AN ABSTRACT OF THE THESIS OF

Michael John Regner for the degree of Master of Science in Pharmacy presented on June 7, 1984.

Title:

Evaluation of the Effectiveness of Three Methods Designed to Inform Patients about Side Effects

Abstract approved: Redacted for Privacy

Freya Hermann

The effectiveness of three methods designed to inform patients about digoxin side effects was evaluated. Subjects were randomly assigned to receive information about their digoxin by one of three treatment methods: (1) verbal consultation alone, (2) A.S.H.P. printed leaflet, or (3) both verbal consultation and leaflet. Treatments were administered by a registered pharmacist. Effectiveness of the information was measured by use of a telephone questionnaire designed to assess the subjects ability to use the information given the facts and conditions of a hypothetical case.

Telephone questionnaires were completed on 52 of the original 72 subjects entered. All subjects were taking digoxin at time of telephone interview, with 90% of subjects reporting having taken it for greater than 1 year. Subjects' reported comprehending both the verbal consultation and written leaflet material "very well".

Analysis of variance was performed to evaluate the differences in effect between the three treatment methods. Subjects receiving both verbal and written information scored higher (mean=2.40) as compared to those subjects who received only verbal consultation (mean=1.11) or written leaflet alone (mean=1.61). There was no statistically significant difference between the mean scores of subjects receiving verbal versus written information only.

The impact of prior side effect information from various sources was evaluated as a possible variable affecting the results. Neither the physician nor pharmacist, as prior information sources, were found to contribute significantly to the treatment towards enabling subjects to recognize and respond more appropriately.

These data support the findings of other studies which suggest that written materials are an essential component of programs aimed at educating patients about side effects. There is no evidence to support the use of written materials in place of verbal consultation.

EVALUATION OF THE EFFECTIVENESS OF THREE METHODS DESIGNED TO INFORM PATIENTS ABOUT SIDE EFFECTS

by

Michael John Regner

A Thesis

submitted to

Oregon State University

in partial fulfillment of the requirements for

the degree of

Master of Science

Completed June 7, 1984

Commencement June 1985

APPROVED:

Redacted for Privacy

Associate Professor of Pharmaceutical Sciences in charge of Major

Redacted for Privacy

Dean of College of Pharmacy

Redacted for Privacy

Dean of Graduate School

Date thesis is presented June 7, 1984

Typed by Elaine Plaggert and Barbara Duffy for

Michael John Regner

TABLE OF CONTENTS

LIST OF TABLES

EVALUATION OF THE EFFECTIVENESS OF THREE METHODS DESIGNED TO INFORM PATIENTS ABOUT SIDE EFFECTS

INTRODUCTION

Educating patients about prescription drugs has become an increasingly important aspect of our health care system. Patient awareness of the need for observing precautions and following directions has been promoted. The goal of educating patients has been to reduce the incidence of inappropriate drug usage, adverse drug reactions, and poor compliance.[1]

Traditionally, physicians have been expected to inform patients. Ley has summarized various reports indicating that patients are dissatisfied with the information they receive from their physicians.[2] He suggests that contributing to this dissatisfaction were the facts that physicians did not provide adequate information regarding warnings of side effects and interactions, that patients often did not understand what they were told, or did not remember a large portion of the information. Ley as well as other authors have reported studies of the failure of communication between the health care provider and patient. These studies confirm his suggestions.[3-5]

Dissatisfaction by patients led a consortium of consumer organizations to petition the Food and Drug Administration (F.D.A.) in 1975, requesting that written information on the hazards of prescription drugs be

provided.[6] In particular, consumers expressed concern over information on adverse drug reactions. They specifically endorsed the use of printed handouts as the format for routinely, providing patient information on prescription drug products.

The F.D.A. has required such information for oral contraceptives since 1970 and more recently responded to the consumer organization petition by proposing written guidelines for patient package inserts (PPI's) to be dispensed with each new prescription for ten more drugs or drug classes.[8] These required PPI's were to have been printed leaflets that described the drug's potential risks, benefits, and instructions for use. Specific objectives of the PPI's were to improve compliance, increase patient awareness of the need to avoid certain foods and drugs, and aid in early recognition and interpretation of side effects. The PPI program was to be expanded eventually to all drug products.

