

Checklist for assessing the reporting of the updating methodology in updated guidelines.

Background:

To maintain their validity, clinical guidelines (CGs) require a regular update, due to a possible obsolescence because of new scientific research [1]. Although there is no gold standard for the methodology of updating guidelines, as far as we know, it consists of three components: identifying new evidence, assessing the need to update, and communicating, in some manner, the update process and results [2-7]

The process of updating CGs is not standardised across different institutions, possibly due to the fact that there is little scientific literature and methodological consensus available on this subject [2,7,8]. It is necessary to establish a process for updating CGs, which might ensure the validity of all recommendations. At this moment the updating process for CGs is immature and the lack of research in this field has a lack of optimal strategies and, consequently, facilitating the existence of variability, imprecision, and insufficient transparency. Clearly, more work is required to identify a strategy or set of strategies that combines rigour and feasibility.

As a necessary first step, we will develop a reporting checklist incorporating methodological standards to guide the research needed to optimise the reporting of updating CGs.

Objective of this project:

To develop a checklist to establish what information and how it should be presented in updated guidelines.

Methodology:

1. Development of the initial list of items.

We will develop the initial list of items and domains through discussion and brainstorming, taking into account: 1) a systematic review of the available evidence about updating CGs [2], 2) a systematic review about the updating guidance in the available guideline methods handbooks [7], 3) an international survey to guideline developers [8], and 4) our own research team experience.

2. Item optimisation.

2.2: Assessment of updated CPGs.

We assessed empirically the initial version of the instrument with a convenience sample of updated CPGs, to make sure all items and domains necessary for evaluating methodological information are included.

2.1: Semi-structured interviews.

To understand and explore challenges and issues regarding the updating process of CGs we conducted semi-structured interviews with different experts who updated at least one CG the last year. In addition, we discussed the initial list of items with the interviewees and asked them what they thought about the items and what items are lacking.

2.3: Delphi consensus survey.

To obtain feedback about the comprehensiveness, clarity, coverage, and overlap of the included items in the initial list of items a Delphi consensus survey will be conducted. A sample of different experts with different geographical backgrounds, different professional responsibilities, and interested in the methodology of updating CPGs, will be included in the survey.

In each round the participant will be asked to rate the items on a 7-point Likert scale for the suitability of the item in the updating instrument. In addition, the participants will be asked to agree whether the inclusion of the item changes the perception on 1) the completeness, 2) usability, and 3) quality of an updated guideline. A space for adding free text comments will be provided, to suggest alterations or additional items. The first round will also collect demographic information of the participants (expertise in process and working field).

After the first round all the items will be grouped in three categories: median ≥ 6 , $4 \geq$ median ≤ 5 , median ≤ 3 . The participants will be informed the results of the first round the items in the group with a median ≥ 6 will be included and the items in the group with a median ≤ 3 excluded, if important issues in the free text area are absent. The items of the first round with the results of 4 or 5 will be tested once more. The Delphi consensus survey will be continued until there are no items in the middle group.

2.4: External review survey.

A single-round survey will be conducted to collect feedback from a wider sample of experts about the tools' comprehensiveness, clarity, coverage, and overlap of items, of a wider sample of experts. We will aim for a sample of approximately 100 participants.

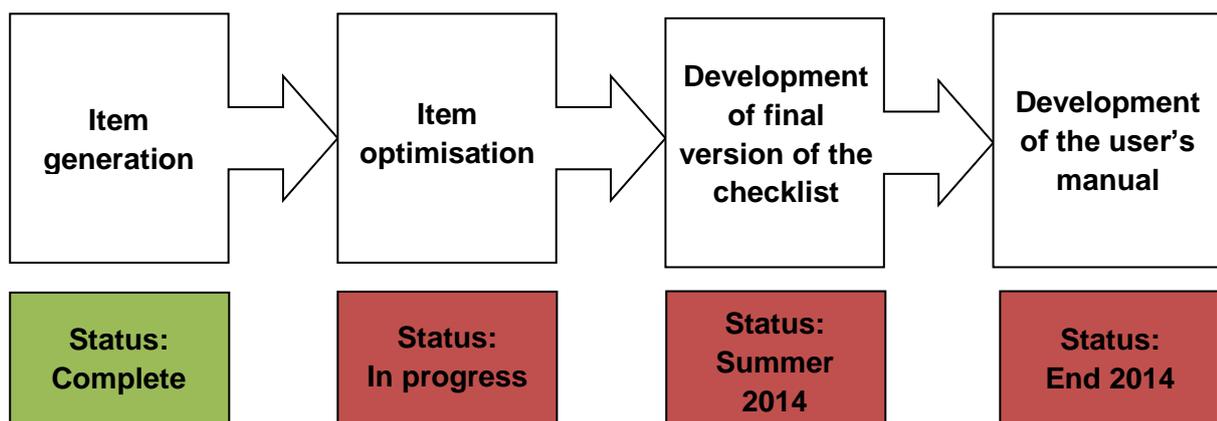
3. Development of the final version of the tool.

With the results obtained in the pilot study, semi-structured interviews, the Delphi consensus survey, and the external review, the initial version of the checklist will be improved sequentially. Subsequently, a final list of items will be published on a website, along with the publications of the methods and results.

4. Development of the user's manual.

We will develop a user's manual to help guideline users applying the checklist. The following sections will be reported for each item: item description, where to look for the item, how to score the item, and additional considerations to help the evaluator.

Figure 1: Development process and planning for the checklist.



After reading this document, and you are interested in participating, or if you have any doubts, please do not hesitate to contact us.

Robin W.M. Vernooij, rwmvernooij@cochrane.es

Melissa Brouwers, mbrouwer@mcmaster.ca

Pablo Alonso-Coello, palonso@santpau.cat

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