

Dual Back-Translation vs. Single Back-Translation Methodology for Clinical Outcomes Assessments (COA)

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OBJECTIVE

The objective of this study was to determine whether performing dual back-translations rather than a single back-translation only improves the translation quality of a Clinical Outcomes Assessments (COA). This study aims to provide a quantitative assessment of the revisions yielded from dual and single back-translations, and the benefits of employing either process.

BACKGROUND

After an English source COA is translated into a target language (harmonized forward translation), it is then translated back into English. This “back-translation” is performed to ensure the translation is conceptually equivalent to the source. The back-translation is created by an independent linguist with no knowledge of the source text. Review and reconciliation of a back-translation against the source may indicate an error either in the harmonized forward translation or in the back-translation. Following the reconciliation step, the original translators are notified of the findings and are asked to make necessary corrections to the forward translation or confirm that finding is simply a back-translation error [1]. If the forward translators state that the finding reflects an error in the back translation, the back translator is notified for confirmation or additional discussion.

Previous research has been conducted on the effectiveness of back-translation methodology, regardless of whether one or two back-translations are used. A study by Gordon-Stables *et al.* found that 14% of the 50 items reviewed revealed an error in the forward translation. They concluded that a back-translation may be a useful tool to “catch misunderstandings” in the forward translation [2].

ISPOR’s *Best Practices for Translation and Cultural Adaptation* does not include a recommendation on the number of back-translations that should be performed, leaving that decision to the linguistic validation practitioners. While it is often the case that only one back-translation is used, a second back-translation may sometimes be requested by an instrument developer [1].

Previous research on the value added from dual back-translations exists. A recent study by Furtado *et. al* compared the difference between using one and two back-translators. Their conclusions determined that just one out of two back-translations might find subtle issues in the forward translation or slight misinterpretations of the text. This study also revealed that ePRO instructions, which might be misinterpreted, benefit from a back-translation [3]. The results of the study by Furtado *et. al* were qualitative in nature while the results of this study will present quantitative results on the value added when using a second back-translation.

METHODS

A total of 89 different back-translations were available for analysis. Of the 89 back-translations analyzed, there were 47 unique languages were represented.

Four COAs were translated using dual back-translations:

- 26 back-translations of a physical assessment questionnaire containing 1507 words with medical terminology.
- 33 back-translations of a physical assessment questionnaire containing 593 words with lay terminology.
- 14 back-translations of a COPD questionnaire containing 713 words with medical terminology.
- 16 back-translations of a cancer treatment questionnaire containing 403 words with lay terminology.

For all documents using the dual back-translation process, one specific type of revision was analyzed. For the purposes of this study, these types of revisions are called “Revision Type A”.

To be considered a “Revision Type A,” the revision must fulfill ALL of the following criteria:

- Two back-translations were reviewed simultaneously.
- One of the two back-translations is conceptually equivalent to the source text.
- One of the two back-translations is NOT conceptually equivalent to the source text.
- Translators confirm that there is an error in the forward translation requiring revision.

“Revision Type A” was sought out to determine in how many instances a second back-translation was needed to reveal an error in the forward translation. This will also demonstrate how often the additional back-translation is beneficial to ensuring that the forward translation is conceptually equivalent to the source.

Situations NOT analyzed in this study include instances in which the forward translation was confirmed to be correct, despite a discrepancy in one or both of the back-translations. These were excluded from the tabulation, because this study classifies changes made to the forward translation as an indicator of back-translation value.

The following Romanian example is a “Revision Type A” scenario:

| Source | Translation 1 | Translation 2 | Harmonized Translation | Back-Translation 1 | Back-Translation 2 | Discussion |
|---|---|---|---|---------------------------------------|---|---|
| How much difficulty did you have getting dressed today? | Câtă dificultate ați întâmpinat azi la îmbrăcare? | Cât de dificil a fost să vă îmbrăcați astăzi? | Cât de dificil a fost să vă îmbrăcați astăzi | How hard was it to get dressed today? | How difficult was it to dress yourself up today? | CTI: Back-translation 2 says “getting dressed up” as if more formal than one would normally get dressed, or for special occasions. This should reflect “getting dressed” in general. Translators: Changed translation in order to better reflect the English. |
| | | | Revised Translation: Câtă dificultate ați întâmpinat azi la îmbrăcare? | | Revised BT: How difficult was it to get dressed today? | |

As observed, one back-translation did not reveal the error in the harmonized forward translation, while the other back-translation did reveal the error, prompting a revision to the harmonized translation.

After review of all dual back-translations, the second back-translation was removed and all documents were reviewed twice: once looking at only the column labeled “back-translator 1,” and a second time looking only at the column labeled “back-translator 2.” The purpose of this was to compare the number of forward translation revisions resulting from review of dual back-translations to the number of forward translation revisions resulting from review of a single back-translation.

For analysis of the documents using single back-translation methodology, one specific type of revision was analyzed. For the purposes of this study, these revisions are called “Revision Type B” As was the case with analysis of “Revision Type A,” these types of revisions were sought out, in an attempt to determine the value of the back-translation in improving the forward translation.

To be considered a “Revision Type B,” the revision must fulfill ALL of the following criteria:

- One back-translation was reviewed.
- The back-translation is NOT conceptually equivalent to the source.
- Translators confirm that there is an error in the forward translation, requiring revision.

