

ORIGINAL RESEARCH

Developing methods guidance for health researchers: literature review of proposed and applied strategies

Malena Chiaborelli^{a,*}, Julian Hirt^{b,c,d,e}, Matthias Briel^a, Frances Shiely^{f,g,h}, Anne-Laure Boulesteix^{i,j}, Gordon Guyatt^k, Frank Bretz^{l,m}, David Moher^{n,o,p}, Derek Stewart^g, Stefan Schandelmaier^{a,q}

^aDepartment of Clinical Research, CLEAR-Methods Centre, University Hospital Basel and University of Basel, Basel, Switzerland

^bDepartment of Clinical Research, Faculty of Medicine, University of Bern, Bern, Switzerland

^cDepartment of Health, Eastern Switzerland University of Applied Sciences, St Gallen, Switzerland

^dInstitute of Health, Midwifery and Nursing Science, Medical Faculty, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany

^eIBI Centre for Evidence-Based Healthcare Eastern Switzerland, University of Adelaide, Adelaide, Australia

^fTRAMS (Trials Research and Methodologies Unit), HRB Clinical Research Facility, University College Cork, Cork, Ireland

^gHealth Research Board (HRB), Trials Methodology Research Network (TMRN), Galway, Ireland

^hSchool of Public Health, University College Cork, Cork, Ireland

ⁱInstitute for Medical Information Processing, Biometry and Epidemiology, Faculty of Medicine, LMU Munich, Munich, Germany

^jMunich Center for Machine Learning, Munich, Germany

^kDepartments of Medicine and Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Canada

^lNovartis Pharma AG, Basel, Switzerland

^mMedical University of Vienna, Center for Medical Data Science, Institute of Medical Statistics, Vienna, Austria

ⁿMethodological and Implementation Research Program Centre for Journalology, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada

^oSchool of Epidemiology and Public Health, Faculty of Medicine University of Ottawa, Ottawa, Ontario, Canada

^pInstitute of Health Policy, Management & Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada

^qMTA–PTE Lendület "Momentum" Evidence in Medicine Research Group, Medical School, University of Pécs, Pécs, Hungary

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Abstract

Objectives: Health researchers benefit from methods guidance (MG) for planning, conducting, analyzing, and interpreting research studies. How to develop MG that is trustworthy and researcher-friendly is unclear; existing strategies for developing MG are fragmented and lack a coherent framework. The STRategies for developing REseArch Methods guidance project aims to provide such a framework for developers of MG. As a first step, we reviewed the literature to identify proposed and applied strategies for developing MG and explored possible knowledge gaps.

Methods: We conducted two literature reviews. First, a scoping review of the methodological literature to identify proposed strategies for developing MG. Second, a review of a purposeful sample of recently published MG articles to examine strategies applied in practice. We applied a qualitative content analysis to both sets of publications using one shared codebook. In addition, to identify possible knowledge gaps, we contrasted the findings with the established development processes for clinical practice guidelines and reporting guidelines.

Results: The first review included 17 publications, and the second review included 102 MG articles. We identified possible development steps including assessing the need for MG, establishing a working group, considering the findings from methodological studies, gathering input from interest-holders, testing the new MG, and disseminating and implementing MG. In addition, we identified various approaches to perform the steps including systematic reviews of previous guidance, reviews of methodological practice, simulation studies, surveys or interviews of interest-holders, consensus methods, and public review. Mapping these findings with established development processes identified areas that have so far received limited attention within MG development, including considering evidence from methodological research, judging the certainty of this evidence, reporting of MG, and approaches to implementation.

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* Corresponding author. CLEAR Methods Center, Division of Clinical Epidemiology, Department of Clinical Research, University Hospital Basel, University of Basel, Totengässlein 3, 4051 Basel, Switzerland.

E-mail address: malena.chiaborelli@usb.ch (M. Chiaborelli).

