Cognitive Debriefing of Clinical Outcomes Assessment Questionnaires with Subjects Aged 65 and Older

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OBJECTIVE

The objective of this study was to test the hypothesis that subjects aged 65 and above are less likely to comprehend Clinical Outcomes Assessment (COA) questionnaire items during cognitive debriefing interviews of translated questionnaires. A common perception exists that subjects in upper age groups are less likely to comprehend patient questionnaire items during cognitive debriefing interviews than subjects of younger ages. This study seeks to determine the veracity of this hypothesis.
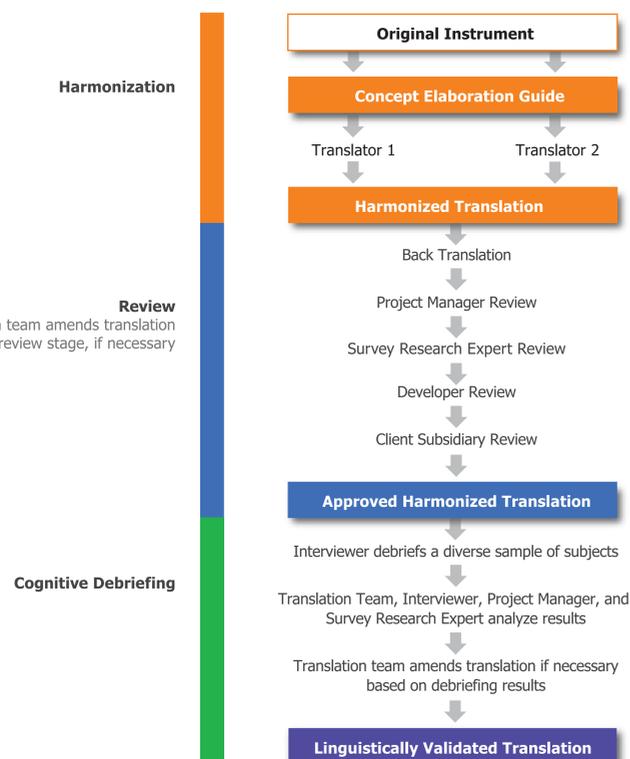
BACKGROUND

Previous research indicates that subjects of advanced age may provide data with less validity or be unable to complete questionnaires as a result of impaired cognitive ability. A study by Jobe and Mingay showed that older subjects required more time to answer questions. Older subjects in the sample had greater difficulty with questions requiring long-term recall, for example, "what year were you married" [1]. A study by Brazier et. al. showed that subjects aged 75 and older may be less inclined to complete entire questionnaires as a result of being more susceptible to respondent burden. This will subsequently result in lost data during studies because questions are left unanswered. To remedy this problem, interviewer-administered questionnaires are recommended in order to prevent data loss in studies with subjects of advanced age [2]. Other studies conflict however, and show no difficulties for older subjects when completing patient questionnaires. A study by Tidermark et. al found that 65+ subjects were able to complete questionnaires such as the SF-36 and EQ-5D for before-treatment and after-treatment assessments and provided valid data for analysis. There also appeared to be no issues with subject responsiveness [3]. Additional research has found that questionnaires intended for older populations may need to be adapted when used in different countries. A study by Leung et. al. showed that Chinese subjects of advanced age have different concerns than their counterparts in the US. This study found that US subjects are more open to respond to questions relating to emotional and social quality of life than older Chinese subjects. It was also found that Chinese subjects were more forthcoming in a focus group whose goal was to elicit responses to questions regarding emotional and social effects of their disease [4]. While these studies may address issues related to cognitive ability and responsiveness, none test comprehensibility of concepts, which this study seeks to investigate.

