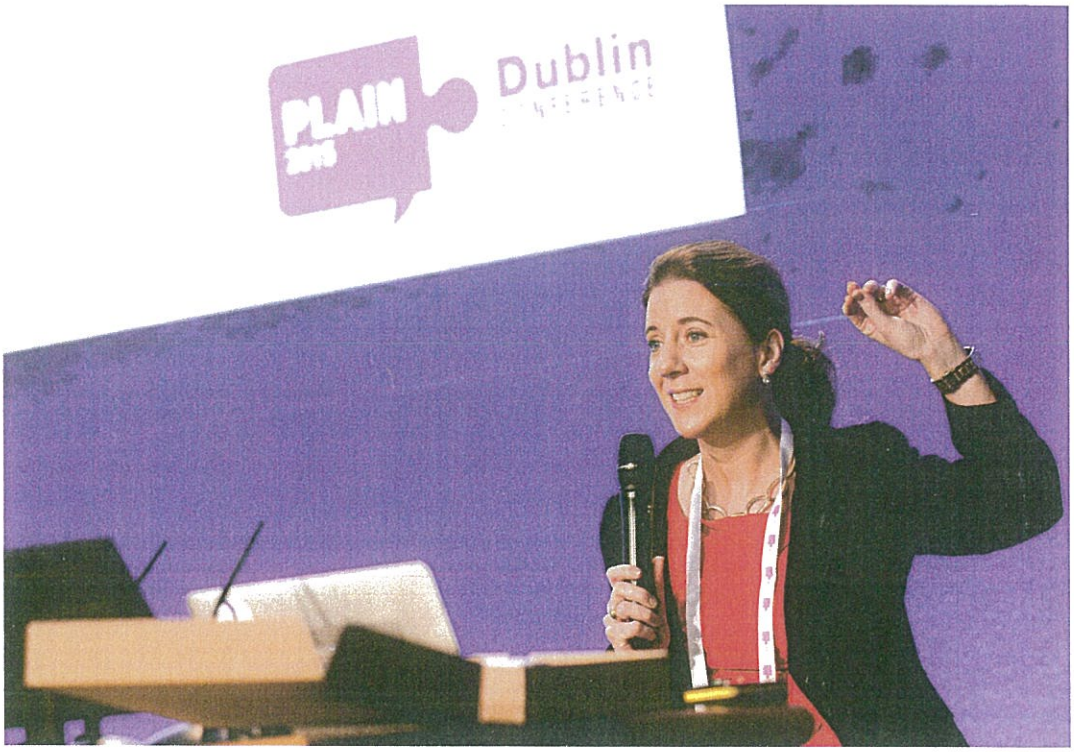
Communicating clearly about medicines

Making sure that the information that is provided to patients about their medicines requires clear language, a balanced visual design, and an information strategy. All three might need more attention.

Authors:
Dr. Laura J Sahm. School of Pharmacy, University College Cork, Cork.
Dr. Karel van der Waarde. Graphic Design-Research, Geldrop, The Netherlands.

Background?

This article is based on a presentation we gave at the PLAIN 2015 conference in Dublin (17-20 September 2015), which focused on '*Clearer language, greater efficiency and effectiveness*.' The conference was jointly organized by **The Plain Language Association InterNational** (PLAIN) and the **National Adult Literacy Agency** which is Ireland's leading organisation in the promotion and development of plain English.



We applied the conference theme to the different kinds of visual information that patients receive when they need to take medicines. We collected and analysed a number of examples that might be challenging for healthcare professionals and for patients. We then examined these from both a pharmacists' as well as a designers' point of view. As an initial step, we describe some of the underlying reasons for these problems and suggest some opportunities.

Are these real problems?

There are several points in the process, of providing patients with their medicines, that pose risks. Most of these risks have been identified, but the actual situations and examples are rarely published. And just to be clear: these examples are only used to illustrate and discuss the understandability and readability of pharmaceutical information from the perspective of the reader.

a. *Confusing* packaging: Metronidazole & Metformin / Zithromax / Lexapro.

