

The role and value of written information for patients about individual medicines: a systematic review

Janet Grime MMed Sci,* Alison Blenkinsopp PhD,† David K. Raynor PhD,‡ Kristian Pollock PhD§ and Peter Knapp PhD¶

*Research Fellow, Primary Care Sciences, Keele University, Staffs, UK, †Professor, School of Pharmacy, Keele University, Staffs, UK, ‡Professor, School of Healthcare, University of Leeds, Leeds, UK, §Senior Research Fellow, School of Nursing, University of Nottingham, Nottingham, UK and ¶Senior Lecturer, School of Healthcare, University of Leeds, Leeds, UK

Abstract

Correspondence

Janet Grime
Primary Care Sciences
Keele University
Staffs
ST5 5BG
UK
E-mail: j.c.grime@keele.ac.uk

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Objective To review research on the role and value of written medicines information for patients from the perspective of patients and health professionals.

Context Providing written information to patients about their medicines is acknowledged as a priority but there is poor understanding of how best to meet patients' needs.

Method A sensitive search strategy was developed to maximize the identification of relevant studies. We used a data extraction form designed to appraise qualitative research. Findings were synthesized into a narrative account.

Main results There were three broad categories of study: those which related to policy initiatives; those where the aim was to increase compliance; and those concerned with using information to support decision-making ('informed patient' studies). While the policy initiative and compliance studies reported that, mostly, patients were positive about written information, the 'informed patient' studies showed a more complex picture. Patients valued medicines information tailored to their condition. They did not want it to be a substitute for spoken information from their doctor. Not everyone wanted written information but those who did wanted sufficient detail to meet their need. Need varied over time and between patients. The small number of studies relating to health professionals showed widespread ambivalence towards using written information. Some thought it should be brief and simple, only partially disclose side-effects and saw its main role as being to increase compliance.

Conclusion The different perspectives of patients and health professionals, and the diverse and changing information needs of patients pose a challenge to providers of written medicines information.

Introduction

Medicines are the most common intervention in health services in the developed world. Patients require information to help them use their medicines safely and effectively, and to facilitate an understanding of the possible harms and benefits of treatment.¹ In the UK, current policy prioritizes the provision of comprehensive information for patients both as an entitlement and a resource for effective self-management of health.²⁻⁴ In the European Union, the only form of written information that every patient receives about their medicine is the manufacturer's patient information leaflet which is inserted in the medicine package.⁵ Patients of course may be given, or seek, written and spoken information from a range of other sources.

Patient dissatisfaction with the amount and quality of medicines information has been frequently reported.⁶⁻¹⁰ Research has also documented adverse consequences of patients being inadequately informed about their medicines.^{11,12} Criticism of the poor quality and inappropriate content of much patient information about medicines has been frequently voiced.^{7,9,13} In addition, little is known about the amount, content, media and timing of written information provision which patients find most appropriate and useful.¹⁴

We undertook a systematic review of the effectiveness and, role and value of written information about medicines as well as exploring best practice in information design.¹⁵ The two strands of the review ('effectiveness' and 'role and value') addressed specific objectives. This paper reports the findings of the latter strand, examining research which investigated the role and value of written information on specific medicines, from the perspective of patients and professionals. While the effectiveness strand of the review was concerned with whether written medicines information works, the role and value strand was interested in how the intervention works and in what context.

Method

Searching and sifting

The same search strategy was used to find studies for both the effectiveness and the role and value parts of the review. A range of full text and bibliographic databases was searched (13 in total, including CINAHL, Medline and Embase) from 1970 onwards, using a comprehensive strategy. We excluded papers not in English due to the difficulty of interpreting qualitative data in a foreign language. We used a mixture of thesaurus terms and keywords developed iteratively in Medline. The problem of defining *role and value* and translating this into a finite list of searchable keywords meant a very broad strategy was required to find relevant studies. The need to search for common words like 'medicines', 'patient' and 'information' made the construction of keyword searches problematic, particularly in health databases. This resulted in a search strategy which was sensitive rather than specific.

To augment the electronic searches, the reference lists of papers reporting studies included in the review were scrutinized for additional studies. The same electronic databases as above were searched to find systematic reviews. We were unable to identify any systematic reviews, but found five narrative reviews.^{6,16-19} The reference lists of these reviews were searched to find additional references. Additional methods included hand searching and citation searching. Citation searching was applied to the references cited in those role and value papers that were identified by searching electronic databases and which met the inclusion criteria for the review. The 28 role and value papers had been cited in 209 papers, of which 137 had not been identified by the original database searches. Scrutiny of the titles and abstracts of these 137 identified two further studies which met the inclusion criteria for the review. Full details of the search strategy are available elsewhere (<http://www.hta.nhsweb.nhs.uk/>).

In total 50,127 references were retrieved and review team members considered first their title

and then the abstract. The vast majority of irrelevant papers were easily eliminated on the basis of title or abstract alone. Where there was uncertainty, the full paper was obtained (413 papers). The database search was augmented with searching the citations of papers identified from the sifting process using Web of Science 2005. The end result was that 30 papers from 29 studies were found.

