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Quality assurance in medical translation

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ABSTRACT

Translation and interpreting help mediate knowledge in the world of medicine or pharmaceutical research, but are rarely the focus of healthcare researchers' attention unless a mistranslation triggers severe clinical consequences, including health or life hazard, or becomes the reason for lawsuits or financial claims. It is therefore crucial to ensure sufficient standards of quality in medical translation and interpreting. This article discusses medical translation quality, translator training and qualifications, translation quality management procedures, with particular focus on back-translation and parallel translation in the light of improving the quality of translation and interpreting for the medical sector. The author presents a model for medical translation quality assurance and provides helpful tips for medical translators.

KEYWORDS

Translation, interpreting, translation errors, medical translation, quality assessment, translation review.

1. Introduction

Although translation does not occupy the most central position in the world of medicine, it certainly plays an important role in knowledge mediation: sharing medical research results, publicising new findings in the international scientific community and marketing new medicinal products and medical devices are key features of this role (cf. Andriesen 2006; Montalt-Resurrecció and Shuttleworth 2012). Apart from books, articles and presentations, translated medical texts primarily include registration documents, such as application dossiers for the registration of new medicines and medical devices, as well as instruction manuals for medical equipment and instruments, and documents for clinical trials. Medical translators who are responsible for mediating professional communication are expected to have considerable expertise in translation and in a given subject area. What is more, written materials, such as health surveys, patient consents, posters, leaflets etc. need to be made available to foreign patients whose command of a given language may be insufficient. This is frequently performed by medical translators who specialise in professional-layman communication. A separate group of facilitators is constituted by public service interpreters, who mediate communication between professionals, and also between healthcare professionals, e.g. hospital staff and patients. Therefore, medical translators and interpreters facilitate the communication process between patients and medical professionals because the failure to communicate with a patient may lead to health or life-threatening situations if a physician is unable to obtain information from a patient (cf. Heine 2003).

Medical translation plays an ancillary role in medical research and practice,

but it is also worth remembering that medicine is one of the major areas which involve translation:

Medical translation may well be the most universal and oldest form of scientific translation because of ubiquitousness of human anatomy and physiology (after all, the human body is much the same everywhere), the long, venerable and well-documented history of medicine, and the hitherto uniform character of the language of medicine, at least in the West (Fischbach 1998:1).

There is a growing tendency in healthcare communication to focus attention on the patient (Montalt 2012:13; Krystallidou 2012:74-95) and it is now generally acknowledged that there is a need for qualified medical translators and interpreters to facilitate mediation in interlingual and intercultural medical settings, resulting in a number of translators specialising in this particular area worldwide. It appears, however, that the quality of medical translation is subject to improvement, which particularly concerns translator training and qualifications, as well as verification measures applied to detect translation errors in medical texts. That is because quality becomes an issue of vital significance when a translation or interpreting error affects the quality of medical care or reliability of data gathered in the course of clinical trials.

The purpose of this paper is to discuss the importance of quality in medical translation and interpreting, to present various methods of quality assurance in medical translation, to reflect on the qualifications of medical translators and to provide suggestions regarding medical translation quality assurance.

2. Consequences of errors in medical interpreting and translation

The reason why the quality of medical translation and interpreting is so emphasised is the fact that a translation error may trigger severe clinical consequences (cf. Márquez Arroyo 2007:74). Translation errors in scientific articles and presentations may affect an author's reputation. Healthcare services may be adversely influenced, if translation (or interpretation) is misleading either for a physician or a patient, or if vital piece of medical information fails to be translated accurately and, as a result, a patient's condition may not be diagnosed or treated properly.

2.1 Errors in medical interpreting

While the main focus of this paper is on translation quality assurance, it is also worth noting the significance of accuracy in interpreter-mediated healthcare communication. Flores et al. (2003) studied interpreting errors, their frequency, categories and potential clinical consequences. Their analysis of audio recordings and transcripts of pediatric encounters in a hospital outpatient clinic shows that errors in medical interpretation are quite common. The average number of errors was 31 per session, and 63% of all errors had potential clinical consequences. Errors were divided

into the following five categories – omission, addition, substitution, editorialisation, and false fluency:

Omission: The interpreter did not interpret a word/phrase uttered by the clinician, parent, or child.

