The Effect of Each Stage in the Translation Methodology for PRO Measures

Gordon-Stables, R., Wild, D.W[1]

[1]Oxford Outcomes Ltd, Oxford, OX2 0JJ, United Kingdom

Introduction

As trials become increasingly multinational there is a need for PRO measures to be translated and linguistically validated for use with people speaking a variety of languages. Wild et al. (2005) published a principles of good practice document which suggested a series of quality control steps for the development of linguistically validated measures. The generally accepted principles of good practice in this area include the following steps: 2 forward translations and their reconciliation, 2 back translations, back translation review, developer review, harmonisation meeting,cognitive debriefing interviews and proofreading.

However, little research has been done into the contribution of each of the stages toward the final goal of a conceptually equivalent translation.

Objectives

The objective of the study was to assess the effect of each stage in the accepted translation methodology for PRO measures.

Methodology

The questionnaire chosen for this study was the Anti-Clot Treatment Scale (ACTS) which had been translated into Canadian French, French and German, amongst other languages. Leaving aside the forward translation and back translation stages, where the whole text is changed, the grid for each stage was reviewed, and changes counted. The types of changes were also considered, to evaluate what each step contributes to the overall translation process. The text of the first forward translation was used as a basis for counting changes.

Results:

The following table shows the number of changes for each stage in the process[1]. A key to the types of change is provided below the table.

Measure: ACTS	Forward Translation Reconciliation		Back Translation Review		Client/Developer Review		Harmonisation[2]		Cognitive Debriefing		Proofreading	
Language	Investigator	FT2	Major	Minor	Major	Minor	Major	Minor	Major	Minor	Major	Minor
French	7	8	6	0	0	0	5	4	0	0	0	9
German	1	3	1	4	0	2	1	2	0	0	0	13
Canadian French	0	19	2	9	0	0	0	14[3]	0	3	0	14

Key
Forward Translation Reconciliation stage:

***Investigator** – the investigator uses their own translation but makes corrections because they spot an error, or they think of a better way of phrasing it.*
***FT2** – the investigator either uses forward translation 2, or uses an amalgamated translation based on their own and forward translation 2.*

Other stages (back translation review, client/developer review, harmonisation, cognitive debriefing and proofreading):

***Major** – a misunderstanding or mistranslation of the source text, or an omission*
***Minor** – a change of word for a word that has the same or similar meaning but is an improvement in the context.*
a spelling or grammatical error, a typographical error, or a formatting error
a change due to harmonisation, where the original translation is not incorrect

The following table shows some examples of changes made during the translation process for the ACTS.

Forward Translation Reconciliation

Language	Source text	Investigator's Forward Translation	Second Forward Translation	Reconciled Translation	Comments
Investigator					
French	Please circle the number in the box that best describes your views.	Merci d'entourer le chiffre dans la case qui correspond le mieux à votre réponse.	Veuillez encercler le chiffre dans la case qui descrit le mieux votre opinion.	Merci d'entourer le chiffre qui correspond le mieux à votre réponse.	The investigator has reconsidered their translation and simplified it, as they believed that "circle the number in the box that…" was overly heavy and therefore translated as "circle the number".
German	Not at all A little Moderately Quite a bit Extremely	Überhaupt nicht Kaum Etwas Ziemlich Sehr	Überhaupt nicht Etwas Mäßig Erheblich Äußerst	Überhaupt nicht Ein wenig Mäßig Ziemlich Sehr	Investigator has used their own translation with an updated version of "a little" to improve the way the response options match the questions.
FT2					
French	How bothered are you by the possibility of bruising as a result of anti-clot treatment?	Dans quelle mesure la possibilité d'avoir des bleus à cause de votre traitement par anticoagulants vous a-t-elle gêné(e) ?	Dans quelle mesure la possibilité d'avoir des ecchymoses en raison d'un traitement anticoagulant vous ennuie-t-elle ?	Dans quelle mesure le risque d'avoir des bleus à cause de votre traitement par anticoagulants vous ennuie-t-il ?	Investigator has used elements of both forward translations and inserted a modification.
German	INSTRUCTIONS: We are interested in your experiences of anti-clot treatment during the past 4 weeks.	ANLEITUNG: Es geht um Ihre Erfahrungen mit der Behandlung mit gerinnungshemmenden Medikamenten in den letzten 4 Wochen.	ANWEISUNG: Wir sind an Ihrer Erfahrung mit der Antikoagulansbehandlung während der letzten 4 Wochen interessiert	ANLEITUNG: Wir sind an Ihren Erfahrungen mit der Behandlung mit gerinnungshemmenden Medikamenten in den letzten 4 Wochen interessiert.	Investigator has used their translation of the main terminology but has used the second forward translation's rendering of 'we are interested'.
Canadian French	THANK YOU FOR YOUR HELP	MERCI BEAUCOUP DE VOTRE AIDE	NOUS VOUS REMERCIONS DE VOTRE COLLABORATION	NOUS VOUS REMERCIONS DE VOTRE COLLABORATION	The Investigator has taken the second forward translation.

