

Effects of Written Drug Information on Patient Knowledge and Compliance: A Literature Review

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Abstract: The prospect of patient-oriented prescription drug labeling has focused increased attention on the effectiveness of written information for the consumer. Studies which have evaluated the effects of written prescription drug information in a patient population are reviewed. Several studies indicate that written information can be effective in improving patient compliance with regimens for antibiotic therapy. However, for drugs used on a long-term basis, written information as a sole intervention has not been shown to be sufficient for improving patient compliance. Patient knowledge of less commonly known information,

such as precautions, side effects, or special directions is frequently improved by written information. Listing a drug's side effects has not been shown to increase the reported experience of side effects; however, one study suggests that patients may be more willing to report side effects to a health professional if they are listed in the written information. The trend for recent studies has been to focus on the "milieu" in which written information is provided or to systematically vary structural features of the information in order to improve the quality of drug communications. (*Am. J. Public Health* 69:47-52, 1979.)

Educating patients about prescription drug therapy is becoming an increasingly important aspect of health care. Noncompliance rates of 30 to 80 per cent are consistently reported in the literature.^{1,2} The cause of noncompliance can be traced frequently to the failure of communication between the health care provider and patient.³⁻⁵ Therefore, several programs have been instituted to counsel patients about prescription drugs. An important component of many of these programs is the use of written prescription drug information sheets to reinforce and augment verbal consultation.⁶

Activity by consumer groups and the federal government, including a provision for patient information in the proposed Drug Regulation Reform Act of 1978, has increased the likelihood that enhanced labeling for a wide variety of prescription drugs may soon be required. This enhanced labeling, i.e., patient package inserts (PPIs), would be in the form of preprinted sheets that describe a drug's risks, potential benefits, and instructions for use.

The prospect of widely required patient package inserts has stirred great controversy. Critics suggest that PPIs could disrupt the doctor-patient relationship, increase inappropriate self medication, produce suggestion-induced

side effects, foster the transfer of prescription drugs among patients, and alarm patients to the point that they will disregard their physician's advice. Supporters suggest that PPIs may contribute to improved compliance with drug regimens, increase patient awareness of the need to avoid certain foods and drugs which can cause hazardous interactions, and aid in early recognition and proper interpretation of drug side effects.

The ultimate effects of PPIs will likely depend on factors such as the content and form of information, the method of distribution, characteristics of the patient and provider, and the environment in which the PPI is dispensed. However, at present it is appropriate to develop reasonable goals for written prescription information for patients. Can PPIs effectively communicate information to patients to improve their knowledge about prescription drugs? Can PPIs help to improve compliance? In what other ways will the PPI affect health care?

Two types of studies bear upon these issues: 1) Surveys of oral contraceptive (OC) users (patient labeling has been required for oral contraceptives since 1970); and 2) studies that have utilized and evaluated the effects of locally prepared written prescription drug materials in a patient population. Two recent surveys of oral contraceptive users and former users indicated that the OC insert is generally reported to be received, read, understood, and positively evaluated.^{7,8} However, in addition to the inherent limitations of survey methodology, there is difficulty in generalizing results of these surveys of young, usually healthy women who take medication to prevent pregnancy, to populations of sick patients who are taking medicine to control, cure and prevent a disease. This paper will review studies which have evaluated

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the effects of written prescription drug information in patient populations.*

The form of written information studied has varied from stickers or enhanced typed labeling for medication containers to multiple page brochures and pamphlets. The dispenser of the written information has usually been a nurse or a pharmacist rather than a physician. Because of the diversity of forms and content of written information utilized, it would be extremely difficult to tabulate results on this basis. However, a four-fold classification may be made on the basis of the type of drug studied; 1) short-term antimicrobial therapy, 2) drugs used on a longer term basis, 3) studies which simultaneously utilized written information for a number of miscellaneous oral drugs, and 4) non-orally administered drugs.

Antimicrobial Drugs

Improved compliance was evident in three studies in which a printed reminder supplied by the pharmacist was compared to usual pharmacy dispensing procedures.⁹⁻¹¹ Sharpe and Mikeal⁹ utilized both a sticker for the medication bottle informing patients to finish all the medication unless otherwise indicated, and a one-page sheet that explained why patients should not discontinue consuming medication, even if their conditions improved. The study was conducted at a clinic serving primarily lower income patients. Extensive pre-testing indicated that a large type size and easy-to-read material was necessary for the information sheet to be an effective instrument.

In two studies^{10, 11} regimen-oriented reminders (such as pill calendars and special packaging) combined with written instructions produced improved compliance when compared to usual pharmacy dispensing procedures.

