Influence of Font Sizes on the Readability and Comprehensibility of Package Inserts

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Summary

The new European readability guideline draft for package inserts recommends a minimal font size of 12 pt and 16 to 20 pt for medicines which are more frequently used by visually impaired patients. However, research results illustrate that smaller font sizes are easier to read.

Therefore, the written readability test was used to investigate how font size influenced the information locatability and comprehensibility. Fifteen questions focusing on the package insert contents and 17 questions focusing on participants' opinions were compiled. The study examined one package insert available on the German medicines market and its optimized model version. Both were printed in 9 different font sizes, between 7 and 16 pt.

The 205 participants were significantly more often unable to locate and understand information in the original, 6.7 to 16.0 % and 15.0 to 27.0 %, as compared to the model, 2.8 to 6.7 % and 9.2 to 14.7 %. Font size only had a minor influence on locatability compared to other optimization possibilities, optimal being between 9 to 12 pt. However, larger font sizes decreased the locatability, while comprehensibility was not influenced.

On the basis of these findings the new readability guideline draft for package inserts should be reconsidered. The 9 pt font size is ideal and more realistic and therefore should be recommended in this guideline, as the minimum used in package inserts.

Zusammenfassung

Der neue Entwurf der europäischen Lesbarkeitsrichtlinie für Packungsbeilagen empfiehlt eine minimale Schriftgröße von 12 pt und 16 bis 20 pt für Arzneimittel, die häufiger von Patienten mit Sehbeeinträchtigungen verwendet werden. Jedoch sind Studiendaten verfügbar, die belegen, dass kleinere Schriftgrößen besser lesbar sind.

Deshalb wurde der schriftliche Lesbarkeitstest verwendet, um den Einfluss der Schriftgröße auf die Auffindbarkeit und Verständlichkeit der Informationen zu untersuchen. Fünfzehn Fragen richteten sich in dem Test auf den Inhalt der Packungsbeilagen, und 17 Fragen bezogen sich auf die Meinungen der Teilnehmer. Die Studie prüfte eine auf dem deutschen Arzneimittelmarkt verfügbare Packungsbeilage und deren optimierte Modellversion. Beide Gebrauchsinformationen wurden in 9 verschiedenen Schriftgrößen zwischen 7 und 16 pt gedruckt.

Die 205 Teilnehmer konnten signifikant schlechter die Informationen in der Originalpackungsbeilage finden und verstehen, 6,7 bis 16,0 % und 15,0 bis 27,0 %, im Vergleich zur Modellversion mit 2,8 bis 6,7 % und 9,2 bis 14,7 %. Die Schriftgröße hatte nur einen geringen Einfluss auf die Auffindbarkeit im Vergleich zu anderen Optimierungsmöglichkeiten und war am besten zwischen 9 und 12 pt. Jedoch verringerten größere Schriftgrößen die Auffindbarkeit, während die Verständlichkeit generell nicht beeinflusst wurde.

Auf der Basis der Studiendaten sollte der neue Entwurf der Lesbarkeitsrichtlinie überarbeitet werden. Eine 9 pt Schriftgröße ist gut geeignet und wesentlich realistischer. Sie sollte deshalb in dieser Richtlinie als minimale Schriftgröße für Packungsbeilagen empfohlen werden.

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1. Introduction

The United Nations state that everyone shall have the right to receive information of all kinds and states should develop strategies to provide information for everyone [1–2].

Article 59 (3) of the amended European Union's medicine law, Directive 2001/83/EC, demands that medicine package inserts are legible, clear and easy to use and that readability test results should reflect this [3–4].

Above all, however, package inserts' readability is still consistently criticized [5–9]. Small writing in particular causes major problems [10–11]. In addition to font size, the typeface, type colour, line spacing and background are also important as they all contribute to the readability [12–13]. Furthermore, although the European Commission's 1998 readability guideline recommends a minimum font size of 8 pt many package inserts still fail to implement this recommendation [14–16].

The new readability guideline draft, revised September 2006, recommends applying a general font size for optimization, of at least 12 pt. In addition, package inserts from medicines more frequently used by visually impaired patients, should contain font sizes of between 16 and 20 pt [17]. Organizations which represent people, such as the European Blind Union, are demanding these new guideline recommendations [18-19]. For example, the Royal National Institute for the Blind (RNIB) state on the basis of their experience and expert advice that „The larger the minimum type size, the more people you will reach." [19].

However, researches exist which prove that 10 and 11 pt are optimal font sizes for package inserts, as these sizes are more legible [10, 20]. In the Bernardini et al. study which examined 8 to 14 pt (points) font sizes, nearly half of all 578 participants estimated that 10 pt and 11 pt were the most appropriate font sizes [10]. Paterson and Tinker measured the speed at which 4, 6, 8, 10, 12 and 14 pt font sizes are read. They found that 10 pt was the optimum [21]. In a later investigation, both authors estimated that an 11 pt font size was read significantly faster than 10 pt [22]. Bernardini et al., Paterson and Tinker found that 9 and 12 pt font sizes are only slightly inferior to 10 and 11 pt [10, 22]. In addition, font sizes 14 pt and larger are more difficult to read [23].

