

Preempting Difficulties in Linguistic Validation: The Use of Face Validation to Create More Sound Translations

Mary C. Gawlicki, MBA; Melissa Handa, MA; Shawn McKown, MA

— Corporate Translations, Inc. —

OBJECTIVE

This poster seeks to explain the benefits provided by the supplemental pre-translation process of face validation.

BACKGROUND

The process of linguistic validation is complex especially when working with a variety of languages in widely divergent cultural settings. The ability to clearly delineate concepts and synchronize wording within an instrument before the linguistic validation process begins not only significantly improves the original instrument but also aids in optimizing its translatability, ensuring greater uniformity between multiple linguistic adaptations and saving time and resources along the way.

METHODS

As part of a case study, face validated questionnaires were compared to the original versions of the corresponding instruments. Questionnaires that were already psychometrically validated were excluded from this study. First, a summary of common issues uncovered by the process of face validation is discussed, then resulting changes are discussed in-depth to clarify difficulties that each issue would have created for the linguistic validation process had they not been corrected. A cost-benefit analysis was also conducted to confirm the value of this supplemental linguistic validation phase.

THE FACE VALIDATION PROCESS

1. Sponsor develops a questionnaire for use in a multinational clinical trial.
2. Face validation is performed by a minimum of two survey research experts and two linguistic experts.
3. Suggestions for improving translatability, consistency, and clarity within the questionnaire are offered. If available, a patient may be consulted at this point to review the modified questionnaire.
4. Individual feedback is combined in one report in which summary suggestions are documented and rationale explained.
5. Sponsor reviews face validation report and incorporates suggested changes into the questionnaire where appropriate.
6. Additional rounds of review may be performed at the Sponsor's request.
7. The final version of the questionnaire is agreed upon and used for the linguistic validation process.

Case Study 1 This instrument measures the prevalence of visual disturbance and their effects on the patient				
Original wording of question	Problem(s)	Discussion	Proposed Solution	Results
We would like to ask some questions about your eyesight. Please select the response that best applies to you. 1) In the last three weeks, have you experienced any visual disturbances or problems with your eyesight (e.g. appearance of overlapping shadows, after images, shimmering, flashing or trailing lights; streamers or floaters in your peripheral vision)? <input type="checkbox"/> Yes If yes please continue and answer the following questions <input type="checkbox"/> No	<ul style="list-style-type: none">• Does not indicate that the questions relate to problems with eyesight• Double-barreled question	The key concept (visual disturbances) should be clearly defined at the beginning of the questionnaire so that the subject is able to answer this item and those that follow as intended. As worded, this clause is double-barreled—it is possible for someone to have problems with eyesight without experiencing visual disturbance.	We would like to ask some questions about problems you may be experiencing with your eyesight. These problems are called visual disturbances and may include but are not limited to the appearance of the following: overlapping shadows or after images; shimmering, flashing or trailing lights; or streamers or floaters in your peripheral vision. Please select the response that best applies to your experience of visual disturbances in the past three weeks. 1) Have you experienced any visual disturbances? <input type="checkbox"/> Yes If yes go to Question 2. <input type="checkbox"/> No If no, thank you and please return the questionnaire.	Subject instructions expanded for clarity. Visual disturbances classified as a type of eyesight problem, removing the double-barrel. All subsequent questions modified as shown below to emphasize recall period. 1) In the past three weeks, have you experienced any visual disturbances? Recall period left at 3 weeks to correspond to trial visit schedule. Proposed solution accepted. Parenthetical definition expanded and moved to instructions. Its early inclusion and emphasized text makes it clear to the subject what he should be thinking about when answering the questionnaire. Proposed solution accepted.
5) How often do you experience a visual disturbance when adjusting to changes in the lighting (e.g., coming indoors on a bright sunny day)? <input type="checkbox"/> Always <input type="checkbox"/> Often <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input type="checkbox"/> Never	Incorrect verb tense Responses order from high (always) to low (never) versus question 6 (below) which are ordered in the reverse manner.	Subject may misconstrue the recall period thinking that the question refers to a typical day rather than in the last three weeks. All response scales within the questionnaire should be oriented the same way - either from most frequent to least frequent or the reverse.	5) How often did you experience a visual disturbance when adjusting to changes in lighting (e.g., coming indoors on a bright sunny day)? <input type="checkbox"/> Never <input type="checkbox"/> Rarely <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="checkbox"/> Always	Proposed solution accepted. Verb changed to past tense to eliminate recall period confusion. Proposed solution accepted. The different-facing scale was flipped to maintain consistency between response sets. Recall period added to question by Sponsor for added clarity.
6) During the last three weeks, how much have you been bothered by... (Circle one number on each line): <input type="checkbox"/> Not at all <input type="checkbox"/> A Little <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit <input type="checkbox"/> N/A: Do not experience	Responses ordered from low (not at all) to high (Quite a bit) Wording of recall period modified slightly.	All response scales within the questionnaire should be oriented the same way - either from most frequent to least frequent or the reverse. Unnecessary changes to wording may confuse the respondent.	6) How much have you been bothered by... (Check one box on each line below): <input type="checkbox"/> Did not experience <input type="checkbox"/> Not at all <input type="checkbox"/> A little <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit <input type="checkbox"/> Extremely	Proposed solution accepted. Responses left in low to high order to match change in previous question. Proposed solution accepted. Change to wording of recall period incorporated. Recall period modified to "in the past three weeks" for consistency.

