Medicines information for patients: Insights into research and practice for medical writers

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Abstract

Many people do not take their medicines as prescribed, and medicines can cause harm if not used appropriately. In addition, in most health systems there is increasing discussion about involving patients in decisions about their health – including decisions about the medicines they use. In addressing these issues, medicine information for patients can play a key role in supporting patients to get the best out of their medicines. For the information to work, it needs to be both accessible and understandable – this is easy to say, but less easy to put into practice. This article draws on research and practice to help answer the questions:

- Why is medicines information for patients so important?
- What sort of medicines information do people want?
- How can we write and deliver such information?

Keywords: Medicines information, Patient empowerment, Patient leaflets, User testing, Readability, Risk communication

Why is medicines information for patients important?

Medicines are the most common intervention in developed health systems and up to half of people taking long-term medicines do not take them as prescribed.[1] In addition, medicines are one of the most common causes of harm in healthcare. Information for patients about their medicines can impact on both these areas.[2] Such information is also important because decisions about taking a medicine are one of the most obvious applications of the promotion of choice and decision-making in health – a move gaining ground across the developed world. In the UK, a recent government policy document adopted the mantra of patients organisations, i.e. 'no decision about me without me'.[3]

European Union legislation

Importantly, medicines are one of the few healthcare interventions where patients routinely receive a piece of legally mandated information; the PL. In European Union (EU) legislative terms, PL stands for 'Package Leaflet'. In this article I shall use the more appropriate term 'Patient Leaflet'. This comprehensive leaflet, written and supplied in the medicine pack by the manufacturer, has been mandated since 1999,[4] with subsequent legislation requiring testing of the leaflets coming into force in 2005.[5] I use the term 'comprehensive' leaflets advisedly, as the patient leaflets are indeed comprehensive, with everything in the Summary of Product Characteristics (SmPC) included, but 'in a form understandable to the patient'. As a consequence of reflecting the SmPC, the leaflet is largely about negative aspects of the medicine, i.e. contraindications, precautions, and side effects.

The introduction of the testing of patient leaflets in the EU was a game changer because without a successful and documented test, no licence for a new medicine will be now granted. The testing is often referred to as 'readability testing' but the wording in the relevant directive is 'The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use'. Guidance associated with the Directive describes a process called 'user testing' as one of the methods that can be used.[6] In practice, most testing uses this method, developed in Australia by Professor David Sless.[7] It is a type of performance-based testing: can potential users find and understand key points of information for safe and effective use? There are two components to the testing. The first is quantitative – how many can find and understand key points? The second is

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qualitative; open questions about what people find useful and not useful. I will describe this process in more detail later.

Partnership in medicine taking initiatives

Alongside the development of legislation about medicines information, a re-framing of why people don't take their medicines as prescribed has been taking place. In the UK in 1997 a landmark document developed the idea of improving medicine taking through a partnership approach with patients.[8] This was part of a sea change in thinking, with the notion that intentional non-compliance (a conscious decision not to take) is as important as unintentional non-compliance (where barriers stop people taking, such as forgetting). The thrust of the thinking behind this document was that if people are given the opportunity to take part in decision-making about their medicines, they might be more likely to take that medicine as agreed. More recently in the UK, official guidance has re-stated that approach: 'Addressing non-adherence is not about getting patients to take more medicines per se, rather it starts with an exploration of patients perspectives of medicines and the reason why they might not want or are unable to use them'.[9] The provision of appropriate information for patients is central to taking forward this approach.

What sort of medicines information do people want?

Our thinking on going forward with research into medicines information for patients was shaped by focus groups we ran with people with asthma in the early 2000s.[10] We asked people what they thought about the medicine leaflets they received, and got some very straight answers: 'you throw them away don't you', 'they don't inspire you', 'things we want to know don't come first', 'priorities are those who wrote it, not patients' and 'people who suffer should help write leaflets'. More recently, we undertook a systematic review of the research published internationally on written medicine information for patients (for the UK Department of Health).[2] Alongside this review we undertook workshops with key stakeholders, including people who take medicines. Finally, as part of this work, we reviewed best practice in writing and information design, through analysis of key texts to produce guidance for people who write medicines information for patients.

