Reading Digital Medicine Leaflets in Mobile Devices an Interactive Study Conducted in Brazil

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Abstract. This paper describes an interaction study conducted in Brazil that aimed to investigate how people read a digital medicine leaflet in a mobile device. This insert summarizes the main typographic characteristics of Brazilian current digital leaflets. Tests were held with the participation of 20 volunteer individuals and consisted of four stages: (1) definition of participants' profile, (2) task 1: finding specific information in the digital leaflet, (3) Task 2: reading the digital leaflet in a mobile device, (4) follow-up interview. According to the results of the interaction test, there is evidence that the current structure of the digital medicine leaflets in Brazil is not designed for access via mobile devices. The findings of this study point to the need of information design guidelines for the Brazilian digital medicine leaflets, considering interactivity and navigability aspects. It is important to propose new solutions for digital leaflets and test them with people, in order to ensure the legibility and usability of these documents.

Keywords: patient information leaflets, mobile devices, usability.

1 Introduction

Medicine information leaflets are frequently regarded as documents with several problems concerning legibility and readability. Small letters, lack of attractiveness, technical language, poorly defined information hierarchy and paper transparency, among others, are examples of these deficiencies [1-5]. In contrast, the literature states that medicine leaflets play a very important role in providing information about healthcare for patients [1-3]. In order to make people become aware of the rational use of medicines and to help them getting involved in medical decision making, the PILs (patient information leaflets) are considered tools to empower patients [6-9]. Such discourse is a central point of some health policy moves in countries around Europe, US, Australia and New Zealand [2].

Legislations enacted in several countries try to address these issues, but the lack of strong evidences about how to write, design and deliver information about medicines has led to many different approaches [2]. In Brazil, since 2003 the National Health Surveillance Agency (Anvisa) regulates form and content for medicine leaflets [10], [11]. Along with regulations for the print versions of leaflets, Anvisa has also instituted the digital medicine inserts, available online on the system *Bulário Eletrônico*

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(electronic archive of medicine leaflets). This database has been released in 2005 [12] and provides free access to information leaflets for many of the medicines sold in Brazilian drugstores. There are two versions available for each leaflet: one produced to inform patients and another specifically made for health professionals. The first one must contain summarized information, written in appropriate and plain language [11]. On the other hand, leaflets intended for the use of health professionals need to present technically detailed information [7]. Distinguishing between professional and patient information leaflets is a legal obligation in Brazil since 2003, as a revision process of the national legislation about medicine leaflets [10], [13]. These changes in legislation have also been important in order to provide tools for the management of medicine leaflets produced in Brazil, creating an electronic system to that purpose called *E-Bulas* and the abovementioned archive of medicine leaflets, *Bulário Eletrônico* [12], [13], [14].

With the rise in sales of smartphones and the growing number of accesses to the web in mobile devices in Brazil, it is important to consider designing content to be accessible in such equipments. However, the current structure of *Bulário Eletrônico* demonstrates lack of concern to this statement. Patient and professional information leaflets are available as PDF files, which demand that people download them before having access to the content. Moreover, the configuration of these digital leaflets is clearly oriented for print and not for reading in electronic devices.

2 Digital Medicine Leaflets as Print Documents

Despite the efforts made by Anvisa to regulate and establish a minimum quality standard for content and form of medicine leaflets, the electronic versions of these documents are practically ignored in the Brazilian legislation. The current legal text, published in 2009 and corrected in the beginning of 2010 [11], provides guidelines to typographic aspects such as the choice of typeface, minimum body size for text setting, measure of text columns, leading – interline spacing –, text alignment, use of uppercase letters, bold, italic and underline to highlight text passages. All these specifications clearly define formatting of print documents. There is only one paragraph that describes the form of leaflets for publication in *Bulário Eletrico*, stating that these versions should not be set in more than one column of text.

Comparing the currently available digital leaflets to the literature about typography, there is evidence that many problems regarding legibility and definition of hierarchy occur in the formatting of the leaflets. Such problems include excessively lengthy lines of text, insufficient leading, tracking disorders, with altered word spacing and weak differentiation of hierarchical levels of information. Thus, the documents available on the electronic archive of medicine leaflets still show several deficiencies related to the graphic presentation of content. So, it is questionable if the problems detected can have any influence in reading the digital leaflets in mobile devices, due to the limitations in the screen size, the interaction in the touch interface, the use of zoom and pan gestures.

