

How best to assess paper quality for package leaflets – weight or opacity?

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■ ABSTRACT

The opacity has a significant influence on the legibility of package leaflets. This applies for example to the contrast between font and paper colour. The results of two investigations of 258 randomly selected German package leaflets show that opacity is a more appropriate tool for assessing paper quality than the paper weight recommended in the readability guideline.

■ ZUSAMMENFASSUNG

Wie lässt sich die Papierqualität von Packungsbeilagen am besten bewerten – mittels Papiergewicht oder Opazität?

Die Opazität hat einen signifikanten Einfluss auf die Lesbarkeit von Packungsbeilagen. Dies betrifft z. B. den Kontrast zwischen der Schrift- und Papierfarbe. Unter Berücksichtigung der Ergebnisse von zwei Studien mit 258 randomisiert ausgewählten deutschen Packungsbeilagen ist die Opazität ein besser geeigneter Qualitätsparameter des verwendeten Papiers als das in der Readability Guideline angegebene Papiergewicht.

■ KEY WORDS

- opacity
- readability guideline
- package leaflet
- package insert
- paper weight

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1. Introduction

Recommendations to ensure an appropriate paper quality for package leaflets have been part of various European Union guidelines over the years. The first readability guideline, published in 1998, stated “*Paper weight should be no less than 40 g/m². Thinner paper may be too transparent and thus difficult to read.*” [1] The current guideline version, published in 2009, changed this to “*The paper weight chosen should be such that the paper is sufficiently thick to reduce transparency which makes reading difficult, particularly where the text size is small. Glossy paper reflects light making the information difficult to read, so the use of uncoated paper should be considered.*” [2] Also the MHRA’s Committee on Safety of Medicines, Working Group on Patient Information outlines the importance of the paper weight in its report “Always read the leaflet”; however, without providing any specification [3].

Any increase in paper thickness/paper weight demands more space for leaflets within packaging – thereby influencing the production process, including costs. At and beyond a certain volume, the folded package leaflet requires larger outer packaging, forcing changes in packaging lines for the pharmaceutical industry. Allied to the increased 9pt minimum font size for package leaflets recommended in the updated readability guideline – and the continual increase in the word count – larger leaflet sizes and an increased volume of the folded leaflet seem inevitable [3, 4]. This promotes a closer look at thinner paper.

A study of different papers used in package leaflets showed that paper weight and thickness are not universal quality parameters, because paper with low grammage can have a similarly high opacity – the measure of impenetrability of visible light – to heavier paper [5].

However, no European Union guideline defines the meaning of “sufficiently thick”. This begs the question of whether thick paper or high paper weight is best for

package leaflets, or is opacity a better criterion for assessing the qualities of paper with regard to legibility?

To provide solid responses to these questions, the data from two studies were analysed.

2. Material and methods

The representative selection of 271 German package leaflets available in 2005 was involved in a study in which every package leaflet investigated was analysed using 152 validated quality criteria and by measuring 242 other values; including paper weight, word count, contrast between font and paper colour (PAINT2 study) [4]. The opacity of these leaflets was measured by OP papirna s.r.o. (Olšany, Czech Republic) according to ISO 2471.

The second study used was the PAINT3 study; here all 271 package leaflets were readability tested between September 2008 and May 2009 in Jena (Germany) and its surrounds using the written readability test method – this method is accepted across the EU and removes “...any external negative influences which may occur in a face-to-face interview” [6]. Each off the 5091 participants tested just one package leaflet, using only the written instructions provided in the questionnaire, under one tester’s supervision. In accordance with predefined criteria, minimum 15 people were recruited per leaflet, with healthcare professionals excluded. Twenty five questions were asked related to the content of each leaflet to assess the locatability and comprehensibility using a questionnaire. In addition, participants’ opinions were requested to 18 different aspects of the package leaflets, such as contrast and motivation to read the information.

All data was coded in a SPSS 18.0 statistic program table and rechecked via double data input. Afterwards, averages, minimum, maximum and correlation coefficients after Spearman were calculated using this software.

3. Results

Of the 271 package leaflets, 13 had to be excluded from measuring the opacity according to the following predefined criteria (3 × self-adhesive labels, 5 × package leaflet with soiled edges, 2 × coloured paper, 2 × leaflets with coated paper, 1 × unmeasurable leaflet). The remaining 258 package leaflets were from 79 different pharmaceutical companies. Three quarters (n = 191) were from medicines available only on prescription. At 75.6 %, the portrait format was most commonly used, followed by the landscape format (22.5 %); the remaining 1.5 % used a quadratic size. Only three leaflets used glossy paper (0.4 %).