Back Translation Review

Language	Source text	Reconciled Translation	Back Translation 1	Back Translation 2	Back Translation Review	Updated Translation
Major						
French	How much does anti-clot treatment limit your diet? (e.g. food or drink, including alcohol)	Dans quelle mesure votre traitement par anticoagulants entraîne-t-il des restrictions au niveau alimentaire (consommation de certains aliments ou boissons, comme l'alcool) ?	To what degree does your treatment with anticoagulants entail dietary restrictions (consumption of certain foods or drinks, such as alcohol)?	To what extent does your anti-clot treatment lead to dietary restrictions (consumption of certain foods or drinks, such as alcohol)?	Oxford Outcomes The part of both back translations that is in brackets is not quite the same as the source English. The source is far more general – implying that the participant should think about food and drink as well as alcohol. By saying "such as alcohol" the back translations are directing the participants' thoughts far more than the source English does. Please confirm the translation reflects the meaning of the source English. Investigator Well… the French version uses "alcohol" as an instance of food or drink that the patient is not able to consume anymore for instance. To stay closer to the original, we can use the literal "y compris""(consommation de certains aliments ou boissons, y compris l'alcool)" (consumption of certain foods or drinks, alcohol included). Oxford Outcomes New wording accepted	Dans quelle mesure votre traitement par anticoagulants entraîne-t-il des restrictions au niveau alimentaire (consommation de certains aliments ou boissons, y compris l'alcool)?
German	How much of a hassle (inconvenience) are the occasional aspects of anti-clot treatment? (e.g. the need for blood tests, going to or contacting the clinic/doctor, making arrangements for treatment while travelling etc.)	Wie viele Umstände (Unannehmlichkeiten) verursachen die gelegentlichen Begleiterscheinungen der Behandlung mit gerinnungshemmenden Mittel? ……(z.B. die Notwendigkeit von Blutuntersuchungen, Besuche im Krankenhaus / beim Arzt, Vorkehrungen für die Behandlung wenn man unterwegs ist, usw.)	How much trouble (problems) do the occasional side effects of your treatment with anticoagulant drugs cause? … (e.g. the need for blood tests, visits to the hospital / doctor, returning early for treatment when you're travelling, etc.)	How many circumstances (unacceptable ones) do the occasional accompanying effects of the treatment with anticoagulant medicines give rise to? …(e.g. the necessity for blood examinations, visits to the hospital/ to the doctor, precautions regarding the treatment if one is travelling, etc.)	Oxford Outcomes The back translations miss out "contacting the clinic/doctor". Please confirm that the translation has both "going to" and "contacting". Investigator In this context two kinds of contact might be taken into account - direct or by phone. The direct contact is covered by "Besuche" (visits), so phone calls indeed need to be added here (a direct rendering of 'contact' is not advisable in German).	Wie viele Schwierigkeiten (Unannehmlichkeiten) bringt die Behandlung mit gerinnungshemmenden Medikamenten gelegentlich mit sich? ……(z.B. die Notwendigkeit von Blutuntersuchungen, Besuche oder Anrufe im Krankenhaus / beim Arzt, Vorkehrungen für die Behandlung wenn man unterwegs ist, usw.)
