Egger V., Point of View

Point of View – Large Print Patient Information Leaflets (PIL)

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First presented at the AID'08 conference, Mälardalen University, Eskilstuna, Sweden (Applications of Information Design).

1. Introduction

Minimum readability standards and readability testing are an integral part of the procedure for the application for marketing authorization of medicines in Europe. Pharmaceutical companies are also required to provide 'alternative formats' of package leaflets. So far this was largely restricted to Braille versions issued on request from patient organisations. However, only a minority of visually impaired people read Braille. Most would benefit more from appropriately designed text.

As someone who has tested the readability of medical information for the European market and also works in the area of inclusive design it seemed a logical step to address this issue. Rather than rely on general guidance, I decided to test this – literally. But first, setting the scene...

1.1. Legal framework and guidelines

Council Directive 92/27/EECⁱ requires that 'the label text shall be easily legible, clearly comprehensible and indelible' (article 4) and that 'the package leaflet must be written in clear and understandable terms for the patient and be clearly legible.' (Article 8)

Council Directive 2001/83/EC^{II} and Council Directive 2004/27/EC^{III} add further dimensions to the requirement:

- The name of the medicinal product to be expressed in Braille format on the packaging, and the marketing authorisation must ensure that the package leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially sighted (Article 56a). The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use. (Article 59[3])
- The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority. (Article 61[1])
- The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. (Article 63[b] 2)

A common template has been provided for the structure and content of patient information leaflets which all leaflets must conform to. (QRD [Quality Review of Documents] template, version 7.2, 10/2006)^{iv}

Alternative format information must also conform to this template. The notes to applicants mention the general requirement: 'Applicants shall ensure that, on request from patients' organisations, the package leaflet is made available in formats appropriate for the blind and partially sighted.' (Annotated template, 7.2, pp. 14, 17)

Guidance concerning Braille documents and alternative formats for partially sighted people^v has been published pointing out a few issues that should be considered in a Large Print leaflet and again referring pharmaceutical companies to patient and disability groups for reference.

1.2. Some figures on visual impairment

In industrialised countries the elderly represent the fastest growing segment of people with visual impairments. Nearly 30 million people in the European Union are blind or partially sighted; this figure takes into account the varying definitions of visual impairment. It is very difficult to calculate exact numbers, particularly because the number of visually impaired elderly people is increasing who are not in an official register.^{vi}

Nearly 90 % of all blind and partially sighted people in Europe are over the age of 60, and two thirds are over the age of 65.

Worldwide more than 82 % of all people who are blind are 50 years of age and older, although they represent only 19 % of the world's population.

More than 90 % of the world's visually impaired people live in developing countries. $^{\mbox{\tiny vii}}$

Older adults are the prime consumers of prescription drugs as figures published in Germany demonstrate: in 2003 an over 70 year old was given an average of 1000 prescribed doses of medicine, whereas a 20–25 year old less than 60 doses (Nink and Schröder, 2005^{viii}).

Though the main source of information for patients is still the doctor or medical personnel (83,8%), 65,3% of respondents also mentioned the patient information leaflet as a prime source of information, and 36% of respondents aged over 60 felt uncertain about the instructions given (WIdO-Monitor, 2003, source: Nink K., Schröder H., WIdO 53, 31, 2005^{ix}).

A study on impaired vision and the ability to take medication concluded, that 'visual acuity, contrast sensitivity, and stereopsis should be considered potential risk factors for impaired ability to implement a medication regimen in older adults'. (Windham, Griswold, Fried, Rubin, Xue, Carlson, 2005, pp. 1179–1190)^x

1.3. It's just part of a communication challenge

Alternative formats seen in a purely physical context of readability is rather short sighted – no pun intended.

Gale R. Watson mentions in her article on Low Vision in the Geriatric Population 'studies have shown that unintentional non-adherence to drug therapy in older patients is due to forgetfulness, complex dosing, or poor understanding of the medical regimen'. (Gale R. Watson, Journal of the American Geriatrics Society, 49:317–330, 2001)^{xi}

Research into adherence to medication regimes in HIV/AIDS patients in South Africa showed that appropriately designed written material can have a positive impact to improve adherence and is essential for enabling patients to make appropriate decisions about their medicine taking. While the authors did not focus on text readability, they nevertheless took into account limited literacy, which effectively keeps people from being able to read information. Of course an association with visual impairment is quite a bold leap because low literacy raises a number of quite unrelated issues to low vision. Nevertheless, this confirms the important role of 'appropriate design' – using the term in its broadest possible sense.

