Translating "medicalese": The case of informed consent forms

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Abstract

Informed consent forms (ICFs) are documents used in clinical research to inform prospective participants about – and obtain their consent for – partaking in a clinical trial. Evidence suggests that ICFs may not be fit for purpose because their linguistic and textual features exceed the comprehensibility needs of their non-expert target audience. These issues also affect medical translators who translate ICFs for prospective participants of international trials. This article discusses some of the main challenges of translating ICFs, such as specialised terminology and jargon, lexico-syntactic complexity, and text length, and argues for increased training and collaboration to mitigate these difficulties in medical translation.

Introduction

In recent years, demand for medical translation services has risen exponentially, with industry reports ranking healthcare as one of the largest segments of the translation market.[1] A key driver of this growth has been the proliferation of international clinical trials in the life sciences sector, spurred in part by the COVID-19 pandemic, which generated considerable volumes of documents for translation. These texts range in nature and content from highly specialised materials for clinical trial professionals (e.g., clinical study protocols and investigator's brochures) to those concerning patients (e.g., patient questionnaires and informed consent forms [ICFs]). Of these, the latter are essential to clinical trial development as the principal mechanism for obtaining individuals' consent to participate in a trial. Yet, there is evidence that ICFs are not fit for purpose,[2–4] an issue which can be exacerbated when these texts are translated into other languages.

What are informed consent forms?

ICFs are documents used in a variety of healthcare contexts, most notably in hospital settings and clinical research studies, to record a subject's agreement to undergo a particular treatment or care regimen. They are predicated on the principle of informed consent, which in clinical research refers to the "written, dated and signed" decision to "take part in a clinical trial, taken freely after being informed of its nature, significance, implications and risks".[5] They form part of a larger dossier alongside expert-facing texts such as the study protocol, but unlike these documents which are aimed at clinical trial professionals, ICFs address non-experts or lay persons. Since they are based on complex information from the study protocol and other related materials, it is essential that ICFs are adapted and recontextualised for a new target audience.

ICFs serve a dual function: to inform prospective participants about important aspects concerning the trial and to obtain their consent to participate. This two-fold purpose is reflected in the typical structure of an ICF, which commonly includes:

- An **information sheet** outlining aspects such as study purpose, proposed treatment and administration schedule, eligibility and exclusion criteria, risks and benefits, and data protection provisions;
- A **declaration of consent** to be signed by the participant or their legal representative.

The above functions, together with the legal and ethical validity of the consent process, rest on an individual's ability to understand the information they are given and make voluntary and informed decisions about their participation.

However, there is a growing body of research showing that ICFs often exceed the comprehensibility needs of their non-expert audience.[2,3] While several factors contribute to this incompatibility between text and reader, from document length to a lack of visual aids, studies claim that the complexity of the text itself is the main obstacle to patient comprehension. Issues such as specialised terminology and jargon, sentence length and structure, and volume of information all play a role in limiting how well target readers process the information ICFs contain; this, in turn, reduces their effectiveness as vehicles for informed decision-making.

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The complex nature of ICFs becomes even more challenging in translation. A considerable proportion of clinical trials are international, multinational, and/or multicentric, requiring that their documents be translated into local languages to facilitate recruiting local participants and running the trial. Yet translating information from one language into another can be complicated when dealing with patient-facing medical texts. There may be asymmetries in the doctor-patient relationship in the local context, as well as differences in the nature of this relationship between the source and target cultures. Medical translators, thus, need to be aware of how medical information is conveyed to patients in the target context and of the norms and expectations governing a doctor-patient exchange, particularly in a context that requires the patient's active, explicit consent.

Challenges of translating informed consent forms

Medical translation has become an increasingly popular specialism, ranking second after the legal

specialism among language professionals, according to a 2023 industry survey.[1] This trend is reflected in the rising availability of academic- and professional training programmes in medical translation, which offer instruction in handling a range of medical text genres, including ICFs. This type of training is essential. Not only is this a high-risk, zero-error domain, but it also entails particular challenges that medical translators need to be aware of to successfully mitigate them. We explore the most pressing of these issues below.

