Exploring and employing user centred research methods to optimise patient information leaflets

Molly Smyth

ABSTRACT

Patient Information Leaflets (PILs) are the documents which are obliged by law to accompany medicines. They are packaged within the medication box and play an important role in explaining associated risks, dosages, side effects and other key information. With strains on health services reducing allotted patient appointment times, Patients Information Leaflets play a crucial role in providing patients with critical health information doctors were previously obligated to explain (Adepu and Swamy, 2012).

Authors of PILs are assuming patients can understand complex written healthcare information (Graham and Brookey, 2008). This assumption is false and research carried out by the Royal College of GP's in 2014 found that 42% of patients struggle to understand how to properly take their medication. This suggests that PILs are not communicating as intended, leaving users misinformed and vulnerable.

The research within this study used hormonal contraceptive prescriptions, to identify common problems which exist in Patient Information Leaflets. Hormonal contraceptive prescriptions have been chosen as the exemplar since they are heavily prescribed- twenty-five percent of women of re-productive age use hormonal contraceptives (Smith, 2010). User centred research approaches have been employed to identify problems and solutions for the optimisation of Patients Information Leaflets. These methods in order of their conduction were, an online survey, interviews and Regulatory Impact Analysis.

Analysis and cross comparing of results from online surveys, interviews and regulatory impact analysis led to the identification of three major themes and subsequent recommendations.

1. The formatting of Patient Information Sheets needs to prove online versions as well as paper based versions.
2. Improved communication methods such as annotated storyboards will see better patient compliance.
3. The language used in the documents is not appropriate considering the patients' needs.

Addressing these themes with solutions is expected to optimise Patient Information Leaflets.

KEYWORDS

Patient Information Leaflets: The document provided to a patient, typically in their medication packaging. UK law means pharmaceutical companies must provide a Patient Information Leaflet.

Introduction

Research methods were chosen based on how to obtain data in the time frame available. An online survey targeted at students at Loughborough University using the contraceptive pill was used to gather a broad and diverse range of data from a high number of respondents. The aim was to gain a general overview of PIL interactions and expectations. Since this project is using the contraceptive pill as an exemplar, the primary inclusion criteria for the survey was that the participants must be female and using a hormonal risks. The cohort was separated using quotas to match the UK population into whether English was their first language or not. The survey used purposeful and convenience sampling. It was created online and shared in the Loughborough Design School Forum. Multiple choice questions are used to group predicted answers, while preference questions allow data to be ranked. Open ended questions were used minimally since they do not easily allow qualitative data. The questions on the online survey were as follows:

1. Is English your first language?
2. What type of contraceptive pill are you taking ?
3. Without checking, do you know the brand name of the contraceptive pill you are taking?
4. Have you read the Patient Information Leaflet for your most recent prescription of contraception?
5. Do you read the Patient Information Leaflet every time you collect a renewed prescription for contraception?
6. If you still have the relevant Patient Information Leaflet please take a look. What are you able to deduce about the medication? Select all that apply.
7. Do you understand all the information presented in the Patient Information Leaflet?
8. Do you believe plain English is used in your Patient Information Leaflet?
9. Please select the 3 most important pieces of information that is most important to you about your prescription.

Interviews enabled in depth information to be gathered from a range of stakeholders. Since the survey identified the problems which exist for users who do not speak English as a first language, the interview instead focused on the different way in which digital natives and non-digital natives understand information. Digital natives is a term used to describe those born after 1980- the generation commonly referred to a millennials (Palfry & Gasser, 2008). For the purpose of this study, digital natives/ non-digital natives will be referred to as millennials/ non-millennials. 12 participants were interviewed; 6 millennials and 6 non millennials. These participants were recruited using convenience sampling methods. This method was chosen as it allowed the project to progress quickly. The interview questions were:

1. Is the level of your English a problem in understanding Patient information sheets like this?
2. What would you do if you lost a patient information sheet? 2.1 Why would you do that?
3. Do you use online booking services with your GP?
4. Do you believe Patient Information Sheets can be improved?
5. If something is printed on thing paper, is it less important? If so, how?
6. Look at this flow chart/ carton strip/ mind map: Do you think this, or something similar could be helpful in explaining the way to use your prescription?
7. What is your order of preference for the three presentation styles?
8. What is your order of preference for these format styles?