Case Study 2 This instrument measures the frequency and severity of the symptoms associated with pterygium and how they impact the patient's day-to-day life.				
Original wording of question	Problem(s)	Discussion	Proposed Solution	Results
This questionnaire includes 17 questions about the symptoms you may experience associated with your pterygium and the effect those symptoms may have on your life. A pterygium is a non-cancerous growth of the clear, thin tissue that lies over the white part of the eye (conjunctiva) and invades the clear window (cornea) that overlies the pupil and colored part of the eye (iris). One or both eyes may be affected.	Repeated use of may Positioning and emphasis of the definition Invades and overlays	The second occurrence of "may" was not needed to convey the intended meaning. Remove it to improve the sentence grammatically. This important definition was placed at the end of the introductory paragraph; it does not stand out as important. Visually separate the definition from the rest of the text and bold the term "pterygium" for emphasis. This terminology may be too technical for lay subjects. We recommended using simpler terminology to replace the terms; the purpose of the definition is to make sure that subjects understand what the disease is.	This questionnaire includes 17 questions about the symptoms you may experience associated with your pterygium and the effect those symptoms may have on your life. A pterygium is a non-cancerous growth of the clear, thin tissue that lies over the white part of the eye (conjunctiva) and invades the clear window (cornea) that overlies the pupil and colored part of the eye (iris). One or both eyes may be affected.	Proposed solution accepted. Other minor adjustments also made. Proposed solution accepted. Sponsor maintained original wording.
If you did not experience a symptom in the past 7 days please choose "None of the time," then indicate "Not applicable" for the severity of the symptom. If you did experience a symptom, when asked about the severity of the symptom, please indicate the most severe that the symptom has been over the past 7 days.	Use of two different verbs to indicate the same task (e.g. choose, indicate) If you did not experience a symptom	The use of two different verbs for one task makes the instructions less cohesive. Use one term throughout; consider changing to "check" which is more specific to the method of answering. As worded, this could be interpreted as "if you did not experience any symptoms. Add the word "particular" before "symptom" to emphasize the need to assess each symptom individually.	If you did not experience a particular symptom in the past 7 days please choose "None of the time," then choose "Not applicable" for the severity of the symptom. If you did experience a symptom, when asked about the severity of the symptom, please choose the most severe that the symptom has been over the past 7 days.	Proposed solution accepted. The instruction "indicate" was replaced by "choose" for greater synchronicity. Proposed solution accepted. The word "particular" was added before "symptom."
...discharge (a thick, stringy, sticky substance)	Unnecessary adjective	The use of the third adjective "stringy" was not needed to adequately define "discharge." Remove "stringy" from definition.	...discharge (a thick, sticky substance) from your eye(s)?	Proposed solution accepted. The term "stringy" was removed.
In the past seven days, how annoyed were you about the effect your pterygium has on your eye(s)? Not at all, A little aggravated, Somewhat aggravated, Very aggravated, Extremely aggravated	Verb tense Inconsistent use of adjectives (e.g. annoyed, aggravated)	The verb "has" does not match the verb "annoyed" or the reference period of "in the past seven days." Replace "has" with "had" for improved grammar and consistent verb tense. The question asks how annoyed the subject was and then provides response options pertaining to aggravation. Modify the response scale, so that it uses the same term as the item.	In the past 7 days, how annoyed were you about the effect your pterygium has on your eye(s)? Not at all, A little annoyed, Somewhat annoyed, Very annoyed, Extremely annoyed	Sponsor maintained original wording. Proposed solution accepted. The word "aggravated" was replaced by "annoyed" throughout the response scale.
Not applicable, No difficulty, A little difficulty, moderate difficulty, quite a bit of difficulty, a lot of difficulty	Response set gradations too close to be distinguishable	It may be difficult for respondents to distinguish between these two options, especially once translated. Create clearer response gradation by changing these two points to "great difficulty" and "very great difficulty."	Not applicable, No difficulty, A little difficulty, moderate difficulty, great difficulty, very great difficulty	Sponsor maintained original wording.

