

# Development of a quality appraisal tool for case series studies

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## Background

- Case series studies (CSs) represent the weakest observational study design as they are prone to various types of biases: selection, detection, performance, attrition, reporting, and publication
- There are circumstances when CSs are the only form of research evidence available on the effectiveness and safety of interventions
- There is no consensus about which items to include in a quality checklist for CSs
- No universally accepted validated tool exists for assessing the methodological quality of CSs

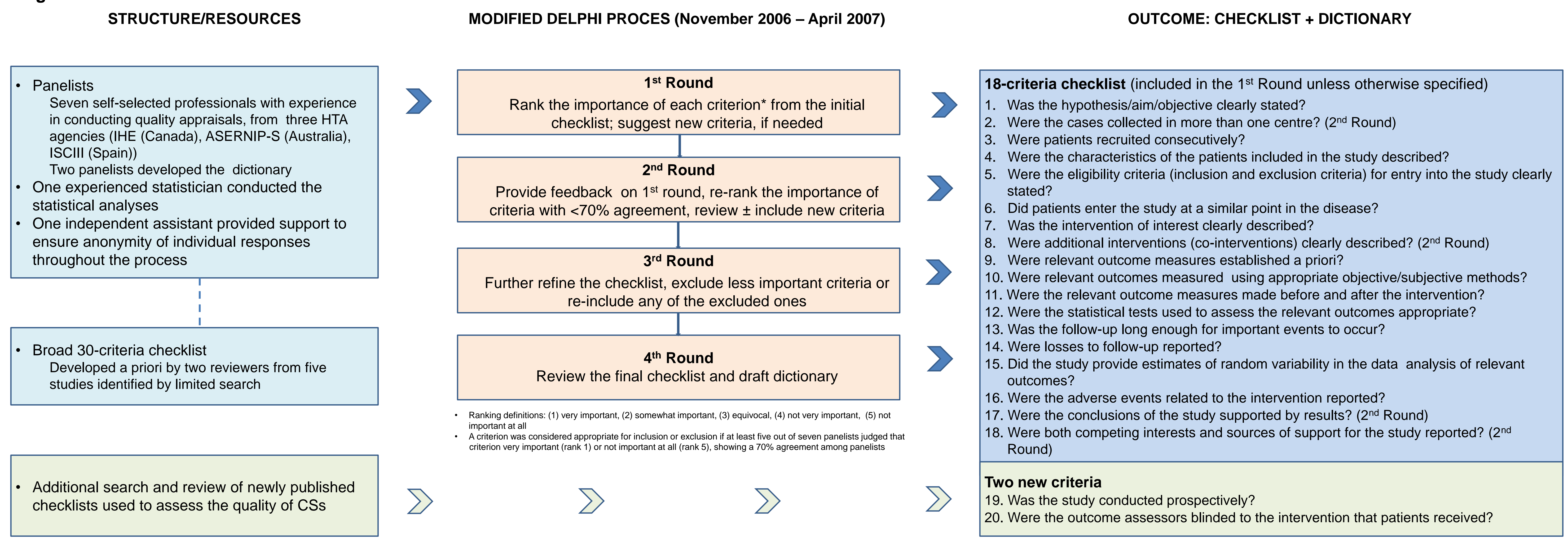
## Objective

A need for a quality appraisal checklist for CSs was identified by the Health Technology Assessment (HTA) Program at IHE. The purpose is to describe the processes for developing the quality appraisal checklist.

## Method

- An initial broad list of 30-criteria to assess CSs was compiled through a limited search of the literature
- A four-round modified Delphi technique was used to develop the new checklist (see Figure 1)
- An additional literature search of other published CSs checklists was conducted to identify any omitted criteria
- A dictionary was generated for the newly developed checklist

Figure 1



## Results

- A four-stage e-mail-based modified Delphi process culled the initial list of 30-criteria to a more “user-friendly” 18-criteria checklist. No new criterion was added to the list by the panel members.
- The supplementary literature review of published checklists indicated a paucity of checklists designed to appraise CSs and a lack of details on their development.
- Two new criteria were added to the checklist based on the results of the literature review.
- The newly developed 20-criteria checklist includes criteria that examine: study objective, design, and population, intervention and co-intervention(s), outcome measures, statistical analysis, results and conclusions, competing interest and sources of support (see Figure 1).
- An initial pilot study indicated a need for further improvements of the checklist and dictionary. First-hand experience with the use of the checklist and dictionary in various HTA reviews indicated a general level of satisfaction and several suggested improvements such as refinement of wording and inclusion of supplementary notes for reviewers.
- The amount of time required for applying the checklist varied with the complexity of the clinical topic, how well the information was reported in the study, and the experience of the reviewer. A learning curve was noted by the reviewers.

### Reference

Moga C, Guo B, Schopflocher D, Harstall C. *Development of a quality appraisal tool for case series studies using a modified Delphi technique*. Methodology paper. Edmonton AB: Institute of Health Economics. 2012.

Available at: <http://www.ihe.ca/publications/library/2012-publications/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique/>.

## Key messages

- The use of subjective judgment by a self-selected group of HTA professionals who rated each criterion based on their personal perception and opinion about its importance, infers that this checklist is only as valid as the opinion of the experts.
- The expertise of the panel members might have influenced the selection process of criteria, therefore the checklist may not reflect the criteria seen to be crucial for assessing methodological quality of CSs outside of the HTA field.
- The review of published checklists was found helpful for comparison of the content and verification of the inclusiveness of the newly created checklist.
- No scale or numeric score was developed for the checklist; hence the recommendations (a) to establish a cut-off point to separate “high-quality” studies from the “low-quality” ones, or (b) to identify some criteria from the checklist which are relevant to a specific condition/technology and focus more on discussing the outcomes from the studies that meet those selected criteria.
- The dictionary needs to be customized prior to conducting the assessment to increase its usability and reduce disagreements between reviewers.
- The checklist serves as a good starting point to examine the quality of reporting and risks of bias and with some modification and adaptation it can be used in future HTA work.
- Majority of criteria in the CSs checklist focus on reporting aspects while fewer criteria examine how the study was executed. Although ‘reporting’ is not a direct measure of the quality of a study, it allows a reader to assess the validity and applicability of the study’s findings.
- The value of our new checklist is that it has an accompanying, user friendly dictionary and validation of the checklist is an ongoing priority.

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