Quality in Primary Care 2005;13:101–3

Patient perspective

Risks and benefits of medicines: essential patient information in a quality service

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Modern medicines can bring enormous benefit both to individual patients and to the health of the public. But all medicines carry some risk. This short article focuses on the difficulties for patients of accessing information about the benefits and risks of medicines that they are being prescribed.

Professor Sir Alasdair Breckenridge, Chairman of the Medicines and Health Care Regulatory Agency (MHRA), in his recent oral evidence to the Health Select Committee on the Influence of the Pharmaceutical Industry said:

> 'I think that the other area that I would pick up is that of the education of the public in terms of risk and benefit. A lot of the discussions which have taken place in the Select Committee have been about the safety of medicines and relatively little about this concept of risk and benefit. When we change a licence, we do not do this purely based on a safety profile of a drug. If we did this, there would be no anti-cancer drugs available and there would be no anti-HIV drugs because the adverse reactions to them are huge. They have got to be balanced against the benefits which these drugs have.'[1]

The decision facing patients for whom drug therapy is an option is to balance the benefits of taking the medicine with the risks attributed to that medicine. This is particularly important for those with chronic conditions for whom long-term drug therapy is a possibility, and for patients on multiple medication although the same principles apply for those patients with acute but self-limiting conditions. But where are patients going to get this information?

The patient information leaflet (PIL) is the statutory source of information about a medicine and should accompany each prescribed medicine. The information included is governed by statute and must accurately reflect the summary of product characteristics (SPC). There has been much criticism of PILs. Doctors report that some patients are frightened by the list of side-effects enumerated in the PILs and may be reluctant to take the medicine. There is evidence, anecdotal from patients and patient organisations as well as more systematic reports, that patients do not always find PILs useful or relevant.[2] Many patients read only part of the leaflet and it is estimated that around 1 in 10 never read it at all. Possible reasons for this include:

- the information is not always written in a clear and easily understandable way
- the information in the PIL is not ordered in a logical way
- patients do not always understand the technical terms used
- risks are not always explained in a meaningful way
- the print is too small for the patient to read
- the patient does not receive the PIL in their own language.

The MHRA has recognised the need for PILs to be improved and an Expert Working Group of the Committee on Safety of Medicines (CSM) has been established to advise, within the regulatory framework, on a strategy to improve the quality of information provided with medicines in order to meet patient needs.

There are, however, further problems for patients with regard to the PIL: it may not be up to date and not every patient receives one. In a recent study it was estimated that some 17% of patients do not receive a PIL.[3] But from the patient's perspective perhaps the most relevant factor about the PIL is that in most cases, the patient receives the information too late as the PIL is normally included with the medicine only when it is dispensed. Furthermore, the PIL is with the medicine and frequently in a sealed bag that the patient is unlikely to open until they leave the pharmacy with their medicine. This means that patients do not have the benefit of the PIL before being given a prescription.

A discussion about the risks and benefits of a treatment should be part of the consultation that the patient has with the doctor or other healthcare professional before starting a new medicine. This is inherent in informed consent but also in the concept of involving patients in their own care, so important for people with long-term conditions. An ideal situation would be:

- the need for treatment is agreed
- treatment options are explored

- particular medicines are recommended
- the PIL is discussed with the patient in the consultation.

Using the PIL in the consultation would have the advantage that the healthcare professional would be familiar with the information that the patient receives and be able to answer any queries that the patient may have. It could also help ensure that the clinician was familiar with other medicines including over-the-counter (OTC) and herbal medicines that the patient may be taking and that the patient understood the risks and benefits of taking that particular medicine. The majority of PILs are published in the Association of British Pharmaceutical Industries (ABPI) *Electronic Medicines Compendium*. Furthermore, it should be possible with new information technology for a copy of the PIL to be printed in the surgery and given to the patient. It could also be printed in a larger size of print and not the small size needed when the PIL is to be squeezed into a small packet. However, the experience of most patients in primary care is that the PIL is seldom used in the consultation.