The key findings were that, prior to 2006, most people did not value the medicines information they received, and there was concern about complex language and poor visual presentation of information. Crucially people did not want written information as a substitute for spoken information from their health professionals. They valued the idea of information which is tailored and set in the context of their particular illness, and also information that contains a balance of benefit and harm information. The information design review of key texts (subsequently published separately[11]), came up with 10 principles, most of which will be well known to medical writers (see Box 1).

Box 1 Ten ground rules for good document practice

1. Short familiar words and short sentences
2. Short headings that stand out
3. Type as large as possible
4. Leave white space
5. Use bullets for lists
6. Be conversational
7. Use the active voice
8. Use non-justified text
9. Use bold lower case for emphasis
10. Pictures and graphs do not necessarily help

Adapted from: Raynor DK, Dickinson D. Key principles to guide development of consumer medicines information. *Ann Pharmacother* 2009;43:700–6.

How can we write and deliver such information?

Communicating side-effect information

One of the most important points patients say they want to know about their medicines is about side effects – but in the past we have been poor at expressing this information. We have tended to use difficult medical words to describe side effects, have given only vague (if any) information about how likely they are to happen, and not enough about what to do if the patient should get those side effects. In terms of frequency, our research on the understanding of verbal terms such as 'common', 'uncommon', and 'rare' led to a change in EU policy with the revision of guidance on the use of such terms. We found that members of the public grossly overestimated the chance of side effects when using these terms alone.[12] Our research also showed that percentages confuse many people, including lack of appreciation of figures less than 1%. This has led us to the use of wording similar

to so-called 'natural frequencies', for example, 'affects less than 1 in 100 people'. One approach is to combine words and frequencies, e.g. may have advantages, for example, 'rare (affects less than 1 in 1000 people)'.[13]

Benefit information

Although most medicine leaflets now include more detailed information about side effects, informed by the new EU readability guideline,[14] there is still a long way to go in providing 'benefit' information. If people are to make good decisions about their medicines, they need to be able to balance the 'chance of benefit' from taking a medicine with the 'risk of harm'. The influential document 'Always read the leaflet' from the Medicines and Healthcare products Regulatory Agency (MHRA) supported this argument, saying that leaflets 'are too negative, with insufficient information on the benefits of taking the medicine, making it difficult for the patient to assess risk versus benefit'.[15]

More recently, the EU draft legislation on 'Information for patients' included the sentence 'The package leaflet shall include a short paragraph which sets out the benefits and potential harms of the medicinal product'.[16] Alongside this there is the latest template for patient leaflets (from the Quality Review of Documents (QRDs) group of the European Medicines Agency) which describes how information on benefits of treatment can be included.[17] However, this guidance talks about benefit information in very limited terms, such as how a medicine works, rather than any numerical values about likelihood of benefit.

This is an important distinction because, as we now present harm information numerically (e.g. 'affects less than 1 in 100 people'), if we are really going to give people information to be able to make a balanced decision, then they need benefit information in numerical terms.

However, our research to-date suggests that including benefit information in numerical terms may pose problems. We presented people both in the UK and in Australia with patient leaflets with numerical benefit information about a medicine based on an anti-platelet medicine. This included information about how the medicine worked, the general benefits in terms of reducing the chance of heart attack and stroke, and the following numerical information (based on trial data):

'If 100 people took this medicine for 2 years:

- 3 of them would be saved from having a heart attack
- 1 of them would be saved from having a stroke'

The consensus was that the principal of including more benefit information was a good one. However, the presentation of numerical benefit information provoked strong feelings, and even disbelief and shock. Many struggled to understand the numerical information and some thought it was a mistake, as it was 'too low'.

User testing

As mentioned above, the most common way of implementing the EU Directive on 'consultation with target patient groups' was to adopt a process of 'user testing'. This performance-based testing contrasts with previous content-based testing, such as readability formulae or the use of checklists.[18] It is based on how information performs, not what it contains. It assesses whether information can be found and understood by potential users of the medicine, in one-to-one interviews. It is worth noting that readability formulae are largely based on word and sentence length and readability depends on so much more. It is also worth noting that if you calculate the readability score for a piece of text written backwards, it will achieve the same score when written forwards (as it contains the same words and the same length sentences). Box 2 describes the key processes in user testing. A key point to note is that it is an iterative process: you test the information, identify problems, then you remedy those problems using research evidence and good practice in writing and design. Then you test again. Clearly, simply testing the information alone does not improve it – so the testing has to be married with expertise in good writing and design practice.