Data extraction

We adapted a data extraction form developed by Greenhalgh *et al.*²⁰ for their systematic review of research into innovation and diffusion. This framework was selected because the papers reviewed in their study, like ours, used a variety of methodologies. Two reviewers independently completed a data extraction form for each study. These were compared and where differences were evident, the reviewers met to resolve them. Two papers were excluded at this stage. One had marginal relevance and the other had many important methodological limitations. The main purpose of the data extraction form was to provide a comparative structure as a basis to reflect on the study, to decide on the paper's key messages. We wrote to the authors of seven of the nine papers which used a qualitative methodology, (but not to one who had written an accompanying book⁷ or one who had done a quasi qualitative content analysis of drug information leaflets²¹), to request any additional data and to seek their views on our analysis of their paper.^{10,22-27} Six authors replied and additional information was included in the data for analysis.

Analysis

The main findings of each paper were recorded on the data extraction form. This was relatively straightforward for the quantitative studies. For the qualitative studies, we considered what authors said in the discussion alongside data in the results. In addition to analysing the primary data as reported by each author, the

reviewers also noted what they had learned about the authors' perceptions of the role and value of written information. For example, in the introduction to papers some authors emphasized the importance of written information to increase compliance or aid decision making.

At the end of this process we compiled a list of ways in which patients and professionals used written information, and a set of factors which patients and professionals used to evaluate the material. Common uses and evaluation of written information were identified and contradictory findings were probed to consider factors that might explain the differences. We used a narrative synthesis method. Dixon-Woods *et al.*²⁸ point out the lack of transparency in the work of the synthesizer with narrative summary. However, the synthesis strength lies in being able to cope with a large and diverse evidence base.

Results

Methodology employed by studies

The 27 studies in the review took place over more than 25 years and in three continents using a variety of methodologies. Seventeen studies used a quantitative methodology; mainly surveys (12). Most questionnaires consisted of closed questions in which participants selected a response category from a list pre-determined by the researcher. Nine of the studies were qualitative using predominantly focus groups or semi-structured interviews. One study employed mixed methods.

Nine studies (eight quantitative, one qualitative) did not recruit participants on the basis of being people who were taking or had recently taken medicines relating to the written information that was being investigated. These studies will be referred to as 'hypothetical' studies. From them, we learned about patients' normative positions in relation to information and medicine taking, which was not necessarily what they would actually do when faced with the situation under exploration.

Rationale behind studies

Three broad categories of study were identified. Twelve had been carried out in response to *policy initiatives* about written medicines' information (Table 1). Most initiatives concerned the introduction of legislation to require written information to be available with each medicine. The motivation for eight studies concerned the use of written information to increase *patient compliance* with medication, based on a perception of patients as uninformed and medical knowledge as authoritative and certain (Table 2). Seven studies explored the use and

usefulness of written information to help patients participate in treatment decisions (Table 3). In the latter, in marked contrast to the 'compliance-oriented' studies, these '*informed patient*' studies incorporated a view of the patient as someone taking reasoned decisions about the use of medicines based on their personal understanding, experiences and priorities.

The value of written information to patients

- (1) Do patients read information that is routinely available on medicines?

Table 1 Papers reviewed categorized as arising from *policy initiatives* in relation to written medicines information

Country (reference)	Method	Hypothetical*
USA (33)	Structured home interview with 2669 women taking oral contraceptives who had potentially received a short insert and a longer brochure about the 'pill'	No
USA (56)	Same study as above	
USA (38)	Laboratory based study with 265 outpatients & 151 employees evaluating a leaflet on diazepam	Yes
USA (39)	Laboratory based study with lay people (35 students, 42 general public), pharmacists (31) & doctors (32) to assess desired disclosure of side-effects for fictitious drug	Yes
USA (31)	Controlled trial with 285 hypertensive men who either received written information alone (during consultation or with medicine) or written & spoken information about a diuretic. Control group received no additional information	No
Italy (40)	Questionnaire sent to patients who had received one of two leaflets (standard or experimental) with either their prescription drug (contraceptive pill, ranitidine) or OTC medicine (2 types of laxative, ibuprofen) 6992 patients responded	No
Belgium (36)	Structured home interview using 84-item questionnaire with stratified sample of 400 of general population to find out their views on written information inserted in medicines' packages	Yes
UK (37)	Laboratory based study with healthy volunteers linked to a university, to specify and rate items of information about a fictitious drug to treat stomach problems	Yes
Belgium (44)	Questionnaire sent to 1500 GPs and 500 specialists (28% response rate) to determine attitudes to written information inserted in the medicines' package	Not applicable
UK (29)	Questionnaire completed in face-to-face interview with 117 older inpatients. An example of a PIL for an unspecified medicine was shown to them before the interview	Yes
UK (45)	Laboratory based study. 1st phase: 18 doctors ranked information. 2nd phase: 240 people rated leaflets about a fictitious drug for stomach problems	Yes
UK (35)	Structured telephone interview with 196 patients who had collected their own prescriptions from 3 pharmacies, to find out if they read the medicine PIL.	No
Australia (25)	Six focus groups, 57 participants currently taking at least 1 prescription medicine. Four groups were given written information (unspecified) during the group session and 2 were mailed written information for one of the medicines they took a week before hand	Mixed

*'Hypothetical' studies recruited participants who were not actually taking or had recently taken medicines relating to the written medicines information that was being studied.

