Welcome to the Translation Section editorial!

What we call ‘lay-friendliness’ is a key characteristic of Patient Information Sheets (PIS), which are tightly regulated on a European level to guarantee a comprehensible document that contains usable information for patients. It is clear that we, as translators, need to make an effort to improve language access as a means of empowering patients in decision-making about their own care. Strategies to support patients play an important role in understanding the causes of illness, protecting their health, and taking appropriate action. Yet, professional translators often primarily focus on the faithfulness of the translation to the original document rather than on the comprehensibility of the translated version, forgetting that often messages that work well with one language-speaking audience may not work for audiences who speak another language.

In the following article, Lorenzo Gallego Borghini gives an overview of lay-friendliness of PIS translations in Spain. Enjoy the article!

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Literality of translations is affecting the quality and readability of research patient information sheets in Spain

Background
In Spain, clinical research is a source of a great deal of work for biomedical translators. In 2013 alone, the Spanish Agency of Medicines and Medical Devices (AEMPS) approved 759 clinical trials, of which 74% were international multicentre studies, a percentage which has risen from previous years: 58% in 2012, and 60% in 2011.1 The conduct of international multicentre studies means, of course, that many clinical research documents are being translated into Spanish. The law no longer requires the research protocol to be translated into Spanish,2 but many ethics committees still request a copy in Spanish. On the contrary, the patient information sheet (PIS) and the informed consent form (ICF) must be written in the subject’s ‘own language’ (lengua propia), and therefore translation of the PIS/ICF has become a mandatory legal step in the approval process of any multinational research study. The final recipients of these texts, i.e. patients, are lay persons, and with this in mind, the translations should be written in clear and understandable language; at the same time, however, they should be accurate and adapted to the target legal and social framework. However, in reality, some things are not being done properly.

Problems in informed consent documents
What clinicians are saying
In a study of 101 sequentially selected PIS/ICF documents, a good percentage of which were likely translations as the sample included all clinical trials approved in the previous two years, it was found that 97% of these documents require readers to possess secondary to higher education levels; the authors concluded that the PIS/ICF documents analyzed were unacceptably difficult for readers, a situation which might even affect the validity of the consent process.3 Other experts in Spain have also questioned the quality of PIS/ICFs with complaints such as the following (in Spanish originally):

- ‘Many information sheets are (poor) translations from English, done by people who lack the necessary clinical experience; ethics committees are forced to review and rewrite them’;4
- ‘[…] informed consent documents are usually literal translations […]; they are too long and have too many technical words, which make them difficult for patients to understand’;5
- ‘[…]one of the problems with terminology may be related to translations that are too literal or not adapted to our local culture. In the current era of globalization, a new approach is needed to produce accurate translations, based on a multidisciplinary approach, taking into account the

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specific context and the local characteristics while being faithful to the source texts.\(^6\)

Bhatta\(^7\) has pointed to a key question: ‘The informed consent forms are [...] translated and then back-translated to ensure that they retain their original meaning. This emphasis on literal translation serves largely to satisfy the legality of the process rather than the information and comprehension needs of the community or individuals who may potentially participate in research.’

The objections of research ethics committees
I recently studied a sample of 100 review letters from Spanish research ethics committees (RECs) to learn more about quality issues in PIS/ICFs potentially related to translation. I found that almost a third of all the objections raised to the PIS/ICF document could be related to the translation from English. In addition, Spanish RECs criticize the translations of these documents in harsh terms and replicate the remarks cited above: they find them too long and dense, they consider the style to be awkward, confusing and cumbersome, and they point out many terminological and cultural pitfalls.\(^8\) When analyzing them in detail, it becomes clear that poor — often too literal — translations are behind many of the issues noted by RECs.

Examples of issues found in literal translations
Literality affects all levels of language but most notably aspects such as the following:

Repetitions
Informed consent forms in English are full of repetitions. For instance, the word study is used preceding all the elements related to a clinical trial and is repeated every time these elements are mentioned: the study doctor, the study personnel, the study drug, the study treatment, the study site, the study visits, etc. The English language tolerates these repetitions much better, perhaps because English words tend to be shorter and fewer articles and prepositions are used. For instance, study doctor (four syllables) literally translates into Spanish as médico del estudio (seven syllables), and study drug (three syllables) can be medicamento del estudio (nine syllables — three times as long!) if translated literally.

