Gained in translation

Science at the multilingual crossroads

Einem Text in einer fremden Sprache Gehör verschaffen, wird oft genug einen neuen Text eher als eine Übersetzung im landläufigen Sinne verlangen.

Jürgen Habermas (*1929)

According to Habermas, making a text heard in a foreign language will often require a new text rather than a translation in the ordinary sense [1]. Among translation theorists, there has been debate about when a text is still a translation and when it is the result of a different textual operation. While this question may be of academic interest, it has little merit for modern translation practice—where translation comes in many shapes and forms and covers a wide range of diverse activities, including adapting or rewriting a text in the target language to reach a specific audience.

How the translator goes about transposing a text will depend on which purpose the text is to fulfil in the target culture. Should the translation be recognised as such (something which has been referred to as 'overt' translation [2]), or should the translation not read like one, effacing any differences between the source and target cultures (analogously referred to as 'covert' translation [2])? This will either be explicitly specified by the client—or it will be implicit from the type of text to be translated.

The feature article in this issue's translation section is a good example of a text calling for a 'covert' translation, one which is specifically tailored to the target reader's situation. The article shows translation to be a complex of decisions rather than mere linguistic recoding. Language is not the goal of translation, it is only a necessary instrument. Language competence, such as knowledge of grammar, correct usage, and appropriate terminology, is important, but it is not what translation is about.

The purpose of an informed consent document (ICD) is to enable potential study participants to make an informed decision about whether or not to participate. To achieve this, the text will have to be adapted to whatever it is a German, Spanish, Dutch, or Polish patient should know about studies performed in their specific countries, which may differ substantially in their cultural and social backgrounds, legal requirements, health care systems, infrastructures, beliefs, religions, and value systems.

The English-language ICD, therefore, basically serves as raw material for the translation. We read that the target-culture recipient has to be addressed differently than his source-language counterpart, units of measurement have to be converted and country-specific legal provisions added. Icons, images, or even entire graphical layouts may have to be adapted to the conventions prevailing in the target culture to facilitate understanding.

Consisting of a series of decisions to be taken, then, translation ideally includes all parties involved in either producing or receiving a text, e.g., the author (or the party commissioning the translation), the translator, and the reader. The translation process will be most successful if based on teamwork—the magic behind many a successful project. In this, translation is no exception.

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METM—An abbreviation translators should know

Mediterranean Editors and Translators, or MET for short, is an association of language service providers (LSPs) who work mainly into or with English. So far, there have been 5 MET meetings, or METMs: METM05 and METM06 in Barcelona, METM07 in Madrid, METM08 in Split, and METM09 in Barcelona. In addition to plenary and poster sessions, METMs offer a wide range of workshops relevant to LSPs. Although not specifically directed to medical language professionals, many of the MET workshops do have a medical spin.

Last year's METM was entitled *Translation, Editing, Writing: Broadening the Scope and Setting Limits*, reflecting the wide variety of services provided by language experts. In this, as the conference title aptly suggested, we are constantly challenged to not only expand our thinking, knowledge, and skills but also to define our personal limits. A number of reports on METM09 have been published, each providing a personal, insightful, and entertaining account of the meeting and giving it broad coverage [1-4].

METM10 in Tarragona, Spain

METM10, which will take place from **28–30 October 2010** in Tarragona, Spain, bears the title *Facilitating knowledge transfer—through editing, translation, coaching*, with workshops covering topics as diverse as practical statistics (regression and multivariate analyses), editing and revising, correct referencing, plagiarism, effective paragraphing, or genre analysis of research articles.

MET—a knowledge-sharing and peer-teaching network. METM—an abbreviation to remember.

For more information, go to http://www.metmeetings.org.

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Generating informed consent documents for multinational clinical trials in Germany: Where medical writing and translation meet

by Susanne Geercken

Have you ever been sick and yet had to make a difficult and far-reaching decision?