The prospect of the FDA requiring patient package inserts by the F.D.A. brought great controversy and debate among various patient and professional groups, and the FDA. Opponents to this program suggested that mandatory PPI's could disrupt the physician-patient relationship, increase inappropriate self-medication, prompt patients to imagine side effects, foster the transfer of prescription drugs among patients, and alarm patients to the point where they

would reject drug therapy.[9-11] Moreover, these groups argued that information could be distributed more efficiently outside of the restrictive demands of the proposed system, and that therefore the F.D.A. action was unnecessary.

In accord with the political philosophy of the Reagan Administration and in response to the protest of health professionals, the Department of Health and Human Services first stayed, then rescinded the mandatory patient package insert regulations. A statement was issued expressing the belief that innovative and effective steps toward more patient information were already being taken by the private sector. As a consequence of governmental action, the burden of solving the problem with patient information had now been shifted away from the government. The F.D.A.'s findings from a large consumer survey conducted in 1982, however, showed that the problem still existed.[12] Patients reported receiving information regarding side effects from the physician only 26% of the time and from the pharmacist only 11% of the time.

The first step toward resolution of this problem was the organization of the National Council on Patient Information and Education (NCPIE) in 1982.[13] This organization encourages its professional organization membership to develop and direct programs for individual health care professionals. The AMA, USP, and NARD are some of the organizations which have developed written materials for patient

information.

The literature reflects various attempts at evaluating patient information materials. Research evaluating the content and format of written prescription drug information prior to 1980 has been reviewed by Morris.[14] He found general agreement that written drug information improves patient knowledge of special directions, precautions, and side effects; written information improves patient compliance in short-term medication regimens.

More recent studies have also evaluated the content and format of the written information provided. Methodological design has focused attention on the specific characteristics of the information provided and population receiving it. Written information has been studied that was used for short-term antimicrobials, benzodiazepines, cimetidine, and non-steroidal anti-inflammatories. Guidelines for the content of the written materials utilized in these studies were either developed by the investigators or adopted from the F.D.A. proposal, Canadian Society of Hospital Pharmacists, or the American Society of Hospital Pharmacists. A recently published article in this journal evaluated the effect of specific demographic variables. Several studies have evaluated the effectiveness of non-written formats for presenting information, and have included non-private and private verbal instruction, and follow-up telephone instructions.

Objectives for this research have been to measure the effect of written drug information on patients' knowledge and comprehension,[15-19] compliance,[17-19] and attitudes.[15-19] Results again reconfirm the conclusion that written instructions may augment verbal instruction and thus provide an important format for re-inforcing optimal patient drug administration behavior.[16-18] Subjectively, patients' satisfaction with the treatment and information they received are increased with written materials.[15-19] Written PPI's were again found to increase patient knowledge of the specific medication's name,[15] proper use,[15-19] potential side effects,[15,16] special precautions,[16] and action to be taken in the event of a missed dose.[15,18] There was no evidence that increased patient knowledge contributed toward an increase in side effects actually experienced.[15] Informed patients were, however, more likely to report side effects if they occurred. Results also indicated that patient knowledge and comprehension of written information may be influenced by the patients' age, years of education, and reading environment. In contrast, the patients' occupation, sex, or previous drug use were not correlated.[18] The verbal acknowledgement by the pharmacist of the importance of the written information was also correlated with increased patient awareness and utilization of the PPI material.[19]

The potential for changing patient knowledge and compliance has recently been reviewed in the context of the

health decision model.[20] The authors describe that the pharmacist can influence patient decisions and behavior through instruction, clarification, and reinforcement. However, patient decisions can only be influenced if the information is available, understood, and remembered at the time it is needed. Research has shown that patients usually remember best the first instructions presented, and those which are emphasized and repeated.[21] The number of statements is important because the fewer the instructions given, the greater will be the proportion remembered.[21]

Thus, one finds continued support in the literature for the use of specific written drug information aimed at patient education. Data from research conducted thus far has raised still other questions which need to be studied. One such question is whether a specific format or vehicle for providing information should be preferred for conveying a specific type of information. In evaluating the role of written information, Hermann has proposed several advantages of using written material to convey side effect information.[22] Accordingly, it may be more effective to provide patients with written side effect information that could be readily retrievable when patients need it rather than telling them about the side effects when they purchase their medication.

