Sources of information on medicines for patients

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Key words

- Medicines
- Patient information
- Patient empowerment
- Patient information leaflets
- Drug safety

Word count: 3,058

Reference count: 23

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1. **Introduction**

   Everyone should all expect accurate, accessible and usable information about their medicines. A generation ago the only source was the label on the bottle. Since then, there has been a gradual increase in the information available. Pharmacists started to include additional administration and safety information on the label (in addition to dosing), and then leaflets started to appear – notably with non-oral dose forms such as inhalers.

   Work on developing more comprehensive leaflets (recognisable as the type of information available now), began in the late 1980s, with the research on the 'Bloggofen' style of leaflet (1). This was overtaken in the mid-1990s with an EU initiative to provide inside every pack what are generally called PILs (Patient Information Leaflets). These comprehensive leaflets (covering indication, warnings and precautions, administration and side effects) became mandatory in 1999 (2), and from 2005 were required to be tested for readability with members of the public – so-called 'user testing' (3). Alongside these developments has been the rise of the Internet, and the now myriad number of unregulated sources of information about medicines.

   The focus has shifted over this time from basic 'how to use' information, through to more information on safe use and, latterly, giving patients information to enable them to make an informed decision about whether a medicine is right for them. In 2005, the Committee of Safety of Medicines (CSM) published guidance called 'Always read the leaflet', which noted the variable quality of PILs (4). Subsequently, despite improvements arising from user testing, the so-called 'Shortcomings' report from the European Commission in 2015 (based on a literature search and a Europe-wide stakeholder survey), said there was further room for improvement (5), later repeated by a report from the UK Academy of Medical Sciences (6)

2. **Main body of article**

   The main sources of medicines information for patients in the UK are:
   (a) 'official' sources, authorised information by UK and EU regulators (via pharma companies), and the NHS
   (b) organisations representing patients such as health charities
   (c) commercial sources.
   This article will focus on text based information (e.g. in hard copy leaflets and websites).

   - *Patient information leaflets(PILs)*

   PILs are the most widely available source of hard copy information, as companies are required to include them inside every pack. Regulated by the European Medicines Agency (EMA) and national authorities such as the UK Medicines and Healthcare Products Regulatory Agency (MHRA), they are comprehensive in content as they have to 'reflect' the information in the Summary of Product Characteristics (SmPC; full technical information aimed at prescribers and other health professionals) (2 – Directive) .

   A template for the information includes 5 main headings:
   - What X is and what is it used for
   - What you need to know before you take X
   - How to take X

        ○   Possible side effects

        ○   How to store (7)

As well as being included inside every pack, the leaflets are available on www.medicines.org.uk. Leaflets are also mandated in other regions, notably the USA and Australia, where the degree of regulation varies (8)

- *Patient alert cards and safety information*

In addition to the package leaflet, regulators may require other 'risk minimisation materials' to be produced by the company for medicines considered higher risk. These can include information generally known as 'educational materials' for patients – such as a booklet or patient alert card (again subject to close regulation and approval).

- *NHS produced content*

In 2017 NHS.UK started publishing new information on 100 common medicines on its beta website, after a number of years without any in-house NHS web-pages about specific medicines https://beta.nhs.uk/medicines/ (developed in collaboration with pharmacists at the NHS 'UK Medicines Information'). There has been extensive user feedback, and the new pages are described as 'person-centric, not product-centric'. They will be integrated into the NHS website and be available for syndication. In addition individual NHS organisations such as Hospital Trusts and CCG produce bespoke information leaflets.

- *Commercially produced content*

There are a number of commercially produced websites which include standardised information about medicines. These include:

a) Patient UK (www.patient.info) – these information sheets about most common medicines are the same information provided by some GP computer systems (accredited by the NHS quality mark 'The Information Standard').

b) NetDoctor (www.netdoctor.co.uk) - contains information written by health professionals and the website contains a section on medicines including details of specific medicines.

- *Patient support organisation content (leaflets, booklets or website)*

Many charities and patient organisations included medicines information as part of wider information or specifically about medicines.

All of the above information is available online, however, when patients search the Internet for information on medicines they will get many hundreds of unregulated sites. Interestingly, in the CSM report in 2005 (before widespread use of the Internet) it was noted that people wanted access to 'a range of sources'.

What type of information do patients want?

Patients need information which helps them with:

(a) decision making about whether the medicine is right for them, and

(b) on-going decisions about the management of the medicine and interpreting symptoms.

