Informing the design of mobile device-based patient instructions leaflets: the case of Fentanyl patches

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Abstract: Patient Information Leaflets accompanying medicine are heavily regulated by European and individual national legislation in the way they need to be designed, written, and produced. Further, the design of these leaflets is still firmly anchored in a printed document-based paradigm. This means that transposing them for use by mobile devices such as smart phones or tablets is a process that is not well understood. This paper shows how Information Designers can offer insights to a problem that will become increasingly prevalent as the demands on the ‘message’ surpass the medium of the paper based document and seek to harvest the potential of mobile devices to offer hypertext, multimedia and tailored information. This paper investigates the problem via a case study examining pain relieving (Fentanyl) transdermal patches and offers some lessons learnt from this experience, in order to open up and shed light on this emerging aspect of information design practice.

Keywords: Information Design, Patient Information Leaflets, Mobile devices,

1. Preamble

Fentanyl is one of a small number of drugs that may be especially harmful, and in some cases fatal, with just one dose, if used incorrectly. It is used for the management of chronic and intractable pain. For home use, patients are prescribed the drug in the form of transdermal patches, that is, adhesive patches that are stuck on the skin so the drug is absorbed in this way. In 2010, the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA), showcased the manufacturers’ Patient Information Leaflet as an example of ‘best practice’ (MHRA, 2010). Yet, only a few years after, the same agency issued a safety warning via the UK government offices (MHRA 2014) noting that there had already been three reports of serious incidents, two of them involving children, and strongly urged advising patients and carers to follow the instructions on the carton and in the accompanying leaflet. Given this state of affairs, the questions must be asked about how
effective is the leaflet; about what should we be doing to increase its effectiveness, and more generally, to increase the health literacy of patients and carers.

2. Introduction

Patient Information Leaflets (PILs) refer specifically to the printed paper-based information that accompanies medicinal products. These leaflets are found in the carton that contains the medicine. The instructions for the patients should leave no margin for error since correct usage can be extremely critical. Patients who do not take their medicine correctly may not respond to therapy, and get no relief from symptoms, but they may also place themselves at great risk.

Due to the critical nature of the information contained in the leaflets, the information design and presentation are heavily regulated by bodies such as the MHRA, the European Medicines Agency (EMA) and the Federal Drug and Food Agency (FDA) in the USA. There is a recommended format of headings and order in which the information is presented. These measures are laid down in order to ensure “clarity, consistency and accuracy of the medicinal product information.” It is mandatory for PILs to accompany every medicine package: the authoring of PILs is the responsibility of the manufacturer and leaflets for new medicines must undergo readability tests for a licence to be granted. Typically, in readability tests, testers are asked to read the leaflets and perform certain tasks, e.g. find the correct dosage for a certain patient. Pictograms (Katz et al, 2006) are also subject to the same readability criteria. The criteria are metric based and require a high success rate (between 80-90%) on the tasks’ accomplishment. The purpose of these tests is to demonstrate that the leaflet is

“...written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals.” (European Commission, 2001 and 2009)

This level of regulation is a considerable achievement and represents over three decades of work from various actors including: consumer organisations; regulatory bodies; pharmaceutical companies; marketing and communication experts; academic pharmacists and information designers. It is a continuous process including considerations such as include information in braille on the packaging (European Commission, 2005).

However, regulatory frameworks can only offer a basis on which to work, and information designers can offer input into creating more attractive and usable layouts and writing styles (Waarde, 1998; Bohm, 2014; Dickinson et al. 2010). The limits of regulatory frameworks, especially where compliance with regulations is mandated, can be seen in other cases, notably web accessibility, where following the guidelines does not automatically guarantee a good user experience [Petrie & Bevan, 2009]. Nor should regulatory frameworks be expected to cope with every contingency, and while readability tests may be carried out, users in real life situations may need more support to find crucial information at the moment they need it.
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In addition, advances in the ways that drugs are dispensed, such as nasal sprays and transdermal patches, and even wearable insulin pumps mean that knowledge and training (Gani et al. 2001) is critically needed by patients and carers to help them understand how to handle these new pathways and avoid dangers. Although the guidelines of PILs can be adapted, a regulatory framework cannot be expected to cope with every instance. Some manufacturers collect frequently asked questions (FAQs) and include answers to them in the leaflet, thus adding this information at the end of the mandated format. This is actually a feature of the version of PIL for fentanyl patches in the USA. When a drug is particularly problematic, the regulation agency may take extra measures to inform the public. In the case of Fentanyl patches, the FDA has released information in a number of formats, such as warnings and advisories including two videos, because it