Table 2 Papers reviewed categorized as being based on a perception of the *uninformed patient* and certainty of professional's knowledge

Country (reference)	Method	Hypothetical*
UK (57)	Survey questionnaire (11 questions, only first 7 reported on in this paper) about a leaflet on antibiotics, completed by 289 patients	No
Netherlands (30)	Observation in pharmacy of 80 patients buying OTC medicines followed by structured home interview	No
UK (34)	Questionnaire completed in face-to-face interview with 80 members of general public in a shopping centre, self completed by 48 pharmacists and 66 GPs. Different questions asked of the three groups. Patients shown a PIL for an unspecified medicine	Yes
USA (32)	Telephone interview by pharmacist of 85 older patients to evaluate a chemotherapy leaflet. (Cancer patients involved in development of leaflet)	No
Australia (46)	Content analysis of written drug information (more than 91 items) for patients given out by rheumatologists	No
Australia (43)	Structured home interview (and medication assessment) with 204 older people to explore medicine information needs. Older people shown an example of a leaflet for a medicine they were not necessarily taking	Yes
UK (22)	Ten qualitative interviews with patients, and 4 focus groups with 22 parents of children attending 2 schools, about OTC medicines	Mixed
USA (42)	Mixed method. Focus groups and interviews with patients to develop written information on contraceptive pill. Questionnaire to staff to get views on the leaflet developed	No

*'Hypothetical' studies recruited participants who were not actually taking or had recently taken medicines relating to the written medicines information that was being studied.

Table 3 Papers reviewed categorized as being based on the perception of the patient as *informed* and involved in treatment decisions

Country (reference)	Method	Hypothetical*
UK (41)	10 focus groups (62 patients) to review written information, some condition based but all including treatment	No
UK (21)	Clinical specialists reviewed materials independently using a structured checklist	Not applicable
Switzerland (23)	Content analysis of all leaflets on NSAIDs printed in 1998–99	Mixed
	Semi-structured interviews with 76 chronic pain patients, and 54 controls about medicine information preferences. Content analysis of 16 antidepressant leaflets	
Canada (26)	19 focus groups (88 members of public, 27 doctors, 35 pharmacists) to understand patient information needs and review written medicines materials	Yes
UK (10)	4 focus groups (23 patients with asthma) to explore medicine information needs	No
UK (27)	14 focus groups (88 respondents) made up of psychiatric patients/carers, psychiatrists, psychologists, nurses, occupational therapists, managers	No
UK (24)	Semi-structured interviews with 30 members of depression self-help group	No
	Content analysis of antidepressant leaflet	

*'Hypothetical' studies recruited participants who were not actually taking or had recently taken medicines relating to the written medicines information that was being studied.

In the policy initiative and compliance studies (Tables 1 and 2) some researchers partially assessed the value that patients placed on written information from the percentage of participants who said that they read them.^{22,25,29–36} For

prescribed medicines, most participants (range of 60–95%) said that they had read written information accompanying the medicine at least once. This was usually when the medicine was first prescribed. It was uncommon for patients to

read the same information on subsequent occasions. One study showed that fewer patients read leaflets that came with over-the-counter medicines, even if they had never taken the drug before.³⁰ Although one reason given for reading the information was that it was the first time the medicine had been purchased.^{22,30}

While the policy initiative and compliance studies reported that most patients were generally positive about written information received, the informed patient studies (Table 3) showed a more complex picture. All of these studies were qualitative, using focus groups and/or semi-structured interviews, which allowed respondents to dwell on what was important to them. The topics raised by respondents were broader than those investigated in the policy initiative and compliance studies, which were mostly quantitative in approach. Respondents talked about the difficulty of getting information, not just about their medicines but also their illness and the range of treatment options. They talked about how spoken information from health-care professionals was valued more than written information. Indeed, researchers in one study found it difficult to get the focus group members to discuss written information at all.¹⁰

(2) How much information is desired?