Colcher and Bass¹² studied compliance and clinical course for three groups of children receiving penicillin treatment for streptococcal pharyngitis. One group of children received intramuscular injections, the second group received a prescription (with "routine verbal instructions" given to parents), and a third group of parents received, with the prescription, specific counseling and a one-page sheet describing the need for taking penicillin for a full ten days. High antimicrobial activity in the urine was observed for 80 per cent of the children in the counseled-informed group and for 87 per cent of the group receiving injections. Both of these groups were significantly superior to the "verbally instructed" group (58 per cent of which had evidence of high antimicrobial activity). There was no significant difference between the groups in terms of the number of treatment failures as measured by positive throat cultures. However, both the injection and counseled-informed groups had significantly fewer relapses. In less well-controlled studies, improved compliance was evident when written instructions were used in combination with other educational interventions for children receiving antibiotic therapy.^{13, 14}

The impact of instruction cards given in conjunction with private medication counseling by a pharmacist was

evaluated by Madden.¹⁵ One hundred and twenty outpatients were placed in the experimental group and results were compared to an equal size control group that received the usual pharmacy services. Pill counts taken at home visits six to eight days after initiation of treatment indicated a significant reduction in the medication error rates for the experimental group. Assessment of patients' knowledge about drug treatment indicated that the experimental group had significantly better understanding of the medication regimen.

A Swedish study specifically designed to test the effects of a patient package insert was conducted by Eklund and Wessling.¹⁶ "Package enclosures" (tiny pre-folded pamphlets) were delivered with medication to every other patient receiving antibiotic therapy. Telephone interviews were conducted with 360 of 483 patients receiving prescriptions. Two-thirds of the patients said they read all or part of the PPI. Eighty per cent positively evaluated the PPI. Compliance was measured by asking patients to count the number of tablets remaining and calculating the deviation from the expected number of doses remaining. There was no difference between the insert and no insert group on this measure or in knowledge of the drug's name and indications for use. However, the insert group did have better knowledge of the side effects and contraindications and they reported a better dosage schedule (the insert advised patients to space their dosages evenly throughout the day).

Two additional studies found that written instructions did not improve compliance or drug knowledge beyond the augmented counseling of a pharmacist.^{17, 18} Verbal and/or written counseling was superior to usual pharmacy procedures. There was no difference in the report of side effects among experimental groups.

Taken as a whole, these studies offer support for the conclusion that written information can improve patients' knowledge of and compliance with antibiotic regimens. Improved compliance by written information is probably a result of specifically informing patients not to discontinue treatment prematurely and reinforcing the importance of taking medicine as directed. Simple reminders, such as stickers, clocks on the prescription label, and one-page information sheets, can help communicate this information to patients.

However, for written instructions to be effective, they must be read, understood, and remembered by patients. Although it is possible to question the results of the Eklund and Wessling study¹⁶ because of their reliance on self-reported pill counts, there is no reason to believe that patients in the insert and no insert groups would have differentially lied about the number of pills remaining in the bottle. It is possible to speculate, therefore, that patient information that is not sufficiently attractive, easy-to-read, and "directive" cannot be expected to change patient behavior.

In two studies^{7, 16} the presence of small "package stuffer" PPIs, was recalled by only two-thirds of patients receiving them, whereas, in other studies, verbal review and explanation of written instructions by a health care provider was part of the study procedure. This verbal review probably enhanced the perceived value of written instructions. Sharpe and Mikeal⁹ found that even among a population of predominantly lower income patients, only about five per

*A series of tables detailing the method, design, and results of the studies cited herein are available from the authors upon request.

cent of the subjects failed to read the written instructions, and daily inspection of the floor and trash receptacles in the pharmacy dispensing did not reveal any discarded information sheets.

Drugs Used on a Long-Term Basis

Whereas, antibiotics are usually used for only ten days, patients may need to take other drugs for weeks, months, years. Sackett, et al.,¹⁹ manipulated both health education and augmented accessibility of medical follow-up for 230 Canadian steelworkers with primary hypertension. The health education intervention consisted of an intensive program including brochures, slide-tape presentations, pill taking reminders, etc. Although this intensive program was highly effective in teaching subjects about the management of hypertension, it did not lead to improved compliance.

Twenty-five hypertensive patients were counseled at their neighborhood pharmacy by McKenney, et al.²⁰ Each patient was seen monthly for counseling for five months. A two-page hand-out described the drug therapy and several other pamphlets, flip charts, etc., were used as consultation aids. Results indicated that patients receiving the education program were significantly better informed about hypertension and its treatment than were controls. During the counseling period, study patients were significantly more compliant than controls. However, after the counseling period, study patients returned to their initial level of compliance.