Finally, a Regulatory Impact Analysis was conducted. An RIA involves identification of the problem that needs to be addressed. In this instance: Poorly designed Patient Information Leaflets are miss-leading patients and causing healthcare issues. Next, the desired outcome is identified: To optimise Patient Information Leaflets to ensure they present relevant information in an appropriate manner. Then, the methods which could be used to bring about this desired change are identified and ranked according to how much change each method can bring. The Regulatory Impact Analysis was carried out by the research who used ergonomic experience and literature reviews to provide an assessment.

Format Changes	Communication Changes
PDF emailed PIL	Flow charts
Paper booklet style	Checklists
A3 Sheet	Glossary's
Phone App	Table of Contents

For the RIA, each format and communication methods were rated between -10 and 10 for the following groups within society:

- Those with visual disabilities
- Those with cognitive disabilities
- Those whose native language is not English (or the relevant language in print)

The following statements were also rated:

- What is the predicted impact of this change on an individual's health?
- What is the predicted economic impact?
- What is the estimated level of compliance from companies making PILs?
- What is the estimated level of compliance from patients?

The minimum score was -70 and maximum 70.

Theme 1: Bringing the format into the 21st century

The format refers to the presentation of the Patient Information Leaflet. For example, the current format for the PIL was an A4 sheet. When interviewees were asked how PILs could be improved, 75% of all participants mentioned the format as a way of improving the documents. The need to bring PILs into the 21st century is supported by interviews results which showed that 50% of non-millennials and 83% of millennials would look online if they lost a PIL (figure 2).

It is interesting that just 16.7% of millennials would directly contact their doctor, while almost double (33%) of non-millennials would contact their doctor. The reason for this could be attributed to NHS strains making doctors' appointments being hard to come by. It is a common insight into millennial behaviour that they like information instantly, thus it is possible they are averse to the idea of waiting for a doctor's appointment. In light of this, the document should be available online. This would reduce the risk of patients searching online and following incorrect information.
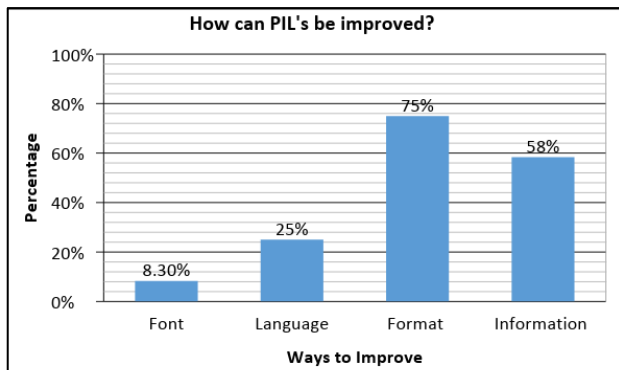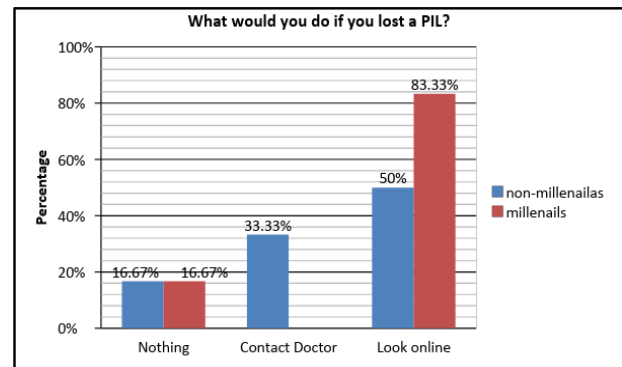
Figure 1: How PILs can be improved

