STUDY PROTOCOL

Developing the RIGHT extension statement for practice guideline protocols: the RIGHT-P statement protocol [version 1; peer review: 1 approved with reservations]

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Abstract

Background: A protocol for a practice guideline can facilitate the guideline development process, ensure its transparency, and improve the quality of the guidelines. However, there are currently no

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1

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reporting guideline for guideline protocols.

Methods: We intend to develop an extension of the Reporting Items for Practice Guidelines in Healthcare (RIGHT) statement for guideline protocols (RIGHT-P). We will follow the toolkit for developing a reporting guideline developed by the Enhancing the QUALity and Transparency Of health Research (EQUATOR) network. We will form a multidisciplinary international team of experts. The development of RIGHT-P will be conducted in 12 steps grouped in three stages over a two-year period.

Results: The results of RIGHT-P statement will be presented in an article to be published later.

Conclusion: This report describes the process of RIGHT-P statement development. We believe RIGHT-P will help guideline developers improve the reporting of guideline protocols and indirectly improve their quality and the quality of guidelines.

Registration: We registered the protocol on the [EQUATOR network](#).

Keywords

practice guideline; reporting guideline; RIGHT statement; protocol; EQUATOR

This article is included in the [Research on Research, Policy & Culture](#) gateway.

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[view](#)

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Any reports and responses or comments on the article can be found at the end of the article.

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Author roles: **Luo X:** Conceptualization, Data Curation, Formal Analysis, Investigation, Writing – Original Draft Preparation; **Akl EA:** Methodology, Writing – Review & Editing; **Zhu Y:** Validation, Writing – Review & Editing; **Lv M:** Formal Analysis, Investigation; **Liu X:** Formal Analysis, Investigation; **Song Y:** Writing – Review & Editing; **Wang P:** Data Curation, Formal Analysis; **Wang J:** Formal Analysis, Investigation; **Song X:** Writing – Review & Editing; **Amer YS:** Methodology, Writing – Review & Editing; **Litvin A:** Methodology, Writing – Review & Editing; **Chen Y:** Conceptualization, Funding Acquisition, Project Administration, Supervision

Competing interests: Yaolong Chen, Xufei Luo, Elie A. Ak, and Yasser S. Amer are members of RIGHT Working Group. The authors have no other financial competing interests to declare.

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Abbreviations

AGREE: The Appraisal of Guidelines for Research and Evaluation
 E&E: Explanation and Elaboration
 EQUATOR: Enhancing the QUALity and Transparency Of health Research
 GIN: Guideline International Network
 GRADE: The Grading of Recommendations, Assessment, Development and Evaluation
 PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
 PROSPERO: International prospective register of systematic reviews
 RIGHT: Reporting Items for practice Guidelines in HealThcare
 RIGHT-P: RIGHT for practice guideline protocols
 SR: Systematic Review
 SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
 WHO: World Health Organization

Introduction

Trustworthy practice guidelines can inform clinical practice and decision-making and improve clinical outcomes.¹ However, high-quality guidelines are currently scarce,^{2–5} despite many methodological advancements in the field,^{6–8} and the fact that most guideline developers have produced manuals and handbooks to support their processes.^{9–11} One potential explanation for this could be the lack of a standardized processes to develop and report the guideline protocols in a transparent format.

A research protocol is intended to help researchers to improve the quality of that research by defining a priori the methods to be followed and contributing to its transparent reporting. It is essential to have a standardized way to report these protocols. For example, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for protocols (PRISMA-P) was developed in 2015 to improve the reporting quality of systematic reviews and meta-analysis protocols.¹² One study¹³ showed that the reporting quality of protocols of clinical trials has improved by 8.8% since the publication of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement.¹⁴

To our knowledge, there are no widely agreed on guidelines or standards for how guideline protocols should be reported. The World Health Organization (WHO) guideline development handbook¹¹ proposes that guideline protocols should address 17 topics. A 2019 study found that the contents of existing guideline protocols are diverse and vary.¹⁵ In 2017, a multi-international group of experts developed Reporting Items for practice Guidelines in HealThcare (RIGHT) statement reporting guideline for practice guidelines.⁶ Given the importance of guideline protocols, we will form an international group of stakeholders to develop the reporting guideline for guideline protocols. We intend to develop the RIGHT-Protocol (RIGHT-P), as an extension of the RIGHT statement for practice guideline protocols. The purpose of this paper is to describe the methods to be used for the development of the RIGHT-P.

