Priscilla Heynderickx, Sylvain Dieltjens, Geert Jacobs,
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Hochfeldstrasse 32, CH-3012 Bern, Switzerland
info@peterlang.com, www.peterlang.com, www.peterlang.net

JANTIEN VAN BERKEL / MARINEL GERRITSEN*

Patient Information Leaflets in Flanders and the Netherlands: Unnecessary Differences?

1. Introduction

Non-compliance with medication is a significant behavioral issue threatening health, even in well-developed countries. Patient Information Leaflets (PILs) are one means to enable a patient to use medication appropriately and consequently decrease non-compliance. To reach these goals the EU has issued directives and guidelines for PILs distributed within the member countries. The directives – which are mandatory – are mostly concerned with the required information but do not address style and content. The guidelines – which are not mandatory – can be interpreted by EU members according to their specific needs. In other words, the EU regulations leave room for differences in PILs among the EU countries. On the basis of what we know about the impact of culture on document design (Hoeken *et al.* 2003), we expect that the designers of PILs will use this latitude and adapt PILs to the culture of the country in which the PIL is available. In this chapter we first investigate whether pharmaceutical companies in Flanders and the Netherlands use this scope for the style and content of their PILs using a corpus analysis. Next we investigate by means of an experiment whether the differences we found in PILs between the two countries are necessary for patients or if uniformity makes sense.

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2. Differences between Flemish and Dutch PILs: a corpus study

2.1. The impact of culture on PILs: expectations

From an economic point of view, Europe may be a union, but from a cultural point of view, there are still many differences among EU countries. Hofstede (2001) and Claes and Gerritsen (2002, 2007) show, for example, that the cultural values of Flanders and the Netherlands differ considerably, even though the same language is spoken in both countries. Since cultural values influence many aspects of daily life, including communication (Claes/Gerritsen 2002, 2007), we can expect that they also have an impact on health communication and consequently on PILs. Cultural values are used in health communication studies to explain, for example, variance in preferences for the style and content of communication about breast-health (Oetzel *et al.* 2007) and the effectiveness of the content of anti-smoking messages (Chang 2009). To date, little research has been performed to determine whether cultural values also impact PILs. The cultural value expected to most influence written medicine information is Hofstede's uncertainty avoidance. In this study we investigate whether this value has impact on the content and style of PILs.

Uncertainty avoidance has to do with how people manage risk and to what extent they try to avoid risk. People from high uncertainty avoidance cultures choose, for example, a stable career, formulate regulations, rely on experts for advice, search for absolute truths and reject deviant ideas and behavior. People from low uncertainty avoidance cultures do not fear risks and do not need to know the exact effect of the risks they take (Claes/Gerritsen 2002; 2007). Since uncertainty avoidance is related to risk and threat, this value appears to be significant in consumer health information. Gerritsen, Nederstigt and Orlandini (2006) found that differences in Dutch and German PILs could be explained by differences in uncertainty avoidance between Germany and the Netherlands. They found that German PILs are

much longer and more detailed, more structured, use more specific terminology and mention more risks than their Dutch equivalents.

In our study we investigate whether two countries that differ significantly in uncertainty avoidance, Flanders and the Netherlands, also differ in the style and content of PILs. The scores for uncertainty avoidance are 97 for Flanders and 53 for the Netherlands on a scale where 0 stands for low uncertainty avoidance and 100 for high uncertainty avoidance (Hofstede 2001). According to Hofstede (2001), the difference in uncertainty avoidance is the most important difference in cultural values between Flanders and the Netherlands.

In this study, style is conceived as the length of the PIL and the way the information is structured. Uncertainty avoidance might have an impact on the precision of the information given in the sense that high uncertainty avoidance may warrant exacting details. For that reason we can expect that the higher the uncertainty avoidance in a culture the more details are described precisely and as a consequence the longer a PIL will be. The structure of a PIL may enhance precision and facilitate reading. Therefore, we may expect that in high uncertainty avoidance cultures structure markers such as headings occur more often than in cultures with lower uncertainty avoidance.