Although the effect of written side effect information on patient knowledge and compliance has been reported, the

actual utility of information to patients who experience side effects is not known. Specifically, it is not known what impact the method for transmitting information has on the patient's ability to attain specific performance objectives. To measure this outcome would be ideal, however, this would be practically impossible to observe. As an alternative and the closest approximation to the patient's actual performance one can describe to a patient the symptoms and the conditions under which they are experienced and record the patient's interpretation and intended action.

The purpose of this study was to evaluate the effectiveness of three different ways of informing patients about side effects. Effectiveness was measured as the ability of the patient to use the information given the facts and conditions of a hypothetical case.

METHODOLOGY

The study was conducted at a state university teaching facility. All methodology were approved by the Committee on Human Research. Subjects met study eligibility requirement if they were between 20 and 80 years of age and presented to the Ambulatory Pharmacy with a new or refill prescription for digoxin. A majority of subjects had been evaluated and were already being followed through the General Medicine, Family Practice, or Cardiology Clinics. Screening for subject eligibility was performed by a pharmcy technician who noted the subjects birthdate on their clinic card. Eligible subjects had their name, address, and telephone number recorded for follow-up evaluation purposes (Appendix A). While waiting for their prescription(s) to be filled, each subject was given an Informed Consent Form (Appendix B). Each patient was asked to read, sign, and return the consent form to the pharmacist upon receiving their medication. Subjects who were unable to read, understand, or chose not to sign the consent form were automatically excluded.

Participating subjects were then randomly assigned to one of three treatment groups representing the independent variable. Each group received information about their digoxin medication by one of three methods. The three methods consisted of: (1) verbal consultation alone (Appendix C); (2) A.S.H.P. printed leaflet (Appendix

D),[23] or; (3) both verbal consultation and printed leaflet.

Pharmacy technicians were responsible for flagging the subject's digoxin prescription with the appropriate colored indicator alerting the pharmacists to the treatment method. Upon filling the prescription according to normal procedure, the pharmacist detached the colored flag indicator from the prescription, initialed it, and stapled it to the outside of the bag along with the subject's pick-up call number. As subjects appeared at the dispensing window to pick up their prescription(s), the same pharmacist who had filled the prescription(s) was alerted. This pharmacist was responsible for collecting the signed informed consent form, dispensing the medication, and delivering the information by the appropriate method.

Each subject receiving the printed leaflet material was told that it contained important information about their digoxin medication and that they should read and consult it. Subjects who received verbal consultation were given approximately 2 to 3 minutes of semi-private consultation. The consultation contained the essential elements abstracted from the digoxin leaflet. The content of both the verbal and written instructions were reviewed by the medical staff in order to reflect local practice and to avoid any discrepancies with information that might be presented by the clinic practitioners.

Each pharmacist was trained to ensure that the infor-

mation was presented in a manner consistent from one consultation to another. This consistency was accomplished by the use of a developed guideline (Appendix C), and by subsequently voice taping each pharmacist prior to their participation. Each pharmacist was able to present the information using spontaneous conversational format. In addition, an outline of the consultation (Appendix E) was posted at the dispensing window, out of view of the subject, to serve as a memory cue for the pharmacist. Periodic checks were also made during the study to avoid problems.

Subjects were mailed a postcard (Appendix F) 3 to 4 days after their clinic visit. The postcard informed subjects that an interviewer would be contacting them by telephone in approximately one week and guaranteed confidentiality of information they provided. Seven to ten days after the clinic visit the investigator contacted each subject by telephone and recorded their response to each question on the questionnaire (Appendix G). Average length of time for telephone interview was approximately 5 to 7 minutes for each patient. This time period, from clinic visit until telephone interview, was selected because it represents the approximate time needed before digoxin-induced side effects would be manifested with initial therapy. The time period alotted for telephone interview was strictly adhered to in order to ensure consistency of measurement between subjects.

