SOP for Guidelines published under the banner of PHO-IAP

Version 1
Date: 14/05/2021

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Introduction

Guidelines are "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."

It is envisaged that under the banner of PHO-IAP, task forces for specific focus areas can be created and their remit can be extended to actively participate in formulation of guidelines for various clinical areas.

There could also be a place for position papers on guidelines published by international consortiums to adapt them to Indian setting and achieve wider dissemination.

Core criteria for trustworthy guidelines (IOM) include that they should:

1. be developed by a knowledgeable, multidisciplinary panel of experts with expertise both with respect to disease and methodology, and represent multiple perspectives, and include varied stakeholders including patient representatives
2. be based on a systematic review of the existing evidence
3. consider important patient subgroups and patient preferences as appropriate
4. be developed through an explicit and transparent process that minimizes distortions, biases, and conflicts of interest
5. provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations
6. be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

Guideline recommendations, whether strong or conditional, are not intended to dictate a rigid standard of practice. They should be used to inform decisions that depend on the patient's unique circumstances and preferences.

The SOP document should clearly specify the following key areas

1. How to choose the subject for guidelines/ position paper

2. Who is to take the lead on a specific guideline document?

3. How to go about choosing the team to draft the document?

4. Peer review

5. Procedure for involving people from other chapters of IAP where needed.

6. Timelines for drafting and who takes the onus of revising them every few years

7. Format of guidelines including nomenclature

8. Where to be published

9. Authorship guidelines

10. Funding for guideline formation

1. How to choose the subject for guidelines/ position paper

Any member of PHO-IAP can suggest a suitable subject based on the need and scope. This could be shared with the Chairperson/ Secretary and after discussion presented to PHO Executive for approval.

2. Who should Chair the guideline Subcommittee?

This can be the PHO-IAP member with the proposal or the InPOG Subcommittee chairperson or any other senior member of PHO with expertise in the field as decided by the EB. There should also be provision for inviting another member who has much wider experience of the subject and methodology.

Roles ofGuideline CommitteeChair:

- To ensure that Guidance is developed in accordance with the procedure laid
- To decide the composition of the Writing Group and to identify and involve relevant stakeholders, including patient groups where appropriate.
- To lead the scoping exercise and develop the questions.
- To agree with the parameters of the literature search and how the output will be presented to the writing group.
- To convene meetings of the Writing Group, physical or virtual.
- To delegate sections of the Guidelines to writing group members
- To ensure the initial draft is submitted within 1 to 2months of receipt of the literature review to the Task Force.
- To ensure that relevant stakeholders review a draft of the Guidance e.g. professional bodies, patient groups.
- To inform the PHO-IAP if any new information makes the Guidance obsolete/ requiring updating/ alteration.

3. How to go about choosing the team to draft the document?

- The guideline development group should include individuals from all the relevant professional groups and different sectors of medicine (Public/ private/ trust). The members should have certain

level of experience and publication in the said field.

- The size of the subcommittee would depend on the specific clinical area but may be specified (eg minimum of 6-12)
- To avoid bias, there should not be more than 2 members from a given institution. On occasions where the writing group Chair feels that this cannot be complied with, the reasons must be documented.
- There should be participation of patient voice: support group/ patient member

4. Peer review

- The draft document should be reviewed by an national/ international reviewer with expertise in the area and cognizant of healthcare dynamics in India
- It should also be reviewed by an expert from India specifically with regards to methodology

5. Procedure for involving people from other chapters of IAP where needed.

Depending on the clinical area under consideration, it may add to the value of guidelines to invite representation from other chapters of IAP, Medical or Radiation Oncology or Lab Medicine. The person should be a leading national expert to be suggested by the Chair subject to approval by the PHO Executive

6. Timelines for drafting and who takes the onus of revising them every few years

The first draft should be submitted within 2 months of formation of the subcommittee and the final draft within 4 months

It is the onus of the subcommittee to periodically review the guidelines/ suggest amendments or revise guidelines in light of new scientific evidence

7. Format of guidelines including nomenclature

The guidelines should be referred to as PHO-IAP guidelines and adhere to the following format:

Scope and Purpose

1. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem.

