Translation of patient information leaflets: Trained translators and pharmacists-cum-translators – a comparison

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Numerous studies have shown that Patient Information Leaflets (PILs) are generally difficult to understand for ordinary people and that this may be one of the reasons why a high percentage of patients fail to take their medication correctly. A study by Askehave and Zethsen (2002), based on textual analysis and relying on comprehensive extratextual procedural knowledge, has shown that translated Danish PILs were, without exception, more complex than their STs. But why is this so? One possible explanation could be that PILs are very frequently translated by pharmacists, who do not possess the linguistic tools and translational knowledge necessary for expert-to-layman translation or interlingual translation. This article reports on an empirical study that falls into two parts. The first aims to identify possible differences in the translations of these two types of translator in terms of lay-friendliness. The second aims to describe the nature of the differences found between these two types of translator, and discusses whether they could potentially be detrimental to lay-friendliness in PILs.

1. Introduction

An extensive amount of research has been conducted into expert-lay communication and the intricacies it involves; however, what happens when expert-lay communication is translated? This is the case with Patient Information Leaflets (PILs) in the European Union (EU). A PIL is the written information included in a medicine package, which has to accompany all medication and inform patients about dosage, side effects, etc. According to EU law, PILs must be supplied by the pharmaceutical company seeking authorization to market the medicine in the EU. Original PILs are normally produced in English, the language of the authorization procedure, and must subsequently be translated into all EU languages.

Several studies have shown that PILs are difficult to understand (e.g., Askehave & Zethsen, 2000b, 2003; Clerehan & Buchbinder, 2006; Dickinson, Raynor, & Duman, 2001; Lægemiddelstyrelsen, 2004; Pander Maat & Lentz, 2010; Raynor, 2007) in direct contrast to the intention of the genre. Patients today demand to be actively involved in their own health, and the concept of patient empowerment has attracted increasing attention; however, in order for patients to be empowered, it goes without saying that

it is essential that they understand the information provided. Thus, the importance of lay-friendliness in patient information cannot be emphasized enough. A study from the UK shows that up to 50% of people on long-term medicines do not take them as prescribed (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008). Several explanations for this are given, one of them linked to the misunderstanding of prescription instructions and limited education about the medication (Haynes et al., 2008, p. 19).

In relation to lay-friendliness in PILs, research focus has almost exclusively been on the English-language PIL. However, a complication that can further challenge lay-friendliness in PILs is translation. A single study, based on textual analysis, has shown that translated PILs (English-Danish) are more complex than their source texts (STs) (Askehave & Zethsen, 2002). Askehave and Zethsen analyse the nature of the increased complexity and offer several explanations for this phenomenon, for example the fact that the PIL is a mandatory, and therefore extremely regulated, genre (Askehave & Zethsen, 2003), and also that a *skopos* conflict may exist between (a) providing correct and lay-friendly patient information and (b) ensuring a fast and smooth approval procedure (for example, by not deviating from previous terminological practice) (Askehave & Zethsen, 2002). Perhaps the most important explanation, according to Askehave and Zethsen, is the fact that many PILs are translated by pharmacists who may not have the necessary translational skills, and they venture the hypothesis that these medical translators revert to the expert register they know, even when the English PIL (the ST) is lay-friendly.

Askehave and Zethsen did not know to what extent Danish pharmaceutical companies use medical professionals for translational purposes, so in 2010, Nisbeth Jensen carried out a study in order to find out who the translators of Danish PILs were. The study shows that Danish pharmaceutical companies use either medical professionals or translators to an almost equal extent (Nisbeth Jensen, forthcoming). However, it was also shown that the companies using pharmacists as translators currently have a greater number of EU PILs, that is, the majority of Danish PILs are translated by pharmacists. To our knowledge, there has never been any empirical research on how the two types of translator do in fact translate PILs, and hence whether some of the comprehension difficulties found in connection with PILs can be linked to the choice of translator. The aim of this study is therefore to test the following hypothesis:

Subject matter experts translate differently from trained translators in cases where expert-lay communication is further complicated by interlingual translation.

At the same time, we will attempt to answer the following research questions:

If there is a difference, how is it manifested in the TTs?

Is the difference of a nature likely to be detrimental to lay-friendliness?

