<u>Cognitive interviewing (CI) - to identify sources of interpretation dissonance in in patient-reported outcome measures (PRO)</u>

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Interview approaches in cognitive interviewing can be studied in the literature, ^{1–4} and variations exist. This is a framework for one approach for CI-PRO.

APPROACH: The talk/read aloud approach is used to engage an observational and cognitive evaluation of how respondents interpret items. Explaining that the process is for the evaluator to understand the appropriateness of the form is important to allow respondents to understand what is going on, and that they are not being evaluated. Patients read, complete and discuss individual chunks of the scale like the instructions, item stems or item responses, and explain what they are thinking about the meaning and how they would respond. Actual completion of the item is advised to engage the real cognitive process. Then probes are used to explore in more depth how individual words, or the entire item, is understood. Usually at the end it is useful to gather the respondent's perceptions of the overall scale about the relevance/burden, whether important issues are missing and any final comments. This can inform the evaluators' understanding of the overall content validity of the tool being assessed.

The evaluator should both record the discussion and keep notes. The notes can be back-up information, reflective of the evaluators' impression and should reflect any nonverbal clues about how the respondent interprets or responds while navigating the measure or completing the items.

Read aloud: Determine if it is difficult for the interviewers or respondent to read the instructions or question. Allow the respondent to talk through their initial understanding of the instructions or item to explore their initial understanding prior to probing. Probe their understanding of what is stated, and the construct(s) being assessed. Follow the instrument format in the order the respondent would: title, instructions, and items.

As you listen, interpret and explore their response considering the following. Multiple problems may be identified per item and issues can be subgrouped or classified (later). Synthesis of the findings can be by items. Coding of the issues that rise can be performed as listed below. It may be necessary to develop additional codes.

Clarity/comprehension: Identify problems in how respondents understand the intent or meaning of the question. Explore the overall meaning of the individual words, and the entire instruction/item stem/responses until it is clear how the item is interpreted; identify aspects/words that are ambiguous or variably interpreted.

Relevance: Determine the perception of the respondent about the relevance of the overall construct; and then explore the reasons why the item is or is not relevant.

Inadequate response definition: 1. Explore whether the responses are aligned with posed question (root and stem concordance); 2. Determine if there are potentially meaningful responses that are not available to the respondent; 3. Determine if there are problems with assumptions made or the underlying logic in processing the responses.

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Reference point: Explore how respondents interpret the item in terms of what reference standard they use when calibrating their response to an item: if they are clear about what time frame the evaluation is referring to, or if an item is being calibrated in one specific context and not another. Determine if the participant must draw on prior knowledge or memories and whether these are accessible or have changed over time. Assess if the "valuation" or reference standard has changed with time. Assess whether the wording/framing of the construct or reference point might lead to bias in the calibration.

Perspective modifiers: Explore reasons why one respondent might interpret an item differently than another based on their personal situation, personality, biology, gender, attitudes, beliefs, life or work roles, professional roles, experiences, culture or environmental factors. Assess whether items are acceptable across respondents who vary in these aspects. Assess potentially sensitive or biased items/wording.

Calibration across items: After exploring individual items determine whether responses to one item affected how another item on the scale was interpreted or calibrated.

Participants can have difficulty calibrating their responses to items on an outcome measure for a variety of reasons. The following is a list of major categories.

Clarity/Comprehension (C)

Refers to when the terms/words used in an item or response are ambiguous or incorrectly interpreted by respondents.

Relevance (R)

Refers to when an item is not relevant to participants (e.g., task not possible or important in their circumstances)

Inadequate response definition (IR)

Refers to when response options provided are: 1. not mutually exhaustive or have missing options, or 2. are not matched to the questions posed.

Reference Point (RP)

Refers to when participants have difficulty calibrating their responses to an item because their reference points have changed (e.g., response shift) or the item has unclear reference boundaries (e.g., time interval or context). Includes when participants are unable to recall information needed to calibrate their response.

Perspective Modifiers (PM)

Perspective modification occurs when items are interpreted differently by respondents based on a personal factor, life experience or environmental factor.

Calibration Across Items (CAI)

Refers to when the response to one item is modified by the patient's response to a previous item.

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References:

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