Appraising the quality of clinical practice guidelines in traditional Chinese medicine using AGREE II instrument: A systematic review

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Summary
Objectives: The aim of this study was to investigate the quality of clinical practice guidelines (CPGs) of traditional Chinese medicine (TCM) published in journals and books using AGREE II instrument for further enhancing TCM CPG development.

Methods: A systematic search of relevant guideline websites and literature databases (including Chinese Guideline Clearinghouse, PubMed Wanfang Data Knowledge Service Platform, VIP Online Publishing Platform, China National Knowledge Infrastructure and SinoMed) was undertaken from inception to December 2015 to identify and select CPGs related to TCM. Four independent reviewers assessed the eligible TCM CPGs using the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument. Their degree of agreement was evaluated by intra-class correlation coefficient (ICC).

Results: From 2380 citations, 115 TCM CPGs were included. The mean scores for each AGREE II domain were as follows: (i) scope and purpose (mean±SD=41.1±19.6); (ii) stakeholder involvement (mean±SD=37.6±15.1); (iii) rigour of development (mean±SD=20.1±10.9); (iv) clarity and presentation (mean±SD=33.3±15.4); (v) applicability (mean±SD=10.5±4.5) and (vi) editorial independence (mean±SD=11.4±7.6). Only 10% (n=12) TCM CPGs were rated as "recommended". The ICC values for TCM CPGs appraisal using the AGREE II ranged from 0.76 to 0.93.

Conclusions: The quality of TCM CPGs has remained suboptimal according to AGREE II instrument evaluation. The use of AGREE II in the development process ensures that these considerations are incorporated, and more efforts must be made to improve the quality of TCM CPGs. Therefore, an evidence-based method should be used, and reporting the full texts according to AGREE II checklists for the further TCM CPGs development to ensure the translation of evidence into practice.

1 INTRODUCTION

Clinical practice guideline (CPG) plays an important role in improving quality, safety, and effectiveness of care by applying evidence-based medicine and providing healthcare practitioners with expert summaries of the most recent evidence. However, the quality of CPGs developed by different organisations varied a lot, guideline users and stakeholders must make judgements about the quality relative to the specific context in which they are using the CPGs. CPGs were initially based on consensus among experts, guideline development has been gradually formalised and now consists of evidence-based guidelines.

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was published by a group of international guideline developers.
developers and researchers. The AGREE is a reliable and useful tool for assessment of guidelines, and the purpose is to provide a framework for assessing the quality of guidelines, provide a methodological strategy for the development of guidelines and inform what information and how information ought to be reported in guidelines. AGREE instrument has been used widely in many countries to assess and validate the quality of CPGs, including CPGs for the management of particular diseases.

China has maintained a dual healthcare delivery system that incorporates both Traditional Chinese Medicine (TCM) and Western medicine. Over past two decades, an increasing number of TCM CPGs have been developed by some academic associations and the government providing the normative diagnostic and therapeutic methods for the clinical practitioners in China. The Chinese guideline clearinghouse (CGC) includes approximately 100 TCM CPGs that have mostly been developed by the members of the China Association of Traditional Chinese Medicine (CATCM) and China Academy of Chinese Medical Sciences (CACMS). The TCM CPGs are less consistent, and the standards are poorer, so it is necessary to evaluate the assessments of CPGs before developing these guidelines. In other words, a thorough understanding and investigation of the current status of TCM CPGs is essential for quality management of TCM CPGs. Although, some studies had focused on the quality of some diseases treatment by TCM interventions using AGREE, the efforts to evaluate whole TCM CPGs (published in journals and books) have not been studied sufficiently yet. Considering these needs, the aim of the study was to investigate the quality of TCM CPGs published in journals and books using AGREE II instrument for further enhancing TCM CPG development.

2 | METHODS

2.1 | Study design

This study conducted a review of CPGs using the AGREE II instrument.

2.2 | Review protocol

This study was performed in accordance with the guidelines from preferred reporting items for systematic reviews and meta-analyses (PRISMA).