Figure 2: What interview participants would do
if they lost a PIL

The need to have an online PIL in conjunction with a paper-based version stems from the interviews which showed the value that participants place on paper. It is interesting that younger participants placed more value on paper documents which may be an indication of a lack of exposure to valuable paper documents in an online world. After assessing plausible formatting methods, the results from the RIA show the most effective formats would be a paper booklet teamed with an App. The App takes into consideration the need of non-native English speakers as Apps can easily translate the information while inbuilt phone devices can read the App based PIL allowed to the impaired user. Finally, a significant driver for the need to keep paper based PILs stems from the risk of alienating the poorest and most vulnerable members of society who do not have access to the internet and thus would rely on paper PILs accompanying their medication. This is particularly important considering the number of prescriptions which are given to the elderly and disabled who are most likely to not have access to the internet.

The A3 sheet scored lowest because it fails to address the needs of the cognitively disabled and those who do not speak English. Learning from the survey results which show just 4% of participant read their PIL with every prescription, it can be assumed the A3 sheet would follow in a similar direction. The PDF scored well but interviews revealed concern around accidentally deleting emails. The PDF may also be more difficult than the App to translate, making it less inclusive. The App is second only to the booklet where the physical paper and ability to provide step by step instructions lends itself to the most helpful and valuable format.
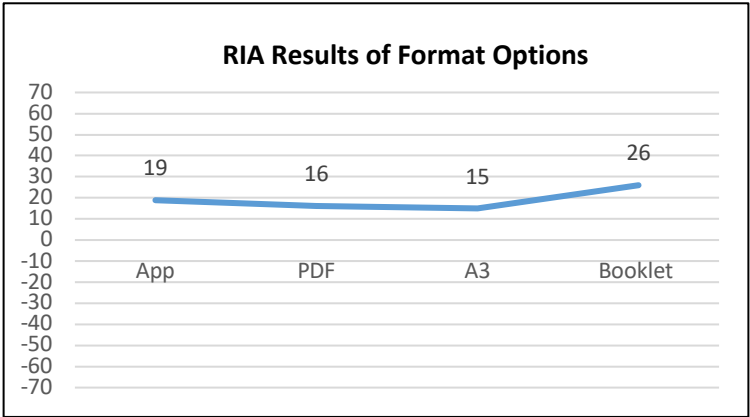
RIA Results of Format Options

(values shown: App = 19, PDF = 16, A3 = 15, Booklet = 26)

Figure 3: Regulatory Impact Analysis of Formatting Options:

Theme 2: Improving communication methods can be improved to ensure better compliance

When participants of the online survey were asked "what are you able to deduce about the medication" from the PIL, there was a disparity between what information they could deduce and what information they would like to see. Figure 4 shows that 22% of participants were able to work out when to take their medication compared to 36% of participants identifying when to take the pill as in the top 3 most important pieces of information (seen in figure 5). Similarly, 29% of participants wanted to know what to do in an emergency, yet just 16% were able to identify this information from the PIL. Also, the survey results show that just 35% of participants could identify the name of their medication. Emphasis must be placed on the generic name of the medicine in product information sheets. Emphasis can be achieved through using a larger font, reverse ink printing and white space. This will aid patients in re-calling the name of the medication in the case of an emergency or lost patients records. Ultimately, this data suggests that the PILs are not effectively communicating with their audiences.

What are you able to deduce about the medication?

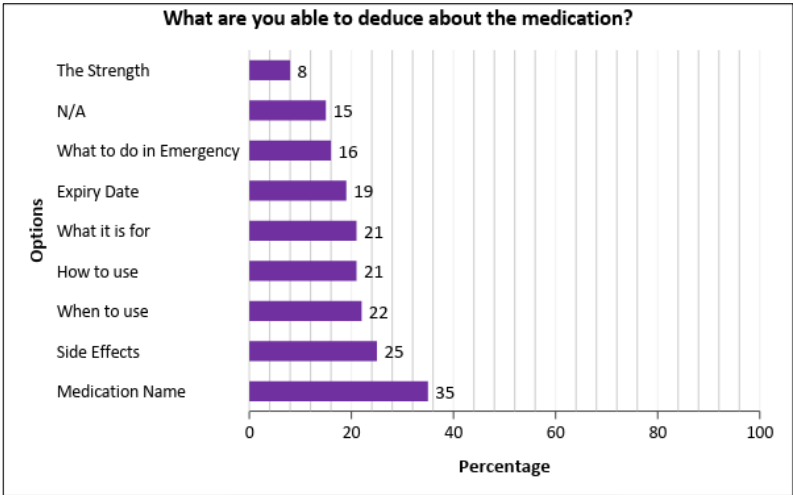| Options	Percentage
The Strength	8
N/A	15
What to do in Emergency	16
Expiry Date	19
What it is for	21
How to use	21
When to use	22
Side Effects	25
Medication Name	35