Following Gerritsen, Nederstigt and Orlandini (2006), PIL contents can be construed as the inclusion of risks and medical terms. Uncertainty avoidance could influence the number of risks described and whether the risks are explicitly reported or not. We expect that in cultures with high uncertainty avoidance, such as Flanders, more risks will be mentioned and explicitly described in PILs than in cultures with lower uncertainty avoidance, such as the Netherlands. Uncertainty avoidance might also have an impact on the use of medical terms and whether a specific medical term is explained or not, because using and explaining these terms enhances the precision of the information. The higher the uncertainty avoidance the more we can expect that medical terms are used and explained.

In consideration of the difference in uncertainty avoidance between Flanders and the Netherlands, the following expectations are formulated. The hierarchy for Flemish and Dutch PILs is Flemish PIL > Dutch PIL for:

- Style: E1: length of the entire text of the PIL
  E2: extent to which the PILs are structured
- Content: E3: a. number of risks mentioned
  b. number of risks that are elucidated
  E4: a. number of medical terms used
  b. number of medical terms explained

2.2. Method

2.2.1. The corpus

Pain medication containing Ibuprofen was chosen in the first place because these medications do not differ in composition between the two countries. Moreover, these painkillers are 'over the counter' (OTC) products in both countries and PILs are important for OTC products, because consumers only obtain drug information via the accompanying PILs. A third reason for choosing Ibuprofen is that there are several brands on the market and, therefore, a variety of PILs are available.

The corpus consists of five leaflets (PILs) from Flanders and five from the Netherlands. The most recent PILs were found on the Internet or obtained from a pharmacy. The paper versions were scanned and digitalized to a Word document so that the PILs could be easily compared. The Flemish PILs are written in all three official languages of the country, French, Dutch and German, and by law these have to provide the same information. For this study, only the Dutch section of the PIL was considered. Table 1 lists the PILs used for this study.

2.2.2. Measuring instruments

In order to determine the *length* of the PIL (E1) the total number of words in each PIL was counted, using the option 'word count' of Microsoft Word 2000. As a consequence, words identified by the Microsoft Word software as one word in Dutch, were counted as one word.

In order to compare the structure of the PILs (E2) the following structure indicators were counted in the entire PIL:

- headings
- subheading
- enumeration, such as bullets, numbers, etc.
- line spacing.

These features of *structure* indicators were selected to determine the complexity of the structure of the PIL. Counting was performed using the original PILs (PDF or paper versions) since converting a PIL into Word could cause changes in the layout. Structure indicators were counted by two independent observers in order to increase accuracy. Inter-observer variation was minimal.

To analyze *risk*-information (E3), initially, the number of risks was counted (E3a). Risks of medication use reflect the consequences of adverse events and interactions with other medications. Every possible consequence was counted as a separate risk. Subsequently, the risks were divided into elucidated risks and those that were not elucidated (E3b). For the elucidated risks, the harmful consequences of the risks were explained. For example: *Dit geneesmiddel kan ernstige gastro-intestinale voorvallen veroorzaken* (This medicine can cause severe gastro-intestinal symptoms to occur). For the non-elucidated risks, however, the harmful consequences of the risks were not explained. Here, it was not clear what the risk means, or how and why it is risk at all. An example is: *Terughoudendheid is geboden bij personen met infecties* (Abstention is necessary for people with infections). In order to increase the reliability of the findings, risks were counted by two independent observers. Inter-observer variation was minimal.

To determine whether uncertainty avoidance influences the use of *medical terms* (E4a), we counted the terms and analyzed whether these terms were explained for the consumer. For this study, medical terms were considered specialist terms, i.e. words or expressions that are not trivial and not used in daily language. To determine whether or not a word is a specialist term, the Dutch authoritative dictionary of the vernacular was used as a standard (Van Dale 2005). Ingredients or substances mentioned in the PIL, such as 'Hypromellosum' and 'Crospovidon', were included as medical terms, because they are not found in the Van Dale dictionary.