Box 2 Key steps in user testing process

1. Select 15 key points which are relevant to the safe and effective use of the medicine concerned
2. Design and pilot a questionnaire which tests finding each piece of information and then its understanding through expression in the participants' own words or answering the question to a scenario
3. Recruit 10 or 20 people from the target patient group
4. Interviewed each participant individually, asking them to use the leaflet to answer the questions. (The target is that for each point 90% need to find the information, and 90% of those be able to show understanding.)

5. The interview concludes with open, qualitative questions about what they liked and didn't like about the leaflet. (Some regulatory authorities such as the MHRA place as much value on the qualitative questions as on the quantitative questions.)
6. The results are then analysed, identifying the questions that people struggled to find or understand, and looking at their general comments
7. The leaflet is then revised to remedy those problems, using research evidence and good practice in writing and design
8. Test again on a further 10 or 20 people
9. Analyse the results and if problems remain, go round the loop again.

Wider application of user testing

User testing is highly versatile and can be applied to any leaflet format, e.g. large print leaflets, audio versions, and web-based medicines information. It can also be applied to other forms of information such as medical device 'Information for use'. This also includes materials produced by health services such as the booklet supplied in the UK to everybody who takes lithium. During development, the booklet was revised and went through two rounds of user testing, with many changes. This included the heading 'Risk factors for toxicity' becoming 'What can make the level of lithium in my blood get too high'?, a good example of the use of conversational language in such materials. Clinical trial patient information sheets have also been tested and improved.[19]

We have also user tested the European Public Assessment Reports (EPAR) Summaries. The full EPARs describe the potential benefits and risks of a medicine and how the regulators came to the view that the benefits outweigh the risks. The EPAR Summary is a 'short lay version … written in a manner understandable to the public' and designed to 'give the public adequate information to understand the basis for approval'. Our testing of both the web and hard copy version of an EPAR Summary found that only 25% of the points of information tested reached the performance levels set for leaflets. Qualitative questions showed considerable confusion about the purpose of the document. After revision and re-testing the number of points found and understood rose to between 70 and 80%. Qualitative comments on the original document included 'It's not user friendly from the start. It's more like something from a lecture'. In contrast, talking about the revised version, one participant said 'It's in bullet points and easier to read than paragraph after paragraph of information'.

One example of applying user testing to materials for health professionals is our SmPC testing with doctors. It was no surprise to find that these documents tested poorly. The qualitative feedback was very instructive, with use of words like 'muddled' and 'information buried'. We went through an iterative process of testing four formats for SmPCs, with the final version performing much better than the one we started with. We will be forwarding the results of this research to the European Medicines Agency to inform current consultations on the future of SmPCs and package leaflets.

As with all information, one of the keys to the revised SmPC was clear signposting with good headings and sub-headings – the same approach as that which works for lay people. Other testing that we have undertaken has been with the educational materials supplied with Risk Management Plans in Europe and Risk Evaluation and Mitigation Strategy documents in the USA. This includes information for both health professionals and for patients, and it is very clear from this work that writing for health professionals really is the same as writing for patients – both want plain, clear, and easy to access information.

Key messages

Recent trends in policy and practice, along with the research evidence which are described can inform how we go forward with medicines information for patients.

- As well as supporting safe and effective medicine taking, people need medicines information to let them understand the associated benefits and harms. This can then allow a more informed decision to be made.
- The risk of a side effect can be better described using a '1 in 100 people' format, rather than just verbal terms or percentages.
- Preliminary research suggests that the provision of benefit information numerically presents problems and further research is needed.
- User testing can, with small numbers of participants, help to identify problems in written medicines information. However, expertise in good writing and design is needed to resolve those problems.

- Experience with the revision and testing of materials with both patients and professionals suggests that the same principles apply – both want plain, clear, and easy-to-access information.

The Pharmacovigilance Directive of 2011[20] required the Commission to present a report 'regarding the readability of the summaries of product characteristics and the package leaflets and their value to the healthcare professionals and the general public' and that they should then make proposals for improvement 'to ensure that they represent a valuable source of information for healthcare professionals and the general public respectively'. We hope that the findings of the research described above will contribute to that report.

Declaration of interest

Professor Raynor is co-founder and academic advisor to Luto Research (www.luto.co.uk) which develops, refines, and tests health information.

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