Addition: The interpreter added a word/phrase to the interpretation that was not uttered by the clinician, parent, or child.

Substitution: The interpreter substituted a word/phrase for a different word/phrase uttered by the clinician, parent, or child.

Editorialisation: The interpreter provided his or her own personal views as the interpretation of a word/phrase uttered by the clinician, parent, or child.

False Fluency: The interpreter used an incorrect word/phrase, or word/phrase that does not exist in that particular language (Flores et al. 2003: 7).

The analysis reveals that the largest number of mistakes are made by ad hoc interpreters – random mediators who are not trained in translation or medicine, e.g. children, other family members or bilingual hospital staff. What is more, in comparison to hospital interpreters, ad hoc interpreters made more mistakes which could potentially have clinical consequences, and the most frequent type of error was omission. This included omitting questions about allergies to medical products, omitting dosage instructions, frequency or duration of drug administration, omitting significant information about a patient, such as facts from medical history, symptoms or other key information concerning the patient's condition, confusing drug administration routes, advising a patient not to answer personal questions, etc. (Flores et al. 2003).

The results of the study seem to be an argument for stricter rules of selecting interpreters, who need to have appropriate skills and expertise. What is interesting, interpreting errors tend to result from lack of attention or insufficient command of language, rather than cultural differences (Felberg and Skaaden 2012), which means that they could be reduced by adequate training, peer observation and feedback sessions. Thus, their potentially dangerous clinical consequences could be avoided.

The study results also indicate that medical interpreters are expected to have adequate command of both source and target languages, and to provide very precise and neutral interpretation of the message – without omissions, additions or expressing an interpreter's personal views, which are categorised as errors by Flores et al. (2003). This approach means that frequently, total accuracy is expected of medical interpreters, with very little tolerance for any reformulations they might want to use. One of the reasons for the 'total accuracy' demand is the concern that knowledge may be distorted in intercultural communication (Montalt 2012:18). Precise rendition is what protects the translated message from being distorted. Frequently, however, demanding accuracy is simply not sufficient: an interpreter should receive adequate training and support in his or her professional development.

2.2. Errors in medical translation

An incident which exemplifies a health-threatening potential of an error in written medical translation is a series of knee replacement surgeries, described by Fakler et al. (2007). The operations involved an erroneous use of the knee prosthesis in Germany in the years 2006-2007, as a result of which 47 people were harmed. Two different types of that knee prosthesis are available – for use with or without cement. The source-language label on the package of the prosthesis included the information that the femoral component was "non-modular cemented," which was incorrectly translated as "non-cemented" or "without cement" (Fakler et al. 2007: 1). For over 12 months, medical professionals who performed or assisted in the operations were unaware of the fact that prosthesis elements had not been implanted in the correct manner. In this particular case patients suffered as a result of a very basic translation error, but it should be noted that it was the combination of human and system failure which contributed to this series of health-threatening incidents. Apparently, control mechanisms had either failed or had not existed at all (cf. Fakler et al. 2007:3). This case is merely an example which illustrates the potential clinical impact of an error in a medical translation undetected due to insufficient translation quality control.

It is not only mistranslation that may have clinical consequences. Readability is also a critical issue. Patients do not follow written treatment guidelines when they lack clarity (Nisbeth and Zethsen 2012), which can be the case in translated patient information leaflets (PILs). Failure to comply with recommended use instructions may be potentially health-threatening.

Adequate quality assurance procedures thus help eliminate errors and improve clarity of translated medical documents by ensuring the provision of qualified professionals and control measures for the detection of mistranslations, discrepancies or cohesion issues.

