discipline, specialty, gender, geographic distribution, and other characteristics of the group members to form a GWG that meets the needs of guideline development.

The GWG should generally include experts from different disciplines, such as evidence-based methodologists, clinical experts, front-line clinicians, healthcare practitioners, pharmacologists, and other related stakeholders. Since most of the disease areas covered by CPG-TCM are named by Western diseases, it is also necessary to consider including Western medicine clinical experts in the disease area. Furthermore, the development of guidelines should consider inviting stakeholders such as policymakers, decision-makers, patients, and/or their families to participate. The detailed workflow of the GWG can be found in Fig. 1.

## 6. Conflicts of interest management

The management of conflicts of interest has an important impact on the objectivity, impartiality, and credibility of guideline development and should be properly managed throughout the guideline development process. Conflicts of interest can be broadly classified into financial and non-financial.<sup>12–15</sup> Financial conflicts of interest arise when members of the GWG have financial interests that may influence the development of guideline recommendations, including personal income, personal patents, research support, and funding (from individuals or institutions). A Cochrane systematic review found that financial conflicts of interest among guideline development members were associated with favorable recommendations.<sup>16</sup> Non-financial conflicts of interest refer to conflicts of interest other than financial interests, such as situations where a GWG member holds a position as a consultant for a company or organization related to guideline development or has a family member with a disease related to the guideline topic. It is essential to manage conflicts of interest effectively throughout

the guideline development process to maintain the integrity of the guidelines.

In TCM, there are different schools of thought, including the Shang Han School, the Yi Shui School, and the Dan Xi School.<sup>17</sup> As these schools may differ in the use of drugs and treatment approaches due to their different theoretical foundations, personal academic perspectives may cause bias in the development of recommendations and undermine the quality of the guidelines.<sup>18</sup> Such bias can be considered a non-financial conflict of interest, or an academic conflict of interest. Some researchers believe that the impact of non-financial conflicts of interest on guidelines is likely to be greater than that of financial conflicts of interest.<sup>19</sup> Therefore, the management and declaration of academic conflicts of interest (such as schools) should be emphasized in the process of CPG-TCM development.

The severity of conflicts of interest is graded as follows: serious conflicts of interest, less serious conflicts of interest, and no conflicts of interest. For different grades of conflicts of interest, the solutions are as follows: (1) Serious conflicts of interest: if the member agrees, he/she can participate in the development of the guidelines after the risk of conflicts of interest is reduced to less serious by releasing the relevant interest; if he/she cannot release the relevant interests, he/she is not allowed to continue to participate in any part of the guideline development; (2) Less serious conflicts of interest: the member can participate in all discussions and provide relevant expertise; however, their participation in the voting of consensus recommendations, as well as the writing and co-authoring the guideline, requires approval from the Conflicts of Interest Management Committee; and (3) No conflicts of interest: the member may participate in any steps of guideline development.

## 7. Identification of clinical questions

Clinical questions in CPG-TCM should be closely focused on the needs of clinical decision-making, and should be derived from various clinical aspects such as etiologic risk factors, disease prognosis, screening and diagnosis, prevention, treatment, rehabilitation, disease distribution, and clinical economics. Currently, CPG-TCM focuses on issues related to the effectiveness and safety of various interventions, including Chinese herbal medicine, proprietary Chinese medicine, and acupuncture. To organize clinical questions in

CPG-TCM, the PICO (Population, Interventions, Comparisons, Outcomes) format is commonly used. However, considering the specificity of TCM, the SICO (Symptoms, Interventions, Comparisons, Outcomes) format may also be useful for clarifying clinical questions in CPG-TCM.

## 8. Search and evaluation of ancient Chinese medicine books

Evidence is the basis for the recommendation of clinical practice guidelines, including CPG-TCM. Ancient books can provide valuable evidence for the unique characteristics of TCM.<sup>20</sup> However, the current method of searching for evidence from ancient books through manual searching is inefficient and may lead to poor reproducibility of results. To address this issue, TCM ancient book databases have been developed, which can facilitate the retrieval of ancient evidence.<sup>21</sup> There are three main types of TCM ancient book databases: bibliographic databases, full-text databases, and graph databases. The most recommended ones are the full-text database of the Chinese Medical Classics<sup>22</sup> and the Ancient and Modern Medical Records Cloud Platform (<http://www.yiankb.com/>), which was developed by the Institute of Information Research Institute of the Chinese Academy of Traditional Chinese Medicine.<sup>23</sup>

In the current development of CPG, most evidence evaluation systems and strength of recommendation grading consider ancient evidence as non-normative expert consensus, which is V-level evidence.<sup>24</sup> For the long-term development of CPG-TCM, the development of evidence grading and recommendation system for ancient Chinese Medicine Books plays a crucial role. In 2021, scholars from China developed an evaluation system for ancient books evidence with a total score of 10, including both citation volume and authorship.<sup>25</sup>