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Conclusion: This study provides an overview of proposed and applied strategies for developing MG, highlights needs for conceptual development, and provides a structured starting point for guidance for developing MG. © 2026 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keywords: Methods guidance; Evidence-based research practice; Quality of research; Methods review; Meta-research; Research on methods

Plain Language Summary

Almost every method used in health research comes with its own guidance, sets of advice and suggestions on how to plan and carry out the research, as well as helping with the analysis and interpretation of the results. When this guidance is clear and can be trusted, it helps researchers produce evidence that is valid and useful. However, the process for developing such guidance is currently unclear. The aim of this project called STREAM is to create a framework for developing trustworthy and user-friendly MG. In this manuscript, we report on two literature reviews that will inform the new strategies. In the first, we looked for existing publications that suggest strategies for developing MG. Secondly, we examined recently published MG articles to see how they were developed. We also compared our findings with established development processes for other kinds of guidance: clinical practice guidelines and reporting guidelines. As a result, we found many possible and complementary strategies for developing MG: forming a working group, reviewing previous research, seeking input from interest-holders, testing the guidance, and actively supporting dissemination and use. We also identified important areas where further research is needed. For example, we found that it is currently unclear how previous research should inform MG or how to optimally present it. In summary, our reviews identified various possible strategies for developing MG but also important gaps that the framework for developing MG should address.

1. Introduction

High-quality evidence is essential for optimal health care. Much of the available evidence, however, is limited by avoidable methodological flaws, which can lead to biased findings [1–3], waste of resources [4–8], and ethical concerns [9,10].

Methods guidance (MG) plays a key role in improving research quality. MG provides explanations and recommendations on study design, conduct, analysis, and interpretation of results and conclusions [11]. MG may be initiated mainly by individual researchers, research collaborations, and regulatory agencies. Researchers, ethics committees, funding agencies and regulatory bodies rely on MG to ensure methodological rigor and transparency. Yet, how to optimally develop MG that is relevant, valid, and easy to adopt remains unclear.

To address this gap, the STRategies for developing REsearch Methods guidance (STREAM) project will develop a structured framework for creating researcher-friendly and effective MG [12]. As a first step, it is important to identify any strategies already proposed in the methodological literature and also to better understand the current practice of MG development. One previous review of 44 MG articles identified considerable variation in approaches to MG development but did not provide sufficient detail to inform the new framework [13].

The aims of this study were to [1] identify any proposed strategies for developing MG [2], identify strategies applied in recent MG articles, and [3] explore possible differences

between proposed or applied MG development and the established development processes of clinical practice guidelines and reporting guidelines.

2. Methods

We conducted two reviews: a scoping review to identify proposed strategies for developing MG and a review of a purposeful sample of recently published MG to describe the applied strategies for MG development. We applied a combined qualitative content analysis to both reviews. In addition, to identify possible gaps, we contrasted the findings from the qualitative analysis with the established development processes of clinical practice guidelines [14] and reporting guidelines [15]. We published the protocol [12].

2.1. A scoping review of proposed strategies to develop MG

We considered guidance for scoping reviews [16–19]. We started the search process with an initial set of seven relevant publications that we had identified through literature searches informing the Library of Guidance for Health Scientists (LIGHTS, www.lights.science) [20]. LIGHTS is an open-access database for MG articles. From this set, we performed backward and forward citation searching via Citationchaser [21,22]. In addition, we searched Google Scholar, used AI-based search engines, and screened the

What is new?**Key findings**

- We identified possible steps and approaches for developing methods guidance (MG), including assessing the need for MG, considering findings from methodological studies, gathering input from interest-holders, testing the new MG, and disseminating and implementing MG.

What does this add to what is known?

- We identified publications that make suggestions for developing MG, characterized development processes used in practice, and compared the findings with guidance development processes in related fields.

What is the implication, what should change now?

- Fragmented suggestions for developing MG and current practice provide useful candidate items to inform a new framework for how to develop MG.

reference lists of the MG articles included in the review of applied strategies (see [Appendix 1](#) for the full search details). For each additional eligible publication identified through any of these search strategies, we repeated backward and forward citation searches until we found no further eligible publications [22]. We completed the final citation search on June 18, 2025. We did not run a Boolean database search because our previous work on identifying MG showed that such searches perform poorly in terms of both sensitivity and precision (Hirt et al 2023; Hirt et al 2024). Even after professional search design and repeated refinement, strategies based on terms related to ‘MG’ missed relevant papers while retrieving several hundred thousand records, making screening infeasible [23].

Reviewers (SS, JH, MB, or MC) independently, and in duplicate, screened titles and abstracts to assess potential eligibility using Rayyan [24]. For full-text screening, we used MAXQDA software. One reviewer (MC or SS) highlighted relevant sections or, if none were relevant, recommended exclusion. A second reviewer (MC or SS) checked the highlighted text and searched for additional relevant sections. The two reviewers met regularly, discussed disagreements, and reached consensus.