In Spanish, lexical repetitions are considered a sign of poor style. When translating into Spanish, there are alternatives to using the term estudio every time. For example, the study doctor can become el investigador, which sounds less like a ‘big word’ in Spanish than investigator in English, and the study site can simply be el hospital. The term research study itself is best translated as ensayo clínico, as many RECs demand,\(^8\) or as investigación, which does not mean the same as English investigation. Other times, the word study can be left out in the translation, as it adds no significant meaning in the communicative context.

Univocality
One of the features of literal translations is univocality — the notion that there must be an exact correspondence between one source word and one target word. Univocality is certainly desirable for scientific terms, especially in highly technical contexts. However, in PIS/ICFs, many terms are not actually scientific or technical, even if found more often in this genre, and some variation may benefit readability in a target language like Spanish, which does not tolerate repetition well, even within the same document. It is the case of terms like visita, which can be rendered as visita, yes, but can also be cita o control.

A troubled client once got back to me about a translation and asked me to amend it by introducing the term procedimiento exactly every time procedure appeared in the original. I could not make them understand that this word is utterly meaningless and that it can be translated not only as procedimiento but also as actividad, prueba o estudio (as in assessment), and can sometimes even be left out; indeed, the common sentence You will have the following procedures can be Le harán lo siguiente, where the notion of procedure is carried by the verb hacer (to do, to perform).

Discourse
As mentioned above, Spanish tends to repeat less. One of the reasons for this is that the traditional Spanish discourse relies more on what has already been said and what readers already have in their heads. For this reason, literal translations of English into Spanish tend to ‘grow’ by 15% to 20% regarding the source text. However, a good use of more traditional Spanish rhetoric can keep this ‘growth rate’ at about 5% or 10% maximum, and this is especially true for these texts, considering the number of lexical repetitions which can be suppressed easily in Spanish with no loss of meaning. This phenomenon was explained very well by López Ciruelos in what I believe to be a landmark article for Spanish translation.\(^9\)

Abbreviations and acronyms
Acronyms are not used equally in English as they are in Spanish. In fact, In Spanish, abbreviations and acronyms are used less frequently than in English and different shortening procedures are used, most notably the selection of one stronger
element in a compound. For example, whereas in English the abbreviation MRI is widely understood, Spanish has chosen the stronger word in the compound to shorten the name of this diagnostic procedure, and so resonancia magnética nuclear becomes resonancia in colloquial Spanish, much more often than the abbreviation RM or RMN, which are confined to technical jargon and the written language. Therefore, why not translate MRI as resonancia in informed consent forms if that is the term that patients are using in Spain? And the same can be said for names of diseases, such as systemic lupus erythematosus, which in Spanish can be shortened as lupus, using the core word instead of the acronym LES. Yes, there are other types of lupus, but again, Spanish relies more on what has already been said and on the communicative context, and the specific form of the disease will be clear earlier in the text and of course on the patient’s mind. However, many clients demand to see an acronym in the translation exactly where there is an acronym in English, and otherwise they seem to think the translation is missing something.

Grammar and syntax
Many grammatical and syntactical problems are caused by interference with English in these translations. One of them is the excessive use of possessives, which again are used far less in Spanish; when translated literally, these can lead to clearly ungrammatical expressions, such as su médico del estudio for the your study doctor (but literally, your doctor of the study). There are also marked differences in the use of demonstrative pronouns, and thus many sentences which begin with this is or these are in English need to be rephrased in Spanish for clarity, such as This is a randomized study, which should be either Este ensayo es de tipo aleatorizado or El ensayo es de tipo aleatorizado.

Other problems are found in adverbs ending in -ly, which correspond to Spanish adverbs with the -mente ending. However, in Spanish these endings produce longer words and are used less frequently (these do sound more like ‘big words’ than in English), in favor of other expressions. For example, we do not use -mente adverbs for frequencies, and thus daily and weekly are better translated as todos los días or una vez al día and todas las semanas or una vez por semana instead of diariamente and semanalmente; we do not use these adverbs either for administration routes, so we prefer to say por vía intravenosa instead of intravenosamente (intravenously).