3. Medical translation quality

Translation quality is a complex issue because, apart from accuracy and correct language use, it involves such factors as client satisfaction and compliance with contractual requirements, and is largely determined by text type, function and expectations in the community related to translation (Gouadec 2010, EN 15038). Medical translation quality assurance involves designing efficient control methods for error detection, readability testing and commissioning adequately qualified professionals to perform medical translation. Hence, one of the critical issues seems to be what qualifications (and training) are required of professional translators of medical texts, and what steps can be taken in order to ensure adequate translation quality. There are no generally applied regulations concerning

medical translation, or translator training; there are however guidelines developed by translators' associations, including the International Medical Interpreters Association (IMIA), developed to support translators, interpreters and their clients.

3.1 Qualifications of medical translators and interpreters

Particular qualifications which should be required of medical translators and interpreters are subject to debate, and there are controversies regarding academic (medical or pharmaceutical vs. linguistic) background of medical translators (Fischbach 1998; O'Neil 1998; IMIA 2009; Nisbeth Jensen and Korning Zethsen 2012). It is indisputable, however, that handling medical translation demands specific skills.

According to IMIA, medical documents should be translated by professionals who have "a native or near-native, formal level of language proficiency, analytical capabilities, and deep cultural knowledge in the source and target languages" (2009:3), at least college level formal education in the source and target languages, preferably including translation theory and practice. Such professional medical translators should have expert knowledge of the subject matter terminology, understand the source text (thereafter ST), have proficient writing skills and adequate skills in using specialised, professional dictionaries and glossaries. Their professional expertise should also include the ability to conduct terminology research (IMIA 2009:3).

Translating medical texts, just like translating any other text, requires writing skills, while writing is not usually the key feature of medical curricula, and neither are translation strategies. Even though this is still widely debated, linguistic proficiency seems to be necessary because a target text (thereafter TT) produced by a physician with no theoretical training in medical writing may not be sufficiently reader-friendly (O'Neil 1998:73).

A medical translator's command of medical English and his or her writing skills should also involve a range of genres and registers. A translator should be able to transfer medical information for patients in a way which will foster understanding, i.e. without using unnecessary jargon, complicated syntax, or rarely used vocabulary. Translating documents which are written for medical professionals, on the other hand, requires specific terminology and discourse markers typical of similar texts produced in the target language. Therefore, a translator's linguistic competence involves general and specialised languages. Ideally, a medical translator would not be a medical professional, but an especially trained translator, i.e. a linguist who underwent appropriate training, a view which is also supported by IMIA (2009:4-5).

One reason why it would be unrealistic to expect every medical text to be

translated by a specialist medical professional is that “there will always be more medical translations than can be handled by the relatively few physicians who translate [and] medical translation will perforce be done by non-physicians” (O’Neil 1998:69). What is more, medical texts concern a range of areas of medicine and pharmacology, therefore it would be even more difficult for translation assignments to be completed successfully if only an oncologist could translate a text on cancer, or only a cardiologist could be commissioned to translate documents for cardiac patients, etc. (O’Neil 1998:75). On the other hand, the level of expertise required to understand the ST may also be so high that cooperation with a professional who specialises in this particular area may be necessary. What is beyond any dispute is the fact that a medical translator needs to have some background knowledge of medicine to make sure that a message is transferred without distortions, which is one of the critical issues in interlingual and intercultural knowledge mediation (Montalt-Resurrecció and Shuttleworth 2012).

Formal medical training is only one way of developing medical knowledge necessary for adequate translation. Some information on the background of medically knowledgeable linguists is provided by the results of a survey Marla O’Neil (1998) conducted among translators who are not physicians, but specialise in medical translation. Out of those 33 translators (“medically knowledgeable linguists”) 5 studied medicine or participated in medical courses, 7 worked in a position which was indirectly related to healthcare or medicine, 6 participated in translation courses with particular focus on medical translation, 25 had access to medical professionals, 11 were close relatives of a medical professional, 6 had a medical condition which resulted in doing background research and contact with medical professionals (the sum of the figures is higher than 33 because respondents could provide more than one answer). Significantly, most respondents admitted that their work was hardly ever proofread. What is more, even if proofreading was performed, it was not always undertaken by a medical or healthcare professional. The reality of medical translation shows that translators must assume sole responsibility for the quality and accuracy of medical translations, which seems to be one of the factors behind the often poor or substandard quality of medical translation, rather than merely the question of medical versus linguistic educational background of the translator.