2.2. A review of applied strategies to develop MG

We considered guidance for reviews of applied methods [25–27]. We used LIGHTS as the source for MG articles. LIGHTS’ search strategy includes manual searching of journals, journal sections and journal article types, and other collections of MG. LIGHTS applies the following eligibility criteria: (1) the publication is a journal article

or MG document from an agency such as the European Medicines Agency (EMA) or US Food and Drug Administration (FDA); (2) the title or abstract explicitly indicated the aim to provide MG (accepting any alternative expression); and (3) the MG addresses a topic relevant to health research in humans. For this study, we applied two additional criteria: (4) the article includes a section describing the development process of the MG (since we aimed to understand development processes, the many guidance articles that do not include a methods section were not useful for this review); and (5) we excluded reporting guidelines and quality assessment tools (since we focused on less studied types of guidance, particularly guidance for understanding, selecting, and applying methods) [12].

We used purposeful sampling to maximize diversity of development approaches. We began with an initial set of eligible articles published between January 2020 and December 2024 (then the last 5 years). Eligibility assessment and coding were conducted concurrently. During the qualitative analysis, we identified development steps and approaches for which our sample provided rich information, and steps and approaches for which our sample provided only superficial information. For those areas with superficial information, we purposefully enriched the initial sample with selected MG articles published before 2020 [25–27].

2.3. Combined qualitative content analysis

We started with an initial codebook prestructured based on our experience from indexing MG papers for LIGHTS ([Appendix 2](#)). We modified, refined, and expanded the codebook during the qualitative analysis [28], working on both samples simultaneously.

We then used MAXQDA software for an initial round of coding restricted to broad categories [28,29]. Two reviewers (MC and SS) iteratively coded the data and regularly met to discuss disagreements and reached consensus. After these initial coding rounds, MC continued coding.

We derived the final themes by grouping-related codes and categories into overarching concepts.

2.4. Comparing the findings with two established processes to develop other types of guidance

We compared the findings of the combined qualitative analysis with existing development processes of two other types of guidance: clinical practice guidelines [14] and reporting guidelines [15]. Rather than a normative benchmark, our aim was to identify additional development elements described in these processes that did not appear in our two reviews, but which might provide valuable input for the planned new framework for developing MG. We considered the 18 steps for developing clinical practice guidelines [14], and the 18 steps for reporting guidelines

[15]. MC and SS then mapped our codebook against these 36 steps. We considered any steps not already included in the codebook potential “gaps”, ie, aspects that did not occur in the proposed or applied development processes that we reviewed but might be useful for developing MG.

We created a heat map showing, for each step, the richness of information that the four sources provided. To do so, we used three categories to describe richness: minimal, moderate, and comprehensive.

3. Results

For the scoping review of proposed strategies, we screened 3245 records, retrieved 149 full texts, and included 17 publications (flowchart in Appendix 3). Table 1 shows the included publications, and Appendix 4 lists all full-text–assessed articles.

The review of applied strategies included 102 MG articles, most published between 2020 and 2024. To ensure representation of less common methodological approaches, we included 13 earlier publications, the oldest from 2015 (Appendices 5 and 6).

We identified 14 steps for developing MG (Table 2). We grouped them into four predevelopment steps, seven core development steps, and three postdevelopment steps. The order in which we present the steps is not intended to imply a fixed sequence; steps may occur in a different order, in parallel, or iteratively (Appendix 7). Appendix 9 maps the steps for developing clinical practice guidelines [14]

and reporting guidelines [15] against corresponding codes from our codebook. When no corresponding code was available, we added the newly identified step or approach to our collection and recorded it as a possible gap. The complete codebook is available in Appendix 8. Table 2 presents a heatmap indicating, for each step, the richness of information that we observed in the four sources.

3.1. Predevelopment steps

3.1.1. Assessing the needs for MG development

The reviewed documents described several approaches to needs assessment, including input from interest-holders (Akl et al 2024). For example, Grading of Recommendations Assessment, Development and Evaluation (GRADE) recommends group discussions and brainstorming over real examples [30]. Another approach is to critically review a sample of publications that applied the method under consideration. For example, when one group considered the need for MG on drug discontinuation trials, they examined a sample of published trials and identified methodological problems that warranted new MG [46]. Another approach is to perform a systematic review of previous guidance.

