A Proposal of Essential Reporting Items for Practice Guidelines in Health Systems (RIGHT)
RIGHT working group

BACKGROUND

Standards of Reporting of Clinical Trials and Systematic Reviews

In order to improve the reporting of randomized controlled trials (RCT) and systematic reviews, international groups have developed the CONSORT(Consolidated Standards of Reporting Trials) [1] and PRISMA (Preferred Reporting Items of Systematic reviews and Meta-Analyses) [2] statements, respectively. These statements indicate minimum reporting standards which enable readers to understand the design, conduct, analysis and interpretation of the study or review, and to assess the validity of results,

Quality of Reporting of Practice Guidelines

Over the past 30 years practice guidelines [3] have become an increasingly popular tool to improve the quality of healthcare. Clear, transparent, and applicable guidelines enable health care providers to understand and implement recommendations that positively impact patients and populations. However, the reporting quality of practice guidelines is often poor. In 2000, Grilli and colleagues found that of 431 guidelines produced by specialty societies and published in MEDLINE, 67% did not report any description of the stakeholders, 82% did not report explicit criteria to grade the scientific evidence that supported their recommendations, and 87% did not report whether a systematic literature search was performed. [4]. A 2005 survey found that WHO published a large number of recommendations of many different types, in many different formats, and WHO had no standards for reporting recommendations [5]. In our pilot work, we found more than 30 terms have been used to represent guidelines in the titles of WHO documents containing recommendations (Box 1).

Box 1. Terms used to represent guidelines in titles of WHO documents

guideline, guidelines, guidance, guide, recommendations, statement, manual, guiding principles, Handbook, document, report, rapid advice, booklet, toolkit, management, framework, care, criteria, classification, initiative, module, interventions, medical reasons, textbooks, policy, response, role, technical paper, technical consultation, technical note, tool, treatment

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The development of standards of reporting for Practice Guidelines

In 1992, the US Institute of Medicine (IOM) defined eight "desirable attributes" of clinical practice guidelines: validity, reliability and reproducibility, clinical applicability, clinical flexibility, clarity, documentation, development by a multidisciplinary process, and plans for review [6]. In 1993, Hayward et al. developed a structured abstract for clinical practice guidelines [7], and in 2003, the Conference on Guideline Standardization (COGS) published a checklist for Standardized Reporting of Clinical Practice Guidelines [8]. However, items of COGS mainly focused on clinical medicine and were not applicable to public health and health systems recommendations; items have not been updated since 2003; and the items were not structured like CONSORT and PRISMA; and the items were difficult for guideline developers to apply.

AIM:

1. To develop essential reporting items for guidelines in health systems to ensure the comprehensive and transparent reporting of such guidelines.

METHODS

We base our methods on those proposed by *David Moher* and colleagues for developers of health research reporting guidelines (Table 1) [9].

Table 1 Recommended steps for developing a health research reporting guideline and project timeline

Item Number	Tasks	Time line
1	Identify the need for guideline	2013.9
2	Review the literature	2013.10-12
3	Obtain funding for the guideline initiative	2013.11-12
4	Identify the research team	2013.12-2014.2
5	Modified Delphi process [10] to reach consensus	2014.2-4
6	Present and discuss results of the Delphi process	2014.4
7	Draft the final checklist	2014.5
8	Pilot test the checklist	2014.6
9	Develop the guidance statement and publication strategy	2014.7
10	Discuss knowledge translation strategy	2014.8
11	Develop an explanatory document	2014.8
12	Seek feedback and revise as appropriate	2014.8-9
13	Evaluate the impact of the reporting guideline	2014.8-9
14	Develop a web site for the guideline	2014.8-9
15	Translate and adapt guideline	2014.9-
16	Update guideline	2015-

1. Identify the need for guideline

See background.

2. Review the literature

2.1 We conducted a literature search to identify articles about standards of reporting of guidelines and other related methodological articles that might inform the panelists, especially in relation to checklist items of standard reporting. The search strategy in Medline was following:

((guide*[Title/Abstract]) AND report*[Title/Abstract]) AND standard*[Title/Abstract], filters: Publication date from 1990/01/01 to 2013/12/31. We identified 8568 citations, however no studies addressed our question except for the two papers discussed above [7-8] .

2.2 We also investigated the reporting quality of all 135 published guidelines approved by WHO Guidelines Review Committee from 2007 to October 2013.   We selected WHO guidelines as our sample because they address a broad range of topics and types of guidelines, and they have   the potential for enormous global health impact.

3. Obtain funding

Funding was obtained from the Open Fund of Key Laboratory of Evidence Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, China.

4. Research team and declaration of interests

The RIGHT Working Group consist of two subgroups: the reporting items development group (RID group) and the Delphi panelists group (DEP group).