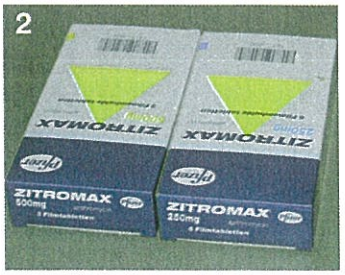
The first risk is confusion of medicines in the pharmacy setting: Today pharmacists are being confronted with new packaging on a weekly basis, specifically in Ireland, due to the introduction of interchangeable and generic medications. The increased availability of drugs with similar packaging containing different drugs and/or different strengths of the same drug increases the cognitive burden on the pharmacist and may increase the risk that a patient receives the wrong medicine. The visual similarity of some outer packaging does not help this (figures 1, 2, and 3). Whilst every pharmacist is aware of this risk and will thus take extra precautions when dispensing, nonetheless this takes extra time and effort which could be avoided if packaging was required to be discernible from every other package.

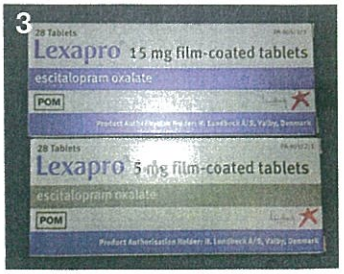
b. *Poorly readable* outer packaging for POM medicines: Perindopril

Even if different medicines can be clearly distinguished, the reading of some of the vital texts

Figures 1,2 & 3

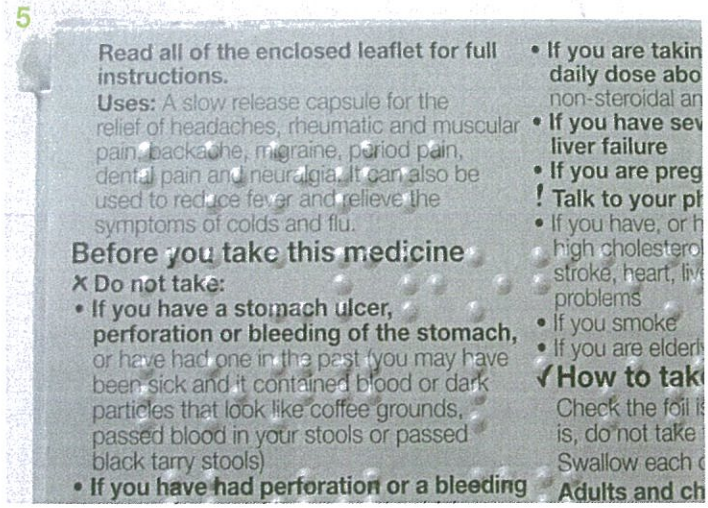
Metronidazole & Metformin / Zithromax / Lexapro.
The packaging of these medicines looks very similar, which increases the risks of confusion





Figures 4 and 5

Perindopril (POM) and Ibuprofen (OTC). The text on these boxes is hard to read: it takes more effort than necessary to decipher the text



on the outer packaging is made more difficult by small type, low contrast, and distorted letterforms. The visual design of the package, especially the combination of the colours, typefaces, and braille code requires extra effort to decipher the detailed information (figure 4).