The number of emergency room visits by adult asthmatics following an educational program designed to teach patients about both the disease and drug usage was investigated by Mainman, Green, and Gibson.²¹ One-half the 245 study patients received a booklet and all patients received some counseling from a nurse. For two-thirds of the patients, the nurse-counselor was herself an asthmatic, and for one-third a nonasthmatic emergency room nurse delivered counseling. Patients who received counseling from the asthmatic nurse had few subsequent visits to the emergency room. Delivery of the booklet was not a significant factor, nor did it interact with any variables. However, examination of the simple effects suggested that patients who received the booklet from the nonasthmatic nurse had the most frequent revisits to the emergency room.

Hecht²² found that increased verbal and written counseling did not lead to significantly better compliance after discharge for 47 tuberculosis patients (although there was a trend for medication errors to decrease as the amount of teaching increased). However, Rosenberg^{23, 24} found that an educational program (including pamphlets) led to greater recognition of medications and reduced readmissions.

Three forms factorially combined with three "contents" of thiazide information were used in an experiment by Dwyer.^{25, 26} Information was printed on onion skin paper, a 6-panel brochure, or a one-page sheet. The contents included basic descriptions, medium detail (basic information plus what to do if problems occur), or high detail (all the previous information plus rationales for why problems arise). Forty-one newly diagnosed hypertensives were given one of these

nine types of inserts at the hospital pharmacy and interviewed one month later. There was no difference in knowledge or compliance among the groups; however, there was some suggestion that the perceived risk of drug therapy may have been associated with the interaction of form and content. With only about three to six subjects per group, Dwyer's approach and results can, at best, be considered a source of interesting ideas of further study.

Ley, Jain, and Skilbeck²⁷ examined the effects of leaflets for antidepressants and tranquilizer drugs that varied in reading difficulty. Twenty patients each received either an easy, moderate, or difficult-to-read pamphlet and a sticker for the medication container that reiterated dosage instructions. A control group received no written instructions. Pill counts taken at the first follow-up visit indicated a significant trend for fewer medication errors associated with easier-to-read leaflets. The difficult-to-read leaflets did not differ from a no leaflet condition.

Several studies have examined the effects of written communication on knowledge and other therapy outcomes. Clark and Bayley²⁸ found that a "programmed instruction" brochure led to greater knowledge than a handout or a no-written-information control. Other studies suggest that brochures²⁹ and one-page sheets^{30, 31} improve knowledge about drug therapy and are positively evaluated by patients.

Whereas several studies indicated that written information can be a useful adjunct to help educate patients, improved compliance is not an assured outcome. The study by Sackett, et al., indicates that even "mastery learning" does not necessarily improve medication-taking behavior. The improved compliance in the study by McKenney, et al., is likely attributed to the fact that patients were being intensely and continuously monitored by a health professional, but once this monitoring period concluded, compliance returned to prior levels. In the study by Ley, et al., the fact that pill counts were taken on the first revisit probably make these results more applicable to short-term drug therapy. Therefore, at present it must be concluded that written information by itself has not been associated with improved long-term compliance. However, to our knowledge, extensive evaluations of any number of other interventions used to improve long-term compliance have not shown any technique to be successful. Long-term improved compliance, like any behavior change, remains extremely difficult to accomplish. Currently, the best approach seems to be a multi-faceted educational and behavioral intervention tailored to the needs of the patient.

Miscellaneous Oral Drugs

In two studies,^{32, 33} the "milieu" in which written drug information was dispensed was systematically varied. Clinite and Kabat³² varied: 1) whether pharmacists did or did not dispense a one-page sheet describing the patient's medication and 2) whether or not the pharmacist gave verbal instructions. The subjects were 62 outpatients. Pill counts indicated no significant differences in compliance among the groups although medication errors were fewest with both the written sheet and verbal review and greatest when only the

sheet was dispensed. Patients receiving the written sheets alone were least knowledgeable of the medication name but most knowledgeable of the medicine's side effects. Those receiving the sheet and verbal review were most aware of the consequences of omitting a dose.