The amount of information in written medicines' materials was a factor in lay perceptions of their value. Six of nine studies that reported on patients' preferred amount of information found that most wanted detailed explanations about medicines and, when given a choice, more rather than less information.^{33,36-40} However, one of these reported higher levels of readership for a shorter insert on contraceptives compared with a detailed brochure.³³ Paradoxically, patients were more satisfied with the depth of explanation in the brochure, which they were asked to read during the interview. Two studies concluded that patients were put off reading information that was too detailed.^{25,29} In Vander Stichele's *et al.*³⁶ study 67% of patients wanted a concise leaflet, but 88% also wanted it to be comprehensive. This was a 'hypothetical' study which took place in Belgium at a time in the late 1980s when written information consisted of technical

information designed for professionals, rather than leaflets written specifically for patients. Coulter *et al.*⁴¹ wrote of the fine balance between providing too much and too little information. Their focus group members thought that many of the leaflets they reviewed (some were condition as well as medicine-based) were too basic to be helpful, while one or two were too technical. They criticized leaflets for not admitting to scientific uncertainty or supporting assertions with references to primary sources. The twin issues of differences in methodology and variations in the type of information studied limit our ability to interpret the findings of these studies. However, they do raise questions about what patients mean by 'concise', 'detailed' and 'comprehensive' in relation to written information and point to a very wide range of variation in individual preferences and across different illness settings and experiences.

(3) What information is valued, and from what sources?

Few papers addressed these aspects but many similarities were identified in the things that patients wanted to know about their medicine in three studies:^{10,26,27}

- Diagnosis. Is this the right treatment for me?
- Other forms of treatment for the condition – both drug and non-drug.
- Name of medicine.
- When and how to take the medicine. Dosage.
- Purpose of medicine/intended therapeutic effect.
- Consequences of not taking the medicine.
- What it feels like to take the drug.
- How long the drug was likely to be prescribed.
- Interactions with other medicines.
- All side-effects with a likelihood of their occurrence.
- What to do about side-effects.
- Long-term effects and risk of damage.

One issue to emerge from the 'informed patient' studies was that lay experiences were seldom, if ever, incorporated in written medicines information. An analysis of a booklet about antidepressants published by a leading UK self-help organization revealed substantial

discrepancies between the professional advice and explanations about antidepressants it reflected, and the actual experience of taking antidepressants which was reported by patients.²⁴ Herxheimer expressed concern about the preparation of leaflets by employees of the pharmaceutical industry who are far removed from the patients who will read them.²¹ Patients with asthma in Raynor's *et al.*¹⁰ study valued experiential knowledge and felt that this should be incorporated in written leaflets about medicines. Patients queried the independence of information in leaflets produced by pharmaceutical companies with a vested interest in promoting their products, and the content of medicine leaflets was thought to be dictated more by medico-legal issues than the needs of patients.^{10,27}

Role of written information from a lay perspective

Few of the quantitative studies explored how patients used written information. Vander Stichele *et al.* listed patients' normative motives for reading a leaflet.³⁶ These included deciding whether to take a medicine; to know more about it; for reassurance and to be able to comply with therapy. In Morris's *et al.*³³ study women wanted an oral contraceptive leaflet to tell them what to do if they missed taking a pill. (Ross *et al.*⁴² also had this particular role in mind when developing a leaflet on oral contraceptives.) Jazieh *et al.*³² developed a leaflet with the help of cancer patients to inform about side-effects from chemotherapy. Patients found it useful when deciding on the need to seek professional help following chemotherapy, as well as informing friends and family about treatment. Older people in Thompson and Stewart's⁴³ study felt that written information was particularly useful for people with hearing or memory problems.

The qualitative studies provided most data on how patients used or thought they would use written information. Koo's *et al.*²⁵ respondents read information leaflets if:

- they took responsibility for their own care

- the medicine prescribed was for a serious condition
- they had had a previous problem with a medicine
- they were a caregiver and administering the medicine to a child for example,

Hughes *et al.*²² found that an over the counter medicine leaflet was more likely to be read if the medicine was considered to be 'strong' or for a child.

Written information could be retained and re-consulted if the need arose. This was particularly useful when patients were unwell and perhaps unable to take in what they were told.²⁷ Many of Nair's *et al.*²⁶ focus group members felt they did not have a clear understanding of their diagnosis. They thought it important to include condition-based information in a medicine leaflet to be able to check that the medicine was relevant for them. Ideas for self-help could assist patients to take responsibility for their own care and recovery.^{24,41} Thus a major role for written information was in helping people to care for themselves or others.

Uses of side-effect information

Patients' desire for information about adverse effects was a common finding. There was a range of uses for such information. Jazieh and Brown³² found it helped patients decide whether or not a symptom was a side-effect and if prompt action was required. Other uses included reassurance that the medicine was going to be suitable for their particular circumstances,^{23,27} to prepare patients for what might happen, and to use medicines safely by knowing, for example, what OTC medicines should not be taken in conjunction with a prescribed medicine.²⁷

Nair *et al.*²⁶ said that their respondents wanted information on adverse effects to help them decide whether or not to take a medicine. This was a 'hypothetical' study. Respondents in two other studies reported that information about the pros and cons of a medicine increased their uncertainty.^{23,25} In practice then, the same information about the beneficial and adverse

effects of a medicine could cause some patients to worry, while empowering others to take treatment decisions. Information, however, was not necessarily written in a way that helped patients make treatment decisions. Herxheimer analysed the content of patient leaflets on non-steroidal anti-inflammatory drugs (NSAIDs) and concluded that the information on potential harm and benefit was written in such a way that patients could not decide whether and how much of an NSAID was suitable for them.²¹ Coulter *et al.*⁴¹ were critical of the tendency of written information to be over-optimistic and stress the benefits of treatment but downplay the side-effects.