Maureen McKenzie-Tylor from the Communication Research Institute gave a paper at Vision Plus 3 in 1997, outlining a case study on the design of medical

information (McKenzie, 1997^{xii}). 'Our initial exploratory research revealed that consumers of a particular drug were so confused by complex and rapidly updated usage instructions that many were unable to manage taking the drug.' The case study clearly demonstrated that compliance is the combined result of credibility, navigability, clarity of understanding, legibility and action-oriented information.

In an ideal world an integrated approach should be taken to help people access and understand medical information. Still, the physical format of the information determines whether a person can access it at all – independent from any other qualities it may or may not possess.

1.4. A (very) brief excursion into typography

General guidelines concerning Large Print information have been published by the RNIB in their *see it right* range of publications.^{xiii}

- Choice of an appropriate typeface
- Opaque paper to minimise bleed through of ink
- Black ink on white/off white matt paper
- 16 to 22 point typeface (Clear Print requires 12 to 14 points)
- Preference for medium or bold typefaces
- Left alignment
- 1,5 to 2 times line spacing
- Maximum of 70 characters per line (better: 55 to 60)
- If using bold, ensure white space within characters is not detrimentally diminished
- Minimise italics
- Minimise all caps
- Do not use underlining
- Do not use hyphenation
- Different elements should be clearly separated (levels of headers, text, illustrations)
- Use of navigational aids (list of contents, page numbering, paragraph spacing)
- Use of rules to separate columns

Dedicated typefaces for people with poor vision have been developed, but what is suitable for someone with poor vision may not be so easy to read for normally sighted people. Tiresias.org, for example, found that their typeface Tiresias LP Font on the one hand 'is significantly more legible than either Times New Roman or Arial', on the other hand 'people with poor reading vision seemed to appreciate Tiresias more than people with fair or good reading vision.'^{xiv} The American Printing House for the Blind (APH) has also developed such a typeface known as APHont.^{xv}

Several standard fonts have been identified as suitable for use in Large Print information, for instance Frutiger. Arial also has similar key characteristics and is therefore often used as an alternative available on most computers, although the shapes of letters like e, a, o or figures 3 and 6 lack the openness of Frutiger.

A study with dyslexic readers also showed that there is a sharp decline in reading rates below a certain critical print size, and that dyslexic readers require larger critical print sizes to attain their maximum reading speeds. (O-Brien, Mansfield, Legge, 2005, pp. 332–349)^{xvi}

1.5. Integrating inclusive and 'regular' formats

At the beginning of all PIL formats stands a text document base on the EUtemplate. The final text is usually passed to a graphics department who produces the layout of the leaflet to be printed and inserted into a pack.

Large Print formats will never be inserted into the packaging and are unlikely to ever be handled by design departments or printed commercially in large quantities. They have to be quick and easy to produce as electronic documents by someone who has no special design or software knowledge (Figure 1).

Once the shape and size of the leaflet is no longer determined by tight production parameters, a standard format like A4 can be used.





2. Readability testing of Large Print leaflets

When searching for information in a document people scan for highlights and pointers that help structure the information, such as headlines, an index, paragraphs, page numbers, colour coding, some way to communicate levels of hierarchy and order. What if scanning is not an option? How can good readability be achieved in terms of gaining an overview and understanding of a document for someone who can only see a small fraction of the complete text at any one time? (Figure 2)

I took a very pragmatic, no frills approach. It was important to come up with a solution that could be produced easily without the aid of a designer, and that could be implemented with standard office software. The intention was to identify which text and layout features the design should focus on.

The test method used was based on the one developed by David 'Sless and Rob Wiseman^{xvii}, European Guidance also refers to this method. Participants were 20 blind and partially sighted people, recruited via the Hilfsgemeinschaft der Blinden und Sehschwachen Österreichs^{xviii} (Association for the Blind and Partially Sighted

in Austria). The only criteria for the selection of subjects were: Participants must be registered blind or partially sighted and must be able to read printed text.

Comprehension of content was not an issue, however, participants of course commented on the content during the interview.

Figure 2: Only fractions of the text are readable.



2.1. The leaflets

Two different Large Print versions of the same leaflet were prepared (Figure 3). Both designs were based on Clear Print and Large Print guidelines as outlined earlier.

Even though research and various guidelines state that bold typefaces are preferred, we decided to set body text for the test PILs in a regular type weight, in order to leave some room for highlighting important information through type weight.

