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Enhancing CPM Guideline Transparency: The JUST-CPMPG Framework

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ABSTRACT

Current reporting checklists are insufficiently thorough and detailed to be used in Chinese patent medicine (CPM) standards. Based on the Reporting Items of Practice criteria in Healthcare (RIGHT) statement, this research attempts to define reporting criteria for CPM. To create the first pool of reporting items for CPM guidelines, we used data from the RIGHT statement and its expansions, current reporting requirements for TCM, and CPM guidelines. To hone and clarify the items, 17 experts from various disciplines took part in two rounds of the Delphi process. Ultimately, the RIGHTforCPM checklist was evaluated and approved by 18 reputable professionals in the area of TCM and reporting criteria. The RIGHT for CPM checklist, which has 51 items divided into seven categories and 23 subjects, was created by adding 16 new things and changing two items from the original RIGHT statement. Four sections (Basic information, Background, Evidence, and Recommendations) and seven topics comprise the new and revised items: title/subtitle (one new and one revised item), registration information (one new item), brief description of the health problem (four new items), guidelines development groups (one revised item), health care questions (two new items), recommendations (two new items), and justification/explanation for recommendations (six new items). In addition to helping practitioners better comprehend and apply CPM rules, the RIGHT for CPM checklist is dedicated to giving users direction for thorough, transparent, and detailed reporting.

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1. Introduction

China is unusual in that its basic, secondary, and tertiary healthcare systems include both Western medicine and traditional Chinese medicine (TCM). Approximately 40% of medical services are provided by TCMac [1]. The healthcare system heavily relies on a variety of TCM procedures, including Chinese herbal medicine [2], acupuncture [3], Tai chi [4], and Chinese patent medicines (CPM) [5]. Since TCM is becoming more and more well-known abroad, its globalization is not only a natural need but also a historical imperative [6]. The 72nd WorldThe official incorporation of TCM into the global mainstream medical classification system was marked by the Health Assembly's review and adoption of the 11th version of the International Classification of Diseases (ICD-11), which included a chapter on traditional medicine derived from TCM for the first time [7].
In order to standardize clinical practice and provide doctors suggestions based on the most recent research, clinical practice guidelines are essential. In China, both TCM and Western medicine guidelines are widely used and helpful in directing medical practice [8]. Although TCM recommendations took a while to create, their number has increased quickly and their quality has greatly improved [9, 10]. However, there is still need for improvement in the TCM standards' methodology and reporting quality [11]. Several attempts have been made to do this. Based on the RIGHT statement[13], a checklist (RIGHT for TCM)[12] for TCM criteria was created for reporting. Based on the evaluation of recommendations, Research and Evaluation II (AGREE II) criteria, an evaluation checklist

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appropriate for Chinese recommendations (AGREE-China)[14] was created for methodological quality [15]. The evolution of these assertions collectively encourages the standardization, openness, and scientificization of TCM standards.

In China and even globally, CPMs—which were established based on TCM theory—are a crucial component of the drug supply security framework. In China, the Ministry of Health's criteria for Chinese patent formulation contain almost 4000 CPMs, whereas the Pharmacopoeia of the People's Republic of China (2020 Edition) has 1617 Chinese patents. CPMs accumulate a lot of data and evidence and are essential in the treatment, prevention, and rehabilitation of many illnesses [16–18]. A standardized research project on the clinical application of CPM for the treatment of dominant illnesses was formed at the national level to encourage the logical use of CPMs, which led to a sharp rise in the number of CPM recommendations. Some aspects relevant to CPM are not included in the RIGHTforTCM checklist, and there is presently a lack of a comprehensive examination of the reporting quality of CPM guidelines [12]. The specifics of the selection and inclusion criteria, sources, treatment plan, route of administration, appropriate indications, and description of concurrent conditions should all be included in depth in CPM guidelines.