2. Background and legal framework

Ensuring lay-friendliness in translated PILs is a goal that relies on a complex process (see Fig. 1 below) and due to the fact that PILs are governed by legislation, limited freedom is available in pursuit of this goal. The PIL became a legal requirement in 1992 with Council Directive 92/27/EEC requiring all medication packages to be accompanied by a PIL (Council of the European Communities, 1992), which means that the PIL is a so-called mandatory (i.e., legally regulated) genre (Askehave & Zethsen, 2003). Therefore, it is governed by several regulations and standards, which influence both the structure and content of PILs, and also their translation. According to Article 59(1) of Directive 2001/83/EC, PILs must be drawn up in accordance with the Summary of Product Characteristics (European Parliament and Council, 2001). Like the PIL, the Summary of Product Characteristics is one of the documents that must be produced by the pharmaceutical companies when applying for marketing authorization with the European Medicines Agency (EMA), but this text is an expert-to-expert text which describes contents, side effects etc. for a professional readership such as doctors and other healthcare professionals using expert terminology. The fact that the PIL must be drawn up in accordance with the Summary of Product Characteristics turns it into a type of "intralingual translation" (Jakobson, 1959/2000; see also Zethsen, 2007, 2009) as it comprises a change in receiver group from expert to layperson (as opposed to interlingual translation, which takes place between two languages). According to Article 63(2) of the above Directive, PILs must be "written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals". Furthermore, this article states that PILs must be "clearly legible in the official language or languages of the Member State(s) in which the medicinal product is placed on the market".

The EMA has become increasingly aware of the importance and challenges linked to lay-friendliness and has introduced several initiatives to improve PILs such as templates in all EU languages, a readability guideline and user testing of each PIL. In relation to translation, it is very problematic, however, that the user testing is only mandatory for a single language version. This could in principle be any language version, but the English PIL is always produced first as it has to be submitted first in the marketing authorization process, and also, the materials to be submitted after the user testing must be in English, which means that usually it is the English version that is tested. English-language PILs constitute only a fraction of the EU PILs – through the Centralised Procedure, all PILs must

be available in all EU languages, which means that all leaflets must be translated into 23 languages.[1] The translations from English into all other languages are made after the opinion of the Committee for Medicinal Products for Human Use has been received, which means *after* the EMA has granted the marketing authorization.

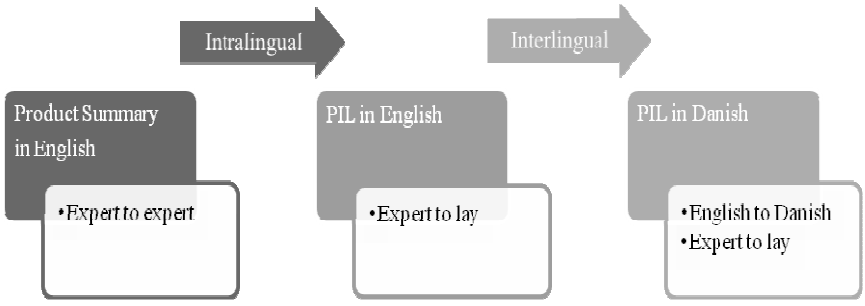

Figure 1: The production process of a Danish PIL (Askehave & Zethsen, 2011)

2.1. What does EU legislation say about translation?

We know from the above that PILs should be legible, clear and easy to read in all EU languages and that this is the responsibility of the marketing authorization holder (in consultation with the EMA). There are very few guidelines from the EU about the important process of moving from an approved and tested English PIL to 23 language versions of this ST so it is very much left to the mercy of the marketing authorization applicants. A little help, or rather the only help, is to be found in the "Guideline on the readability of the labelling and package leaflet of medicinal products for human use" (European Commission, 2009). In this document, the EU Commission states the following (2009, p. 22):

(1) 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.
(2) The quality of translation should be the focus of a thorough review by the applicant/marketing authorization holder once the original package leaflet has been properly tested and modified. It is important

that the outcome of the user consultation is then correctly translated into the other languages.

(3) 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.

Re 1: It is not very clear what exactly is meant by this requirement and consequently how it is to be fulfilled – apart from ensuring that the original ST is as clear and easy to understand as possible. Each language pair will undoubtedly pose its own challenges to the translator because of language system differences, cultural differences, etc., but there is nothing a pharmacist drafting the original English PIL can do about that. The only suggestion that comes to mind would be a translation guide explaining the conscious choices made in the original with lay-friendliness in mind, for example reminding the translators by means of specific examples that the active voice, personal pronouns, lay terms, etc. are deliberate choices and should not be changed back into expert register. Such a guide could be very valuable, but we doubt that this is how the requirement is interpreted and that such guides are in fact produced.