The process for developing clinical guidelines included formal consensus methods as an additional approach to needs assessment [14].

3.1.2. Defining goal and concept of the MG

The specific considerations mentioned in the documents (such as EMA guidance) [35] included defining its intended

Table 1. Publications included in the scoping review of proposed strategies for developing MG

Publications addressing the entire development process of MG
Process for developing MG articles of the GRADE working group (focus on systematic reviews and clinical practice guidelines) [30,31]
Process for developing MG articles of the STRATOS group (focus on observational studies) [32]
Process for developing FDA guidance (focus on clinical trials) [33,34] ^a
Process for developing EMA guidance (focus on clinical trials) [35] ^a
Process for developing ICH guidance (focus on clinical trials) [36,37] ^a
Publications addressing selected aspects of MG development
Review of FDA and EMA guidelines for conducting trials on psychiatric drugs [38].
Commentary on FDA guidance practices in drug development [39].
Qualitative study about conflicts of interest in EMA guidance documents [40].
Paper suggesting a framework for communicating confidence in methodological recommendations for systematic reviews and meta-analyses [41].
Paper proposing phases of methodological research in biostatistics [42].
Paper exploring the use of implementation science in the methods context [43].
Review of guidance papers on regression modeling [44].
Review of the development of “methodological frameworks” [45].
Paper introducing a database of MG [20].

MG, methods guidance; GRADE, Grading of Recommendations Assessment, Development and Evaluation; STRATOS, STREngthening Analytical Thinking for Observational Studies; FDA, US Food and Drug Administration; EMA, European Medicines Agency; ICH, International Council for Harmonisation.

^a These publications apply to MG but also to other types of EMA, FDA, and ICH guidelines, such as those on pharmaceutical quality, efficacy, safety, and regulatory.

Table 2. Identified steps to develop MG and richness of information across the four sources

Identified steps to develop MG	Review of proposed strategies to develop MG	Review of applied Strategies to develop MG	Clinical guidelines development process [14]	Reporting guidelines development process [15]
Predevelopment steps				
Assessing needs for MG development	Moderate	Minimal	Comprehensive	Moderate
Defining goal and concept of the MG	Comprehensive	Comprehensive	Moderate	Minimal
Involving interest-holders	Moderate	Comprehensive	Comprehensive	Minimal
Considering organiational aspects	Moderate	Minimal	Comprehensive	Moderate
Core development steps				
Considering evidence from methodological research	Moderate	Moderate	Comprehensive	Minimal
Judging the certainty of evidence from methodological research	Minimal	Minimal	Comprehensive	Minimal
Gathering input from interest-holders	Comprehensive	Comprehensive	Comprehensive	Comprehensive
Formulating recommendations	Moderate	Minimal	Comprehensive	Minimal
Drafting and reporting	Moderate	Moderate	Moderate	Moderate
Building consensus	Moderate	Comprehensive	Moderate	Comprehensive
Testing the new MG	Minimal	Comprehensive ^a	Moderate	Moderate
Postdevelopment steps				
Dissemination and implementation	Comprehensive	Comprehensive ^b	Moderate ^b	Comprehensive ^b
Assessing implementation and effectiveness	Moderate	Minimal	Moderate	Moderate
Updating, extending, and withdrawing MG	Moderate	Moderate ^c	Comprehensive	Comprehensive

The categories “minimal,” “moderate,” and “comprehensive” and the shading indicate our perceived richness of information that the four sources provided for each step. “Minimal” indicates no or only superficial information, for example, one document briefly addressed the step in a single sentence. “Moderate” indicates substantial information, for example, one or more papers dedicated a paragraph to the step. “Comprehensive” indicates detailed elaboration on a step, for example, a full section or entire manuscript.

MG, methods guidance.

^a We complemented our initial sample with seven articles that tested the new MG.

^b Comprehensive or moderate for dissemination but minimal for implementation.

^c We complemented our sample with two articles that updated previous MG.

use, target users, scope, and definitions of the methodological topic. Other conceptual considerations included desirable characteristics of the MG such as simplicity, accessibility, or compatibility with related MG. Further considerations concerned specifying the intended format such as a checklist, question-and-answer, template, decision support tool, or interactive website. These elements could be outlined in a work plan or concept paper as specified in EMA and ICH documents [35,36].