This is the situation patients[1] find themselves in when they consider taking part in a clinical trial. It is a sign of respect to the patients, then, to dedicate special effort to writing patient-friendly informed consent documents (ICDs) for clinical trials. The following article gives an example of the steps involved in achieving this goal.

Stakeholders

Of course, first and foremost, ICDs are targeted at patients. Apart from this, however, we need to look at two further stakeholders, namely investigators and ethics committees.

Patients

As mentioned above, patients who consider clinical trial participation will typically be sick (unless they are healthy volunteers in early development studies), a situation associated with increased vulnerability. Particularly patients with chronic diseases may have gone through an ordeal of previous, potentially unsuccessful, treatment attempts. Whether or not to participate in a trial will mean yet another difficult health-related decision with uncertain outcome [Box 1].

Interestingly, the questions that are on patients' minds when they consider their choices go far beyond the purely medical:

- How long will the study take and how often will I have to come to the study site? Will there be any unplanned visits that may be difficult to fit into my daily routine?
- Will I have to travel far to get to the study site? Do I need to find somebody to take me there?
- Does it involve any overnight stays in the hospital, so that I need a babysitter for the kids?[2]
- What kinds of treatments, examinations and tests will have to be carried out? Compared to the standard treatment, will the treatments be more painful or more time-consuming?[3]
- What will be the patient's responsibilities in the study? What will the treatment cost and will all the costs be covered? ... Will travel expenses be reimbursed?[3]

Apart from this, the medical details will have to be considered. To tackle the difficult task of weighing the potential benefits of a study against its risks, the patients need to be told about study procedures, treatment plans, side effects and the treatment options outside the study in a clear, concise and readily understandable way.

Box 1—ICD Working Group

Based on a growing awareness that patient informed consent documents (ICDs) can be a key factor in helping patients understand clinical trials and make an educated decision about participating, Pfizer Germany in 2008 set up an interdisciplinary working group for developing more patient-friendly ICDs. The working group consisted of clinical research, medical and patient relations experts from Pfizer Germany and representatives from local patient advocacy groups across several indications. The project proved to be a highly instructive experience for everybody involved: the patient representatives took home a better understanding of the tightly woven legal and regulatory framework around clinical trials while we at Pfizer learned about the practical and very personal implications of deciding about clinical trial participation. The group started out by putting together a 'patients' wish list' of desirable improvements in ICDs, revealing a need for better text organisation and design and simplified language. For the remainder of the four sessions, the group sat down for collaborative, hands-on editing of existing text material: sentences were shortened, abstract language reworded, complex issues explained in simple, accessible language, redundant information deleted and information missing from the patient's perspective added. The effort resulted in a patient-friendly core template for future use across studies conducted in Germany. In response to suggestions from the group, the new ICD format also includes a one-page summary-cum-table of contents and uses icons and coloured boxes for easy navigation. The collaborative editing experience also resulted in a set of rules for ICD authors to help them design patient-friendly ICDs. The approach taken at the time is also confirmed in a recent article by Jan Geißler, who reports similar experiences and conclusions in regard to informed consent from the perspective of patients [1].

1 My article will focus on ICDs for Phase II-IV treatment studies (excluding vaccines). I will therefore use the term 'patient' rather than 'participant' throughout this document.

2 The above list of questions emerged from the collaborative working group to improve informed consent documents Pfizer set up with patient representatives in 2008 [see Box 1].

3 These items are taken from a list of patient concerns in an article by Jan Geißler [1], page 5

Generating informed consent documents for multinational clinical trials in Germany

Investigators

It is never an easy task to recruit suitable patients into clinical studies. In Germany, apart from other impediments to recruitment, many people are mistrustful of the pharmaceutical industry and clinical trials[4]. The investigator will therefore have to make extra efforts during the informed consent discussion to address these concerns. The ICD can be a tool to help the investigator reach out to potential trial participants, especially if it is:

- Designed to help get patients interested in the trial
- Comprehensive yet clearly organised to support the investigator in structuring the informed consent discussion

Ethics committees

As part of their role in protecting patient rights, ethics committees will carefully review the study ICDs submitted for compliance with legal requirements. In Germany, they will have a particularly keen eye on whether patients have been adequately informed of their rights with regard to data protection and mandatory patient insurance. Other items high on the ethics committees' priority list are that the ICD be as short as possible and that all medical terms be explained in lay language.