The questionnaire was divided into two major sections. The first section was designed to gain information regarding the subject's exposure to prior information sources, duration of drug use, and experience with side effects. Other questions pertained specifically to the subject's awareness, and comprehension of the information presented to them by the pharmacist, and contained in the printed leaflet. The second section of the questionnaire was designed to evaluate the subject's ability to recognize and react appropriately to potential medication related side effects. Each subject was presented four hypothetical cases involving side effects commonly associated with drug therapy. Three side effect cases were used because they represent typical side effects associated with possible digoxin toxicity. A fourth side effect case was used because it is not normally associated with digoxin therapy, but instead, typically represents a common drug allergic response. In addition to the four side effect questions, two administration questions were included to allow for the evaluation of non-side effect related content.

For each case, subjects were asked to select the option which described their intended behavior in these circumstances. Each subject was encouraged to utilize any written information given to them at the time they received their medication to help answer the cases. All telephone interviews were conducted by one pharmacist interviewer who was

blinded to the method used in presenting information to a specific subject.

A summation of the subjects' responses on the side effect cases (1=correct, 0=incorrect) is the dependent variable. The independent variable is the method used for presenting the side effect information. The effect of prior side effect information was also evaluated by the use of analysis of variance. The analyses of variance were performed using the Statistical Package for the Social Sciences.[24]

RESULTS

Seventy-two subjects were entered into the study between December 1, 1982 and May 31, 1983. During the later part of this period, subject availability declined until finally during the last month, only 2 subjects were entered. This marked decrease in eligible subjects was thought to be due to a change in the departments' cash collection policy. It was felt that the slow rate of entering patients may eventually affect the consistency of treatment intervention, and thus a decision was made at this point to terminate data collection.

The distribution of treatment among subjects entered and subsequently interviewed is shown in Table I. Telephone interviews were completed on 52 subjects. Twenty of the initial 72 subjects could not be reached within the four day period alloted for evaluation. The dropout rate from each treatment group was similar, verifying that there was no treatment selection bias.

Subject Background

All 52 subjects were taking digoxin at the time of the interview. Greater than 90% of subjects had already been taking digoxin for at least one year, while only 9.6% of patients had taken digoxin for less than one year. Table II shows the distribution of treatments by the duration of therapy.

TABLE I: TREATMENT DISTRIBUTION

METHOD	NUMBER OF SUBJECTS INITIAL (n=72)	EVALUATED (n=52)
1. Verbal	26 (36.1%)	19 (36.5%)
2. Written	24 (33.3%)	18 (34.6%)
3. Verbal & Written	22 (30.6%)	15 (28.9%)

Two subjects (3.8%) reported having side effects which may have been a result of their digoxin medication. Three others had experienced side effects which would not normally be associated with their digoxin medication. The impact of actual experienced side effects, as a source of prior information affecting subjects abilities, could not be evaluated because of the small number of incidences reported.

Twenty-eight of 33 subjects (84.8%), who had been given written information, remembered receiving it. Twenty-six subjects (78.8%) had read the material at the time of interview, and 23 subjects (69.7%) still had the information available for use at the time of the telephone interview. Table III shows self-reported patient's comprehension of the information. More than half of the subjects (58%) reading the material prior to the interview said they understood it "very well". The remainder (42%) reported they had understood it "fairly well". Ninety-four percent of the subjects receiving verbal consultation remembered it. Approximately two-thirds (66%) of these subjects said they understood the verbal consultation "very well" and the other third understood it "fairly well".

TABLE II: DURATION OF DIGOXIN THERAPY

TIME	NUMBER OF SUBJECTS (n=52) TOTAL	ASSIGNED TREATMENT		
		VERBAL	WRITTEN	VERBAL & WRITTEN
LT 30 days	1 (1.9%)	0	0	1
30-365 days	4 (7.7%)	3	1	0
GT 365 days	47 (90.4%)	16	17	14

TABLE III: SUBJECT'S PERCEIVED COMPREHENSION OF TREATMENT

UNDERSTANDING	WRITTEN (n=26)	VERBAL (n=32)
VERY WELL	15	21
FAIRLY WELL	11	11
NOT SO WELL	0	0
NOT AT ALL	0	0

Performance on Test Questions

A summary of all subjects' responses to each question is shown in Table IV. For comparison, the range of the dependent variable, indicated by the success rate of subjects to side effect cases, is given in Table V. Results indicated that the questionnaire was adequate in discriminating between responses of subjects.