Written vs. spoken information

The main reason given by nearly a quarter of older people in Thompson and Stewart's⁴³ sample, as to why they thought leaflets were not particularly useful, was that their doctor could tell them the same information. They regarded him as a preferred source of advice. Patients in this and other studies^{10,25,33,35} valued spoken information from professionals over written information, partly because it was felt to be a more responsive medium which could be tailored to the needs of individual patients.¹⁰

Difficulties in establishing convenient access to professionals, particularly doctors, meant that in practice, patients often had to rely on written information.²⁵⁻²⁷ A further barrier was how confident patients felt about talking to professionals and asking questions. Written information could help in this respect. Giving medicine leaflets to patients demonstrated that information about drugs was a legitimate topic for patients to raise with professionals,²⁷ and could suggest appropriate questions for them to ask.⁴¹ Thus giving written information to patients could help build relationships by making it easier for patients to ask questions during consultations with health professionals.

Conflict between written and spoken information was an issue for some patients.^{23,27,43} When appraising medicines' information the source was more important than whether the

information was written or spoken. Patients mostly attached greater importance to the word of the doctor, than to the text of a leaflet.^{10,31} In one study, only 2% of people said they would follow the instructions in written information rather than what the doctor said, should advice conflict.³⁶ Inconsistent information though may result in particular problems of interpretation and uncertainty for patients.²³

Professionals' views of written information

Only one study focused exclusively on health professionals' views of written medicines information,⁴⁴ with nine others including some relevant data.^{21,26,27,34,38,39,42,45,46} While in principle they generally supported the idea of informing patients about their medicines, in practice written information was used infrequently and selectively. Professionals were more concerned with compliance. Vander Stichele *et al.*⁴⁴ identified three clusters of professional response: 20% of the doctors surveyed were 'moderately positive', 44% 'ambiguous to neutral' and 36% 'overtly negative'. The 'positive' doctors tended to be younger and to see written medicines information as a substitute for spoken information, whereas those who were 'overtly negative' blocked patient access to written information in some circumstances. In Mottram and Reed's³⁴ study, 80% of GPs and pharmacists surveyed thought that medicines information leaflets were useful, though not necessarily for all patient groups. A quarter of pharmacists and 15% of GPs thought they might be unsuitable for patients with psychiatric disorders.

Several studies found resistance amongst professionals to giving patients full information about side-effects.^{26,27,34,39,45} Even in Fisher's *et al.*³⁸ study which found high levels of agreement between doctors and the public about what constituted a useful information leaflet, the public attached greater importance to information about adverse effects. Professionals were concerned that such information might increase non-compliance.^{26,27}

Just under half of the rheumatologists that replied to an invitation by Buchbinder *et al.*⁴⁶ to

send a copy of written medicines information that they routinely gave to their patients said they did not provide any such material. Analysis of the information materials that were in routine use led the researchers to be concerned about its quality. There was wide variation for example in the list of side-effects given for the same medicine in different leaflets. Many leaflets had not been updated since they were first written.

In a project involving patients to develop written information on oral contraceptives, the researchers found that while family planning staff thought the leaflet easy to understand, less than a quarter said they would use it as a reference source with patients.⁴² Professional ambivalence was also evident in two focus group studies.^{26,27} No written information was routinely handed to patients on psychiatric wards, which was the setting for Pollock's *et al.*²⁷ study. While there was a general consensus that the provision of information to patients about their medicines should be improved, hospital staff regarded the need for this to be less pressing than did patients. Consultants showed great variation in their approach to the giving of information, whether written or spoken, and other ward staff tended to follow their lead.

Discussion

Overview of findings

To our knowledge, this is the first systematic review to consider user perspectives on written medicines information. The number of studies (27 over a period of 30 years) seems small given the widespread use of such information and (the more recent) recognition of its importance. The nature of written medicines information routinely provided to patients varied considerably over time and according to the setting. Despite these limitations, the review has produced findings that are important and relevant to considerations of the role and value of written medicines information.

Written information was widely read on the first occasion a medicine was prescribed. Patients valued written materials which set the

information within the context of the illness that the medicine was being used to treat. While not everyone wanted written information, those who did, wanted sufficient detail to meet their need. Needs varied over time and between patients. Many patients wanted to know about the adverse effects of medicines. There was concern about the independence of information written by pharmaceutical companies. Written information was used in many ways. It could be used to help decision making; both initially about whether to take a medicine or not, and in on-going self-care. Patients did not want written information to be a substitute for spoken information from their doctor.