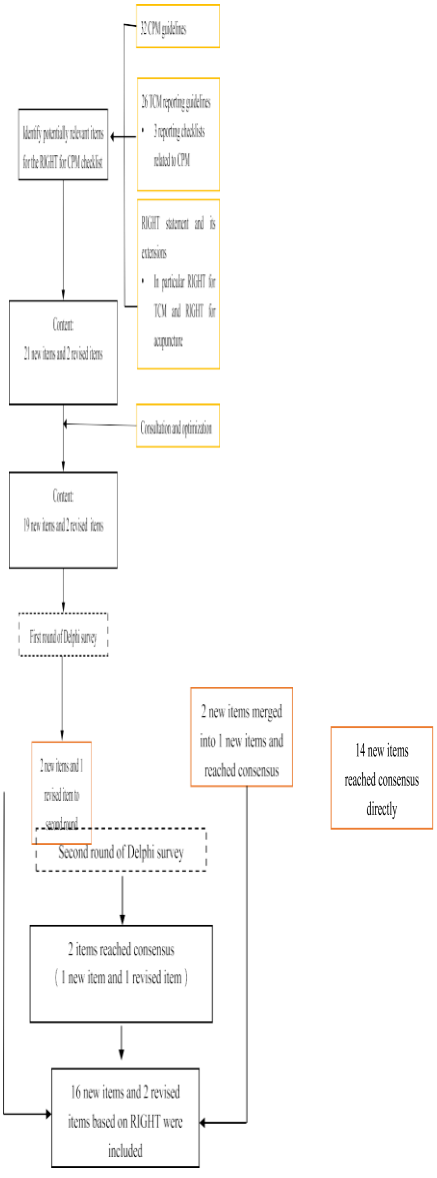

Fig.1. TheprocessofgeneratingtheitemsfortheRIGHTforCPMchecklist.

prescription drugs, pharmaceutical safety measures for certain groups, and advice for doctors. Consequently, a customized reporting checklist for CPM requirements must be created. Currently, the only global reporting standard that may be used to inform clinical practice, public health, and health system standards is the RIGHT statement [13]. In order to improve reporting quality and openness in recommendations, more than 100 investigators in more than 20 countries have utilized the RIGHT statement to assess the quality of guidelines up to this point [19–23]. The RIGHT working group started the creation of an extension for CPM guidelines (RIGHTforCPM) with the goal of promoting improved reporting, distribution, and use of CPM-focused recommendations in order to enhance the reporting quality of CPM guidelines.

2. Techniques

3. The published protocol describes the development process of the RIGHTforCPM checklist [24]. The development was carried out exactly according to the plan, with the exception of adding a clinical specialist in TCM to the head advisory group. The many stages of the development process are shown in Fig. 1. formation of the working group
A coordination group, a Delphi panel, and an advisory group are all part of the RIGHT for CPM working group. According to WHO guidelines, all collaborating participants declared their interests [25], and none of them had any financial or intellectual conflicts of interest that might have affected the study. The coordination committee initially developed and discussed the contents at each stage of the development process. Discussions were undertaken to obtain a consensus on either substantial revisions (significant changes to the items, merging or eliminating items, and adding new items) or minor modifications (revisions of the items' details) based on comments from the Delphi panel and advisory group.

