A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines

DK Raynor,1* A Blenkinsopp,2 P Knapp,1 J Grime,2 DJ Nicolson,1 K Pollock,3 G Dorer,4 S Gilbody,5 D Dickinson,6 AJ Maule7 and P Spoor8

1 Pharmacy Practice and Medicines Management Group, School of Healthcare, University of Leeds, UK
2 Department of Medicines Management, Keele University, UK
3 School of Nursing, University of Nottingham, UK
4 Patient consultant, West Sussex, UK
5 Department of Health Sciences, University of York, UK
6 Patient information consultant, London, UK
7 Centre for Decision Research, Leeds University Business School, UK
8 Health Sciences Library, University of Leeds, UK

* Corresponding author

Executive summary

Health Technology Assessment 2007; Vol. 11: No. 5
How to obtain copies of this and other HTA Programme reports.

An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (http://www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public and private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:
– fax (with credit card or official purchase order)
– post (with credit card or official purchase order or cheque)
– phone during office hours (credit card only).

Additionally the HTA website allows you either to pay securely by credit card or to print out your order and then post or fax it.

Contact details are as follows:
HTA Despatch
Email: orders@hta.ac.uk

C/o Direct Mail Works Ltd
Tel: 02392 492 000

4 Oakwood Business Centre
Fax: 02392 478 555

Downley, Havant PO9 2NP, UK
Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods
Paying by cheque
If you pay by cheque, the cheque must be in pounds sterling, made payable to Direct Mail Works Ltd and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of HTA on CD?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. HTA on CD is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.
Executive summary: Written information available to patients about individual medicines

Background
Everyone needs written medicines information at some time. Statutory information for patients is provided as manufacturers’ patient information leaflets (PILs), included as an insert in the medicine package. This is the only written information every patient should receive about their medicine. There is a range of other sources of information that patients may receive from their healthcare provider or may access independently.

Objectives
This report addresses two main objectives.

- What are the role and value of written information available to patients about individual medicines from the perspective of patients, carers and professionals?
- How effective is this information in improving patients’ knowledge and understanding of treatment and health outcomes?

Methods

Data sources
A range of full text and bibliographic databases was searched for research on (a) the role and value and (b) the effectiveness of written patient information for individual medicines (up to late 2004). Citation searching and handsearching were also carried out.

Six experts in information design were asked to cite relevant key references, and stakeholder workshops (including patients and patient organisations) were held at the beginning and end of the review.

Study selection
Abstracts and/or titles were assessed by two reviewers. The role and value studies were defined as examining the use and usefulness of written medicines information. Effectiveness trials [randomised controlled trials (RCTs)] examined how well-written medicines information works.

Data extraction

Role and value
These were grouped as arising from three perspectives: responses to policy initiatives; the uninformed patient and certainty of professional knowledge; and the informed, involved patient.

Effectiveness
This comprised descriptive, methodological and outcome data, classified in relation to treatment-related knowledge, attitudes or behaviour.

Data synthesis
Study characteristics were tabulated and the results qualitatively synthesised, along with findings from the information design and stakeholder workshop strands.

Results

Extent of research
From over 50,000 citations, 413 were considered. Of these, 64 papers reporting 70 studies were included (36 papers reporting 43 RCTs in the effectiveness strand and 28 in the role and value strand).

Study characteristics
The setting, timing and content of interventions varied considerably. Reporting of interventions and methodological quality was often poor. Outcome measures varied, and were mostly bespoke, precluding quantitative synthesis. Few studies used patient-centred outcome measures, addressed health professionals’ perspectives or used web-based information.

Information design review and stakeholder workshops
The information design review yielded a list of key principles for application by writers of medicines information for patients. The stakeholder workshops proved invaluable in ensuring a patient perspective throughout, a model other researchers may find useful.