The following study investigated if an increase in font size, as demanded in the readability guideline draft, will generally improve the possibility to locate and comprehend the information provided in package inserts.

2. Methods

The methods used in this study are based on the PAINT1 survey, a Cross-Over-Comprehensibility-Test of five original and five model package inserts [24].

A telmisartan package insert available on the German medicines market (original) and a compatible model package insert, both used in the PAINT1 survey, were again investigated here. Each package insert provided identical contents, however, the model was improved using over 100 quality criteria [24]. Text, layout, colour design, and readability were all optimized, while difficult words, abbreviations and long sentences were omitted. Both package inserts were printed in every font size between 7 and 16 pt except 15 pt. The layout, content, wording, number and print types per line were identical in each original version. The only differences were font size and format size. The same applied to the model package insert.

Test procedure

The written readability test according to Fuchs, was used here, as this test procedure is officially recommended by the German Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte, Berlin), accepted by every other agency in the European Union and also fulfills the guideline [24–26]. The verbal face-to-face interview was intentionally not used here, to prevent any influence on participants' answers resulting from the interviewers' mimics and gestures. Interview logging errors caused by incorrect interpretation and/or incorrect documentation of the participants' verbally formulated answers were therefore also reduced. In addition to all this, the written readability test is an accepted method which requires fewer participants than necessary in a face-to-face interview.

The test consisted of a questionnaire containing 15 questions, all related to key messages concerning the package inserts' contents and a further 17 questions relating to the participants' opinions of the investigated package inserts. The same questionnaire was used for each package insert.

Each participant recruited had to be capable of independently reading and answering the questionnaire, using only the written instructions provided. The participants' written answers to the 15 content questions were categorized by the tutors as follows:

1. Answer not found
2. Wrong answer
3. Right answer

In the first category, participants were asked to indicate if they were unable to find the questioned information, by ticking the appropriate box. This was then assessed by calculating the number of boxes ticked. The readability test correct answers corresponded with the information provided in the investigated package inserts.

Participants

Adults aged 50 years and older and adolescents between 13 and 19 years were purposely recruited here, as these two groups have slightly more difficulty locating and understanding the information provided in package inserts [24]. It is important to note that visually impaired people were not excluded from this study. Testing both groups also enabled investigating differences in locating

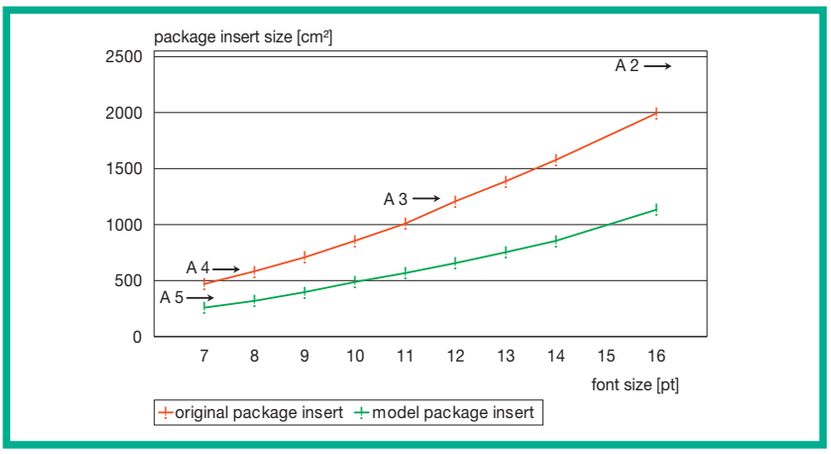

Fig. 1: Format sizes in the original (text total: 1359 words) and the model package insert (text total: 579 words) itemized according to font sizes.

Font size (pt)	Original package insert			Model package inset		
	Size (cm x cm)	Area (cm²)	Norm size (cm²)	Size (cm x cm)	Area (cm²)	Norm size (cm²)
7	18.0 × 26.1	469.8	–	13.2 × 19.6	258.7	–
8	19.7 × 29.6	583.1	A4 (623.7)	14.2 × 22.5	319.5	A5 (311.8)
9	21.6 × 32.8	708.5	–	16.1 × 24.7	397.7	–
10	23.5 × 36.4	855.4	–	17.8 × 27.4	487.7	–
11	25.5 × 39.6	1009.8	–	19.2 × 29.6	568.3	A4 (623.7)
12	27.6 × 43.8	1208.9	A3 (1247.4)	20.7 × 31.7	656.2	–
13	29.7 × 46.7	1387.0	–	22.1 × 34.1	753.6	–
14	31.5 × 50.1	1578.2	–	23.5 × 36.4	855.4	–
16	35.3 v 56.5	1994.4	~A2 (2494.8)	27.0 × 42.0	1134.0	A3 (1247.4)

and understanding the provided information. Children attending a school in Zella-Mehlis (Germany) were questioned by pharmacists during March and April 2007. The adult group were questioned in their own homes around Jena, Bad Salzungen, Suhl and Zella-Mehlis in Germany.

