



# Issues in the Translation and Linguistic Validation of ePRO and IVRS Instruments

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## Objectives:

Both computer based and Interactive Voice Response System (IVRS) ePRO instruments are increasingly used in clinical trials. As a result translations of such instruments are also increasingly required. Whilst the approach recommended in the ISPOR translation task force papers (Wild et. al 2005, 2009) should still be used, ePRO instruments present some unique challenges during their translation and linguistic validation. This study seeks to clarify what some of those challenges are, and how to meet them.

## Methodology:

Oxford Outcomes translation and linguistic validation projects involving ePRO (both screen based and IVRS) were reviewed to produce a list of tips on how best to localise such instruments.

## Results

The table on the right describes the issue of concern and the suggested solution based on our experiences.

Issue	Suggested Solution
Handheld computers (PDAs) have limited screen space. This can affect the space available to translators for translations of titles etc. This can also affect software applications on PCs due to the size of dialog boxes or pop-up messages.	Giving translators information about limited screen size up front (e.g. letting them know that they have a certain number of characters available to them for the translation of an item) will avoid having to shorten strings later in the process.
Participants in IVRS studies have to listen to the item prompts. The longer a prompt is, the more difficult it is to keep in mind all the information in the item.	Prompts should not be too long and have too many concepts (this helps both translators and participants).
<p>A common approach in software development is the use of concatenation (where a sentence is split in the software coding and put back together at run time). A hypothetical IVRS example of this might be:            String 1 = You said that the pain you experienced was            String 2 = none            String 3 = mild            String 4 = severe            String 5 = in the last 24 hours.</p> <p>When the IVR system is running, depending on what a participant has previously answered, the system will create the appropriate sentence from these 5 strings. So, if the participant previously answered 'severe' to a question about pain, the system would play String 1, String 4 and String 5, giving the sentence 'You said that the pain you experienced was severe in the last 24 hours'. It can be difficult for translators to translate concatenated strings appropriately, as the grammar of the foreign language may not allow this building block approach in the same way that English can.</p>	Concatenation is best avoided. If concatenation cannot be avoided, then it is important to give translators clear indications of what strings or prompts can be put together by the system when it is running, to allow them to make the best translation possible.
<p>In some paper PRO instruments, question stems are split from the rest of the question.            A hypothetical example might be:            How often does your diabetes:            1. stop you from travelling as much as you like?            2. prevent you from doing things you like to do?            3. etc...</p> <p>Not only can this cause problems for translators, but due to limited screen space on an ePRO, the participant may be looking at more than one screen for a series of questions. If the question stem is only at the top of one page, they may forget what the question stem was. Similarly with IVRS, if the question stem was only read out once, it would be difficult for the participant to remember what it was, or know if the following questions belong with the question stem.</p>	When working with ePRO instruments, we would recommend not splitting questions in this way.
Developers of ePRO systems often have strings or prompts that are reused for new systems. If translators only see the new prompts that need translating, inconsistencies may result.	It is worth providing translators with existing translations leveraged from previous translation projects to ensure consistency, if these are available.
Cognitive debriefing	Ideally cognitive debriefing of the translation should be carried out via the medium of final delivery (e.g. if it is on a handheld computer, the participants see the instrument on a handheld computer). Logistically though, this can be difficult to organise, so a compromise used for screen based ePRO is to have the ePRO developer build a translated version of the ePRO instrument, and then take screenshots to be used during the cognitive debriefing interviews. For IVRS, cognitive debriefing interviews can take place via telephone to simulate how participants will be hearing the prompts.
During the building of translated versions of software/web applications, and in the recording of IVRS prompts, errors can be introduced.	It is worth having a linguist check the final translated software, or, in the case of IVRS, listen to recorded prompts to ensure no errors have been introduced at software building or prompt recording stage.

## Conclusion:

With some forward planning, the challenges of translating and validating an ePRO instrument can be met, ensuring a translation that is conceptually equivalent and suitable for use in the target country with the target patient population.

## References:

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