Canadian French	How much of a hassle (inconvenience) are the occasional aspects of anti-clot treatment? (e.g. the need for blood tests, going to or contacting the clinic/doctor, making arrangements for treatment while travelling etc.)	Jusqu'à quel point le côté occasionnel du traitement anticoagulant est-il dérangeant (incommodant)? (ex. les prises de sang, aller chez le médecin/à la clinique ou prendre rendez-vous, organiser les traitements pendant les déplacements, etc)	To what extent is the occasional aspect of anticoagulant treatment bothersome (inconvenient)? (e.g. blood tests, going to the doctor/ clinic or making an appointment, organizing treatments during trips, etc.)	Up to what point is the occasional aspect of your anticoagulant treatment disturbing (inconvenient) (e.g. blood tests, visiting the doctor/ clinic or making an appointment, organising treatment when travelling, etc)	Oxford Outcomes Original English has "going to or contacting the clinic/doctor", whereas both back translations have "making an appointment" for "contacting". Could you confirm that the translation is ok here or if it should be reworded to better reflect the English? Investigator This version would be closer to the original English Jusqu'à quel point le côté occasionnel du traitement anticoagulant est-il dérangeant (incommodant)? (ex. les prises de sang, se rendre ou contacter la clinique/le médecin, organiser les traitements pendant les déplacements, etc) Oxford Outcomes New wording accepted, but should it be « se rendre á ou contacter la clinique » and could you provide a back translation for the record? Investigator We can add 'à'. Jusqu'à quel point le côté occasionnel du traitement anticoagulant est-il dérangeant (incommodant)? (ex. les prises de sang, se rendre à ou contacter la clinique/le médecin, organiser les traitements pendant les déplacements, etc). Back translation: To what extent are the occasional effects of the anticoagulant treatment bothering you (inconvenient)? (e.g. blood tests, going to or contacting the clinic/the doctor, organizing treatments while travelling, etc.) Oxford Outcomes Wording accepted	Jusqu'à quel point le côté occasionnel du traitement anticoagulant est-il dérangeant (incommodant)? (ex. les prises de sang, se rendre à ou contacter la clinique/le médecin, organiser les traitements pendant les déplacements, etc).
Minor						
German	How much of a hassle (inconvenience) are the daily aspects of anti-clot treatment? (e.g. remembering to take your medicine at a certain time, taking the correct dose of your medicine, following a diet, limiting alcohol, etc.)	Wie viele Umstände (Unannehmlichkeiten) verursachen die alltäglichen Begleit-erscheinungen der Behandlung mit gerinnungshemmenden Medikamenten? …..(z.B. daran zu denken, die Medikamente zu einer bestimmten Zeit zu nehmen, die richtige Dosis zu nehmen, auf die Ernährung zu achten, Alkohol einzuschränken, usw.)	How much trouble (problems) do the everyday side effects of your treatment with anticoagulant drugs cause? … (e.g. consider taking the drugs at a specific time, taking the right dose, watching your diet, limiting alcohol, etc.)	How many circumstances (unacceptable ones) do the everyday accompanying effects of the treatment with anticoagulant medicines give rise to? …(e.g. thinking about them, taking the medicine at an appointed time, taking the correct dose, taking care of nutrition, limiting alcohol, etc.)	