A minimal of 5 participants from each group were recruited for every package insert and font size. For example, the 7 pt original was tested by a minimum of 5 school children and 5 adults. This gave a minimum of 20 participants per font size investigated.

All data retrieved from the completed questionnaires was coded and inserted into a SPSS (statistics programme) table via double data input for checking. The median of the time needed to answer all 15 questions relating to the package insert content had to be calculated. Fractions for "correct", "incorrect" and "answers not found", were determined for all 15 questions in total.

The fractions of located and correct answers, and the time needed to answer the questions were subsumed in three font size groups to investigate significance. As illustrated in the studies described above, 10 and 11 pt are the best font sizes and 9 and 12 pt only slightly inferior, all are therefore summarized in one group. Smaller and larger font sizes formed the other two groups.

3. Results

The original package insert contained 1359 words, the model contained 579 words. Each was formatted using font sizes between 7 and 16 pt, printed on both sides of A5 to A2 paper (Fig. 1). The package insert expanded according to font size, and the more extensive original became even larger.

A total of 205 people answered the questionnaire, 109 adolescents and 96 adults. At the time of the survey, participants were aged between 13 to 19 years (adolescents) and 50 to 88 years (adult group) with an average age of 16 and 59 years. Two thirds of people interviewed were female (63.5 %).

The adult group stated the following as their highest education: 8th class 16.7 %, 10th class 41.7 %, A-level 6.3 %, technical college 15.6 %, and university 19.8 %.

Over 90 % of answers were located in every font size model. Therefore, the section of information not located in this group was as little as 2.8 to 6.7 %, with the 11 pt font size proving to have the highest locatability. However, the range of information not located in the original group was always between 6.7 and 16.0 % greater compared to the model (Table 1).

Major difficulties locating the information in each original package insert were again illustrated in the longer amount of time needed to answer all 15 content questions: originals 11.8 to 15.0 min and models 10.0 to 13.6 min. With the exception of the 16 pt original, less time tended to be needed to locate information when a font size of between 9 and 12 pt was used (Table 1).

Testing differences in fractions of information not located between the three main font size groups (7 to 8, 9 to 12 and 13 to 16 pt) showed that the medium font sizes were slightly more advantageous. However, this was not significant (Kruskal-Wallis test).

The information contained in each individual font size model package insert was always better comprehended than the originals (Table 1). However, font size was not found to have an influence on comprehensibility.

Table 1 shows that the locatability (answers not found and time needed to answer) and comprehensibility results were in total always significantly better when the model package insert was used (Mann-Whitney U test). In addition, participants were more able to locate and understand the information in the model package inserts, in each font size investigated. This was often additionally significant (Mann-Whitney U test).

Pharm. Ind. 70, Nr. 5, 584–592 (2008)

Table 1: Fractions of requested information which was not located or comprehended and the time needed to answer all 15 content questions, itemized for each original and model package insert and respective font size.

Font size (pt)	Fraction of information not located (%)			Fraction of information not comprehended (%)			Time needed to answer all 15 content questions (calculated median; min)			n	
	Original	Model	p	Original	Model	p	Original	Model	p	Original	Model
7	9.8	5.7	n.s.	19.0	10.8	0.014	14.5	12.0	n.s.	13	14
8	8.5	6.7	n.s.	27.2	9.8	<0.001	15.0	11.0	n.s.	11	12
9	12.1	3.4	0.008	27.0	10.4	0.002	13.6	10.0	0.044	11	12
10	9.1	3.0	0.025	20.6	11.3	0.023	12.7	10.0	n.s.	11	11
11	12.2	2.8	0.007	15.0	11.6	n.s.	13.9	10.6	n.s.	11	12
12	6.7	3.0	n.s.	24.3	11.4	0.001	13.0	10.8	n.s.	11	11
13	10.9	4.4	n.s.	18.5	9.2	0.027	15.0	12.7	n.s.	11	12
14	8.7	6.0	n.s	21.8	14.7	n.s.	15.0	10.5	n.s.	11	10
16	16.0	4.8	0.014	22.9	10.9	0.049	11.8	13.7	n.s.	10	11
total	10.4	4.4	<0.001	21.3	11.0	<0.001	13.8	11.1	0.006	100	105
7–8	9.2	6.2	n.s.	22.8	10.3	<0.001	14.7	11.8	n.s.	24	26
9–12	10.0	3.0	<0.001	21.7	11.1	<0.001	13.5	10.5	0.004	44	46
13–16	11.7	5.0	0.002	21.0	10.4	<0.001	14.0	12.2	n.s.	32	33

n.s.: non significant.

Table 2: Fractions of requested information, which was not located or comprehended and the time needed to answer all 15 content questions, itemized for each original and model package insert and respective font size according to participant age.