Re 2: When the pharmaceutical company has produced the translations, the national medicines agencies – in Denmark, the Danish Medicines Agency – have 14 days to check the translations and report back to the EMA and the pharmaceutical company using Quality Review of Documents (QRD) Form 1 (European Medicines Agency, 2010). Again, it is not very explicitly described exactly how this check should be carried out. The national medicines agencies have to rate the overall quality of translation on a scale of Very Good, Good, Acceptable or Unacceptable, but the categories are not further defined or explained. Furthermore, according to the QRD Form 1, focus is on "Missing words or sentences", "Scientific [sic] incorrect translations (e.g., terminology)", "Inaccuracies (incorrect translations – including spelling, punctuation, grammatical mistakes)" and "Editorial, stylistic changes (e.g., rephrasing)". Clearly, the main focus of these categories is on technical correctness and accuracy and not on lay-friendliness. This could be very problematic as the translations are not user tested, which means that these checks by the Member States constitute the only real control mechanism that is supposed to ensure that the receivers are provided with lay-friendly texts.

Re 3: This is the only direct recommendation as regards the translation process, but it remains quite vague, and it only concerns macro-strategies. The guidelines warn against "strict literal translation"; instead, translations should be "faithful", and preserve the "core meaning" of the original thus allowing for "regional flexibility".

The warning against strict literal translation seems somewhat unnecessary as this kind of translation is very unusual, and it is quite self-evident that it would not be a good overall strategy when writing for laymen. The recommendation of faithful translation reflects the fact that the technical information in a PIL is crucial, but the reader (if a trained translator) may be somewhat confused by the use of the concept of "faithful" translation, which is normally contrasted with "free" translation in Translation Studies (though the two concepts are not mutually exclusive). When referring to preserving the "core meaning" and allowing for "regional flexibility", the concept of free translation is evoked. This contrast may create confusion, and it is hard to tell from the recommendation how much flexibility is allowed in reality.

3. Medical translation and translators

Medical translation is one of the oldest disciplines of translation (Fischbach, 1986, p. 16), and literature on the subject is quite extensive. However, not many empirical studies focus on the medical translator as such. Quite a few scholars, though, have discussed who should translate medical texts, and opinions diverge. Whether medical professionals or professional translators should translate medical texts is even said to be the oldest discussion in the medical translation field (Fischbach in Márquez Arroyo, 2007, p. 74). Below is a literature review of professional translators vs. pharmacists-cum-translators.

3.1. Professional translators

Even though professional translators may have some medical knowledge, some argue that they are not able to perform medical translation because they are not subject-matter specialists. Translation businesses sometimes find that translators lack medical translation expertise (Andriesen, 2001, p. 5). A translator without extensive medical knowledge might have difficulties both in comprehending the ST and in re-expressing the meaning in the TT (Gile, 1986, p. 27). Professional translators, on the other hand, would be familiar with different translation techniques and instruments, which is why some scholars find that professional translators produce better translations as they master "the techniques of translation, research and documentation" (Lee-Jahnke, 2005, p. 81).

3.2. Pharmacists-cum-translators

Previous research within Translation Studies has shown that medical professionals have a tendency to translate in an uncritical and very direct way (Askehave & Zethsen, 2000b, 2002) and that some medical professionals see literal translation as the ideal way of translating (González Davies, 1998, p. 100). This may, however, result in inelegant and sometimes incomprehensible texts (Gile, 1986, p. 28). Also, some medical professionals view specialized terminology as the most important factor in medical translation. This is, for example, seen in a study carried out by González Davies in which she had medical specialists assess students' medical translations. The specialists saw specialized terminology as being of paramount importance, whereas syntax and grammar were the least relevant points, and cohesion and coherence were considered to be of minor importance (1998, pp. 99–100).

Moreover, medical professionals tend to stick closely to their expert language to ensure medical accuracy (Gal & Prigat, 2005, p. 489). Other researchers have found that medical professionals have weak writing and translation skills (O'Neill, 1998, p. 74).

Of course, some researchers also say that both translator types can perform medical translation (e.g., Montalt Resurrecció & González Davies, 2007, pp. 34–35), or that preferably, the two groups should work together (Askehave & Zethsen, 2000b, p. 36).