Oxford Outcomes The back translations do not convey exactly the same meaning as the source English, which is asking how much of a hassle (irritating inconvenience) the aspects (not 'side effects') of anti-clot treatment that are mentioned are. Please confirm that the translation reflects this. Investigator German version is not about side effects (would be "Nebenwirkungen") - however, given the backward translations I understand that there is a risk of misunderstanding. A direct rendering of 'daily aspects' would be unclear in German (has a strong connotation of 'point of view', 'look' in German), so I'd suggest to render this using 'how much of a hassle (inconvenience) does anti-clot treatment involve each day'. For 'hassle' I'd suggest "Schwierigkeiten" (trouble, difficulty)	Wie viele Schwierigkeiten (Unannehmlichkeiten) bringt die Behandlung mit gerinnungshemmenden Medikamenten jeden Tag mit sich? …..(z.B. daran zu denken, die Medikamente zu einer bestimmten Zeit zu nehmen, die richtige Dosis zu nehmen, auf die Ernährung zu achten, Alkohol einzuschränken, usw.)
Canadian French	Not at all A little Moderately Quite a bit Extremely	Pas du tout Un peu Modérément Assez Extrêmement	Not at all A bit Moderately Somewhat Extremely	Not at all A little Somewhat Enough Very much	Oxford Outcomes The back translations suggest there could be confusion over "Assez". Could you confirm here that "Assez" sits well in this scale between "Modérément" and "Extrêmement"? Investigator I agree that 'assez' would probably be seen as being closer to modérément but it is the most common translation of 'quite a bit'. The word 'beaucoup' would probably fit in the middle of modérément and extrêmement. But 'beaucoup' means 'a lot' and may not be seen as being equivalent to 'quite a bit'. Oxford Outcomes "A lot" is most likely to be seen as more than "Quite a bit", although this is fairly subjective. If there is less risk of "beaucoup" being misinterpreted than "assez", then we should use "beaucoup". Investigator If you want an option that fits between moderately and extremely, I would keep beaucoup. We can also test this during the interviews. Oxford Outcomes OK. New wording: Pas du tout Un peu Modérément Beaucoup Extrêmement	Pas du tout Un peu Modérément Beaucoup Extrêmement
Canadian French	How much does the possibility of bleeding as a result of anti-clot treatment limit you from taking part in your usual activities? (e.g. work, shopping, housework etc.)	Jusqu'à quel point le risque de saigner en raison du traitement anticoagulant limite-t-il votre participation à vos activités courantes? (ex. travail, magasinage, travaux domestiques)	To what extent does the risk of bleeding due to the anticoagulant treatment restrict your participation in your current activities? (e.g. work, shopping, housework)	Up to what point does the risk of bleeding due to the anticoagulant treatment limit your taking part in your normal activities? (e.g.. work, shopping, housework)	Oxford Outcomes Back translation 1 has "current activities". Please confirm that the translation is correct for "usual activities". Investigator Both 'courantes' or 'habituelles' can be used. Habituelles can be used. Jusqu'à quel point le risque de saigner en raison du traitement anticoagulant limite-t-il votre participation à vos activités habituelles? (ex. travail, magasinage, travaux domestiques) Oxford Outcomes New wording accepted	Jusqu'à quel point le risque de saigner en raison du traitement anticoagulant limite-t-il votre participation à vos activités habituelles? (ex. travail, magasinage, travaux domestiques)