Other Options The following table outlines other quality control techniques and discusses how they differ from face validation.		
	What is it?	How does it compare to face validation?
Concept Elaboration Guide	A document which is utilized by the forward translators and project manager. It serves to ensure that all concepts are understood by the translators in the way they were intended. Additionally it may be used to clarify medical terminology, colloquialisms or other potentially problematic text within the source questionnaire.	A concept elaboration guide can only ensure items are clearly communicated to translators for accurate rendering in their target language. The added explanation is not provided to subjects responding to the questionnaire. Face validation assists in producing the most clearly communicated English version with an eye to providing comparable translations that can be appropriately understood by subjects of all language backgrounds.
International Harmonization	A review process involving the project manager, survey research expert and forward and back-translators assigned to a given project, held by means of a conference in which the subject instructions, survey items and response sets are reviewed one-by-one. Translators are asked to confirm that the final translation matches the concepts contained in the original instrument. At this time they are also encouraged to point out any issues they faced during the translation or debriefing processes.	International harmonization is conducted after all translations have been created and cognitively debriefed among subjects to make sure that all language versions are consistent and accurately convey the concepts present in the original document. International harmonization does not clarify confusing or misleading concepts within the source questionnaire. The cost of face validation is the same regardless of how many translations are being produced. The cost of international harmonization increases as more languages are added to the project making the value of the investment in face validation greater.
In-Country Subsidiary Review	A review of the forward translation, carried out by the client's designee, usually a clinician or study site administrator. This reviewer suggests modifications for cultural appropriateness and to maintain consistency with trial terminology.	In-country subsidiary review is an important quality control step, but it is performed separately for each translation, meaning that it can be difficult to maintain consistency between reviewers. During face validation, the client developer ensures that all concepts are communicated as clearly as possible within the source document which ultimately allows for greater cohesion between different language versions.
Survey Research Expert Review	A procedure by which a researcher with an advanced degree in questionnaire development and survey methodology reviews the back-translation for conceptual equivalency with the source document and helps to assess subjects' comprehension of translated items.	The survey research expert is also one of the individuals responsible for performing face validation. Typically, at least two individuals will work together to perform this assessment; whereas, expert review is only performed by one individual. Expert review also occurs after the source document has already been finalized and it is therefore too late to correct any conceptual, grammatical, or formatting errors.
Cognitive Debriefing	A process by which trained bilingual interviewers debrief subjects, who have already reviewed the questionnaire being tested on their own time, to assess their ability to paraphrase the instructions, questions, and response options within the questionnaire, indicating any difficult or confusing terms to the interviewer.	Cognitive debriefing is a crucial phase of linguistic validation, highlighting any lingering subject comprehension difficulties and working to correct them. Changes, however, can only be made in accordance with the concepts expressed in the original questionnaire—if a concept is consistently misunderstood across translations but corresponds directly with the source document, no changes can be made. Face validation works to identify these trouble spots before translation is performed, saving time during the translation and interviewing processes and increasing the probability that concepts will be relevant in a variety of cultural/linguistic settings.