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In order to maintain reason and scientific validity, a decision was reached after discussion with the project initiators (YL Chen, CP Wen) if there were significant disagreements among the working group members. Gathering the first items Through thorough evaluations of (1) CPM guidelines published in journals, (2) TCM reporting rules, particularly those pertaining to CPM research, and (3) the RIGHT statement[13] and its ex-tensions[12,26–29], the coordination team members developed the first elements of RIGHT for CPM. The advisory group's input led to revisions to the list. To gather published CPM guidelines and TCM reporting guidelines, the coordination team examined the following databases: PubMed, Embase, CochraneLi-brary, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese biomedical literature service system (CBM), Wanfang Data, and VIP. Additionally, the website of RIGHT (http://www.right-statement.org/) provided us with the RIGHT statement and its expansions [12,13,26–29]. The protocol contains the trieval strategy [24]. The coordination committee evaluated the reporting quality of the included CPM recommendations using the RIGHTforTCMchecklist [12]. Items that are especially pertinent to CPM standards but do not conflict with the RIGHT for TCM checklist were carefully chosen [12]. Concurrently, while developing the elements required for the RIGHT for CPM checklist, the coordination group took into account specific features of the TCM reporting rules, especially those in the CPM sector. Following a review by the advisory group specialists, the first pool of items for the RIGHT for CPM checklist was created. The coordination group then jointly prepared a list of prospective items for the RIGHT for CPM checklist, which were then carefully reviewed, improved, and consolidated. Delphiconsultation The RIGHT statement and the original set of elements for the CPM checklist served as the basis for the coordination team's electronic questionnaire design. To help Delphi panels comprehend each subject, the questionnaire typically includes one or two illustrations. To enable Delphi specialists to provide helpful criticism and recommend changes for the items, open-ended questions were included. A total of seventeen technical specialists from the Delphi panel were asked to fill out the questionnaire on their own. The specialists possess extensive knowledge and/or real-world experience in the areas of TCM research, evidence-based medicine, guideline methodology, and reporting recommendations formulation. We had two Delphi consultation rounds in order to get to an agreement on the items' inclusion [30, 31]. The experts were asked in both rounds whether they agreed, disagreed, or were unsure about the inclusion of this item, as well as any amendment ideas [29]. The Delphi experts were also asked to suggest any other issues they thought might be pertinent in the first round. Both new items presented in the first round by at least one responder and issues for which agreement could not be reached were included in the second round. Following both rounds, we gave the panelists thorough input, updated a few things, and examined the Delphi experts' viewpoints. The proportion of panelists who agreed with the inclusion was used to determine the degree of agreement for the achievement. The following guidelines served as the foundation for the items' inclusion: (1) Things having a consensus level of less than 75% were eliminated; (2) Things with a consensus level of 75% or more and no major divergent opinions were directly taken into consideration for inclusion; (3) items with a consensus of 75% or higher but with significant divergent opinions from the panelists in the first round were taken to the second round of the Delphi survey following discussion and revision among the coordination group; and (4) items that received agreement of 75% or higher without divergent opinions were included in the second round of the Delphi survey. Examining and accepting the checklistThe final version of the RIGHT for CPM checklist was created by the coordination group after a preliminary version was created based on the findings of the two Delphi survey rounds. The advisory group was then asked to evaluate, edit, and approve all of the items. 3. Findings Creation of the Correct for CPM Checklist The coordination committee methodically gathered the RIGHT statement [13] with all completed extensions, 26 TCM-related reporting standards (Appendix 2), and 32 CPM recommendations published in journals (Appendix 1). The coordination committee gathered three items from the original RIGHT statement that required adjustment, as well as 21 initial issues not addressed by the original RIGHT checklist for possible inclusion in RIGHTforCPM. An initial pool of 19 new items and two updated items from the RIGHT checklist were developed after consultation with the head supervisory group (Ap-pendix 3). Based on the original set of items, a Delphi questionnaire was created. Responses from all 17 panelists were received in both rounds of the Delphi consultation. Appendix 4

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contains the Delphi panels' basic information. Fifteen new items and two altered items obtained agreement out of the 68 free-text comments gathered in the first round of the Delphi poll. We brought three new items to the second Delphi round. One item [Offers ideas for non-TCM physicians on the use of CPM. (If relevant)] was eliminated since its consensus level was only 64.7%, while two other items ultimately obtained consensus. Appendix 5 displays the consensus levels for the new and updated items. Additionally, the coordination group made changes to the some items' wording based on input from experts. Following each Delphi survey round, the coordination committee also addressed the experts' feedback. The coordination group then sent the consensus items to the advisory group for approval and assessment, and they made some further refinements in response to the comments. Table 1 displays the completed version of the RIGHT for CPM checklist. The checklist has seven sections, twenty-three subjects (including one new topic, Registration information), and fifty-one items (16 new items, two items that were amended from the original RIGHT checklist, and 33 items that were directly taken from the original RIGHTchecklist). Justification for the RIGHT for CPMchecklist's updated and expanded items fundamental details. -Item S1 (Title/subtitle): Indicate in the title that the page is a Chinese patent medicine guideline. "Clinical Practice Guidelines on Treating Influenza in Adult Patients with Chinese Patent Medicines" is one such [32]. -ItemR1c(Title/subtitle): Explain the purpose of the guideline, such as nursing care, prevention, treatment, or rehabilitation. -Explanation: The majority of Chinese patent medicine recommendations emphasize nursing, treatment, prevention, and rehabilitation. Consequently, guidelines

Table1
TheRIGHTforCPMchecklist.

Section/Topic NumberItem	
Basicinformation	
Title/subtitle 1a	Identifythereportasaguideline, thatis,with "guideline(s)" or "recommendation(s)" in the title.
1b	Describe the year of publication of theguideline.
S1	Identify the document as a Chinesepatentmedicineguidelineinthetitle.
R1c	Describethefocusoftheguideline,suchastreatment,prevention,rehabilitation,or nursing care.
Executivesummary 2	Provideasummaryofthe recommendationscontainedintheguideline.
Abbreviations andacronyms3	Defineneworkeyterms,andprovidea list of abbreviations and acronyms ifapplicable.
Correspondingdeveloper 4	Identifyatleast1corresponding developerorauthorwhocanbecontacted about the guideline.
Registrationinformation S2	Indicatewhethertheguidelinehasbeen registered,andifso,providedetailsabout the registrationplatform andapprovalnumber.