Developer Review

Language	Source text	Translation after Back Translation Review	Developer Review	Updated Translation
Minor				
German	**How confident are you that your anti-clot treatment will protect your health? (e.g. prevent blood clots, stroke, heart attack, DVT, embolism)**	**Wie zuversichtlich sind Sie, dass die Behandlung mit gerinnungshemmenden Medikamenten Ihre Gesundheit schützt? (z.B. Blutgerinnsel, Schlaganfälle, Herzanfälle, TVT, Embolien verhindert)**	**Developer We need to check with the client [regarding DVT]** **Client's response:** **"DVT, i.e. deep vein thrombosis may best be translated as "Tiefe Beinvenenthrombose". The patients may however use a more simple term. In my colloquial environment, people call it "Thrombose". Blood clot may be ransiated as "Blutgerinnsel" and this is far less clear and specific. I am not at all convinced that anybody in Germany uses an abbreviation for this indication, i.e. TVT. Since "Thrombose" is quite sure, that is what people say."**	**Wie zuversichtlich sind Sie, dass die Behandlung mit gerinnungshemmenden Medikamenten Ihre Gesundheit schützt? (z.B. Blutgerinnsel,-Schlaganfälle, Herzanfälle, Thrombosen, Embolien verhindert)**

Harmonisation

Language	Source text	Pre Harmonisation Translation	Comments from Harmonisation Meeting	Updated Translation
Major				
French	Please be sure to answer all questions.	Merci de vérifier que vous avez bien répondu à toutes les questions.	Simpler formulation on line with the English original	Veuillez répondre à toutes les questions.
German	How much does the possibility of bleeding as a result of anti-clot treatment limit you from taking part in vigorous physical activities? (e.g. exercise, sports, dancing, etc.)	Wie sehr schränkt die Möglichkeit, dass aufgrund der Behandlung mit gerinnungshemmenden Medikamenten Blutungen auftreten könnten, Sie darin ein, sich körperlich intensiv zu betätigen? …….(z.B. Sport treiben, tanzen, usw.)	Add the concept of "exercise" back in. Vigorous physical activity is not necessarily sport **Investigator** OK to add strenuous physical activities. **Oxford Outcomes** OK	Wie sehr schränkt die Möglichkeit, dass aufgrund der Behandlung mit Gerinnungshemmern Blutungen auftreten könnten, Sie darin ein, sich körperlich intensiv zu betätigen? …….(z.B. anstrengende körperliche Aktivitäten, Sport treiben, tanzen, usw.)
Minor				
French	We would be grateful if you could help us by filling out this questionnaire.	Ce questionnaire va nous aider à connaître votre opinion. Merci de nous aider en répondant à ce questionnaire	Changed the tense in the first sentence to make it lighter, does not change the meaning.	Ce questionnaire nous aidera à connaître votre opinion. Merci de nous aider en répondant à ce questionnaire.
German	Anti-Clot Treatment Scale	Fragebogen zur Behandlung mit gerinnungshemmenden Medikamenten	Gerinnungshemmende Medikamente' is changed to 'Gerinnungshemmer' as that's the more commonly used term in German and closer to the English (which does not mention drugs or medicines). **Investigator** OK - both terms can be used (and are commonly used), I don't have any specific preference, though I tend to think that "Gerinnungshemmer" is slightly more on the colloquial side. The notion of 'medicine' is implicit in "Gerinnungshemmer". **Oxford Outcomes** For the purposes of harmonisation with other languages, use "Gerinnungshemmer".	Fragebogen zur Behandlung mit Gerinnungshemmern
Canadian French	Anti-Clot Treatment Scale	Évaluation du traitement anticoagulant	"Scale" or "Questionnaire" should be in title, harmonised with rest of the languages.	Questionnaire sur les traitements par anticoagulants Questionaire on treatments by anticoagulants

