

Practice chairman's address: To be or not to be taken? That is the question

Theo Raynor discusses research into information on patient leaflets and medicines labels and calls for this to be improved and better used

We know that most people do not take their medicine as prescribed; it is normal behaviour. Most people do not always obey the speed limit, most people do not eat their five portions of fruit and vegetables a day and most people certainly do not take 30 minutes of exercise three times a week as they should. So, not taking medicines as prescribed is normal behaviour — we all do it. The Concordance Initiative suggested that if more people were involved in decisions about their medicines they might be more likely to take their medicines as agreed. But, of course, to get more involved and to make decisions about risks and benefits of medicines, the theme of our conference, then people need usable information.

My first piece of practice research was during my preregistration trainee project, when I wondered whether people actually understood the labels we put on our medicines. So, I selected a number of these labels and asked people what they thought they meant. I found that "One to be taken every eight hours" was understood to mean every eight hours for two doses only. People thought about the day in terms of the hours between when they wake up and when they go to bed, rather than as 24 hours, so taking a medicine every eight hours for two doses is logical from that lay perspective. I also looked at additional labels like "Complete the prescribed course" and "Avoid alcoholic drink" and found that there was wide misunderstanding of these labels. Particularly noticeable is use of the word "avoid", which appeared to lead people to make decisions on what suited them.

It is worth remembering that in the UK in the early 1970s it was still common to label medicines "The tablets" or "The liquid" and so when I did summer vacation work at Boots The Chemists in Skegness, it was only a few years after people were routinely not being told the name of their medicine. Clearly it was impossible for patients to take any part in any decision-making, or even consider the risks and benefits of a medicine, when they did not even know its name. Anyway, we have come a long way since then and we now have comprehensive leaflets for patients inside every pack. But there is still great room for improvement.

Written medicines information

Why is written information important? We have seen that if patients are to take part in decision-making they need access to information about the treatment options. Without good information, they cannot make an in-

formed decision. Patients need to be able to access the information and then they need to be able to understand the information when they find it. Of course, in many countries, patient information leaflets are the bedrock of the information that people get. The US has had a voluntary framework up until now. Leaflets there are computer-generated in the pharmacy and typically a lot shorter than the leaflets we in the UK are used to. However, it is worth noting that the US Food and Drug Administration has recently started to become more active in the area of consumer medicines information and have been developing guidelines and, indeed, its own medicines information, posted on the FDA website.

In Australia, there is what I would call enlightened legislation. The Country took a collaborative approach to developing consumer medicines information and this involved all the key stakeholders, including patients, regulators, professionals, drug companies and, crucially, information design experts in the form of the Communications Research Institute of Australia. In Europe, we have had rigid legislation, where leaflets have to contain all the information in the Summary of Product Characteristics, but in a form understandable to the patient. These are generally supplied as package inserts and have been a legal requirement across the EU since 1999.

Existing leaflets supplied with medicines in the UK do not meet patients' needs. In a focus group study with people with asthma in the early 2000s, we discussed their medicines information needs. In particular, we were interested in their views on the leaflet that came with the medicine. Quotes that came out of that focus group work included:

- "Too small and folded and in the box"
- "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"
- "People who suffer should help write leaflets"

The last two quotes show how important it is that we involve patients in the development and testing of leaflets, which are, after all, for their use.

Our research has also been helpful in showing what people do with the leaflets that come with their medicines. We undertook community pharmacy based studies in 1999,

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research team focuses on how medicines are used in primary care, including the effective delivery of medicines information for patients. The research is undertaken in the context of a partnership approach to medicine taking. Research funding has been obtained from the UK NHS R&D programme, the National Lottery, the Healthcare Foundation, the Wellcome Trust and the Drug Information Association. Recent publications have appeared in the *BMJ* and *The Lancet*. The team's work has been presented in continental Europe, the US, the Far East and Australia. Professor Raynor is chairman of the International Pharmaceutical Federation working group on medication literacy and he has advised the Medicines and Healthcare products Regulatory Agency on policy in consumer medicines information. He is also chairman of a university spin-out company, Luto Research Ltd, which provides consumer information testing services to the pharmaceutical industry.

