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How to write a guideline: a proposal for a manuscript template that supports the creation of trustworthy guidelines

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Key Points

- The proposed guideline manuscript template is the first detailed template for transparent and complete reporting of guidelines.
- Consistent application of the template may simplify preparing an evidence-based guideline manuscript and facilitate its use.

Trustworthy health guidelines should provide recommendations, document the development process, and highlight implementation information. Our objective was to develop a guideline manuscript template to help authors write a complete and useful report. The McMaster Grading of Recommendations Assessment, Development and Evaluation Centre collaborated with the American Society of Hematology (ASH) to develop guidelines for the management of venous thromboembolism. A template for reporting the guidelines was developed based on prior approaches and refined using input from other key stakeholders. The proposed guideline manuscript template includes: (1) title for guideline identification, (2) abstract, including a summary of key recommendations, (3) overview of all recommendations (executive summary), and (4) the main text, providing sufficient detail about the entire process, including objectives, background, and methodological decisions from panel selection and conflict-of-interest management to criteria for updating, as well as supporting information, such as links to online (interactive) tables. The template further allows for tailoring to the specific topic, using examples. Initial experience with the ASH guideline manuscript template was positive, and challenges included drafting descriptions of recommendations involving multiple management pathways, tailoring the template for a specific guideline, and choosing key recommendations to highlight. Feedback from a larger group of guideline authors and users will be needed to evaluate its usefulness and refine. The proposed guideline manuscript template is the first detailed template for transparent and complete reporting of guidelines. Consistent application of the template may simplify the preparation of an evidence-based guideline manuscript and facilitate its use.

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The full-text version of this article contains a data supplement.

Introduction

The development of evidence-based guidelines involves a structured process of content prioritization, evidence synthesis, making informed judgments, writing reports for end users, and disseminating the guidelines. This can be time consuming, but tools to standardize and facilitate each step of the process are increasingly available.[1] Despite this, there is still important variation in guideline reporting that can be confusing for end users.[2] Although checklists for adequately reporting guidelines are available, providing practical writing tools has the potential to enhance completeness and transparency for guideline authors, as well as understanding by end users.[1,3,4]

Practical guidance for guideline development is available through the checklist created by the Guidelines International Network (GIN) and McMaster University[4] and implemented in GRADEpro software (www.gradepro.org). Item 15 of this checklist addresses "Reporting and peer review" and provides pointers for guideline formatting, authorship, and peer review. In addition, tools like the AGREE II instrument describe in detail items that need to be reported to be able to adequately assess and use a guideline.[3] Since publication of the GIN-McMaster checklist, other sources for guidance on guideline reporting have been issued. Among them, the RIGHT (Reporting Items for practice Guidelines in HealThcare) Working Group provided a tool containing essential items, and the CheckUp panel provided a checklist for reporting updates of guidelines partly based on AGREE II.[1,5] Although checklists can enhance standardization and quality of reporting, they still require guideline authors to translate individual components into an actual narrative manuscript that meets the requirements for publication in peer-reviewed journals. Also, when preparing a manuscript for publication in a peer-reviewed journal, there is a need to observe space constraints, adopt a writing style, and meet reader expectations that are not covered in existing guidance. Therefore, practical guidance for what a guideline should contain is lacking. A guideline manuscript template, grounded in an optimal development and reporting checklist, can make the task of guideline authors more efficient, ensure high-quality standardized guideline reports, and optimize transparency and understanding by end users. At present, no such practical template exists for guideline authors.

The McMaster GRADE Center collaborated with the American Society of Hematology (ASH) to develop 10 guidelines on various topics related to the prevention, diagnosis, and treatment of venous thromboembolism (VTE). The aim of this article is to describe the development of the guideline manuscript template for the ASH guidelines project, which may function as a practical tool for guideline developers beyond ASH.