The average paper weight was 52.5 g/m² (minimum 38.9 g/m², maximum 85.8 g/m²), whereby only 9 leaflets had a grammage of less than 40 g/m² and accumulations were found in the following three groups: 40, 50 and 60 g/m² (± 2 g/m²). The average opacity was 83.2 % (minimum 72.0 %, maximum 94.2 %) with a strong accumulation between 80 and 90 % (fig. 1). The date of the most recent update bore no significant influence on paper weight or opacity. However, a significant correlation exists between paper weight and opacity (p < 0.001; correlation coefficient: 0.500).

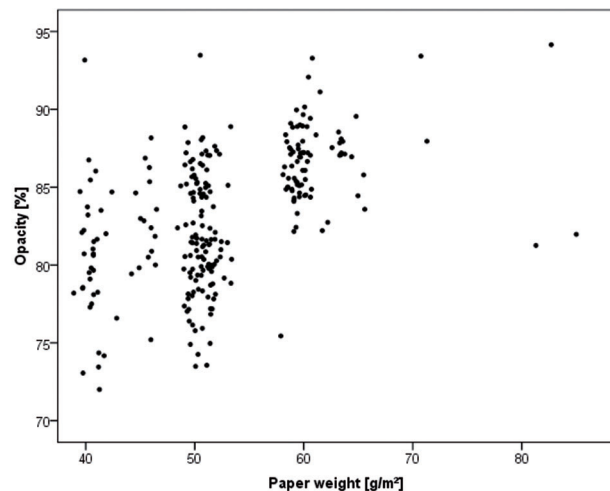


Fig. 1: Opacity and paper weight distribution (n = 258 package leaflets) (Source: all figures and tables were made by the authors).

Other correlations were found; an increase in the number of words contained in the 258 leaflets investigated, corresponded to a significant decrease in paper weight, opacity and font size and an increase in the format size (p ≤ 0.001; correlation coefficients: -0.203, -0.256, -0.363 and 0.824).

The average contrast between font of the main text and paper was 14.0 : 1 (minimum: 2.4 : 1; maximum: 19.2 : 1); measured after standardised scan and using the software Colour Contrast Analyser, version 1.2, whereby the contrast per package leaflet is the mean of measurements in five different chapters.

Both – the opacity and paper weight – showed a low; however, significant correlation to the contrast, whereby the opacity showed a higher correlation (p = 0.001, correlation coefficient: 0.211 versus p = 0.003, correlation coefficient: 0.186). Table 1 illustrates that the opacity influence on the contrast was highest in the group of lowest paper weight.

Of the two colours most frequently used, black has a significantly higher contrast, whereby pharmaceutical companies used higher grammages here, but smaller font sizes (table 2). The 141 package leaflets with black font and a minimum opacity of 80 % showed – at 15.3 : 1 – a significantly higher contrast than the remaining 39 leaflets with black font and lower opacity (13.8 : 1; p < 0.001).

The readability test results showed that the participants required, on average, 25 minutes (minimum: 11, maximum 41) to locate and provide the information relating to the 25 content questions. Increasing the opacity or the paper weight means less time was required by the participants (correlation coefficient of opacity: -0.170 [p = 0.006]; correlation coefficient of paper weight: -0.134 [p = 0.031]); however, the font size had 1.5 times, and the word count 4.4 times, higher correlation coefficients than the opacity. This illustrates the main influence of the word

■ **Table 1**

Correlation of the opacity and the contrast between the colour of the font and the paper found in package leaflets.

Paper weight [g/m ²]	Number of package leaflets [n]	Correlation opacity/contrast	
		significance [p-level]	Correlation coeffi- cient after Spearman
38 to 42	33	0.008	0.456
48 to 52	113	0.003	0.281
58 to 62	63	not significant	-0.067
Total	258	= 0.001	0.211

■ **Table 2**

Contrast between font and paper colour, opacity and paper weight itemised according to the font colour.

Font colour	Number of package leaflets [n]	Contrast	Font size (descender to ascender line) [mm]	Opacity [%]	Paper weight [g/m ²]
Black font	180	15.0 : 1	2.4	83.8	53.5
Blue font	30	9.5 : 1	2.6	81.6	48.4
p-level between font colours (Mann-Whitney U test)	-	< 0.001	= 0.001	0.033	= 0.001
Total	258	14.0 : 1	2.4	83.2	52.5

count on the locatability; particularly, as the volume of text correlated with the opacity.

