Outcomes of International Trials can be Affected by Poor-quality Translations

The 8-language trial is completed, the data analysis is done. The medical writers have started writing the report. Then something happens. One of the writers notices that the answers to some of the most crucial questions in the French questionnaire do not match those from the other language versions. You take a closer look and find out that, indeed, the French questionnaire has not been translated correctly. In fact, it is so bad that much of the French research data should be discarded. The answers cannot be pooled with those from other language areas because the meaning of the questions had gone lost in translation.

A trial organiser's nightmare? No, I am afraid not… This one has happened for real!

Quality in translation is important. Everybody knows that. While an error in an instruction guide for a microwave is simply annoying, an error in a medical document can injure or kill a patient, and in the worst case it can put you in front of a US jury sympathetic to a grieving widow. In the translation world some terrible stories go around about injury and death due to translation errors in medical instruction text (see sidebar). Below I will show you how to stay away from US court rooms, and also how to prevent a nightmare scenario such as described above.

It is really rather simple: make sure your source text is of high quality and free of errors, jargon and ambiguities, then involve qualified translators who know what they are doing, and check or test the quality. High-quality medical translation results from the combination of human expertise and language skills, of computer-assisted translation (CAT) tools, and of very serious quality assessment. In the optimal mix of these three, the translation quality will be high and the risk of court cases close to zero.

Translation Errors Can Kill

Fortunately it does not happen very often, but people can get injured as a result of poor medical translations. In France, four patients died and dozens of others were injured due to an incorrect translation. Hospital staff had translated the software messages of a medical device that was used for the treatment of prostate cancer patients. For 12 months, and due to a translation error, the system administered radiation overdoses, with fatal outcomes for four patients.

In Germany, 47 patients who had undergone total knee replacement suffered a lot of pain and had to go for a second surgery after it turned out that the knee components had to be cemented into the femur. The translated instructions stated that the new knee could be implanted without using cement.

Human Factor

The human language skills and expertise can be found in experienced medical translators. Remember that it is very hard to polish up a poorly translated (or written) text. 'First time right' is key; when the initial translation is done by a quality translator, reviewing this work takes far less time and the risk that any errors are overlooked is minimised. It goes without saying that medical translators must be native speakers of the target language and be very experienced in medical. The golden rule is that one translator makes the initial translation, the next one will review the work, and a proofreader will make sure no errors survived these steps. This process is also what customers can expect to receive from a translation provider certified under ISO 17100:2015, the recent translation services standard.

Computer-assisted Translation

Translation memory (TM) tools are widely used CAT tools. These specialised tools are available 'off the shelf' from a dozen different developers. When such tools are used, the source and target language segments are stored, during translation, in a database. A segment is most often a complete sentence, but segment can also be defined as a string of text between punctuation, or as a bullet item in a list. Whenever a previously translated segment occurs again (further down in the same text, or in a new text), the translation memory software will present the existing translation and the translator can accept it, or simply revise it, and go on to the next segment. These tools help translators to be more consistent in the use of specific terms, and to be more cost-effective. The human translator has the lead in this process; the CAT tool is an efficiency tool. CAT tools are different from what is referred to as 'machine translation' (MT), where a computer provides the translation. The best MT example is Google Translate. Many people also find this a good example of how poorly computers can translate. And up to a certain level they are right; often such automated translations make not much sense, can be laughable, and should be used with the utmost care. However, MT output can certainly be used for 'gisting' purposes, giving the reader the gist of what the source language version roughly says; in certain cases this may be enough. And MT may have a bad name, but especially for language combination that are in high demand, for example from English into French, the output is not all that bad. As long as the English source text is clear and simple, without errors and ambiguities, the French will come out rather well. Even so, the output of MT should always be very carefully reviewed and compared with the source text. MT will be beneficial when this review time takes considerably less than the amount of time it takes for the traditional translation plus review.

Quality Assessment

Part of creating a high-quality medical translation is quality assessment. Translation services providers do QA as part of their work, and if they are ISO certified, they can be expected to do it, although not every provider takes this seriously enough. There are automated QA tools that can detect errors in translations. These tools will identify words or sentences that have not been translated, numbers and values that are different in source and target languages. They will also mark decimal points vs. commas, and thousands separators that are often different in English than in most other languages. It would be good if QA tools would also be able to check if word like 'not' or 'increased' have been correctly translated; these are the types of errors that can injure or kill a patient. Apart from automated QA tools, the human involvement is crucial. There are various additional ways to assess translation quality. One is to let two independent translators make a translation and then carefully compare the two. Another one is the back-translation, which is a QA method almost exclusively used for clinical trial documents. The most precisely documented method is referred to as 'the ISPOR method'. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) proposed a very detailed framework for the translation of instruments such as questionnaires.1 It includes translation into the target language by two independent translators, then these forward-translations are reconciled into one ideal version. The reconciled version should then be translated back into the source language by an independent translator, a native speaker of the original source language. The back-translation must be carefully compared with the reconciled forward translation, which will be finalised at the end of this process. This final version must then be tested, also referred to as 'cognitive debriefing'. During this test, the translated instrument is used on representatives from the target population in which the questionnaire will eventually be used. Only after it is clear that the translation is correct can it be used during a trial.

Why Would a Translation Still Contain Errors?

Often, translation errors are caused by the low-quality level of the source text. It is hard to correctly translate a poorly written text, and if translation providers notice a source text is not clear, they should be asking you questions about the specific meaning of certain phrases. If they do, your alarm bells should go off. Often the translators are the first 'close readers' of your text and when they have questions, you should take these very seriously, and even be prepared to revise your original text. Translators are usually highly-educated professionals and if they don't understand something, this tells you more about your text than about them. And if they don't fully understand your text, how likely is it that the average reader will?