3 Investigating How People Read Digital Leaflets in Mobile Devices

In order to address the questions raised before about reading digital leaflets in mobile devices, an interaction test with 20 participants was conducted in Brazil. It was designed based on former research on reading strategy for print leaflets held by Fujita [15], and on the study about interaction in handheld devices by Pottes [16]. The interaction test also followed some of the guidelines for readability tests conducted in the European Union, especially regarding the number of participants [17]. Each person was asked to read a fictitious digital leaflet in an iPod Touch device, and then to engage in a follow-up interview. The leaflet prepared for this study was set in order to reproduce the most frequent typographic patterns found in Brazilian digital inserts. Therefore, the main characteristics of the document were:

- Size: A4 (210 × 297 mm);
- Margins: 28 mm (superior and left), 26 mm (inferior and right);
- Typeface: Times New Roman;
- Body size: 10 pt;
- Leading (interline spacing): 12 pt;
- Column measure: 156 mm – 109 characters per line;
- Text alignment: justified.

All results were video recorded, and participants' navigation in the digital leaflet, the use of zoom and pan gestures were assessed through screen captures.

3.1 Defining Participants' Profile

In this first part of the interaction test, participants were asked to write down in a questionnaire some information that could be used to identify their profile. This includes genre, age, level of education and also data about habits of reading patient information leaflets, opinions about quality of graphic presentation of these documents and familiarity with mobile devices.

The sample of 20 participants was selected so as to have equal numbers of male (n = 10) and female (n = 10) individuals, since this study did not consider possible discrepancies in the variable genre. Former research did not indicate the occurrence of noticeable disparities in the distribution of genre in readers of medicine leaflets [4]. Concerning age, there was no control over this variable and the sample was formed by people from the following groups: 18–25 years old (n = 13), 26–30 years old (n = 2), 31–40 years old (n = 3) and more than 50 years old (n = 2). The analysis of level of education showed that most of the participants (n = 12) were undergraduate students.

When asked about familiarity in reading patient information leaflets, participants generally rated themselves with medium or high levels (n = 12). Regarding quality in the graphic presentation of leaflets, the results point that it has been assessed as medium (n = 6) or low (n = 12). Comments justifying these opinions frequently cited the same deficiencies indicated in the literature, particularly the small letters (n = 15). Opposed to the familiarity with printed leaflets, most of the participants were unfamiliar with digital leaflets (n = 18). However, this is not due to lack of contact with electronic devices. It has been found that participants had medium or high levels of familiarity with mobile devices (n = 18).

Since not all of them declared to be accustomed to using devices such as iPod, iPhone and iPad, a brief training stage was offered to level the people who engaged in the interaction test. Participants had a small tutorial on how to use zoom and pan gestures (these last ones referred to as horizontal and vertical scrolling) to navigate through a PDF file opened in the web browser Safari for iOS on an iPod Touch. The first practical task of the interaction test started after this stage.

3.2 Task 1: Finding Specific Information in the Digital Leaflet

In this first task, participants were asked to find some pieces of information in the text of a fictitious digital leaflet prepared for the study. The questions have been formulated in order to contextualize situations in which people need to find information in leaflets, as recommended by Maat and Lentz [18]. To provide the answers, participants had to relate aspects of graphic presentation and understand the hierarchy of text elements in the digital leaflet.

When asked to find a warning, people often confused this kind of information with secondary headings (n = 5) or lists (n = 11) due to the similarity in the typographic setting. Similar findings were reached when participants had to relate a primary heading to another element in the document hierarchy. Different kinds of information, such as the main title of the leaflet (n = 3), secondary headings (n = 18) and warnings (n = 2) have been pointed as answers, along with the correct item (n = 4). Some individuals indicated more than one item as answer, so the sum of results is more than the number of participants.

To finish this task, people should find a specific section of the text and differentiate a third level heading from a warning. Because of variations in the length of these two sorts of information, the participants could tell one from the other easily, despite the resemblance in the typographic patterns of both. In this case, context of the information in the text aided people to distinguish the hierarchical structure, but the same did not occur on the first questions, when the typographic style of formatting confused the participants and led them to relate items improperly.

After this task of finding information, the individuals were requested to read the leaflet in the following step.