2.3 | Data sources and searches

Chinese Guideline Clearinghouse, PubMed were searched as an international databases, and Wanfang Data Knowledge Service Platform, VIP Online Publishing Platform, China National Knowledge Infrastructure (CNKI) and SinoMed were searched as domestic databases for TCM CPG. The searches were conducted in December 2015. Other sources such as Google, Amazon and Dangdang website were searched for TCM guidelines published as books, in addition, the reference lists of all the obtained papers were searched. Hard copies of all the articles were obtained and read in full. A search strategy using the keywords "guidelines", "statement", "recommendations", "traditional medicine", "traditional Chinese medicine", and "Chinese herbal medicine" were employed (full search strategies are presented in Appendix S1). Data regarding details such as development groups, financial source, development year and evidence grading system were collected for each document identified as a TCM CPG.

2.4 | Inclusion and exclusion criteria

The inclusion criteria were as follows: (i) complete CPG text is available in English or Chinese; and (ii) CPG contains recommendations regarding TCM interventions. If the CPGs had updates, only the most recent version was assessed.

The following literatures will be excluded: duplicate guidelines, guidelines for patients, editorials, translations of guidelines, secondary or multiple publications and short summaries.

2.5 | Quality appraisal of guidelines

We employed the latest version of the AGREE II instrument to evaluate each TCM CPG meeting our inclusion criteria. According to AGREE II handbook, each CPG was scored on 23 items within six domains. Domain 1 (scope and purpose) is divided into three items: guideline objectives, health questions, and population application. Domain 2 (stakeholder involvement) is based on three items: guideline development group, preferences of target population, and target users. Domain 3 (rigour of development) includes eight items: systematic methods used to search evidence, criteria for selection, strengths and limitations of the evidence, methods for formulating the evidence, health benefits and side effects of recommendations, explicit links between recommendation and supporting evidence, expert reviewers, and updating guideline for future use. Domain 4 (clarity and presentation) includes three items: recommendations
specific and unambiguous, different options for management, and key recommendations. Domain 5 (applicability) includes four items: facilitators and barriers, advice/tools to implement recommendations into practice, resources for implications and auditing criteria. Domain 6 (editorial independence) is based on two items: editorial independence from the funding body and conflicts of interest of the guideline development members.

In this study each TCM CPG was scored by four independent reviewers (L Yao, YL Chen, XQ Wang and XE Shi) according to AGREE II user manual. Among the four reviewers, L Yao and XQ Wang major in integrative medicine, YL Chen is a methodologist in guideline development and XE Shi is a physician in TCM rehabilitation. Besides, L Yao and YL Chen had rich experiences in the application of AGREE II and published a study about using AGREE II to assess Chinese guidelines. XQ Wang and XE Shi were trained to use the AGREE II instrument through the online tutorials on the AGREE website.

The user manual defines each item and assists the user in determining a CPG’s score for that item. Items were scored based on a scale ranging from 1 (absence of item) to 7 (item is reported with exceptional quality). Domain scores were calculated by summing item scores within each domain from each reviewer, then standardising them as a percentage of the maximum possible score.

AGREE II protocol states that no overall score is calculated to determine if a CPG is recommended or not recommended. Instead, TCM CPGs in this study were recommend if the TCM CPGs have >4 domains scoring >50%.

2.6 | Statistical analysis

We performed a descriptive statistics analysis using the calculation of the total score by each reviewer and the score per domain. The independent-sample test was used for comparison of two samples and one-way ANOVA was used for multi-comparison. Agreement between each reviewer’s scores was tested using a two-way ANOVA with single-rater two-way intra-class correlation coefficients (ICCs) for each domain across all guidelines. According to a previous study, the degree of agreement between 0.01 and 0.20 was deemed minor, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, and 0.81-1.00 very good. A value of $P<0.05$ denoted statistical significance. All tests were two-sided. Statistical analyses were conducted using SPSS version 19.0 (SPSS Inc., Chicago, IL, USA).

3 | RESULTS

3.1 | Search results

We identified 2380 records from databases, guideline websites and manual searches after excluding duplicated records, of which 166 records were considered to be potentially relevant; after selection, a total of 115 TCM guidelines were satisfied the inclusion criteria (Figure 1). More detail information of the included TCM guidelines could be seen in Appendix S2.

