

**Cognitive interviewing (CI) - to identify sources of interpretation dissonance in patient-reported outcome measures (PROM)**

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Cognitive interviewing is a semi-structured interview process that explores how individuals understand, mentally process and respond to survey instructions, items and response options; and whether an individual perceives the items/measure as reflecting the intended construct or attribute being assessed.

Interview approaches in cognitive interviewing[1–3] can be studied in the literature and variations exist[4]. This is a framework for one approach for CI-PROM.

**APPROACH:** The talk/read aloud approach is used to engage an observational, qualitative and cognitive evaluation of how respondents interpret items. Explaining that the process is for the evaluator to understand the appropriateness of the questions is important to allow respondents to understand the purpose of the interview (to test the questions, not the respondent). It is important they know that they are not being evaluated. Patients read, complete and discuss individual chunks of the scale starting with the instructions, and proceeding to the item stems and item responses. As they read they think out loud to explain what they are thinking about the meaning and how they would respond. Actual completion of the item is advised to engage the actual cognitive process. Then probes are used to explore in more depth how individual words, or the entire item, is understood. In progression you explore comprehension, recall, judgement/response calibration. That is after exploring how they understand the item then you explore how they made the calibration or decisions to select a specific response option. At the end of the interview it is useful to gather the respondent's perceptions of the overall scale including its relevance, burden, whether important issues are missing, and any suggestions.

The evaluator should both record the discussion and keep notes. The notes can be back-up information, reflective of the evaluators' impression and can include any nonverbal clues about how the respondent interprets or responds while navigating the measure or completing the items e.g. hesitancy, emotional response, literacy challenges, navigation problems.

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 be likely to read : 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 (see list of categories below). Synthesis of the findings can be by items or by problems. Coding of the issues that rise can be performed as listed below.

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.

While using talk aloud and probes explore the issues above considering the following:

**Clarity/comprehension:** Explore how respondents understand the intent or meaning of the title, item and response options . Explore the overall meaning of item then 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.

Tell me what this question means?

Tell me about any parts of this question that are not clear to you?

What does \_\_\_ WORD \_\_\_\_\_ mean?

What does this response mean?

Was any part of this question unclear to you?

**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. e.g. washing hair for bald men, difficulty walking for those in wheelchairs, difficulty with yard work for apartment dwellers.

Is this question/issue relevant to you? Why ? Why not?

How was this item relevant to you?

**Inadequate response definition:** 1. Explore whether the responses are aligned with posed question (root and stem concordance) e.g. importance in stem and frequency in responses ; 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. e.g. double barreled responses moderate pain and difficulty

Did all the answers make sense?

How did you decide which answer fit you best?

**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 “evaluation” 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.

When you were thinking about your answer what time were thinking about? What did you compare yourself to? Do you think your perspective on this question has changed over time? Why?

**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.

Were there any words or aspects of this question you found offensive or insensitive?

Do you think this question applies to people of different ages, genders, and cultures?

Do you think your work or community affects how you would answer these questions?

Are there unique things about you that might make you think differently about this question than other people, than you did before your problems started?

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

Was how you answer this question affected by any other questions?

Link to an instructional video: <https://www.youtube.com/watch?v=OVRgH0OrQPM>

References:

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