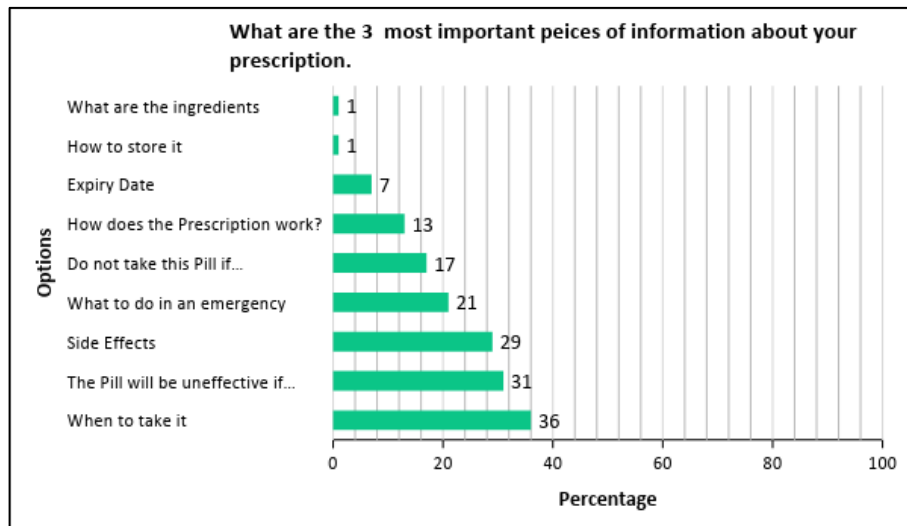Figure 4: What can participants deduce from their own PILs?

Figure 5: What are the three most important pieces of information about the prescription?

In a bid to improve how PILs communicate with their users, research was conducted into alternative communication methods. Interviewees were asked which methods of communication they preferred. The results seen in figure six show story boards and flow charts are similarly preferable for millennials and non-millennials respectively. The maximum score of 18 was calculated through each 6 participants giving 1 point to their least preferable communication method and 3 points to their most preferable method. Considering these results, a method of combining story boards and flow charts was deemed a balanced use of imagery and words to appeal to most audiences. The use of images aid non-literary patients while some simple words can aid clarity. A compromise between the two cohorts needs would be to provide an annotated story board as a communication method.
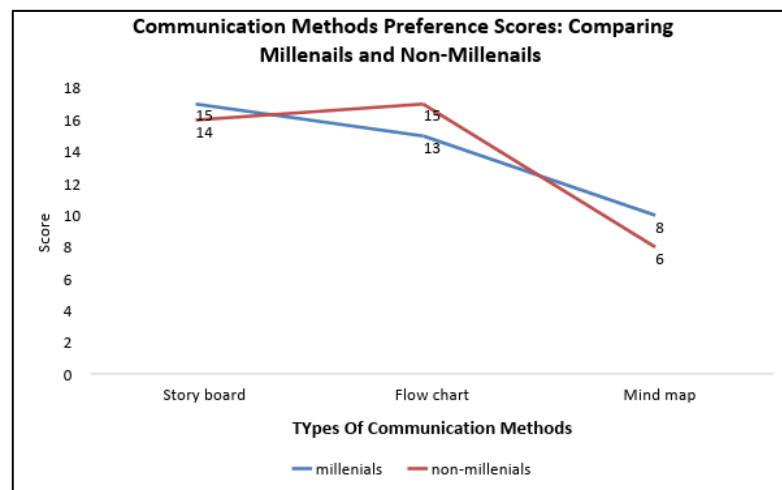

Figure 6: Communication preferences interview results.