3.2 | Guideline characteristics

The TCM guidelines covered a range of topics. 68.7% (n=79) TCM guidelines published in 2011-2015. 59.1% (n=68) TCM guidelines developed by Chinese medical institute and 24.3% (n=28) developed by China Academy of Chinese medicine science. 86% (n=98) TCM guideline focused on diagnosis and treatment. In terms of funding, 44.4% (n=51) TCM guidelines were supported by the government, and another 24.3% (n=28) reported receiving guideline society funding.

FIGURE 1 Flow chart of TCM CPGs search and selection
Approximately 40% TCM guidelines graded the level of evidence or recommendation, using various grading systems (Table 1).

### 3.3 | Quality assessment of guidelines

#### 3.3.1 | Consistency

The ICC values, which indicate the overall agreement between reviewers, generally received higher reliability scores. The ICC values for TCM CPGs appraisal using the AGREE II ranged from 0.76 to 0.93 (Table 2). The ICCs for the AGREE appraisal conducted by the four reviewers were lowest in the “applicability” domain (0.76) but higher in the other five domains (all≥0.8), which indicated the intra-reviewer item score agreement was good. Domain scores of the AGREE II quality assessment are illustrated in Table 2.

#### 3.3.2 | Scope and purpose

This domain evaluates the overall objectives, expected benefits or outcomes and target population of the guidelines. TCM CPGs included in this study had a mean AGREE II quality score of 41.1%. Quality scores varied big between the individual TCM CPGs for this domain with a standard deviation of 19.6%.

#### 3.3.3 | Stakeholder involvement

This domain evaluates the degree of relevant professional group involvement, whether the views and preferences of the target population have been considered and whether the definition of target users has been clearly presented. The overall score in this domain was low with a mean of 37.6% (SD=15.1%). Over 60% TCM CPGs scored <25% and only 26% (n=30) TCM CPGs scored >50%.

#### 3.3.4 | Rigour of development

This domain addresses the method of evidence search, grading, summary and the formulation of the recommendations. The mean score for this domain was 20.1% (SD=10.9%). 75% (n=87) TCM CPGs scored <25%, 26% (n=30) TCM CPGs scored 50%-75% (Table 3). Most TCM CPGs failed to demonstrate the association between evidence and the recommendations. However 24.3% (n=28) TCM CPGs declared that they will be updated when new important evidence appears, whereas none of them provided a timeline for updating.

#### 3.3.5 | Clarity and presentation

This domain generally evaluates the presentation and format of guidelines. The mean score was 33.3% (SD=15.4%), which was relatively higher than the rigour of development, applicability and editorial independence domains. 58.3% (n=67) TCM CPGs in this domain scored <25% (Table 3), only 13.9% (n=16) TCM CPGs scored >50%. The key recommendations in most TCM CPGs were not easy to identify, and the clarity of the recommendations was poor. None of TCM CPGs stated how the full text was reported.

#### 3.3.6 | Applicability

This domain evaluates the consideration of facilitators or barriers to CPG implementation and monitoring criteria. The mean score of this domain was 10.5% (SD=4.5%), which was the lowest of all the domains. All the TCM CPGs in this domain scored

### Table 1 | Characteristic of 115 TCM guidelines

| Categories                        | No of guidelines (%)|
|-----------------------------------|---------------------|
| **Publication year**              |                     |
| 2003-2006                         | 5 (4.3%)            |
| 2007-2010                         | 31 (27.0%)          |
| 2011-2015                         | 79 (68.7%)          |
| **Scope of guidelines**           |                     |
| Prevention and treatment          | 7 (6.1%)            |
| Prevention                        | 1 (0.9%)            |
| Diagnosis and treatment           | 98 (86.0%)          |
| Treatment                         | 4 (3.5%)            |
| Technology                        | 3 (2.6%)            |
| Comprehensive<sup>a</sup>         | 1 (0.9%)            |
| **Development organisation**      |                     |
| Ministry of health                | 3 (2.6%)            |
| Medical doctor association        | 4 (3.5%)            |
| Chinese Medical Institute         | 68 (59.1%)          |
| China Academy of Chinese Medicine Science | 28 (24.3%) |
| Hospital                          | 10 (8.7%)           |
| Comprehensive<sup>b</sup>         | 2 (1.8%)            |
| **Publication**                   |                     |
| CSCD Journal                      | 21 (18.3%)          |
| Non-CSCD journal                  | 66 (57.4%)          |
| Book                              | 28 (24.3%)          |
| **Funding**                       |                     |
| Industry                          | 0                   |
| Government                        | 51 (44.4%)          |
| Guideline society                 | 28 (24.3%)          |
| Not reported                      | 36 (31.3%)          |
| **Evidence grading system**       |                     |
| GRADE system                      | 3 (2.6%)            |
| TCM grading system                | 31 (27.0%)          |
| Oxford system                     | 3 (2.6%)            |
| Other system                      | 5 (4.3%)            |
| None                              | 73 (63.5%)          |