From the above, it appears that pharmacists-cum-translators may well lack the skill of maintaining or adjusting the level of formality and complexity of the PIL text, and it seems fair to hypothesize that, in relation to lay-friendliness, there may be linguistic differences between Danish PILs from pharmaceutical companies that use medical professionals and those from pharmaceutical companies that use professional translators.

In spite of the many opinions (only some of which rely on empirical research), there seems to be a lack of empirical research investigating and comparing the translation products of professional translators and medical professionals, respectively, to see if any differences are found.

4. Study design

A contrastive corpus of 54 English EU PILs and their Danish translations was compiled to investigate the differences in the translation products of the two types of translator. The corpus consists of PILs from pharmaceutical companies using pharmacists as translators (n = 27) and from pharmaceutical companies using trained translators (n = 27). The corpus selection, analysis framework and analysis procedure are further described below.

4.1. PIL corpus

Based on investigative findings that identified who the majority of Danish PIL translators are (Nisbeth Jensen, forthcoming), it was possible to source PILs from each contacted company and match these PILs with a translator type. All language versions of EU PILs that have been authorized through the centralized procedure are freely available on the EMA website (http://www.ema.europa.eu/). These PILs have all been through the EMA's strict authorization process including being subjected to the same legal requirements and time constraints, and using these authentic PILs ensures ecological validity. Furthermore, these PILs are meant to live up to the requirements of producing a clear and understandable text that enables its users to act appropriately.

4.1.1. Corpus selection

Some pharmaceutical companies stated that they sometimes used translators and sometimes pharmacists. However, to avoid blurring translator categories, only pharmaceutical companies exclusively relying on *either* translators *or* medical professionals were included in the corpus. Furthermore, identical double PILs (i.e., PILs for similar drugs where two or more PILs were identical, and thus not new translations) and PILs reserved for use by health professionals were excluded. PILs intended for initial use by a health professional, but potentially for later self-administration, were included as such PILs would be the only source of information for patients when they were at home, and, for example, needed to inject themselves. These criteria left a sample of 27 PILs translated by translators. When the potential corpus of PILs translated by medical professionals was subjected to the same criteria, a potential corpus of 76 resulted. It was not possible to match the two corpora based on medicine type as the medicines encompassed too many different diseases and conditions. The 27 PILs translated by translators were spread over seven pharmaceutical companies, as were the PILs translated by pharmacists. The pharmaceutical companies that used only translators had a number of PILs ranging from one to five (1, 3, 4, 4, 5, 5, 5) whereas the number from the seven pharmaceutical companies using pharmacists-cum-translators ranged from three to 27 (3, 5, 8, 9, 11, 13, 27). In order for the two corpora to be as similar and comparable as possible, with PILs from all seven companies, a spread was chosen for the medical professional corpus similar to that of the translator corpus but proportionate to the number of PILs each company had (2, 3, 4, 4, 4, 5, 5). The random sampling function in Excel was used for the actual choice of pharmacist PILs.

4.2. Analytical framework

To be able to assess whether any differences exist between the translation products from pharmaceutical companies that use translators and pharmacists, respectively, and to gain insight into the nature of potential differences, an analytical framework was necessary. For the purpose of this article, two elements have been selected for analysis: an example of the medical register used in PILs – the use of Latin-Greek terms, as well as a feature of specialised register in general – the use of nominalization.

4.2.1. Latin-Greek terms

Because a PIL is an expert-to-lay genre, the use of medical register should be limited to elements that the lay receiver will understand. Latin-Greek (LG) terms are one of the most frequently quoted elements hampering lay-friendliness, both in English and in Danish, one reason being that patients may misunderstand terms that medical experts consider to be "common" (Thompson & Pledger, 1993), indicating a gap between what experts would perceive as common terminology and what laypeople would (Dahm, forthcoming; Hadlow & Pitts, 1991; Jucks & Bromme, 2007).

The use of LG terms in Danish is even more problematic than in English because of the linguistic differences in usage between English and Danish (Pilegaard, 1997; Zethsen, 2004). LG terms are much more widespread in everyday discourse in English than in Danish as Zethsen points out: "In contrast to English, Scandinavians still mostly use native, simple and immediately understandable words [...] when talking about a medical subject in a non-expert context" (Zethsen, 2004, p. 134). When LG terms are transferred from English into Danish, the complexity level is thereby drastically raised. It is therefore possible for a translator to make a text more or less lay-friendly depending on her/his choice of terminology.

