

## Rethinking the Analysis of the Cognitive Interview in Patient Reported Outcome Measures Design

### Introduction

Cognitive interviewing (CI) or cognitive debriefing (CD) is now recognised as a significant part in the developmental process of clinical outcome assessment (COA) measures and the assessment of their linguistic validity and cross-cultural equivalence. Despite this, studies reporting the application of CI in COA development studies, generally lack a clearly defined rationale for selecting the appropriate technique, analysis and reporting.

In their 2005 paper, Wild et al<sup>1</sup> while acknowledging the lack of consistency in the term “*cognitive debriefing*” go on to define it as the: “... *testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation...*”

Although the FDA (2009) Guidance for Industry<sup>2</sup> states that documentation to support content validity should include amongst other information, cognitive interview summaries or transcripts, it lacks any reference to the different techniques and their strengths and limitations. Irwin et<sup>3</sup> al in their PROMIS study report the questions used during the interview but, offer no further information on the rationale for techniques selection. Furthermore, the ISPOR PRO Good Research Practices Task Force report: part 2<sup>4</sup> while providing some guidance on the application of cognitive debriefing, also lacks reference to the different techniques and their respective strengths and limitations.

### Should COA developers and agencies undertaking cross-cultural adaptation be more specific in reporting the ‘why’ in the selection of the CI?

Defining the “why” is particularly important as there are two contrasting objectives in the use of cognitive interviews which need to align with the objectives of the research. These are the Reparative and Descriptive Approach.



The Reparative and Descriptive Approach should not be seen as a dichotomy as studies may contain elements of both and can be utilised at different points in the developmental process. However, it must be recognised that there are conceptual differences between the two opposing objectives which clearly need to be made explicit as part of the developmental and reporting process.

Willis<sup>5</sup> considers that the selection of the interviewing technique should be done according to the intended analysis strategy rather than deciding after the fact. However, the rationale behind the selection of a specific technique from the different techniques is rarely described in the COA development literature.

## Selecting the appropriate CI technique

There is a range of techniques for systematically eliciting and recording individuals' comments on items when they respond to a questionnaire.

The major techniques include, concurrent probing (questions asked during each item response), retrospective probing (questions asked after all item responses), and concurrent verbalization ('think aloud' during each item response). It is noteworthy however, that each technique has its limitations. For example, Think-Aloud places a high burden on participants and concurrent or retrospective verbal probing by the researcher has the greater potential for interviewer bias.

Ericsson and Simon<sup>6</sup> preferred concurrent verbalization because, according to their model, concurrent probing is more disruptive to task performance. Willis<sup>7</sup> acknowledged that concurrent probes may produce 'local reactivity' (where probes about an item encourage respondents to identify spurious problems with the item) and 'extended reactivity' (where probes about one item encourage respondents to identify spurious problems with other items).

## Analysing the CI data

When it comes to analysis of the data obtained from CI, as part of COA development, again little information about appropriate analysis is available.

Willis<sup>5</sup> describes five-analysis strategies which are:

1. **Text: Summary:** In which dominant themes, conclusions and problems are described in words
2. **Cognitive coding:** Focus on respondent behaviour
3. **Question Feature Coding:** Focus on the behaviour of the evaluated survey questions
4. **Theme coding:** Creation of labels to describe observed phenomena
5. **Pattern Coding:** Discovery of patterns and associations in participant responses



Each of the five-strategies have their strengths and drawbacks. For example:

**Text Summary** are rich in data and quick to produce, but their limitation is the volume of data.

**Cognitive Coding** enables the quantification of the data and is based on a theoretical underpinning, but results in a loss of information due to coding.

**Question Feature Coding** is suitable for quantification as coding frequencies can be reported, but coding results in information loss.

**Theme coding** can fully describe question functioning enabling decisions to be made on the usefulness of the question providing the required information.

## Other aspects of analysis in need of consideration

Having decided on the analytical approach other issues needing attention include:

- How to aggregate data across interviews (*Should interviewers conduct their analysis then compare and combine?*) (*Should there be a collaborative approach from the start?*)
- The importance of sample size on what can be done analytically
- Level of analysis (*Should we have multiple levels of analysis e.g. with interviews, across interviews and subgroups?*)

## Which CI and analysis strategy is best?

When this question is asked the response should be “Best for what”?<sup>5</sup> It is worth remembering that multiple approaches can be used in the investigation and for different elements of the questionnaire. Availability of resources and time constraints are also contributory factors in selecting the analysis strategy. In application it is not a one-size-fits-all.

## Writing the report

In the reporting of studies incorporating CI's it is essential that there is no lack of critical detail and that all key elements of the study are not overlooked in the write-up.

We agree with Boeije and Willis<sup>8</sup> that due to different ways in which cognitive interviews can be conducted, it is not practical to set a single standard for reporting. Nevertheless, we believe that at a minimum the write up should include the following.<sup>8</sup>

- Background on the development of the COA
- Rationale for determining the sample size
- Rationale for selecting the interviewing technique
- Level of training and expertise of the interviewers

## Final thoughts

This paper has attempted to bring to attention some of the key aspects of conducting, analysing and reporting of the application of cognitive interviews as part of the developmental process of Clinical Outcome Assessments. This has included (a) clarifying the study objective i.e. Reparative v Descriptive, (b) selecting the appropriate variant to meet the study objectives e.g. Think aloud v Verbal probing, (c) analytical strategies e.g. Text Summary, Theme coding, (d) report writing. And finally, outlining what we consider as essential elements not to be overlooked in the reporting stage.

## References

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Email: [info@healthoutinsights.com](mailto:info@healthoutinsights.com)

Tel: +44 (0) 1367 615 052

[www.healthoutinsights.com](http://www.healthoutinsights.com)