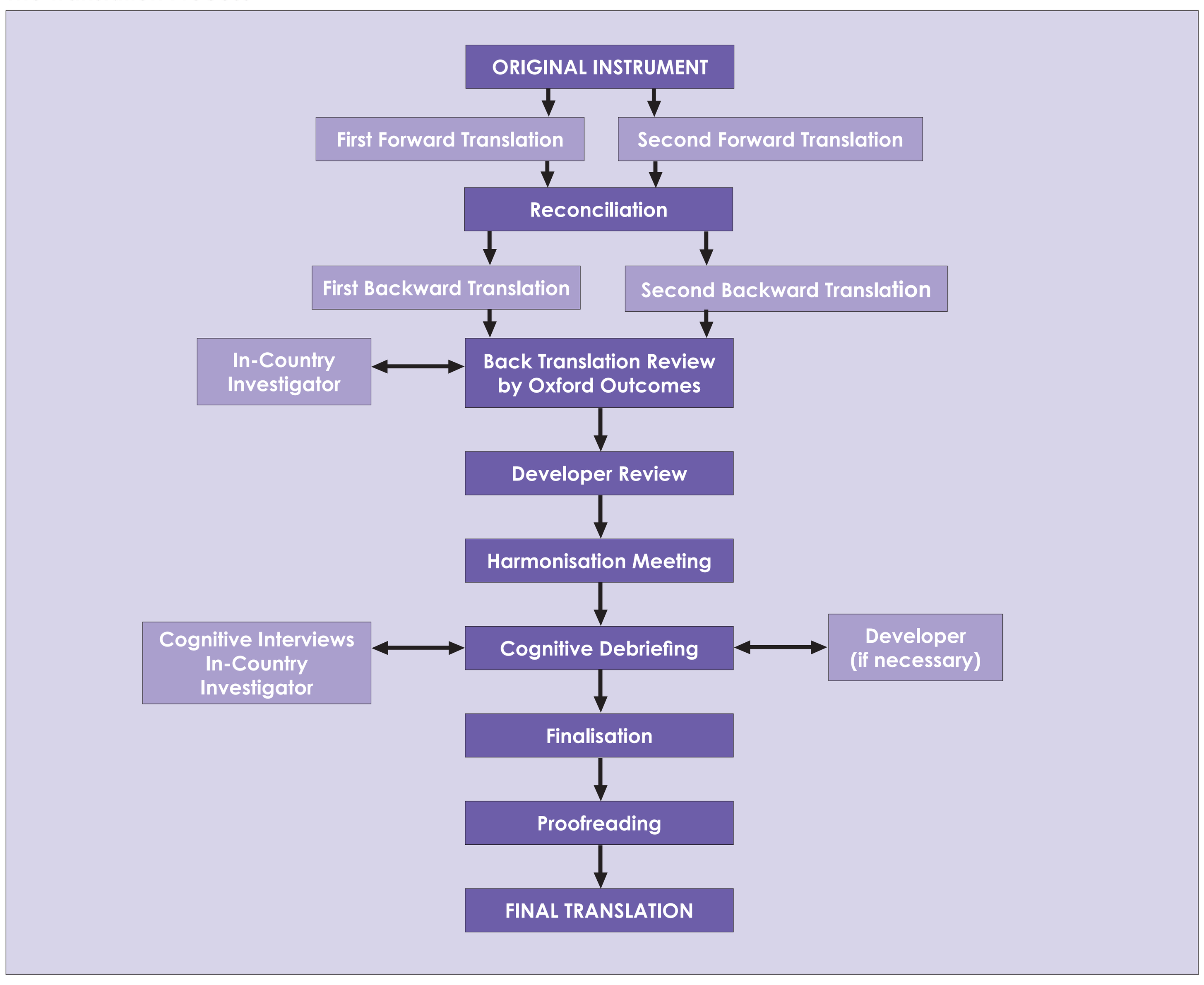
Cognitive Debriefing

Language	Source text	Draft Translation for Cognitive Debriefing	Suggested Change and Reason for Change	Updated Translation
Minor				
Canadian French	How time-consuming is your anti-clot treatment?	Jusqu'à quel point trouvez-vous que votre traitement par anticoagulants prend beaucoup de temps?	I suggest adding ….de votre temps (takes a lot of your time). This will prevent being interpreted as 'take a lot of time to cure or solve the problem' (which is not what is meant) Jusqu'à quel point trouvez-vous que votre traitement par anticoagulants prend beaucoup de votre temps? Oxford Outcomes Wording accepted.	Jusqu'à quel point trouvez-vous que votre traitement par anticoagulants prend beaucoup de votre temps?
Canadian French	How confident are you that your anti-clot treatment will protect your health? (e.g. prevent blood clots, stroke, heart attack, DVT, embolism)	Jusqu'à quel point êtes-vous confiant que votre traitement par anticoagulants protègera votre santé? (ex. préviendra les caillots sanguins, AVC, crise cardiaque, phlébite, embolie)	Several subjects made mistakes or did not know what AVC meant. I recommend to spell out AVC: accident vasculaire cerebral Oxford Outcomes Wording accepted.	Jusqu'à quel point êtes-vous confiant que votre traitement par anticoagulants protègera votre santé? (ex. préviendra les caillots sanguins, accident vasculaire cerebral, crise cardiaque, phlébite, embolie)