Stakeholders' wish list

From these stakeholder interests, the following core requirements for ICD documents can be deduced:

- Carefully structured, affording quick overview
- As comprehensive as necessary, but as short as possible
- Easy to understand, using adequately simple language
- Providing practical information relevant for the patients' daily routine
- Containing all information on legal rights

How do we go about satisfying this wish list? Typically, in international pharmaceutical companies like Pfizer, multinational clinical trial programmes are planned and developed centrally at global R&D or Clinical Research units for deployment in different countries worldwide. This involves the generation of one set of clinical trial documents, generally in English. These core documents, including a study-specific ICD core template, will be sent out for use in all of the countries participating in the clinical trial. The core template contains all the necessary study-specific information that should go out to the patients. However, to ensure that the stakeholders' needs outlined above will be catered to in this setting, the English core ICD template will need to undergo some further processing, which involves three steps: translation into German, localisation and customisation.

Translating the ICD

Typically, ICDs are not highly technical texts. They are therefore considered to be relatively easy to translate. Yet, a number of challenges are involved in translating ICDs from English into German.

4 Jan Geißler [1], page 6.

Box 2—Assent forms

Assent forms are documents to provide information on a clinical trial to under-age patients. The language and contents of the document has to be written to be readily understood by the age group addressed. Since under-age patients cannot give legally binding consent, Assent forms cannot stand alone, they always need to be accompanied by a full consent form to be read and signed by the parents or legal representatives.

Language-related challenges

Unlike English, German has two forms of address—the polite, formal 'Sie' and the casual, non-formal 'Du'. This does not constitute a problem when translating ICDs for adult patients, where the formal address 'Sie' will be used by default. However, decision-making is necessary when translating what are called *Assent forms* targeting under-age patients between the ages of about 14 and 17 years (as pointed out by Marion Alzer, personal communication) [Box 2]. In Germany, young people typically start being addressed using the formal 'Sie' from the age of 16 onwards. Using the formal address with adolescents younger than 16 tends to make them feel uncomfortable, creating an unwanted language barrier. One way of solving this problem is to use the informal 'Du' in the document and add a comment for the 16-17 year olds, explaining why this choice was made.

The fact that English uses gender-neutral forms for terms like 'patient' while German does not, can make for another translation challenge in ICDs: When the English-language ICD for a trial on breast cancer speaks about 'patients with breast cancer', the reader will not know whether this refers to female patients only or to both male and female patients; the term covers both options. In fact, some breast cancer trials are done only in women, some will include both men and women. Since German does not have a gender-neutral term for 'patient', to pick an adequate translation the translator will have to find out whether the trial involves just women or both men and women: if the study is done in female patients only, the correct term would be 'Patientinnen mit Brustkrebs' [female patients with breast cancer]. If the study includes both men and women, the translation would be 'Patientinnen und Patienten mit Brustkrebs' [male and female patients with breast cancer]. This means that *implicit* information in the English text will have to be made *explicit* in the German text.[5]

5 Even though the politically correct way in German would be to use both the female and the male form (Patientinnen und Patienten, as suggested in the text) in studies involving men and women, in practice, this approach is not very reader-friendly and is therefore often abandoned. For convenience sake, the male form is understood to include the female form. It is therefore quite acceptable in German to use the *male* form only ('Patienten') in studies that *involve both men and women*. It would *NOT* be acceptable, however, to use the *female form only* ('Patientinnen') in studies that also include male patients (such as breast cancer studies in men and women). Discussion about this convention, of course, is ongoing from a gender-equality point of view.