The subanalysis of two package leaflets groups with similar word counts (600 to 1400 and 2800 to 3200 words) confirms this. It showed no correlation between locatability time and the opacity of the paper. Also, no influence of the opacity on the fraction of located information and the comprehensibility was found.

The analysis of the 18 requested participants' opinions of the package leaflets showed that other aspects exerted a greater influence than the opacity. For example, the font size had 2.6 times and 4.2 times higher correlation coefficient on the following two requested opinions – “The contrast between the colours of the font and the paper supports the readability of the text.” and “The text is easy to read.” – than the opacity. An investigation of a leaflet group with a similar font size (2.25 to 2.55 mm; n = 128) showed no significant influence of the opacity on both requested opinions.

4. Discussion

According to the results and the readability guideline, opacity influences legibility, as do other aspects such as font type, font size, and paper and font colour [2]. However, it showed no influence on the readability, which covers the locatability and comprehensibility of the information provided in package leaflets.

The findings illustrate that thicker paper or higher paper weight do not ensure good legibility as, according to table 1, paper types with similar grammages, e.g. of around 50 g/m², have a broad range of impenetrability of visible light from low to high levels. This is supported by findings of Feldmüller et al. published in 2011, on basis of 60 investigated paper types used in package leaflets [5]. Furthermore, paper types with low grammage are appropriate if they have a sufficient opacity. The qualities of such thin papers with high opacity are interesting given that the aforementioned continual volume of text increase and the rise to minimum 9pt font size recommended in the readability guideline since 2009 require larger leaflet formats [2, 4, 7]. If the end-folded larger sized leaflet – with

thinner paper – requires similar space to the currently used higher grammage leaflet, then time and cost-intensive changes to the packaging process can be avoided.

While accepting that many paper types used in the 2005 package leaflet study may no longer be in use, the results of this investigation illustrate that the opacity is a more appropriate quality parameter than the paper weight as it has stronger correlations to legibility aspects. Therefore, the European Commission should consider updating the readability guideline by replacing the emphasis on paper weight with opacity. This step would bring the readability guideline in line with other accepted guidelines, such as the norm DIN 1450 published in April 2013, which defined the opacity as a character carrier dependent effect on the legibility without mentioning the paper weight [8].

In addition, a minimum opacity should be defined for package leaflets. Paper types with minimum 80 % opacity are already available and significantly increase the contrast between the font and its background.

5. Conclusion

The paper weight is less appropriate for assessing paper quality than the opacity; therefore, it should be replaced by the opacity in the readability guideline and in practice.

Conflict of interest

The authors declare that they have no conflict of interest.

They confirm that all patient/personal identifiers have been removed or disguised so the patient/person(s) who participated in this study are not identifiable and cannot be identified through the details provided.

REFERENCES

- [1] European Commission. A guideline on the readability of the label and package leaflet of medicinal products for human use, Brussels, 29. September 1998. http://pharma.be/assets/files/854/854_128901376878944246.pdf, accessed July 20, 2015.
- [2] European Commission. Guideline on the readability of the labelling and package leaflet of medicinal products for human use, Revision 1, 12 January 2009. http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf, accessed August 22, 2014.
- [3] MHRA. Always Read the Leaflet – Getting the best information with every medicine:1–165. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet_getting_the_best_information_with_every_medicine.pdf, accessed July 10, 2015.
- [4] Fuchs J, Werner S, Scheunpflug C, Götze EA, Elstermann K, Scheffel K et al. Excessive medical information increase in package inserts. *Int J Clin Pharmacol Ther* 2010;48:781–90.
- [5] Feldmüller T, Wesch M, Kutscha M. Die EU Readability Guideline: Auswirkungen auf die Packungsbeilage. *PharmInd* 2011;73:441–46.
- [6] CMD(h). Position paper on user testing of package leaflet – Consultation with target patient groups (Compliance with article 59(3) of Council Directive 2001/83/EC), Doc. Ref.: CMDh/234/2011 – February 2011. http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/_procedural_guidance/Consulation_PatientsGroups/CMDh_234_2011.pdf, accessed August 22, 2014.
- [7] Wolf A. An analysis and evaluation of the development of the QRD human product information template used in package leaflets [dissertation]. University of Bonn, 2014.
- [8] DIN Deutsches Institut für Normung e. V. DIN 1450. <http://www.din.de/cmd;jsessionid=S1H1TR5HJ7FNSB8PYKCYWZ.1?languageid=de&workflowname=dinSearch>, accessed August 22, 2014.