Background

The RIGHT statement's initial item was updated to include kinds like screening and diagnosis, which are often not relevant for CPM recommendations. -ItemS2 (information about registration): Indicate whether the guideline has been registered and, if yes, provide the approval number and registration platform information. The Practiceguideline REgistrationfortransPAREncy (PREPARE)(http:/guidelinesregistry.CN/) has this guideline registered (PREPARE-2022CN445), for instance. [33]. -Explanation: Registering clinical practice guidelines may boost transparency, enhance cooperation, and cut down on duplication [34]. Before beginning the development process, we advise registering guidelines on the PREPARE platform. This encourages openness and prevents duplication of effort throughout the process. Background. -Item S3 (Short explanation of the health issue): Explain the classification, etiology, pathophysiology, diagnosis, and symptoms of illnesses from a Chinese medical standpoint. For instance: "Functional dyspepsia, a currently prevalent functional A succinct explanation of the health issue or issues

The purpose of the guideline and its particular goals Give an overview of the problem's fundamental epidemiology, including its prevalence/incidence, morbidity, mortality, and the cost (including financial) it causes. S3 Explain the categorization of illnesses from a Chinese medical viewpoint, including its categories, etiology, pathophysiology, diagnostic criteria, and syndromes. S4: Explain how Chinese patent medications are now being used to treat the condition. S5: Explain the benefits and

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drawbacks of using Chinese patent medications to treat the disease.
S6 Explain the need or importance of creating guidelines for the use of Chinese patent medicines on this subject. 5 Explain the purpose of the guideline and its particular goals, such as enhancing quality of life, reducing costs, or improving health indicators like mortality and disease prevalence. The term "functional gastrointestinal disease" refers to a group of clinical symptoms that include persistent or recurrent episodes of epigastric pain, upper abdominal burning sensation, postprandial fullness, early satiety, eructation, hiccups, nausea, and other upper abdominal discomfort. It falls under the TCM categories of "epigastralgia" and "gastric distension." The major symptoms of dyspepsia are upper abdominal fullness, which manifests as "gastric distension," and upper abdominal pain, which manifests as "epigastric pain." [35]. -Item S4 (Short description of the health issue): Explain how Chinese patent medications are currently being used to treat the illness. "Inclinical diagnosis and treatment, TCM syndromedif" is one example. One or more target populations 7 Describe the key group or populations that are impacted by the guideline's suggestion or recommendations. End users and settings 8a Describe the guideline's intended main users, including primary care physicians, clinical specialists, public health practitioners, program administrators, and policymakers, as well as other possible users. 8b Explain the location or benefits and drawbacks of using Chinese patent medications to cure illnesses. -For instance: "Currently, CPMs in the treatment of FAM have issues with indication, therapeutic effect, and ambiguous effect characteristics." Three national TCM guidelines either don't address CPMs at all or provide few details on how they are made and used. Lack of understanding of TCM philosophy and practice may lead to incorrect syndrome distinction in clinical practice, which may result in inappropriate doses, combining Chinese and Western medications without good justification, and unwarranted CPM combinations. Standardized therapy is thus crucial for the prevention and management of bronchialasthmain China. [37]. -Item S6 (Short explanation of the health issue): Explain why it is important or necessary to provide guidelines for the use of Chinese patent medicines on this subject.
-For instance, "CPM is a significant part of TCM and is widely used in the treatment of kidney disease in China." CPM has emerged as a crucial and supplementary therapy to the all-encompassing therapeutic program for chronic kidney disease (CKD), particularly for outpatients with stable symptoms. Nonetheless, there are still a lot of instances of incorrect CPM, and in particular, Western medicine doctors' lack of systematic training in syndrome classification and treatment is likely to impact the effectiveness of CPM and might result in negative side effects. Therefore, it is necessary to develop guidelines for the clinical use of CPM to treat stages 3–5 of CKD (without dialysis). [38].
-Item R9a (Guideline development groups): Explain the selection process for each contributor including their roles and duties (e.g., steering committee, guideline panel, external reviewers, systematic review team, and methodologists). The guideline panel should include at least one clinical expert in Western medicine and one expert with a background in pharmacology in addition to clinical TCM specialists. -Explanation: The primary goal of creating CPM guidelines is to encourage the proper use of CPMs. Western medicine clinical specialists' participation in the guideline-development process may help make the recommendations more understandable and applicable to physicians with Western medical training. Clinical pharmacy specialists may improve CPM recommendations to more closely mimic clinical practice. Proof.