It is also worth mentioning that Spanish has a much freer word order within sentences thanks to its preserved verbal system. When the rigid word order of English is kept in a translation, the result can read artificial, awkward, and clearly foreign. For example, a simple sentence such as A total of 100 patients will take part in this study can be best translated into Spanish placing the verb at the beginning and the subject at the end: Participarán en esta investigación 100 pacientes. This also enables us to remove a total of, as the figure is no longer placed at the beginning of the sentence.

Legal and cultural adaptation
Choosing cognates for translating legal terms can be a bad idea, not only because the target text can sound poorer but also because it can have legal implications. For example, literal translations usually include the word divulgación for disclosure in the context of data protection, but divulgación in Spanish has the meaning of public dissemination rather than disclosure between two authorized parties — which is far beyond the scope of the use approved by patients when they sign an ICF. The terms used in the Spanish Data Protection Act¹⁰ are comunicación and cesión. REC systems systematically complain about this.⁸

Cultural problems arise when paragraphs concerning different healthcare systems are translated without proper adaptation. For instance, in texts from the US, anything to do with payment, co-pays, payers, medical bills, etc., should be adapted to our free-of-charge universal-access system; trademarks and USANs or BANs should be changed for Spanish trademarks and INNs; and Anglo-Saxon volume measures should be transformed into decimal units (such as the number of teaspoons of blood to be collected, which in Spanish should be expressed in milliliters).

The reasons behind this situation
Summed up, all of these issues clearly affect the quality and the readability of these all-important documents in clinical research. One of the main reasons may be, as pointed out by Bhutta,⁷ that literal translation serves largely to satisfy the legality of the process, and less attention is paid to the actual adaptation to the target culture and the comprehension needs of the readers. Sponsors seem to be very fond of literality, perhaps because it is easier for them to monitor these texts if they find recognizable cognates in the same place as in the source text. Indeed, many translators in Spain are subject to what has been called ‘monitored translation’ (traducción vigilada),¹¹ i.e. translation that is assessed for quality using non-professional criteria such as cognate correspondence or symmetrical punctuation, even by individuals who are not speakers of the target language, which is relatively feasible.
with Spanish given its relative transparency, its closeness to English and their shared roots.

In fact, another reason for this fondness for literality is that many sponsors use backtranslation as a quality control procedure; of course, a literal translation will translate back into English more easily, and the review process will be smoother and require less effort. But is this real proof that the translation is good? In my opinion, of course, it is not.

The renowned legal translation scholar Anabel Borja12 has suggested that literality has traditionally been conceived as being equal to fidelity. However, as this professor points out, fidelity can also be understood to mean fidelity to the meaning, and excessive literality can have the opposite effect. The source language structures do not need to be replicated to obtain the same effects, including legal effects.12

Finally, but very importantly, the translation market in the clinical research sector in Spain, and in Latin America also, has been taken over in the last few years by large multinational agencies employing computer-assisted (and even automatic) translations tools. These companies apply an industrial approach to what is fundamentally intellectual work and are driven more by increasing their profits at any cost than by an actual interest in translation. The cost reduction frenzy also leads them to employ very junior translators who are eager to get started and are ready to accept their aggressive discounts for matches and their unfair work conditions, but have little expertise in such a sensitive field as human research. The predominance of these companies is seriously affecting the quality of medical translations in Spain and in Latin America.

What can be done

A radical solution to the problem with ICF translations in Spain would be not to translate them at all but to write them from scratch in Spanish and cap the maximum number of words at around 2,500. Indeed, in Spain the Coordinating REC Centre has proposed a sample PIS/ICF to be used by sponsors,13 but in reality ICFs are almost always translated from English, and some of the latest ones I have seen had more than 10,000 words.

How to tackle the trends in industrial translation is a different question altogether and one that specialized translators should take up very seriously. Ideally, sponsors should understand that literality is not a guarantee for legality or a sign of quality in translation, especially in the English to Spanish pair and in such a sensitive context as this one — important information to be read by lay persons, many in stressful situations. It should be understood that literality is not a synonym for fidelity or accuracy. It is up to us translators, and also up to language service providers, to convey this message to the industry.

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