Quality, accessibility and readability in medical translation

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1 Introduction

Quality, readability and accessibility are three aspects of the patient-related dimension of medical translation. The quality of medical texts translated for lay recipients is associated with three key concepts: patient-centred care (PCC), personalised medicine (PM) and translational medicine (TM), as these involve stressing the critical impact of information transfer, including recontextualisation and communication (Montalt 2017; Montalt, Zethsen and Karwacka 2018: 28). Patient-centredness, which is the acknowledgement of the role of the patient as the focus of interest in healthcare context, is closely associated with quality, readability and accessibility; accessibility ensures that a patient is able to and knows how to access healthcare services, while readability enables a patient to comprehend their condition, understand their treatment and use medicines or medical devices in a safe way. Quality medical translation for patients needs to be readable and is a prerequisite for accessible healthcare which overcomes language barriers.

This trend is reflected in guidelines concerning language use in texts addressed to patients and can be traced in various normative acts. The European Commission Directive 2004/27/EC, for instance, includes a requirement for patient information to be ‘legible, clear and easy to use’ and to be also presented in Braille or another format accessible to visually-impaired patients. This directive ensures that the information on how to use a drug in an adequate and safe way is conveyed in a manner and form that enables the users to comprehend the content and comply with the recommendations for use (cf. Andriesen 2008). It also shows how readability, accessibility and quality are interrelated and interdependent concepts; high-quality documents addressed to patients are readable and accessible to various groups of patients, including visually-impaired ones or those with limited health literacy, thus securing access to health-related information.

This chapter is divided into three sections, each in turn addressing the concepts of quality, accessibility and readability in medical translations. The first section provides an overview of the problems and definitions associated with medical translation quality, followed by approaches related to factors such as compliance with legal requirements...
or medical translator competence. The following section focuses on accessibility in healthcare, which is here primarily understood as the overcoming of language barriers in health services. The aim of this section is to explain how access is conceptualised, how it is connected to language, and what strategies can be adopted to secure healthcare accessibility. Lastly, the final section focusing on readability discusses the relevant definitions and regulations, together with an overview of studies into the readability of medical texts.

2 Medical translation quality

The quality of translated medical texts has historically received significantly less attention in the medical community than medical and pharmaceutical research or the practising of medicine (cf. Abootorabi and Moeinzadeh 2017). However, given that a mistake in medical translation may jeopardise the chances of a research paper being published or of being of clinical consequence (see for example, Wolz 2015: 248–250), the quality of translated medical texts has in recent years received increasingly more attention from researchers and translation professionals alike (see for example, Garcia-Castillo and Fetters 2007; Fernández Piera and Ardura Ortega 2012; Nisbeth Jensen 2012; Abootorabi and Moeinzadeh 2017).

Although the quality of medical translation is frequently conceptualised by researchers and specialists in the field as a requirement for literal accuracy and precision, it is conceptual accuracy (i.e. retaining the same meaning) that is actually desirable, as opposed to word-for-word rendition (Garcia-Castillo and Fetters 2007: 77). ‘Cultural equivalence’, which is understood as ensuring that the cultural concepts in the target text can be adequately perceived by recipients, is a frequently stressed notion in the context of medical translation quality (Garcia-Castillo and Fetters 2007: 77), alongside sensitivity to factors such as race, ethnicity, language variations, gender, age and religion. In terms of practical aspects of medical translation quality, researchers frequently mention handling intralingual variations such as dialects, or the necessity to check target texts for errors or mistranslations by means of pilot testing or the use of various quality assessment models (Garcia-Castillo and Fetters 2007: 77). What needs to be emphasised is that quality assurance starts (or should ideally start) before a translation assignment is commissioned, i.e. when the source text is drafted. This stage includes predicting potential culture-specific problems and assuring compliance with the conventions and requirements of specific text genres or functions, such as readability and clarity in expert-lay communication.