Methods

The checklist created by the GIN and McMaster GRADE Center provides guidance toward developing trustworthy guidelines at each step of the process and forms the backbone for guidance in the GRADE Handbook.[4,6] The GRADE approach includes items that relate to aspects of question formulation, evidence assessment, and formulating recommendations and are integrated in the GIN-McMaster checklist.[4] GRADEpro software (https://gradepro.org/) was designed to facilitate and standardize the development process as much as possible, and this software is continually improved. Deliverables generated using this software include GRADE evidence profiles, evidence-to-decision (EtD) tables, and guideline implementation and dissemination tools. There is also a section intended to help facilitate writing the guideline manuscript, which currently provides recommended document section headings only.

Ten ASH VTE guideline panels addressed topics that included 20 to 30 recommendations per guideline. The guideline panel chairs and vice-chairs proposed to adopt a manuscript template for summarizing panel recommendations for dissemination in peer-reviewed journals. The approach for developing this template was determined by ASH in collaboration with a methodology working group composed of McMaster GRADE group members and guideline panelists.

The first ASH guideline template was drafted by H.J.S. and J.B. based on unpublished guideline templates used for various organizations, including the World Allergy Organization (WAO), World Health Organization, government guideline groups, and the existing template sections in GRADEpro.[7–17] The draft was then iteratively refined using input from the ASH VTE Guidelines Methodology Working Group, ASH staff, scientific journal editors, patients, and guideline panel chairs and vice-chairs. Further comments from the ASH Guideline Oversight Subcommittee and ASH staff were incorporated, after which the draft was discussed with guideline panel chairs and vice-chairs. Repeated edits were incorporated as needed based on discussion between the ASH VTE Guidelines Methodology Working Group and those involved in guideline development.

The guideline manuscript template was considered final once all relevant parties provided feedback and the ASH VTE Guidelines Methodology Working Group considered it ready for use. Important changes relevant for all guidelines were allowed after guideline panel chairs and vice chairs started using the template.

Results

Development of the manuscript template took 7 months, from May to November of 2016. The final template was available at the end of November of 2016, well before guideline chairs started writing the guideline manuscripts. The template was used to report 15 already published and 2 upcoming ASH guidelines.[18-32] Guideline manuscript authors tailored parts to their guideline's specific requirements, for example the treatment of pediatric VTE and also sickle cell disease guidelines simplified or combined sections on Benefits and Harms and Burden when very limited evidence was available. Substantial changes to the template would have been allowed but were not requested after it was brought into use.

Manuscript template

See Supplement 1 for the complete guideline manuscript template, and note the following characteristics:

1. The Title clearly identifies the manuscript as a guideline and includes the year of publication. Author Information meets journal-specific criteria.

2. The Abstract focuses on the guideline's objective, target audience, general development methods, number of recommendations, and selected key recommendations.
3. The Summary of Recommendations functions as an executive summary, which includes an introduction for the topic at hand, interpretation of strong and conditional recommendations, and all guideline recommendations, including important justifications.
4. The Main Text provides the guideline's specific objectives, description of the health problem, methodology regarding panel composition and coordination, guideline funding and conflict-of-interest management, formulation of questions, evidence review, including assessment of the certainty, recommendation development, document review process, and guidance for using the guidelines. For each recommendation, the summary of evidence, benefits, harms, other EtD judgements, and main conclusion and research needs are reported; online supplements and direct links to evidence profiles (EPs) and EtDs can be used for more complete or different presentations of evidence and judgments. Further, guideline recommendations are compared with what other guidelines have recommended to clarify potential differences. Limitations of the guideline-development process are reported, and a plan for guideline adaptation and updating is provided, as well as advice for future research.

Meeting checklist requirements

The proposed manuscript template meets all criteria for reporting, as specified in the GIN-McMaster, RIGHT, and AGREE II checklists, as well as the Institute of Medicine standards.[1,3,4,33] Table 1 summarizes where each checklist domain has been covered in the manuscript template.