Proofreading

Language	Source text	Translation to be Proofread	Reason for Change	Updated Translation
Minor				
French	During the past 4 weeks	AU COURS DES 4 DERNIÈRES SEMAINES	Typo (small case and underline)	Au cours des 4 dernières semaines
German	How much of a hassle (inconvenience) are the occasional aspects of your anti-clot treatment? (e.g. the need for blood tests, going to or contacting the clinic/doctor, making arrangements for treatment while travelling etc.)	Behandlung wenn	Comma needed	Behandlung, wenn
Canadian French	How confident are you that your anti-clot treatment will protect your health? (e.g. prevent blood clots, stroke, heart attack, DVT, embolism)	accident vasculaire cerebral,	Missing the accent	accident vasculaire cérébral,

The Translation Process



The reconciliation stage causes the investigator (who in this case is performing the reconciliation as well as one of the forward translations) to reconsider their forward translation in the light of the second forward translation. Changes were therefore effected either because they had an idea of how to improve their own translation, or because they used ideas from the second forward translation to improve the translation (including simply using the second forward translation).

The back translation review caught items where the translation required improvement, or did not match the concepts in the source English. Again, the stage causes the investigator to look critically at their translation from another point of view.

Some minor changes were made at developer review stage. The small number of changes was partly because the developer decided to delay decisions on certain items until the harmonisation stage, but is also testament to the success of the first stages of the translation process in creating a translation that the developer felt conveyed the concepts in the desired fashion. Despite relatively few changes at this stage, the process is important as it allows the developer to advise on wordings that may have been misinterpreted by both the investigator and the reviewer of the back translation. The developer is, of course, best placed to advise on the concepts and intended meanings of the items in their questionnaire.

The harmonisation meeting allowed tweaks to be made so that all language versions were conveying the same meanings. The relatively high number of changes for Canadian French stems from the French and Canadian French translators agreeing to use the same wordings across both languages where possible. Unusually in this project, discussions in the harmonisation meeting allowed the developer to rethink some of the source wording.

For this project, few changes were needed at cognitive debriefing stage, showing that the process so far had produced translations that were understood as intended by the targeted patient group. It is common that few changes are made at this stage, as the previous quality control steps should have refined the translation to the point where the measure is likely to be well received by the target patient group. However, it is not recommended that this stage be left out on this basis, just as it would not be recommended to leave out cognitive debriefing of an original instrument.

The proofreading stage in this project served its purpose – catching formatting and grammatical errors that may have been missed during wording discussions. The second proofreaders caught errors missed by investigators, due to involvement with the same text over several weeks potentially dulling their ability to spot minor errors.

Conclusion:

As the translations went through the methodology, improvements to the quality and accuracy were made. The forward and back translation processes iron out problematic wordings. Although in terms of numbers of changes the developer review and pilot testing appear to have little effect, these stages serve as an important check of the previous steps. Proofreading is an important step in removing formatting and grammatical errors that may have crept in during the translation process.

Although the number of languages was limited, the study was useful as a window onto the "real" effects of the methodology as opposed to the theoretical. The opportunity exists for more research moving forward, looking at a larger number of languages translating the same instrument.

References:

Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A. & Erikson, P. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in Health 2005 N.8, V.2:94-104

Footnotes
1 *A change that recurs throughout the document only counts as one change. Some changes may override changes in previous changes. These overridden changes will still have been counted.*
2 *This does not include changes made due to changes to the source at harmonisation stage.*
3 *Many of these changes were due to harmonisation of the two French versions.*

Oxford Outcomes