In the absence of medical translation certification scheme, medical translators themselves need to decide if they are qualified enough to perform the specialised translation tasks that they are considering to take on. On the other hand, it seems that both a medical professional and a medically knowledgeable linguist can successfully translate medical texts, provided they have sufficient skills, training and experience. The ideal pattern would involve medical professionals editing texts translated by linguists and linguists editing texts translated by medical professionals, as the quality of medical translation can be assured by means of

implementing special standards or procedures for error control to support competent translators.

3.2 Verification and review in medical translation

To improve medical translation quality, a translation process can be designed. It would involve a pre-translation preparation and analysis of the ST, its actual translation and multi-step verification of the TT. The verification process should not only involve error detection, but also conventions and requirements regarding various text types and functions (cf. Mobaraki and Aminzadeh 2012), including readability and clarity in expert-lay communication.

IMIA (2009:6-11) suggest the following steps in the translation process: first the final (electronic) version of the ST is prepared – it is crucial that the ST is 'final,' as this will reduce the risk of errors or ambiguity in the TT. Poorly written or confusing passages are likely to be as poor or confusing in the target language. IMIA also suggest that medical STs should be devoid of figurative language and ambiguity. They also should be culture-neutral, except for documents addressed to specific audiences, e.g. segregated by gender or age group, or those intended for specific, for instance educational or marketing, purposes. Therefore, a pre-translation process should ideally be designed to verify that a final version of a source text is sent to the translator.

In the next step of the translation process a translator reads the text and decides if she or he is qualified to translate the text, i.e. render its meaning accurately, which is followed by the essential stage of translation (IMIA 2009: 8). The translation should be meaning for meaning rather than word for word, it should be precise, accurate, natural and correct in terms of language use: syntax, grammar, spelling, and terminology.

Finally, the TT is subject to verification: the translated document is reviewed and edited by another professional, who ideally should have more subject area expertise and be more experienced than the translator. It is then proofread, ideally by a third person. Both review and proofing should be done by means of careful comparison of the two language versions (IMIA 2009). It may be necessary to adapt the TT to local, for example legal, requirements concerning an informed consent form (ICF) and other medical documents (Fernández Piera and Ardura Ortega 2012: 291). This, however, is provided by client's own specialists rather than a translator, and it certainly should never be considered without consulting the client.

The model of a translation process with multi-step verification by two professionals ensures sufficient measures for quality assurance; however, it is not economical and can be time-consuming. This may mean that yet another condition for improving the quality of medical translation is client

education. Another crucial aspect of quality assurance is negotiating realistic deadlines and budgets. Obviously, if a text is to be translated and then verified by two professionals, the budget and deadline should be agreed with consideration to realistic time and money necessary to perform all tasks involved in the translation and editing process.

The above-mentioned multi-step verification model for medical translation is one of several solutions developed for quality assurance. A popular method of translation review is back-translation, i.e. translating the TT 'back' into the source language. It is important that back-translations should be provided by an independent translator who did not handle the original 'forward' translation of a given text.

IMIA advise against applying back-translation as a method for verification for the reason that it might not reveal "the target language contextual and usage nuances" (IMIA 2009:2) and, if the text is translated literally by the first translator, its back-translation may seem appropriate. What may also appear as an inaccurate rendition in the back-translation is frequently an adaptation made by the translator which fully conveys the meaning of the ST, but is lost in back-translation (IMIA 2009:3).

