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Guideline

Publishing clinical prActice GuidelinEs (PAGE): Recommendations from editors and reviewers[☆]

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ABSTRACT

Transparency Ecosystem for Research and Journals in Medicine (TERM) working group summarized the essential recommendations that should be considered to review and publish a high-quality guideline. These recommendations from editors and reviewers included 10 components of essential requirements: systematic review of existing relevant guidelines, guideline registration, guideline protocol, stakeholders, conflicts of interest, clinical questions, systematic reviews, recommendation consensus, guideline reporting and external review. TERM working group abbreviates them as PAGE (essential requirements for Publishing clinical prActice GuidelinEs), and recommends guideline authors, editors, and peer reviewers to use them for high-quality guidelines.

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Abbreviations: PAGE: Publishing clinical prActice GuidelinEs; TERM: Transparency Ecosystem for Research and Journals in Medicine; IOM: Institute of Medicine; WHO: World Health Organization; GIN: Guidelines International Network; AGREE II: Appraisal of Guidelines for Research and Evaluation II; RIGHT: Reporting Items of Practice Guidelines in Healthcare; PICO: patient, intervention, comparison and outcome; GRADE: Grading of Recommendations Assessment, Development and Evaluation.

[☆] Our journal and Journal of Evidence-Based Medicine will publish this article jointly.

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Introduction

In 2011, the Institute of Medicine updated the definition of clinical practice guideline,^{1,2} which implied that the development of clinical practice guidelines is moving toward an era of more evidence-based and transparency.² Although some international organizations, including World Health Organization and Guidelines International Network, as well as many methodologists have published a number of manuals and articles on guideline development, reporting and evaluation,^{3–7} the primary target users of these documents are the developers or researchers of the guidelines. However, editors and reviewers of academic journals often find that authors submit guidelines that lack a lot of key information and critical contents, which affects the judgment of the quality of the guidelines. In addition, previous studies have not provided specific recommendations on what annexes need to be submitted along with the guideline manuscript by guideline developers for editors and reviewers to better assess the transparency of the guidelines. Therefore, it is necessary to summarize the essential recommendations that should be considered to review and publish a high-quality guideline. Editors and journals may consider including the following requirements in Instructions for Authors, or integrating them in the journal's submission system. So that authors can submit relevant materials as comprehensively as possible at the submission stage.

Systematic review of existing relevant guidelines

Systematic review of guidelines refers to a systematic and comprehensive search of all relevant guidelines or recommendations in a field or specific clinical question, and a critical evaluation of developing principles and methods was conducted to present the current status and evidence gaps of guidelines or recommendations in the field.⁸ The process is essentially similar to the classical systematic review of interventions, with differences mainly in that (1) the review team should include guideline developers; (2) the samples included are guidelines rather than clinical studies; (3) the quality evaluation tool is Appraisal of Guidelines for Research and Evaluation II (AGREE II)⁹; (4) the analysis outcome may be the recommendations, etc. Before initiating a new guideline, conducting a systematic review of existing relevant guidelines^{10,11} not only can help developers to determine the necessity for the new guideline (deciding whether it should be to update, adapt or directly use existing recommendations), but also help developers to obtain additional data and information (such as key clinical questions, the evidence, and recommendations) for new guidelines.¹²

We recommend that authors should conduct a systematic review of similar existing guidelines prior to their guideline development, and when their new guidelines are submitted, the main findings of the systematic review of guidelines should be included in the guideline or submitted it as an attachment.

Guideline registration

Guideline registration refers to the registration of important information such as the title, purpose, developers, methods, and conflicts of interest of the guideline through a public registration platform before guideline development in order to promote transparency of guideline development, avoid duplication and facilitate guideline implementation and dissemination.¹³ Guideline registration can also increase opportunities for engaging patients and the public in guideline development and incorporate the values and preferences of patients and the public. Guideline developers, funders, researchers, patients, practitioners, reviewers, and editors can benefit from guideline registration. The core items of the

registry include: basic information about the developer, background, methods of evidence retrieval, synthesis and grading, funding sources, conflicts of interest management, external review, etc.¹³ Existing registration platforms for guidelines include the International Practice Guideline Registration Platform (<http://www.guidelines-registry.org>) and the Guidelines International Network registration platform (<https://g-i-n.net/international-guidelines-library/>). When the new guideline is published, the registration number should be reported.

We recommend that developers should register their guidelines at registration platforms when they decide to launch a new guideline or update/adapt one. The registration number should be reported in the guideline and authors/developers should submit supporting documentation regarding the registration of the guidelines to the submitted journal.