This was one of the conclusions of a 2007 NHS funded systematic review on the role and effectiveness of written information about medicines (9). It also described the need for PILs to contain a balance of the possible negative effects with the potential benefits – later described as the Achilles heel of PILs (10). People need to be able to balance benefits and harms if they are going to be able to make informed decisions about their medicines. The AMS report recommended that PILs

be revised to present a clearer, more simplified and balanced appraisal of the benefits and potential harms of the medicine. Patients may, however, be surprised by the perceived lack of benefit of many medicines. A study of people taking statins gave the following information: "If 17 people like you take this medicine over the next 5 years, one of them will be prevented from having a heart attack or stroke". Patients were seen to have overestimated the benefits of statins and expressed surprise at the numerical information. (11)

Earlier research showed patients did not want written information to be a substitute for spoken info from professionals (9), supported by a key findings of the EU 'Shortcomings' report, saying not only that the leaflet should not stand alone, but that the information should be integrated to become part of the care process.

In terms of content, patients want information which is relevant to them – which means that the hard copy leaflets listed above are less able to meet their needs – as they are all 'one-size fits all' (5,9,12). Conversely , Internet based information (if well-structured and layered) can allow readers to focus in on the information important to them.

What sources are currently used?

Evidence relating to the use of medicines information sources for patients is patchy, and much is not current. A 2010 study found 97% were aware of the PIL supplied with the medicine, and 35% said they had read at least some of the leaflet. This was considerably higher for first-time users (71%) - however, for repeat users, nearly 60% said they had never or rarely looked at the leaflet after the first supply (13). The side-effects section was most commonly read and was the most common specific reason given for reading the PIL. Morecroft et al in 2013 surveyed in-patients and found 74% said they read the leaflet (42% always and 32% for new medicines) (14).

What is the purpose of the information and does it work?

Before we can know if something works we first need to decide on the desired outcomes. With health information we need to make a distinction between effect on knowledge and understanding, and impact on behaviour. The former could be said to be the primary function and that whether it increases adherence or not is a more balanced issue. It could be argued that an informed decision not to take a medicines is a good outcome for the individual (15) and hence the focus here is on the impact on knowledge and understanding – not on what action the patient subsequently takes. The 2007 NHS systematic review found some health professionals saw increasing adherence as its prime function – contrasting with patients who saw an informed decision not take the medicine as an acceptable outcome. The review found 'no robust evidence' that written information improved medicine adherence (9).

A Cochrane review examined if written information about individual medicines can improve knowledge or attitudes, or change behaviours. Several trials, while using different types of information and different measures, found written information improved knowledge. The review concluded that it is important that medicines information be well written and designed (based on best practice for its information design and content), to maximise the possibility of improving knowledge (16).

A key change in the nature of PILs took place from 2005, when EU legislation required that they "reflect the results of consultations with target patient groups to ensure [they are] legible, clear and easy to use" (3). Most pharma companies fulfil this obligation by 'user testing' — where lay people

are asked to test the PILs. There are two parts to the interview: the first determining whether people can find and understand key points of information; the second asks open questions about what they did and did not like about the leaflet (3). These responses are particularly useful because their views are informed by their having had to use the PIL to answer the questions in the first part of the interview. So, the testers provide feedback on what is wrong with a PIL, allowing the application of expertise in information writing and design to make improvements. The PIL is then tested again. It is important that 'real' people do the testing, not expert patients. Expert patients are important in providing strategic advice, but for testing the information itself it is only the man or woman 'in the street' who can tell us if the leaflet is fit for purpose for ordinary people.

User testing has resulted in improvements to PILs since 2005, but there are still issues that need to be addressed to maximise their benefits. The EU Shortcomings report called for the implementation of user testing to be more iterative, rather than being undertaken mechanistically, without a focus on the cyclical 'test-improve-test' approach (5)

How information should be presented for maximum effect
There is no single 'right way' to present information (whether in hard copy or on screen) – rather there are general principlees associated with good information writing and design which need to be applied. Such principles have been described in a review from the wider discipline of information design (18) and an EU guideline on 'readability' focussed on PILs (19). An overall principle is to write conversationally, addressing the reader as "you" – this helps ensure the writer uses simple, everyday language. It also helps engage with people who don't do much reading or writing – conversation is their main mode of communication. Using the active voice is key here: *Researchers studied the effect of X'*, rather than '*The effect of X was studied'*. A good way of determining whether what you have written is, indeed, lay friendly, is to read it aloud to see whether it sounds conversational. Importantly, pictures and graphics need to be simple and shown to be understandable through testing. They are not a panacea – anything in pictorial form is not necessarily easier to understand – and can mean different things to different people. Layout and design are just as important as the wording used – the look of a document and how attractive and easy to read it looks is critical to its effectiveness – it can determine whether it is read at all. Secondly, if it is read, the layout dictates how well people can navigate around it. Other key tools include using bullet points to organize lists, using bold lower-case text for emphasis and lay friendly headings and sub-headings.

