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Challenges to Read and Understand Information on Pharmaceutical Packages

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Abstract. In Europe, package leaflets and the outside of medicine packaging provide information about medicines for patients and healthcare providers. Patients, mainly elderly men and women, often take several different medicines on a daily basis. Handling pharmaceutical packaging and leaflets is an unavoidable necessity for them. To read and understand information on pharmaceutical packages requires a combination of physical ability (eyesight and dexterity) and intelligence (relating information to a personal situation). Healthcare providers face similar challenges in their everyday work. Preventing mistakes while administering medication is a subject that concerns healthcare providers all over the world. Unfortunately, accidents with medicines occur because the visual design of information is not seem sufficient to enable people to act appropriately.

In order to evaluate the visual design of information, it seems essential to differentiate between findability, readability, understanding and application. Ignoring these different actions leads to practical problems and increases the risks related to the handling and use of medicines. Currently different types of readability tests are used to evaluate the readability. However, none of them is applicable as such for evaluating findability, readability, understanding and application. Consensus about the test methods and test criteria still needs to be reached, and their validity and reliability are continuously discussed.

In this paper, some of the main factors influencing the practical use of information on pharmaceutical packages are described. The paper examines current practice and the related European guidelines on readability and testing methods. It shows that these guidelines only cover a small area of relevant factors, and they do not really help practice to develop suitable designs of packaging and package leaflets. Thus, it seems necessary to develop specific guidelines for the designing and testing of medicine packaging.

The paper is part of a project on developing tools to produce user-friendly pharmaceutical packages that are easy to open with easy to read and appropriate instructions. These two are critical factors for the safe use of pharmaceuticals. The project includes cooperation between VTT Technical Research Centre of Finland and Avans University in the Netherlands.

Keywords: readability, pharmaceutical packaging, package leaflet, readability test, packaging graphics

1.   Introduction: Is there a Problem?

Medicine packaging and package leaflets provide information to different groups of people. These groups can be characterized as 'consumers', 'patients' and 'healthcare professionals'. Each of these groups can be further subdivided according to particular situations and contexts. For example, the patient group can be crudely subdivided into 'long term users for chronic diseases', 'incidental short term users' and 'patients in hospitals'. The group healthcare professionals consists of different professions such as pharmacists, nurses, doctors and hospital pharmacists. All these groups require different types of information to suit their particular needs. However, it is a necessity for all these groups to be able read and understand given information on pharmaceutical packages.

Visual information will not optimally reach users if the instructions are hard to read or understand. Readability of the text is one of the factors that is causing everyday challenges to people. For example for patients, often elderly men and women, who might have to take several medicines on a daily basis must read, interpret and consider several pharmaceutical packages at the same time. This causes insuperable challenges in everyday life. Health care professionals face similar challenges in their work environment. Preventing mistakes while administering medicines is a subject that concerns healthcare workers all over the world.

In order to apply information correctly to a specific situation, at least four steps need to be undertaken. The information need to be found ('findability'), read ('readability'), interpreted ('understandability') and applied ('applicability'). All four factors are influenced by graphic variables like the size of the text, type face, colours and contrasts, number of different languages used, and the use of pictures [1,2,3]. Each of these four steps can go wrong and can create problems for people who need to handle medicine packaging. In order to reduce the potential risks involved, it seems worthwhile to investigate the visual design of the information on medicine packaging in relation to these four steps and consider the extent to which the current designs helps or hamper these steps.

2.   Current State of Readability Testing and Guidelines in the European Union

In most cases medicines are packed in primary packaging (e.g. blister packaging) and secondary packaging (e.g. cardboard box), inside the secondary packaging is the primary packaging and the packaging leaflet.

The basis of the contents and design of the package leaflet and packaging is given in a European guideline [4]. According to this guideline information must be 'written and designed to be clear and understandable' and the package leaflet must be tested to show that it is 'legible, clear and easy to use'.

2.1 Writing: Information Contents

The information that must appear on the packaging and in the package leaflet is stated in the European legislation (Directive 2004/27/EU) [5]. In addition, the European Medicines Agency has developed a template and instructions to provide practical guidance to write this information [6]. The use of a template has very clear benefits for the standardisation of packaging and package leaflets. On the other hand, it is unlikely that strict standards will be 'the most optimal format in all circumstances' [7]. There might be a need for a variety of

alternative formats that are sensitive to the differences between medicines, people, languages, and contexts of use [7]. Surprisingly the purpose of use of the pharmaceutical (for what disease the medicine is intended) is not an obligatory mention in the EU Guidelines [4], although for the user it is one of the main criteria of choosing the medicine.