The development process for clinical guidelines uses structured research questions, typically following the patients, intervention, comparison, outcomes (PICO) framework, to define the goal [14].

3.1.3. Involving interest-holders

3.1.3.1. Identifying interest-holders. The documents mentioned a wide variety of interest-holders that develop or use MG. Interest-holders included researchers who are topic experts in the area addressed by the MG and researchers working in research-performing organizations in

academia or industry who use the guidance, funders, ethics committees, health authorities, NGOs, journal editors, and health-care professionals, as well as patients and the public. In selecting interest-holders, guidance developers also considered equity, diversity, and inclusion criteria. For example, the developers of MG for acupuncture trials included interest-holders from different regions worldwide: specialized clinicians, trialists, methodologists, statisticians, and patient representatives [47].

3.1.3.2. Engaging interest-holders. Approaches to engage interest-holders included issuing open calls for participation; nominating experts; reviewing previous MG to identify methodologists; contacting interest-holders through established working groups; purposive and convenience sampling; snowball strategies; and recruiting via email or social media. Some documents mentioned financial incentives and nonmonetary benefits, such as authorship, experience, or career advancement opportunities. Developers may invite interest-holders that have no competing interests to

participate in the MG development process. In case conflicts of interest exist, they may be disclosed appropriately. For example, an analysis of EMA and FDA guidelines offered explicit recommendations for managing conflicts of interest [38,40].

The process for developing clinical guidelines [14] additionally suggested approaches for managing conflicts of interest: for instance, individuals with competing interests may participate in MG development but not vote on recommendations related to the conflict, among other measures.

3.1.3.3. Defining roles of interest-holders. Interest-holders can take different roles in the MG development process including core groups, steering committees, consensus panels, and writing groups. Groups can be organized as inner and outer groups (ie, working on the same topics but with more or less responsibilities) or as multiple working groups focusing on different topics. Some articles made explicit the roles of individuals within a group such as lead, supervisor, external reviewers, or expert consultants.

3.1.3.4. Setting up group processes. Processes and approaches for working with interest-holders included communication channels such as email, phone, and face-to-face encounters and the organization of group events such as meetings, workshops, and webinars. For example, a group developing guidance for mixed methods systematic reviews used a series of teleconferences and annual face-to-face meetings, supplemented by regular email correspondence [48].

The development process for clinical practice guidelines [14] provided detailed suggestions on setting up group processes, including establishing how and how often communication with panel members would occur; ensuring that all members have equal opportunities to contribute during discussions and decision-making; defining procedures for handling conflicts; setting a quorum for meetings; and planning meeting logistics and documentation. The development process for reporting guidelines [15] provided additional considerations for preparing face-to-face meetings including size, duration, logistics, agenda, preparatory materials, and recording.

3.1.4. Considering organizational aspects

This step addresses activities such as registering the planned MG, defining timelines for completing the MG, or establishing a process for making the new MG official. For example, within its guidance development process, the FDA includes a public comment phase and defines specific timeframes for this step to support timely finalization of guidance documents [33].

The processes to develop clinical practice guidelines [14] and reporting guidelines [15] mentioned additional organizational considerations such as budgeting, acquiring funding, and clarifying legal requirements.

3.2. Core development steps

3.2.1. Considering evidence from methodological research

MG developers may review existing methodological studies or conduct new ones. We noted that some conceptual papers referred to “methodological evidence” [30,41–43,45] but did not provide a clear definition. None of the included MG articles used this term. Also, several conceptual papers [30,41–43,45] referred to methodological studies, and many of the included MG articles drew on them. Nevertheless, none of the included documents provided a clear account of the various types of methodological studies; the descriptions were often vague and inconsistent across documents.

The lack of clarity around the concept of methodological evidence and methodological study types contrasted with the development process for clinical practice guidelines, which rely on well-established concepts of clinical research and clinical study types [14].

