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Developing the RIGHT-COI&F extension for the reporting conflicts of interest and funding in practice guidelines: study protocol

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Background: Conflicts of interest (COI) and funding may influence the development of practice guidelines, but there are no internationally endorsed guidelines specifically focusing on the reporting on issues related to COI and funding in practice guidelines. Our aim is to develop an extension of the essential Reporting Items of Practice Guidelines in Healthcare (RIGHT) for COIs and Funding in practice guidelines (i.e., RIGHT-COI&F).

Methods: We will follow the Enhancing the QUALity and Transparency Of health Research (EQUATOR) network's toolkit for developing a reporting guideline in six stages: (I) identifying the need for the extension; (II) registering the project and setting up working groups; (III) collecting the initial items; (IV) reaching consensus on the items to be included; (V) revision and formulation of the final checklist; and (VI) dissemination and implementation. We intend to form a multidisciplinary international team of experts to collect and evaluate the items and plan to complete the full reporting guideline in about 2 years.

Discussion: The RIGHT-COI&F statement will help guideline developers improve their reporting of issues related to COIs and funding, and subsequently improve the reporting quality of their guidelines. Journals editors, guideline users and evaluators will benefit from a more complete and transparent reporting of COI.

Trial Registration: We have registered the protocol on the EQUATOR network (<https://www.equator-network.org/library/reporting-guidelines-under-development/reporting-guidelines-under-development-for-other-study-designs/#RIGHT-COI>).

Keywords: Clinical practice guidelines; conflicts of interest (COI); funding; Reporting Items of Practice Guidelines in Healthcare statement (RIGHT statement); transparency

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Introduction

Practice guidelines are intended to inform diagnosis and treatment decisions, narrow practice gaps, improve the quality of health care, and possibly reduce medical expenses (1-6). Interests, both financial and non-financial (related to, e.g., academic career progress or social status) may affect the objectivity and independence of those involved in guideline development, thus constituting conflicts of interest (COI) (1,7,8). COI and the involvement of funders may cause bias during the development process of guidelines and subsequently affect their trustworthiness (1,9,10).

COIs are commonly encountered in guideline development (11,12), and may in some cases negatively affect the trustworthiness of the guidelines. In 2009, five experts who associated with pharmaceutical companies participated in developing the guidelines for the management of influenza A (H1N1) of the World Health Organization (WHO) (13), but none of their COIs had been properly declared and managed in advance. In 2020, WHO retracts opioid guidelines after accepting that industry had an influence due to undue influence of opioid manufacturers in guideline development process (14). Above two examples on negative consequences of the lack of transparency or incomplete disclosure of COI on guidelines have led to the credibility of the WHO and the trust in the global public health system. Studies of COI in guideline development have identified deficiencies in different aspects, such as COI disclosure, and across diseases and fields, including oncology, acute ischemic stroke, endocrinology, and heart disease (15-21). Meanwhile, the reporting rate of COIs and funding in both Chinese and international guidelines has been shown to be low and the level of detail in the disclosure varies greatly (22-26). Because inappropriate handling of COI and funding may undermine guidelines' trustworthiness (1,11,27-29), guideline developers have strived to address this issue.

Guideline-producing organizations such as WHO and the American College of Physicians have developed processes for the declaration and management of COI and require the sources of funding to be clearly reported (30-32). Such processes, if fully implemented, can optimize the credibility of the guidelines (33,34). Although handbooks for guideline development typically provide general guidance for declaring and managing the funding and COI, they commonly lack specific guidance. Adequately reporting of the basic information of COIs and funding helps the readers to accurately comprehend the nature and extent

of the role of COI and funding in the guidelines, thus enhancing the credibility of the guidelines.

To improve the completeness and quality of guideline reporting, the Reporting Items of Practice Guidelines in Healthcare (RIGHT) Working Group developed the reporting standard for healthcare practice guidelines in 2017 (35). To date, investigators have developed or are developing multiple extensions to the RIGHT statement, such as for guideline adaptations (36), patients/public version of guidelines (37), traditional Chinese medicine (TCM) guidelines (38), and acupuncture guidelines (39). Such reporting checklists and extensions enable guideline developers to better report their guidelines and guideline users to access the key information easily and quickly. Although the RIGHT checklist (includes 22 items) has two items (items 18 and 19) related to COIs and funding (35), further refinement of the standard is needed (e.g., describe how users of the guideline obtain the COIs related statement or describe the effect of funding on the recommendations of this guideline, etc.). We decided to develop an extension to the RIGHT statement to clarify areas of COIs and funding in guidelines with the support of the RIGHT Working Group. This extension aims to standardize the reporting of COIs and funding to improve guideline development and uptake.