METHODS

Seven (7) COAs pertaining to arthritis and joint pain were translated into 45 languages. Cognitive debriefing interviews were conducted on 5 subjects each per language, during which the subjects may point out concepts that they do not understand. The total numbers of misunderstood items were tallied for each subject per debriefing interview. The standard deviation of the entire sample's age was calculated. That standard deviation was then used to organize the subjects into age groups. After creation of the age groups, the average number of misunderstood items per age group was calculated. An ANOVA test was then used to determine the statistical significance between the age groups. The hypothesis was that subjects aged 65+ are less likely to comprehend items in translated COA questionnaires, while the null hypothesis was that age has no correlation with one's ability to comprehend items in translated COA questionnaires. Additional qualitative analyses were done on the actual items, phrases and words that the subjects misunderstood.

LINGUISTIC VALIDATION

Linguistic Validation is a process conducted to confirm that a COA questionnaire is acceptable for use in different languages and in different cultural contexts. Without this careful development of a translation and subsequent cognitive debriefing, one could not be reasonably certain that the adapted instrument is both conceptually equivalent to the original and can also be clearly understood by the average patient. The linguistic validation process begins with two translators independently translating the instrument into the target language. The translators then exchange drafts and work together to develop one reconciled or "harmonized" version. At that point, the harmonized translation is provided to a third translator who translates the text back into English without access to the original English. Both the harmonized translation and the English back-translation are reviewed by a project manager and a survey research expert; adaptations to the translation are made as needed. Once the final translation has been approved, it is debriefed among in-country native speakers of the language, with varying demographic and educational backgrounds, to check for conceptual equivalence and clarity.

Harmonization	Original Instrument
	Concept Elaboration Guide
	Translator 1 / Translator 2
	Harmonized Translation
Review — Translation team amends translation after each review stage, if necessary	Back Translation
	Project Manager Review
	Survey Research Expert Review
	Developer Review
	Client Subsidiary Review
	Approved Harmonized Translation
Cognitive Debriefing	Interviewer debriefs a diverse sample of subjects
	Translation Team, Interviewer, Project Manager, and Survey Research Expert analyze results
	Translation team amends translation if necessary based on debriefing results
	Linguistically Validated Translation

RESULTS

Table 1 shows some of the characteristics of the sample.

Table 1: Sample Characteristics

Total sample size	n = 225
Average age	55.3
Standard deviation age	13.6
Average years of education completed	12.9
Standard deviation of years of education completed	3.7
Females in the sample	157
Males in the sample	68

Individual data collection forms from 225 subjects were analyzed. The age standard deviation of the sample was 13.6. Based on the standard deviation, the subjects were organized into 5 groups. Table 2 shows the average number of misunderstood items for each age group.

Table 2: Averages per age group

Age Group	Sample members	Average years of education	Gender (m:f)	Average number of misunderstood items
20-32	17	15.6	1 : 16	0.471
33-46	40	13.6	10 : 30	0.375
47-59	78	13.1	27 : 52	0.354
60-73	69	12.4	23 : 45	0.323
74+	21	11.0	7 : 14	0.286
Total (Average age = 55.3)	225	12.9	68 : 157	0.351

It can be observed initially that comprehension increased with age. However, the results of the ANOVA test yielded a p-value of 0.064, dismissing any correlation between age and comprehension. The p-value can also dismiss the hypothesis that subjects aged 65+ are less likely to comprehend questionnaire items, thereby supporting the null hypothesis: no correlation can be found between one's age and their ability to comprehend translated COA questionnaire items.

Additional qualitative analyses showed that terms and phrases were consistently problematic across all languages and subjects regardless of age. Such examples were "stiffness," as it relates to joint stiffness resulting from arthritis, "rheumatoid" and "worst possible pain." All observed comprehension issues did not appear to relate to the age of the subjects.

CONCLUSIONS

Review of the average number of misunderstood items per subject in the various age groups initially indicates that the subjects aged 65 and older are more likely to comprehend items than the younger age groups. However, the p-value of 0.064 demonstrates no statistical significance between one's age and their ability to comprehend items in translated COAs. Further qualitative analysis showed commonly misunderstood items that were not specific to any age group. It can be concluded from this study that subjects aged 65 and older are able to comprehend translated COA items as well as their younger counterparts.

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