<sup>a</sup>Including two or more scopes in a guideline. <sup>b</sup>Developed by two or more organisations in a guideline.
3.3.6 Editorial independence

This domain addresses issues and competing interests of the guideline development members. The mean score was 11.4% (SD=7.6%). 84.3% (n=97) TCM CPGs scored <25% (Table 3). Thirteen TCM CPGs scored >50%. 44% (n=51) TCM CPGs reported receiving government funding, and 24% (n=28) TCM CPGs reported receiving guideline society funding. However, none of the TCM CPGs declared the potential conflicts of interest (COI) of the guideline developers.

3.3.8 Overall assessment

This assessment concerns "the rating of body quality of the guidelines and whether the guideline would be recommended for use in practice". According to the appraisal of the individual domains and overall scores, only 10% (n=12) TCM CPGs were rated as "recommended".

3.3.9 Stratification of TCM CPGs quality

Table 3 presents the means of the domain quality scores from year of publication (2003-2006, 2007-2010, 2011-2015); form of publication,
including whether the guidelines published in the journal of Chinese Science Citation Database (CSCD, a Chinese equivalent of Science Citation Index), non-CSCD journal or book; funding (any funding, not reported), and evidence grading system (any grading system, no grading system). There was a significant difference in scope and purpose domain quality related to year of publication, form of publication and funding. The scores from TCM CPGs available in recent 5 years were significantly higher than those from the other group on five domains: scope and purpose, stakeholder, rigour of development, applicability and editorial independence. TCM CPGs from CSCD journals got higher scores than non-CSCD journals and books on four domains: scope and purpose, rigour of development, clarity and presentation and applicability. And the scores from TCM CPGs receiving a funding were higher than not reported receiving a funding on three domains: scope and purpose, rigour of development and editorial independence. No significant difference was obtained on TCM CPGs whether or not adopting an evidence grading system except rigour of development.

4 | DISCUSSION

This is the first systematic evaluation of the quality of the whole published TCM CPGs in China using a standardised appraisal instrument. Overall, the quality of included TCM CPGs was poor as the mean scores of the whole TCM CPGs were low than 50% among the six domains, and the scores varied significantly across domains and between guidelines (Table 2). However, the quality of the TCM CPGs was increasing over time. Relatively, the strongest domain was “scope and purpose”, and the worst quality domain was “applicability”. Figure 2 presents a comparison to Chinese non-TCM CPGs and international CPGs, by AGREE domain, of the Chinese non-TCM CPGs assessed by Chen et al.15 and the international CPGs assessed by Alonso-Coello et al.19 Alonso-Coello et al. reported the quality of CPGs across a wide range of healthcare topics published since 1980. Chen et al. assessed the quality of TCM CPGs and non-TCM CPGs published in the peer reviewed medical journals. All of the domain scores in our study were lower than the international CPGs, particularly in the “rigour of development” and “editorial independence” domains, and higher than Chen et al. Low quality TCM CPGs have low scores, particularly within the domains of “rigour of development”, “applicability” and “editorial independence”. Specifically, a low score for “rigour of development” is worrisome because this domain may be a stronger indicator of quality than any of the other domains in AGREE II instrument. CPGs have been widely developed and support implementation with the aim of improving healthcare processes and patient outcomes, so using a standardised appraisal instrument to make judgement the quality of CPGs is very important.

Most of the TCM CPGs described their specific and focused clinical questions and target populations well. Though the score of “scope and purpose” domain was low than 50%, big improvement in the “scope and purpose” domain was found over time in the most recent 5 year period (Table 3). This can be improved by providing specific information and clear summaries.