The use of medical terms was analyzed by making a distinction between medical terms used with an explanation and medical terms with no further explanation (E4b). An example of a medical term with explanation is: *De werking van digoxine (middel dat de hartwerking verbetert) kan beïnvloed worden* (The effect of digoxin (drug that improves the performance of the heart) could be influenced by…). An example of a medical term without explanation is … *kan de werking van methotrexaat verminderen* (… could decrease the effects of methotrexate). To increase reliability, all terms were counted by two independent observers. Inter-observer variation was minimal.

2.2.3. Data processing

Statistical analysis of the data was performed using SPSS 17.0. For all data, the mean per country was calculated. To determine whether these means differed significantly, independent sample t-tests were executed.

2.3. Results

Table 1 presents the number of words found in the Flemish and Dutch PILs. The means of the *length* of the text (E1) of the entire PIL do not differ significantly between the countries (t (8) = 1.77, p=.12).

Dutch PILs		Flemish PILs	
Name	Number of words	Name	Number of words
Advil	761	Advil	825
Nurofen	697	Nurofen	1,679
Ibuprofen Kring	1,050	Ibuprofen EG	1,532
MP Ibuprofen	972	Spidifen	1,318
CF Ibuprofen	1,465	Adulfen Lysine	1,345
Mean (SD)	**989 (303.2)**	**Mean (SD)**	**1,339.8 (323.1)**

Table 1. Number of words in Dutch and Flemish PILs.

Table 2 presents the means of the counts of the *structure indicators* in the PILs (E2). The total number of structure indicators is significantly

higher in Flanders (M=78.4) than in the Netherlands (M=45.4) (t (8) =2.6, p<.01). The number of subheadings in the Flemish PILs (M=15.8) is also higher than in the Dutch PILs (M=2.2) (t (8) =6.7, p<.01). The difference between the Flemish and the Dutch PILs in enumeration indicators approaches significance (t (8) =2.1, p=.07). There are no significant differences between the countries in either the number of headings (t (8) =0.1, p=.95) or in the number of line spacings (t (8) =0.0, p=.96).

PILs	Mean (SD) headings	Mean (SD) sub-headings	Mean (SD) enumerations	Mean (SD) line spacings	Total (SD)
Dutch	15.4	2.2	11.4	16.4	45.2
	(2.1)	(2.5)	(11.8)	(9.7)	(15.1)
Flemish	15.6	15.8	30.2	16.8	78.4
	(6.0)	(3.8)	(15.9)	(16.4)	(24.1)

Table 2. Structure indicators in Dutch and Flemish PILs.

Table 3 presents the means of the total number of *risks* (E3a) divided into elucidated risks and non-elucidated risks (E3b). It appeared that in Flanders (M=78.2) more risks are mentioned than in the Netherlands (M=50.0) (t (8) =2.40, p<.05). There were no significant differences between Flanders and the Netherlands in elucidated and non-elucidated risks, but the difference in elucidated risks approached significance (t (8) =2.20, p=.06).

PILs	Mean number elucidated risks (SD)	Mean number non-elucidated risks (SD)	Total (SD)
Dutch	29.8 (12.8)	20.2 (8.8)	50.0 (15.6)
Flemish	51.8 (18.5)	26.4 (8.8)	78.2 (21.7)

Table 3. Risk information in Dutch and Flemish PILs.

Table 4 presents the means of the number of *medical terms* (E4a). The Flemish PILs (M=43.4) use significantly more medical terms (t (8) -4.44, p<.01) than Dutch PILs (M=11,2). There is no significant difference between Flanders and the Netherlands in the number of medi-

cal terms with an explanation (t (8) =1.970, p=.09). The difference in the number of medical terms without an explanation approaches significance (t (8) =2.4 p=.07).