2.2 Design: Visual Usability

The challenges to read information on pharmaceutical packages are highly influenced by graphical design of the packaging and the typographic variables. These variables include - amongst others - font size and typeface, word spacing, colours used, contrast, layout, use of headings, symbols and pictures, etc. [1,2,3]. However, the typographic variables are not the only factors affecting readability. Different packaging shapes and materials, such as curves and opacity, also affect readability [1].

There are several problems with the description of typographic variables. For example, the metric system is used for dimensions like page size, paper size and margins while typographical units are used to describe the vertical dimension of type.. A 'point' has long been the unit for measuring type size. The size of one point varies between 0.35 to 0.38 mm, depending on country, so it is a relative unit [8]. In addition, the type face affects the text height – e.g. Garamond is a small font and Futura is a large one because Garamond has a relatively smaller x-height in relation to its capital height and smaller width/height ratio, while Futura has a relatively large x-height in relation to its capitals and also bigger width/height ratio. Moreover, many computer programs use line height, in which line height is 120% from text height. This is a questionable ratio, because there is little relation between the height of a character and its point size. Typedesigners can choose the height of a character as long as they keep the baseline the same. This is why a '9 point Arial' is substantially larger than a '9 point Times New Roman'. Simply multiplying the type size in points by 120% does rarely create an optimally readable text. In order to determine and compare the text height of printed font, the x-height needs to be measured [9].

The EU Guideline [4] advises to choose packaging colours to ensure a good contrast between the text and the background. Good contrast on the other hand is not defined. Many factors, such as contrast, level of lighting, gloss, level of eye adaptation, level of alterness and disturbance, etc. affect how easily people can see and read text [3, 10]. Thus, a good contrast is also related to the user's eye adaption in case contrast is evaluated by users. The exact values can be obtained through experiments. Visibility of an object depends strongly on both size and contrast. It is easier to recognize larger type sizes even with low tone value contrast levels than smaller ones [3]. Size and contrast of text have significant effect on reading speed and interpretation of information [3, 11].

EU guideline [4] provides in section 'A recommendations for the packaging leaflet' several points of advice about the graphic design. Little of this advice is based on evidence, and most of it is very hard to apply in practice. Most of the advice focuses on separate issues without putting these into an overall context. For example, the guideline states for package leaflets:

> "The type size should be as large as possible to aid readers. A type size of 9 points, as measured in font 'Times New Roman', not narrowed, with a space between lines of at least 3 mm, should be considered as a minimum."

This looks like usable advise, but in practice it is very hard to apply. 'As large as possible' does not really aid readers. If all texts are really 'as large as possible', a reader would not be able to

discern the structure of a text. Headings, paragraphs, and captions would all scream for attention. Furthermore, the typographic terminology is not very clear in the guideline. The words 'not narrowed' probably indicates 'condensed'. The last line of this guidance is most problematic. It states 'should be considered as a minimum'. A designer who reads this guideline 'considers this minimum' and could simply decide that it is not suitable. Through this consideration, the designer accurately follows the guideline, but can completely ignore the intention of it.

For labelling (that covers both outer and inner packaging) EU guideline [4] states in section B:

"The particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm."

The difference between the typographic descriptions is apparent. For package leaflets the type size needs to be compared with the relative size '9 points Times New Roman' while for packaging, the absolute dimensions of a lower case x is used. Furthermore, it is strange that for both dimensions of 7 points (packaging) and 9 points (leaflet) the same minimal line space is advised. This is in conflict with most of the typographic literature.

Further advice states:

"Applicants and marketing authorisation holders should make best use of the space available to ensure that the important information is clearly mentioned on prime spaces on the outer and immediate packaging, presented in a sufficiently large type size."

and:

"Colours should be chosen to ensure a good contrast between the text and the background to assure maximum legibility and accessibility of the information. Highly glossy, metallic or reflective packaging should be avoided, as this affects the legibility of the information."

These advice only cover a small area of relevant graphic design factors and leave many issues completely open. According to the typographic literature [e.g 12], the type size of the different components of a text need to be balanced in such a way that these individual components can be read, and at the same time that the relations between components becomes visually clear.