One of the factors which are critical for the quality of medical translation is the design of the project. The International Standard ISO 17100:2015 was developed to help in the implementing of quality assurance procedures at various stages of translation projects and it is followed by a number of translation agencies. The standard ensures adequate human resources (competent translators, revisers and reviewers), properly designed pre-production (e.g. managing client enquiries, assessing feasibility, drafting agreements with the client), translation (including checks, revisions, reviews and proofreading) and the post-production process. In general, the standard offers guidelines on checking the translation for the presence of omissions and semantic, grammatical or spelling mistakes. Its overall aim is to ensure ‘compliance with relevant translation project specifications’ (ISO 17100: 2015) rather than providing measurable parameters for assessing translation quality (Montalt, Zethsen and Karwacka 2018). The International Medical Interpreters
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Association (IMIA) guide also addresses the translation project design and recommends a set of standard good practices:

1. Have a central source document repository at the institution in question
2. Establish a central translation management point
3. Prioritise translation needs
4. Recruit, qualify, select and manage vendors
5. Know how to request a quote
6. Negotiate realistic deadlines
7. Know which sources should be created and maintained to aid the translation and quality control processes (Txabarriaga 2008: 8–12).

Institutions which handle translated texts develop their own medical translation verification procedures. The IMIA applies a two-step verification process involving two editing rounds (Txabarriaga 2008: 17). Another commonly used tool for medical translation quality assurance is the back-translation procedure (cf. Fernández Piera and Ardura Ortega 2012), particularly in the sector of medical research and clinical trials, as it is required by Ethics Committees and regulatory authorities in a number of countries (Grunwald and Goldfarb 2006: 2). The procedure involves translating the target text ‘back’ to the source language by another translator and comparing the two source language texts to see if the message is accurately transferred (for further discussion see e.g. O’Neil 1998, Garcia-Castillo and Fetters 2007; Bundgaard and Nisbeth Brøgger 2018). Studies show that the procedure ‘can improve the accuracy of translated text by highlighting different possibilities and challenging the translator’s choices’ (Garcia-Castillo and Fetters 2007: 79), however it also needs to be noted that its usefulness is debatable. Translators are sometimes confused about the procedure or its role in the project (Bundgaard and Nisbeth Brøgger 2018: 219–220). Back translations are also costly and time-consuming, and they do not, for instance, help reveal ‘the target language contextual and usage nuances’ (Txabarriaga 2008: 2) or awkward word-for-word transfer. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) uses a review method with two parallel forward translations; this means that two translators prepare their own translations independently. These are then reconciled, then two back translations are produced, compared and reconciled, and finally, after a review and a harmonisation, the target text is developed (Andriesen 2008: 15–16). Parallel translation can also be a standalone quality assurance method, where two parallel translations are produced, then compared, reconciled and accordingly adjusted (Andriesen 2008: 16). Several other instruments can be used to verify the comprehensibility of the translated material in medical translation projects, including the following: pilot testing or readability tests on focus groups of lay recipients (cf. Andriesen 2008: 15–16; Garcia-Castillo and Fetters 2007: 77–78); statistical reviews, which assess readability based on the length of sentences and words used in a document; independent evaluations e.g. by patient organisations; or an additional edit round, i.e. commissioning yet another proofreader of the source text (cf. Andriesen 2008: 15–16). Finally, cognitive debriefing can be used in the verification process of translated questionnaires or scales. This debriefing involves collecting feedback from a sample group of lay respondents on how they understand the wording of a question or statement in order to check if it is adequately readable and lay-friendly while still conveying the original concept (cf. Engel and Koester 2014).
However, despite these various guidelines and regulations, medical translation quality level still varies from project to project (cf. Andriesen 2008). Garcia-Castillo and Fetters (2007: 75) reviewed factors affecting the quality of medical translation, covering both practical aspects of medical translation and external factors which influence the process. The former include translation qualifications, checking target texts for various errors (linguistic, content-related, etc.) including mistranslations, but also the costs of these checks and the question of who is or should be financially responsible for ensuring the quality of medical translation in healthcare institutions (Garcia-Castillo and Fetters 2007: 79; Wolz 2015: 248–250). The external factors include socio-economic considerations such as discrimination or health disparities, and problems related to the patient, such as confidentiality (Garcia-Castillo and Fetters 2007: 78). Although Garcia-Castillo and Fetters (2007) mention the cost of translations amongst the practical aspects of medical translation, budget limitations may be considered an extrinsic factor as they affect the choice of the translator, the selection of quality assurance measures, and may even result in the elimination of the review stage. Extrinsic factors affecting medical translation quality also include legal issues (Garcia-Castillo and Fetters 2007: 79–100), especially the extent to which medical translation and interpreting are mandatory in particular settings or contexts. The failure to provide quality translation or interpreting may mean acting against human rights (when language barriers do not allow access to medical care), or against the Helsinki Declaration which stipulates the ethical principles for medical research involving human subjects (such as when a participant in a clinical trial is not informed about the experiment due to language barriers).