We present types of methodological studies that may inform MG and that we identified in the documents:

- R-reviews of the methodological literature: These studies review existing methodological publications. For example, the STRENGTHENING Analytical Thinking for Observational Studies (STRATOS) initiative proposed reviewing existing MG as a basis for developing new MG [32]. Another group proposed reviewing empirical methodological studies [41]. For example, MG developers reviewed existing MG to inform new MG for assessing the context suitability of systematic reviews [49].
- R-reviews of applied methods: These studies analyze applications of the methods as reported in health research studies. For example, to inform MG for eliciting surveys items, the MG developers reviewed a sample of 57 published survey development studies [50].
- - Meta-epidemiological studies: These studies analyze published studies and assess the association between methodological study characteristics and study results. One conceptual document proposed them as a potential input to MG [41].
- S-simulation studies: These studies test statistical methods based on simulated datasets. For example, a simulation study supported the development of MG on matching in cluster randomized trials [51].
- E-experimental analysis of real datasets: These studies test methods in real datasets [41,42]. For example, a study used data from a large birth cohort to compare different methods to address missing data [52].

- - Methodological randomized studies: These studies randomize study teams or other research participants to the use of alternative methods. One conceptual document referred to these studies [41].
- - Methodological case reports: These reports share a team's experience with a specific methodology (analogous to case reports in the clinical literature) [41]. For example, developers of an MG on contextual analysis in implementation research considered their experience from a previous research project [53].
- T- heoretical approaches: Sometimes, especially for statistical topics, MG developers may rely on theoretical studies. For example, a group used theoretical reasoning and mathematical derivations (and also simulation studies) to derive MG on predictor models [54].

In addition to identifying types of methodological studies, two articles discussed how these different types can complement each other and, over time, contribute to consolidating the evidence-base for methodological recommendations [41,42]. For instance, early methodological studies may include simulations to test a method, while later methodological studies may focus on application in real studies and consider implementation challenges [42].

3.2.2. Judging the certainty of evidence from methodological research

One of the conceptual papers only briefly addressed judging the certainty of evidence from methodological research [41]. The lack of this step in the context of MG may indicate a potential gap, given the central role of this step in the process for developing clinical guidelines [14]. Therein, rating the certainty of evidence is highly formalized, including explicit approaches for reporting the results of the quality ratings such as risk of bias tools [55] or the GRADE approach [56].

3.2.3. Gathering input from interest-holders

The reviewed documents mentioned various approaches including surveys, interviews, focus groups, Q methodology, and choice experiments. In addition, MG collected input as part of consensus processes (presented as a separate step below). Also, we often saw less formal approaches such as informally collecting feedback from collaborators, brainstorming or discussing over a set of examples or scenarios, sometimes recorded and qualitative analyzed. For instance, GRADE relied on discussing examples [30,31]. FDA [33], EMA [35], ICH [36], and STRATOS [32] proposed a public commentary phase, ie, publishing an advanced draft and collect feedback from anyone interested, as a core method.

3.2.4. Formulating recommendations

One conceptual article by Trikalinos et al [41] proposed a framework to articulate recommendations. The framework suggested four steps starting with defining the contextual factors of a recommendation; breaking down the possible recommendation into testable and nontestable components; assessing the recommendation across key dimensions: evidence, feasibility, applicability, and expected impact and finally determining the strength of the recommendation to indicate the level of obligation. STRATOS recommended including examples, possibly using real or simulated data, to illustrate inappropriate and appropriate methods [32].

The development process for clinical guidelines, specifically the GRADE approach, provided extensive guidance on formulating recommendations based on the available evidence, including formal strategies for determining the direction of recommendations and their strength [14]. Available are also templates for transparent reporting to ensure actionable recommendations that are transparent about the evidence base and specify the populations and contexts to which the recommendations apply [14]. In clinical practice guidelines, agreeing on recommendations was the main subject of the consensus process among the guideline developers.

3.2.5. Building consensus

Formal consensus techniques mentioned in the documents included the Delphi technique, nominal group technique and modifications of those. Some groups specified criteria for defining consensus and used voting. For instance, a group developing MG for reducing measurement bias in trials performed a Delphi consensus among 40 experts [57]. We also frequently saw informal approaches, ie, when developers build consensus based on open discussions among interest-holders without applying any formal approach.

3.2.6. Drafting and reporting

This step addresses the writing process, typically requiring multiple rounds of refinement, that results in a draft and includes finding a clear structure for the new MG. For example, the developers of MG for translating evidence from pragmatic trials to clinical practice compiled a list of trial design choices that served as the organizing framework for the guidance [58]. Templates may be used to standardize the format of the MG. None of the MG articles referred to a specific approach to reporting or any existing reporting guideline.