2.3 Testing: Effectiveness?

An example of a test method for package leaflets is described in the guideline [4]. The test consists of at least three series of one-to-one interviews. The first series is a pilot test and consists of three to five interviews. After that, at least two series of ten interviews is undertaken. In total, between 23 and 25 people are interviewed for each package leaflet. In each interview, a participant reads the test-leaflet and the interviewer asks about 15 questions. The questions are related to the activities that poses the highest potential risks. The interviewer takes notes and scores the correct answers. The aim of the test is to meet the success criteria in total of 20 participants. For each question, at least 16 people out of 20 need to be able to find and understand the information. It is clear that the impact of choosing these only 20 participants is critical, and might lead to different conclusions. This test method for package leaflets mainly concentrates on the 'findability' and 'understandability' of the printed information. However, it does not specifically measure each of these actions separately. Rather surprising, there is neither obligation nor advice to test the outer packaging of medicines.

3. Future Perspectives in Readability Testing

Based on the above described limitations of the current guidelines it seems obvious that other kind of approaches in solving the reading and understanding challenges are requested.

3.1 Readable Text is a Prerequisite for Understanding

It seems essential to differentiate between the four steps that are mentioned earlier. findability, readability, understanding and applicability. Information needs to be found first and visually interpreted after that. If a text can be read – it is readable for the reader, but this does not mean that it can be understood. Findability and readability of the text are prerequisites for understanding and comprehension of the message. The interdependency can be described as:
  A) Findability: text can be detected
  B) Readable: text can be read
  C) Understandable: content of text can be understood (comprehension)
Prerequisites for comprehension (C) are findability (A) and readable text (B). Keeping this interdependency in mind, it becomes clear that in order to achieve understandable text, it is worthwhile to investigate readability.

Challenges to read information on pharmaceutical packages are highly influenced by the typographic variables and graphical design of the packaging. The challenges to understand the information on pharmaceutical packages relate to the comprehension of the information, choice of words, number of languages used etc. Both poor readability and difficulties in understanding the information are possible risk factors for the safe handling of medicines.

In addition, the contexts affect the easiness to read and understand information on pharmaceutical and handling and use of medicines. One example is the similarity in packaging that can bring serious risk in handing and use of medicines. For example two years ago in a Finnish hospital two bottles used in a hospital environment were mistaken with serious consequences [13]. One of the bottles contained sucrose liquid while the other one contained caustic detergent liquid. Accident happened when a nurse accidentally gave the detergent to three infants. The accident highlighted the importance of packaging information in communicating differences and help recognition. Similar risks and communication problems can occur also e.g. with packaging designs too strongly uniformed by the brand image (as a product family). According to a study made by a Finnish pharmacist magazine similarity in packaging is causing problems every week in eight out of ten pharmacies [14]. In total 40% of private Finnish pharmacies responded to the query, and over 50% of the respondents felt that the biggest problem was too similar packages for different medicines (from the same company) [14]. The respondents were also concerned how the users of the medicines, often elderly people, will differentiate the packages at home [14]. Larger type size and use of colours in indicating the strength of the medicine were desired by the pharmacists [14].

3.2 Development of Novel Readability Testing

There are several options how readability testing of the information of pharmaceutical packages could be improved. At the moment the testing criteria, validity and reliability still need to be ascertained. It is necessary to develop and evaluate alternative testing methods. First

of all, aiming to improve the validity and reliability of the test, a trained sensory panel could be used in testing instead of using a small number of subjects (n=20) in a consumer test.

Understanding the connection between the choice of graphic variables and the easiness to read is very important. Criteria for the measurable graphic variables should also be considered, since simply by stating "good contrast" or "large type size" a consensus of the criteria will be unclear. When designing packaging graphics, the starting point should be that measured values could be used as designing tools for visual quality and even to predict the final easiness of reading.

Test methods to assess the easiness to open packages by descriptive sensory profiling [15, 16] and to evaluate the easiness to read text [1,2] have been developed at VTT. The 'Easy to open' test method is intended to be used while studying the easiness to open packages with various types of opening mechanisms. The sensory expert panel evaluates the easiness to open the sample packages in two replicate sessions by using the method VTT-5631-09. The descriptive profiling method is used by a trained sensory panel (n=10), which assesses the attributes describing the easiness to open the sample packages concerning both the opening mechanism and package by visual and tactile evaluation by using a linear intensity scale of 0-10. Now the 'Easy to read' test method intended to be used while studying the easiness to read text on packages and package leaflets will be developed by using a similar approach. The 'Easy to read' test will be published after finalizing its validation process and setting the acceptance criteria by consumer panels.

4. Conclusions

In order to use information about medicines, it is necessary that this information can be found, read, understood and applied. The current way of develop this information is tightly controlled and regulated. The textual contents are stated in legislation and must follow a strict template that is identical for all medicines. The visual design of packaging and package leaflet is guided and controlled by European guideline on Readability. And the testing of the information in package leaflets is obligatory. This approach of 'writing, designing, testing' is commendable but also has proven to deliver results that can be critically questioned.