Font size (pt)	Fraction of information not located (%)		Fraction of information not comprehended (%)		Time needed to answer all 15 content questions (calculated median; min)		n	
	Original	Model	Original	Model	Original	Model	Original	Model
Younger participants (13 to 19 years of age)								
7 to 8	8.7	8.1	24.7	10.6	12.3	10.0	13	14
9 to 12	11.9	3.6	21.3	9.3	13.1	9.6	24	24
13 to 16	11.8	7.8	23.0	9.8	12.5	10.7	17	17
Older participants (50 to 88 years of age)								
7 to 8	9.7	3.89	20.5	10.0	21.0	16.0	11	12
9 to 12	7.7	2.42	22.2	13.2	14.3	14.3	20	22
13 to 16	11.7	2.08	18.8	12.4	16.0	15.0	15	16

Comparisons between the total results of both participant groups showed that the adolescent group located slightly less of the information requested (information not located: original 11.1 %, model: 6.1 %) than the adults 50 years and over (information not located: original 9.5, model 2.7 %). However, the older participants needed more time to answer each of the 15 content questions (calculated median: original 15.8 min, model 12.9 min) compared to the younger group (calculated median: original 14.9 min, model 10.0 min).

The fraction of incorrect answers was almost equal in both groups (younger people: original 22.7 %, model 9.8 %; older: original 20.7 %, model 12.4 %).

The Chi-Square test after Pearson calculated no significant differences between younger and older participants in the fractions of incorrect answers. Adults were able to locate significantly more information in the model package insert ($p = 0.032$). No significant advantage was observed in the original group. However, younger people in total answered all 15 content questions significantly faster (original: $p = 0.023$, model: $p = 0.001$).

Table 2 classifies results in the three main font size groups and both participant groups for the model and the original package insert. After Kruskal-Wallis test calculation, significant differences caused by different font sizes were not found in any of the three main package insert groups, itemized for both participating age groups. The time needed to answer all 15 content questions was slightly improved in the older participant group, when font sizes of between 9 and 12 pt were used. Using larger 13 to 16 pt font sizes did not lead to any further improvement.

Participants' education level or gender was not found to have any significant influence.

Table 3: Participants' opinions of the original and model package insert, itemized for each font size investigated and in total.

Font size (pt)	"The first impression of this package insert motivated me to read further." (calculated median)		"The information requested in the 15 content questions was easy to find." (calculated median)		"The content of this package insert was easy to understand." (calculated median)		"Would you like all package inserts to be like this one?" (calculated median)	
	Original	Model	Original	Model	Original	Model	Original	Model
7	3.71	2.57	1.73	1.73	1.80	1.75	2.78	2.00
8	3.29	2.00	2.00	1.73	2.00	1.45	3.67	1.67
9	3.57	2.00	1.78	1.45	1.67	1.64	2.57	1.70
10	4.00	1.56	2.20	1.36	2.00	1.30	4.43	1.78
11	3.71	1.56	2.00	1.33	1.90	1.33	2.17	2.11
12	3.86	1.45	2.00	1.60	2.29	1.27	2.83	1.30
13	4.00	1.64	2.22	1.55	2.38	1.27	2.60	1.76
14	3.83	2.57	2.14	1.89	2.00	1.56	2.00	1.83
16	4.00	2.13	2.00	1.89	2.00	1.64	3.40	1.88
total	3.67	1.86	1.97	1.60	1.99	1.47	2.81	1.76
	mostly no	mostly yes	mostly yes	mostly yes	mostly yes	yes	other	mostly yes
7 to 8	3.54	2.25	1.84	1.73	1.89	1.61	3.00	1.82
9 to 12	3.79	1.63	1.97	1.43	1.94	1.39	2.80	1.71
13 to 16	3.92	1.96	2.10	1.76	2.14	1.48	2.67	1.78

Ranges of the calculated medians and their assessment scales for participants personal opinions of the package inserts: 1.00 to 1.50 = "yes", 1.51 to 2.50 = "mostly yes", 2.51 to 3.50 = "other", 3.51 to 4.50 = "mostly no", 4.51 to 5.00 = "no".

Table 3 shows a selection of participant opinions which, similarly to the results described above, were always better in the model package insert group compared to the original. In addition, Table 4 demonstrates that the total results were always better and the single results for each font size were often significantly better with the model package insert (Mann-Whitney U test).

In the other 13 opinion statements relating to each individual package insert, the model always proved to be better or equally as good as the original.

Significant differences between the results presented in Table 3, itemized for the three main font size groups investigated (Mann-Whitney U test), were only found twice in the results of the model package insert. Thus, participants with 7 to 8 pt font sized models were significantly less motivated to read the package insert than the group with the medium 9 to 12 pt font sizes ($p = 0.006$). People with 9 to 12 pt font sized model package inserts stated that they were significantly more able to locate the requested information compared to the group with the largest font sizes ($p = 0.020$).

Table 4: Differences in results presented in Table 3 between the original and model package insert, itemized for each font size investigated and in total.