Specialised terminology and medical jargon

One of the main challenges of translating ICFs, and patient-facing medical texts in general, is the presence and use of specialised medical terms and jargon instead of more common, lay-friendly alternatives. This encompasses a variety of terminological choices: from medical terms of Greek and Latin origin (e.g., *ecchymosis* instead of *bruise*; *cephalalgia* instead of *headache*) to references to procedures, devices, or processes where lay alternatives might not exist (e.g., *screening*, *randomisation*, *interventional trial*). There are also differences concerning how specialised medical terminology is presented, whether it is introduced without being adequately defined or contextualised, or whether the authors used explicitation strategies alongside these concepts.

In these scenarios, medical translators are potentially faced with sourcing lay-friendly alternatives for expert terms, deciding whether to include any additional explanations in the translation which might not be present in the source, and if so, which approach to apply in each situation. This changes the nature of the translation brief and sees medical translators taking an active role in enhancing comprehensibility for patients. Doing so, however, can have a knock-on effect on the translation workflow, as translators may need to conduct additional terminology research, which can impact delivery times and project rates. Medical translators may also need to consult with their clients or project managers as to whether – and which of – these textual interventions would be allowable for their projects and educate their stakeholders about what constitutes an appropriate text for a lay target readership.

Lexico-syntactic complexity

Another characteristic of ICFs that impacts both comprehensibility and the translation process is their complex sentence structure. These texts tend to include excessively long sentences,[6] with multiple subordinate clauses nestled in equally long paragraphs. While these are typical hallmarks of expert-facing text genres, they are not appropriate for lay readers who may struggle to follow the information they contain. Sentences are not only long, but they also can be incoherent and/or inconsistent in order and structure, requiring medical translators to "untangle" them and streamline the flow of their translations. This, too, can impact agreed-upon budgets and turnaround times, as these editing tasks may fall outside the scope of their translation briefs.

ICFs also pose lexical challenges to translators. Not to be confused with technical jargon, lexical complexity refers to other wording and phrasing that makes these texts difficult to understand. This includes a host of issues:

- Nominalisations and disproportionately using nouns over verbs, often in combination with the passive voice (e.g., *the investigation will be conducted* instead of *we will investigate*)
- Compound nominal and adjectival phrases (e.g., *phase IV, multicentre, open-label, double-blind, randomised clinical trial*; *recurrent major depressive episodes*)
- Phrasal verbs (e.g., *follow up*, *fill out*, *slow down*, *rule out*), among others.

Lexico-syntactic calque is another major challenge in medical translation. Characterised as a "borrowing" or interference from another language (the source), calque can occur at the word level, producing word-for-word literal translations, or at the sentence level, whereby the translation follows the sentence structure of the source language, rendering the output stylistically unnatural and awkward. Gallego Borghini (2012) provides a comprehensive overview of these risks as well as suggested strategies to

mitigate them in his work on translating English-to-Spanish ICFs for clinical trials and notes that these issues help explain why Ethical Review Boards complain about poor readability and comprehensibility in ICFs and their translations.[7]

Amount of information

Related to lexical and syntactic complexity is the issue of how long ICFs are or should be. Given their legal and ethical functions and the health risks to which prospective participants need to consent to partake in a clinical trial, ICFs contain a substantial amount of information ranging from medical processes and procedures to legal provisions on an individual's rights and data protection. This leads to the "wall of text" problem: Authors of ICFs include too much technical detail, partly to comply with established ICF text conventions and partly to avoid any potential liability by covering all possible bases. Yet, this can have the opposite effect, in that readers might struggle to process and retain essential trial information. Repetitions are also common, whether verbatim or by rephrasing the same content in different ways, which may be confusing to readers. This reinforces the need for medical translators to communicate with their clients and advise them about what may or may not be appropriate for a lay audience.