The limited research available on health professionals' views suggested widespread ambivalence about using written information. Many professionals thought that it should be brief and simple, emphasize the benefits of a medicine and only partially disclose side-effects. Some saw the main roles for written information as increasing compliance and saving time in the consultation. Two studies conducted by health professionals expressed concern about the quality of written information and whether it was written in a way which enabled patients to make on-going decisions about the use of medicines.^{21,46}

Implications for practice

Dixon-Woods⁴⁷ identified two distinct discourses in patient information materials. One stems from a biomedical perspective and is concerned with educating patients in order primarily to bring their thinking in line with health professionals and increase compliance with treatment. The other discourse values patient agendas and is concerned with empowering patients and engendering a more equal relationship between patients and professionals. Dixon-Woods⁴⁷ points out that patient and professional interests often coincide and it is too simplistic to see the two discourses as oppositional. However they differ in their orientation to the patient. A patient education discourse sees patients as passive recipients of information written by experts as an instrument of compliance with

professional judgement. The patient empowerment discourse conceptualizes patients as being competent, rational and resourceful actors using information as a resource aiding decision-making and illness management.

In our review, the studies whose rationale was to increase compliance operated in terms of a patient education discourse, while studies that explored the use of information to facilitate the involvement of patients in their care incorporated a patient empowerment discourse. Health professionals may agree in principle that it is desirable to meet patients' information needs. However, in practice the evidence indicates that patient compliance is often their first priority. If they believe giving patients full information about medicines could lead to non-compliance, there is potential for conflict between what patients would like to know and what information professionals would like them to know. This was evident in professional concern about patients receiving detailed information on side-effects. In fact, there was no clear evidence of a simple relationship between the provision of written information on side-effects and compliance. Similar findings have been reported for written information on non-drug procedures⁴⁸ and spoken information.⁴⁹ Nevertheless it appears that there are differences between patients and professionals regarding the purpose of written medicines information.⁵⁰

Pound *et al.*⁵¹ found that research showed patient resistance towards medicines was seen by professionals to stem from mistaken lay perceptions and beliefs about medicines, rather than from actual problems experienced in using medicines. They argue against this notion and the consequent emphasis on developing ways to modify patient behaviour, and reason instead for safer medicines and improved prescribing. The latter would include professionals helping patients in their lay evaluation of medicines by providing information. In our review, there was evidence of professional concern about the poor quality of some available information and whether it did reliably inform patients about potential benefit and harms of a medicine, though few studies looked at this. Some patients

did not consider information written by medicine manufacturers to be sufficiently independent and questioned its credibility and reliability. Thus leaflets inserted in medicines' packages may not be seen as trustworthy.

Varying information needs over time and between patients makes the idea of a one-off, standard medicines leaflet that would meet all (or even most) potential needs unfeasible. Many patients wanted written medicines information to be set in the context of their illness. The patient information leaflets currently inserted in medicines packages are about medicines not illnesses. Computer-generated handouts printed and given out in the consultation would allow information to be tailored to individual patients and their conditions.¹⁷ However, this method relies on prescribers sourcing and/or generating written medicines information, and the limited evidence in the review showed that professionals did not routinely give out existing materials. Similar findings have been reported for spoken information.⁵²⁻⁵⁴

Not all patients want to be involved in decision making about treatment and even amongst those that do, desire may vary over time.⁷ Written information which details possible harms and benefits of taking a medicine is likely to be helpful to a patient trying to decide whether or not to take a medicine. The impact of the same information on a patient who wishes to devolve decision making to the doctor could be negative and increase uncertainty and worry. A range of patient responses to information was found in this review. Decisions about whether to take medicines, in what quantities, and for how long are not one-off events, but iterative processes, shaped by the interaction between changing knowledge and experience. Patients with chronic conditions learn from experience, and some patients thought that this knowledge should be incorporated into medicine leaflets. This would necessitate professionals recognizing and valuing lay expertise. Evidence from outside the review suggests that there is professional reluctance to acknowledge or use lay expertise in this way.^{54,55}

Patients preferred to receive medicines information from their doctor. Leaflets were not

considered to be an acceptable substitute, though they were useful to reinforce what the doctor said, and could be retained to read at leisure and re-consult if the need arose. Professionals should not see written information as an alternative to talking to patients about their medicines. Patients are often reluctant to ask questions in the consultation. Written information endorsed by a health professional, is one way that professionals can encourage patients to ask questions.

Conclusions

The different and changing information needs of patients, especially, in relation to illness of varying severity and duration, poses a challenge to the writers and providers of written material. Nevertheless, greater awareness of the difference between lay and professional perspectives on written medicines information, and the wide range of purposes it can serve, is a pre-requisite for the provision of the personally tailored and appropriately staged information materials that patients evidently require.