Font size (pt)	First impression on reading the package insert (p)	Locatability of information (p)	Comprehensibility of information (p)	Preferred future package insert (p)
7	n.s.	n.s.	n.s.	n.s.
8	0.009	n.s.	n.s.	0.017
9	0.004	n.s.	n.s.	n.s.
10	0.016	0.047	n.s.	0.013
11	0.010	0.013	0.037	n.s.
12	<0.001	n.s.	0.008	0.007
13	0.007	n.s.	0.004	n.s
14	n.s.	n.s.	n.s.	n.s.
16	0.005	n.s.	n.s.	0.013
total	<0.001	<0.001	<0.001	<0.001

n.s.: non significant.

In relation to the statement "The letters are big enough for me", the participants assessed the 7 pt font size in both package inserts as significantly less appropriate when compared to all the other font sizes ($p < 0.001$). In this case, the 7 pt font size always received a neutral assessment (calculated median: original 3.00 and model 2.57) while every other font size investigated was more positively accepted (original: 1.09 to 1.67; model: 1.00 to 1.50).

4. Discussion

Influences of font size on locatability and comprehensibility

The results demonstrate a significantly higher rate of locatability and comprehensibility of information in the model package insert than in the original, independent of the font size used. These findings are identical to those found in the PAINT1 survey, which investigated five package inserts available on the German medicines market and their optimized versions [24].

Pharm. Ind. 70, Nr. 5, 584–592 (2008)

The original and model package insert group results illustrate that font size did not influence comprehensibility. The originals' more varied results are presumably due to the significantly greater difficulties experienced locating and understanding the provided information.

However, it was discovered that font sizes can influence the locatability, even when only seldom significant. But using more participants, could lead more frequently to significant differences.

For example, the participants' ability to locate information printed in 9 to 12 pt font sizes was greater and faster than with smaller or larger print versions. These findings were more obvious in the model package insert group than the original, presumably due to the models' significantly greater locatability and comprehensibility, which may have reduced other negative influences on the result.

As mentioned in the introduction, Paterson and Tinker found that 10 and 11 pt font size texts can be read significantly faster than smaller or larger print, whereby 9 and 12 pt were only minimally slower to read [21-22]. This is comparable with findings in this study.

Boyce reported that font sizes greater than 14 pt have a more negative effect on the reading rate, as the reader recognizes the words more slowly in comparison to smaller written texts [20]. Furthermore, more eye movements, such as fixations and reversals, were necessary with 6 and 14 pt font sizes than when reading 10 pt print [23].

When 578 Italian participants were questioned, results showed that most people preferred the 10 pt (22.7%) and 11 pt (23.0%) font size. Less participants preferred smaller (8 pt: 7.4%, 9 pt: 15.1%) or larger font sizes (12 pt: 15.7%, 14 pt: 12.1%). Vital differences in the preferred font size of people over 50 years and younger groups were not observed [10]. This result is also illustrated in Table 2. Older and younger participants were significantly well able to locate and understand the requested information using the medium font sizes. Larger font sizes had no significant advantage.

However, apart from the font size, the vast differences which exist in the results between the original and model package inserts, demonstrate that there are more important possibilities which might improve the locatability and comprehensibility of information such as, improving comprehensibility by avoiding difficult words, non-quantifiable phrases like "high doses", abbreviations, long sentences and repetitions. Furthermore, the model's condensed text, design and the use of different font colours which contrasted well with the paper, also had a positive influence [24].

Other authors also published similar findings [27–29]. For example Watanabe wrote: "Type size alone may not be responsible for poor readability. Other factors that may be contributing to this difficulty include letter and line spacing, letter contrast, print and background colour, and type style." [29]. To correlate with this, Bix stated that the presence or absence of serifs and the sign stroke thickness, were further possibilities for optimization [30].

Besides recommendations from patient organisations, such as the Royal National Institute for the Blind and the European Blind Union, other publications exist which suggest using font sizes of between 12 and 22 pt for patient medicine information [5, 8, 18, 19, 31–33].

Eyles et al. placed two identical texts printed in different font, either 12 or 14 pt, in front of 186 people who then selected the version which was in their opinion easiest to read. 83% of people preferred the version in 14 pt font size, however the reading which followed provided no specific indicators for this decision [34]. Kirkpatrick and Mohler investigated seven American phenytoin information leaflets without patients, using instead the Singh Readability Assessment Instrument which according to the test parameters preferred only 14 pt as an optimal font size [35]. However, Singh who developed this test system for brochures on the basis of other publications, expressed the following doubts on the necessity of 14 pt font size: "Given that only three subjects (from 20) commented on the 14-point type size suggests that the recommendation made by Doak et al. (1985) may be incorrect and that readers may find smaller type sizes just as acceptable." [36].

Smither and Braun recommended font sizes of between 12 and 14 pt as they found that these were easier to read [37]. However, their results were based on two label investigations with 19 younger and 20 older adults in the first survey and 18 younger and 16 older people in the second survey. Furthermore, bottle and box labels are much shorter than package inserts. In addition, they did not investigate readers understanding or retention of information compared to the font size study presented here. In a study of short texts containing 210 words in only 18 pt font size, Price 1967 concluded that this font size could help a greater number of readers [38].