3.2.7. Testing the new MG

In this step, guidance developers test a preliminary version of the new guidance before finalizing it. We identified various purposes of testing such as assessing clarity, usefulness, feasibility, or fit for purpose. When the MG included instruments such as scoring scales, developers sometimes conducted formal validity studies (comparing the new instrument with a reference standard) or reliability studies (assessing variation when applied by different raters). Testing the new MG involved members within or

outside the research team, sometimes involving target users who applied the new MG to hypothetical scenarios, published papers, or real studies. Approaches to collect the outcomes of the testing included interviews, focus groups, surveys and informal written feedback. For example, the developers of “Right Review”, a web-based tool to suggest methods for knowledge synthesis, tested the tool to assess clarity and face validity. They asked potential users outside the research team to apply the tool to illustrative case studies before collecting feedback using surveys [59].

3.3. Postdevelopment steps

3.3.1. Dissemination and implementation activities

Most documents focused on dissemination rather than implementation. Publication as a journal article was the most prominent method for dissemination. We found many other approaches including conference presentations; webinars; creating project websites; inclusion in specialized databases such as LIGHTS; promotion on social media; distribution through mailing lists or newsletters; placement on internal websites; and developing accompanying teaching materials. Some documents recommended defining a publication strategy, including planning timelines, considering format and visuals, targeting specific interest-holders, and identifying multiple communication channels.

The processes to develop clinical practice guidelines [14] and reporting guidelines [15] additionally suggested translation to different languages.

Activities supporting implementation included providing training; integration into journal instructions; and developing digital tools including software packages, code, or web applications. One group emphasized that code should be well documented in the MG publications [44]. Another group discussed the adoption of an established conceptual framework for implementation science to the methods context [43]. Suggestions included to consider MG complexity, broader and local research environments, costs of applying the method, peer norms, researchers’ expertise and self-efficacy, and the adaptability of the guidance to users’ needs.

3.3.2. Assessing implementation and effectiveness

Sometime after publication, MG developers may assess if and how researchers implemented the new MG in practice. Outcomes to assess implementation may include fidelity, adoption, sustainment, penetration, acceptability, adherence, feasibility, and appropriateness [43]. For example, the developers of a web-based decision support tool for evidence synthesis evaluated its implementation using an online survey directly embedded in the tool, and analytics from Twitter and Google [59]. Going one step further, MG developers may also assess whether the new MG led to observable effects on the quality or results of research [43]. The development process for clinical practice guidelines [14] recommended randomized studies when feasible, or cautious before-after evaluations otherwise.

3.3.3. Updating, extending, and withdrawing MG

After sometime, MG developers may reconsider updating, extending, or withdrawing the MG. They may define a fixed time interval or triggers to assess the need for any of these changes. Possible triggers included reviews of the methods literature to identify new developments or systematic evaluations of the guidance in real-world applications. An example is the updating process of MG for rapid reviews from the Cochrane Collaboration [60]. Originally published in 2021 [61], developers issued an update in 2024 [60]. To inform the update, developers assessed researchers’ adherence to and understanding of the original guidance through a mix-methods study and reviewed the literature for related publications published since the original guidance. Another example was the extension of MG for statistical analysis plans from late-phase to early-phase clinical trials [62]. On withdrawing, FDA [33,34], EMA [35], and ICH [36,37] recommend to withdraw guidance when new research shows that it should no longer be used, or when a newer version of the guidance becomes available.

The processes to develop clinical practice guidelines [14] and reporting guidelines [15] suggested specifying a process for monitoring the literature and factoring in the funding required for future updates. They cautioned against frequent small updates and instead recommended occasional major updates with clear version numbers and detailed documentation of changes.

4. Discussion

We reviewed proposed and applied strategies for developing MG and compared the findings with the established development processes for clinical practice guidelines and reporting guidelines. Overall, this process yielded a broad spectrum of steps and approaches which, together with a comprehensive collection of references and examples, will provide a useful starting point for the development of the planned guidance for MG developers.

We did not identify any general and comprehensive account of strategies for developing MG. The five groups that proposed a development process for MG focused on different aspects of guidance development while remaining vague on others, underscoring the need for a coherent framework for developing MG.