A critical factor determining the quality of medical translation is the competence of the medical translator (O’Neil 1998; Txabarriaga 2008; Garcia-Castillo and Fetters 2007). One reason why this factor is so important is that translators may be – and quite often are – the sole persons responsible for the quality of the translated material in those cases when their work is not proofread or edited (O’Neil 1998). What is more, a target text produced by a more competent translator is more likely to become a high-quality end product after editing than a poorly translated text with editing and other quality assurance procedures in place (cf. Andriesen 2008). Despite the general agreement that medical translator competence is significant in translation quality, specifying a method of testing a medical translator’s language skills and other translation competences is yet to be determined in translation research (Garcia-Castillo and Fetters 2007: 77). Moreover, ad hoc interpreters or translators, such as family members or hospital staff, who are not properly trained are sometimes employed to facilitate communication in healthcare settings (Garcia-Castillo and Fetters 2007: 77), which potentially increases the risk of mistranslations and, consequently, the possibility of clinically relevant errors.

IMIA lists the following parameters as ‘The Profile of a Competent Translator’ (Txabarriaga 2008: 3):

- A native or near-native level of language proficiency in the source and target languages
- Deep cultural knowledge of the source and target languages
- Formal education in the source and target languages at least at college level (ideally including courses in translation theory and practice)
- Analytical capabilities
- Writing skills
- Expert knowledge of the subject matter terminology
• Full understanding of the source text
• Competent use of specialised dictionaries
• Preparedness to conduct terminology research to validate equivalents in the target language

Furthermore, Txabarriaga (2005, qtd in Txabarriaga 2008: 3) emphasises the following indicators of medical translation proficiency:

knowledge of the subject matter, knowledge of relevant terminology, the ability to discern meaning in context and transfer it within the target language constraints, i.e., accurately (all meaning has been transferred), precisely (all nuances of the language, tone, intent, style have been preserved in the target language), correctly (grammar, syntax, orthography rules have been observed), completely (no part of the original was omitted and nothing has been added to the target text), and consistently (specific terms, stylistic elements and language-specific norms have been used consistently throughou).

An even wider range of competences deemed conducive to producing high-quality translation can be found in the model developed by PACTE (Procés d’Adquisició de la Competència Traductora i Avaluació, PACTE 2003, 2005, 2008), which proposes a range of various sub-competencies. Table 5.1 presents the definitions and examples of

Table 5.1 Medical translator sub-competences based on the PACTE model of translator sub-competences (Karwacka 2018; cf. PACTE 2003, 2005, 2008)¹

<table>
<thead>
<tr>
<th>Sub-competence (PACTE model)</th>
<th>Description (PACTE model)</th>
<th>Medical translation sub-competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilingual sub-competence</td>
<td>Procedural knowledge required for communication in two languages</td>
<td>Specialised medical language in source and target languages, including terminology and acronyms; lay and professional terms; registers; controlled terminologies and classification</td>
</tr>
<tr>
<td>Extra-linguistic sub-competence</td>
<td>Declarative knowledge; general knowledge, domain-specific knowledge, bicultural competence, etc.</td>
<td>Background medical knowledge, bicultural competence: culture-specific concepts</td>
</tr>
<tr>
<td>Knowledge about translation</td>
<td>Declarative knowledge of translation function and aspects of the profession</td>
<td>Standards, conventions and procedures relevant to medical translation</td>
</tr>
<tr>
<td>Instrumental sub-competence</td>
<td>Procedural sub-competence; use of resources, information and communication technologies</td>
<td>Use of medical databases, repositories of texts, dictionaries, CAT tools, etc.</td>
</tr>
<tr>
<td>Strategic sub-competence</td>
<td>Procedural sub-competence; ability to identify translation problems and apply procedures to solve them</td>
<td>Ability to apply medical translation procedures appropriately</td>
</tr>
<tr>
<td>Psychophysiological components</td>
<td>Memory, perception, attention, intellectual curiosity, perseverance, rigour, creativity, logical reasoning, analysis and synthesis, etc.</td>
<td>Decision-making, thoroughness, honesty, punctuality, etc.</td>
</tr>
</tbody>
</table>
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each of those sub-competences alongside examples pertaining specifically to medical translation.