Medication instructions and the privacy with which pharmacists' instructions were given were varied by Beardsley, Johnson, and Wise.³³ In the "high education" condition, patients received both verbal and written instructions and in the "low education" condition only verbal instructions were administered. Compliance measured by home or telephone interviews indicated that the high education-high privacy group had significantly fewer noncompliers than any other group. High education with privacy also led to the greatest duration of patient-pharmacist interactions and more questions being asked. Knowledge of special instructions and how to take the medicine, measured immediately after the consultation, was greatest for the high privacy-high education group. Immediate knowledge of how long to take the medicine was greatest in the high privacy-low education (verbal review only) group. A knowledge test administered seven to ten days after drug dispensing indicated that the high privacy-high education group had greatest recall of special instructions.

Wandless and Davie³⁴ studied geriatric patients in the rehabilitation units of a British hospital. Patients received: 1) only verbal instructions; 2) verbal instructions plus a medication calendar; or 3) verbal instructions plus a small medication identification card. Results indicated that both the calendar and card led to significantly fewer errors. In another compliance study of geriatric patients, counseling by the pharmacist led to improved knowledge of the drug schedule and better compliance after hospital discharge.³⁵ Memory aids (a tear-off daily calendar and tablet identification card) used in addition to counseling did not significantly improve compliance beyond counseling alone and a "pill wheel" drug dispenser tended to decrease compliance. In a survey of 88 senior citizens who received a written medication sheet with their drugs,³⁶ over three-fourths said they learned something about the medicine and would like the sheets for other drugs. About one-fourth said the sheet caused changes in administering medicines.

The usual prescription label as a source of written instructions was studied by Boyd, Covington, Stanaszek, and Coussons.³⁷ During the course of a home interview, prescriptions were graded for completeness of labeled directions. Greater directions on the label were significantly associated with greater comprehension of the name and number of daily doses. The authors also reported a positive relationship between increased information on the label and compliance.

Newcomer and Anderson³⁸ administered a drug counseling program (including printed medication instructions) to 47 surgical inpatients. After discharge, study and control patients were interviewed at home. Based on self-reports, there was no significant difference in medication compliance, knowledge of the frequency of dosage, or purpose of the drug. However, the study group did have better knowledge of the name of the drug, common side effects and optimal

dosage intervals, and they were more likely to report adverse drug effects to their doctor.

Six studies examined pharmacist-dispensed sheets for a number of miscellaneous drugs without taking compliance measures. Written information utilized varied, i.e., index card size sheets,^{39, 40} folded sheets attached to the medication container,⁴¹ handwritten individualized pages,^{42, 43} and a check-sheet.⁴⁴ In general, these studies indicated that knowledge of special precautions, how to correct for missed dosages, and which foods or drinks to avoid was increased. Knowledge of the medicine's name and the number of side effects reported was not increased by written information. Patients positively evaluated the sheets and indicated a desire to receive them for additional drugs. Results were mixed as to whether the information increased patient satisfaction.

Studies which have simultaneously examined the effects of written instructions for a series of drugs tend to be consistent with studies of drugs and on a long-term basis. Several studies indicated that written instructions can be an effective way of enhancing the communication of drug information to patients, especially information on special instructions and precautions. The Wandless and Davie study³⁴ indicates that simple instructions can help older people take their drugs on schedule. Although the continued surveillance by the staff and pill counts every two days likely helped mediate their results, the fact that the patients receiving the cards had better compliance than a control group that had the same surveillance indicates a positive effect of the written instructions. The lack of significant results in the other compliance studies again suggests, however, that written information may not, by itself, lead to improved adherence to the prescribed regimen.

In two of these studies, subjects were asked to report the side effects of the drug,^{39, 40} and in both there was no difference between groups that received written instructions and those that did not. However, Newcomer and Anderson³⁸ found that one-half the patients receiving written instructions and verbal consultation who experienced an adverse reaction reported its occurrence to their physician. None of the control patients reported such a reaction. One of the frequent criticisms of patient package inserts is that they will increase the experience of adverse reactions. The above studies, however, suggest that the reporting of adverse reactions, and not the experience of adverse reactions, may be enhanced by the written instructions.

Non-Orally Administered Drugs

In addition to studies of orally administered drugs, studies have examined written drug information for a vaginal cream and for the Progestasert intrauterine device (IUD) (which contains a drug along with the IUD). Benson, Gordon, Mitchell and Place⁴⁵ compared a company-produced patient IUD brochure to one proposed by the Food and Drug Administration (FDA). The brochures differed in content, organization, and wording. The company brochure had illustrations and was of greater length. One of the brochures and a questionnaire was sent to 348 women who had used the Progestasert IUD in a clinical study. Eighty-five per cent (256

women) returned the questionnaire. In general, comprehension of the two brochures was comparable. More subjects judged that the company brochure was promotional and patients receiving this brochure had a better understanding of some of the usage directions. The FDA brochure was judged by more people to have a clear discussion of the potential dangers of the system. Respondents indicated a preference for a longer and illustrated brochure.