However, the blind back-translation technique is frequently used to verify the accuracy of translation (cf. Andriesen 2006, Fernández Piera and Ardura Ortega 2012), and its advantages have been subject to research (Berkanovic 1980; Andriesen 2006). Berkanovic (1980) conducted a study on the effect of language of a health survey on patients' responses. It involved an analysis of Spanish speakers' responses to the Spanish version of a survey which was a translation of an English ST in comparison with the responses given by another group of Spanish-speaking patients during the same interview, but in English. The results show that there are considerable differences between the two groups in the perceived seriousness of patient's medical condition and the perceived efficacy of care. In the group which was asked questions from the Spanish language version of the survey, those parameters were substantially lower than in the English version interviews. The back-translation revealed that the Spanish language version sounded unnatural: according to the opinion of the person who performed the back-translation, the general meaning of the survey would be understood, but they would be perceived as clumsy, if not funny. Therefore, it could be concluded that the respondents may have taken the English language interview more seriously than the Spanish language interview. Back-translations would have allowed for the identification and correction of unnatural language (Berkanovic 1980). On the other hand, it can be claimed that the double verification process suggested by the IMIA would also be a useful tool here, even without applying the blind back-translation technique.

The back-translation method is widely used in the sector of medical research and clinical trials, as it is required by Ethics Committees and

regulatory authorities in a number of countries (see Grunwald and Goldfarb 2006:2), but it should not be implied that the sole purpose of back-translation is compliance with formal requirements. If it is handled in a professional manner, it is an effective error detection tool (Andriesen 2006:15-16).

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has developed a complex review method consisting of performing two parallel forward translations, which are later compared in order to reconcile both versions, then performing two back-translations, which are also compared and reconciled. This is followed by a review and harmonisation of the translated text. As effective as the method appears in the role of an error detection measure, it is both costly and time-consuming (Andriesen 2006:15-16).

One step of the verification model applied by ISPOR — i.e. parallel translations — also constitutes a separate review method. Two professionals translate the ST simultaneously and a third person (or one of the translators) compares the two versions and makes all the necessary adjustments. As a result, the final TT is a compilation of the best parts of the two parallel translations. This method also generates additional costs, but: “in this case the additional cost has a much more direct and positive effect on the quality of the final document than is the case with a back-translation” (Andriesen 2006:16).

Yet another quality management system is used by FACIT, an organisation which manages the preparation, distribution and interpretation of questionnaires which measure health-related quality of life of patients with chronic illnesses. FACIT adopt a complex, multi-step procedure which involves two independent 'forward' (initial) translations, reconciliation of the translations, back-translation, independent reviews performed by 3-4 experts, formatting, proofreading and pilot testing with patients. The process involves a number of linguists and medical specialists, and it favours quality over deadlines and budget restrictions.

The procedures described above, which help ensure sufficient quality of translation and avoid errors which may cause clinical consequences, are not always implemented. In fact, translators admit that their work is rarely or never verified (cf. O’Neil 1998:72), which means that they assume sole responsibility for the quality of their translation. It is worth noting that IMIA Guidelines (2009) imply that the translators themselves are also responsible for assessing whether their level of competence is sufficient for a particular translation task. There are certain steps translators can take in order to maintain a satisfactory level of medical translation. It should not be forgotten that the first step in translation verification is the ‘final eye,’ i.e. the translator’s own editing just before the text is deemed ready and sent to undergo subsequent steps of quality assurance process. It requires the capacity for a critical attitude towards a

translator's own work. Taking into consideration medical translation quality problems discussed in this paper and presented in other works (e.g. Berkanovic 1980; Andriesen 2006; Fakler et al. 2007; Márquez 2007) it seems that several recommendations can be made to translators to help them avoid potential errors. These tips are listed below.