In summary, produce a high-quality source text, select reliable translators, and check their work. The risk of having to discard all French answers to your most crucial questions is then close to zero.

Cheap Can Be Risky

A few years ago, the UK government invited translation companies to submit a bid for all government interpretation work. One of the lowest bidders won the contract. However, it soon became clear that they could not deliver: instead of 1200 interpreters, they only had 400 or so. In the midst of this, the company was taken over and it took the new parent company quite some time, and a lot of effort, to put things right.

The Swedish government did something similar concerning all government translation work. Again, one of the lowest bidders won the contract and, again, the winner could not deliver. In the end, even the Prime Minister's department refused to work with the selected company.

Also in this case, the result was that hospitals, courts and asylum centres were not getting the services they needed, jeopardising the health of patients and causing asylum procedures to take many months instead of weeks.

What these cases have in common is that the selected company, which on paper had an attractive price-performance ratio, could not meet the requirements. The price was low, for sure, but so was the quality. The net savings resulting from both of these tenders are probably negative, and all stakeholders have been very unhappy.

The Clinical Trial Regulation and its Impact on Language

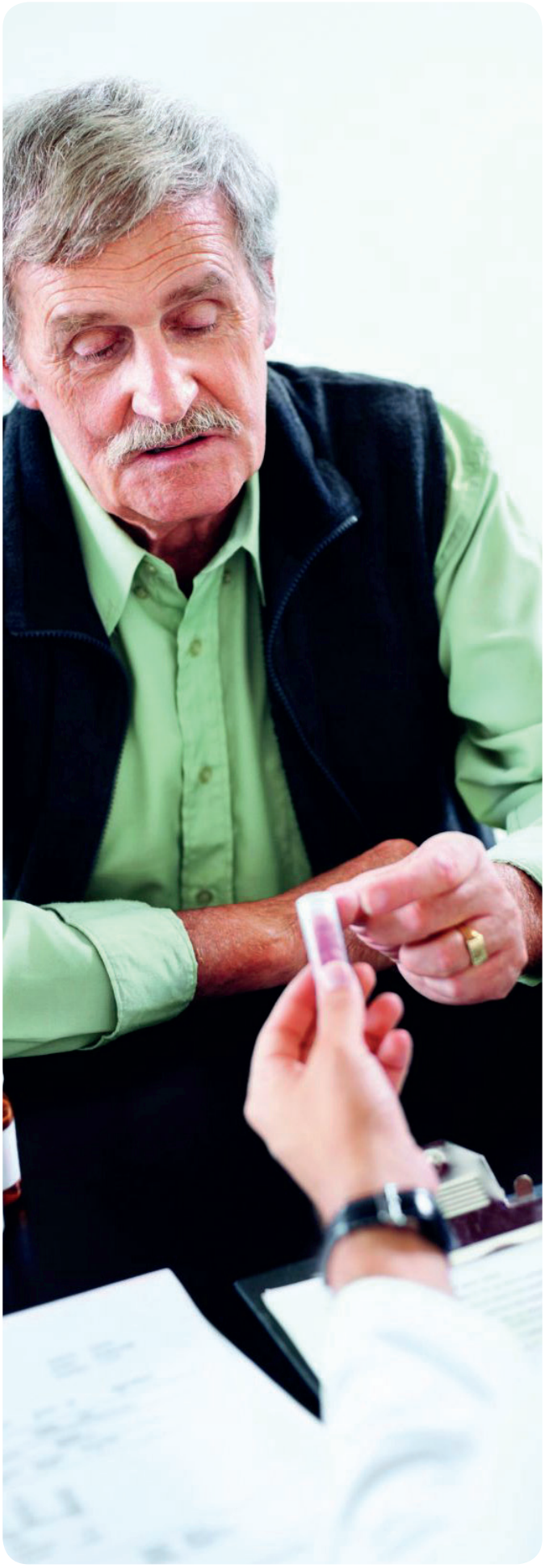
The new Clinical Trial Regulation (EU 536/2014) defines lots of new requirements for trial organisers, but most of these do not concern language and are therefore outside the scope of this article. Let's take a language look at the regulation.

Language of Dossier

A concerned EU member state can decide on the language requirements for the application dossier. It should be in a 'commonly understood language in the medical field', which may be different from the national language, as long as it only concerns 'documentation not addressed to the subject' (art. 26). This means that the government of, for example, Germany may agree to accept an English-language dossier, but that documents to be used by, or for, participants, such as informed consent form or questionnaires, should be translated.

Language of Informed Consent

Before obtaining informed consent, the potential subject should receive information to enable him or her to understand all aspects, including all risks, of the trial. This information has to be 'comprehensive, concise, clear, relevant, and understandable to a layperson', and the trial organiser must verify that the subject has understood all information (art. 30). This means that it is up to the national authorities to decide how to assess whether the information is 'clear' and 'understandable'



to the subject. It can be expected that this means that the ICF must be translated in the national language(s), which is rather common practice anyway.

Language of Official Reports
A concerned member state can request the translation in the EU language of their choice of 'inspection reports of third country authorities concerning the clinical trial'. The trial sponsor shall submit such reports 'in an official language of the Union' as indicated in the request (art. 53). This means that the trial sponsor may need to provide several translations of these reports, depending on what the member states demand.

Language on Labels
The concerned member state can decide in what language the label information of the trial medicine must be provided. The trial medicine may be labelled in several languages (art. 69).

Reference

1. 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, vol. 8, no. 2, 94-104) https://www.ispor.org/workpaper/research_practices/PROtranslation_adaptation.pdf

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