Exploring the utility of a validated quality appraisal tool

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Background

- Case series studies (CSs) are sometimes the only form of research evidence available from which to obtain evidence in health technology assessment (HTA) reviews and systematic reviews
- There is no consensus about which items to include in a quality checklist for CSs
- The IHE checklist and instructions for use build upon some previous tools, empirical evidence, and expert consensus

Objective

- To introduce the IHE quality appraisal tool for CSs studies--Development (Phase I) and Preliminary validation (Phase II) (Figure 1)
- To summarize user feedback/experiences and outline potential challenges (Table 1)
- To provide practical solutions for using or adapting the checklist to various HTAs (Table 1)

Method

- Feedback obtained formally and informally from 15 researchers
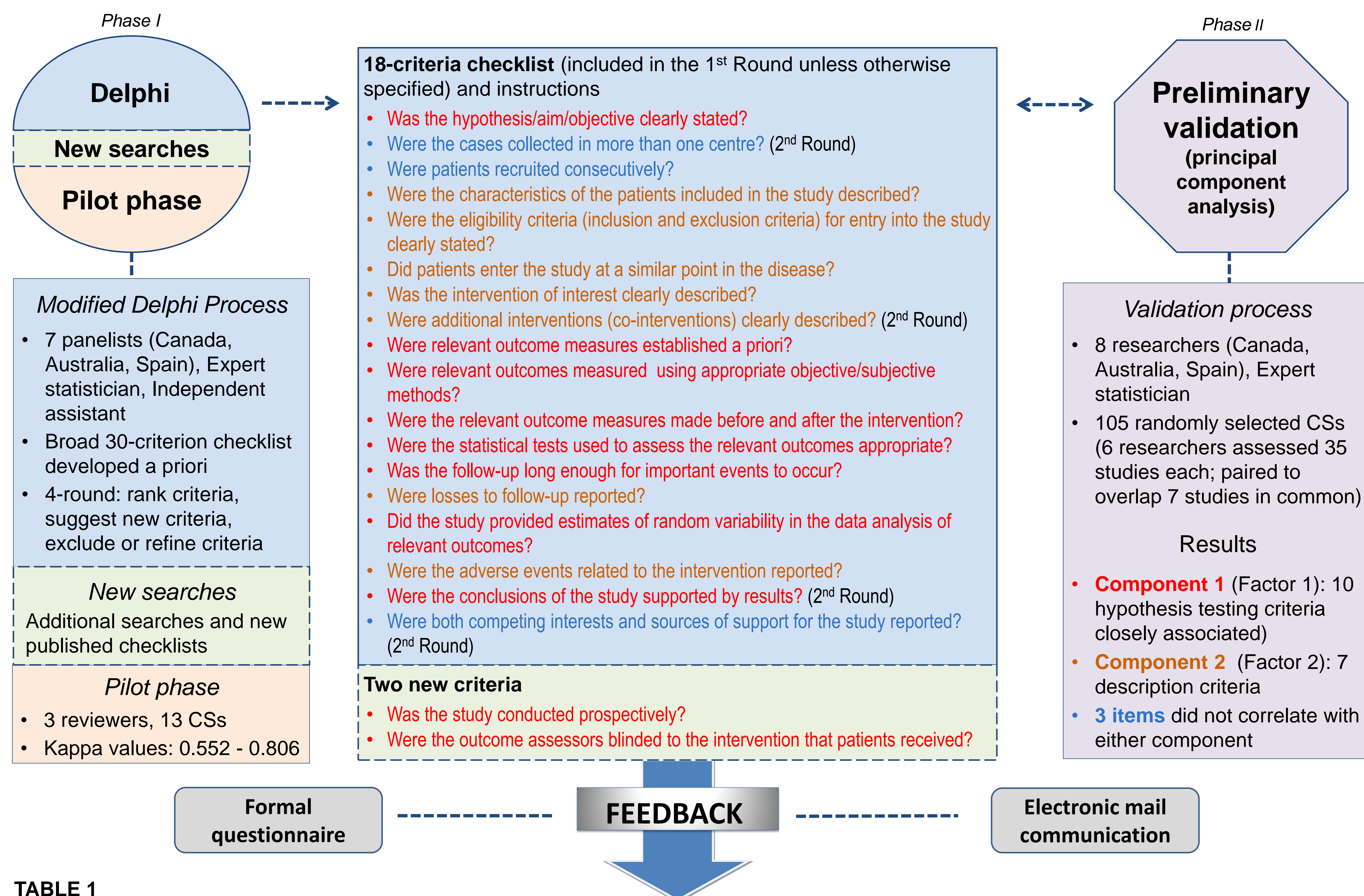- Questions focused on the relevance, clarity, usefulness

