

BMJ Open Study protocol for developing the evaluation instrument of guideline adherence to GRADE approach (GRADE-Check)

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ABSTRACT

Introduction Many clinical practice guidelines (CPGs) claim to use Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, but its implementation varies. This suggests that CPG developers, methodologists and users would benefit from an instrument to evaluate the extent to which CPGs adhere to GRADE approach. Such a structured instrument is currently unavailable. Accordingly, this study will develop an evaluation instrument for assessing guideline adherence to the GRADE approach, which we have named 'GRADE-Check'. The goal is to target items to which CPGs fail to adhere and that potentially have serious consequences resulting in inaccuracies in certainty of evidence and inappropriate direction or strength of recommendations, thereby discriminating across CPGs in issues of importance.

Methods and analysis The panel will include up to 25 individuals with specific knowledge and expertise, including experienced authors, educators and methodologists on CPGs methodology and GRADE approach from relevant organisations. The instrument will focus on the key elements of GRADE, aiming for clarity for GRADE experts and non-GRADE experts to apply. The development process for GRADE-Check will consist of the following five phases: (1) recruitment of a panel of GRADE experts; (2) development of objectives and scope for the development of GRADE-Check and criteria for item selection; (3) generation of candidate items through a literature review and panel consultation; (4) panellist discussion to construct the initial draft and extended explanation manual and (5) user testing.

Ethics and dissemination This study has been approved by the Medical Ethics Committee of Zhongnan Hospital of Wuhan University (no. (2025047K)). Our research findings will be published in peer-reviewed journal articles and presented at academic conferences. Additionally, the dissemination plan will include considerations for the development of implementation manuals, a dedicated project website and training tools.

INTRODUCTION

The development and implementation of clinical practice guidelines (CPGs) play a crucial

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This work will be conducted by an international team with authoritative international expertise in clinical practice guidelines methodology in general and Grading of Recommendations Assessment, Development and Evaluation approach.
- ⇒ We employ multiround, multistakeholder user testing integrated with interactive interviews to generate sufficiently comprehensive feedback for content validity.
- ⇒ We do not report the methodology of subsequent assessments of the instrument's other psychometric properties in this protocol.

role in improving healthcare quality and patient outcomes. However, the quality and consistency of CPGs can vary, which may lead to suboptimal patient care. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach is a widely recognised and accepted method for developing high-quality CPGs. Over 120 organisations worldwide have endorsed or used the GRADE approach, including the WHO, the American College of Physicians and UpToDate.¹

Despite the widespread adoption of the GRADE approach, there remains considerable variability in adherence among CPGs claiming its use.^{2–5}

MeSH terms define guideline adherence as 'conformity in fulfilling or following official, recognised, or institutional requirements, CPGs, recommendations, protocols, pathways, or other standards'.⁶ In this paper, we use the term adherence to describe conformity of the CPGs to the GRADE approach as described in authoritative GRADE writings including but not limited to official GRADE Working Group guidance.



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Recent surveys reported that while many CPGs profess to use the GRADE approach, their implementation varies significantly.^{2 3 7} CPG developers in the USA were inconsistent in applying the GRADE approach, with limitations including failure to provide a summary of the evidence, and failure to adhere to guidance regarding rating certainty of evidence and characterising strength of recommendation.² A methodological study of Australian CPGs reported that the GRADE approach was inconsistently applied with limitations including failure to report how the authors framed or developed their questions, failure to rank outcomes by importance, and failure to transparently describe reasons for rating down or rating up the certainty of evidence.³ Some CPGs did not assign the certainty of evidence rating based on GRADE categories of high, moderate, low and very low.⁸

These limitations suggest that many CPG authors are not taking full advantage of the GRADE approach and are confusing readers who anticipate a claim that using GRADE ensures implementation of key GRADE practices. The growing complexity of GRADE guidance, with its continuous expansion and increasing level of detail, has made it challenging for both new and existing users. To address this issue, the GRADE approach should focus on core elements, simplify key concepts and provide structured assessment methods to enhance usability. In response to these challenges, Core GRADE was developed.^{9–16} Further, GRADE users would benefit from an approach, ideally in the form of a checklist, to evaluate the extent to which CPGs that claim to be using GRADE actually adhere to GRADE approach. And this simplification of GRADE would clearly be taken into account when we develop the new instrument to evaluate adherence to GRADE approach.