PILS	Mean number of terms without explanation (SD)	Mean number of terms with explanation (SD)	Total (SD)
Dutch	6.8 (3.4)	4.4 (2.5)	11.2 (3.6)
Flemish	32.0 (22.6)	11.2 (7.5)	43.4 (15.8)

Table 4. Medical terms in Dutch and Flemish PILs.

2.4. Corpus study: discussion and conclusion

The expectation that Flemish PILs would be longer than Dutch PILs (E1) has not been confirmed; there was no difference between the countries in mean text length. This is probably due to the large inter-variation within the two countries (Table 1).

The expectation that the Flemish PILs would be more structured than the Dutch PILs (E2) has been partly confirmed: the total number of structure indicators and the number of subheadings was higher in the Flemish PILs than in the Dutch PILs, but there was no difference in line spacing or headings between the countries. The latter is probably due to EU regulations: EU guideline 2001/83/EG, article 59 indicates which headings should be presented and in which order. Therefore, EU countries only have the option to subdivide subheadings.

The expectation that PILs in Flanders would mention more risks than in the Netherlands (E3a) was confirmed. The expectation that risks would be more elucidated in Flanders than in the Netherlands (R3b), however, was not confirmed. The precision with which risks are presented does not appear to be more common in Flanders than in the Netherlands. Our results suggest that uncertainty avoidance can be linked to the number of risks mentioned but not to the precision in which they are mentioned.

The expectation that more medical terms would be used in Flanders than in the Netherlands (4a) is confirmed: the Flemish PILs contained more medical terms than the Dutch PILs. It was anticipated

that elucidating medical terms would increase precision and thus increase the avoidance of uncertainty; so elucidated medical terms would appear with greater frequency in the Flemish PILs (E4b). This expectation was not confirmed; elucidating medical terms does not appear to be more common in the Netherlands than in Flanders. It seems that uncertainty avoidance can be linked to the number of medical terms used but not to the precision with which they are presented.

Despite uniform regulations in the European Union and a common language, PILs in Flanders and the Netherlands show significant differences in the number of structure indicators, risks mentioned and the use of medical terms. Since the aspects that occur significantly more often in Flanders all aimed to reduce risk, the difference between the Flemish and the Dutch PILs could be due to higher uncertainty avoidance in Flanders than in the Netherlands.

Not all expectations were confirmed: no differences were found in PILs for headings, text length, presentation of risks (implicit or explicit), or explanation of medical terms. It appears that the frequency of risk descriptions and medical terms, rather than whether or not they are elucidated, can be explained by uncertainty avoidance. Apparently, elucidation of terms is not related to uncertainty avoidance but related to other still unknown factors. Further research is needed to explore these factors.

This corpus analysis was limited due to the relatively small size of the corpus. A second limitation of our study is that only the influence of uncertainty avoidance was tested. Other cultural values, such as power distance (the extent to which one is willing to accept inequality in power (Hofstede 2001) or the number of referrals to a doctor were not investigated, although they also could have an influence on PILs.

Our corpus analysis has shown that there are quite a number of differences in style and content between Flemish and Dutch PILs for Ibuprofen and that these differences are, to a great extent, in line with our expectations based on the much higher uncertainty avoidance in Flanders than in the Netherlands. The next question is whether these differences in PIL design are necessary and whether PILs from one's own culture lead to a better medicine use than PILs from another culture. For that reason we performed an experiment reported in the next section.