Vanderplas and Vanderplas checked the reading speed of different font sizes with 28 older people aged between 60 and 83 years in two surveys and suggested with caveats using 12 to 14 pt font sizes for this age group on the basis of their results. However, they recommended using 8 to 12 pt print for younger people. In their first study they investigated font sizes of 10, 12, 14, 16 and 18 pt and concluded a general increase of font size is associated with higher reading speed, although the reading speed in 12, 16 and 18 pt font was very similar. However, in 10 and 14 pt there was a decrease. In the second investigation they compared text passages approximately 250 words in length printed in 12 and 14 pt. Contrary to the first experiment 14 pt point was associated with slightly higher reading speed (24.01 versus 23.18 characters per second). In addition, the participants' opinions regarding ease of reading in relation to type size were not significant [39].

Aberson and Bouwhuls investigated the silent reading abilities of 55 people aged between 35 and 90 years, all of whom were frequent readers. After reading short texts of 534 words (average) printed in 6 different font sizes, they found rapid increases in readability as letter size increased, however, after reaching an optimum a gradual decline occurred when letters became larger. The font size optimum at a 33 cm reading distance for participants with the highest acuity was calculated 10 pt and approximately 34 pt for the group with lowest acuity. They recommended for any case a larger font size than 8 pt. Furthermore, both researchers found that increasing font size can not compensate impaired visual acuity, and people with this handicap did not reach reading rates of normal sighted people [27].

In 2004 Drummond et al. published a study of 180 visually impaired people after they read the instructions on their eye drop bottles. Patients with a Snellen acuity of 6/24 preferred a 16 pt font size, while those with 6/36 preferred 18 pt and 6/60 preferred a 22 pt font size [40]. The WHO classifies people with a Snellen acuity of 3/60 or less as blind [41]. This means that a blind person may see a sign at a distance of 3 m, while a person with normal sight may be able to see it at distances of up to 60 m. However, the majority of patients with a visual acuity of 6/18 were in fact able to read their instructions. Details such as the font sizes used on the eye drop bottles or the number of participants per group were not provided, therefore making it difficult to understand why font sizes were recommended [41].

As no clear database exists to date, which can prove whether 12 pt font sizes or larger are generally better for package inserts than smaller, as recommended in the new readability guideline draft (European Commission 2006), further points should be discussed to explore whether or not this guideline suggestion will actually help or hinder an individual's ability to locate and comprehend information safely.

Package insert format

An investigation of 68 German package inserts from frequently used medicines selected in 2000, found that the package inserts contained an average of 1496 words [15]. As Fig. 1 illustrates, printing this volume of text in a 12 pt font size will create an A3 double sided package insert, 16 pt will create an A2, while 20 pt would create a colossal package insert which could very easily overwhelm the reader and may even contribute to incorrect use of the accompanying medicine. Whereas, a 9 pt font size would only create approximately A4 format as recommended in the readability guideline [14, 17].

Furthermore, there are many package inserts available in the European Union, which contain up to 6000 words or over. Applying a 12 pt font size or more to these will lead to extreme formats which people may find particularly difficult to manage. Moreover, people might be very surprised by the large font, which could look very similar to a school book and diminish any sense of confidence to use the medicine [5, 28]. In addition, storing these large, yet important package inserts for further use will also be extremely difficult, as refolding such large pages will prove very challenging for many people, particularly the elderly. Another point to note is that larger medication boxes will be required just to accommodate these vast leaflets and consumer advocates could declare this as deceptive packaging.

In addition, while investigating a German package insert, our research group found that using an 11 pt font size only, together with columns 9 cm wide, often lead to lines containing only 3 or 4 words and caused much more hyphenation than a 9 pt print. Therefore, 10 or 11 pt font sizes should only be used when the lines are not too short.

Implementing the readability guideline recommendation

The investigation of 68 German package inserts showed that more than half of the leaflets had an 8 pt font size or larger than that recommended in the guideline, after a comparison with Arial font printed in 8 pt [14-15]. A WIdO 2005 study of package inserts from the one hundred most used medicines in Germany, found that not one of these leaflets fulfilled the 1998 guideline recommendation. However, they did not provide any method which could explain the differences of both study results [16].

Unpublished research just recently completed by our research group, who randomly selected 271 package inserts from all those available on the German medicine market in the year 2005, found that 43.2 % contained the text printed in 8 pt or more, with an average text volume of 2004 words.

Every person including the 10 million blind and visually impaired people (approximately 2 % of the European population) [42, 43], has a right to be given easy access to all necessary medical information. This is very important and must be put into practice. Therefore, on the basis of Directive 2001/83/EC as amended by Directive 2004/27/EC, the "… marketing authorisation holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially sighted." [3, 4].