Methods

In this study, we define a guideline protocol as a document detailing the processes and methods to be followed for developing, adapting or updating guidelines. We will follow the toolkit on how to develop a reporting guideline recommended by Enhancing the QUALity and Transparency Of health Research (EQUATOR) Network to develop the RIGHT extensions for guideline protocols.¹⁶ We will build RIGHT-P as an extension to the RIGHT checklist⁶ while building on the WHO guideline development handbook,¹¹ as well as other guideline manuals collected through a systematic search. The target users of RIGHT-P are guideline developers/adapters, guideline evaluators, and guideline stakeholders. We expect to complete the development of RIGHT-P within two years, from August 2021 to December 2022. The process will consist of three stages: preparation, drafting the RIGHT-P checklist, and testing and dissemination. The detailed development process is illustrated in Figure 1, and the timetable is showed in Table 1.

STAGE 1 Preparation

Draft the protocol

To enhance the transparency and quality of the RIGHT-P development, we registered it on the EQUATOR network. We have also developed the protocol we are reporting in this paper, and the development of RIGHT-P will be initiated after the publication of this protocol.

Figure 1. Flowchart of the development process for RIGHT-P. RIGHT, Reporting Items for practice Guidelines in Healthcare.

Establish RIGHT-P working groups

We will establish three expert groups, a steering committee, a consensus expert group and a secretariat team. The steering committee will consist of 3-5 experts with rich experience in guideline development and reporting standards. The steering committee will form the consensus expert group, manage conflicts of interest of all participants in the project, provide consultation on the RIGHT-P development process, assure the quality of the development process, and approve the final version of the RIGHT-P.

The secretariat team includes three members from the RIGHT Working Group, of which Xufei Luo is the team's leader and contact person for the RIGHT-P project. The team's responsibilities are to coordinate the consensus expert group and the steering committee, conduct the background research, such as, a systematic review on published guideline protocols, draft the initial RIGHT-P checklist, organize Delphi meetings, manage email communications, and draft the final RIGHT-P article.

Table 1. Timeline for development of RIGHT-P.

Stages	Steps	Year Months	2021					2022																	
			Tasks					8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	
1	1	Draft the Protocol																							
	2	Establish working groups																							
	3	Conduct a systematic survey of the guideline protocols																							
	4	Cross-sectional survey																							
	5	Review the guideline manuals																							
2	6	Generate the initial pool of items																							
	7	The first round of Delphi																							
	8	The second round of Delphi																							
	9	Use the RIGHT-P to evaluate published guideline protocols																							
	10	Approval of the final RIGHT-P checklist																							
3	11	Develop the guidance statement and explanatory document (E&E)																							
	12	Translate RIGHT-P to other languages																							

RIGHT, Reporting Items for practice Guidelines in HealThcare; SR, Systematic Review; E&E: Explanation and Elaboration.

The consensus expert group will consist of 20-30 multidisciplinary and international experts whose role is to participate in the Delphi survey and approve the final version of the RIGHT-P checklist. We will invite experts from the Guideline International Network (GIN), the Appraisal of Guidelines for Research and Evaluation (AGREE) Collaboration, the RIGHT Working Group, and the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group. We will also invite representatives of guideline developers/adapters and guideline users to participate in this expert group.

Conduct systematic survey of the guideline protocols

We are conducting a systematic review of published guideline protocols; that review has been registered on the PROSPERO (International prospective register of systematic reviews) website ([CRD42021135732](#)). We intend to extract the information reported for the protocols with published guidelines and then try to generate an initial pool of items for consideration in the RIGHT-P.

Cross-sectional survey and review the guideline manuals

We will design questionnaire to investigate the knowledge, attitudes, and behaviors of guideline developers/adapters, guideline users, and other stakeholders regarding the guideline protocols. The questionnaire consists of three parts: (1) the basic information about participants (e.g., gender, age, working time, title, units of employment, profession); (2) the knowledge, attitudes and behaviors with regards to developing and publishing a guideline protocol, and the degree of support for the development of the RIGHT-P; (3) request to propose 3-5 items that the RIGHT-P should address. We plan to use a convenience sample of 20-30 stakeholders outside the consensus expert group. We will use [SurveyMonkey](#) for data collection.