3.3 Task 2: Reading the Digital Leaflet in a Mobile Device

As an instruction to carry on this second task, participants were asked to read the digital leaflet naturally, as if they were in a real situation of use of that medicine. Thus, there was no need to read the whole document, only the parts they use to read. In addition, the individuals should perform this reading loud, so that their comments and the precise indication of what sections in the text they were paying attention to could be registered in audio.

The results of this phase of the interaction test revealed frequent use of pan gestures to scroll in both horizontal and vertical directions. From the 20 participants, it has been noticed that 14 used this pattern as a way to move through the text of the digital leaflet. Another important aspect observed was the orientation of the device. There was a subtle preference for the horizontal arrangement, maintained throughout the task by ten users. Among the remaining individuals, eight used the device in the vertical orientation to perform the complete reading task, whilst two other people, although having started the activity with the iPod Touch in the vertical position, opted to change it to the horizontal arrangement.

Using zoom gestures was also a recurring feature during the reading of the digital leaflet. Throughout the tests of the 20 participants, it was observed that they used gestures to zoom in content 70 times, while zoom out was used 58 times. In some cases, inaccurate gestures of panning or zooming made people involuntarily activate the text selection tool. In this situation, a magnifying glass appears to help the user select the desired passage of text. However, this feature is not intended to assist in reading and may cause some kind of discomfort to individuals. This is an event observed in 12 of the 20 interaction tests, with a total of 28 documented occurrences.

In a more detailed examination of specific aspects of the interaction test, it was found that the reading time varied greatly between users, with a minimum of 1min 53s and a maximum of 16min 20s. In average, people took approximately 7min 33s to read the leaflet. Among the 14 items in the text structure, the ones that demanded longer reading time of the participants were: *4. What should I know before using this medicine?* (2min 7s average), 8. *What kinds of harm this medicine can cause?* (1min 30s) *6. How should I use this medicine?* (1min 13s). Fig. 1 shows the average time calculated for all 14 topics in the digital leaflet used during the reading task.

Results obtained for use of zoom (Fig. 2) reveal relevant parallels with the time that participants required in reading the leaflet. Similarly, the items on which participants used more gestures tom zoom in and out were: *8. What kinds of harm this medicine can cause?* (zoom in: n = 11, zoom out: n = 12), *4. What should I know before using this medicine?* (zoom in: n = 13, zoom out: n = 9), *6. How should I use this medicine?* (zoom in: n = 9, zoom out: n = 9). In addition, topic *1. Why is this medication prescribed?* also presented results that stand out for the use of the zoom (zoom in: n = 10, zoom out: n = 8), although the average reading time was low (28s). This must be due to the fact that this section has a smaller length than the others previously mentioned.

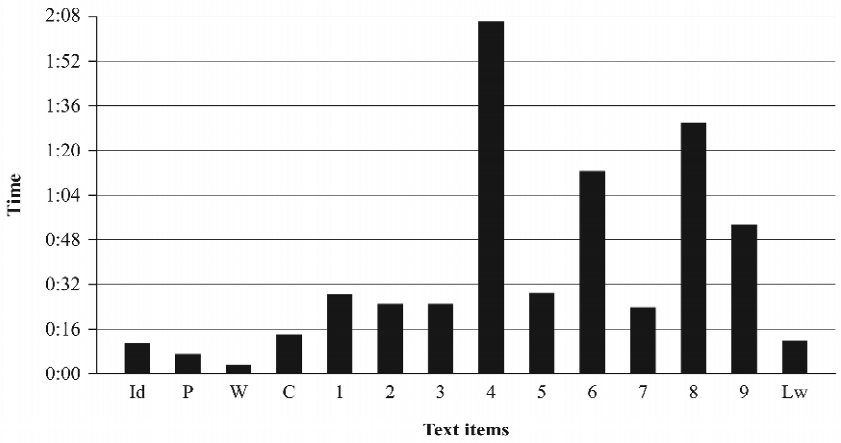

Fig. 1. Average time required by participants to read each item of the digital leaflet

Id: Medicine identification – name and active ingredient; P: Presentation; W: Warnings; C: Composition; 1: Why is this medication prescribed?; 2: How does this medicine work?; 3: When should I not use this medicine?; 4: What should I know before using this medicine?; 5: Where, how and for how long can I store this medicine?; 6: How should I use this medicine?; 7: What should I do if I forget to use this medicine?; 8: What kinds of harm this medicine can cause?; 9: What if someone uses a larger amount of this medicine than indicated?; Lw: Legal wording