These skills address the critical factors affecting the quality of medical translation and allowing for the production of conceptually equivalent texts in which information and culture-specific elements are handled in compliance with target conventions. The competence model also includes sub-competences which are necessary in larger translation projects. For example, CAT tools can positively impact the end product quality, as the use of a termbase ensures a consistent use of terminology throughout a project. Some of the psychophysiological components are not specific only to medical translation, but they remain a crucial aspect of medical translator competence.

Nisbeth Jensen (2012) maps medical translation sub-competences on the PACTE model and compares the competence of translators who are also medical professionals with the set of sub-competences ideally possessed by professional translators. Her study indicates that although medical professionals are more likely to have sufficient background knowledge to perform medical translation tasks, they might not have the other sub-competences crucial in medical translation, such as knowledge about translation or some of the instrumental or strategic sub-competences. Consequently, neither medical nor linguistic certification seems to reliably ensure medical translation competence, which is why interviews, questionnaires and sample translation tests provide more adequate information on the competence profile of a translator.

Various analyses of source and target texts show that certain areas pose particular problems in medical translations. They include the incorrect use of specialised medical language and terminology, problems in managing polysemy, inadequate use of evidence-based medicine (EBM) language, inadequately managed implied information in medical texts (Karwacka 2013, 2016), insufficient readability (Karwacka 2016, Kościalkowska-Okońska 2018), and discourse-related problems (Walkiewicz 2018). For these reasons, it is important to ensure that translation quality assurance begins at the pre-translation stage, based on contribution from clients, translators, proofreaders, project managers and other invested parties, but that it also includes a well-planned translation and editing stage, and that this continues until feedback from clients is collected, translators informed and translation memories updated.

3 Medical translation and accessibility

Accessibility in healthcare can be understood as an unobstructed possibility of using a service or to reach a provider or an institution when necessary, in a manner which is adequate to the needs of an individual patient or the whole community (Levesque, Harris and Russell 2013: 1). Accessibility involves approachability (‘people facing health needs can actually identify that some form of services exists, can be reached, and have an impact on the health of the individual’, Levesque, Harris and Russell 2013: 5), acceptability (‘cultural and social factors determining the possibility for people to accept the aspects of the service’, Levesque, Harris and Russell 2013: 5), availability, accommodation, affordability, and appropriateness (‘the fit between services and clients’ need, its timeliness, the amount of care spent in assessing health problems and determining the correct treatment and the technical and interpersonal quality of the services provided’, Levesque, Harris, Russell 2013: 6). These correspond with specific ability dimensions: ability to perceive, ability to seek, ability to reach, ability to pay, and ability to engage (Levesque, Harris and Russell 2013: 5).
The World Health Organisation specifies accessibility as follows:

Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions:

- Non-discrimination
- Physical accessibility
- Economic accessibility (affordability)
- Information accessibility.

Information accessibility ‘includes the right to seek, receive and impart information and ideas concerning health issues’ (WHO 2002: 13). This access to information, however, ‘should not impair the right to have personal health data treated with confidentiality’ (WHO 2002: 13), which may be jeopardised e.g. when health information is transferred via _ad hoc_ interpreters, such as other patients or hospital staff. Consequently, medical translation (including interpreting) is the _sine qua non_ condition for overcoming language barriers and securing accessibility for ethnic minorities, migrants or other persons with limited language proficiency. Sign language interpreting and intralingual transcription into Braille ensure information accessibility for severely hearing-impaired or visually-impaired patients. Intralingual translation secures information accessibility for those with limited health literacy through lay-friendly, easy to read materials. Meaningful access does not only involve the availability of translation services, but also ensures that the target texts satisfy the needs of the recipients. If the postulate of affordability is to be met, translation and interpreting services in healthcare settings should be free of charge for the patients who require them, and the most efficient way of ensuring this is by introducing a reimbursement system for language services within healthcare settings (Chen, Youdelman and Brooks 2007: 366).