“has continued to receive reports of deaths and life-threatening side effects in patients who use the fentanyl patch [...] the reports indicate that patients are continuing to incorrectly use the fentanyl patch..." (FDA 2013)

Drug companies routinely publish the leaflet online, in portable document format (.pdf) so that it retains all the characteristics of information presentation as the paper based documents. In this way the online version is consistent with the paper version. But the .pdf of a document is linear, and may not transform gracefully to a small screen of a mobile phone. Anecdotally, many people in our survey report needing to use the official patient information online because the paper leaflet gets lost or damaged, while others simply expressed a preference to access information online. A recent study (Hammerschmidt & Spinillo, 2014) tested the use of mobile devices to access the .pdf of the patient leaflet. Interestingly the test participants, although they performed more poorly using the pdf on a tablet devices than with the paper based.pdf, firmly believed that the mobile devices would be their, and others’, preferred way of interacting and obtaining such information.

New technologies now offer us new ways to access information, but also new ways to present information. However, it is not always clear what to present and how to present it. On the other hand, it is important to have access to mandated formats.

This paper presents the results of a case study that investigated transposing the authoritative.pdf version of the manufacturer’s PIL for Fentanyl transdermal patches into an interactive presentation rendered for a tablet device. The idea was that as well as having access to the .pdf, patients could use the new rendering to go quickly to the information they wanted, rather than have to read through information that was not appropriate to their situation; in addition, some information visualisation techniques and graphical elements were tested. The purpose of the study was to answer the research question regarding the contribution of Information Design to this situation by creating a prototype and evaluating it with a variety of stakeholders.
3. Case Study

An overview of the research undertaken, in terms of the literature review, data collection and analysis, the creation of a prototype, and its evaluation is given. In all the activities, the involvement of stakeholders was heavily emphasized, since this is a complex problem space in which there are many human centred interests and activities.

3.1 Literature review phase

The main tasks in the literature review phase were to carry out a general investigation into patient error in medication use which reveals the worrying extent of the problem – between 30-50% of those prescribed medicine are not taking it correctly (Barber, 2002) - and more specifically, a review of work regarding patient information, especially in terms of PILs. This included studying the design rational behind the formats for PILS set out in various legal frameworks with regard to the content and presentation of PILS, especially in terms of the rendering the equivalent information online. This revealed that there are no suggestions in the regulatory framework about how newer ways of consuming information with the use of mobile devices such as tablet and phones, should be handled. There is an underlying assumption that the leaflets should be transposed to electronic formats in exactly the same way as it was on paper. However, in the general literature there are suggestions for pictograms (Katz et al. 2006, Mansoor & Dowse, 2004) and other visual aids (Waarde, 1998) as well as many other studies on improving PILs (Bouayad-Agda et al., 1998, Dickinson et al., 2001; Dickinson et al., 2010; Dickinson, 2014; Dixon-Woods, 2001; Maat & Lentz, 2010, Harris et al, 2015). Finally, elsewhere, in computing literature, there are attempts to provide support to health information seekers by determining the context of use, so that the information can be better tailored to needs (Schmidtke et al., 2014).

3.2. Investigating problems with Fentanyl transdermal patches

A series of semi-structured interviews with seven healthcare professionals from a provincial hospital located in Sparti, Greece, were undertaken, during six visits to the hospital and related premises. In terms of their roles: three of those interviewed were doctors and four were nursing staff, and all were involved in offering training to patients and carers regarding the use of the patches.