“Revision Type B” was tabulated to determine the number of errors revealed in the same four COAs when only one back-translation is reviewed. Situations NOT analyzed in this study include instances in which the forward translation was confirmed to be correct, despite a discrepancy in the back-translation. Improvements to the forward translation truly determine the value of a back-translation, specifically in cases where only one is used.

The following Spanish example is a “Revision Type B” scenario:

| Source | Translation 1 | Translation 2 | Harmonized Translation | Back-Translation | Discussion |
|---|--|--|---|---|--|
| Do you have any prescribed rescue medication? | ¿Le han recetado algún medicamento de rescate? | ¿Le han recetado algún medicamento de rescate? | ¿Le han recetado algún medicamento de rescate? | Have you been prescribed any rescue medication? | CTI: The source is asking whether the patient actually has this medication in their possession, whereas the BT seems to ask simply if it has been prescribed. Please revise if necessary. Translators: Change implemented. |
| | | | Revised: ¿Tiene algún medicamento de rescate recetado? | Revised: Do you have any prescribed rescue medication? | |

LINGUISTIC VALIDATION

Linguistic Validation is conducted to confirm that a Clinical Outcomes Assessment (COA) questionnaire is acceptable for use in different languages and cultural contexts. This careful translation development and subsequent cognitive debriefing confirms that the adapted instrument is both conceptually equivalent to the original and clearly understood by the average member of the target population. 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. A third translator then translates the harmonized 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 analyst; 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.

RESULTS

Table 1 shows the total number of forward translation revisions yielded from dual back-translations and also displays which of those were “Revision Type A.” (i.e. forward translation errors discovered by just one of the two back-translations).

| Questionnaire | Total forward translation revisions made using dual back-translations | Total forward translation revisions as a result of both back-translators identifying the forward translation error | “Revision Type A” |
|--|---|--|-------------------|
| 1507 word physical assessment questionnaire (medical concepts) | 67 | 63 | 4 |
| 593 word physical assessment questionnaire (lay concepts) | 43 | 43 | 0 |
| 713 word COPD questionnaire (medical concepts) | 66 | 60 | 6 |
| 403 word cancer treatment questionnaire (lay concepts) | 8 | 7 | 1 |
| Totals | 184 | 173 | 11 |

Out of all the revisions, 11 out of 184 forward translation revisions (6%) were discovered in one of the two back-translations. Furthermore, analysis of dual back-translated documents revealed that Type A Revisions were specific to certain language families, as demonstrated in Table 2.

| Language Family | Languages | “Revision Type A” |
|-----------------|--------------------------|-------------------|
| Indian | Kannada (India) | 2 |
| | Marathi (India) | 1 |
| Slavic | Czech (Czech Republic) | 1 |
| | Polish (Poland) | 1 |
| | Romanian (Romania) | 1 |
| | Russian (Israel) | 1 |
| Asian | Chinese (Singapore) | 1 |
| | Hiligaynon (Philippines) | 1 |
| | Thai (Thailand) | 2 |

Table 3 compares the total number of forward translation revisions yielded from dual back-translations to the total number of forward translation revisions yielded from single back-translations (“Revision Type B”).

| Questionnaire | Total forward translation revisions made using dual back-translations | Total forward translation revisions made using single back-translations (“Revision Type B,” back-Translator 1 only) | Total forward translation revisions made using single back-translations (“Revision Type B,” back-Translator 2 only) |
|--|---|---|---|
| 1507 word physical assessment questionnaire (medical concepts) | 67 | 65 | 64 |
| 593 word physical assessment questionnaire (lay concepts) | 43 | 43 | 43 |
| 713 word COPD questionnaire (medical concepts) | 66 | 65 | 61 |
| 403 word cancer treatment questionnaire (lay concepts) | 8 | 7 | 8 |
| Totals | 184 | 180 | 173 |

As observed in Table 2, the questionnaires containing medical terminology benefitted from dual back-translation, as a greater number of revisions to the forward translation were made using dual back-translations as opposed to single-back translations.

Overall, the results reveal that the second back-translation added value for specific language families: Indian, Slavic and Asian. Furthermore, a second-back translation may add value if the text contains medical terminology. Table 1 demonstrates that “Revision Type A” occurred 10 times between the two questionnaires with medical terminology, but only 1 time between the two questionnaires containing lay terminology.

It should be noted that the forward translations reviewed at this stage were not final validated translations. After back-translation review, the translated documents underwent subsequent quality checks. These checks are conducted by bilingual in-country native reviewers or clinicians who compared the translation to the source to ensure conceptual equivalency. In some cases, a questionnaire may also undergo cognitive debriefing, in which the questionnaire is reviewed by 5 or more native speakers of the target language [4].

CONCLUSIONS

While previous studies have concluded that inclusion of a second back-translation will improve translation quality, our findings are more mixed. In this research, the second back-translation proved to add some small benefit to Slavic, Asian and Indian language translations, particularly in documents containing medical terminology. Other language families were observed to be less problematic, such as Latin or Germanic-based languages more closely related to English. Overall, during analysis of the dual back-translation methodology, “Revision Type A” occurred only 6% of the time. As a result, this study concludes that the quality of forward translations using either dual or single back-translation methodologies is similar, and that the addition of a second back-translation provides only a small benefit from a quality perspective.

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