Guideline protocol

A guideline protocol is a planning document that describes how a guideline will be developed, including detailed process of the methods and timeliness.³ A guideline protocol can increase the transparency of the guideline development process, and help developers improve the efficiency of development. For journal editors, reviewers, and clinicians, comparing guideline protocols can help them understand the entire steps of guideline development and judge the quality of the final published guideline. Ideally, a protocol should be written in accordance with the appropriate reporting guidance.¹⁴ The Reporting Items of Practice Guidelines in Healthcare (RIGHT) working group is developing a checklist for guideline protocols, and the checklist has been published;¹⁵ developers can refer to the core items of RIGHT or other protocols.^{7,16–18}

We recommend that developers should write a protocol prior to the development of the guideline. When the guideline is published, it should be stated in the guideline where the protocol is available or submitted as an attachment. Developers should describe any changes in the full text of guideline what is inconsistent with the protocol.

Stakeholders

Besides content specialists (clinical expertise), panelists should come from other disciplines relevant to the guideline, including methodologists, health economists, patient representatives, et al. Clinical pharmacists and nurses should be also included if recommendations are relevant to them.¹⁹ Multidisciplinary panelists can play better roles in selecting clinical questions, retrieving and evaluating research evidence, and formulating recommendations, as well as reducing potential financial and professional conflicts of interest.¹ On the other hand, multidisciplinary development team is an important indicator for evaluating the methodological and reporting quality of guidelines.^{7,9} Generally, the multidisciplinary panelists can be divided into a steering committee, a secretary group, an evidence review group, a consensus group for recommendations, and an external review group. However, those groups can be added, subtracted, or combined according to the specific content and characteristics of the guideline.²⁰ A guideline should also have a chief clinical expert and a chief methodologist.

We recommend that authors should submit a detailed document of which stakeholders were involved in guideline development and what their corresponding roles and specific tasks.

Conflicts of interest

Conflicts of interest arise when primary interests (public interests) are influenced by secondary interests (personal interests)

Table 1
PAGE (Publication of Clinical Practice Guidelines: essential recommendations).

Component	Submission
Systematic review of existing relevant guidelines	Submit a systematic review of existing relevant guidelines as an attachment, or add the main findings of the systematic review in the guideline.
Guideline registration	Submit a registration number and report the number in the guideline.
Guideline protocol	Submit a guideline protocol and report where the protocol is available in the guideline.
Stakeholders	Submit a document of which stakeholders were involved in guideline development and what their corresponding roles and specific tasks.
Conflicts of interest	Submit a declaration form of conflicts of interest (both financial and non-financial) for each member, as well as management methods, process, and results.
Clinical questions	Submit a document of the methods and processes used to collect and select clinical questions.
Systematic reviews	Submit systematic reviews that supported recommendations.
Recommendation consensus	Submit a document of decision-making process and minutes of meetings from evidence to decisions.
Guideline reporting	Submit a table indicating on which page and in which section the relevant content appears based on AGREE reporting checklist or the RIGHT checklist.
External review	Submit a document of the external review process, the review comments, and the guideline changes made to these comments.

in guideline development.¹ Conflicts of interest may cause beneficial effects to be overestimated and harmful effects to be underestimated, which is an important potential source of bias in guideline development, and may lead to a crisis of confidence in guideline.²¹ Panelists with financial conflicts of interest are more likely to make judgments and decisions in favor of the recommended drug at the stages of clinical question identification, evidence inclusion and evaluation, and recommendation formation in guideline development. Panelists with non-financial conflicts of interest are more likely to make judgments and decisions in favor of their own specialty or field.²² It is essential to establish an independent conflicts of interest management committee. All participants involved in the development of the guidelines should be under the supervision of this management committee.^{23,24}

We recommend that authors should submit the declaration form of conflicts of interest for each member, as well as management methods, processes, and results.

Clinical questions

The source, number, and clarity of clinical questions in guidelines not only determine their recommendations but also have an impact on their dissemination and application, especially if the clinical questions have low relevance to frontline clinicians or the questions are poorly expressed.²⁵ Clinical questions can be obtained from the current literature (relevant guidelines, systematic reviews, or clinical studies) and from a survey of representative guideline users. Whether it is derived from the literature or research, the original questions need to be removed, combined, ranked according to their importance, and formulated into PICO (patient, intervention, comparison and outcome) style. In general, clinical questions with a high disease burden, high social concern, controversy, large differences in treatment or emerging new research evidence are more likely to be included in the guideline, but the total number of finalized questions will be limited to between 10 and 20 generally.²⁶

We recommend that authors should submit a detailed description of the methods and processes used to collect and select clinical questions.