2002 and 2006, where we recruited patients as they were collecting their medicines and then telephoned them a week later to ask them about their medicines information leaflet. In the latest study we found that 97 per cent had noticed the leaflet, and that is a considerable improvement on the previous two studies where the figure was 88 and 83 per cent, respectively. It seems that since the compulsory introduction of leaflets in 1999, patients have now become more aware of these leaflets. We found that 71 per cent of first time users of the medicine had read some of the leaflet. However, one of the worrying findings was that 60 per cent of repeat users (ie, people who had had the medicine before, often for long periods) had rarely or never looked at the leaflet since the first time they received the medicine. Clearly, much can have happened in terms of the information about that medicine over that period and if

people are not referring to the leaflet after a number of years, we need to remedy that situation. However, it is good that most people are now aware of the leaflet and when people first get a medicine about three-quarters of them do read some of it.

This year we completed a systematic review of research in this area for the NHS R&D Health Technology Assessment programme. We called this project (available at www.hta.nhsweb.nhs.uk) MILK for short, which stands for Medicines Information Leeds and Keele because it was a collaboration between the two universities, along with input from experts such as Gill Dorer, who was our patient consultant, and David Dickinson, an information design consultant.

The project had four arms. The first was a systematic review of randomised controlled trials to determine whether written information works or not. We also did a systematic review of the qualitative research to look at the use and usefulness of written medicines information. In addition, there was an information design review, because we expected that we would find few pieces of research which looked at information design as applied to medicines leaflets. However, we knew that there was lots of resources out there about information design in general. We wanted to come up with the key principles for writing good medicines information for people to use in the future. And, finally, we held two stakeholder workshops at the beginning and end of the study. This was requested by the funders to ensure a patient perspective in the preparation of the review and in the interpretation of the findings. This had a major impact on our thoughts and processes in undertaking the review.

The principle finding was that most people do not value the written medicines information they have received in the past. In addition, they do not want written information to be a substitute for spoken information from their prescriber. And provision of this information did not usually increase knowledge, satisfaction or compliance. I think it is important that we take on board the strong desire that people have for spoken information from their prescriber. They acknowledge that they need written information to back that up, because they cannot remember everything a prescriber tells them, nor does the prescriber have the time, but they do want that spoken information, that interaction.

Crucially, patients do not see improving compliance as a function of leaflets. From the patient's perspective an informed decision not to take a medicine, after reading any information, is an acceptable outcome and that, of course, is entirely reasonable. However, the research shows that some health professionals think that a major role for leaflets is simply to improve compliance. We also need to take account of the fact that the research shows that patients' would like written information to help decision-making in two ways.

First, they need the information to make initial decisions about whether to take a medicine

or not. In this situation they need information about the range of treatments available and, of course, this is before the prescribing decision is made. Secondly, and equally important, they say they need information for ongoing decisions about the management of their medicines and interpreting any symptoms they might have. They may need this information at various times after the prescribing decision.

At the moment, we tend not to differentiate between these two needs and simply provide one piece of information which is supposed to cover both options. We need to consider how we can go forward to meet patients' need in this respect.

The information design review resulted in the distillation of 10 key principles:

- Use short familiar words and short sentences
- Use short headings that stand out
- Use type as large as possible
- Leave white space
- Use bullets for lists
- Be conversational
- Use the active voice
- Use non-justified text
- Use bold lower case for emphasis
- Pictures and graphics do not necessarily help

Most of this is common sense but, in the past, we have often not applied it to the written information we have produced. I want to pick out, in particular, the principles related to being conversational and using the active voice. The Plain English Campaign recommends that we try to write as we speak. This is because most people do not actually read much — they rely day-to-day on spoken communication, whether it be with family and friends or through the media. If we write as we speak then people are more likely to be able to associate with that and find it usable. For example, you would never say to a patient, as you were giving out his or her medicines, "One is to be taken three times a day". You would say "Take one three times a day" and so that is the wording that we should be using on our labels and our leaflets.

So what are the implications for health care that came out of this review? The first is that regulators and producers of written medicines information need to involve patients at all stages of the information development process, allowing their needs to be better reflected. They should also use the findings on information design that have come out of this review to improve the quality and usefulness of their products. As spoken information remains the priority, health professionals should make sure that written information is not used as a substitute for discussion. Pharmacists should encourage patients to use the written information they get and should welcome the questions that this might raise.