It was not possible to interview patients and carers because of ethical constraints. Instead, research was carried out looking at the most commonly encountered problems mentioned in online support groups of patients who use Fentanyl and their carers. In addition, an online survey was carried out, with 253 respondents. Briefly, the profile of the respondents were more women than men (64% women and 36% men), with age range from 18 to over 65. The bulk of the respondents aged between 18-34 (64%) and 35-65 and above (36%). 81% had finished tertiary education.

The healthcare professionals were asked what they felt were the main difficulties for patients and their carers. A sample of the most common questions they answer for patients
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(who, in their experience, either a) do not consult the leaflet; or b) do not find the information on the leaflet; or c) do not recognise the information as applicable to their case) are listed below:

- How do I stick it on?
- How often should I change it?
- Which parts of the body are the best to use /are there specific parts which are better than others?
- How can I bathe, if I have a patch stuck on me?
- The plaster came off, what should I do when that happens?
- What do I do about the side effects of itchiness, diarrhoea?
- Is the sticky part the actual drug (how does it work?)?

The most common mistakes on the part of the patients and their carers as reported by the healthcare professionals (in approximate order of frequency) were:

- Applying the wrapper of the plaster onto the skin, instead of the plaster itself
- Applying the plaster in difficult to stick places, e.g. where there is body hair
- Applying the plaster without having swabbed the skin to prepare it
- Forgetting to remove the old plaster before applying the new one
- Applying the plaster in inappropriate places: e.g. where it will rub on clothing, or come into contact with objects, etc.

Some of these questions and mistakes were found in the topics of concern to patients and carers in the online support groups. Their topics of concern were analysed and categorised into the following groupings (in order of perceived importance):

1. Issues regarding the application of the plaster: Frequent reports of difficulties for the patches to stay stuck; how to correctly apply the patch again when it has come unstuck; exactly which parts of the body can help with the unsticking problem
2. The importance of ambient temperature: Patients record experiences of using the patch in high temperatures and having signs of overdosing. Others noted that wearing the patch during very long and hot baths have also caused the same signs
3. Dosage instructions: Concern over accidental death of a carer from fentanyl overdose caused by mishandling of patches; uncertainty about how the dosage of the patches can be lowered
4. Can the dosage be lowered? People report experimenting with the dosage, by cutting the plaster in half and sticking half a plaster, does this really work, how dangerous is it, can the other half be used?
5. Stopping the use of Fentanyl patches: Withdrawal symptoms are common after cessation of the use of patches, and patients and carers draw attention to this, and emphasise the importance of gradual lessening of use.
6. Storage: Because of the opiate content of the patches, patients and carers are concerned about the security of storage especially from substance abusers.

7. Interaction with other drugs or substances: Since the patches are used by people with a wide range of health problems, of which pain and its management is but one manifestation, patients and carers are particularly worried about interactions with other drugs.

With regard to the correspondence of these concerns to the kind of information provided by the manufacturer of the PIL, some information, for instance the secure storage of the medicine, regards an issue that is beyond the remit of the PIL. However, other concerns, like whether it was possible to halve the dose or interfere with the frequency of patch application by cutting one dose in half, require serious responses in the PIL discouraging tampering with the product, and clearer information about how the product ‘works’.

3.3 PILs for Fentanyl transdermal patches; the opinions of stakeholders

It is recognised that, with regard to PILs, there has to be a trade-off between the amount of information in the PIL and how much patients really need. Comparison of PILs for the same product and same manufacturer but conforming to different regulatory frameworks (i.e. from Greece that conforms to the European standard, from the USA and from Australia) revealed differences in length and in organisation. Even though the Greek one was far shorter than its US counterpart, the healthcare professionals still felt that some parts of the PIL were not needed for the patient. As an example, they felt that details regarding the action of the drug were not understandable by the patient. Further they felt that people were probably not paying much attention to the PIL and that just the length of the document would discourage some. Results from the online survey corroborated some of these opinions. Of the 253 replies:

- 59.3% replied that they always read PILs
- 25.9% replied that they frequently read PILs
- 12.4% that rarely read PILs
- 2.4% choose never to read PILs

To these quantitative results, the respondents added comments to the effect that they wanted the information, even if they choose not to read it always. Those who replied that they rarely read PILs noted that they got the information from other sources, such as verbal advice from healthcare professionals and pharmacists. Amongst those who always read PILs, they complained that they were not written in a way they could understand; that there was too much information that probably was of no use to them even if they could understand it; and that often they did not find the information they wanted, or did not find it easily.