In addition, we will review the guideline development manuals and handbooks to collect the potential items. We will systematically search and analyze the guideline development manual, extract the relevant contents about the guideline protocols, and then classify and compile the relevant contents into the initial pool of RIGHT-P items.

STAGE 2 Drafting the RIGHT-P checklist

Generate the initial pool of items for consideration

Based on the findings of the systematic review of the guideline protocols, the results of the cross-sectional survey and the review of handbooks, we will formulate a pool of initial items for consideration in the RIGHT-P. In addition, we will

categorize the initial items into basic information, background, development methods, evidence, recommendations, and other information. We will use Microsoft excel 2016 software in the collection and management of all data and items.

Delphi consensus meeting

We will use a modified Delphi method to reach consensus on the RIGHT-P items. We will use a 7-point Likert scale for determining whether an item should be included. Participants will score each initial item on a scale of 1-7 for inclusion, with a score of 1 indicating strong disagreement with the inclusion of the item and a score of 7 indicating strong agreement with the inclusion of the item.¹⁷ We plan to have two rounds of the Delphi survey to collect the opinions, comments, and suggestions of the participants via the SurveyMonkey. If necessary, we will hold online meetings to help reach consensus through the [Zoom Cloud Meeting App](#).

We will send the initial list of items to the consensus expert group members via the SurveyMonkey, and the first round of Delphi survey will allow the experts to score each item of the initial RIGHT-P checklist and give suggestions and modifications. At the same time the participants can add the items they consider important and not included in the initial item pool.

After collating the results of the first round of Delphi survey (median score for each item), we will generate the second round of Delphi questionnaire. If the median score of an item ≥ 6 , we will include the item; if the median score of an item is between 3 (exclusive) and 6 (exclusive), we will enter it in the second round of Delphi survey; if the median score of an item is ≤ 3 , we will exclude it.¹⁷ We will collate suggestions and comments, and consider them when drafting the list of the second round of Delphi survey. Suggestions and comments from experts will be recorded and responded to one by one.

We will conduct the second round of Delphi survey two months after the first one, using the same scoring scheme as in the first round. We will exclude items with a median score ≤ 3 and include items with a median score ≥ 6 . For items with a median between 3 and 6, the steering committee will make the final decision regarding inclusion/exclusion after considering expert suggestions and comments from the second round.

All ideas and comments will be recorded and documented by the secretariat team, and after the second round of the Delphi survey, the steering committee will generate a RIGHT-P checklist draft version 1 and revise for final approval via email.

Use the RIGHT-P to evaluate published guideline protocols

To assess the feasibility and applicability of the RIGHT-P checklist draft version 1, we plan to use it to evaluate published guideline protocols that included in prior systematic survey. We will use the results of that step to copy with any further edits to the draft RIGHT-P checklist version 1.

Quality assurance and final approval

Upon revision of the RIGHT-P checklist based on the results of the evaluation for guideline protocols, we will generate a draft version 2 of the RIGHT-P checklist. We will invite the guideline developers/adapters, guideline users, and other stakeholders to provide feedback and perform external review regarding the draft version 2 checklist. Finally, we will send the revised draft checklist version 2 to the steering committee and the consensus expert group for final approval. To ensure that the RIGHT-P project runs smoothly, we plan to record each step of the process in detail and post it on the RIGHT statement website after the RIGHT-P checklist is published.

STAGE 3 Implementation and transmission

Develop the Explanation and Elaboration (E&E) document

Once the final RIGHT-P checklist is finalized, we intend to develop detailed explanations and elaborations document to explain and provide example(s) for each item to facilitate the understanding and adoption of the reporting checklist by the target users.

Translate RIGHT-P to other languages

To facilitate the understanding and dissemination of the RIGHT-P, we plan to contact those interested to translate the RIGHT-P checklist into non-English languages such as Chinese, French, Japanese, Korean, and Spanish. We will post the

different language version on the RIGHT statement website as soon as they are finalized. In addition, the readers who are interested can contact the RIGHT-P developers to collaborate on its translation into the language of their choice.