4. 1 Reporting items development Group (RID group)

- Role
    - To draft the proposal
    - To draft the items
    - To design questionnaires
    - To organize Delphi panelists
    - To send emails to panelists and collect and analyse the data
    - To draft the final report
- Team leaders:
    - Yaolong Chen, Chinese GRADE Center, Lanzhou, China
    - Susan L. Norris, Guidelines Review Committee Secretariat, WHO
- Team members: Kehu Yang, Liang Yao, Qi Wang, Xiaoqin Wang, Dang Wei, Jinhui Tian, Bin Ma, Yali Liu, Zhenggang Bai

4.2 Delphi panelists group (DEP group)

- Role
    - To review the proposal and provide comments
    - To decide the number of items included in final guideline
    - To decide which items need to be included
- Panelist: We will invite up to 16 panelist using following criteria:
    - Members must have research experience in one or more of following areas: guideline development, GRADE, AGREE, CONSORT/PRISMA/AMSTAR, systematic reviews, health policy and health systems, and evidence-based medicine.
    - Language, gender equality and wide geographic representation will be considered when selecting panelists.

5. Modified Delphi Approach

We will have three rounds modified Delphi process to achieve consensus and use a 9-point scale for expressing agreement for the reporting item (Box 2). We will use **SurveyMonkey®** (https://www.surveymonkey.com/) as the survey tool. The definitions of agreement and consensus are provided in Box 3 and the proposed process is described in Box 4.

Box 2. 9-point scale for expressing agreement with the reporting item										
Disagree strongly	1	2	3	4	5	6	7	8	9	Agree strongly

Box 3. Definition of consensus of essential reporting items for practice guidelines	
Response format	9-point scale(1=strongly disagree; 9-strongly agree)
Definition of agreement with an item	when 75% or more of participants choose 7-9
Definition of disagreement with an item	when 75% or more of participants choose 1-3
Definition of ambivalence to a item	when 75% or more of participants choose 4-6

Definition of no consensus within the group	All other types of responses
Analysis of responses	• Items with agreement are included in the final version and removed from subsequent rounds • Items with disagreement will be removed • Items which are rated as ambivalent or where there is no consensus will be modified to reflect points raised by the RID group and included in the next Delphi round

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Box 4.   Organizing the Delphi process

Questionnaire design

To generate a list of items for consideration based on results of the literature review and analysis of WHO guidelines.

First round:

The following will be sent by email to the 16 panelists:

An introductory letter and background material including current data and research about proposed items

The link to the online questionnaire

A reminder letter will be sent and a subsequent telephone call will be made to non-responders after 1 week.

Second round:

The following will be sent by email to the 16 panelists:

Letter of thanks and instructions

Feedback from panelists and the RID group

The link to the online questionnaire

A reminder letter will be sent and a subsequent telephone call will be made to non-responders after 1 week.

Third round:

The following will be sent by email to the 16 panelists:

Letter of thanks and instructions

Feedback from panelists and RID group

The link of online questionnaire

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6. Present and discuss results of the Delphi process

We will have a conference call including representatives of the RID and DEP groups to present and discuss the results of the Delphi process.

7. Draft the final checklist

Based on the results of Delphi surveys and conference, we will draft the final checklist.

8. Pilot test the checklist and diagram

We will ask a small number of guideline developers to use the checklist and provide feedback.

9. Develop the guidance statement and publication strategy

Based on the pilot and feedback, we will draft the guidance statement and submit it for publication in peer-reviewed journals.

10. Discuss knowledge translation strategy

We will disseminate the statement through the following channels:

• Share the report and checklist to EQUATOR, GRADE working group, CONSORT Group, Cochrane Collaboration, AGREE Collaboration, International Society for Evidence-Based

Health Care, G-I-N et al.

- Send the statement to guideline developers around world
- Draft a chapter for the WHO handbook for guideline development (citation)

11. Develop an explanatory document

We will develop a detailed justification and explanation of the essential reporting items of practice guidelines to inform and educate users and facilitate implementation.   .

12. Seek and deal with feedback and revise as appropriate

We will seek feedback from all stakeholders to improve the checklist and guideline.

13. Evaluate the impact of the reporting guideline

We will conduct a cohort study to evaluate the impact of the essential reporting items of practice guidelines.

14. Develop web site

As a very important implementation strategy, we will create a web site for essential reporting items of practice guidelines. The checklist can be downloaded from the web site both as PDF and DOC files. We will also link the web site with the EQUATOR Network.

15. Translate and adapt essential reporting items of practice guidelines

We will translate the checklist and guidelines into different languages. We will welcome and collaborate with other guideline developers who want to adapt this tool to other types of guidelines, such as Traditional Chinese Medicine guidelines.

16. Update guideline

We will review the reporting guideline every 3 years, revising it as indicated, taking into account feedback on the checklist as well as new information and publications in the scientific literature.

References

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