However, when both the professionals and patients and carers were asked to rate different groupings of information into 3 categories of ‘very important’, ‘important’ and ‘less important’, the results show a mixed picture, with some clear agreement and some strong disagreement. Figure 1 below shows the consolidated results of this exercise.
The qualitative comments that accompanied the ratings showed that both healthcare professionals and online survey respondents had difficulty rating the information according to the headings. In some cases the rated importance of the heading did not correspond the rated importance of the information under the heading, or the sequence of headings were not meaningful to them.
Accordingly, an iterative card sorting exercise was carried out to understand what kind of headings and their information contents helped the stakeholders. Figure 2 below shows the results of the card sorting; the information of the 26 cards was drawn from the 3 versions of the fentanyl transdermal patches PILs that were studied. The main information to be gained from this were the seven groupings of information for patients and their carers (shown in blue at the top of each information box).

An interesting result from these exercises was the importance non-medical professionals gave to information that medical professionals felt was not useful for patients. Such information is side effects and interactions with other drugs. The health professionals in our
study felt that this information was not needed by their patients and their carers because each patient was under the care of a team of doctors and nurses. However, the online survey respondents felt they wanted all the information. The doctors were of the opinion that patients spent too much time and effort on these information units, and neglected to pay deep attention to the important instructions for using and disposing of the plasters.

3.4 PILs in other renderings
A number of alternative ways of presenting the information, especially videos which are a popular means of presenting such information were studied. The range here was from the authoritative to the amateur, with some carers and patients feeling strongly enough about the subject to create their own explanations of what to use to help fellow sufferers and their families. A further source of instructional material was from blogs, support group newsletters and other informal sources.

In addition, a small review of literature was carried out to discover the trends in online health information seeking. The 253 respondents in the online survey were also asked to state whether they used mobile devices (smart phones and tablets) and if so, what they used them for:

- To have access to email (90%) 
- To have access to the Internet (78%) 
- To get news (76%) 
- To take photographs (71%)

Asked if they would like to download PILs if they were available, 76% of those who used mobile devices, answered positively.

This result agrees with the finding of (Hammerschmidt & Spinillo, 2014) that people are very open to electronically based information. Of course, the fact that many people search generally online for health information in a browsing mode should not be confused with looking up a PIL for dosage instructions at a critical moment.

3.5 Creating a prototype of a tablet based PIL
Taking the results of the research and associated analyses, along with general guidelines for accessibility and usability of web based information, and more recently mobile web based information, and retaining recommendations and best practice examples results from paper based information design regarding layout, typeface and general content design, a conceptual model of a prototype was built. A conceptual model presents a visualisation of the organisation and the functions of the prototype, along with basic meanings and activities of the system, in order to communicate it to other parties. It is by no means technically accurate, as the aim is to present a system to potential users and for them to understand what it is for. As shown in Figure 3, the model allows for visualising screen contents, navigation through content and gestures for interacting with the content displayed on the device.
Figure 3: Conceptual model of the prototype tablet device based PIL for Fentanyl Transdermal Patch

To build the prototype, Use scenarios were also created, as shown in Figure 4, to trial typical uses of the system as perceived from our research, as well as the information categories derived from the card sorting exercise.