In a collaboration between the universities of Leeds, Wisconsin and Sydney, we recently completed an international evaluation of pa-

tient information leaflets across Europe, North America and Australia. We found that the Australian leaflets best met the quality criteria we set, with a level of 90 per cent compliance. The UK leaflets did nearly as well at 81 per cent but the US leaflets gained a figure of only 68 per cent compliance. The US leaflets we evaluated had only 50 per cent compliance for information about contraindications and precautions such as drug interactions. This study will be published in the *Journal of the American Pharmaceutical Association* in November.

Getting it wrong

In my 25 years or more of researching into this area, I have come across good examples and not so good examples. Two examples of the latter helps explain some of the key issues. The first is "Avoid panty hose and tight underwear". This was on an American leaflet for metronidazole. Of course, for some people taking metronidazole this is indeed an appropriate instruction but, for most, it is not. The most important thing I want to point out, however, is the use of the word "avoid". This is a good example of a word we should not use, whether spoken or written, because "avoid" does not actually tell somebody what to do.

The second example is from another American leaflet for an anti-parkinsonian agent. One of the sections is headed "What should I do if I forget a dose?" followed by "If your next scheduled dose is more than four hours away, take the missed dose as soon as you remember it. If you are scheduled to take another dose in less than four hours, take the missed dose when you remember it but do not take the next dose at the scheduled time. Instead, wait four hours until you take the next dose. Take any remaining doses for that day at least four hours apart. If you miss two or more doses in a row, take only one dose when you remember them. Do not take more than one dose at a time." Clearly this has never been anywhere near a patient for testing — you can spend some time reading it and not understand what you should do if you miss a dose. Those who have written medicines information will know that it is difficult to tell people, in written form, what they should do if they miss a dose, because there are so many variables. This example shows that we must test information on patients, otherwise it may be useless.

Risk and benefit information

We know that side effect information is important for most people — it is always in the top two of any list where patients are asked what information they most want about their medicines. Risk information alone is, however, of little help in decision-making without equivalent information on the benefits. Patients want a balance of harm and benefit information and this is one of the findings from our systematic review. But expressing the likelihood of side effects is difficult. Words like "common" or "very rare" do not work

well. Percentages are not good either, especially percentages less than 1 per cent. It is clear from our work that many people do not think about a percentage less than 1 per cent. They seem to think that a percentage is 1 in 100 or so many in a hundred, so how can you have less than one? So we need to be careful with percentages. Natural frequencies, terms like "1 in 10,000", are better. So it is our practice now to use a combination of words and also natural frequencies, which seems to work well. For example, a side effect might be described as being "Very rare (affects less than 1 in 10,000 people)".

Many will remember a couple of months ago there was a flurry of press reports about the routine use of statins in men over 50 years and women over 60. The National Director for Heart Disease and Stroke said that this blanket approach would save lives, NHS funding and doctors' time. Part of the press coverage, which I presume came from the press release, said: "Although the drugs have been associated with liver problems, muscle wasting and slightly elevated risk of cancer, the British Heart Foundation and the Department of Health say that the benefits outweigh any side effects". But I do not think we can say this: we cannot say that the benefits outweigh any side effects because we have to remember that each statin that would be prescribed would be taken by an individual who would want to have some understanding of the benefits to them and the risk to them. And so if they were at relatively low risk, they might find that 70 people would have to take the medicine for one of them to be saved from a heart attack or a stroke. They would also find (as above) that the drug is associated with liver problems, muscle wasting and a slightly elevated risk of cancer. Would the individual say that the benefits outweigh any side effects? We need to think much more deeply about such approaches.

Testing

How can we ensure that written information meets patients' needs? Last year, *The Independent* reported a study from the Department for Education and Skills: "Millions cannot read well enough for karaoke". They found that songs like "New York, New York" require the reading skills lacked by more than five million adults and nearly 18 million would fail to sing "Angels" by Robbie Williams in karaoke. It is disappointing that the headline was not "Millions cannot read medicine labels and leaflets well enough" — because how much more important is that? But this coverage shows that we need to make sure that the labels and leaflets we produce are understandable for the general population, many of whom have relatively limited reading skills.