Validation of the dependent variable was assessed through a determination of the discriminant and convergent validity of the measures (25). Intercorrelations for the responses to the digoxin-related side effect cases (#1, 2 and 5) were higher than the intercorrelations of the non-digoxin related side effect care, and admininstration cases. The summation of the scores to the three side effect cases represent the dependent variable. These three cases measured the same trait, and were thus analyzed as an index rather than individually. In contrast, correlations among the response to the administration case questions #4 and 6, and to the non-digoxin related side effect case question #3 were much lower which indicated measurement of different constructs.

One-way analysis of variance was performed to evaluate the differences in the effect between the three treatment methods. Table VII displays the mean score for each treatment method used in presenting side effect information. Patients receiving a combination of verbal and written

TABLE IV: HYPOTHETICAL CASES - CORRECT RESPONSES TO INTERVIEW QUESTIONS

QUESTION CATEGORY	CASE NO.	CONTENT	CORRECT RESPONSES
SIDE EFFECT	1	ANOREXIA	18 (34.6%)
	2	BLURRED VISION	28 (53.8%)
	3	SKIN RASH	20 (38.5%)
	5	NAUSEA	20 (38.5%)
ADMINISTRATION	4	MISSED DOSE	46 (88.5%)
	6	PRESCRIBED ADMIN COMPLIANCE	42 (80.8%)

TABLE V: SUCCESS RATE OF SUBJECTS TO SIDE EFFECT CASES

NO. CORRECT RESPONSES	NO. SUBJECTS
0	9 (17.3%)
1	18 (34.6%)
2	11 (21.2%)
3	10 (19.2%)
4	4 (7.7%)

TABLE VI: PEARSON CORRELATION TEST - COEFFICIENTS (r) MATRIX

CASE NO.	CONTENT	ANOREXIA	BLURRED VISION	NAUSEA	SKIN RASH	MISSED DOSE	ADMIN COMPLAINCE	
1.	ANOREXIA	1.0						DIGOXIN SIDE EFFECTS ATTRIBUTED TO TOXICITY
2.	BLURRED VISION	.268	1.0					
5.	NAUSEA	.339	.256	1.0				
3.	SKIN RASH	-.077	.018	.188	1.0			SIDE EFFECT NOT ATTRIBUTED TO DIGOXIN
4.	MISSED DOSE	.010	.149	.038	.04	1.0		
6.	ADMIN COMPLIANCE	-.055	.038	-.015	-.216	-.02	1.0	ADMINISTRATION

TABLE VII: DIGOXIN SIDE EFFECT CASES - CORRECT RESPONSES
(ANOVA TABLE - ONE WAY TEST BETWEEN TREATMENTS)

TREATMENT	SUBJECTS	MEAN	STD DEV	STD ERROR
Verbal	19	1.11	0.81	0.19
Written	18	1.61	1.24	0.29
Verbal & Written	15	2.40	1.24	0.32

(Between all 3 treatments: d.f.=2,51, F=5.79, $p < 0.01$)

(Between verbal & written: d.f.=1,36, F=2.18, p=N.S.)

information had statistically significantly greater scores than those patients receiving either written or verbal information alone. There is not, however, a statistically significant difference between the mean scores of patients receiving written information versus verbal information only. These results indicated that patients receiving both written and verbal information from the pharmacist responded most appropriately to the side effect case questions.

Prior information sources were evaluated to determine their impact as a possible source of variation between treatment groups. Subject's information sources prior to entering the study are summarized in Table VIII. Several patients received prior information from multiple sources. Therefore, each prior source of information was evaluated separately. Two-way analyses of variance were performed to determine if there were any differences between the results of the three treatment methods caused solely by prior information. Results for the prior information sources are also reported in Table VIII. None of the sources alone or in combination with the treatment were found to have an impact on the subject's ability to respond appropriately. Only the treatment was found to affect subjects' responses.

TABLE VIII: IMPACT OF PRIOR INFORMATION SOURCES

SOURCE	NO. SUBJECTS RECEIVING INFO.	TEST STATISTIC ALONE	TEST STATISTIC INTERACTION WITH TX
Physician	20 (38.5%)	F=1.48,p=N.S.	F=1.07,p=N.S.
Pharmacist	21 (40.4%)	F=0.05,p=N.S.	F=0.24,p=N.S.
Written	26 (50.0%)	F=0.38,p=N.S.	F=0.35,p=N.S.
Friends/Relatives	1 (1.9%)	---	---
Nurse	2 (3.8%)	---	---
Video/Cassette	2 (3.8%)	---	---

DISCUSSION

As a consequence of action taken by consumer groups and the Federal Government, research has focused attention on the impact and utility of written information for patients. Studies have demonstrated that written materials can be an effective component of a program to improve patients' knowledge and compliance. Through an analysis of specific performance objectives, Hermann[22] has suggested that the written vehicle offers advantages for conveying side effect information, and therefore may be preferable for this purpose.