The standardized template and rigid information sequence in the package leaflet makes it hard for patients to find information. Standardized warnings are less effective because they need to be consciously ignored if they are inapplicable. Alternative information contents need to be developed and tested. The guidelines related to the design of packaging and package leaflets are hard to use and incomplete. Furthermore, it is very hard to check afterwards if a design conforms to the guidelines. And a critical look at the obligatory testing reveals that this approach only tests one type of user group (representatives of patients) and only the package leaflet. Other user groups, such as nurses or pharmacists, other information sources (packaging), and other contexts (multiple medicines, hospital use) is not tested.

For these reasons, it seems necessary to reconsider the writing, designing and testing of information about medicines on packaging and in package leaflets. One of the possible starting points is to consider the testing method and criteria for packaging. The current legislation and guidelines do not cover this area and it seems appropriate to develop and compare alternative testing methods.

An alternative - or an addition - to the existing consumer test method described in the EU Guidelines is in the pipeline. 'Easy to read' test method intended to be used while studying the easiness to read the text on packages and package leaflets is under development at VTT. The

test method will use the descriptive sensory profiling method. Using this starting point, the aim is to cover issues that are now missing in the current testing, and to help check and compare how the visual design will have impact in actual easiness to read.

References

[1]   Rusko, E. Pakkausmerkintöjen luettavuus, tekstin koko pakkauksissa (Readability of packaging markings, text size on packages). Helsinki 2003. Association of Packaging Tchnology and Research. PTR report n. 50. 41 p.

[2]   Kiesvaara, M. & Kivikataja, R-L. Evira report/ VTT research report ELI8826/88. Makeisten myyntipäällysmerkintöjen selvyys ja havaittavuus-tutkimus (Study on the readability and perception of texts on confectionery packages) . 1988.

[3]   Näsänen, R. Visuaalisen käytettävyyden opas (Guide to visual usability), 2007. Helsinki. Työterveyslaitos. Available from: http://www.ttl.fi/fi/ergonomia/kognitiivinen_ergonomia/visuaalinen_kaytettavyys/Documents/Visuaalisen_ka ytettavyyden_opas_2007.pdf Cited 20.3.2012

[4]   European Comission. Guideline on the readability of the labelling and packaging leaflet of medicinal products for human use. Revision 1, 12 January 2009. Available from http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf Cited 20.3.2012

[5]   Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, 31 March 2004.

[6]   European Medicines Agency. Product Information: Regulatory and procedural guidance. QRD Templates. Available from http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000267. jsp&jsenabled=true#section2 Cited 28.3.2012

[7]   van der Waarde, K. Measuring the quality of information in packaging leaflets: harmful or helpful? Information Design Journal 2008; 16(3). pp. 216 – 228. DOI:10.1075/idj.16.3.05waa.

[8]   Boag, A. Typographic Measurement: a chronology', Typographic papers (1), 1996, pp. 105-121.

[9]   van der Waarde. K. Typographic Dimensions and Conventional Wisdom: A Discrepancy? Technical Communication, 46. (First Quarter 1999). pp. 67 – 74.

[10] Oittinen, P., Saarelma, H. Kuvatekninen laatu. Otatieto 881. Espoo1992. 141 p.

[11] Wogalter, M.S. & Vigilante, W.J. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. Ergonomics Vol. 46 (2003) 4. pp. 327 -344. DOI:10.1080/0014013021000048006.¨

[12] Baines, P., Haslam, A. Type and typography. (2002) London: Laurence King Publishing.

[13] YLE News. Kolmelle hoitajalle syytteet: vauvoille juotettiin syövyttävää puhdistusainetta. Published 1.12.2011. Available from: http://yle.fi/uutiset/kotimaa/2011/12/kolmelle_hoitajalle_syytteet_vauvoille_juotettiin_syovyttavaa_puhdistus ainetta_3072397.html Cited 21.3.2012

[14] Kuosa, T. Vaarallisen yhdennäköistä. Results from the study made by the Finnish pharmacist magazine. Apteekkari 3/12 2.3.2012. pp. 12-17.

[15] Heiniö, R-L., Ström, T., Järvi-Kääriäinen, T. & Ollila, M. How to test the easiness to open packages. . Proceedings of the 17th IAPRI world conference on packaging, Tianjin, China, 12-16 October 2010. pp. 686-690.

[16] Heiniö, R.-L. 2011. Help - easy to use pharmaceutical packaging. DOSIS 27 (2), 59-62.