While in English, medical terms such as pneumonia, appendicitis or colon cancer are readily understood by lay people, in German, the equivalent Latin- or Greek-based medical terms (Pneumonie, Appendizitis, Kolonkarzinom) are reserved for communication between medical professionals. These 'hard words' are considered 'doctors' speak' and typically form a language barrier between the 'educated' doctor and the 'uneducated' patient. Most (but not all) of these Latin- or Greek-based medical terms also have a German-based equivalent (Lungenentzündung, Blinddarmentzündung, Darmkrebs), which should be used for German ICD translation [Box 3].

Culture-related challenges

Most culture-related challenges in ICD translation will come up due to differences in the health care systems in the source (English) and target (German) cultures. Examples include:

- Concomitant medications: Drugs mentioned in the source text are not available or come in different strengths, formulations or drug combinations in Germany.
- Different roles of institutions, such as ethics committees: Because ethics committees in Germany cannot decide on the participation of study participants at individual study sites, the sentence in the original "study enrolment of patients with XYZ disease is at the discretion of the sponsor and Institutional Review Boards/ Ethics Committees at participating study sites" needs to be culturally adapted.
- Terms such as 'assisted living facility' or 'respite care'. These concepts may be difficult to translate because they are not institutionalised in the same way in the target culture.
- Different roles and functions of health care professions: For example, there is no equivalent in Germany for 'nurse practitioner' or 'physician assistant'. Also, the role of the psychiatrist is different in Germany from for example in the US.
- Another translation challenge can come up with units: An LDL level of 3.35 mmol/L does not convey any meaningful information to a German patient unless the expression is converted to the culturally adequate German equivalent of 130 mg/dl. The expression 'a quarter-sized red patch of skin' (i.e. a patch of skin the size of a US 25-cent coin) finds its culturally suitable German translation in the idiomatic and equally graphic term 'Zweimarkstück-großer Fleck' (a skin patch the size of a 2 deutschmark coin).[6]

Box 3—Medical terminology and target audience

In this article, we have defined the target audience of ICDs to be 'patients', who are assumed to be 'lay people'. However, the seemingly homogenous target audience 'patients' can be very diverse. Let's look at two different settings with regard to the 'target audience':

Patients with an acute, life-threatening infection. These patients will neither have the time nor the opportunity to educate themselves about their disease. They are likely to have been rushed to the hospital with no access to the internet or other sources of information. This means that their state of knowledge about clinical trials as such and about their condition is limited: These patients are unlikely to be familiar with the medical terminology associated with their disease. In terms of ICD language, this means that extra care is needed to explain the disease-specific technical terms and procedures in lay language.

Patients with a chronic disease. Let's imagine patients with a chronic disease such as metastatic cancer on the other hand. Most likely, they were diagnosed years ago. If their cancer stage is advanced, they will typically have gone through a series of therapies and medical procedures before. In the process of trying to cope with their disease, they will perhaps have turned to the internet, joined patient advocacy groups and read medical articles and books. So, these patients can be expected to have gained detailed, specific medical knowledge about their disease and the treatments available. In this setting, the use of disease-specific technical terms will be much more acceptable and even appropriate.

When the translator encounters these culture-related translation challenges, he or she will often have to consult the sponsor. Together, the translator—who is the expert on the cultural issues at hand— and the sponsor—the expert on the study specifics—will have to find appropriate solutions for the necessary cultural adaptation in the target text.

With all translation challenges resolved, the German translation is now ready to go through the next phase of the ICD production process—localisation.

Localising the ICD

The next step in the ICD generation process is what I call 'localisation', a term that originated in the computer industry. What do I mean by 'localisation' in the context of an ICD? Today, the requirements for adequately informing prospective clinical trial participants are firmly enshrined in international laws and regulations, including the World Medical Association Declaration of Helsinki, the ICH Guideline for Good Clinical Practice and European Directive 2001/20/EC. In addition, industry standards such as standard operating procedures (SOPs) and policies are in place to ensure implementation of these legal provisions and to safeguard patient rights. All of these legal and

6 Interestingly, the term 'Zweimarkstück-groß', being an idiomatic expression, still refers to the old currency deutschmark; a similar idiomatic expression using 'Euro' does not exist.