Recommendations to medical translators:

- be doubtful of what you can find in glossaries and online resources, and double-check terminology;
- check your text for consistency in terminology;
- carefully compare your text with the source to make sure that the translation is precise;
- make sure your text is translated sense for sense, not word for word; in particular, make sure you treat multi-word terms as single and non-dividable translation units, literal translation of such terms may make the TT incomprehensible;
- avoid ambiguous or unnecessarily figurative language;
- double-check figures, symbols such as < and >, as they may carry significant medical information, e.g. when they relate to blood pressure or vein stenosis values;
- make sure that the TT meets the client's and reader's needs.

Certain more general steps can also be taken by a translator before a translation is commissioned. They are presented below in the form of a set of recommendations.

General recommendations:

- before you start working on a text, make sure that you are sufficiently competent to translate it;
- negotiate realistic deadlines and budget;
- be willing to cooperate with the clients and consult them for background information or anything that is unclear in the ST, as this may potentially add to overall quality;
- do not avoid having your work verified — it is always better to have your translation checked, because it can minimise the risk of health-threatening incidents related to translation errors; if possible — find a partner for mutual verification.

These are common sense steps which may seem similar to the guidelines issued by various translation agencies, recommendations for translation trainees or advice found online, on translator community websites. Although these tips do not guarantee perfect readability or total accuracy, they certainly can be treated as a very helpful checklist, especially for medical translators who are starting in the profession. It should be stressed, however, that a single translator's work should only be one step of the whole medical translation process.

3.3 A model for medical translation quality assurance

Based on the presented requirements for medical translation quality and existing QA procedures, a model can be suggested which may help translators, project managers, as well as healthcare professionals seeking translation services (see Figure 1 below).

The view that crucial quality factors must be secured before the actual translation action commences is sustained in this article. At the pre-translation stage the target readers of the text and/or its purpose need to be established and communicated to the PM (project manager) and the translator and proofreaders. A team of professional linguists, not a single translator, should be responsible for overall quality of translated texts. The team should comprise a translator and one or, preferably, two proofreaders. Their qualifications should include considerable experience in medical translation and proven expertise as well as proven skills – based on translation samples. The author of this article does not support the view that only medical professionals or only linguists can perform medical translation tasks. The skills required in this particular field, i.e. interlingual transfer skills, intercultural communication skills, general linguistic skills, including writing skills and familiarity with medical genres, command of medical language, medical knowledge, IT skills can be acquired along a number of career paths, thus the selection of an adequately skilled professional should rather be based on translation samples and testimonials. Budget and timelines are two critical quality factors: enough time and money should be secured in order to allow for a *team* to work on a translation task. Rush or overnight jobs may potentially compromise quality, especially if they involve splitting a text to meet deadlines. In larger projects, which require splitting, a reconciliator should be involved to avoid inconsistencies which, consequently, needs to be reflected in the time/budget framework. As mentioned earlier, a certain degree of client education is necessary, because clients do not necessarily know how long it takes to translate a text nor how critical proofreading or source quality, which is also an argument for adopting a transparency policy in client communication.

The translation process itself should aim at meeting readers' needs and client's requirements. Medical translation undoubtedly requires utmost precision, because it may potentially influence patients' and medical professionals' decisions, thus affecting healthcare services, clinical studies, etc. The target language needs to be natural, correct and suitable for the purpose of the text and its genre.