Lack of standardised international guidelines

A driving factor behind ICF length is the lack of standardised guidelines governing what they should look like. Although the principle of informed consent is recognised in international agreements and legislation,[8,9] there is no overarching legal framework at the European or international level codifying exactly what information ICFs should contain and how they should be written in terms of content, style, and layout. Some international bodies, such as the WHO, provide their own ICF templates,[10] but there is no legal obligation to use them. Most pharmaceutical companies and contract research organisations conducting clinical trials have their own – usually not publicly available – templates and conventions used in compliance with regulatory authority requirements. These templates generally include similar types of information but vary from one company to another or across countries or regions. They are also not standardised in the style of the EMA Centralised Procedure Package Leaflets which,[11] while imperfect from a readability standpoint, help ensure uniformity across documents prepared by different pharmaceutical companies, manage expectations about what these documents contain and look like, and provide a tool against which to check whether these expectations are met and, if they are not, hold those responsible for running the trial accountable. In the absence of such guidelines, authors of ICFs and their translators must grapple with both uncertainty and variation, which makes it all the more difficult to uphold and implement comprehension-enhancing measures for lay readers.

> The absence of standardised guidelines for ICF writing makes it difficult for translators to uphold and implement comprehension-enhancing measures for lay readers.

The rise of machine translation

A final challenge for medical translators comes from inside the proverbial house: the rise and increasing use of machine translation (MT) in the healthcare domain. Defined as the automatic translation of text from one natural language to another using a computer application,[12] MT has not yet permeated medical translation to the same extent as other specialisms. However, more and more language service providers are integrating custom MT engines trained on existing human translations into their workflows and requiring medical translators to post-edit the output. While this quality training data is likely to help produce better raw translations, MT results tend to be poorer and require more post-editing effort for expert-facing texts or those which are syntactically complex and dense from a thematic and terminological standpoint (author's own translation).[6] With ICFs, MT engines may fail to adequately handle the other challenges inherent in this text genre, adding to the issues medical translators must already contend with when translating patient-facing medical texts. The extent to which MT will be incorporated into medical translation remains to be seen, as is the case for generative artificial intelligence (GenAI) technology, which, nonetheless, shows promise for simplifying complex information and, thus, may find applications in streamlining medical texts for patients, including ICFs.

> For easier-to-understand translated texts for patients, medical translators should combine domain-specific training with pertinent collaborations.

Looking to the future

To overcome these challenges and work towards producing better, easier-to-understand texts and translations for patients, medical translators should seek to combine domain-specific training with collaborations with colleagues and industry stakeholders.

Training for medical translators

It goes without saying that medical translators require excellent knowledge of medical or health-related terminology and concepts in addition to linguistic skills. Research shows most medical translators are either medical experts with knowledge of other languages or trained linguists without formal medical education but who have specialised in medicine through professional practice and training.[13] Supplementing this existing knowledge with training and continuous professional development is paramount to keeping up with the latest developments in a fast-paced, rapidly changing, and highly technical field such as medicine.

Medical translators could also benefit from training on plain and inclusive language to begin considering the health literacy needs of their target audience and adapt their translation choices accordingly. Knowing what is appropriate for a lay target readership in terms of lexis, syntax, style, and visual layout can empower translators to improve the comprehensibility of their translations and advocate for more readable and lay-friendly source texts to their clients and project managers. Technology training would also help medical translators become attuned to the types of errors MT engines are susceptible to, and thus improve their post-editing performance, raise awareness of responsible MT use in the medical domain, and experiment with tools such as AI or speech recognition which may help improve the comprehensibility of their translations.

Knowing what is appropriate for a lay target readership in terms of lexis, syntax, style, and visual layout can empower translators to improve the comprehensibility of their translations.

Fostering collaboration

Of course, these efforts need to be supported by joint initiatives and collaborations between all parties involved in writing and translating clinical trial documentation: from trial sponsors and clinical research organisations to national and international health regulators, such as the EMA, and medical translators and patients themselves. Understanding patients' needs and establishing robust legal frameworks and best practice guidelines to ensure these needs are met are essential for upholding the legal and ethical validity of the informed consent process and delivering a healthcare service that better serves its patients. Effective medical writing and translation take this goal further by providing additional safeguards in support of a patient's right to be given accessible information they can easily understand, ensuring that the consent these patients give is indeed voluntary, free, and informed.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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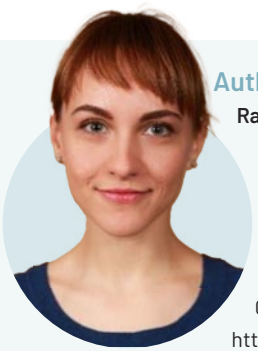

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