Patient and public involvement

Patient and public will not be involved in this study.

Study status

Currently, we are working on reviewing the guideline manuals and generating the initial pool of RIGHT-P items.

Discussion

Despite the fact that few guideline protocols have been published, their importance to guideline development cannot be overstated. This is analogous to the importance of protocols to clinical trials,¹⁴ and systematic reviews.¹² This project will develop an extension of the RIGHT statement for protocols, following the standard methods of international reporting guidelines development.¹⁶ Also, it will engage relevant stakeholders from WHO, AGREE, GIN and other international guideline development organizations.

Since the publication of the RIGHT statement in 2017,⁶ guideline developers have increasingly emphasized reporting on the guidelines and their different procedures, types, fields, and sections. Researchers have developed extensions for patient version guideline (RIGHT-PVG),¹⁸ Traditional Chinese Medicine (RIGHT-TCM).¹⁹ Extensions for acupuncture (RIGHT-Acu)²⁰ and guideline adaptation (RIGHT-Ad@pt)²¹ are currently in development. We aim to enhance and ensure the quality of guideline development by promoting and standardizing the writing and reporting of guideline protocols. The RIGHT Working Group aims to inform guideline developers of the importance of registration²² and protocol drafting, and promote and advocate for protocol drafting in the guideline development process.

We hope that the RIGHT-P will be helpful to guideline developers/adapters in the planning stage of guideline development/adaptation in terms of clarifying the rigorous schedule steps and improving the quality of reporting in the protocol.

Data availability

No data are associated with this article.

Acknowledgements

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Melissa K. Sharp

Health Research Board Centre for Primary Care Research, Department of General Practice, Royal College of Surgeons in Ireland, Dublin, Ireland

Thank you for the opportunity to review this protocol to develop an extension to the RIGHT statement. I do not have major concerns about the content within the article but rather the timeline of the work as, per Table 1, the work is already more than halfway complete. Also, in the text it states what 'the development of RIGHT-P will be initiated after the publication of this protocol' which is clearly incorrect if Table 1 is to be believed. Therefore, I question the whether this is in fact a protocol and whether any of my peer review comments could actually meaningfully contribute to the design or conduct of the study. My comments will likely only be used to clarify results manuscripts which I do not believe is the point of peer review for study protocols.

That being said, I will give my comments nonetheless in order in which they appear:

- The introduction describes the general impetus for the project but I do think it is a bit too short and cursory.
- The description of the three expert groups: steering committee, consensus expert group, and secretariat team is a bit confusing. Assuming that the secretariat team is also involved in the steering committee then there is actually 3 + 3-5 people involved? This is a hierarchical structure, no? The paragraph should be reworded to be clearer about the structure and numbers involved.
- Given that it is said you will 'invite representatives of guideline developers/adapters and guideline users to participate in this expert group', it is surprising that patient representatives are not involved as they are a key stakeholder in guideline development groups. This is confirmed by the statement near the end of the manuscript 'Patient and public will not be involved in this study.'
- It is also unclear how these representatives will be contacted – by the steering committee? Is all participation online/remote? Are all of these representatives from GIN, AGREE, and

GRADE? Are there any geographic or equity concerns to be discussed or addressed?

- I find that the information about the cross-sectional survey and guideline manuals review is extremely vague. It's unclear whether you're drawing on previous literature, pilot-testing the questionnaire, doing any validation, using any frameworks, or adapting any scales, etc. The synthesis process for the initial pool of RIGHT-P items is a bit unclear. Are there any thresholds that you will establish? Will data be double-screened or extracted? Will the initial pool be agreed upon by the steering committee or a broader group?
- The end of the Delphi consensus meeting section seems to get ahead of itself that you will 'revise for final approval via email' then continue describing the process to make edits to version 1 and draft version 2. I also think you need more information about what this 'feasibility/applicability' assessment entails (who is doing it, how is this feedback being given to other members of the steering committee perhaps?, etc.)

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

No

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: epidemiology, public health, reporting guidelines, mental health, meta research, science communication

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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