However, as sufficient data does not yet exist to prove that 12 to 20 pt font sizes generally improve the readability and safe use of package inserts for blind and visually impaired people, as well as the larger group of sighted people, recommending the general use of large fonts seems totally unjustified. Furthermore, there are more facts which demonstrate that such large font sizes can decrease the safe use of package inserts. Moreover, the majority of people are sighted and they too have a right to have information communicated to them through package inserts in the most optimal font size possible.

Pharm. Ind. 70, Nr. 5, 584–592 (2008)

In addition, the study results presented here demonstrate that younger and particularly older participants were well able to read and understand considerably smaller font sizes.

Therefore, a minimal 9 pt font size should be introduced as an appropriate recommendation for the main text.

This suggestion, in comparison to the existing draft, could be more realistically implemented, while at the same time guaranteeing optimal readability. In addition, the possibilities for partially sighted people could be improved, for example, via an internet platform which would immediately provide package inserts for every medicine available in the European Union in the respective language. Such a website must be freely available for every person, and the individual package inserts could then be downloaded in the required font size, by the patient, family members or any health care provider. In addition, as a benefit of this, sighted persons will not be at a disadvantage, and can obtain this important patient information in an appropriate font size.

Furthermore, unachievable recommendations are unacceptable in a guideline, as they would be seldomly implemented. This is particularly important, as the readability guideline is only a recommendation and is, therefore, according to the "Consolidated versions of the treaty on European Union and of the treaty establishing the European community", article 249, not urgently required to be implemented into practice [44].

5. Conclusion

Although package inserts can be printed in font sizes from 12 to 20 pt at great technical expenditure, these font sizes cannot be recommended for the following reasons:

- Font sizes over 12 pt can decrease the readability and locatability of information for young and old people.
- Large font sizes lead to a major increase in format which can additionally cause many problems such as, handling difficulties and more hyphenation.
- There are many other options available to improve the package inserts' readability. If these are put into practice it would have a much greater impact than font size and improve this form of patient information immensely.
- Further options could be implemented to ensure that blind and partially sighted people receive better medicine information.

To summarise the results and aspects outlined in this study, we suggest implementing a more realistic recommendation as a compromise to the readability guideline draft. Why not recommend using a minimum 9 pt font size?

References

[1] United Nations. International Covenant on Civil and Political Rights. Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) 1966 Dec 16, entry into force 1976 Mar 23, in accordance with Article 49. *http://www.ohchr.org/english/law/ccpr.htm*, 16 September 2007.

[2] United Nations. The standard rules on the equalization of opportunities for persons with disabilities. December 20, 1993. *http://www.un.org/esa/socdev/enable/dissre00.htm*, 29 January 2008.

[3] European Parliament and Council of the European Union. Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use. *OJ*. 2001;L311:67–128.

[4] European Parliament and Council of the European Union. Directive 2004/27/EC of the European Parliament and of the Council of 31st March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. *OJ*. 2004;L136:34–57.

[5] Twomey C. An analysis of patient information leaflets supplied with medicines sold by pharmacies in the United Kingdom. *Library and Information Research News*. 2001;25(80):3–12.

[6] Van der Stichele RH, Van Haecht CH, Braem MD, Bogaert MG. Attitude of the public toward technical package inserts for medication information in Belgium. *Ann Pharmacother*. 1991;25:1002–06.

[7] Van Haecht CHM, Van der Stichele RH, De Backer G, Bogaert MG. Impact of patient package inserts on patients satisfaction adverse drug reactions and risk perception: The case of NSAIDs for posttraumatic pain relief. *Patient Educ Couns*. 1991;17:205–15.

[8] Shrank W, Avorn J, Rolon C, Shekelle P. Effect of content and format of prescription drug labels on readability, understanding and medication use: A systematic review. *Ann Pharmacother*. 2007;41:783–801.

[9] Fuchs J, Banow S, Görbert N, Hippius M. The importance of package insert information in the European Union. *Pharm Ind*. 2007;69:165–172.

[10] Bernardini C, Ambrogi V, Fardella G, Perioli L, Grandolini G. How to improve the readability of the patient package leaflet: a survey on the use of colour, print size and layout. *Pharmacol Res*. 2001;5:437–43.

[11] Fuchs J, Hippius M, Schaefer M. A survey of package inserts use by patients. *Hospital Pharmacy Europe*. 2005;4:29–31.

[12] Spencer H. The visible word. London: Royal College of Art; 1968.

[13] Ekstrom I. Printed Materials for an Aging Population: Design Considerations. *J Biocommunication*. 1993;20:25–30.

[14] European Commission. A guideline of the readability of the label and package leaflet of medicinal products for human use. September 29, 1998. *http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/gl981002.pdf*, 29 January 2008.

[15] Fuchs J, Hippius M, Schaefer M. Analysis of German package inserts. *Int J Clin Pharmacol Ther*. 2006;44:8–13.

[16] Nink K, Schröder H. Zu Risiken und Nebenwirkungen: Lesen Sie die Packungsbeilage? Bonn: WidO [Wissenschaftliches Institut der Ortskrankenkassen]; 2005.

[17] European Commission. Guideline on the readability of the label and package leaflet of medicinal products for human use. September 2006. *http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/09_2006/readability_consultation_2006_09_25.pdf*, 29 January 2008.