Objective

The aim of this project is to develop the essential reporting items for reporting COIs and funding in practice guidelines (RIGHT-COI&F) as an extension of the RIGHT Statement, to meet the requirements of complete and transparent reporting of these critical issues.

Methods

We will refer to and adapt the toolkit for developing a reporting guideline recommend by the Enhancing the Quality and Transparency Of health Research (EQUATOR) network (40) (<https://www.equator-network.org/>) and to the methods used in the RIGHT statement and extensions to develop our RIGHT-COI&F (36-39). We plan to complete the project in approximately 2 years (i.e., by July 2023) in the following six stages: (I) identify the need for the extension; (II) register the project and establish working groups; (III) collect the initial items; (IV) reach consensus on the items to be included; (V) revision and formulation of the final checklist; and (VI) dissemination

and implementation. The detailed development process is illustrated in *Figure 1*, and the proposed schedule is shown in *Figure 2*. Because this project will not involve collection of primary data from humans or animals, ethical approval and patient consent are not required.

Identify the need for the checklist

To identify the need for developing this checklist, we searched the published literature and documents for COI and funding, and found only a few specific checklists that are not widely accepted internationally. We will identify the handbooks and manuals of guideline development that cover the principles of COI and funding as well as survey on the reporting of COI or funding; the results of these investigations will serve as the main source of the initial pool of items.

Obtain funding

This project will be funded by The Fundamental Research Funds for the Central Universities, Lanzhou University (lzujbky-2021-ey13). The funder will have no role in the study design, data collection and analysis, writing of the article, or the decision to submit it for publication.

Drafting the protocol and registering the project

To enhance the transparency and quality of the RIGHT-COI&F development, we drafted a project protocol and registered it on the EQUATOR network (<https://www.equator-network.org/library/reporting-guidelines-under-development/reporting-guidelines-under-development-for-other-study-designs/#RIGHT-COI>).

Establishing working groups

RIGHT-COI&F working groups will be composed of experts from different disciplines (statisticians, methodologists, journal editors, and professional medical writers) and multi-country (Switzerland, Canada, UK, Lebanon, Japan, USA, Korea, Spain, China, etc.), and with different fields of expertise (relevant experience in clinical guideline development and COI and/or in systematic reviews/guidelines research methodology). We will also invite members of the RIGHT working group and representatives of patients and the public to join the following working groups.

Advisory group

The advisory group will consist of 3–5 skilled experts who have rich experience in the development of clinical practice guidelines and reporting checklists. The group will review and provide expert advice during the different steps of the RIGHT-COI&F development process. The advisory group will approve the final checklist and accompanying guidance.

Coordination team

The coordination team will lead and coordinate the development process of RIGHT-COI&F and ensure its completion according to the established timeline. The Coordination Team is responsible for forming the initial pool of items for the reporting checklist, responding to the suggestions and opinions of experts in the consensus conference and revising the list. In addition, they will collect feedback, support the other groups, and consult with external parties throughout the development process.

Delphi panel

The Delphi panel will be composed of 20–30 international experts representing a broad range of disciplines. We will invite experts specializing in the management of COIs, as well as members of the Guidelines International Network (GIN), the RIGHT working group, the Appraisal of Guidelines for Research and Evaluation (AGREE) cooperative organization, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group, and other relevant organizations and guideline stakeholders. The Delphi panel will participate in Delphi surveys and/or consensus conferences, vote and agree on items during the checklist formation process, and approve the final version of the RIGHT-COI&F checklist.

Conduct systematic surveys

The coordination team will conduct systematic surveys, including a systematic survey of the reporting of COI and funding in guidelines, and a review of handbooks or manuals of guideline development for recommended policies related to COI and funding. The literature screening and data abstraction will be done by two independent investigators, and discrepancies will be solved by discussion. The coordination team will also conduct a survey among guideline stakeholders for their preferences regarding the reporting of COI and funding in guidelines.