In the past, we tended to look at this in terms of content-based testing (things like readability formulae or check lists) but they do not tell us whether the leaflet works or not. So this led us to performance-based testing; looking at how a leaflet actually performs

when given to a person. The type of performance-based testing generally used now is called "user-testing" and it was developed in Australia at the Communications Research Institute. It assesses if information can be found and if it can be understood. We have used user-testing in our research and teaching over the past few years and, during that time, the EU put into place legislation that requires user-testing for the leaflets of all newly licensed medicines across the community. So the granting of all new licences depends on a successfully user-tested leaflet. This is a major step forward in our attempts to provide people with usable medicines information.

So what does user-testing comprise? Twenty potential consumers in the target group are questioned individually on 15 key points on the leaflet. Can they find the information in the leaflet and can they describe it in their own words? It is an iterative process, with the aim that 16 out of 20 people should be able to find and understand each point. So, in the one-to-one interview that forms the basis of a user-test, consumers might be asked "What does the leaflet say you should do if you want to take this medicine and have a stomach ulcer?". The interviewer then sees whether the consumer can find that information and then whether he or she can explain it in their own words. We decided to use our expertise in this area to set up a university spin-out company to provide a testing service to the pharmaceutical industry, and so LUTO (Leeds University Testing Organisation) Research Ltd was founded in 2004 by myself, Peter Knapp and Mark Gibson.

Our team includes pharmacists, David Wood (our chief executive officer) and John Blenkinsopp (our non-executive director). We are working with the pharmaceutical industry. We have more than 35 clients across 12 EU countries. Our unique selling point is that we have the expertise not only in undertaking the testing but in improving the content and layout of the leaflet before the testing, using our many years of experience. We have undertaken more than 5,000 patient participant test interviews to date and one of our leaflets has been cited on the Medicines and Healthcare products Regulatory Authority website as an example of good practice. LUTO is a perfect example of a spin-out company. It uses the research that we have done over the years in a commercial setting and it is making a difference. We now have leaflets coming on stream that have been through the LUTO process, and we know that patients can find and understand the information they need.

What next?

I believe strongly that effective drugs need effective information. Without that information for the medicine taker, most drugs will not work to best effect. Not ensuring that information is usable by the patient is unsupportable. We need to think about other pieces of written medicines information that people get and whether they should be tested, for ex-

ample, medical devices like blood glucose meters or nebulisers. And what about web-based medicines information, such as medicine guides, and clinical trial information? Both the consent forms people get and the patient information they receive about the drug that is used in the trial are important documents. Surely it is just as important that people can use these pieces of information properly in the way they can use medicines once they are licensed?

Finally, what about medicine labels? My first piece of research, over 25 years ago, showed that the wording used on medicine labels was not understood by many people. There has been a resurgence of interest in medicine label wording in the US, with recent papers by Davis and Wolf, and it is worth noting that many of the UK label wordings that I found did not meet people's needs in the 1980s are still being used unchanged. Also many of these are still in the back of the British National Formulary. It is time to revise and test these label wordings. We have got to make sure our labels keep up with our leaflets. It is one of the most important things that happens in a pharmacy: making sure that the label wordings essential for taking the medicine safely and effectively are understandable.

In summary, if patients are involved in decisions about their medicines then they may be more likely to take them as agreed. To take part in these decisions, patients need usable spoken and written information. Patients want spoken information as the priority, along with well designed and easy to read leaflets and a balance of benefit and harm information. They need information that helps them decide which medicine is right for them, and also information that helps them after starting to take it, to manage the medicine and interpret symptoms. Regulators and professional bodies should consider introducing testing of other medicines-related information. This includes devices, medicine labels and clinical trial information.

Finally, and most importantly, pharmacists should make spoken information their priority, and use the leaflet as a tool to support the spoken information, especially as new improved tested leaflets appear with medicines. Pharmacists should make reference to the leaflet at key points — that is, at first supply, on a change in dose or when a question is raised. Pharmacists should encourage patients to use the written medicine information they receive and to welcome the questions that this vital piece of information may raise.

ACKNOWLEDGMENTS: I would like to thank the teams with whom I work. There is the Pharmacy Practice and Medicines Management Research Group at the University of Leeds; my pharmacy practice colleagues from around the UK; the team that worked on the systematic review of medicines information from Leeds and Keele and elsewhere; and, finally, of course, my colleagues at LUTO Research Ltd.