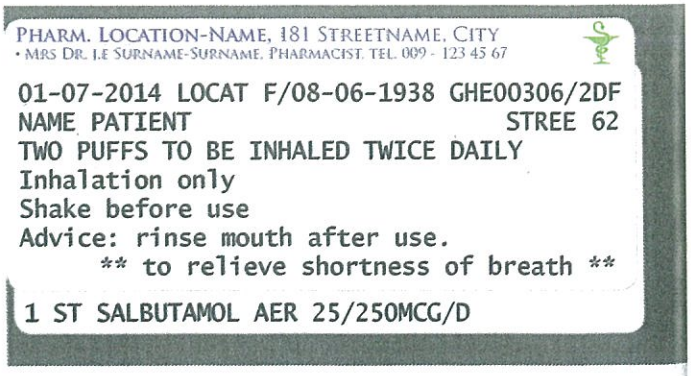
This 200mg Ibuprofen over the counter (OTC) package was bought in England. The first instruction on the back of the box suggests that the outer packaging does not contain all the information, and that a consumer can open the box to check the package leaflet (figure 5). In practice, this is unlikely to happen. The subsequent text is very difficult to read for several reasons: it uses a light version of a typeface, the type is condensed, there is very little space between the lines, the contrast between the black type and the grey background is low, the background is highly reflective, and there are braille dots pushed through the text. There is some empirical evidence that each of these factors individually may reduce readability – a combination of seven such factors has not yet been investigated.

c. *Unstructured pharmacist' labels.*

Pharmacists print labels with specific instructions and these are added to the medication prior to the patient receiving it. However, the visual design shown in Figure 6, does not indicate any hierarchy (what is the most important?) nor a sequence (in which order should I read this information?). This problem has the potential to increase as the pill burden also increases i.e. when patients need to take several medicines at the same time, and they must compare the different labels and work out a daily regimen.

Figure 6

Pharmacy generated labels



d. *Hard to apply* instructions in package leaflets: Crestor.

The package leaflet for Crestor (rosuvastatin) states in the warnings section that patients must 'take special care with Crestor' if they are over 70, or if they are of Asian origin (figures 7 and 8). The concluding line of the list states: "*If any of the above applies to you (or if you are not sure)*". In practice, a prescribing doctor and a pharmacist should know that 'over 70' and/or 'Asian origin' and '40 mg rosuvastatin' do not go together. A patient can only read this package leaflet at home after a doctor has prescribed it and a pharmacist has dispensed it. If a patient who is over 70 and/or from Asian origin does receive this package, it shows that the safety-measures have failed.

The examples on page 19 (figures 7 & 8) show that some of the information that patients receive is easy to confuse, difficult to read, unstructured, and hard to apply in a real life situation. Of course, not all outer packaging, inner packaging, package leaflets, and pharmacy labels suffer from all four of these issues to the same extent. It is however quite difficult to find examples that could be classified as 'absolutely excellent' on all four criteria.

Why do these problems exist? What are the underlying reasons?

There seem to be a number of fundamental causes that make the development and the interpretation of information about medicines difficult. These causes are related to the different frameworks, the development process, the characteristics of different patient and a lack of a coordinated information strategy.

a. Three different frameworks.

Information about medicines can be viewed from a regulatory/legal perspective, an economical/financial perspective, and a healthcare/medical perspective al of which have different aims. The Regulator needs to be sure that the information conforms to the required legislation and guidelines The manufacturer needs to comply with the Regulator but also has to ensure a balance of costs and profits. Finally the third perspective takes the health of an individual patient as the main criterion. Unfortunately, these three perspectives are almost parallel and do not share as much commonality as would be hoped.

b. A linear process that separates writing, designing, and testing

The current regulatory framework in Europe separates the writing, designing and testing of information about medicines. The EMA-QRD template must be used as a basis for the texts on packaging and package leaflets. Some parts of the obligatory texts in the template are not really suitable in all situations. The visual design of the packaging and leaflets is largely determined by marketing and production requirements. This leads to lot of text in a very small space and a strong brand identity. It does not lead to a visual design that supports patients to take their medicines appropriately. Furthermore, it is only the packag leaflet which needs to be tested on a limited number (about 25) of healthy volunteers. The outer packaging is not tested, nor are combinations of three, four, or more medicine packs tested. We feel that 'best practice' should start with the patient. It