The right to full access to medical services results from a number of regulatory acts, including the Universal Declaration of Human Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Rights of the Child, the Framework Convention for the Protection of National Minorities and the International Covenant on Economic, Social and Cultural Rights, as well as from the European Constitution, the European Convention on Human Rights, and from other country-specific constitutions and laws (Baráth _et al._ 2007: 21–38). According to these regulatory acts, everyone should have access to relevant documents and interlingual communication with medical staff, however studies show that patients are not always sufficiently assisted. For instance, a study which investigated the availability of interpreters at 240 healthcare services in 16 European countries in 2012 revealed that 42 per cent of them provided no links to interpreting services (Kluge _et al._ 2012: 258–259). A number of researchers report insufficient linguistic accessibility or inadequate linguistic services as a barrier directly affecting the quality of medical services (see for example, Chen, Youdelman and Brooks 2007: 362–366; Brisset _et al._ 2013: 1238–1246; Wolz 2015: 248–250). That means that language barriers prevent patients from obtaining quality healthcare or even from seeking medical help and make them vulnerable, therefore proving that interpreting is an important factor in the provision of health-related services (Al-Sharifi _et al._ 2019). Such barriers also adversely affect
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provider effectiveness and satisfaction, as they prevent providers from meeting professional standards of care (Bowen 2001). Consequently, they also increase exposure to liability risks. What is more, language barriers may also affect healthcare costs through their effects on service utilisation and health outcomes. However, the potential economic advantages of employing skilled interpreters have not been assessed in detail yet, and such an evaluation would need to be country-specific as the results of estimates for one country might not be transferable to other countries (Bowen 2001). Language barriers may indirectly affect the process of healthcare provision in other ways. For example, they may lead to socio-demographic exclusion and consequently insufficient research participation of language minorities in medical studies, which in turn may cause a bias in study results which do not accurately represent the entire population, or lead to conclusions which erroneously ignore risk factors, disease prevalence or treatment response in certain ethnocultural groups (Bowen 2001). It is especially important in those cases when a minority is particularly likely to be affected by a disease but is underrepresented in a study, and raises serious doubts about the generalisability of research results.

The problems of accessibility are complex, which is why recommended approaches include a number of strategies to address their various aspects. The first step to counteract the consequences of insufficient accessibility is the identification of the issue itself (Wolz 2015: 249), which can be done for instance by means of surveys addressed to healthcare providers and patients. The strategies that are proposed as potential solutions include adequate financing mechanisms, increasing the number of properly qualified medical interpreters (Chen, Youdelman and Brooks 2007: 365–366), ensuring cultural competence training (Wolz 2015: 249), increasing medical interpreting quality by coordinating and standardising applicable practices followed by medical interpreters (Chen, Youdelman and Brooks 2007: 364–366), and raising awareness on the effects of language barriers including their medical, social and legal dimensions, both for institutional service providers and for patients.

4 Readability

Securing access to healthcare involves ensuring readability of texts addressed to patients or other lay recipients such as patients’ parents, guardians or caregivers, and thus making them user- and patient-friendly. The US Food and Drug Administration (FDA) defines readability as ‘the ease of understanding or comprehension achieved by the style of writing’ (2001: 23); they further specify that ‘reading involves both decoding and comprehension. The reader must be able to recognize (decode) the words in the medical device patient labelling as well as comprehend the meaning of the text’ (US Food and Drug Administration 2001: 23). Readability of medical information is regulated by law in a number of countries, and this section discusses regulations in the EU and the US.