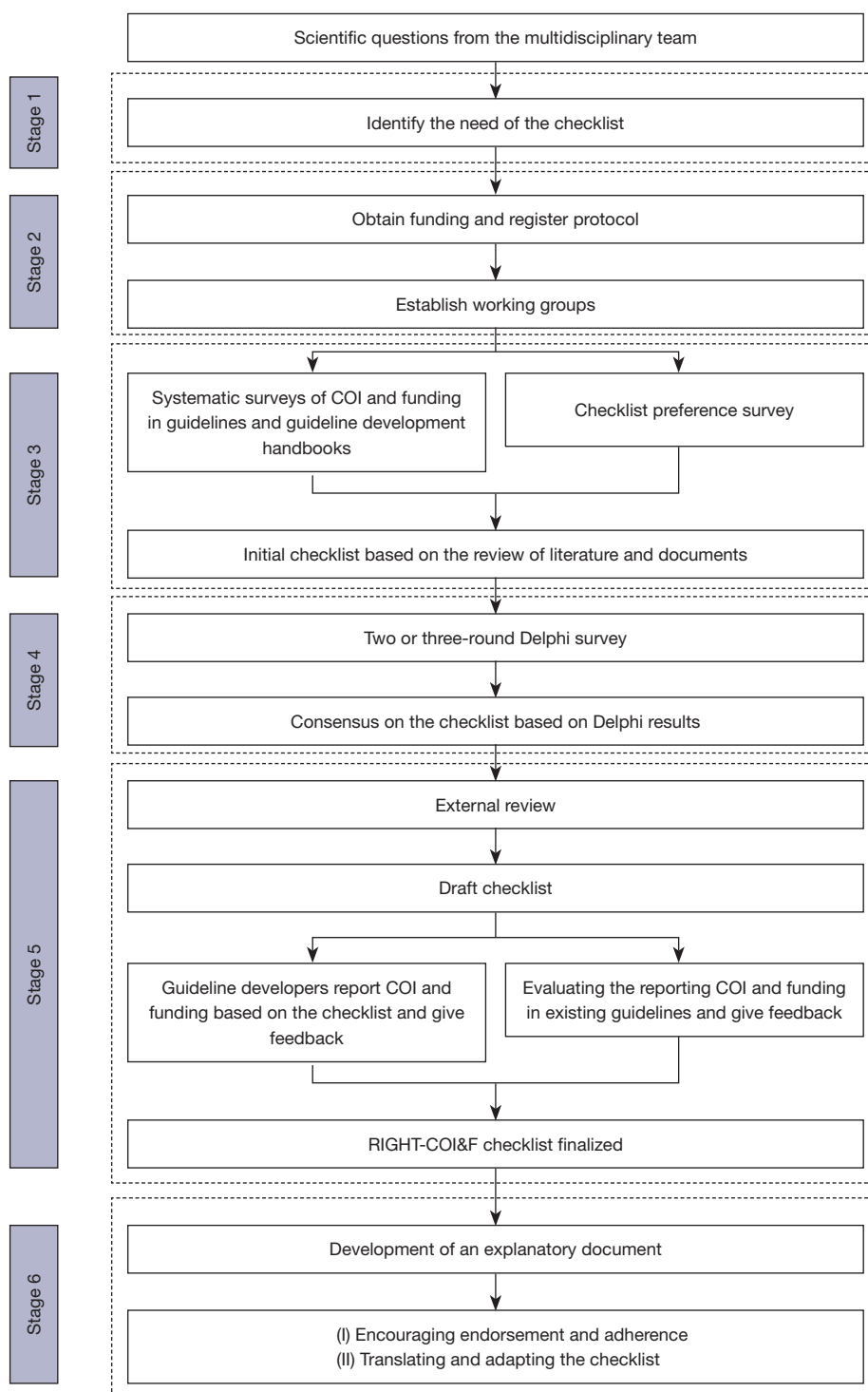


Figure 1 The development process of the RIGHT-COI&F checklist. RIGHT, Reporting Items of Practice Guidelines in Healthcare; COI, conflicts of interest; F, funding.