Figure 4: Part of the scenario for persona
In terms of presentation, following the work of van der Waarde (1998), Dickinson et al (2010), Bouayad-Agha et al. (1998) regarding the ease of use of PILS, there was an attempt to reduce the amount of text with the use of visualisations, as well as the graphical elements inside the text (borders, colours, typographical elements) to make the information easier to scan, since it is acknowledged that this is the dominant reading style on the internet (Kress, 2004, Nielsen, 2007). It also makes easier to understand the relationships between blocks of information and the degrees of importance of information. Figure 5 shows the “artists’ impression” of the tablet with the application open, while Figure 6 shows a typical screen from the application.

Figure 5: The tablet application open showing the start of instructions for applying the patch.

Figure 6: A screenshot showing deeper levels of patch application instructions and explanations.
3.6 Evaluating the prototype
The resulting designs were implemented on a nine inch tablet device, and underwent both formative and summative evaluations. Formative evaluations are used to test systems while they are in the making and allow for corrections, while summative evaluations are done on the completed system. Five evaluators helped with the formative evaluations: three were design students, two of whom were tablet users of more than one year’s standing; the fourth evaluator was a student with no knowledge of design; the last evaluator was a doctor doing his residency practice in a rural community.

Once the changes and corrections had been made according to their recommendations, a more substantial summative evaluation was carried out with ten new evaluators, to identify usability issues as well as to carry out tests similar to the reading tests performed on PILs. Two of these new evaluators had been carers in the past and had administered fentanyl patches. Not all the evaluators were users of tablet devices. In this way we hoped to capture both expert opinion and that of less specialised users, both in terms of content and of use of the content presentation device.

To attempt to simulate real life contexts of use, each evaluation session was carried either in the home of the tester, or outside in a simulation of a travel situation. The user was given the tablet with the application.

For each session, the participants were first informed about the application, and it was emphasised that they should be clear that they were testing it, rather than being tested on their aptitude. Participants were invited to ask questions and then were left to ‘play’ with the application for a short time. This gave participants who were new to tablets a chance to try out the use of the device.

The session proceeded as follows: participants filled out a short ‘entry’ questionnaire, then carried out seven tasks using the tablet and the information presented there, and filled in an ‘exit’ questionnaire. The tasks concerned dosage, application, safe disposal, etc. At the beginning of each task the participant read out aloud the task description and then began to search using the tablet, while doing a Concurrent Think Aloud (CTA) protocol, whereby the participant describes what he is doing as s/he does it. This was a valuable exercise as it captured qualitative reactions of the evaluators, including their emotional reactions. After the completion of the tasks and before the exit questionnaire, the participants were asked to reply to questions about their experience of using the application using a Retrospective Think Aloud (RTA) protocol. Finally, the exit questionnaire asked participants to comment on their overall experience of the application in terms of usefulness and usability.

3.7 Evaluation results
The quantitative data from the evaluation were derived from the time taken to complete a task, combined with the degree of successful completion of the task and the number of
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mistakes. The time-based data were used only as an indication as the participants were also doing CTA, which would slow them down, but provide useful qualitative results. More interestingly, mistakes were considered as serious or trivial depending upon whether the user could recover from them. Generally speaking, the evaluators were able to complete the tasks reasonably quickly, and with a low amount of irrecoverable mistakes.

Content

The evaluators felt that the amount of informational content was a good starting point, and that in future developments, users may want to have access to more information. Some evaluators commented favourably on the filtering mechanisms (gender and age), employed in the application so that only information relevant to the chosen profile was presented, thereby lessening the cognitive load. This was gratifying as reducing the quantity of irrelevant information was one of the original aims of the application, since it had surfaced strongly in the research phase in the online survey.

Operation

There were a number of problems that surfaced, some were trivial to fix, and were a consequence of the implementation, such as the interactive elements not being clear. Interestingly this problem was not evident to the inexperienced user, who managed to complete tasks by using a trial and error method of tapping on everything, rather than looking for indications of interactivity. However, a more serious consequence of this was that some evaluators did not realise that by tapping on a sketch, they could activate a box with explanatory text related to that specific part of the sketch, or that specific sketch in a series of sketches. Having understood this, they retracted some statements about the need for more than just pictures to explain the content.