4.2.1.1. Analysis of LG terms

The analysis of this category was not as straightforward as distinguishing between "LG term transferred" and "LG term deleted or replaced". For example, the LG term may or may not have an equivalent in Danish lay register, or sometimes the translator might choose to use both the Danish lay term and an LG term. Therefore, two main categories were elaborated, that is, "LG terms – lay-friendly option" and "LG terms – non-lay-friendly option".

The category "LG terms – lay-friendly option" includes translation procedures where:

(1) the translator has used a Danish lay term instead of the expert LG term as in:
ST: injection
TT: indsprøjtning
Explanation: The translator could have chosen the term "injektion", but this term belongs to Danish expert register.

(2) the translator has changed the order, that is, s/he gives the Danish term first followed by the original LG term in parentheses as in:
ST: if you are taking *diuretics* (a type of medicine also called "water tablets" which increases the amount of urine you produce)
TT: hvis du tager en type medicin, som kaldes vanddrivende tabletter (*diuretika*). Disse forhøjer den mængde urin, du producerer

or (3) the translator has added a Danish lay explanation or lay term to a LG term as in:
ST: purpura
TT: purpura (spontan blødning i hud og slimhinder)
Explanation: purpura (spontaneous bleeding in skin and mucous membranes)

The category "LG terms – non-lay-friendly option" includes translation procedures where:

(1) the translator has transferred an LG term (without further explanation) in cases where no single Danish word exists in lay register as in:
ST: polycystic ovarian syndrome (PCOS)
TT: polycystisk ovariesyndrom (PCOS)
Explanation: the syndrome PCOS does not have a name in lay Danish, but it will be more difficult to understand for a Danish layperson, because the term "ovary/ovarie" is not used in lay Danish; instead, the lay term is "æggestok" [egg stalk].

(2) the translator has transferred an LG term and lay word or explanation without any changes (such as deleting the LG term) as in:
ST: XX may also be given directly into a vein (intravenously)
TT: XX kan også indgives direkte i en vene (intravenøst)
Explanation: In lay Danish, the term "intravenously" is not used; therefore, the fact that the term has been maintained is likely to hamper lay understanding. Moreover, the lay reader does not necessarily know that "intravenously" is an explanation of "in a vein". It could be interpreted as further information.

(3) the translator has transferred an LG term even though a lay alternative exists in Danish register as in:
ST: XX is recommended for women who have had their *menopause*
TT: XX anbefales til kvinder efter *menopausen*.
Explanation: In lay Danish, the term "menopause" is not used, but instead the term "overgangsalderen" [transition age].

(4) the translator has introduced an LG term even though a lay alternative exists in Danish register as in:
ST: It works by making the blood *clot* at the site of bleeding
TT: Det virker ved at få blodet til at *koagulere* på det sted
Explanation: In the Danish translation, the expert term "koagulere" (coagulate) is used; the natural choice would have been the lay term "størkne", which means "clot".

4.2.2. Nominalization

The use of specialized terminology is often quoted as one of the main reasons why medical texts are difficult for laypeople to understand (Bromme, Jucks, & Wagner, 2005; MHRA, 2005). However, a text can also be translated in a more or less lay-friendly manner at clause level. One of the most quoted elements said to cause difficulty at clause level is the use of nominalizations. In an experimental study, Coleman (1964, p. 186) found that transforming nominalizations using active verbs makes a text easier to comprehend than their nominalized counterparts. The fact that nominalizations may cause problems for laypeople is supported by many other scholars and several reasons have been addressed (Askehave & Zethsen, 2000a; Charrow, 1988; Schriver, Cheek, & Mercer, 2010). First of all, nominalizations make a text impersonal (Charrow, 1988, p. 98). Also, texts including nominalizations are more compact, harder to read and more abstract (Becker Jensen, 2007, p. 53). Halliday (1994) argues that nominalization makes a text difficult for laypeople to understand:

> This kind of nominalizing metaphor probably evolved first in scientific and technical registers, where it played a dual role: it made it possible on the one hand to construct hierarchies of technical terms, and on the other hand to develop an argument step by step, using complex passages 'packaged' in nominal form … [T]he writer presumably knows exactly what it means; but the reader may not, and so this kind of highly metaphorical discourse tends to mark off the expert from those who are uninitiated. (p. 353)

For the analysis, nominalizations were coded both in instances where a nominalization was introduced or split up. An example of an introduction of a nominalization in the corpus (i.e., non-lay-friendly option) is:

ST: To *stimulate* growth
TT: Til *stimulering* af vækst
Explanation: For the stimulation of growth

An example of a nominalization being split up (i.e., lay-friendly option) is:

ST: Some patients… experienced *the development of* heart failure
TT: Nogle patienter... *udviklede* hjertesvigt
Explanation: Some patients…developed heart failure

4.3. Qualitative analysis procedure

The 54 PILs were coded using the qualitative analysis software Nvivo (2011) by one researcher. The researcher did not know to which company and translator group each PIL belonged. As some sections of every PIL are based on a template, the first part, for example, saying "Read all of this leaflet carefully before you start using this medicine", only non-template sections were analysed as only in these sections would the translators have some freedom of choice. Each translated PIL was compared with the English ST PIL, and each lay-friendly element and non-lay-friendly element coded. This procedure was repeated twice for each PIL. Lastly, all codes were checked for consistency.

4.4. Quantitative analysis

For each PIL, the rate per 100 words for each linguistic feature was calculated based on the TT word count. The two groups were then compared using an independent samples t-test to test whether significant differences exist in relation to the use of LG terms and nominalizations. A *p*-value of <.05 was deemed significant.[2]

5. Results

In the following, the results of the analysis of LG terms and nominalisation will be presented.

5.1. LG terms

Table 1 shows the differences between the two translator groups as regards the use of LG terms. The table shows that the two translator types do not differ significantly in relation to mediating LG terms in their translations, that is, by using a Danish lay term instead, by adding a lay explanation to the LG term or by switching the order (putting the Danish first, LG term last) (p = .615). However, the pharmacists make significantly more translation choices that involve using LG terms than the translators (p = .030). Because this category showed a statistically significant difference between the two translator groups, this category is further analysed below to investigate the procedures within this non-lay-friendly category further.

Table 1: Differences between the translators and the pharmacists in their use of LG terms

	Pharmacists	Translators	
	Mean	Mean	*p*-value
LG terms – lay-friendly option	0.76	0.70	.615
LG terms – non-lay-friendly option	1.87	1.26	.030

Table 2 shows the statistical analysis for the four translation procedures that together make up the category “LG terms – non-lay-friendly option”. The table shows that the means are higher for the pharmacists in relation to all non-lay-friendly categories, that is, “LG term transferred without further Danish lay explanation” (mean 0.21 vs. 0.19), “LG term transferred even though a lay alternative exists in Danish register” (1.23 vs. 0.82) and “LG term introduced even though a lay alternative exists in lay Danish register” (0.05 vs. 0.02; it should be noted though that this is based on very few instances). However, there is no statistically significant difference between the two translator types. For the category “LG term and lay word/explanation transferred without any changes”, the two types of translator differ significantly (p = .036), with the pharmacists opting for this procedure more often than the translators.

Table 2: Use of LG terms that are likely to influence lay-friendliness negatively

	Pharmacists	Translators	
	Mean	Mean	*p*-value
LG term transferred without further Danish lay explanation	0.21	0.19	.661
LG term and lay word/explanation transferred without any changes	0.38	0.22	.036
LG term transferred even though a lay alternative exists in Danish register	1.23	0.82	.104
LG term introduced even though a lay alternative exists in Danish register	0.05	0.02	.062

5.2. Nominalization

Table 3 shows the *p*-values for the linguistic lay-friendliness feature "Nominalization", that is, both when a nominalization was introduced and when one was split up by the translators.

Table 3: Treatment of ST nominalizations

	Pharmacists	Translators	
	Mean	Mean	*p*-value
Nominalization inserted	0.49	0.33	.041
Nominalization split up	0.13	0.11	.570

The results show that the pharmacists introduce significantly more nominalizations into their translations than the translators ($p = .041$). There is no significant difference between the two translator groups for "nominalization split up" ($p = .570$), though the mean is slightly higher for the pharmacists.

6. Discussion

The results show that the pharmacists generally use more LG terms in their translations than the translators. They transfer more LG terms without explanation and they transfer or introduce more LG terms even when a Danish lay register term exists. Furthermore, the pharmacists use the translation procedure "LG term and lay word / explanation transferred without any changes" significantly more than the translators. The findings also show that the pharmacists introduce more nominalizations than translators do.