Cost-Benefit Analysis	
Benefits of Performing Face Validity	Costs of Performing Face Validity
<ul style="list-style-type: none">• Improves overall quality and translatability• Synchronizes items, response sets, and recall periods (as necessary)	<ul style="list-style-type: none">• Requires additional time at the beginning of the linguistic validation process• Revised questionnaire needs review and approval by sponsor before initiating translation
<ul style="list-style-type: none">• Replaces ambiguous or colloquial phrases• Identifies items that may present as culturally inappropriate or irrelevant for some subjects	<ul style="list-style-type: none">• Additional cost of analysis (which may be defrayed through improvements made to questionnaire as a result of the process)
<ul style="list-style-type: none">• Improves overall grammar within the questionnaire• Ensures that subject instructions are clear and applicable to the content.	
<ul style="list-style-type: none">• Clarifies response sets that appear incongruous with the item or its recall period	

RESULTS

While standard elements of the linguistic validation process such as concept elaboration, international harmonization, survey research expert review, in-country subsidiary review, and cognitive debriefing all assist greatly in creating a quality translation, none of their benefits are a substitute for face validation. Many of the issues discussed in these case studies could have significantly impeded the translation and cognitive debriefing processes in a variety of ways, including:

- expressing a grammatically awkward concept;
- expressing an untranslatable concept;
- expressing a concept which is not easily understood by subjects,
- expressing a concept that contains more than one distinct idea;
- expressing a concept which is indistinguishable from similar ideas within the questionnaire.

It is more efficient to correct any linguistic or methodological issues within the source document rather than to grapple with these same issues while translating into multiple languages. Also, when a certain concept or word choice is problematic in the original questionnaire, each language may address the issue in a way that is distinct from the others, leading to less uniformity among versions and bringing the concept validity of the translated instruments into question.

CONCLUSIONS

As these case studies confirm, taking steps to maximize the translatability of a questionnaire prior to linguistic validation, through face validation in particular, is highly beneficial to the end-products and can also hasten overall project completion and improve the quality of all language versions of the instrument.

COMMON PROBLEMS IDENTIFIED DURING FACE VALIDITY ANALYSIS

- The use of acronyms rather than full disease or procedure names
- Double-barreled items (items that ask about two or more distinct ideas and should be split into separate questions)
- Technical terminology employed without providing a definition for respondents
- Instruction sets that do not fully explain the task ahead or what is being measured
- Question stems that are not grammatically cohesive with the remaining portion of the item.
- Mention of circumstances or activities that are not relevant to some cultural settings
- Use of the present tense for recall periods that reference the past
- Disparate wording for items within the same battery
- Response sets that are not uniform between similar items
- Response scales that have unclear gradation
- Switching the direction of the response set between items

COMPLICATIONS CREATED DURING TRANSLATION

- Acronyms often do not make sense in other languages, since the words they stand for differ; many languages demand the full term.
- The use of undefined technical terminology can be especially difficult within languages that have no comparable term; the definition will ensure that the meaning is conveyed regardless.
- Without clearly communicated instructions, subjects will not understand the preferred method for answering a question, which aspects of their disease to consider, the timeframe that is being referenced, or how to follow branch points.
- Some situations or activities are not relevant across cultures. This is a particular issue with regard to household chores, such as shoveling snow, vacuuming, or even opening a jar (none of which make sense in an Indian setting).
- Every word comes with certain connotations or alternate meanings—implications which vary by cultural/linguistic setting. Using synonymous, but different, terms to express the same concept throughout the questionnaire should be avoided.
- Response scales may be particularly challenging to translate accurately. Although it may be clear to an English speaker, the gradation that exists between such responses as moderately, somewhat, quite a bit, and a fair amount may be problematic since these options may appear equal to a speaker of another language, making it difficult to select the appropriate response.