However, compliance with the PILs overall remains an issue since the online survey data shows that 96% of participants read their PIL with every new prescription (Seen in figure 7). One explanation for this statistic may be that the participants had been taking the same medicine for a long time, deeming this an acceptable reason not to read the PIL. However, changes to medication can occur with each prescription. To improve compliance, authors of PILs could improve a section titled

"Changes To This Medication". This would allow a breakdown of changes year by year to be explained to patients.
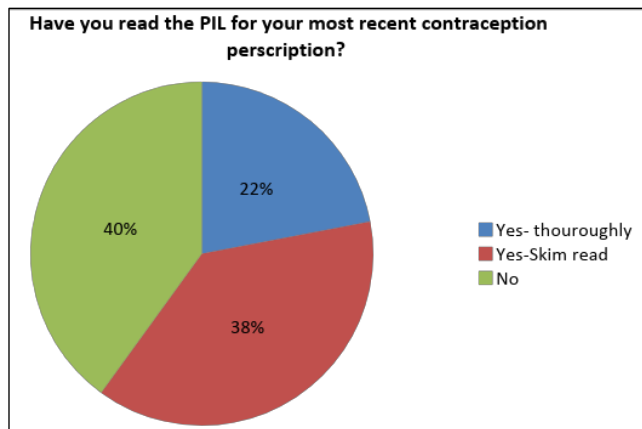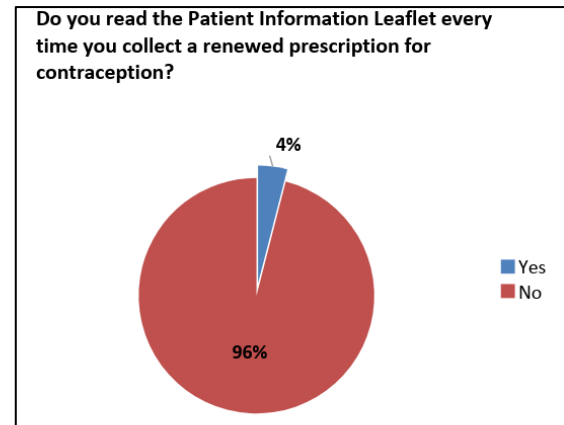

Figures 7: Have patients read recent PILs?

Figure 8: Do patients read every PIL?

For the Regulatory Impact Analysis the researcher included the annotated story board since the interview results proved this to be an appropriate communication solution. Other layouts were also included in the RIA based on the findings from the literature review. Considering predicted resistance from companies printing PILs (due to ink and paper) the Glossary was not deemed the most appropriate communication method as embedded explanations would be sufficient. It was predicted that checklists would increase a user's chance of seeing and comprehending information, thus making them a beneficial addition to PILs. While a contents page enables user to find desired information quickly, it does not have the same level of engagement as a check list. Furthermore, it could encourage patients to read only sections relevant to them at the time. The reason the annotated storyboard is the highest scoring communication method is because the images work towards including non-English speakers. While the annotated storyboard would increase the cost of producing PILs, it is predicted that their benefits outweigh the effect of these costs. Similarly, while companies producing PILs may resist to the inclusion of these changes due to the cost of production, it is predicted that since the changes will reduce the number of medical errors caused by PILs.
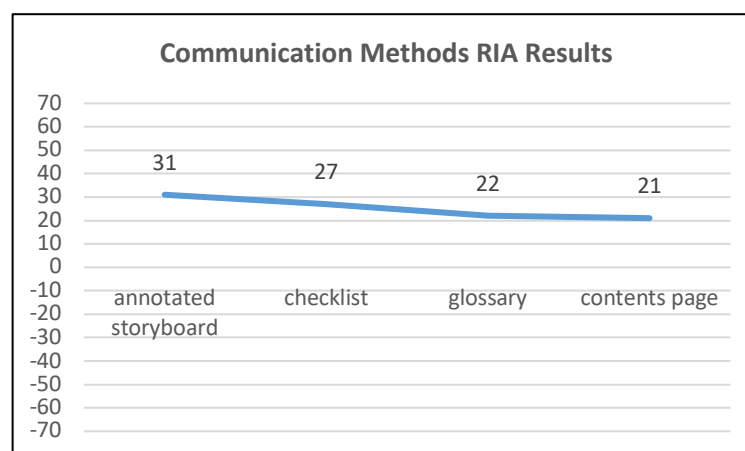