settings for which the recommendation is intended, such as inpatient hospitals, low- and middle-income nations, or primary care. Fertilization offers special benefits. CPMs are frequently utilized in clinical practice and are more portable, patient-friendly, and convenient than traditional Chinese herbal decoctions. Research reveals that roughly 70% of CPMsare recommended by Western medicine practitioners. Meanwhile, the combinationof TCM and chemical medicine is universal in clinical practice, and druginteractions may strengthen the drug efficacy and alleviate side effects. However, because the current indications, therapeutic effects, andcharacteristicsofTCMforthetreatmentofdepressivediso rdersareunclear,leadingtothegeneralproblemofTCMphysi ciansin usingTCMfordrugselection by disease species and lack of syndrome differentiation, which not only haspotential risks but also reduces the clinical utility of TCM." [36]. -Item S5 (brief overview of the health issue): Explain the development groups for the guidelines R9a Explain the selection process used for each member of the steering committee, guideline panel, external reviewers, systematic review team, and methodologists, as well as their roles and duties. The guidelines panel should include at least one clinical expert in Western medicine and one expert in inclinical pharmacy in addition to clinical TCM specialists. 9b List all people engaged indeveloping theguideline,includingtheir (continuedonnextpage)

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-Item S7 (Health care questions): Explain the sources of Chinese patent medications that will be covered by the guidelines (e.g., pharmacopoeia, essential drug lists, medical insurance catalogues, etc.). -For instance: "These CPMs were chosen based on the results of drug prescriptions and were further supplemented with references from the national essential drug list, the national pharmacopoeia, the national Medicare list, and pertinent COPD guidelines." We thoroughly gathered data on CPMs from clinical investigations on COPD by using research material pertaining to the disease. [39]. -Item S8 (Questions on Health Care): Explain the rationale (approaches and outcomes) for the selection of Chinese patent medications in the guide. -For instance, "After combining the aforementioned CPMs, the expert consensus technique ultimately finds that 6 CPMs The final guideline suggests a total of eight CPMs, two of which are based only on expert clinical experience and two of which are backed by considerable data. [40]. suggestions.

-Item S9 (Recommendations): Give specifics regarding the target illness, such as its severity and stages (or levels/grades).

As an example, "Kuntai capsules are advised as a stand-alone treatment for menopausal syndrome." Hot flashes, irritability, sleeplessness, palpitations, dizziness, tinnitus, vaginal dryness, and dyspareunia are among the mild to moderate symptoms that they are recommended for. These signs and symptoms are often linked to kidney yin deficit. [41].

-Item S10 (Suggestions): Explain the signs and symptoms of the ailment that is being treated using Chinese patent medications.

-For instance: "Depending on how their symptoms manifest, patients with acute myocardial infarction may benefit from complementary treatment with particular CPMs in addition to standard Western medicine therapy." For example: (1) Shenmai injection is advised when there is shortness of breath, hand fatigue, dry mouth, heartburn in the hands and feet, and slight tongue enlargement (syndrome of Qi Yin and two deficiencies); (2) Musk Buxin pills are advised when the chest flank is full, lips are purplish, and tongue is purple or dark (syndrome of Qi Yin and bloodstasis). [42].

-Item S11 (Justification/Explanation for Recommendations): Explain the make-up, origin, or source of the suggested Chinese patent medications (if any). As an example, "The pediatric diarrhea patch is made of cloves, cinnamon, and piperplongum, three medications used to treat cold diarrhea caused by deficiencies. [43]. -Item S12 (Justification/Explanation for Recommendations): Explain the formulation, application, and dosage of the suggested Chinese patent medications. -For instance, "Usage instructions: (1) Dosage: a. Orally, six tablets three times a day; b. Capsules: insuit, two capsules each dosage, three times a day. 28 days might be utilized for two or three courses. [44]. -Item S13 (Justification/Explanation for Recommendations): Explain the suggested Chinese patent medicine's mode of administration (e.g., oral administration, external usage, inhalation, etc.). For instance, "Ultrasonic atomization of Houttuynia cordata eyedrops alone is recommended to alleviate dry eye symptoms and enhance meibomiangland secretion in patients with dry eye primarily induced by factors like ocular congestion and local eye issues." [45]. -Item S14 (Justification for Recommendations): Explain the length or course of therapy using the suggested Chinese patent medications. -For instance, "Suggested use: oral, five tablets three times a day, or as directed by the doctor." It is advised that the treatment be received for three to six months. [46]. -Item S15 (Justification/Explanation for Recommendations): Describe the known safety data for the suggested Chinese patent medications as well as any safety measures or concerns for certain groups, such as children, the elderly, pregnant women, those with allergies, etc. -For instance, "Notes: a. It is not recommended to take the treatment when you have a cold; b. People who have menorrhea should not receive the treatment; c. Cold foods are contraindicated." Safety: One instance out of 204 in the group receiving controlled blood capsules had elevated urine red blood cells and white blood cells, however this was shown to be unrelated to the medication. [47]. -Item S16(Rationale/explanation for recommendations): Provide the name or names of any other drugs that should be used in conjunction with the suggested Chinese patent pharmaceuticals, if any. For instance, "Tianzhi granule treatment for 24 weeks improved cognitive function and reduced psycho-behavioral symptoms or liver yang hyperactivity syndrome in patients with mild to moderate vascular dementia (VaD), and the combination with donepezil showed a synergistic effect on cognition." [48].