[18] European Blind Union. Making your information accessible for customers with sight problems. November 2003. *http://www.euroblind.org/fichiersGB/policy.htm*, 29 January 2008.
[19] Royal National Institute for the blind. RNIB clear print guidelines. September 29, 2006. *http://www.rnib.org.uk/xpedio/groups/public/documents/publicwebsite/public_printdesign.hcsp#P6_523*, 19 July 2007.
[20] Boyce PR. Human Factors in Lighting. London: Applied Science Publishers; 1981.
[21] Paterson DG, Tinker MA. Studies of typographical factors influencing speed of reading: II size of type. *J Appl Psychol*. 1929;13(2):120–30.
[22] Paterson DG, Tinker MA. How to make type readable. New York: Harper & Brothers; 1940.
[23] Paterson DG, Tinker MA. Influence of size of type on eye movements. *J Appl Psychol*. 1942;26:227–30.
[24] Fuchs J, Hippius M. Inappropriate dosage instructions in package inserts. *Patient Educ Couns*. 2007;67:157–68.
[25] BfArM [Bundesinstitut für Arzneimittel und Medizinprodukte]. Welche Methoden sind vom BfArM für die Durchführung einer solchen Untersuchung akzeptiert? [Which methods are accepted by the BfArM to perform a readability test?]. January 10, 2007. *http://www.bfarm.de/cln_043/nn_424304/SharedDocs/FAQ/DE/Arzneimittel/pal/fa-ampal-faq.html*, 29 January 2008.
[26] European Commission. Guidance concerning consultations with target patient groups for the package leaflet. May 2006. *http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/user_consultation_200605.pdf*, 29 January 2008.
[27] Aberson DHA, Bouwhuis DG. Silent reading as determined by age and visual acuity. *J Res Reading*. 1997;20(3):184–204.
[28] Zacchrisson B. Studies in the legibility of printed text. Stockholm Göteborg Uppsala: Almqvist & Wiksell; 1965.
[29] Watanabe RK. The ability of the geriatric population to read labels on over-the-counter medication containers. *J Am Optometr Assoc*. 1994;65:32–37.
[30] Bix L. The elements of text and message design and their impact on message legibility: a literature review. *J Design Commun*. 2002;4.
[31] Frost MH, Thompson R, Thiemann KB. Importance of format and design in print patient information. *Cancer Practice*. 1999;7:22–27.
[32] Secker J. Assessing the quality of patient-education leaflets. *Coronary Health Care*. 1997;1:37–41.
[33] Hartley J. Designing instructional text for older readers: A literature review. *Brit J Educ Technol*. 1994;25(3):172–88.
[34] Eyles P, Skelly J, Schmuck ML. Evaluating patient choice of typeface style and font size for written health information in an outpatient setting. *Clin Effectiveness Nurs*. 2003;7:94–98.
[35] Kirkpatrick MAF, Mohler CP. Using the readability assessment instrument to evaluate patient medication leaflets. *Drug Inform J*. 1999;33:557–63.
[36] Singh J. Development of an alternative methodology for determining the readability of text [dissertation]. Richmond: Virginia Commonwealth University; 1994.
[37] Smither JA, Braun CC. Readability of prescription drug labels by older and younger adults. *J Clin Psychol Med Settings*. 1994;1(2):149–59.
[38] Prince JH. Printing for the visually handicapped. *J Typogr Res*. 1967;1:31–47.
[39] Vanderplas JM, Vanderplas JH. Some factors affecting legibility of printed materials for older adults. *Percept Motor Skills*. 1980;50:923–32.
[40] Drummond SR, Drummond RS, Dutton GN. Visual acuity and the ability of the visually impaired to read medication instructions. *Brit J Ophthalmol*. 2004;88:1542–42.
[41] Mathers CD, Bernard C, Iburg KM, Inoue M, Fat DM, Shibuya K, et al. Global Burden of Disease study 2000-2002: data sources, methods and results. GPE Discussion Paper No. 54. Geneva: World Health Organization; 2003. *http://www.who.int/healthinfo/statistics/gbdestimatescasedefinitions.pdf*, 29 January 2008.
[42] European Blind Union. Guidelines regarding implementation of the European Union Directive on medicinal products for human use – package information leaflets (or patient information leaflets) (PIL) accessible for visually impaired endusers. *http://www.euroblind.org/fichiersGB/pil-guid.htm*, 16 September 2007.
[43] Eurostat. Total population at 1 January 2008. *http://epp.eurostat.ec.europa.eu/portal/page?_pageid=1996,39140985&_dad=portal&_schema=PORTAL&screen=detailref&language=en&product=Yearlies_new_population&root=Yearlies_new_population/C/C1/C11/caa10000*, 29 January 2008.
[44] European Union. Consolidated versions of the treaty on European Union and of the treaty establishing the European community. *OJ*. 2002;C325:1–184.

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Pharm. Ind. 70, Nr. 5, 584–592 (2008)