



- Title** **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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Aim

To assess the role and value of written information (info) available to patients about individual medicines.

Conclusions and results

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

Most people do not value written medicines info (WMI) they receive. The poor quality of many leaflets tested may reflect the finding that provision did not increase knowledge. We found no robust evidence that info affected patient satisfaction or compliance. Qualitative evidence shows patients do not see improving compliance as a function of patient info leaflets (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. We found consistent evidence that the way risk descriptor info is portrayed has important effects on side-effect knowledge. Delivering risk info numerically, rather than as verbal descriptors, ensures a more accurate estimation of probability and likelihood of a side effect and risk to health. Readability of WMI is important to patients. Patients value idea of tailored info and a balance of benefit and harm info. Few studies addressed either issue. Most patients wanted to know about side effects. Some patients question credibility of pharmaceutical industry info, although the required PIL is written according to strict regulations. Patients would like WMI to help decision making about whether or not to take a medicine, and for managing medicines and interpreting symptoms. Patients did not want WMI to substitute for spoken info from prescribers. There was evidence of professional ambivalence about WMI.

Recommendations

The authors suggest that regulators and producers of WMI consider the following: involve patients at all stages of the process, use findings on info design and content to improve quality and usefulness, present risk info numerically rather than using verbal descriptors, spoken info remains the priority but should be closely linked to written info so it does not substitute for discussion, encourage patients to use WMI, and welcome questions.

Methods

The authors searched full text and bibliographic databases for research on the role, value, and effectiveness of WMI (up to late 2004). Citation and hand searches were done. Six experts in information design were asked to cite relevant key references, and stakeholder workshops were held. (For more details see Executive Summary link above.)

Further research/reviews required

Apply recognized standards to trial design and conduct, recruit more older people, have longer followup and more use of naturalistic settings, develop, validate, and standardize patient-focused outcome measures, find how to better integrate patient input in info research, and ensure the study of role and value alongside effectiveness in future trials. Determine the content, layout, delivery method, and timing of statutory medicine leaflets that best meets patients' needs, find how to better incorporate individualized benefit and risk info, and introduce more lay experience into the PIL development process. (For more details see Executive Summary link above.)