Despite these problems, the evaluators appreciated features like the possibility of scrolling using the vertical bar to find the information which corresponds to the choice made by a user. This is another way to reduce user effort in information seeking. This feature in combination with the horizontal bar that depicted the seven categories of information helped to reduce ‘time to target’ and showed that there was no need to have these in a central place on the screen, as they can remain in peripheral vision.

Aesthetics

In terms of aesthetics, the participants did not report any particular problem. But they found that the design was not particularly pleasing. Also, it did not communicate a strong identity or brand. The latter was the intent of the design team, so that it could either function as an application interface onto a set of PILs from different manufacturers, or as a template for manufacturers to adopt with their own online versions of PILs.

Overall

Generalising the results regarding the usefulness of the application, its operation and its aesthetics, the evaluators found it a useful tool to support rapid and easy information seeking for medicine usage instructions. They found particularly valuable the notion that
they could access the information at any time and from any device that had the application running on it. They commented on the use of the QR code to scan in the barcode on the packaging as being highly valued as medical names are not easy to spell and many variants in terms of different combinations of drugs as well as drug strengths may exist for one type of medicine.

4. Conclusions

This case study looked at a specific medicine that is classed as a ‘high alert’ medicine. That is, in a table of fifteen such medicines most commonly reported to have caused serious harm or death, it ranks seventh in order of magnitude (Barber, 2002).

Our studies showed that there were discrepancies between what patients and medical professionals perceived as important parts of PILs for Fentanyl products.

Some unexpected results are that this work was carried out using a population that is not English speaking, and who are not heavily exposed to technological solutions. The internet penetration in Greece lags behind other countries in Europe and use of internet based devices is also less widespread. In spite of this, the use of interactive devices to access information was felt to be more effective than paper based information.

Participants in the evaluation study expected the application to make more use of the dynamic information presentation formats. They would have liked to see the use of multimedia, for instance the application of patches as a video. They felt this would be a very appropriate way to use even an animation of the existing sketches. It was explained that this would be quite a departure from the balance of keeping the paper based leaflet consistent with the tablet based information.

The evaluators also suggested a forum for patients to exchange information regarding best practices and practical tips, as long as such features could be filtered by some authority, perhaps the manufacturer, and not disorient the user. This finding was consistent with the new trend in health literacy and information, known as Medicine2.0 or Health 2.0. (Belt et al., 2010) where users have a say in the quality of content from a collective ‘bottom-up’ approach which reflects current needs for knowledge and experience sharing in promoting health literacy.

The main lessons learnt from this experience were that the use of interactive devices to access patient information is welcomed. Users immediately saw the benefit in having access to information on their mobile devices rather than relying on a leaflet that gets misplaced, dirty or damaged. Further we saw that when information presented in this way is restructured, using the information layout and an architecture that is transparent to the user; that allows for graceful degrading of information that is irrelevant for a particular user, by moving it into the periphery, and surfacing more prominently relevant information the results are marked. It allows direct access to wanted information, and obviates having to navigate, albeit via scanning headings, through a linear based document.
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Overwhelmingly, our case study showed that there is a need for more information and guidelines, including good practice, with regard to the information design of ‘instructions for use’ on mobile media. Having just in time access to such information can be a powerful tool if it can be used comfortably and quickly by those in need. Such media offer opportunities for embedding videos, for listening to the instructions while actually carrying them out, and other as yet mostly unused potential. Our results show that patients and carers are ready for such renderings. Swiping through ‘pages’ of ‘brochure ware’ is no longer an acceptable experience for users, however neither is badly designed web based information that is scattered over many screens with embedded videos and other features, where users may be swiping through in a haphazard way in the hope of landing on something useful or required.

We believe the lessons learned from this study are interesting to information designers involved in designing general ‘Instructions for Use’, as well as to further information design research in this highly critical area. The intention is not to replace PILs, but to add to them by transposing the paper document based information into new delivery channels. This gives to information design the opportunity to provide some principled responses to the question of what information should ‘float to the top’ and allows for a new information to be fed back into mandated paper templates.

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