In contrast to existing quality assessment tools (eg, AGREE II)¹⁷ and reporting checklists (eg, RIGHT),¹⁸ the newly developed instrument is specifically designed to evaluate adherence to the GRADE approach, rather than overall guideline quality or reporting completeness. To contextualise the necessity for such an instrument, our research team conducted a systematic survey aimed at identifying and evaluating existing criteria for assessing adherence to GRADE approach in CPGs. Notably, the criteria for determining the application of the GRADE approach were first delineated in chapter 8 of the GRADE Handbook,¹⁹ and more recently, the GRADE Working Group has issued the minimum requirements for asserting the utilisation of the GRADE approach.²⁰ However, these existing criteria exhibited several limitations: half of them lacked response options; none underwent user testing; and none provided supporting manuals. In this context, we confirm that a structured instrument for assessing adherence to GRADE approach is currently unavailable. We, therefore, propose the development, piloting and dissemination of the evaluation instrument of guideline's adherence to GRADE approach (GRADE-Check). The GRADE-Check instrument will assess the extent of adherence of CPGs to the GRADE approach, identify areas for

improvement and provide guidance for CPG developers, methodologists and users. The objective of this protocol is to outline the process for developing GRADE-Check.

METHODS AND ANALYSIS

The development process for GRADE-Check consists of the following phases: (1) recruitment of a panel of GRADE experts to construct the instrument; (2) development of objectives and scope for the development of GRADE-Check and criteria for item selection; (3) generation of candidate items through a literature review and panel consultation; (4) panellist discussion to construct the initial draft and extended explanation manual and (5) user testing (see [figure 1](#)). We intend to complete all five steps and develop the final instrument from January 2025 to May 2026.

Steering committee

Before planning the recruitment of the panel, we formed a steering committee of six experienced researchers (GG, YJ, XY, PA, PD and SY) with collective international expertise in CPG methodology in general and GRADE approach in particular. The steering committee membership includes representation from the GRADE guidance group and expertise in instrument development.

The steering committee will lead the study and provide project oversight. Members developed this protocol and will recruit the panel, organise materials, present proposals, draft the instrument and related materials, and conduct user testing. The steering committee has drafted objectives and scope that, after possible modification and endorsement by the panel, will be used to select the items and guide the instrument development process.

Phase 1: recruitment of the panel

The steering committee will generate a list of potential panellists. The list will include (1) experienced authors of articles providing authoritative guidance on use of GRADE approach; (2) leading evidence-based medicine educators and (3) methodologists from prominent organisations producing CPGs. The steering committee will choose members from this list to create a panel including 20 to 25 individuals with a variety of perspectives. In choosing panellists, the steering committee will attend to equity, diversity and inclusiveness issues of gender and geography. Before enrolling panel members, we will confirm that all individuals volunteer their time and efforts to support the study, with no financial compensation provided for their participation.

Phase 2: development of objectives and scope for the development of GRADE-Check and criteria for item selection

The steering committee members have drafted the preliminary objectives and scope that stipulate the objective of the instrument, potential target users, item selection principles and how to format the items in the instrument. The draft of the objectives and scope is as follows:

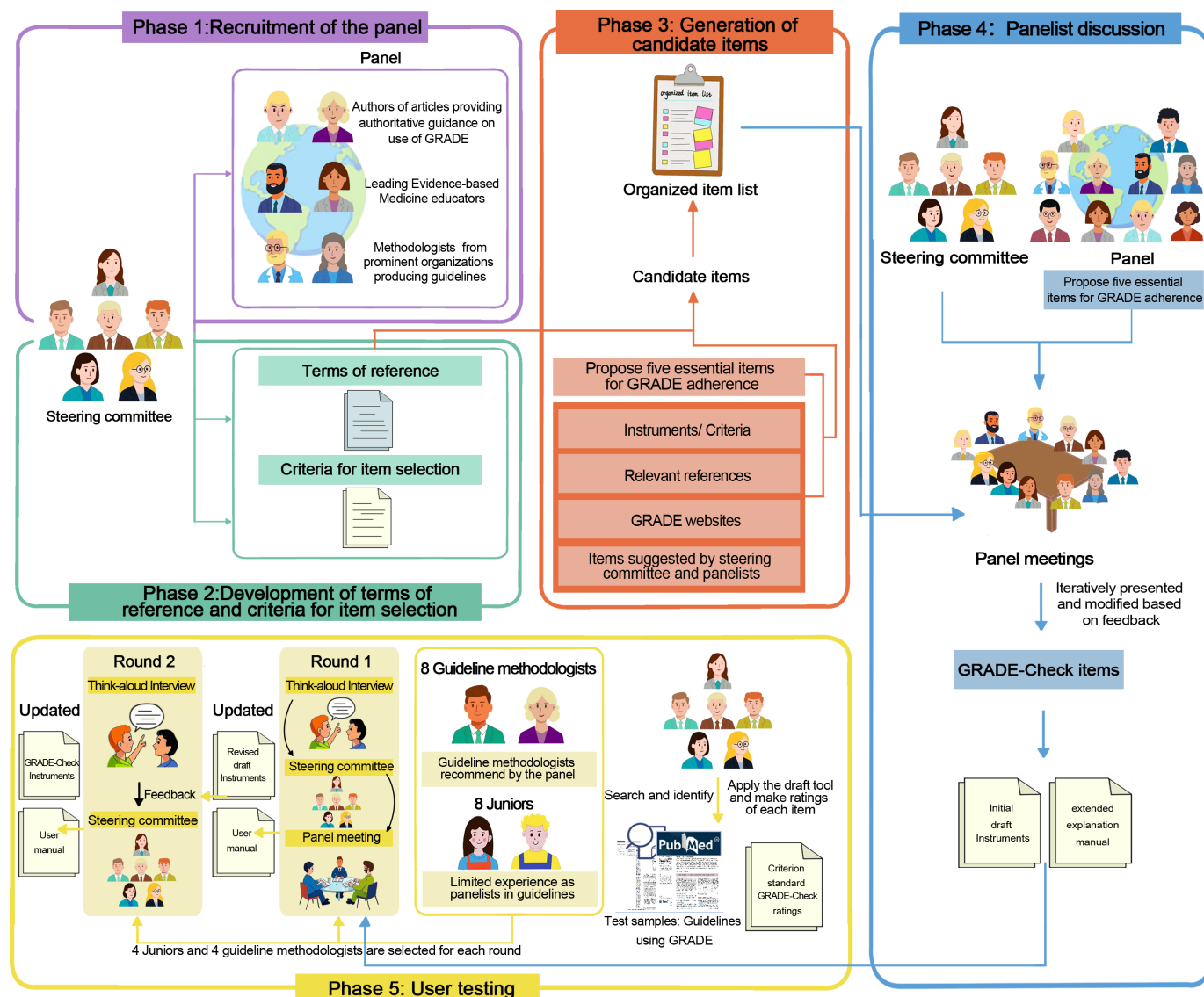


Figure 1 The development process for GRADE-Check. GRADE, Grading of Recommendations Assessment, Development and Evaluation.

Preliminary objectives and scope

- ⇒ The instrument aims to evaluate adherence of clinical practice guidelines (CPGs) claiming to use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) to the essential GRADE approach, and possibly to standards beyond the essential.
- ⇒ The instrument addresses the entire GRADE approach regardless of individual patient or population/public health perspective.
- ⇒ Potential target users include the CPG developers, researchers of guideline methodology, and end-users of CPGs.
- ⇒ To accommodate users with limited GRADE expertise, the instrument will be user-friendly, and straightforward.

The panel will be asked to review these preliminary objectives and scope and provide feedback that the steering committee will incorporate as appropriate. Subsequently, these preliminary objectives and scope will guide the development of the instrument. The steering committee members

have also developed preliminary criteria for choosing items for the instrument. Those criteria are as follows:

Criteria for item selection

- ⇒ Items will focus on crucial GRADE elements for ensuring a rigorous systematic review and guideline process.
- ⇒ Items will address only paired comparison of interventions, including diagnostic impact, but not for diagnostic accuracy, prognosis, or network meta-analysis (NMA).
- ⇒ Items are easy for GRADE experts and non-GRADE experts to apply.
- ⇒ Items are appropriate in balancing “too superficial” and “too detailed”.

Phase 3: generation of candidate items

The items are primarily acquired through two distinct approaches. First, without reference to any GRADE guidance or other materials, steering committee members

will propose five essential items for adherence to GRADE approach.