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References

- 1 Raynor DK. The influence of written information on patient knowledge and adherence to treatment. In: Myers L, Midence K (eds) *Adherence to Treatment in Medical Conditions*. London: Harwood Academic, 1998: 83–111.
- 2 Coulter A. *The Autonomous Patient: Ending Paternalism in Medical Care*. London: The Nuffield Trust, 2002.
- 3 Department of Health. *The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century*. London: Department of Health, 2001.
- 4 Department of Health. *Better Information, Better Choices, Better Health; Putting Information at the Centre of Health*. London: Department of Health, 2004.
- 5 Dickinson D, Raynor DK. Ask the patients – they may want to know more than you think. *British Medical Journal*, 2003; **327**: 861.
- 6 Arthur VAM. Written patient information: a review of the literature. *Journal of Advanced Nursing*, 1995; **21**: 1081–1086.
- 7 Coulter A, Entwistle V, Gilbert D. *Informing Patients an Assessment of the Quality of Patient Information Materials*. London: King's Fund Publishing, 1998.
- 8 Coulter A, Magee H. *The European Patient of the Future*. Maidenhead: Open University Press, 2003.
- 9 Garlick W. *Patient Information: What's the Prognosis?* London: Consumers Association, 2003.
- 10 Raynor DK, Savage I, Knapp P, Henley J. We are the experts: people with asthma talk about their medicine information needs. *Patient Education & Counseling*, 2004; **53**: 167–174.
- 11 Britten N, Stevenson FA, Barry CA, Barber N, Bradley CP. Misunderstandings in prescribing decisions in general practice: a qualitative study. *British Medical Journal*, 2000; **320**: 484–488.
- 12 Stevenson FA, Barry CA, Britten N, Barber N, Bradley CP. Doctor patient communication about drugs: the evidence for shared decision making. *Social Science and Medicine*, 2000; **50**: 829–840.
- 13 Rycroft-Malone J, Latter S, Yerrell P, Shaw D. Consumerism in health care: the case of medication information. *Journal of Nursing Management*, 2001; **9**: 221–230.
- 14 Pollock K. *Concordance in Medical Consultations – A Critical Review*. UK: Radcliffe Publishing, 2005.
- 15 Raynor DK, Blenkinsopp A, Knapp P *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 Technology Assessment*, 2007; **11**: 1–178.
- 16 Morris L, Halperin J. Effects of written drug information on patient knowledge and compliance: a

- literature review. *American Journal Public Health*, 1979; **69**: 47–52.
- 17 Kenny T, Wilson RG, Purves IN *et al.* A PIL for every ill? Patient Information Leaflets (PILs): a review of past, present, and future use. *Family Practice*, 1998; **15**: 471–479.
 - 18 Koo M, Krass I, Aslani P. Factors influencing consumer use of written drug information. *Annals Pharmacotherapy*, 2003; **32**: 259–267.
 - 19 Buck M. Providing patients with written medication information. *Annals Pharmacotherapy*, 1998; **32**: 962–969.
 - 20 Greenhalgh T, Robert G, Bate P, Kyriakidou O. Diffusion of innovations in service organisations: systematic review and recommendations. *The Millbank Quarterly*, 2004; **82**: 581–629.
 - 21 Herxheimer A. Leaflets with NSAIDs do not warn users clearly – a UK survey. *Pharmaceutical Journal*, 1999; **262**: 559–561.
 - 22 Hughes L, Whittlesea C, Luscombe D. Patients' knowledge and perceptions of the side-effects of OTC medication. *Journal of Clinical Pharmacy and Therapeutics*, 2002; **27**: 243–248.
 - 23 Cedraschi C, Piguet V, Allaz AF, Desmeules J, Dayer P. Patient information leaflets and antidepressant prescription in chronic pain patients. *Progress in Pain Research and Management*, 2000; **16**: 887–895.
 - 24 Grime J, Pollock K. Information vs. experience: a comparison of an information leaflet on antidepressants with lay experience of treatment. *Patient Education & Counseling*, 2004; **54**: 361–368.
 - 25 Koo M, Krass I, Aslani P. Consumer opinions on medicines information and factors affecting its use – An Australian experience. *International Journal of Pharmacy Practice*, 2002; **10**: 107–114.
 - 26 Nair K, Dolovich L, Cassels A *et al.* What patients want to know about their medications: focus group study of patient and clinician perspectives. *Canadian Family Physician*, 2002; **48**: 104–110.
 - 27 Pollock K, Grime J, Baker E, Mantala K. Meeting the information needs of psychiatric inpatients: staff and patient perspectives. *Journal of Mental Health (UK)*, 2004; **13**: 389–401.
 - 28 Dixon-Woods M, Agarwal S, Young B, Jones D, Sutton A. *Integrative Approaches to Qualitative and Quantitative Evidence*. London: Health Development Agency, 2004.
 - 29 Bandesha G, Raynor DK, Teale C. Preliminary investigation of patient information leaflets as package inserts. *International Journal of Pharmacy Practice*, 1996; **4**: 246–248.
 - 30 Blom AT, Rens JA. Information about over-the-counter medication: the role of the pharmacy. *Patient Education & Counseling*, 1989; **14**: 181–189.
 - 31 De Tullio PL, Eraker SA, Jepson C *et al.* Patient medication instruction and provider interactions: effects on knowledge and attitudes. *Health Education Quarterly*, 1986; **13**: 51–60.
 - 32 Jazieh AR, Brown D. Development of a patient information packet for veterans with cancer receiving chemotherapy. *Journal of Cancer Education*, 1999; **14**: 96–98.
 - 33 Morris LA, Mazis M, Gordon E. A survey of the effects of oral contraceptive patient information. *JAMA*, 1977; **238**: 2504–2508.
 - 34 Mottram DR, Reed C. Comparative evaluation of patient information leaflets by pharmacists, doctors and the general public. *Journal of Clinical Pharmacy and Therapeutics*, 1997; **22**: 127–134.
 - 35 Raynor DK, Knapp P. Do patients see, read and retain the new mandatory medicines information leaflets? *Pharmaceutical Journal*, 2000; **264**: 268–270.
 - 36 Vander Stichele RH, Van Haecht CH, Braem MD, Bogaert MG. Attitude of the public toward technical package inserts for medication information in Belgium. *DICP*, 1991; **25**: 1002–1006.
 - 37 Berry D, Gillie T, Banbury S. What do patients want to know: an empirical approach to explanation generation and validation. *Expert Systems with Applications*, 1995; **8**: 419–428.
 - 38 Fisher S, Mansbridge B, Lankford A. Public judgments of information in a diazepam patient package insert. *Archives of General Psychiatry*, 1982; **39**: 707–711.
 - 39 Keown C, Slovic P, Lichtenstein S. Attitudes of physicians, pharmacists, and laypersons toward seriousness and need for disclosure of prescription drug side effects. *Health Psychology*, 1984; **3**: 1–11.
 - 40 Miselli M. What information for the patient? Large scale pilot study on experimental package inserts giving information on prescribed and over the counter drugs. *British Medical Journal*, 1990; **301**: 1261–1265.
 - 41 Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? *British Medical Journal*, 1999; **318**: 318–322.
 - 42 Ross BS, Potter LS, Armstrong KA. Improving patient educational literature: an understandable patient package insert for 'the pill'. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, 2004; **33**: 198–208.
 - 43 Thompson S, Stewart K. Older persons' opinions about, and sources of, prescription drug information. *International Journal of Pharmacy Practice*, 2001; **9**: 153–162.
 - 44 Vander Stichele RH, De Potter B, Vyncke P, Bogaert MG. Attitude of physicians towards patient package inserts for medication information in Belgium. *Patient Education & Counseling*, 1996; **28**: 5–13.
 - 45 Berry DC, Michas IC, Gillie T, Forster M. What do patients want to know about their medicines, and what do doctors want to tell them? A comparative study. *Psychology and Health*, 1997; **12**: 467–480.