Similarly, the scores in the “stakeholder involvement” domain were low. These low scores reflect the lack of multidisciplinary teams. Half of the guidelines were developed by only one professional organisations or agencies, and few guidelines included methodologists. The guideline development groups involved methodological experts who could ensure that methodological checks were correctly applied and that the development process was fully documented.16 Moreover, none involved patients in the development process or was piloted among end-users.

For the “rigour of development” domain, most of the TCM CPGs did not report the systematic methods of searching for and selecting evidence or did not describe specific evaluation or recommendation systems. Few of the guidelines were externally reviewed prior to publication. Furthermore, none of the guidelines provided evidence of pilot testing, which is an important issue that would ensure that the guideline can be clinical utilised.

The low score of clarity and presentation reflect reporting of the key information of the full text was not sufficient, which indicate more attention should be payed to improve the reporting quality. Recently, the AGREE working group developed a new checklist for improving the reporting quality of CPGs,32 which can be used in the future TCM CPGs development.

The lowest scores on “applicability” and “editorial independence” were particularly conspicuous. Most TCM CPGs did not consider
organisational barriers to CPG implementation and did not supply monitoring criteria to assess the CPGs' effect. These findings appear to be fairly widespread among the CPGs. The low scores may be the result of poor reporting and could be avoided if the guideline authors provided the electronic edition in the website for free or support that addressed the process concerns listed in the documents. In China, it is widely accepted in medical journals to state the conflict of interest, but such statements are still not widely used in CPG development. The developers of CPGs need to pay more attention to these domains during the development process.

Burgers et al. reported that the quality of guidelines developed by non-industry-funded organisations was higher than those not reported funding. However, in our study, since overall guideline quality was low, it becomes harder to find any difference between industry-funded and non-industry-funded guidelines.

The quality of CPGs published in journals indexed in CSCD was better than those published in non-indexed journals on four domains. This is not surprising because CSCD-indexed journals are required to meet several criteria, comparable to those in non-CSCD-indexed journals, in other words, the peer review in CSCD-indexed journals is more rigorous than in non-CSCD-indexed journals.

In this study, over 60% TCM CPGs did not use an evidence grading system to rate the quality of evidence and recommendations, which might not be convenient for clinical professionals to use the guidelines. And the other TCM CPGs used different grading systems to assess the quality of evidence and recommendations (Table 1). Specifically, there was a lack of strong relevance between the quality of evidence and the strength of recommendations, and many did not consider the consistency of results among the evidences. Consequently, many other organisations developed their own grading systems. Recently, the most widely used and known grading system is the Grading of Recommendations Assessment, Development and Evaluation (GRADE). The aim of this group was to develop a consolidated grading system for evidence quality and strength of recommendations to suggest that further CPGs use a comparable uniform grading system to evaluate the quality of evidence and strength of recommendations.

This review has a few limitations. We included TCM CPGs in journals and books, but we may have missed guidelines published in other forms such as web page, which may be rather more likely to be of lower quality than TCM CPGs included in this study. The AGREE II instrument only assesses the reporting of the different items and not the content validity of the recommendations. TCM CPGs developers could include some of the items listed in AGREE in process, but they did not report them, which may understate the quality of TCM CPGs.

5 | CONCLUSIONS

In conclusion, the quality of TCM CPGs has remained suboptimal according to AGREE II instrument evaluation. The use of AGREE II in the development process ensures that these considerations are incorporated, and more efforts must be made to improve the quality of TCM CPGs. Therefore, an evidence-based method should be used, and reporting the full texts according to AGREE II checklists for the further TCM CPGs development to ensure the translation of evidence into practice.

AUTHORS’ CONTRIBUTION

L.Y., Y.L.C, X. Q. W. and X. E.S. had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. L.Y. and K.H.Y. contributed to drafting and critical revision of the article; L.Y., Y.L.C., X. Q. W. and X. E.S. contributed to the data collection, AGREE process, and data analysis; T.K.G and Y.F.W. contributed to the study design and critical review. All authors contributed to the interpretation of study data and critically reviewed and approved the article before submission.

CONFLICTS OF INTEREST

For all authors, there are no potential conflicts of interest, including no relevant financial interests in any company or institution that might benefit from this publication.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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