## 9. Evidence grading of CPG-TCM

The quality of evidence has a direct impact on the recommendations of guidelines and their strength. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) method is applied to systematic reviews, clinical practice guidelines, and health technology assessment. It is a generally accepted and commonly used system for grading evidence and grading the strength of recommendations.<sup>26</sup>

Clinical research in TCM has its own characteristics, and the evidence from ancient books as a basis for TCM clinical decision-making may be different from modern clinical research, and there is inapplicability in using the GRADE system. Therefore, in 2007, Liu et al. proposed an evidence body of traditional medicine and recommendations for its evidence grading, which classified the quality of evidence into five levels.<sup>24</sup> Level I is a body of evidence consisting of at least two different types of studies in randomized controlled trials, cohort studies, case-control studies, and case series with consistent effects or a sufficient degree of certainty in their results. Level II is quasi-randomized controlled trials or cohort studies or case-control studies. Level III is historically controlled case series or own before-and-after controlled case series. Level IV is case reports and historically documented therapies that have been widely used in clinical practice for a long time. Level V is expert opinion and clinical experience that has not been validated by systematic research or therapies that have not been widely used in clinical practice for a long time in case reports and historically documented therapies. This was updated and improved by Liu and colleagues in 2019.<sup>27</sup> Compared with the original version, the updated version improves the original evidence grading criteria while giving references to the factors for raising and lowering the evidence, and the appropriate type of evidence is given for different outcome indicators.

Current CPG-TCM mostly relies on expert consensus<sup>28</sup> and lacks systematic evidence and methodological support, resulting in low overall methodological and reporting quality of the guidelines.<sup>6,29</sup> While ancient books provide evidence for CPG-TCM, it lacks the support of high-quality TCM clinical research evidence.<sup>30</sup> Moreover, the current GRADE system is not entirely suitable for determining the strength of CPG-TCM recommendations. To address this, in 2020, scholars proposed the grading criteria for recommendations in clinical guidelines/consensus for TCM.<sup>31</sup> This grading system, based on the GRADE, considers the actual situation of TCM evidence and classifies recommendations as "strong recommendation", "weak recommendation", "non-recommendation", or "uncertain". The strength of recommendation considers factors such as clinical research evidence, ancient literature evidence, clinical benefits and risks, health economics, clinical feasibility, clinical acceptability, and patients' attitudes in the recommendation formation process.

## 10. Reporting of CPG-TCM

Abiding by reporting guidelines is essential to improve the reporting quality and transparency of studies. The standardized reporting of guidelines helps editors and reviewers to make comprehensive and accurate judgments on manuscripts, which is conducive to regulating clinicians' treatment behaviors, providing better services to patients, and improving the level of medical services and treatment quality. The RIGHT (Reporting Items for Practice Guidelines in Healthcare) statement is a clinical practice guideline reporting tool, which includes 7 domains and 22 items and is widely used in the areas of clinical practice, public health, and health policy guidelines.<sup>32</sup> However, the RIGHT statement is not fully applicable to CPG-TCM, so the RIGHT Working Group established a working group of TCM clinical experts, methodologists, and epidemiologists to develop two extended versions of the RIGHT statement: RIGHT for TCM<sup>10</sup> and RIGHT for Acupuncture.<sup>11</sup> These guidelines are international standards for CPG-TCM reporting, which can help CPG-TCM developers draft guidelines, improve the scientific and transparent of guidelines, reduce the risk of bias in the guideline development process, improve the quality of CPG-TCM reporting, assist the target audience in quickly grasping the specific content of the guidelines, and promote the dissemination and implementation of CPG-TCM.

## 11. Conclusion

The Development of CPG-TCM in a scientifically designed, rigorously developed, and standardized reporting manner is crucial for guiding clinical practice in TCM, as well as helping clinical practitioners in making evidence-informed decisions. This article has outlined the unique considerations involved in developing CPG-TCM compared to CPG-WM to facilitate the development of high-quality and transparent CPG-TCM.

## Author contributions

Conceptualization: Yaolong Chen and Xiaohui Wang. Investigation: Xuan Yu, Shouyuan Wu, Juanjuan Zhang, Yue Hu, Meng Luo, Hongmei Zhao, and Xuping Song. Writing - original draft: Xuan Yu. Writing - review & editing: Xuan Yu, Shouyuan Wu, Juanjuan Zhang, Yue Hu, Meng Luo, Hongmei Zhao, Xuping Song, Yaolong Chen, and Xiaohui Wang.

## Conflicts of interest

The authors have no conflicts of interest to declare.



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## Ethical statement

Not applicable.

## Data availability

Not applicable.

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