Second, the steering committee will systematically survey whether there are available instruments and articles presenting criteria relating to optimal use of GRADE approach. The survey will include a formal literature search, supplemented by manual reviews of the GRADE handbook, GRADE Working Group website, GRADE centres and networks.

Then, we will compare and organise the items proposed by committee members with the potential items identified through systematic survey into a preliminary list of candidate items.

On the finalisation of panel members, preliminary objectives and scope and criteria for item selection will be disseminated to each member through email. Each member will be asked to propose five essential items for adherence to GRADE approach independently. Following the collection of all feedback, the proposed items will be compiled and duplicates removed. Subsequently, these items will be compared and analysed with the preliminary list of candidate items generated by the steering committee. This process will yield a finalised list of candidate items, as well as records of the sources of each item, including the numbers of documents mentioning the item in the systematic survey, and the numbers of steering committee and/or panel members who proposed the item. These materials will give some sense of relative importance or perceived sensitivity for detection of frequently missed items to inform the further panel discussions in phase 4.

Phase 4: panellist discussion to construct the initial draft and extended explanation manual

Meetings will be co-chaired by YJ and GG. We anticipate that each virtual meeting will last between one and one and a half hours. Meetings will follow an open discussion format, allowing panellists to speak freely. The key role of the co-chairs will be to guide the panel toward consensus. Every meeting will be recorded, and the steering committee will review and construct minutes including the panel's decisions and discussion. Panellists, including non-attenders, will receive recordings along with minutes and be invited to provide further comments.

After the first meeting, each subsequent meeting will begin with a summary of no more than 10 min describing the latest developments, including comments after the previous meeting, outstanding issues and where the project currently stands. Meetings will then proceed to revisit unresolved controversial issues. The preliminary GRADE-Check items will be interactively presented and modified based on feedback from the panellists obtained from open discussion ZOOM meetings between panel members.

Each meeting will focus on the next steps moving towards development of the final instrument. It is estimated that approximately 12 ZOOM panel meetings will be required.

Four guiding questions for panellists to keep in mind when we discuss each item: (1) Is adherence to the item crucial for ensuring a rigorous systematic review and guideline process? (2) Is it easy for GRADE experts and non-GRADE experts to apply? (3) Is the item likely to work for all three target audiences, including CPG developers, methodologists and users? (4) Is the item appropriate in balancing 'too superficial' and 'too detailed'?

Through panel meetings and associated email conversations, the panel will achieve consensus on item selection, instructions for included items and format of the instrument (including response options). If consensus proves difficult to achieve, we will resort to a voting mechanism to reach a final decision. Ultimately, an initial draft instrument and extended explanation manual will be developed. We may include an expanded number of items in the version of the instrument deployed for user testing.

Phase 5: user testing

To identify challenges experienced by potential users of GRADE-Check in comprehending and applying the instrument, we will conduct two-round user tests. Each user test will involve the participants applying the draft GRADE-Check instrument to a CPG that claimed the use of GRADE approach.

Identifying CPGs for user testing

To identify CPGs for user testing, we will search PubMed between 1 January 2025 and 28 February 2025. The search terms to be included are: ((("GRADE"[Title/Abstract] OR "GRADE Approach"[MeSH Terms]) AND ("Guideline"[Publication Type] OR "Guidelines as Topic"[MeSH Terms] OR "Practice Guideline"[Publication Type] OR ("guid*" [Title] OR "Practice Guideline"[Title] OR "clinical guideline"[Title] OR "clinical practice guideline"[Title] OR "recommendation*" [Title] OR "evidence-based guideline"[Title])))). An experienced health sciences librarian will refine our search strategy.

Subsequently, full-text CPGs that claim to use GRADE approach and are written in English will be screened in duplicate. There will be no restrictions on the target diseases of the CPGs to ensure that GRADE-Check applies to all fields and types of CPGs. Team members will identify the most recent 50 CPGs that have described, in their methods to use GRADE approach. Two steering committee members (YJ and GG) will review potential CPGs, starting with the most recent and working backward. They will identify six CPGs with concerns regarding GRADE approach application (posing challenges for checklist use), and two CPGs with no identified concerns.