Systematic reviews

Systematic review refers to the rigorous search, evaluation and synthesis of all relevant studies on a specific topic using bias reduction strategies. Meta-analysis may be, but not necessarily, used as part of this process.²⁷ The new definition of guidelines requires that recommendations should be based on evidence from

systematic reviews.¹ Given the limited resources and time available, and the rapid growth in the number of systematic reviews published in journals in recent years, guideline developers may make full use of existing systematic reviews. However, the quality and timeliness of the proposed systematic reviews need to be assessed before they are used to support the recommendations. If no compliant systematic reviews are available, the systematic reviews required for the guideline should be completed in accordance with the requirements of Cochrane reviews.²⁸ The quality of the evidence should be assessed using Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for existing and new systematic reviews.^{29,30}

We recommend that authors should submit documents of systematic reviews that supported recommendations, whether they are conducted by the authors themselves, or updated and used existing systematic reviews.

Recommendation consensus

The main content of guidelines is their recommendations. Recommendations should not only based on the best currently available research evidence (systematic reviews), but also on a comprehensive consideration of factors such as resource utilization, patient values and preferences, equity and accessibility.³¹ The evidence of decisions developed by the GRADE working group provides a theoretical framework for how to generate optimal recommendations.^{32,33} The GRADE grid proposed by the GRADE working group, along with the classical Delphi method and the nominal group method, provides a way to reach consensus on recommendations.^{34–36} The various factors considered in the decision, and the transparency of the decision-making process, are as important, if not more important, than the scientific nature of the decision.

We recommend that authors should submit the decision-making process and minutes of meetings from evidence to decisions.

Guideline reporting

Reporting checklists can help guideline developers improve the completeness and transparency of guideline writing, enhance the credibility of guideline recommendations, and also make them easier to read by guideline users.³⁷ Studies have shown that the quality of reporting of either clinical researches, systematic reviews, or guidelines is generally low.^{38–40} However, the reporting quality of guidelines can be effectively improved if reporting guidelines are strictly followed. Current tools available to guide

guideline reporting are the AGREE reporting checklist and the RIGHT checklist.^{7,41} Both of them have their own advantages in guiding guideline reporting. One of them, RIGHT, currently has several extensions that can be used for reporting different types of guidelines.⁴²

We recommend that authors should submit a table indicating on which page and in which section the relevant content appears based on AGREE reporting checklist or the RIGHT checklist.

External review

There are still many guidelines that are not published in peer-reviewed journals nor peer-reviewed by external experts after the guidelines are completed. External review of guidelines refers to the review and feedback of several stakeholders who were not directly involved in the development of the guidelines, including the methodology of guideline development and the recommendations formed, to further ensure the scientific validity, clarity, and feasibility of the guidelines prior to formal publication.⁴³ The experts involved in the external review may be clinical experts, methodologists, patient or public representatives, policy makers, etc. Comments from the external review are addressed by the guideline development group, and the guideline is revised based on the comments. The development team documents the comments and the results of the process, and if no changes are made, the rationale should be documented.^{1–3,6}

We recommend that authors should submit a document for external review of the guideline, including the external reviewers, the review comments, and the changes made to these comments.

The above 10 components are the essential requirements that we believe a high-quality guideline should follow when it published (Table 1). We abbreviate them as PAGE (essential requirements for Publishing clinical prActice GuidelinEs). We recommend that guideline authors use them as an important reference when they submit their guidelines to promote transparency. Editors can also consider adding PAGE criteria in Introduction for Authors. Peer reviewers can use PAGE to help them quickly assess the reliability of a guideline, and on that basis, decide whether to publish the guideline. In the future, the working group will promote PAGE via several approaches: (1) provide detailed components explanations and guidance; (2) conduct lectures and training sessions for guideline authors, editors, and peer reviewers; and (3) regularly update PAGE after application.

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Ethical statement

Not applicable.

Declaration of competing interest

None. TERM (Transparency Ecosystem for Research and Journals in Medicine) working group is a multidisciplinary academic organization dedicated to enhancing scientific research and journal transparency, and building an ecosystem of transparency.

Author contributions

Yao-Long Chen and Liang Du conceived of the presented idea and supervised the study process. Nan Yang, Wei Zhao and Yao-Long Chen conducted the literature review and wrote the

manuscript. Wen-An Qi, Chen Yao, Chong-Ya Dong, Zhen-Guo Zhai, Tong Chen, En-Mei Liu, Guo-Bao Li, You-Lin Long, Xin-Yi Wang, Zi-Jun Wang, Ruo-Bing Lei, Qi Zhou and Liang Du reviewing and editing the final draft.

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