The EU Shortcomings report called for more experience and evidence on the use of a key information section (or 'headline section') - listing of five to nine bullet points which summarise the most important points related to that medicine, which has considerable face value (18). A card-sorting study suggested that a revised order of information would enable readers to locate information more effectively. Crucially it showed that lay people see warnings and precautions and side effects as one category and would like a single section on 'usage problems' (20).

We know from a study published before the internet became widely used that people taking more than one medicine would prefer tailored, combined information about their medicines (rather than separate pieces of information about each of them(9). The advent of web-based information means that this is now achievable (although generally not yet available) – with combined information about their various medicines that takes into account any counterbalancing side-effects or additive effects – as well as being more convenient for the patient.

Basis for offering practical advice

The advice to those producing medicines information for patients is to follow good practice in information writing and design, and to user test their information with real people from the target group. Remember that design and layout are as important as the words used. The Shortcomings report recommended examination of the potential for electronic options in the future (5). However, web-based information should not just be a *pdf* of the hard copy – patients value tailored information, set in context of their characteristics and particular illness (9,12). Automated computer systems could also allow for leaflet tailoring in the pharmacy (12).

All professionals should critically appraise the information they give out or recommend – does it follow good practice in information writing and design? As well as recommending sites they trust, professionals need to help patients know the basic rules for assessing such information (such as Great Ormond Street Hospital site's 'who when and why?) (21). PILs are far from perfect, but post user-testing they are much improved and can still make a difference if used in conjunction with input from health professionals. Notably a pharmacist or pharmacy technician can talk to a patient about their medicines each time they are dispensed. The discussion could be centred around the PIL — taking it out of the box and using it as an aide-mémoire — pointing out key points most relevant to that patient (10).

Regulators should note that the negative public and professional views may be linked to the old-style PILs of the past — before user testing - and that the new regulations resulted in improvements. A public education campaign could address this - 'have a look at your new leaflets'.

Advice for patients is to use your pharmacy – and ask for information if it is not offered. The CQC Adult inpatient survey found that 43% of patients said they were not told about which side effects to look out for. (22) Equally, it appears that most people collecting prescriptions from pharmacies are not given any spoken information (23).

Conclusion

Medicines information, if well written and designed, can increase people's knowledge and understanding – enabling them to make informed decisions about their medicines, and helping them to take them safely and effectively. However, patients want such information as support to spoken information from health professionals, notably pharmacists – not a replacement. Steps need to be taken to integrate the provision of medicines information into the care process.

Medicines information should contribute to people making decisions about which medicines are right for them – for this they need to know about the chance of benefit, as well as the possible harms. The primary goal of providing information is to improve people's knowledge and understanding – which may in turn improve their adherence to the medicine. But equally, it may make them decide that the medicine is not right for them.

There are established principles for good information writing and design and information producers should take account of these, as well as involving users to ensure the information is fit-for-purpose through user testing. Equally, health professionals can use these principles to assess the information they supply or recommend.

Passive provision of standardised generic leaflets – whether as hard copy or as a pdf - is outdated and the advent of web-based information offers wide opportunities for people to access tailored information which meets their individual needs. A key challenge is to develop ways of provision which are flexible, to allow uptake of varying amounts and types of information, depending on needs at different times in an illness. Electronic information can meet this challenge, but there needs to be an integrated strategy for electronic PIL formats as part of the care process.

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3. **Key messages box** (150 words, 4-5 bullets)

- Information can improve peoples' knowledge and understanding if well-written and designed – this can be ensured through user testing with members of the public.
- The focus should be on empowering decision making, and supporting safe and effective use (rather than encouraging people to take a medicine)
- People want information that is tailored to their circumstances and needs, not standardised information
- Written information should support, where possible, spoken information from a health professional – not replace it. Ideally the information needs to be integrated into the care process.
- Prescribers and pharmacy staff can use the hard copy patient information leaflets that come with all medicines as part of their information-giving process when medicines are prescribed and supplied.

4. **Information for patients box**

The leaflets inside all medicine packs contain approved information – the quality of these leaflets has generally improved over the past decade, through their readability being tested with members of the public. You can find also these leaflets on www.medicines.org.uk. There is also information on the NHS website of many common medicines https://beta.nhs.uk/medicines. Also, if you want any information about your medicines, ask your pharmacist – that is what they are there for.

5. **CPD activity box**

Choose 2 medicines which patients you care for commonly take – then go to www.medicines.org.uk and https://beta.nhs.uk/medicines and look at the information patients can access there.

- Could you integrate these webpages into what you say to patients when prescribing, supplying or administering a medicine?
- Does your work computer system provide similar information – how does it compare?

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