YJ and GG will ensure that the particular limitations cover the full spectrum including possible failure to appropriately address question formulation, choice of patient-important outcomes; initial classification of studies according to study design; for both randomised trials and non-randomised studies of interventions (NRSI) addressing five domains for rating down and for NRSI two

domains of rating up; appropriately addressing possible subgroup effects; presenting appropriately formatted summary of findings tables; and addressing GRADE criteria for moving from evidence to recommendations.

Recruiting participants for user testing

We will recruit 16 individuals to test GRADE-Check, including 8 individuals with limited experience as panelists in CPGs using GRADE approach and no leadership experience (juniors), and 8 CPG methodologists with leadership experience in developing CPGs using the GRADE approach. We will also ensure that these two groups collectively cover all three target user types of GRADE-Check: CPG developers, guideline methodology researchers and end-users of CPGs. Participants will, like the panel, reflect our attention to equity, diversity and inclusiveness considerations with respect to gender, country and student status, as well as clinical background. GG, PA and PD will identify eligible individuals through suggestions from panel members. We anticipate that we will reach saturation with respect to issues identified with 16 participants. If that proves not to be the case, we will recruit additional participants.

Testing implementation

YJ and XY will apply the draft GRADE-Check to the eight CPGs and make ratings of each item. They will compare their ratings with one another and resolve any disagreements through discussion. If the disagreement persists, they will consult with other committee members. Their ratings will constitute the criterion standard GRADE-Check ratings for each CPG.

The participants will receive one CPG, along with the GRADE-Check and the extended explanation manual. The testing will consist of two rounds, with four juniors and four experts selected to participate in each round in the order they will be invited to the user testing.

In round 1, each respondent will receive one CPG separately which is randomly selected from the eight included CPGs. Following the accepted methodology for think-aloud studies,^{21 22} YJ will conduct an interview of approximately 1 hour with each respondent online. During the interviews, respondents will apply the instrument to the CPG, and for each item, they will articulate the thought process that led to their assessment. YJ will compare the participant's assessments with those of the criterion standard. When mistakes or problems occur, she will explore the reasons for the discrepancies. Finally, YJ will ask the participants about their overall experience with the GRADE-Check, focusing on their understanding and application, and any concerns they have about either the checklist or the associated explanation manual.

A professional transcriptionist will transcribe the complete record of the interviews. YJ and SY will summarise their insights from the interviews and will report to steering committee members who will develop initial suggestions for modifications to GRADE-Check and its extended explanation manual. The panel will

then meet to review the modifications and provide their suggestions.

In round 2, the other eight participants will receive the revised instrument and the manual by email, and they will be reminded to review those files before the GRADE-Check evaluation. Similar to round 1, the eight participants will also each receive one CPG, randomly selected from the eight included CPGs. YJ will conduct an approximately 1-hour online interview with each respondent. Participants will first independently use the instrument to evaluate the guideline (with YJ recording completion time), then explain their thought process behind each item's assessment. Participants can still freely express any issues related to the use of the instrument and manual.

Based on the transcripts, YJ and SY will summarise any newly emerged feedback that could lead to modifications of GRADE-Check and related materials and report to the steering committee. The committee members will then decide whether information saturation has been reached in round 2. If no further modifications are needed, we will determine that the final instrument and manual have been achieved.

DISCUSSION

CPGs are considered a key foundation for quality improvement in healthcare. CPGs claiming to use GRADE without appropriate application may mislead readers and result in unreasonable recommendations. The GRADE-Check instrument aims to evaluate the extent to which CPGs that claimed to use GRADE adhere to essential GRADE approach. Unlike existing quality assessment tools (eg, AGREE II) and reporting checklists (eg, RIGHT), GRADE-Check will be designed specifically to assess adherence to GRADE approach, rather than overall guideline quality or reporting completeness. GRADE-Check can be used independently or in conjunction with these instruments by CPG developers, methodologists and end-users of CPGs. GRADE-Check can help distinguish CPGs that rigorously implement GRADE approach.

Finally, to ensure the effectiveness of GRADE-Check, it will be essential to test it with a broader user base and in diverse usage contexts. We will continuously gather feedback and assess the necessity for any adjustments or refinements.

ETHICS AND DISSEMINATION

This study has been approved by the Medical Ethics Committee of Zhongnan Hospital of Wuhan University (no. (2025047K)). The project's deliverables will include research results disseminated in peer-reviewed journals and presented at national and international conferences. Additionally, it will involve developing implementation manuals, dedicated project websites and training tools to facilitate practical application.

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