It is understandable why it is sometimes deemed useful to provide the layman with an expert term, along with a lay explanation, in case they want to search for more information about their illness or need the expert term to make sure that there are no contraindications when taking other medication. However, using an LG term when the Danish term or explanation is already present can rarely be justified, except in connection with specific illnesses, and may in fact confuse the lay reader. Using both an LG term and a lay explanation does not necessarily help the patients if they do not understand the LG term, because the explanation can be interpreted as extra information and not necessarily as an explanation of the expert LG term. Finally, it may be argued that those patients from the target group who find it difficult to process written information in the first place may be intimidated by too large a number of unrecognizable words, even when these are explained, which ultimately may have a negative impact on the likelihood of their reading the PIL at all.

As far as the larger number of nominalizations is concerned, there is no doubt that the pharmacists are more accustomed to the use of nominalizations as part of their expert language. They are probably not aware that in many cases nominalizations raise the level of formality in a text and make it less accessible. Also, they are probably not aware of the deagentivizing effect, which is especially confusing in cases where the agent is expected to act, for example, use an asthma inhaler for the first time, but where the patient may be unsure of who is to perform the acts required.

The results indicate that the pharmacists tend to overrate the competences of the PIL receiver, supporting Bromme et al. (2005, p. 571) in their claim that there is a good deal of evidence that experts have difficulty in adapting their advice to the information needs of laypersons. The pharmacists may be influenced by their own expertise, and thus may struggle to distinguish between their own knowledge and that of the receiver – a phenomenon dubbed "the curse of expertise" (Hinds, 1999, p. 205, see also Askehave & Zethsen, 2003; Lentz & de Jong, 2009). The translators, on the other hand, who are not experts in pharmaceuticals, seem to have a better ability to assess the knowledge level of the lay PIL receiver,

maybe because they themselves belong to this receiver group, or at least are no more than semi-experts.

Research also suggests that medical professionals lack knowledge about translation theory and methods, even language in general, and therefore have problems targeting a text at a specific receiver group such as the layman (Askehave & Zethsen, 2000a, p. 68, 2002, p. 24). They simply lack the tools to lower the level of formality.

7. Conclusion

It appears from the above that significant differences as well as non-significant tendencies were found in connection with the two groups of translators. We can therefore conclude that our hypothesis was confirmed to some extent in that only a difference between the two translator types was found for non-lay-friendly choices; no significant difference was found for choices that made the text more lay-friendly. Subject matter experts do translate differently from trained translators in the case of a lay target group. The two categories that were investigated in the present study were LG terms and nominalizations. We can conclude that the pharmacists generally make use of more LG terms when they translate and that they introduce more nominalizations into the texts than the trained translators. Both LG medical terms and nominalizations are known as problematic in connection with comprehensibility, so a likely conclusion is that the preferences of the pharmacist translators are likely to be detrimental to lay-friendliness in connection with PILs.

The analyses have shown that investigating potential differences in the translation product of PILs with regard to lay-friendliness is important for ensuring that patients are provided with optimally lay-friendly information that enables them to act upon the information easily and in an appropriate manner. Therefore, the results contribute to shedding some light on potential differences in the translation products of the two translator types. To our knowledge, this has not been done previously in medical translation research. Moreover, the findings are also valuable from a policy perspective, providing further insights into the process of translating PILs, and allow initial conclusions as to whether there are any changes in lay-friendliness when PILs are translated into Danish by the two different types of translator with different levels and areas of expertise.

This paper reported on the analysis of pharmacists and translators' use of nominalization and LG terms in 54 PILs. These two parameters were extensively used in the translations, but they only form part of a larger analytical framework. In future, it will therefore be interesting also to compare other parameters such as the use of compound nouns, personal pronouns, officialese expressions and other features considered either to enhance or to hamper lay-friendliness.

This study only provides information about translation *products*, and not the translation process and the reasons for the translators' choices. In order to understand the reasons behind the translators' choices of translation procedures, a future study involving focus group interviews with professional translators and pharmacists who translate PILs will be conducted to investigate their opinions concerning lay-friendliness and why they choose to translate PILs in a specific way.

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[1] The EU has 23 official languages including English. One of them, Irish, is not translated into, but PILs are also translated into non-EU Icelandic and Norwegian, so it all adds up to 23 translations.

[2] A *p*-value represents the probability (ranging from zero to one) that the results observed in a study could have occurred by chance. Convention is that a p-value of .05 or below is accepted as being statistically significant (Wood, 2003, p. 124).