3. The experiment: are differences between Dutch and Flemish PILs necessary?

3.1. Introduction

The purpose of a PIL is to instruct the patient on how to take medicine and provide information about the expected effects. On the basis of the similarity-attraction hypothesis (Byrne 1971), we can assume that when a PIL's text has a familiar style and content, it is more likely that the patient will read it, understand the content and follow the instructions – in short the PIL will serve its purpose. We investigated Flemish and Dutch patients to determine whether PILs from a patient's own culture were better appreciated and understood and led to a more appropriate intentional medicine use than PILs from another culture and whether patients preferred a PIL from their own culture compared to one from another culture. Specifically our research questions were:

- RQ1: Do patients *appreciate* the style and content of a PIL from their own culture more than style and content of a PIL from another culture?
- RQ2: Do patients *comprehend* the content of a PIL from their own culture better than a PIL from another culture?
- RQ3: Does a PIL from the patient's own culture lead to more appropriate *intentional medicine use* than a PIL from another culture?
- RQ4: Do patients *prefer* a PIL from their own culture to a PIL from another culture?

3.2. Method

3.2.1. Material

Two PILs (both written in Dutch) were used in this experiment: a newly created Flemish PIL largely based on the existing Flemish PIL for Nurofen (Ibuprofen) and a newly created Dutch PIL based on the existing Dutch PIL for the same drug. The existing PILs for Nurofen were chosen as the basis for the newly modified PILs because the study described in section 2 had shown that the Flemish Nurofen PIL was an archetype of Flemish PILs and the Dutch Nurofen PIL for Dutch PILs in terms of style and content. These PILs explicitly showed the differences found in the corpus analysis. Small changes were made in the existing published PILs used in the experiment:

- In order to avoid the influence of foreknowledge, the name Nurofen was changed to the pseudonym Pharmapren, the name of the active substance was changed from Ibuprofen to Prenex, and the names of the pharmaceutical company were removed.
- The font size of the text was enlarged, because a pre-test showed that our respondents, the elderly (cf. 3.2.2) were not able to read the text of the original PILs.

We focused our study on one section of the PIL, the section that included risk information, since this is critical information for our respondents. The risk section was highlighted to facilitate identification in the PILs presented to the patients.

3.2.2. Respondents

Respondents were 21 Flemish and 25 Dutch elderly native Dutch speakers. We selected elderly respondents since healthcare for this group is an increasingly important issue for the EU as the population grows (SER 1999; SER 2005; European Commission 2008). The elderly are considered high-risk patients because they often take multiple medicines (polypharmacy). There is an elevated risk of medication interaction, patient confusion, and adverse effects because of aging physique and physiology (i.e., notably with regard to their gastrointestinal system, kidney and liver, weight, body structure and metabolism). The elderly recover from adverse effects more slowly than younger patients. In general, the longer a patient uses a medicine, the higher the risk of adverse effects and the elderly are less likely to be alert to adverse effects and take action.

Respondents were solicited for participation in the study in a club for the elderly, senior housing and using a snowball method. We excluded elderly living in a nursing home as they are assisted by staff

when taking their medicine and consequently are not expected to read the accompanying PIL.

Table 5 presents the number and age of the respondents by nationality. The number of male respondents is lower than the number of female respondents, which reflects the reality that, in both countries, women live longer than men (WHO-HFA 2009).

Three respondents from the Netherlands were not able to complete the entire questionnaire due to unforeseen and unpreventable circumstances (such as falling asleep or a taxi that came too early to pick up the respondent), which prematurely terminated the interview process. However, all answers from these respondents are included in the results, and the missing answers were coded as missing values.

Nationality	Mean Age	Range	Men	Women	Total
Flemish	77,6	65-89	7	14	21
Dutch	75,8	65-91	7	18	25

Table 5. Respondents.

3.2.3. Measuring instruments

All data were collected by means of a questionnaire that had been pretested for clarity and applicability. In order to measure *appreciation* (RQ1) of the text, respondents were asked to read the marked text of the PIL (the section on risk information) and to answer questions about style and content on a 7-point scale. Items were recoded for analysis so that 1 was positive and 7 negative. The following eight items measured appreciation of style: word choice, syntax, patient friendliness, comprehensibility of medical issues, amount of medical issues, trustworthiness, language use and clarifications in the text. An example is:

(1) On the whole, this PIL is
Patient friendly O O O O O O O Patient unfriendly.