Important features

Throughout the template, placeholders are provided to tailor the manuscript to the relevant guideline topic while maintaining standardized reporting. These include key aspects, such as Summary of Findings tables, standard wording of recommendations, and EtD frameworks that are accessible through links in the Database of GRADE EtDs and Guidelines (guidelines.gradepro.org) and help others to decide whether to adopt, adapt, or develop recommendations de novo using the "adolopment" framework.[34] This framework is especially helpful for guideline development organizations with limited resources and who may decide to focus on contextualizing existing recommendations rather than going through a full development process. These links also provide access to relevant online supplemental materials. Further, the template includes examples of how to summarize key considerations that led to the recommendation and allows for comparison of the recommendations with other guidelines on the same topic. A section for future research needs for each specific recommendation highlights evidence gaps identified by guideline panels.

Guideline author experience

ASH guideline panel chairs and vice-chairs generally found the template very helpful. Because they were given the opportunity to provide input during the template-creation process, few major issues came up when they started to use the template. Some reported challenges included focusing on key drivers for recommendations and avoiding repetition and redundancies, clear wording for recommendations comparing multiple management pathways, deciding how to tailor their specific guideline, and deciding which key recommendations and considerations to focus on in the Abstract. A reported advantage was that the template's standardized layout facilitated multiple authors to work on the same guideline manuscript. Finally, guidance for including advice on future research for each specific recommendation was much appreciated by ASH guideline panels, because this helps to further develop the evidence base and check whether progress has been made in subsequent guideline iterations.

Discussion

We have reported the approach used to develop a guideline manuscript template for widespread use, based on the GIN-McMaster checklist, input from a multidisciplinary team of guideline developers and users, and extensive previous experience in guideline development and reporting. This practical tool will assist guideline authors by facilitating and standardizing manuscripts while enhancing transparency and will help guideline users by providing a consistent format and wording. The headers of the different sections of the template manuscript are integrated into GRADEpro software, which provides the backbone for a detailed manuscript and makes GRADEpro a complete tool for every step of the guideline development process. By making these tools freely available, we aim to accelerate standardized guideline reporting. The template has been used for 15 published ASH guidelines involving >200 authors,[18-32] and it will be used for additional ASH guidelines, as well as other ongoing guidelines under development by the McMaster GRADE Centre. For specific examples of guidelines that used the template, please visit the Web site "ASH Clinical Practice Guidelines on Venous Thromboembolism" (https://www.hematology.org/education/clinicians/guidelines-and-quality-care/clinical-practice-guidelines/venous-thromboembolism-guidelines).

The manuscript template was designed for reporting a full guideline with transparent description of all considerations and judgments for the entire process. Although not used by ASH to date, small informative recommendation units can be published for specific topics, without waiting for a full manuscript to be ready, to speed up the implementation of up-to-date guidance and development of tools in practice and facilitate referencing specific recommendations. Specific sections of the manuscript template could still be used for such small informative recommendation unit publications.[35,36] Although the template was developed with the intent to be comprehensive, some guideline authors may decide to include additional information to facilitate the use of recommendations in practice.

In our experience, using this template produced long, but detailed, documents, which may be a concern given the typical word limit of journals. However, we preferred to have a comprehensive document that explicitly reported the key aspects that influenced recommendations. Online-only journals may be more flexible with regard to the word limit; if that is not an option, placing sections online only may be a good compromise. In this regard, it may be a good idea to have discussions with editors in advance about the best way to publish the guideline using this template.