2. Conversation Key findings The RIGHTforCPM extension, which was created based on the RIGHT statement [13], adds to the number of extensions of the RIGHT statement for TCM and offers particular reporting items for recommendations centered on the usage of CPM. To create RIGHT for CPM, 16 additional elements were added to the RIGHT statement, covering topics that are very crucial to report under CPM rules. Four aspects of the guideline are covered by the supplementary items:

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background, evidence, recommendations, and basic information. Results pertaining to other TCM studies and checklists

We were pleased to discover during the creation of the RIGHTforCPMchecklist that certain CPM guidelines are listed on the international guidelines registry platform (PREPARE), with information accessible in both Chinese and English. This will significantly increase the transparency of the guideline development process and minimize duplication. As a result, we included a section to our RIGHT for CPM checklist for reporting registration information. Future iterations of the primary RIGHT statement may also take this into account [13]. There are no items specifically focused on CPM in the two other checklists in the realm of TCM guidelines reporting, RIGHT for TCM [12] and RIGHT for acupuncture [27]. In the process of creating RIGHTforTCM, Several CPM-related topics were taken into consideration and talked about. These elements, however, were left off of the final RIGHT for TCM checklist as they were unable to be agreed upon throughout the Delphi process. Thus, a significant vacuum in the current reporting guidance for TCM guidelines is filled in part by the RIGHTfor CPM checklist. The use of CPMs in TCM medicine is anticipated to rise in China and maybe elsewhere in the future because to their shape, which permits consistent dose and easy ingestion. Although CPM is recommended in many TCM guidelines, there is now a growing body of guidelines designed expressly for the therapeutic use of one or more CPMs. It indicates that a wide variety of TCM recommendations may be used with the RIGHTforCPM checklist. While guidelines specifically designed for the clinical application of CPMs can be reported by referring to both the RIGHTforTCMchecklist[12] and the RIGHTforCPMchecklist, we propose that future TCM guidelines that involve recommendations or principles of recommendations for CPMs be reported by referring to the item from the RIGHTforCPMchecklist. Limitations and Implications The RIGHT for CPM checklist may be used for a variety of objectives by different stakeholders. First, while creating guidelines, the creators might use this checklist as an organized foundation. Second, when evaluating CPM guidelines for publishing, journal editors and peer reviewers should use this checklist to make sure that reporting is inclusive and clear. Third, this checklist may be used by practitioners in both TCM and Western medicine to thoroughly and understandably assess guidelines about CPMs, serving as a guide for the sensible use of CPM. There are several limitations to this work. First, the RIGHTforCPM checklist has not yet undergone usability validation to evaluate its practical applicability in reporting adherence to CPM guidelines. Thus, we want to use the RIGHTforCPMchecklist to evaluate the reporting quality of CPM recommendations published in different journals and test the tool's usability. Second, certain originally suggested items did not achieve agreement, even though the checklist items were agreed upon after two rounds of the Delphi process and by an 18-member soft head visory panel. For example, there is still debate about appropriate guidelines for non-TCM doctors using CPM. 3. Findings Based on the agreement of a multidisciplinary workgroup, the RIGHTforCPM checklist is a useful tool for improving the caliber and openness of CPM standards. The RIGHTforCPMchecklist is a tool that TCM guidelines creators, journal editors, peer reviewers, and researchers are urged to use when developing, reviewing, and evaluating CPM guidelines. The efficient and successful use of CPMs in clinical practice will be improved by these initiatives, which will also contribute to the transparency, availability, and accessibility of CPM guidelines.

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