A reliability analysis showed that these eight items had a Cronbach's alpha of .73. From now on, we will only address this summarized variable for appreciation of style.

The following three items measured appreciation of content: information on risks, amount of risks and adverse reaction instructions. An example is:

(2) Instructions on adverse reactions in this PIL are:
Specific O O O O O O O Vague

A reliability analyses showed that these three items had a Cronbach's alpha of .72. From now on, we will only address this summarized variable for appreciation of content.

Comprehension (RQ2) was measured by presenting the respondents with the following case. The respondent had to imagine that he or she had been suffering from joint pain for weeks. Pharmapren had provided good pain relief and they wanted to continue taking it as long as they had pain. Then the respondent was asked to read the risk information and to say whether or not he or she was allowed to use the medicine. The respondent could choose from five possibilities, one of which was the correct answer: one could take the medicine, but one should pay attention to potential side effects.

Appropriate intentional medicine use (RQ3) was measured by using the same case scenario as the one for measuring comprehension, but this time, respondents had to say whether or not they would actually use the medicine. All questions were closed questions.

Preference for either the Flemish or the Dutch PIL (RQ4) was measured by presenting respondents with the alternative PIL (the one they had *not* just evaluated). If a respondent had, for example, judged a Dutch PIL, then they were given the Flemish PIL. Respondents were asked to compare the paragraphs on risk information in both PILs, and to say which PIL they preferred and why.

3.2.4. Design

The design of the first part of the study (RQ1, 2 and 3) was a between-subject design; the respondents had to judge either the Flemish PIL or the Dutch PIL. Half of the Flemish respondents judged the Flemish PIL and half judged the Dutch PIL. Half of the Dutch respondents judged the Flemish PIL and half judged the Dutch PIL. The second

part of the questionnaire (RQ4) was a within-subject design. All respondents had to compare the paragraphs on risk information in both the Flemish and the Dutch PIL.

3.2.5. Procedure

The questionnaire was administered in a face-to-face interview in the respondent's home. The duration of the interviews ranged from 45 to 90 minutes. The questions were read aloud by the interviewer and oral instructions were given, for example, to explain the seven-point scale.

3.2.6. Data processing

Statistical analysis of the data was carried out in SPSS 17.0. Analyses of variance with the factor Country (Flemish, Dutch) were performed for the ordinal variables (appreciation), and Chi-square test for the nominal variables (comprehension, intentional medicine use, and preference).

3.3. Results

Table 6 presents the *appreciation* of style and content (RQ1) of the Flemish and the Dutch PIL by the Flemish and the Dutch respondents. Both groups of respondents appreciated the *style* of the Flemish PIL less than the style of the Dutch PIL (Flemish respondents (F (1, 19) =16.43, $p<0.01$), Dutch respondents (F (1, 23) =22.60, $p<0.01$). The Flemish respondents appreciated the *content* of the Flemish PIL more than the content of the Dutch PIL (F (1, 19) =11.77, $p<0.01$), but the Dutch respondents appreciated the content of both PILs equally (F (1, 23) =3.14, p=.09).

Item	Means of Flemish respondents		Means of Dutch respondents	
	Flemish PIL (n=10)	Dutch PIL (n=11)	Flemish PIL (n=12)	Dutch PIL (n=13)
Style	5.03 (1.05)	3.70 (0.25)	5.06 (0.89)	3.84 (0.32)
Content	2.30 (0.96)	3.94 (1.20)	1.91 (0.94)	2.95 (1.76)

Table 6. Appreciation of the Flemish and the Dutch PIL by Flemish and Dutch respondents (1 = positive and 7 = negative).