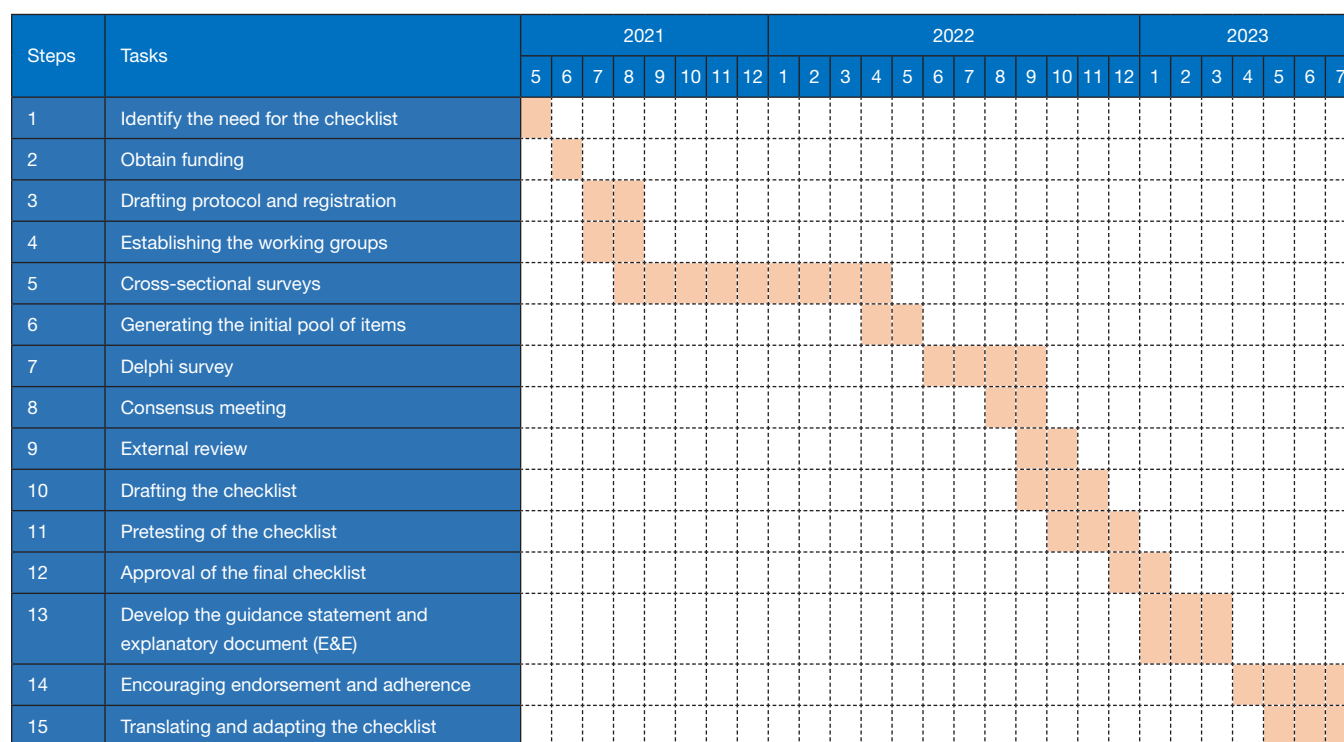


Figure 2 Timeline for the development of RIGHT-COI&F. RIGHT, Reporting Items of Practice Guidelines in Healthcare; COI, conflicts of interest; F, funding; E&E, explanation and elaboration.

Generation of the initial checklist

The coordination team will formulate an initial pool of items for RIGHT-COI&F based on the systematic surveys during regular online or face-to-face meetings. The coordination team will record and review the results of the meetings and draft a report that includes recommendations on the initial version of the reporting checklist. The coordination team will discuss each of the items to refine them if necessary, and generate the first version of the checklist based on the feedback to be evaluated in the Delphi process. We will use Microsoft Excel 2016 software to collect and manage all data and items.

Statistical analysis

To achieve consensus on which items from the list developed in step 6 should be included in the final reporting tool, we will conduct either two or three rounds of a modified Delphi survey, using a 7-point Likert scale for expressing agreement with each potential reporting item (35,41-43). We will use SurveyMonkey (<https://www.surveymonkey.com/>) to collect and summarize the

results. We will determine the agreement with each item according to the median score that the item receives among the panelists (*Table 1*). Items that achieve ‘agreement’ are removed from subsequent rounds and included in the final version; items with ‘disagreement’ are removed from subsequent rounds and excluded from the final version; and items rated as ‘ambivalent’ or where no consensus is reached will be modified to reflect points raised by the Delphi panel and included in the next Delphi round.

Modified Delphi process

During the first round of Delphi surveys, the Delphi panel will have the opportunity to propose items not included in the initial list. In each round, we will include a free text box to suggest changes to the checklist or provide comments. In order to minimize potential bias, the answers will be analyzed anonymously by a medical statistician who is not a member of the Delphi panel. After two or three rounds of Delphi surveys, we will generate a list of reporting items of COI and funding in guidelines, which will be discussed in the teleconference consensus meeting described next.

Table 1 The 7-point Likert scale and the definition of consensus based on the median score (42,43)

Score	Meaning	Median score	Definition of consensus
1	Strongly disagree	Median score of 1–3 points without substantial comments	Disagreement with the item; exclude without further evaluation
2	Disagree		
3	Somewhat disagree		
4	Neither agree nor disagree (neutral)	Median score of 4–5 points, or ≤ 3 or ≥ 6 with substantial comments requesting a major revision of the item	Ambivalence about an item; further evaluation to either retain, modify or exclude the item
5	Somewhat agree		
6	Agree		
7	Strongly agree	Median score of 6–7 points without substantial comments	Agreement with the item; retain without further evaluation

Consensus meeting

We will organize a consensus meeting as a teleconference. Representatives of the coordination team and Delphi panel will be invited to participate and present and discuss the results of the Delphi process to refine the list of items. All suggestions and comments will be recorded and archived by the coordination team, and feedback will be provided via email to form the first draft of the reporting checklist.