Communicating risk is complicated.[4] Both the doctor and the patient need to weigh the relative risks and benefits of the intervention and assess the probability and degree of each in reaching a decision. A greater risk may be considered acceptable by patients in trying to treat an otherwise fatal illness, and a lesser risk in trying to prevent disease in an otherwise healthy patient or population. Most patients and doctors will have some view of the rank of possible risks, but the views of patients and the views of professionals are likely to be different as to what constitutes significant risk.[5]

There is a popular myth that the public believes that there is a pill to cure all ills and that all pills are safe. A problem faced by healthcare professionals is that very little is known about what patients understand about the risks involved in taking medicines. Some patients may never have seriously thought about the risks. Some may have considered that whatever the risks are, they are unlikely to happen to them. Others may have considered that if their doctor or other healthcare professional recommends a particular drug, that medicine must be beneficial and have minimal risk, while others understand well the risks involved.

A further problem is that professionals are not necessarily trained in discussing and interpreting risk with patients. In a recent study by Edwards *et al*, GPs were trained in shared decision making and risk communications, in order to explore the opportunities and challenges for introducing these skills.[6] The authors found that while general practitioners (GPs) indicated positive attitudes towards involving patients, they believed that the opportunities for applying the new skills were limited outside the trial. Doctors were selective about when they felt that greater patient involvement was appropriate and feasible. It is not surprising that the authors also found that time limitations were important in not implementing the approach more frequently.

Over the last year there has been considerable concern about the safety of several prescribed drugs or classes of drugs that are in common use in primary care. These include celecoxib and other selective COX-2 inhibitors, hormone replacement therapy, Depoprovera, the selective serotonin reuptake inhibitors (SSRIs), vioxx and co-proxamol. Reviews by the CSM have resulted in warnings and clarification of use explained in a 'Dear Colleague' letter from the CSM. In the case of vioxx and co-proxamol, the drugs have been withdrawn from the market. It is unfortunate that often the first that the patient knows about the risks is when they hear about it in the media.

In recent years concerns have also been expressed about the safety of OTC medicines, for example the use of aspirin in young people under the age of 18 as well as the safety of some herbal remedies including St John's Wort.

From a patient's perspective it now seems essential that patients are given an opportunity to discuss the risks and benefits of the medicine that is being prescribed and that this should involve use of and reference to the PIL. This opportunity should also be repeated when there is a review of a patient on repeat prescriptions. Furthermore, pharmacists should be willing to clarify with the patient any queries they may have about the risks and benefits of the medicine being dispensed. This is particularly important as the patient may also be purchasing OTC and/or herbal preparations that may interact with the prescribed medicine.

Patients cannot be expected to know in advance the risks and benefits of medicines they are to be prescribed. It is the duty of the doctors and nurses who prescribe the medicine and the pharmacist who dispenses to ensure that the patient really understands before starting treatment the risks and the benefits of the medicines. However, patients do also have a responsibility to read the PIL, to inform the doctor or nurse prescriber about any other medicines they may be taking, including OTC preparations and herbal remedies, and to tell pharmacists before purchasing these preparations about any prescribed medicines they may be taking.

It is acknowledged that these suggestions may take longer than the average seven-and-a-half-minute GP consultation. But the importance to patients of a greater understanding of the risks and benefits of medicines is now essential. And finally there needs also to be a political realisation that both patients and professionals need the time to ensure that patients understand the risks and benefits of the medicines they take.

REFERENCES

1 *The Influence of the Pharmaceutical Industry.* Uncorrected transcript of oral evidence given by Sir Alasdair Breckenridge to House of Commons Health Select Committee, 20 January 2005. London: The Stationery Office.
2 *Safety, Quality, Efficacy: regulating medicines in the UK.* Report by Comptroller and Auditor General, January 2003. London: The Stationery Office.
3 Raynor DK. Consumer Medicines information: an international perspective. *Chronic Illness* 2003;7:7–11.
4 Caplan P (ed.) *Risk Revisited.* London: Pluto Press, 2000.
5 Boyd K, Higgs R and Pinching A (eds). *The New Dictionary of Medical Ethics.* London: BMJ Publishing Group, 1997.
6 Edwards A, Elwyn G, Wood F *et al.* Shared decision making and risk communication in practice. *British Journal of General Practice* 2005;55:6–13.

CONFLICTS OF INTEREST

None.

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