

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

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Executive summary

Health Technology Assessment 2007; Vol. 11: No. 5

Health Technology Assessment
NHS R&D HTA Programme
www.hta.ac.uk





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Executive summary

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: 

- 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

Raynor DK, Blenkinsopp A, Knapp P, Grime J, Nicolson DJ, Pollock K, *et al.* A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess* 2007;**11**(5).

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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.

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ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.

Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.