INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

The structure and expression of clinical questions in guidelines for most traditional Chinese medicine were poor standardized: a systematic review

Gao, YC[1]; Cao, R[2]; Liu, ZH[3]; Liu, MJ[4]; Liao, YD[5]; Feng, YT[4]; Guan, XM[5]; Su, CY[6]; Wang, YQ[7]; Fang, R[8]; Deng, YJ[9]; Xiang, WY[10]; Fei, YT[11].

Review question / Objective: **To systematically investigate the clinical question reporting of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) clinical practice guidelines (CPGs) and traditional Chinese medicine (TCM) CPGs.**
Eligibility criteria: **The inclusion of TCM CPGs adopts the following approach: 15 CPGs were randomly selected from six authoritative Chinese medicine societies (China Association of Chinese Medicine, China Association of Traditional Chinese Medicine, Chinese Association of Integrative Medicine, China Association for Acupuncture and Moxibustion, World federation of Chinese medicine societies, Doctor Society of integrative Medicine, Chinese Medical Doctor Association) and guidelines published by other societies, less than 15 are included. We discarded older versions and duplicate published guidelines.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2023 and was last updated on 19 April 2023 (registration number INPLASY202340064).

INTRODUCTION

Review question / Objective: **To systematically investigate the clinical question reporting of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) clinical practice guidelines (CPGs) and traditional Chinese medicine (TCM) CPGs.**

Rationale: As a well-accepted traditional medicine in China, traditional Chinese medicine (TCM) has real-life advantages in terms of safety, cost and effectiveness, and has been valued in more and more countries and regions. The application of TCM therapies in practice requires direct and exact guidance, and clinical practice guidelines (CPGs), as a systematically developed statement document, can provide clinicians with evidence-based decision-making guidance.

Guideline development is a complex and time-consuming process, with tremendous financial and intellectual investment. The development of the guidelines and the methodological rigor of guideline development and reporting is immense general importance. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approaches, as a gold standard for methodology in the field of current guideline development, provides a structured and transparent approach to assist guideline developers in formulating recommendations. If appropriately used, the application of GRADE approach can produce high-quality guidelines that meet the requirements of guideline development and reporting.

Guideline development is a step-by-step process, where guideline developers and expert penal first identify priority and timely clinical questions, secondarily summarizing evidence through literature searches, and finally formulating recommendations for them based on the evidence. The formulation of clinical questions in this process is one of the most crucial but has significant influence on the subsequent steps. The structured degree of the clinical questions and the specification of the expression expression on the quality of the entire CPGs, especially the recommendations, is self-evident.

Notwithstanding a considerable amount of research into the formulation of clinical questions, the structured and priority selection of clinical questions is the majority, and the research on the reporting of clinical questions in the CPGs is still inadequate and limited. It is currently unclear about the deficiencies of TCM CPGs for the development and reporting of clinical questions and their gaps with the high-quality CPGs. The purpose of this methodological study was to determine the reporting of clinical questions in the TCM CPGs and to understand the gaps with them and the high-quality guidelines.

Condition being studied: Not applicable.

METHODS

Search strategy: Two English databases (Embase, PubMed) and four Chinese databases (Wanfang, Chinese Biomedical Literature Database, VIP Database for Chinese Technical Periodicals and China National Knowledge Infrastructure) will be searched. We will also search the website (https: / / www. GRADEpro.org/) and methodological literature published by two co-chairs to detect GRADE CPGs; the official website of six TCM authority societies (China Association of Chinese Medicine, China Association of Traditional Chinese Medicine, Chinese Association of Integrative Medicine, China Association for Acupuncture and Moxibustion, World federation of Chinese medicine societies, Doctor Society of integrative Medicine, Chinese Medical Doctor Association) will be searched to uncover more TCM CPGs. Search keywords including GRADE Centre, GRADE working group, clinical practice guidelines, etc.

Participant or population: No patient involved.

Intervention: Not applicable.

Comparator: Not applicable.

Study designs to be included: We included the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) clinical practice guidelines (CPGs) published from 1st Jan 2018 to 31st Dec 2022 (guidelines developed with the participation of the GRADE Working Group or two co-chairs, professors Gordon H. Guyatt and Holger J. Schünemann) and traditional Chinese medicine (TCM) CPGs.

Eligibility criteria: The inclusion of TCM CPGs adopts the following approach: 15 CPGs were randomly selected from six authoritative Chinese medicine societies (China Association of Chinese Medicine, China Association of Traditional Chinese Medicine, Chinese Association of Integrative Medicine, China Association for Acupuncture and Moxibustion, World federation of Chinese medicine societies, Doctor Society of integrative Medicine, Chinese Medical Doctor Association) and guidelines published by other societies, less than 15 are included. We discarded older versions and duplicate published guidelines.

Information sources: Two English databases (Embase, PubMed) and four Chinese databases (Wanfang, Chinese Biomedical Literature Database, VIP Database for Chinese Technical Periodicals and China National Knowledge Infrastructure) will be searched. We will also search the website (https: / / www. GRADEpro.org/) and methodological literature published by two co-chairs to detect GRADE CPGs; the official website of six TCM authority societies (China Association of Chinese Medicine, China Association of Traditional Chinese Medicine, Chinese Association of Integrative Medicine, China Association for Acupuncture and Moxibustion, World federation of Chinese medicine societies, Doctor Society of integrative Medicine, Chinese Medical Doctor Association) will be searched to uncover more TCM CPGs.

Main outcome(s): We included the main results of the following study: search results, characteristics of included clinical practice guidelines, structure and expression of clinical questions and recommendations, reflection of clinical questions in recommendations.

Additional outcome(s): Number of clinical questions and recommendations in each guideline.

Data management: The following two kinds of information were extracted: (1) the basic characteristics of the guidelines, including guideline type, scope, whether clinical questions is presented, clinical questions formulation structure, Whether there is a correspondence between the clinical questions and the recommendations, etc, (2) the structure and content of clinical questions information, including the number of clinical questions and recommendations and their correspondence, the structure and expression of clinical questions, the structure elements of the clinical questions are reflected in the recommendation, etc.
We took the PICO (population, intervention, comparison, outcome) model when making a structured classification of the clinical questions. Other structured frameworks of clinical questions such as PIRO (population, index test, reference standard, outcome), PECO (population, exposure, comparator, outcome) and PIFOT (population, intervention, factors, outcome, time) can be referred to the PICO model. We delimited the "comparison point", which refers to a comparison between two interventions or populations, such as a comparison between an intervention and a comparison. Regarding the tendency, it refers to the preference or tendency between the two contrast elements. As for the correspondence between clinical questions and recommendations, we stand for that the main structural elements when presenting the clinical questions were the population and intervention, and the scope of recommendations to answer clinical questions consistent with the clinical questions is considered appropriate and reasonable.

Quality assessment / Risk of bias analysis: Not applicable.

Strategy of data synthesis: Descriptive statistical analysis was conducted, and the proportion of relevant items was calculated.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Language restriction: None.

Country(ies) involved: China.

Keywords: Formulation of clinical questions; Clinical practice guidelines; Traditional Chinese Medicine; The Grading of Recommendations Assessment, Development, and Evaluation.

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