Figures 7 and 8

A rosuvastatin package leaflet includes several phrases that may confuse patients. The leaflet states for example: 'If you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean, and Indian'. What happens if you come from Buthan, Bangladesh, Myanmar, Mongolia, Laos, Thailand, Cambodia or Malaysia? The next sentence mentions: 'Your doctor needs to choose the right start dose of Crestor to suit you.' Wouldn't this be the case for all patients, regardless of their country of origin?

would ask patients and / or their carers what they need and want. Secondly, prototypes would be made in which texts and design are considered together. User testing would be done to check if performance levels are reached. An iterative process would guarantee that patients are really enabled to act appropriately. This process would not only involve regulators and industry, but also doctors, pharmacists, carers, and a variety of patients.

c. Patients have different characteristics

The lack of tailored information for the individual makes information about medicines so hard to understand and apply. The European legislation for medicines standardise the information through a rigorous application of a template. This approach therefore ignores that there are differences between patients (old/young, health literate/less health literate), differences between medicines (OTC/POM, chronic/short term, life threatening/benign), and differences between languages and cultures. There is little in the current supply of visual information that accommodates for this variation.

d. A coordinated information strategy.

A fourth cause of the difficulties that patients encounter is that the information comes from many sources. A prescribing doctor provides oral motivations and instructions, a pharmacist adds oral / written advice and one or more labels per package, the industry adds the obligatory information on the outer packaging and information in the package leaflet. In addition patients frequently have to take more than one medicine, which multiplies the amount from all sources. Motivated patients ask others, search on the internet, join discussion groups, and join patient associations. It is not unlikely however that the more vulnerable patient may not ask or be able to access this information leading them to higher risks.

What can we do about this to alleviate the problems?

It is clear that some of the regulations and guidelines need to be changed. The European Commission is aware of these 'shortcomings' and is currently drafting suggestions. Unfortunately, this seems to have a low priority at the moment.

However at least four actions can be undertaken to alleviate the current situation within the current regulatory framework.

a. Make sure that there is enough 'high level' support.

To change situations it is essential to have support from people at the top of organisations. Most of these projects require the cooperation of many internal departments, and several outsiders. The 'lowest common manager' who can deal with all departments working on the information about medicines is frequently on the board of directors.

b. Build prototypes and alternatives.

To show that it is possible to change the contents and design of information about medicines, it is essential to build models and prototypes. These prototypes can be tested and show which performance levels could be reached. Not only in a digital world, but also simply on paper by visually enhancing the current information so that they can be understood by those with limited literacy and numeracy skills.

c. Gather the right data.

To change legislation and to change situations, it is vital to know what the current state of affairs is. The number of confusable packs, the frequency of incorrect dispensing, the numbers of patients interpreting instructions incorrectly, and so on. It is likely that this kind of research will show a complete range from 'best practice' to 'harmful practice'. Without relevant and reliable data, it is not possible to distinguish between these two.

d. Get the right people around the table.

If it is essential to improve the information that is provided to patients, it is necessary to involve all the people that are engaged: doctors, pharmacists, healthcare professionals, industry, regulators, and patients. A coordinated approach can only be based on a cooperation between these stakeholders.

7

Take special care with CRESTOR:

- **If you have problems with your kidneys.**
- **If you have problems with your liver.**
- **If you have had repeated or unexplained muscle aches or pains,** a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- **If you regularly drink large amounts of alcohol.**
- **If your thyroid gland** is not working properly.
- **If you take other medicines called fibrates** to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- **If the patient is a child:** CRESTOR should not be given to children
- **If you are over 70** (as your doctor needs to choose the right start dose of CRESTOR to suit you)
- **If you are of Asian origin** – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of CRESTOR to suit you.

If any of the above applies to you (or if you are not sure):

- **Do not take CRESTOR 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of CRESTOR.**

8

- **If you are over 70** (as your doctor needs to choose the right start dose of CRESTOR to suit you)
- **If you are of Asian origin** – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of CRESTOR to suit you.

If any of the above applies to you (or if you are not sure):

- **Do not take CRESTOR 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of CRESTOR.**