Table 7 shows the results of the *comprehension* part of the experiment (RQ2). This indicates how many Flemish and Dutch respondents gave the *correct answer* in the case scenario after having read either the Flemish or the Dutch PIL. Respondents from both cultures gave the right answer more frequently after reading the Flemish PIL than after reading the Dutch PIL (Flemish respondents (χ^2 (1) =13.75, $p<.001$), Dutch respondents (χ^2 (1) =4.70, p=.05).

	Flemish PIL		Dutch PIL	
	Correct answers Flemish respondents (n=10)	Correct answers Dutch respondents (n=11)	Correct answers Flemish respondents (n=11)	Correct answers Dutch respondents (n=11)
Case long-term use	9 (90%)	9 (82%)	0 (0%)	4 (36%)

Table 7. Comprehension.

Table 8 shows how many Flemish and Dutch respondents gave the correct answer about their *intentional use of the medicine* in the case scenario (RQ3). For both groups of respondents the Flemish PIL led to a more appropriate intentional medicine use than the Dutch PIL (Flemish respondents (χ^2 (1) =5.74, $p<.05$), Dutch respondents (χ^2 (1) =4.55, p=.05).

	Flemish PIL		Dutch PIL	
	Correct answers Flemish respondents (n=10)	Correct answers Dutch respondents (n=11)	Correct answers Flemish respondents (n=11)	Correct answers Dutch respondents (n=11)
Case long-term use	7 (70%)	8 (73%)	2 (18%)	3 (27%)

Table 8. Appropriate intentional medicine use.

Table 9 shows whether the Flemish and the Dutch respondents *preferred* the Flemish PIL or the Dutch PIL or had no preference (RQ4). Flemish and Dutch respondents clearly preferred the Dutch PIL to the Flemish PIL (Flemish respondents (χ^2 (2) =12.18, $p<.05$), Dutch re-

spondents (χ^2 (2) =12.18, p=<.01). Both groups of respondents explained their preference for the Dutch PIL with similar arguments:

- 'Short and concise.'
- 'Short and simple, ordinary language.'
- 'This text is shorter and contains less difficult words.'
- 'You don't have to have to read a whole bible, do you? In other words; the other PIL is too long.'
- 'This text is obviously shorter and gives the patient the information one needs. Laypersons don't need the medical terms of which they don't know the meaning of.'
- 'Otherwise, you read a lot of stuff you don't understand'
- 'The other text is three pages longer. That isn't necessary; it leads to worrying'.
- 'If you are in pain, you won't read that much.'

In short, the majority of the Flemish and the Dutch respondents preferred the Dutch PIL because of the brevity of the text and the relatively simple language.

Preferred PIL	Number of Flemish Respondents (n=21)	Number of Dutch Respondents (n=22)
Flemish PIL	3 (14.3%)	2 (9.1%)
Dutch PIL	14 (66.7%)	17 (77.3%)
None	4 (19.0%)	3 (13.6%)

Table 9. PIL preference.

3.4. Experiment: discussion and conclusion

The first research question we wanted to answer was*: 'Do patients appreciate the style and content of a PIL from their own culture more than style and content of a PIL from another culture?'* Our results (see Table 6) are not unequivocal. The Flemish respondents appreciated the content of the Flemish PIL more than the content of the Dutch PIL, but they appreciated the style of the Dutch PIL more than the style of the Flemish PIL. The respondents from the Netherlands appreciated the style of the Dutch PIL more than the style of the Flemish PIL, but they appreciated the content of both PILs equally.

The second research question, *'Do patients understand the content of a PIL from their own culture better than that of a PIL from another culture?'* can be answered negatively. The Flemish respondents did comprehend the Flemish PIL better than the Dutch PIL, but so did the respondents from the Netherlands.

We found the same pattern for the third research question, *'Does a PIL from the own culture lead to a more appropriate intentional medicine use than a PIL from another culture?'.* The Flemish PIL led to a more appropriate medicine use than the Dutch PIL among the Flemish respondents and also for the Dutch respondents.