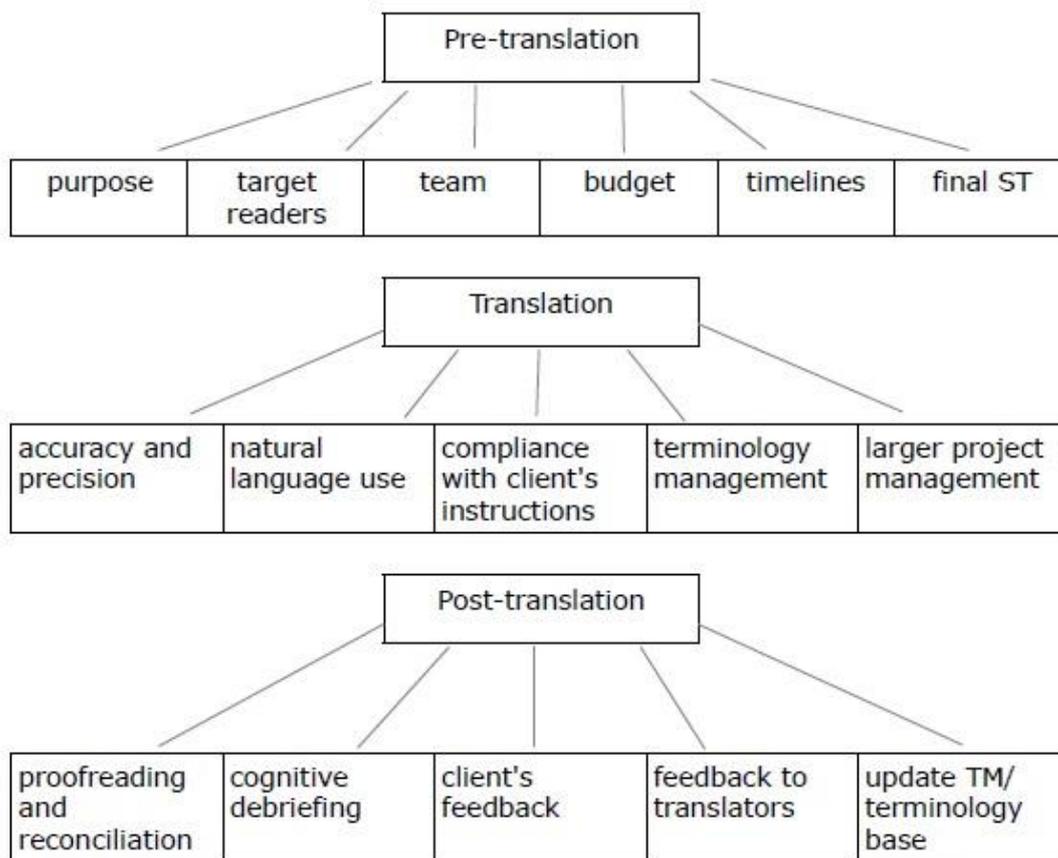


Figure 1. A model for medical translation quality assurance.

After the TT is produced by a translator, it should be proofread for its compliance with the purpose, readers' needs, client's instructions, accuracy, information transfer and linguistic quality. A proofreader's suggested revisions and reasons for them should always be consulted with the translator. Texts for patients (or other layman readers of medical texts) should undergo cognitive debriefing, which tests whether the concepts of ST are transferred into TT and whether they are understandable and/or can be understood in the same way. The process should be concluded with feedback provided to translators and proofreaders in order to secure improvement in medical translation quality. Translation memory and terminology bases should be updated to provide accurate and consistent support in subsequent projects.

The model presented above, which covers the whole medical translation process, is based upon the assumption that translation involves mutual support from clients, translators, proofreaders and project managers. It comprises three stages of translation with their critical areas, which need to be secured in order to meet adequate medical translation quality requirements.

4. Conclusions

In order to facilitate communication with foreign or immigrant patients with limited language proficiency, and provide translated versions of medical documents (regulatory documents, scientific papers, patient forms), professional medical translators need to be employed. The fact that errors in medical translation are rather common implies that there is still room for improvement as far as both verification process and translator qualifications are concerned. Qualified professionals (not ad-hoc interpreters or translators) should be employed to produce medical translation and interpretation. Whether to employ medically knowledgeable linguists or linguistically knowledgeable medical professionals is still a controversial issue, but it seems that the most reasonable solution would be to design a translation and verification system in which texts would be translated by an experienced translator who specialises in the medical field and then verified by an expert, to finally undergo proofreading by a third person. Such a process would change the present situation in which the translator is often the only responsible person in the translation process, rather than a translation team member. The model for quality assurance presented in this paper offers one way of organising a medical translation project. It is designed to promote better standards of quality in medical translation.

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Biography

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