Another concern may be the repetitiveness of the information presented for each recommendation. However, practitioners not may

Table 1. Guideline manuscript template conformation to reporting checklists

Domain	GIN-McMaster checklist (step)	RIGHT (topic)	AGREE II (item)	Guideline manuscript template (page)*
Basic information				
Title	–	1	–	1
Authors	15.3	–	–	1
Abstract	–	–	–	2
Executive summary	–	2	17	3
Abbreviations and acronyms	–	3	–	1
Corresponding developer	–	4	–	1
Background				
Brief description of the health problem	2.9	5	–	6
Aims of the guideline and specific objectives	2.2	6	1	6
Target populations	8.3, 8.7	7	2 & 3	6
End users and settings	5	8	6	6
Guideline development groups	3	9	4	7
Evidence				
Health care questions	8	10	2	9
Systematic reviews	10, 11	11	7, 8	9
Assessment of the certainty of the body of evidence	12	12	9	10
Recommendations				
Recommendations	13 & 14	13	10, 11, 15, 16, 20	13
Rationale for recommendations	13.6	14	5, 12, 20	13
Evidence to decision process	13.1	15	10, 12	9
Review and quality assurance				
External review	15.7, 15.8	16	13	12
Quality assurance	15.6	17	–	12
Funding and declaration and management of interests				
Funding sources and roles of the funder	7.6	18	22	7
Declaration and management of interests	7	19	23	7
Other information				
Access	16.1	20	–	Whole document (eg, citation to guideline, links to EtDs with evidence profiles, and supplements)
Suggestions for further research	13.5	21	–	Each recommendation (EtD)
Limitations of the guideline	–	22	–	15
Updating the guideline	18	–	14	16
Applicability	14.5	14	14	Whole document (eg, feasibility, barriers for each recommendation)
Implementation	16	–	18, 19	Each recommendation (EtD) & 16 (local adaptation)
Monitoring	17.3	–	21	Each recommendation (EtD)

*Supplement 1; –, not addressed.

typically read an entire guideline in one go. More likely, specific recommendations are used to resolve specific clinical questions. This makes each recommendation a stand-alone product that should include all of the necessary information. However, the minor downside of this is that for those who actually read the whole manuscript, including authors and journal editors, it may seem repetitive. Another challenge in this regard is the publication of updated recommendations in a living guideline process. More recent experience from our group suggests that initial publication of all details, possibly with a separate methodology publication, can allow us to focus on the most essential

information regarding changes while referring to previous publications for methodology and findings that did not change.

We acknowledge that there are several limitations to the development process of the guideline manuscript template. First, the template is primarily based on the GIN-McMaster checklist; other guideline developers may use a different approach, although this is a minor limitation because this checklist is the most complete tool that is used worldwide to develop guidelines, and it conforms to most criteria of guideline reporting checklists, such as RIGHT and AGREE II. Second, we aimed to use an iterative process with input from a multidisciplinary group of guideline developers and users, primarily involved in the development of ASH guidelines. Other guideline developers may have different preferences, and other health disciplines may have different needs for clear and complete reporting. Third, we primarily report our experience with using the template for multiple guidelines with 1 organization (ASH), but as the template is used more often and by other organizations we aim to improve it further. Fourth, formal feedback from final users of the guideline or readers of the journal has not yet been systematically collected. Fifth, the impact on widespread use of a similar template on plagiarism software commonly adopted by several journals at the review stage needs to be assessed, and simple linguistic variation of the common part may be suggested when using the template. We acknowledge that the document needs further iterative refinement, and while keeping the overall format a suite of alternative options may be developed (eg, to allow for standardized wording when very limited evidence was available).

In conclusion, the guideline manuscript template that we developed is a free to use detailed tool for standardized, complete, and transparent reporting of the guideline-development process and recommendations. Consistent application of the template, which is encouraged, may facilitate writing of guideline manuscripts and enhance end-users' ability to understand, select, and implement recommendations.

Authorship

Contribution: R.N., W.W., and H.J.S. designed the reported manuscript template, analyzed the manuscript template for agreement with reporting requirements, and wrote this article; J.L.B., N.S., and R.K. designed the manuscript template and critically reviewed this article; P.D., I.N., P.A.-C., A.I., S.K.V., B.R., R.A.M., D.R.A., T.L.O., D.M.W., G.H.L., S.M., P.M., S.M.B., W.L., and A.C. helped to refine the manuscript template, provided user experience data, and critically reviewed this article.

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