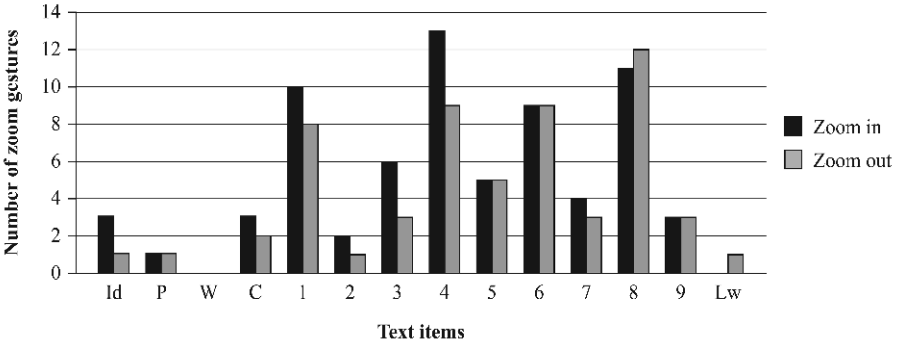

Fig. 2. Use of zoom gestures while reading each item of the digital leaflet

Id: Medicine identification – name and active ingredient; P: Presentation; W: Warnings; C: Composition; 1: Why is this medication prescribed?; 2: How does this medicine work?; 3: When should I not use this medicine?; 4: What should I know before using this medicine?; 5: Where, how and for how long can I store this medicine?; 6: How should I use this medicine?; 7: What should I do if I forget to use this medicine?; 8: What kinds of harm this medicine can cause?; 9: What if someone uses a larger amount of this medicine than indicated?; Lw: Legal wording

Concerning the exploitation of textual structure of the leaflet, it has been noticed that the items pointed out by the results obtained for average reading time and zooming were read by of most participants: item 1 (n = 17), item 4 (n = 19), item 6 (n = 20), item 8 (n = 19). These topics are part of a section entitled *Patient information*. This section attracted in general more people's attention. Information regarding the *Identification of the medicine* (items Id, P, W and C) and *Legal wording* (item Lw) were commonly dispensed by users.

The results for average time of reading and use of zoom gestures point that participants developed a more careful and detailed reading, as intended for this task, in items 1, 4, 6 and 8. Specifically in these topics, the use of horizontal scrolling was frequently observed among participants: item 1 (n = 8), item 4 (n = 11), item 6 (n = 11), item 8 (n = 12). Use of horizontal scrolling is regarded as something tedious and dull, that should be avoided [19]. Additionally, the combined use of scrolling in both horizontal and vertical directions is discouraged [20]. The need of using horizontal scrolling is due to the oversized column measure and the small letters. Therefore, readers need to zoom in so they can identify the typographic characters; in doing so, they must scroll to read a complete line of text. This demonstrates that the graphic presentation of leaflets is not meant for reading in small screens, such as those of mobile devices.

Task 2, focused on reading the digital leaflet in the iPod Touch, ended the practical stage of the interaction test. It was followed by an interview, intended to identify participants' perceptions and opinions about the previous activities.

3.4 Follow-up Interview

This interview included questions about two main themes: (1) the graphic presentation of the digital leaflet and (2) the interaction with the mobile device while reading.

Regarding the first subject, participants stated that the typeface used, Times New Roman, did not create difficulties in reading. The body size, though, has been noticed in different ways by the individuals, yielding two trends: those who considered the body size uncomfortable to read (n = 7) and those who stated it was easy to read (n = 9). Four participants were indifferent to the effects of body size in reading the leaflet. In fact, the type size displayed in the iPod Touch screen varied according to the users' preferences, since it was possible to zoom in and out. Some people preferred reducing the visualization of the document, in order to avoid horizontal scrolling. They were also asked about the text column measure, generally answering that it was too large (n = 14). Evaluations of comfort affirm that this oversized length was uncomfortable to read (n = 11). Answers for indifference (n = 5) and for comfortable reading (n = 4) due to the column measure had less occurrences. In contrast, the last aspect of typography addressed in the interview, leading, showed more positive (n = 12) evaluations than negative (n = 4) or neutral (n = 4) answers.