In the EU, readability requirements and the related issue of accessibility are particularly delineated in the case of package leaflets and labels:

Pack design and labelling ensure that the critical information necessary for the safe use of a medicine is legible, easily accessible and that users of medicines can easily assimilate this information so that any risk of confusion and error is minimised. For non-prescription medicines the clear identification and selection of the appropriate medicine is very important, especially in cases where there is no pharmacist
intervention, therefore, pack design and labelling are considered key elements to ensure the safe use of this type of medicines.

*European Medicines Agency 2011: 3*

The European Medicines Agency’s (EMA) Working Group on the Quality Review of Documents (QRD group) has developed specific guidelines and templates in order to harmonise content presentation in summaries of product characteristics, package leaflets, pack design and labels (cf. Wolf, Fuchs and Schweim 2014: 1; European Medicines Agency n.d.; European Medicines Agency 2016). QRD’s guidelines outline the critical readability and accessibility-related aspects of the written materials for patients. These guidelines are relevant to medical translation as the labels are often translated into various (not only European) languages, and the target text needs to be clear and easily understood in order to ensure that patients understand all the important information and can use a medicine in a safe way:

A good combination of clear/comprehensive information and pack design ensures that the information considered critical for the safe and effective use of a medicine is easily accessible by the consumer or healthcare professional selecting the product, and helps differentiate medicines within the same range (e.g. umbrella brands) to minimise the risk of confusion.

*European Medicines Agency 2011: 3*

QRD recommendations include clear and cohesive presentation of key information such as the name of the active substance, route of administration, indications, dosage and contraindications, including graphically presented information (pictograms), etc. The regulatory basis for this document is Directive 2001/83/EC, which regulates the requirements relevant to package labelling and packaging information, including detailed mandatory information, logos and pictograms. Moreover, layout, font type, and other graphic considerations are regulated by the ‘Guideline on the readability of the labelling and package leaflet of medicinal products for human use’ (Revision 1, 12 January 2009), also called the ‘Readability Guideline’ and ‘Guideline on the packaging information of medicinal products for human use authorised by the Union’ (Revision 14.3, July 2015).

The ‘Readability Guideline’ (European Commission 2009) provides extensive recommendations on those aspects of drug leaflets and labels which affect readability and user-friendliness. These include design, layout, style and syntax, recommendations for preparing the materials for visually-impaired and blind patients, outline for pilot tests of leaflets, etc. The guideline is also a source of templates for labels and leaflets. Medicinal product package labels and patient leaflets in all language versions should conform to the guideline, which makes it a prominent quality-related medical translation norm for EU countries.

The linguistic requirements introduced in the guideline of the European Commission (2009), such as the use of simple vocabulary and the avoidance of long sentences and paragraphs, should be met by both the source and target texts. The guideline does not specify how long a sentence or a paragraph should be, but recommends the use of lists rather than long paragraphs, and these should consist of a maximum of 5–6 bullet points. Side effects should be listed in order of frequency, not by system or class. Sentences should be written in active rather than passive voice and reasoning should be provided for specific recommendations in the leaflet. Instead of repeating the name of the drug, the guidelines
recommend the use of ‘this medicine’ or ‘your medicine’, and all abbreviations, acronyms and medical terms should be followed by an explanation. The document also provides specific guidance on adapting the materials to the needs of blind patients: the Marburg Braille system is recommended, and the packaging should include name of the medicinal product and its strength in Braille. Pharmaceutical companies can also make other information available for the blind and visually impaired, such as leaflets which are provided to patient organisations upon request.

The guideline recommends patient consultations to ‘identify whether or not the information as presented, conveys the correct messages to those who read it. Testing itself does not improve the quality of the information but it will indicate where there are problem areas which should be rectified’ (European Commission 2009: 20). The main purpose of the test is to make sure that the materials are legible, clear and easy to use, and, consequently, ensure compliance with Directive 2001/83/EC as amended and Directive 2004/27/EC.

The guideline also specifically addresses the issue of translation which is subject to quality verification and testing:

The package leaflet should be legible, clear and easy to read in all EEA languages. As a matter of principle it is normally sufficient to undertake patient consultation in one EEA language. […] In the centralised, decentralised and mutual recognition procedure, only the English language version of the package leaflet will be agreed during the scientific assessment. The quality of translation should be the focus of a thorough review by the applicant/marketing authorisation holder once the original package leaflet has been properly tested and modified. During the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way. It is important that the outcome of the user consultation is then correctly translated into other languages.