The fourth research question*, 'Do patients prefer a PIL from their own culture to a PIL from another culture?',* can again be partially answered negatively. The Dutch respondents preferred the Dutch PIL to the Flemish PIL, but so did the Flemish respondents.

Our answers to the four research questions seem to indicate that the effectiveness of a PIL in terms of appreciation of style, comprehension and intentional medicine use is not determined by the cultural background of the patients. Flemish and Dutch patients reacted similarly; they appreciated the style of the Dutch PIL more than the style of the Flemish PIL and they preferred the Dutch PIL over the Flemish PIL. Patients from both cultures comprehended the Flemish PIL better than the Dutch PIL and both groups also had a more appropriate intentional medicine use after having read the Flemish PIL rather than the Dutch PIL. The results of this part of the study are similar to those of Gerritsen, Nederstigt and Orlandini (2006). They also found that in Germany and in the Netherlands a PIL in the style that was not appreciated led to more adequate medicine use than a PIL in the style that was more appreciated. Further research is needed to explore whether this also holds for other countries.

4. Practice implications

Our results lead us to cautiously suggest that the cultural adaptations of PILs for medicines distributed in Europe may not be necessary, since the purpose of the PIL does not appear to be enhanced by cultural adaptation. Our results force us to address a question that was not formulated as a RQ: If one PIL is created for the entire European Union, which type of PIL should pharmaceutical companies provide? Should it be a PIL similar to the Dutch PIL in this study preferred by the respondents and written in a style that is highly appreciated, but not as thoroughly comprehended thus leading to less appropriate intentional medicine use? Or is it better to use a PIL similar to the Flemish PIL, not preferred by the respondents and whose style is not appreciated, but which contains information that is better comprehended and leads to a more appropriate intentional medicine use? We believe that is not in the best interest of the patient to make a choice. Rather, pharmaceutical companies, together with communication specialists, should make a concerted effort to provide patients with information about their medicines that meets the patients' stylistic needs, is appreciated, comprehensible, and leads to appropriate medicine use. Perhaps a PIL alone cannot combine all these qualities and thus supplementary information sources are necessary to ensure that all the information is transmitted in a manner that matches patients' needs and preferences.

Secondly, our study shows that current medicine information resources (in the form of PILs) are not suitable for our respondents – the elderly. Although the elderly are not considered a special interest group with regard to medical information printed on or delivered inside pharmaceutical packaging in the 2009 Guideline (EC 2009), alternatives should be found for this group. This is particularly urgent since the number of elderly people in Europe is growing along with their life expectancy. In the future the elderly will remain vital and autonomous and therefore continue to manage their own medication for a long period of time. Some Dutch pharmacists include a personalized letter with information about the medicine, tailor-made for the patient in question in addition to the PIL for the medicines they dispense; for example, letters with information that focuses on the specific situation of the patient and written in a large font size. This effort to give patients tailor-made information is, in our view, especially important for OTC-medicines, since generally these medicines come with only a PIL as the formal source of information. One potential solution is a website, on which personalised details could be provided, based on a few simple questions that the patient (or caregiver) would answer such as gender, age, use of other medicine, co-morbidity, etc. The subsequently provided information would be short, personal and relevant. It is true that today not all elderly people would be helped by this solution, because many do not access the Internet. A study in the United States (Jones/Fox 2009) shows, for example, that only 50% of the age group 65-75 was online in 2008. However, the benefits from online tailor-made medicine information for the elderly will increase in the future, as the baby boomer generation become seniors. In addition, information via a website could be tailored for other patient groups as well. Unfortunately, EU regulations today make it impossible to mention a web address in a PIL because it is seen as promotional activity for the pharmaceutical industry. Until such time that these EU regulations are rescinded, alternative methods to provide wide access to such an information source remain to be explored.

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