>

> ethical aspects are fully covered in the core ICD template prepared by Pfizer's global Clinical Research Unit.

ICDs used in Germany additionally will need to satisfy the regulatory requirements laid down in the specific German laws and regulations such as the German Medicines Act, the German GCP Ordinance, the German Data Protection Act, and the German Infection Protection Act. Appropriate incorporation of these local legal aspects into the ICD has to be ensured during localisation.

Pursuant to the German Medicines Act, mandatory subject liability insurance has to be taken out by the sponsor of any clinical trial conducted in Germany. The law is very specific about the scope and nature of this insurance. Information about the insurance must be communicated to the patient in the ICD. The German Medicines Act also requires that "trial participants shall be informed of the purpose and scope of the recording and use of personal data, especially medical data". To satisfy this requirement, the law's relevant sections on the use of personal data (together with additional requirements laid down in the German Data Protection Act) are incorporated into the German consent form.

Very conveniently, recommended standard language for these legal aspects is available from the *Working Party of the German Ethics Committees*, a joint committee of ethics committee representatives. Wherever possible, this recommended wording from the ethics committees is used in our ICDs, not least because doing so is likely to ease the ethics committee review process and shorten application turnaround times.

Other German legal requirements affecting the generation of ICDs include those laid down in the Infection Protection Act, which requires certain infectious diseases or detected pathogens to be notified to the competent health authorities, among them HIV (anonymous notification) and hepatitis (notification by name). In studies where such notification is likely to arise, e.g. when the protocol includes testing for the relevant pathogens, the patient will have to be informed accordingly.

Customising the ICD

With the localisation step completed, we can move on to what I call the 'customisation' step. This is the final step in the ICD generation process. Its aim is to ensure that all the requirements on the ICD wish list outlined at the beginning of this article are satisfied. Thus, to ensure a clear structure, every ICD contains an upfront table of contents which includes a short summary of each ICD section. This helps patients navigate through the document and quickly find the decision-making criterion that is most important from *their* point of view. For a better overview, we make ample use of bulleted lists. We use coloured boxes and icons to highlight important information. The document will be carefully edited for shortness, stripping it of any duplicate information and summarising details where this is adequate and possible.

In addition to using lay terms for any medical information, the whole document is screened for other technical terms that need to be explained or 'translated' into lay language. Such terms include 'study site', 'investigator', 'adverse events', 'Phase II', 'randomisation', 'double-blind', etc. Next, extra information will be added, e.g. about the approximate length of the study visits, hospital overnight stays and payment of travel expenses to address the patients' need for practical detail. Sometimes only minor changes are needed to improve clarity: while a study period of 77 weeks seems somewhat confusing, 1 ½ years is a duration any patient can relate to. Similarly, patients are likely to be at a loss (and reminded of those dreadful math lessons back in childhood) when they are asked to drink "2000 ml of liquid before the test"; asking patients to drink "2 litres of liquid", however, will be readily understood and easily followed.

After a thorough internal review and approval process, involving two colleagues independently checking the document for completeness, consistency, and clarity and for compliance with the protocol, relevant regulatory provisions and internal SOPs, the ICD is ready to go out to the ethics committee and, eventually, to the patient.

Summary

As a translator and medical writer, I deal with a great variety of fascinating texts, ranging from highly technical documents, such as autopsy reports, to glossy marketing brochures. Given a choice, my favourite is to write patient informed consent documents for clinical trials. Why? During our collaborative effort with patient representatives it became clear that a well-structured and comprehensible informed consent text truly supports patients in making a decision about their treatment options. So, if I use my best skills both as a translator *and* a writer—in-depth knowledge about language, culture and translation techniques, creativity and experience in text organisation— combined with my know-how about the clinical trials process, and put it into generating a patient-friendly ICD I can really make a difference in somebody's life. Isn't this a great reward for making 'just this extra bit of an effort'?

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Translation resources

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***exemplar* screenshot: words and phrases in context**