FIGURE 1

Phase I

Delphi

New searches

Pilot phase

Modified Delphi Process
- 7 panelists (Canada, Australia, Spain), Expert statistician, Independent assistant
- Broad 30-criterion checklist developed a priori
- 4-round: rank criteria, suggest new criteria, exclude or refine criteria

New searches
Additional searches and new published checklists

Pilot phase
- 3 reviewers, 13 CSs
- Kappa values: 0.552 - 0.806

18-criteria checklist (included in the 1st Round unless otherwise specified) and instructions
- Was the hypothesis/aim/objective clearly stated?
- Were the cases collected in more than one centre? (2nd Round)
- Were patients recruited consecutively?
- Were the characteristics of the patients included in the study described?
- Were the eligibility criteria (inclusion and exclusion criteria) for entry into the study clearly stated?
- Did patients enter the study at a similar point in the disease?
- Was the intervention of interest clearly described?
- Were additional interventions (co-interventions) clearly described? (2nd Round)
- Were relevant outcome measures established a priori?
- Were relevant outcomes measured using appropriate objective/subjective methods?
- Were the relevant outcome measures made before and after the intervention?
- Were the statistical tests used to assess the relevant outcomes appropriate?
- Was the follow-up long enough for important events to occur?
- Were losses to follow-up reported?
- Did the study provided estimates of random variability in the data analysis of relevant outcomes?
- Were the adverse events related to the intervention reported?
- Were the conclusions of the study supported by results? (2nd Round)
- Were both competing interests and sources of support for the study reported? (2nd Round)

Two new criteria
- Was the study conducted prospectively?
- Were the outcome assessors blinded to the intervention that patients received?

Phase II

Preliminary validation (principal component analysis)

Validation process
- 8 researchers (Canada, Australia, Spain), Expert statistician
- 105 randomly selected CSs (6 researchers assessed 35 studies each; paired to overlap 7 studies in common)

Results
- **Component 1** (Factor 1): 10 hypothesis testing criteria closely associated)
- **Component 2** (Factor 2): 7 description criteria
- **3 items** did not correlate with either component

Formal questionnaire --------- **FEEDBACK** --------- **Electronic mail communication**

TABLE 1

Advantages	Challenges	Solutions
• Preliminarily validated • There is some scope to allow some modifications of the tool, to allow for more important quality issues to be highlighted	• Different criteria may be more or less important in a specific topic • No scale or numeric score, or cut-off point was developed for the checklist	• Identify criteria relevant to the project and focus the analysis on studies that met those criteria • Establish a cut-off point to separate "high-quality" from "low-quality" studies
• Generally easy to use when reviewing information and data from similar studies	• Longer time to complete the appraisal, difficult to apply if unfamiliar with intervention	• Obtain clinical and or statistical input from experts in the field of interest
• Includes a set of detailed instructions (Yes; No; Partial; Unclear)	• Some criteria could be difficult to score due to lacking of information or poor reporting or lack of familiarity with intervention	• Customize the instructions prior to conducting the assessment to increase its usability and reduce disagreements between reviewers
• Assess quality of reporting, risk of bias, and aspects of generalizability in before-and-after CSs	• No universally validated tool is available to review multiple types of studies included in a review	• Focus on Component 1 (hypothesis testing) or Component 2 (description of subject/ intervention as per validation results
• General satisfaction with use; useful; low level of disagreement; adds value to reviews		

REFERENCES

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

Guo B, Moga C, Harstall C, Schopflocher D. A principal component analysis is conducted for case series quality appraisal checklist. *Journal of Clinical Epidemiology* 2016;69:199-207.

IHE website: www.ihe.ca/research-programs/rmd/cssqac/cssqac-about

Feedback form: www.ihe.ca/research-programs/rmd/cssqac/cssqac-suggestions