European Commission 2009: 21–22

It is worth emphasising that only one target language version has to be verified and consulted, but the expectation remains that all target texts will be equally readable. However, as various analyses of patient leaflets show (see for example Kościalkowska-Okońska 2018), not all target texts meet this criterion.

The translated versions are expected to be accurate renditions of the original message and use natural language, but they do not specify which particular features are expected to be present in a translation, nor how to achieve this accuracy:

Strict literal translations from the original language may lead to package leaflets which contain unnatural phrases resulting in a package leaflet which is difficult for patients to understand. Therefore, different language versions of the same package leaflet should be ‘faithful’ translations allowing for regional translation flexibility, whilst maintaining the same core meaning.

European Commission 2009: 22

The linguistic features of other medical documents, such as patient brochures or discharge summaries, are not subject to specific readability regulations, although QRD decisions (European Medicines Agency 2019) also concern the wording of the Summary of Product
Characteristics (SmPC). This includes the use of abbreviations and acronyms, subscript and superscript, foreign terms, grammatical gender, measures, health information or the translation of international non-proprietary names (i.e. official standard names for drugs which are not registered brand names). The overall purpose of the QRD decisions seems to be to avoid recurring linguistic (especially stylistic) issues and to ensure consistency, but some attention is given to readability, such as that ‘[i]nformation on the disease should normally be limited to a patient-friendly description of the sections “indications” and “pharmacotherapeutic group” of the SmPC, under their respective headings’ (European Medicines Agency 2019: 5).

In the United States, readability is regulated in FDA documents such as MG (Medication Guide), PPI (Patient Package Insert) and PIFU (Patient Instructions for Use), which concern ‘outpatient Rx products with serious and significant public health concerns and based on (not in conflict with) Professional Information (PI)’ (US Food and Drug Administration). It is emphasised that adequate patient labelling contributes to preventing serious adverse events, improves patient adherence to drug application instructions, and affects the patient’s decision to use a given product (US Food and Drug Administration 2001). Prescription medication labels should be typed in at least 12-point font size, written in non-technical language and organised in question-and-answer format (US Food and Drug Administration 2001). Readability level of patient labelling should be close to the proficiency level at 6th to 8th grade of US education. The guidelines also indicate the importance of appropriate spacing or bullet points (US Food and Drug Administration n.d.).

FDA also regulates the labelling of the more complex medical devices that are aimed at direct patient use, such as insulin pumps or test kits. The regulations emphasise comprehensibility in their safe use and disposal which include explanations for any terminology or jargon and a writing style that takes the patients’ expectations into account. Recommended strategies to facilitate comprehension include repeating and summarising the most important information, organising complex information in tables, concise writing, and the use of lay words with professional terminology in parentheses, italics or otherwise highlighted to signal the appearance of specialised terms (US Food and Drug Administration 2001).

Readability and comprehensibility can be tested in pilot studies which are recommended both by EU and US authorities. The readability of EU package leaflets is verified in legibility and usability tests to ensure that information is presented in a clear, simple and comprehensible manner from the perspective of medicine users and with special focus on the main topics, i.e. indications and contraindications (Pires, Vigário and Cavaco 2015: 3). The Readability Guideline (European Commission 2009: 24) discusses the profile of test participants consisting of at least 20 subjects who are not professionally involved in healthcare and who represent the population sample that is most likely to use the medication in question (thus avoiding socio-demographic exclusion). The group should also include geriatric patients and those with limited health or language proficiency. If the test results suggest that the recipients find it difficult to identify or understand the information in the leaflet, the text needs to be amended and tested again. The threshold value for the readability test result is 90 per cent, i.e. it is assumed that the text is comprehensible if 90 per cent of answers are correct (Pires, Vigário and Cavaco 2015: 3). As mentioned above, readability tests are required for one European language version only (European Commission 2009), which means that readability of different language versions of the same text may vary.
FDA offers guidance for comprehension studies concerning non-prescription drug labelling focusing especially on ‘the major communication message with the greatest clinical consequence to the consumer’ (US Food and Drug Administration 2010: 4). The target level of comprehension is determined at the stage of study planning and it may vary depending on the ‘clinical significance of the primary communication objective’ (US Food and Drug Administration 2010: 4), which may include the understanding of indications and contraindications, dosage, warnings, drug interactions, etc. (US Food and Drug Administration 2010: 4). Secondary communication objectives, which are not obligatory, concern less critical information such as general health information (e.g. when using this product, continue a healthy diet and exercise). The questions designed to check comprehension can be closed or open-ended, but should be ‘direct, specific, and unambiguous’ (US Food and Drug Administration 2010: 8). Multiple-choice questions should not be overused, and the questions should not be biasing or leading. The purpose of these questions is to check understanding, not to test behaviour. If an incorrect answer is provided, there should be follow up questions to identify the source of the comprehension problem (US Food and Drug Administration 2010: 8).