- 46 Buchbinder R, Hall S, Grant G, Mylvaganam A, Patrick MR. Readability and content of supplementary written drug information for patients used by Australian rheumatologists. *Medical Journal of Australia*, 2001; **174**: 575–578.
- 47 Dixon-Woods M. Writing wrongs? An analysis of published discourses about the use of patient information leaflets. *Social Science and Medicine*, 2001; **52**: 1417–1432.
- 48 Garrud P, Wood M, Stainsby L. Impact of risk information in a patient education leaflet. *Patient Education & Counseling*, 2001; **43**: 301–304.
- 49 Stevenson FA, Wallace G, Rivers P, Gerrett D. 'It's the best of two evils': a study of patients' perceived information needs about oral steroids for asthma. *Health Expectations*, 1999; **2**: 185–194.
- 50 Nicolson DJ, Knapp P, Raynor DK, Grime J, Pollock K. Do themes in consumer medicines information literature reviews reflect those important to stakeholders? *Patient Education & Counseling*, 2006; **64**: 112–118.
- 51 Pound P, Britten N, Morgan M *et al.* Resisting medicines: a synthesis of qualitative studies of medicine taking. *Social Science and Medicine*, 2005; **61**: 133–155.
- 52 Berthelot J-M, Glemarec J, Guillot P, Chiffolleau A, Maugars Y, Rodat O. Informing patients about serious side effects of drugs. A 2001 survey of 341 French rheumatologists. *Joint Bone Spine*, 2003; **70**: 52–57.
- 53 Ford S, Schofield T, Hope T. Barriers to the evidence based patient choice (EBPC) consultation. *Patient Education & Counseling*, 2002; **47**: 179–185.
- 54 Smith S, Henderson M. What you don't know won't hurt you. Information given to patients about the side effects of antipsychotic drugs. *Psychiatric Bulletin*, 2000; **24**: 172–174.
- 55 Rogers A, Kennedy A, Nelson E, Robinson A. Uncovering the limits of patient centeredness: Implementing a self-management trial for chronic illness. *Qualitative Health Research*, 2005; **15**: 224–239.
- 56 Mazis M, Morris LA, Gordon E. Patient attitudes about two forms of printed oral contraceptive information. *Medical Care*, 1978; **16**: 1045–1054.
- 57 Dodds L, King R. Factors affecting attitudes to the provision of information with prescribed drugs. *Pharmaceutical Journal*, 1989; **242**: R7–R12.