We created a heat map showing the richness of information that the different sources provided on each development step. These patterns have implications for the panel that will develop the new framework for developing MG. Some steps appear as proposed strategies but not in practice, such as formulating structured methodological recommendations. In this case, the panel may determine whether the gap reflects lack of awareness, low feasibility, limited relevance, or another implementation problem. Other steps appear in practice but lack a clear conceptualization, such as testing a new MG. In this case, the panel may consider its relevance and

potentially incorporate it into the new framework. The map also shows that steps essential in clinical practice and reporting guidelines development are sometimes absent in the MG context, for example, judging the certainty of evidence from methodological research. In this case, the panel may adapt the step to the MG context. For some steps, we observed a need for conceptual development despite their presence in both proposed and applied processes. For example, although we identified substantial information on methodological evidence and possible methodological study types in the documents, synthesizing it proved challenging: conceptual papers lacked clear and consistent definitions, and methodological studies reported in actual MG papers often lacked clear descriptions. Compared with clinical evidence, the concept of methodological evidence appeared greatly underdeveloped. To address this gap, we initiated a separate study to develop a typology of methodological studies [63].

This study has limitations. We could not assess the sensitivity of the scoping review search. As literature searches for methods topics generally have low sensitivity for a variety of reasons [18,23] However, several years of literature searches for the LIGHTS database increase our confidence. Another limitation is that, for the review of applied strategies, we could have sampled additional MG articles to identify further approaches for addressing each development step. Finally, only a small proportion of MG articles report their development process [13] and we intentionally focused on articles that provided such detail. For example, we did not include guidelines from FDA, EMA, or ICH since these documents do not report specific development methods.

Two considerations should be taken into account when interpreting the findings. First, the documents from FDA, EMA, and ICH addressed not only MG but also other types of guidance in the drug development context, such as efficacy, quality, and safety guidance. Second, MG articles do not usually report predevelopment and postdevelopment steps. Therefore, the information about these steps mostly came from the review of proposed strategies.

5. Conclusion

We identified proposed and applied steps and approaches for developing MG. Comparison with established guidance development processes from related areas identified additional steps and approaches that have received limited attention within MG development. We did not identify any general and comprehensive framework for developing MG. These findings will inform the development of such a framework.

CRedit authorship contribution statement

Malena Chiaborelli: Writing — review & editing, Writing — original draft, Project administration,

Methodology, Investigation, Formal analysis, Data curation. **Julian Hirt:** Writing — review & editing, Writing — original draft, Methodology, Formal analysis. **Matthias Briel:** Writing — review & editing, Methodology, Formal analysis. **Frances Shiely:** Writing — review & editing, Methodology, Formal analysis. **Anne-Laure Boulesteix:** Writing — review & editing, Methodology, Formal analysis. **Gordon Guyatt:** Writing — review & editing, Methodology, Formal analysis. **Frank Bretz:** Writing — review & editing, Methodology, Formal analysis. **David Moher:** Writing — review & editing, Methodology, Formal analysis. **Derek Stewart:** Writing — review & editing, Methodology, Formal analysis. **Stefan Schandelmaier:** Writing — review & editing, Writing — original draft, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Stefan Schandelmaier reports financial support was provided by the Swiss National Science Foundation. Frank Bretz reports a relationship with Novartis that includes employment, equity or stocks, and travel reimbursement. Stefan Schandelmaier is receiving funding from the Swiss National Science Foundation (Ambizione grant number 223702) with the expectation to develop parts of his career around the topic of MG. Frank Bretz reports a relationship with professional societies, such as the American Statistical Association, that includes travel reimbursement. Gordon Guyatt is Chief methodologist and board member of the MAGIC Evidence Ecosystem Foundation (www.magicproject.org), a non-for profit organization, which conducts research and guideline methodology and implementation, and which provides a authoring and publication software (MAGICapp) for evidence summaries, guidelines and decision aids. GG has not derived any income from this work. Given his role as a member of the journal's editorial board, David Moher had no involvement in the peer review of this article and had no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to another journal editor. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2026.112483>.

Data availability

The list of included publications and the codebook used for the qualitative content analysis are provided in the manuscript and Appendix. The MAXQDA file for the qualitative analysis will be made available on Zenodo upon publication of the article: <https://doi.org/10.5281/zenodo.19109421>.

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