

The Benefits of Consumer Medicine Information (CMI)*

Prepared by the
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1. Written Information Increases Patient Knowledge and Satisfaction

Patients who receive written information about their medications derive increased personal benefits from the information. The most widely documented of these is increased knowledge.

Industry experts, practitioners, and consumers agree that patients must have some basic information about prescription drugs to adhere successfully to their prescribed drug therapy. Many studies have tested whether the dissemination of written material increases patient knowledge and understanding. For example, a 1983 study of FDA's patient package insert (PPI) for benzodiazepines concluded that the PPI effectively conveyed written drug information to patients, and that knowledge and comprehension varies according to the patient's age, years of education, and reading environment (Ref. 58). In this study, patients who received written patient information scored higher on a knowledge and comprehension test than those who received no written information, and those who completed the test at home scored higher than those who completed it at the pharmacy.

Patients who receive written materials about medications have increased knowledge about the use and effects of the medications (Refs. 38, 42, 44, 47, 48, 52, 53, and 59 through 61). In particular, patients who receive written information show more knowledge about side effects (Refs. 46, 47, 48, 52, and 58), and are better able to attribute adverse reactions to the medications they are taking (Ref. 62). They can more easily discriminate adverse reactions attributable to the medication from other clinical events (Ref. 63).

Patients who receive written information about their medications are more likely to make healthy lifestyle changes (Ref. 60). They are also more satisfied with their treatment (Refs. 33, 42, 47, and 53).

In a review of the literature, one author suggests that provision of written materials may help patients cope with illnesses over time, as their modes of coping evolve and the corresponding need for information changes (Ref. 38).

When presented with written information about their medications, the vast majority of patients read it, particularly if it is the initial prescription (Refs. 38, 40, and 44).

Reading may be thorough or superficial (Ref. 45). Patients report reading the printed information when receiving the first prescription and refills (Ref. 40), and they may read the materials more than once (Ref. 46).

2. Written Materials About Medications Can Increase Patient Compliance

Even more critical to the health care system, studies of the effects of providing written medication information to patients demonstrate that the result can be increased compliance with the treatment regimen (Refs. 38, 47, and 48).

For example, in one study, outpatients who received a patient information leaflet along with their penicillin prescription were tested against patients who received no information at all. Researchers found that a significantly lower proportion of patients who received the patient information omitted doses than those who did not receive the information (Ref. 47).

Similarly, researchers concluded that providing written information to patients with antibiotic prescriptions resulted in significant improvement in drug taking behavior and in knowledge about the therapy prescribed (Ref. 48).

In a study of psychiatric patients, those receiving written information were more compliant in their medication regimens than those not receiving it, and patients receiving both written and oral information were the most compliant (Ref. 7). In another study, patients receiving both written and oral information about their medications were more compliant than those given no information (Ref. 49).

Providing written information has also resulted in fewer patients stopping treatment (Ref. 50). The results of increased compliance may be fewer deaths and lower overall costs of treatment, due to fewer requirements for hospitalizations and nursing home admissions (Refs. 4 and 57).

In a broad review of the effects of written information, Ley (Ref. 36) concluded that most of the studies examined found positive effects resulting from the provision of written information to patients:

- Out of 32 studies examining effects on knowledge, 97 percent found increases;
- Of the 25 studies examining compliance, 60 percent found increases;
- In 7 studies examining therapeutic benefit, 57 percent found increases.

It should be noted that "compliance" represents a broad range of behaviors that are difficult to measure (Ref. 51). Several studies that have sought to measure the effects of written information have failed to find compliance improved by written information (Ref. 44, 52 through 55). However, in a critical review of the methodologically rigorous studies of interventions to improve compliance, Haynes et al. (Ref. 56) concluded that compliance with short-term treatments can be improved by clear instructions, including written information, as well as by other interventions.

Compliance with long-term treatments is more difficult to achieve; no single intervention has been shown to be effective on its own. Rather, improved compliance with long-term regimens requires a combination of interventions, including clear instructions enhanced by written information.

3. Written Patient Information Does Not Have Negative Consequences

There has been speculation about the potential adverse effects of providing information about medications to patients. However, the studies suggest that written information does not increase reports of adverse events (Refs. 38, 42, 44, 45, 48, 52, 53, 62 and 91), nor does oral information (Ref. 65). Two studies that appear to indicate the opposite are flawed. In one case, the authors admit that the written information given to patients was inadequate (Ref. 52) and, in the other, statistical analyses were performed by combining control and experimental groups inappropriately (Ref. 50). A study of psychiatric patients was inconclusive on this point (Ref. 66).

Studies do not show evidence of decreased compliance as a result of written information (Refs. 52 and 66) or evidence of increased anxiety levels (Ref. 60).

4. Relative Effectiveness of Oral and Written Patient Information

Studies examining the relative effectiveness of printed and oral medication information are scarce. However, one study shows that provision of printed information is more effective in increasing patients' knowledge than oral information, and that a combination of the two is best. The authors believe that written materials, particularly those containing information about side effects, may be more effective and timely and less alarming to patients than oral information because most side effects do not occur until after the medication has been taken for a while (Ref. 67). One author suggests that written information should be used to supplement oral instructions that should be tailored to meet the particular beliefs, concerns, and expectations of the individual patient (Ref. 38).

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