For the type size we took the middle ground between Clear Print and Large Print.

Leaflet Type 1: This version simply enlarged the typeface of a normal MS-Word document. Body text was set in 15 point Arial regular in one column with approximately 60 characters per line and 150 % line spacing. The leaflet ran to 15 A4 pages in German, 13 pages in English.

Leaflet Type 2: This leaflet was also set in 15 point Arial regular, but in two columns of about 32 characters each, and 125 % line spacing. Additionally, the table of contents was expanded to include all second level headers. The leaflet ran to 13 A4 pages in German, 11 pages in English.

page 6	
mportant information about some of the ingredients of this nedicine	3. How to take Cefpodoxime Sandoz
Cefpodoxime Sandoz 40mg/5ml Powder for Oral Suspension	40 mg/5 ml
contains sucrose. If you have been told that you have an intolerance	Always take this medicine exactly a war dector has fold you. You show
o some sugars, contact your doctor before taking this medicine.	check with your doctor or
Celpodoxime Sendoz 40mg/5ml Powder for Oral Suspension	pharmacist if you are not sure.
contains aspartame (E951). Aspartame contains a source of	The dispensing label will tell you
henylalanine. This medicine may be harmful for people with a	much of this medicine you should take and how often you should
ondition called phenylketonuria.	take. Please read it carefully. The dose your doctor prescribes
. How to take Cefpodoxime Sandoz 40 mg/	depends on the type of infection an how bad the infection is. It also
5 ml	depends on how well the kidneys
Iways take this medicine exactly as your doctor has told you. You	are working. Your doctor will explain this to your
ould check with your doctor or pharmacist if you are not sure.	010 00 904.
te dispensing label will tell you much of this medicine you	Adults
hould take and how often you should take. Please read it	Teenagers and adults who need
arefully. The dose your doctor prescribes depends on the type of	treatment with celpodoxime are
effection and how bad the infection is. It also depends on how well	usually given tablets. Separate
he kidneys are working. Your doctor will explain this to you	provided with the tablets.
Adults	Children older than 15 days
Feenagers and adults who need treatment with celpodoxime are	The daily amount is worked out
sually given tablets. Separate patient information leaflets are	according to the weight of the child
provided with the tablets.	Usually the total amount each day i 8mg for each kilogram of body
Children older than 15 days	Weight. This is usually sold into two denses
e daily amount is worked out according to the weight of the child.	mono codany spir mo ano doses
nene 6	

Figure 3: Leaflet Types 1 (left) and 2 (right)

Table 1: Comparison of main features for the two leaflets

Туре 1	Туре 2
Single column throughout	Single column for general information at the start of the leaflet and for the index
	Two columns with a vertical rule separating the columns in the main part
Index/table of contents with first level headers only	Index/table of contents with first and second level headers
Text 15 pt regular, 150 % line spacing	Text 15 pt. regular, 125 % line spacing

2.2. The interview

After consultation with the Hilfsgemeinschaft in preparation for the tests two different approaches to questioning were taken, depending on whether a participant would need to use a screen magnifier or not. This decision was based on the fact that searching for information is usually very exhausting for people with visual impairments, even more so if the impairment is such that a screen magnifier has to be used. The questionnaire therefore contained two possible routes for the interviewer to take, depending on the needs of the participant.

2.2.1. Participants who did not use a screen magnifier

If the participant did not need to use a screen magnifier, the interviewer handed over a copy of each of the two versions of the leaflet and asked them to choose their preference – purely based on first impressions, on a 'gut feeling'.

After just a brief look at the two types of leaflets the preference in favour of Type 1 quickly became clear:

- Though the size of the text is identical in both leaflets, the decrease in line spacing alone caused the text to appear too dense and fat for the majority of participants. Better line and paragraph spacing seems to have been the main factor for those who chose Type 1.
- Shorter lines and the bolder appearance seem to have been the main factor for those who chose Type 2.
- The extended index/table of contents of Type 2 played no role at this point.

Comments in favour of **Type 1**: Clear distinction of headers, quicker to spot, it's better structured; The typeface seems a bit thinner, but it reads better if it is not in two columns; The one column format is easier to grasp, the lines are spaced further apart; It's a clearer typeface, a little larger, seems to be easier to understand; It doesn't have two columns, that's easier for me; It seems clearer to me, the line spacing is better; Easier to read, it's larger, all in bold would be even better; It's easier to read; Larger gaps between lines and paragraphs, the bold text is easier to read; More pleasant, text doesn't stick together so much, the other one looks too dense. I prefer one column.