Figure 9: Layout methods RIA Results line graph.

Theme 3: The language used in the documents is not appropriate considering the patient's needs

Multiculturalism is vast within the UK, with the capital, London, being home to 300,000 residents who do not speak English at all - this equates to 22% of London's population. Ignoring this statistic can result in healthcare failures Figure 10 shows that 75% of non-native speakers cannot understand the information presented in the patient information leaflet. This is because the language is difficult to understand and in some cases requires medical knowledge. While 55% of native English speakers claimed to understand all the information, the reliability of this statistic can be called into question as the online survey (results seen in figure 1) show 25% of participants in the survey thought that the changes to the language would improve PILs.
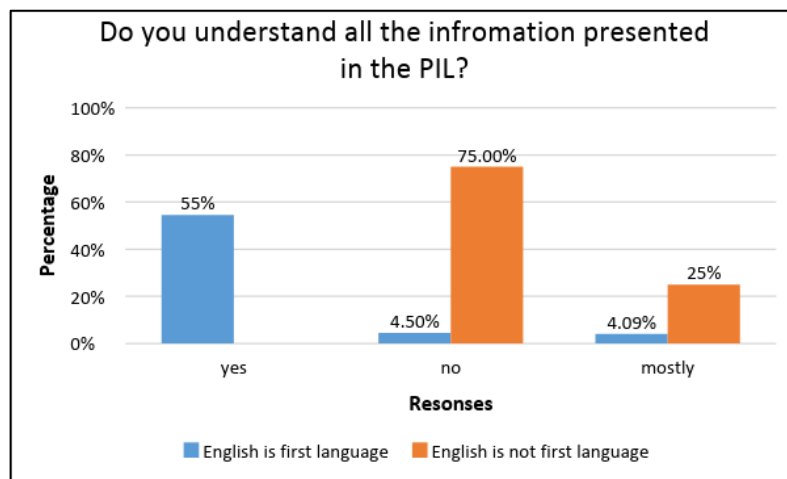

Figure 10: Do you understand all the information presented in the Patient Information Leaflet?

The reliability of this information can be doubted since participants may have been reluctant to admit to a lack of understanding. Ergonomic insight shows that ways of making this information more accessible- i.e.:

- Bad, painful spots on the skin should replace Acne.
- Feeling sick or vomiting should replace Nausea.
- Fluid coming from the breast should replace breast secretion.

Also, to improve the grammar in the PIL, consideration must be given to the sentence length.

See Table 1:

Table 1: Re-wording phrases

Current sentence:	Suggested re-phrase:
"In every 10,000 women who take the Pill for up to 5 years, but stop taking it by the age of 20 there would be less than one extra case of breast cancer found up to 10 years after stopping in addition to the 4 cases normally diagnosed in this age group."	If you take Feanolla, your chances of getting breast cancer increase with age and how many years you use Feanolla for.