Noys and Gordon⁴⁶ distributed a short leaflet with samples of a vaginal fungicidal cream to 157 patients with vaginitis. Subjects were the patients of ten obstetricians throughout the country. Patients were telephoned two or three days after receipt of the medication. Results indicated that 77 per cent said they read the insert (16 per cent had not noticed it and 7 per cent had noticed but not read the insert). Ninety-eight per cent of the women thought that patient information leaflets should be included in packages of medication for various medical conditions. The insert used for vaginal cream was judged good to excellent by 89 per cent of the respondents, 86 per cent said it was helpful.

These two studies suggest that patients desire information on non-orally administered drugs and find the information useful. The finding that women prefer longer and more elaborate contraceptive information is consistent with the results of FDA's survey of oral contraceptive users.⁴⁷

Implications

By examining existing research on written prescription drug information for patients, several conclusions can be drawn about rational goals for patient package inserts and trends and needs for future research can be described.

The behavior that health professionals call patient non-compliance is likely attributable to many different factors. However, some aspects of this problem are certainly due to the failure of traditional modes of communication. Written instructions can serve to enhance the probability that important information can be presented, and will be attended to, understood, accepted, and recalled. However, proper communication by itself does not guarantee that behavioral change (compliance) will take place. It is evident that for certain drugs, patients prematurely discontinue the regimen simply because they do not know that it is important to continue treatment. With longer term therapy, effective communication of the regimen may be considered a necessary, but not a sufficient, condition of compliance. Additionally, interventions which provide social support, efficient feedback, and which are tailored to the patient's needs seem necessary.

Numerous studies have demonstrated that written information for the patient can be an effective aspect of a program to improve patients' knowledge about their therapy. There is no evidence that written information can or should replace verbal consultation. The best effects are evident when both verbal and written information are presented. Cases where written information did not improve patients' knowledge may frequently be due to patient awareness independent of the insert. For example, some studies found that the name or purpose of the medicine was equally well known in the study

and control group.^{13, 16, 29, 37, 38} However, enhanced patient knowledge of side effects and special precautions is frequently found for patients given written instructions.^{13, 37-39, 43}

Many of the studies reviewed in this paper were preliminary demonstration projects or evaluations to discern the effects of providing written information to patients. In some of the more recent research, the trend is to address the question of how to best communicate important drug information to patients. There are two aspects to this trend. Some have sought to define the best milieu to provide written information. Written information seems to work best when delivered in the context of the social support and verbal advice of the health professional. Other studies have sought to vary structural features of the written information. Ley, Jain and Skilbeck²⁷ found that easier to read instructions led to better compliance and Benson, Gordon, Mitchell and Place⁴⁵ found that women prefer longer and better illustrated brochures. However, many more questions need to be answered.

By stressing practicality and external validity, many studies in this area do not possess the methodological rigor that allows one to rule out competing explanations for observed results. For example, when effective, does written communication itself lead to better regimen adherence or are results mediated by non-specific (placebo effect) influences inherent in the research and therapeutic environment?⁴⁸ Increased attention to problems of methodological adequacy is warranted.

The implicit assumption tested by most of these projects was that drug education could improve knowledge which in turn leads to better drug-taking behavior. The diversity of procedures, methods, environments, and definitions utilized do not allow these studies to be interpreted within a single unifying theoretical perspective. In order to ask more specific and relevant questions and to integrate new data into a growing knowledge base, it would be helpful for future research to have a more firmly based theoretical orientation. Several analytical conceptualizations are possible and at the present stage of development it may be useful to investigate the area from multiple perspectives. For example, the Health Beliefs Model⁴⁹ may be useful for studying how written information may influence health-related behavior within the context of an individual's value system and field of action; a communications theory perspective⁵⁰ may be the best for those interested in studying how the structure and method of delivery affect information flow and decision-making. It is also possible that new theories and models are necessary. In order to understand the role of information on improving drug therapy, it may first be necessary to understand more fully how consumers initiate, maintain, modify, and discontinue drug treatment.⁵¹

As research on this subject develops, studies are becoming more methodologically rigorous and more generalizable to the outpatient populations. It is essential that both these factors continue in order to build a firm basis for designing programs to help communicate drug information to patients. Furthermore, since initial evaluations may tend to produce the most dramatic results, it seems advisable to retain a degree of scientific skepticism when predicting the effects of any particular piece of written information.

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