Comments in favour of **Type 2**: The text looks bolder, that's good for me; At first glance I tended towards version 1, but the shorter lines are easier to read with the magnifying glass; Lines are closer together and not so long; The text seems black and bold, lighter text gets hazy; Two columns are easier for me, because I can see the whole line at once.

2.2.2. Participants using a screen magnifier

These interviews confirmed how difficult it is to locate information using the screen magnifier, particularly in a multi-page document. An indication of how information might look on a screen is given in Figure 4. Four of six people said they would prefer to use the standard leaflet, which they can enlarge to their preferred size on the magnifier. One would use the Large Print if the pharmacy provided it. Three of the six would prefer an electronic version.

Participants were unanimous in that the normal patient information leaflet would be usable for them and they remarked on some features the leaflets should have to make them more readable (Figure 5). Most notably they preferred headers either in capital letters, underlined or in a reversed out box to distinguish them from normal text. This was initially surprising, because Large Print guidance discourages the use of exactly these text features. The difference between normal weight and bold, as well as differences in size are rendered meaningless when viewed at great magnification.

Figure 4: Table of contents of Large Print document viewed on the screen magnifier



Figure 5: Normal PIL viewed on the screen magnifier, the ragged edges of the printed text showing.



2.3. Results

2.3.1. Leaflet content

Even though the focus of this test was the graphic presentation of text rather than the content of the leaflets, some issues regarding content were highly relevant for people with visual impairments. Features that are merely unpleasant or annoying and make it a little bit more difficult for normally sighted people become a stumbling block for someone with a visual impairment. The main concerns were:

- Headers, where the information is 'hidden' in a long sentence.
- The long, general introduction. This section is normally ignored by most users, who can easily see that the 'real' information starts somewhere else. Someone who can only see a small portion of the leaflet cannot afford this luxury and has to read through it to find out whether it is relevant or not.
- Index/table of contents should comprise two levels of headers, ideally in combination with a change from long sentences to clear, concise headers (see above).

2.3.2. Leaflet design

For the design of Large Print medical leaflets several indicators have emerged:

- **Text size:** The 15 pt text size (in combination with adequate spacing and line width) seems to be acceptable.
- **Single column design:** A clear preference (10 of 14 people) was given to leaflet Type 1, the single column layout with greater line spacing.
- **Column width:** The main reason for choosing leaflet Type 2 was the narrow line width of about 32 characters, which means that the complete line can be seen at a glance. The way forward may be a compromise between the two, creating single column layouts with shorter lines, possibly 45–50 characters.
- **Line spacing:** As guidance suggests, most expressed a preference for the 150 % line spacing over the 125 %. The smaller line spacing resulted in an impression of bold text. However, some did prefer this bolder visual appearance.
- **Differentiation between headers and text:** Contrary to current readability guidelines capital letters, underlining or reversed-out text would be the preferred format for headers. If headers were to comprise one or two words only, these solutions would be acceptable.
- **Index/table of contents:** The index must be instantly recognisable for what it is. Chapter numbers must be clearly distinguishable from page numbering. Page numbering should immediately follow the header concerned, not be ranged right, even if a dotted line is used to link header and page numbering.

3. Summary

Safe use of medicines is a major concern worldwide, and not being able to read key information, for whatever reason, puts the patient at risk.

Visual impairment does not mean that someone cannot read, it simply means that the format of the material provided needs to be adapted. The many different forms of visual impairment make it impossible to provide a perfect solution for all users. By looking at the highest common denominators it is possible to arrive at solutions that are accessible to a majority of visually impaired users.

These results helped identify such common denominators in the context of the European regulatory requirement for patient information leaflets. Some of the results do not concur with established good typography practice or even previously published guidance on Large Print material. A wider study is planned to gather more evidence and substantiate the findings.

Changes to the layout alone cannot effect a substantial improvement in readability. Some features of the current European template make the leaflet more difficult to read than necessary. These features continually cause difficulties in tests with normally sighted participants, and the requirements of people with visual impairments highlight the need for change.

On another level, in order to succeed, the availability of Large Print leaflets must be publicised so that the service reaches those who need it, and solutions must be manageable and affordable for the pharmaceutical industry.

Judging from the reactions of our test participants, accessible, Large Print medical leaflets would have a wide, appreciative audience.

3.300 words

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