Despite these regulations being in place, package leaflets of medicinal products, and especially sections concerning dosage or adverse drug reactions, can still be difficult to understand, particularly for low-literacy patients (Pires, Vigário and Cavaco 2015: 1–3). Furthermore, although it is commonly agreed that the readability of patient information is important, user tests or readability checks are not always performed on translated texts. Wolf, Fuchs and Schweim (2014) tested QRD template versions 8 and 7.3.1 together with a shorter model template, and concluded that QRD templates can be improved and condensed. They also suggest readability testing of the templates (not only the documents based on them) before they are used. Readability can be checked in pilot studies with comprehension questions, or with the use of readability formulas, for example, the Flesch-Kincaid formula or Simple Measure of Gobbledygook (SMOG), which are based on the length of words and sentences used in a particular text (Wang et al. 2013: 503–514).

Although there are no specific guidelines concerning the quality of texts translated for the purposes of conducting clinical trials (Andriesen 2008), there are European recommendations related to the readability of patient information and the informed consent form (ICF). This information must be presented in writing and should be ‘comprehensive, concise, clear, relevant, and understandable to a layperson’ (European Patients’ Forum 2016: 4–5). The quality and quantity of the information provided to patients are still subject to debate, and the process of obtaining informed consent is sometimes treated as a formality involving rushed box-ticking rather than a meaningful and informative presentation of risks and benefits (European Patients’ Forum 2016: 3). The US regulations state that the ‘information must be in language that is understandable to the research subject’ (US Food and Drug Administration 2018). If information is not provided in the language a participant understands, language barriers adversely affect or even hinder the informed consent process, which illustrates the interdependence of readability and accessibility.

5 Conclusions

Medical translation quality, readability and accessibility are important factors in patient safety, influence a patient’s decision to use a medicine or a service, have an impact on the quality of healthcare services, and can determine the representation of various groups in clinical trials. For these reasons, all three issues deserve interest and concern of various
stakeholders, including translation scholars, health scientists, patient organisations, ombudspersons, etc. As discussed in this chapter, research into quality, readability and accessibility is ontological, descriptive and prescriptive – authors attempt to conceptualise what those phenomena essentially are, describe the various aspects of those problems, and formulate recommendations or strategies for increased patient-centredness, which frequently indicate the need to improve quality, readability and accessibility and raise awareness about those aspects of medical translation. The problematic areas include, in particular, the gap between the needs or expectations and the reality, the friction between literal and semantically accurate translations, as well as verification procedures and pilot tests. Future research will hopefully shed light on those gaps and contribute to more patient-centred medical translation.

Note

1 The description of sub-competences was developed by PACTE (Procès d’Adquisició de la Competència Traductora i Avaluació, PACTE 2003, 2005, 2008) and the division of medical subcompetences discussed in this chapter is based on the PACTE model. The medical subcompetence division presented in Table 1 was also described and published in Polish (Karwacka 2018).

Further reading


An overview of research into medical translation quality and of approaches to the problem.


An analysis of the issue of access to healthcare from the perspective of patient-centredness.


Patient-centredness in medical translation.


Readability testing of package leaflet templates.


The influence of linguistic communication shortcomings on healthcare.

Related topics

Medical Terminology and Discourse, Machine Translation in Healthcare, Inter- and Intralingual Translation of Medical Information
References