2. A detailed description of the health questions covered by the guideline should be provided.

3. There should be a clear description of the target population and target users to be covered by the guideline.

Rigour of development

1. Systematic methods should be used to search for evidence

2. The criteria for selecting the evidence are clearly described.

3. The strengths and limitations of the body of evidence are clearly described.

4. The methods used for formulating the recommendations are clearly described.

5. The health benefits, side effects and risks have been considered in formulating the recommendations.

6. There should be explicit link between the recommendations and supporting evidence.

Clarity and Presentation

1. The recommendations should be specific and unambiguous.

2. The different options for management of the condition or health issue should be clearly presented.

3. Key recommendations should be easily identifiable.

Applicability

1. The guideline not only describes areas of application but also barriers to its application.

2. The guideline provides advice and/or tools on how the recommendations can be put into practice.

3. The potential resource implications of applying the recommendations should have been considered.

Methodology:

1. The panel prioritizes clinical questions that drive decision-making and that specify the population, intervention(s), comparison(s),and patient-

focused outcomes.

2. A research team systematically identifies and synthesizes the best available evidence, including evidence on baseline risks of a disease, health effects of interventions, patient values, resource utilization, impacts on health equity, and barriers to and facilitators of implementation.

3. Literature review must include as a minimum, date of search, databases searched (e.g. PubMed, Ovid, Cochrane), keywords used, time period covered, inclusion criteria exclusion criteria.

4. The guideline panel will use the Grading of RecommendationsAssessment, Development and Evaluation (GRADE) approach to interpret the evidence and form recommendations using theGRADE Evidence-to-Decision (EtD) framework, which makes explicit all judgments about evidence and the rationale for a recommendation

5. Strong recommendations are framed as “the panel recommends...,” whereas conditional recommendations should be expressed as “the guideline panel suggests…”

6. The draft recommendations and EtD frameworks are made available for external review by all stakeholders.

This formal approach reduces the risk of bias from unmanaged conflicts of interest and makes the underlying evidence, assumptions, values, and

judgments transparent and trustworthy for endusers, including clinicians and patients.

Key Components of guidelines

- Background sections
- Aims
- Description of the health problem(s)
- Description of the target populations
- Methods
- Guideline questions
- Recommendations
- Recommendation statements
- Summary of evidence
- Research needs
- Limitations
- What other guidelines are saying and what is new in these
- guidelines
- Revision or adaptation of the guidelines

Supplements

Guideline panel membership

Disclosure-of-interest forms

GRADE EtD frameworks

GRADE evidence profiles

The GRADE criteria can be found at http://www.gradeworkinggroup.org.

8. Where to be published

The guideline committee should endeavour to publish the guideline document in Pediatric journals such as Indian Pediatrics (most preferred) and Indian Journal of Pediatrics or PHOJ as appropriate based on the target audience. The document should therefore adhere to the guidelines given as by Indian Pediatrics.

The guideline document should also be available on the PHO-IAP website. It can also be discussed whether these documents can be placed on the IAP website

9. Authorship guidelines

The authorship of the document should adhere to the appended guidelines from Indian Pediatrics

10. Funding for guideline formation

The guideline-development process could be wholly funded through the general operating budget of PHO-IAP/ PHOCON or, for some guidelines, with collaborating nonprofit organizations. Direct funding from for-profit

entities that could be affected by the guidelines should not be accepted. Members of Guideline committee should not receive funding for guideline production, except for covering costs of travel.

Position Papers

A Position Paper does not follow the formal development process for Guidelines and Good Practice Papers. The appropriate Task Force can decide to endorse a guideline or write a position paper based on consensus by the executive committee members on a particular subject based on sound knowledge and literature, rather than propose a PHO-IAP Guideline.

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