Key findings
Most people do not value the written medicines information they receive. The poor quality of
many leaflets tested, in terms of content and layout, may reflect the finding that provision, more often than not, did not increase knowledge. No robust evidence was found that the information affected patient satisfaction or affected compliance. Qualitative evidence shows that patients do not see improving compliance as a function of PILs; an informed decision not to take a medicine is an acceptable outcome. This contrasts with some professionals’ view that increasing compliance was a prime PIL function.

There was consistent evidence that the way in which risk descriptor information is portrayed influences side-effect knowledge. Delivering risk information numerically, rather than as verbal descriptors, ensures a more accurate estimation of the probability and likelihood of a side-effect and the risk to health.

The readability of medicines information is important to patients, with concerns about complex language and poor visual presentation. Patients value the idea of information that is tailored, set in the context of the particular illness of the individual patient, and containing a balance of benefit and harm information. Very few studies addressed either issue. Most patients wanted to know about any side-effects that could arise. Some patients question the credibility of pharmaceutical industry information, although the required PIL is written according to strict regulations.

Patients would like written information to help decision-making, first for initial decisions about whether to take a medicine or not. Hence people value information about the range of treatments available (needed before the prescribing decision). Second, they need information for ongoing decisions about the management of medicines and interpreting symptoms. Patients did not want written information as a substitute for spoken information from their prescriber. Although not everyone wanted written information, those who did wanted sufficient detail to meet their needs.

Some health professionals thought that information for patients should be brief and simple. There was evidence of professional ambivalence about written medicines information; they did not always actively recommend leaflets and were in some cases reluctant to provide certain information, particularly on side-effects.

### Conclusions

The combination of a quantitative and qualitative review, an exploration of best practice in information design, plus the input from stakeholder workshops allowed this review to look at all perspectives and explore issues not anticipated in advance. There is a gap between currently provided leaflets and information that patients would value and find more useful. The challenge is to develop methods of provision flexible enough to allow uptake of varying amounts of information on a variety of aspects, depending on needs at different times in an illness.

### Implications for healthcare

To improve written medicines information, it is suggested that regulators and producers of written medicines information consider the following:

- Involve patients at all stages of the process, enabling their needs to be better reflected.
- Use findings on information design and content to improve the quality and usefulness of their products.
- Present risk information numerically rather than using verbal descriptors.

Spoken information remains the priority, but should be closely linked to written information so, in the authors’ opinion, health professionals should:

- Ensure written information is not used as a substitute for discussion.
- Encourage patients to use written medicines information and welcome the questions this may raise.

### Recommendations for research

In general:

- Apply recognised standards to trial design and conduct, recruit more older people, have longer follow-up and more use of naturalistic settings.
- Develop, validate and standardise patient-focused outcome measures.
- Investigate how patient input can be better integrated into medicines information research.
- Ensure the study of role and value alongside effectiveness in future trials.

Specific research areas that should be addressed are the following:
Executive summary: Written information available to patients about individual medicines

- Determine the content, layout, delivery method and timing of statutory medicine leaflets which best meet patients’ needs.
- Investigate how individualisation, and benefit and risk information can be better incorporated.
- Study how to introduce more lay experience into the PIL development process.
- Undertake more studies of health professionals’ perspectives, exploring incorporation of written medicines information into the consultation.
- Undertake more qualitative research on how different types of patients and carers use medicines information in different settings and over time.
- Implement studies of the effectiveness, and role and value, of emerging Internet-based medicines information.

Publication

The Health Technology Assessment (HTA) programme, now part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the costs, effectiveness and broader impact of health technologies for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care. The research findings from the HTA Programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’.

The HTA Programme is needs-led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, the public and consumer groups and professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA Programme then commissions the research by competitive tender.

Secondly, the HTA Programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Thirdly, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer-reviewed by a number of independent expert referees before publication in the widely read monograph series Health Technology Assessment.

Criteria for inclusion in the HTA monograph series

Reports are published in the HTA monograph series if (1) they have resulted from work for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors. Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 03/44/06. The contractual start date was in October 2004. The draft report began editorial review in December 2005 and was accepted for publication in June 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.