Recommendations

The findings in this report should be adopted by authors of Patient Information Sheets. It can be predicted that the adoption of these findings would lead to a reduction in medical errors. However, further research should be carried out to quantify the effectiveness of these findings in improving PILs. Extensive user testing must also be carried out to ensure the App uses human computer interaction design principles. This research may include a yearlong study with a pharmaceutical brand. The study would compare the number of medical errors from previous years against the number of medical errors in the trial year to assess improvements. While expensive, this study would provide conclusive evidence either way to confirm or dismiss the idea that said proposal would optimise PILs.
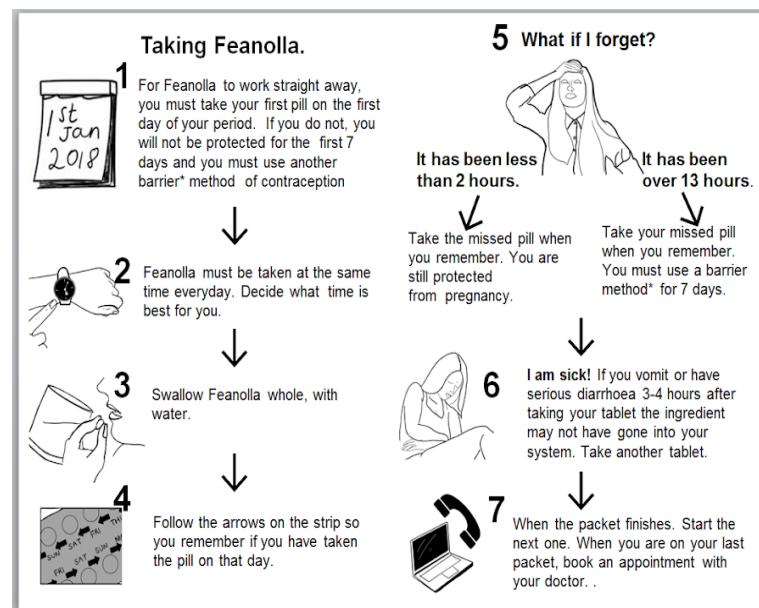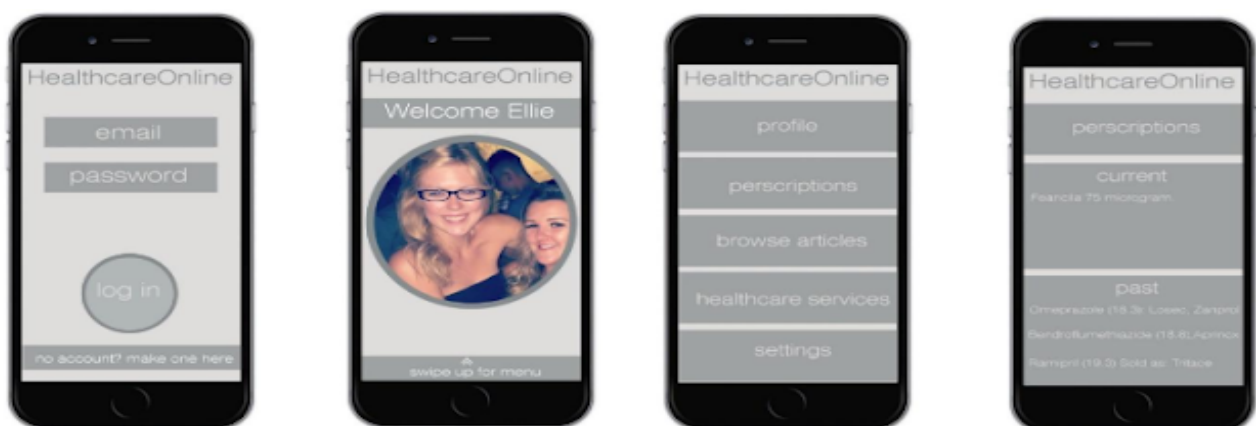

Figure 11: Example of an annotated story board.

Figure 12: Example of an app designed for PILs.

References

Brookey, J. and Graham, S. (2008). *Do patients understand?* [online] 12(3). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037129/ [Accessed 28 Feb. 2017].

Palfry & Gasser (2008), *Born Digital- Understanding the First Generation of Digital Natives*, Basic Books.

Smith, J. (2010). *The pill: Woman's best friend?* The Telegraph. [online] Available at: http://www.telegraph.co.uk/women/womens-health/7728971/The-Pill-womans-best-friend.html [Accessed 23 Feb. 2017].

Swamy, M. and Adepu, R. (2012). *Development and evaluation of patient information leaflets (PIL) usefulness*.