External review

When a draft of the list in step 8 is completed, it will be externally reviewed by individuals with extensive experience and expertise in the development of reporting guidelines and who have not participated in the Delphi survey or the consensus meeting. The reviewers will be invited to comment on the usability, integrity and formulation of items. We will refine the checklist accordingly.

Formulating the draft checklist

Based on the results of the Delphi surveys, consensus meeting and external review, the coordination team will help the advisory group to draft the final checklist and send it to the Delphi panel for their review for accuracy and correctness.

Pilot test and examination of validity

The checklist produced in step 10 will be applied to report the COI and funding of three ongoing guidelines. The developers of these guidelines will be invited to examine the

checklist. We will design a questionnaire for this survey and solicit the opinions of these guideline developers to improve the checklist. Two investigators will also use the checklist to assess the reporting status on COIs and funding in a sample of 10 guidelines published in the past 2 years.

Development of the guidance statement and publication strategy (finalized RIGHT-COI&F checklist)

We will draft a statement based on the pilot test, and submit it to a peer-reviewed journal for publication.

Development of an explanatory document

The Coordination Team will develop a detailed explanatory and elaborative document for the basic reporting items to inform and guide users and facilitate the implementation of the checklist. The Delphi panel will be invited to review the document and provide suggestions.

Encourage endorsement and adherence

We will disseminate the statement as follows: (I) we will submit the reports and the checklist for endorsement by EQUATOR, the RIGHT website (<http://www.right-statement.org/>), and other relevant publicly accessible websites; (II) we will present the results at international academic conferences, such as the GIN Annual Meeting, and the Cochrane Colloquium; (III) we will distribute the statement to interested guideline developers and users worldwide; (IV) we will conduct lectures and training for guideline developers and users on how to use the RIGHT-COI&F checklist.

Translating and adapting the checklist

We welcome any initiatives to translate or adapt the checklist by and in collaboration with guideline developers throughout the world to suit their country-specific settings of use.

Updating the checklist

We will review the reporting checklist every 3 years and revise it as needed, including feedback from users of the checklist and new information from scientific publications.

Patient and public involvement

We will not directly involve patients in our study, but will analyze the survey from patient and public viewpoints and preferences to inform potential projects. They will provide their comments on the reporting items.

Discussion

The main output of this project is an extension of the RIGHT checklist for reporting COI and funding, as well as an explanatory document. To ensure the quality and smooth progress of this project, we plan to record each step of the process in detail and post it on the RIGHT website. We will disseminate the RIGHT-COI&F list by publishing it in peer-reviewed journals, introducing it to relevant stakeholders and translating it into different languages. Meanwhile, we will continue to seek feedback from guideline developers, users and stakeholders, and update the checklist according to the latest research evidence and feedback.

Whether a guideline is reported in a standardized manner or not is one of the key factors that determine whether it can be promoted efficiently and implemented smoothly (44). Since the publication of the RIGHT statement in 2017, guideline developers have increasingly used it to increase the transparency and clarity of their guidelines (36-39).

It is important to note that the original RIGHT statement includes two items (four sub-items) related to funding and COI: (I) declaration of specific funding sources for each phase of guideline development; (II) reporting the role of funders in guideline development, dissemination, and implementation; (III) declaring the types of COI associated with the guideline (financial and non-financial); and (IV) reporting how the COIs were evaluated and managed

and how users of the guideline can access the declarations of interest. These items, however, do not address details such as how COI and funding should be reported, who should manage them, how they should be managed, and how the results of COI and funding are related to the final recommendations of the guideline. We will address these issues with the RIGHT-COI&F extension, a more detailed reporting checklist focusing specifically on COI and funding.

The RIGHT-COI&F statement will help guideline developers with the reporting of COIs and funding, and improve the reporting quality of the guidelines. Journal editors, guideline users and evaluators will particularly benefit from more complete and transparent information on COIs and funding.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-2123/coif>). YX is funded by China Scholarship Council (No. 202106180043). EAA declares that he has contributed to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field. YC declares that he is the co-founder of the RIGHT Working Group. JE declares that he has contributed to the development of the RIGHT statement. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Because this project will not involve collection of primary data from humans or animals, ethical approval and patient consent are not required.

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