Opposed to what has been observed in tasks 1 and 2, participants stated they could easily distinguish the various hierarchical levels of information in the digital leaflet (n = 14). This result is similar to the answers of users about difficulties during the interaction with the mobile device. Eleven individuals did not point any problem while reading the digital leaflet, and 13 people said that the graphic presentation of the document aided them in reading the leaflet on the iPod Touch. In spite of this, participants raised some questions, such as the use of excessive scrolling, that were

not considered difficulties but indicate only a partial approval of the leaflet for reading in mobile devices. So, the full positive evaluations (n = 6) were less numerous than negative (n = 7) and partially positive (n = 7) evaluations. Thus, most participants recognized some issues of the visual presentation for reading on small screens, even if such difficulties have not led them to consider this structure a hindrance to read the digital leaflet.

When asked about the situations in which they could read a digital leaflet, participants' answers revealed also details regarding the priority between the print and the digital version; in what kind of devices they would read the digital leaflet; conditions to reading this kind of document in mobile devices; situations and the main goal of reading leaflets. The number of answers in each category is presented in Table 1. It shows that the people who engaged the interaction test prioritize print leaflets.

Table 1. Classification of responses about the use of digital leaflets for the participants

Category	Participants answers	n. answers
Priority	Print leaflet	14
	Digital leaflet	5
Kind of device	Mobile devices	4
	Other electronic devices (e.g. *desktops*)	2
Conditions	Appropriate system for reading in electronic devices	4
	People need to know *Bulário Eletrônico*	1
Situations	Lack of the print leaflet	16
	Before buying the medicine	8
	During medical consultation	1
Main goal	Answer doubts about the medicine	6

Table 2. Classification of responses about the use of digital leaflets for other people, in participants' opinion

Category	Participants answers	n. answers
Priority	Print leaflet	7
	Digital leaflet	10
Kind of device	Mobile devices	9
	Other electronic devices (e.g. *desktops*)	2
Conditions	Appropriate system for reading in electronic devices	5
	People need to know *Bulário Eletrônico*	3
	Reducing number of steps to access the digital leaflet	2
Situations	Lack of the print leaflet	11
	Before buying the medicine	3
Main goal	Answer doubts about the medicine	4

When asked to project these impressions on the use of digital leaflets by other people, results were noticeably different. Participants demonstrated they think that other individuals could prioritize digital leaflets instead of the print documents. Table 2 shows the complete results obtained for this question.

To finish the follow-up interviews, participants' were asked if they thought that mobile devices are an appropriate means to read digital leaflets. Most of them stated that these devices can be used to that purpose, totaling 18 answers approving this use and only two neutral answers.

4 Conclusions and Final Considerations

According to the results of the interaction test, it is possible to assert that the current structure of the digital medicine leaflets available at the Brazilian online database for medicine leaflets is not designed for access via mobile interactive devices. The PDF file formatted as print document displayed in the small screen made not only visualizing sections of the text difficult, but also searching and finding information within the text. Thus, interaction and navigation are negatively affected by the digital leaflet structure.

The typographic variables, notably the body size and the column measure, required users to frequently use gestures to zoom and scroll in two directions, which contradicts guidelines found in the literature. Regarding the typeface used in document formatting and the interline spacing; users did not have demonstrate difficulties caused by such variables. Regarding the hierarchy of information in the digital leaflet, results show that typography in the document, instead of providing cues to participants about the structure of the text and helping them distinguish the relationship between textual elements, led to misinterpretations of how content was organized. In some cases, people pointed out the lack of distinction between hierarchical levels as a difficulty, mainly in what concerns locating information in the leaflet. For other individuals, these relationships were more satisfactory than the standard of printed leaflets, which led to positive evaluations of digital leaflet.

In conclusion, the visual presentation of the digital leaflet did not aid participants to read medicine information in the device. The document did not provide options for users to choose a comfortable setting of typographical aspects, so people have had to struggle to be able to access the desired information. The tolerance that was found in the study, in an environment with controlled conditions, may not occur in real contexts of use, especially in situations of stress. So, it is pertinent to search for alternative solutions, based on user-centered design.

The findings of this study point to the need of information design guidelines for the Brazilian digital medicine leaflets that consider interactivity and navigability aspects in order to ease reading and information searching/finding. Moreover, the structure for Brazilian digital medicine leaflets must not only be designed but tested with people to ensure their legibility as well as their usability, taking advantage of the resources available through software for mobile devices.

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