Results of the present study have shown that the combination of verbal and written methods is superior to either verbal or written method alone for enabling subjects to recognize medication related side effects and respond correctly. Research conducted by Ley[21] has found that verbal information alone is often inadequate, primarily because patients tend to forget proportionately more information as the amount of information given to them is increased. Thus, patients given the written leaflet had an advantage in that they did not need to rely upon their retention of the side effect information, which by nature, is often detailed and voluminous.

Interestingly enough, this leaves one to explain why the written information alone was not as successful as the combination. During the interview, it was confirmed that the

written leaflet was retained by most subjects, and apparently well comprehended. Most subjects had utilized the material as a reference when they answered the interview questions. Many subjects requested a brief period of time to locate their written material prior to the administration of the questionnaire. It appears that the verbal instruction may have contributed through a process of repetition and reinforcement, as well as by acknowledging the importance of the written information. Studies evaluating information in general have confirmed the superiority of using a combination of verbal and written techniques for educating patients.

Although this study was unable to show a statistically significant advantage of written information alone over verbal instruction alone, the trend in results was in the expected direction. This inability could either be explained by the fact that (1) there is no statistical difference between these two methods, or (2) the study lacked the necessary sensitivity to detect a difference. The small sample size or the questionnaire, as a measurement instrument, may have contributed toward a lack of sensitivity.

Results on the question designed to ascertain whether subjects were able to recognize and react appropriately to a side effect not related to digoxin, and those concerned with the ability to manage drug administration did not show a

difference between methods. Subjects from each treatment group responded equally poorly on the non-digoxin side effect question. This may again be due to a lack of difference or inadequate sensitivity of the study. The poor response rates may be attributed to the fact that no definitive information had been presented regarding non-digoxin related side effects. This study did not evaluate what impact a statement definitely excluding other symptoms as side effects may have on patients' abilities to differentiate between drug related and other effects.

All three treatment groups were equally able to plan regarding the proper administration frequency and appropriate course of action in the event of a missed dose. There was no difference detected between groups, indicating that none of the methods could be shown to be preferable for conveying this type of information. Possible explanations for this high success rate include: (1) the information doesn't require the same amount of reinforcement and retention as with side effects, or (2) the instruction on the prescription label helped to reinforce the correct behavior. Since all treatment groups responded well, it must be determined whether this information is needed as a part of the written material. To determine this, a study needs to be designed which evaluates these formats versus a control group not receiving any additional information.

Subjects who reported receiving side effect information

from sources other than those utilized in the study did not respond more appropriately than those who did not. The data indicate that whether or not subjects had prior side effect information did not have an impact on the effectiveness of the treatment.

There are limitations to this study that prevent general extrapolation of these results. The study was conducted in a single hospital ambulatory pharmacy involving a small number of patients. Thus, there were inadequate data for some of the levels of the variables, such as length of digoxin therapy, and actual experienced side effects. In addition, the study evaluated the effect of information relating to only one drug, digoxin. Research on compliance supports the fact that long-term behaviors are much more difficult to influence. Thus, one could speculate that the vehicle utilized for presenting the information may have a greater impact on subjects' behaviors associated with short-term medication therapy. Finally, this study measured intended behavior rather than actual behavior subjects' elicit when a side effect is experienced. Long-term multicenter trials designed to evaluate the effectiveness of informational vehicles in patients who actually experience side effects are needed to confirm these results.

CONCLUSION

Research has only begun to define the role of various informational vehicles in providing specific patient drug information. This study was conducted in an attempt to evaluate three methods designed to inform patients about side effects by measuring intended performance behavior. The combination of verbal consultation along with written leaflet information was the most effective method for enabling patients to recognize and respond appropriately to digoxin-related side effects. These data support the findings of other studies which suggest that there is no evidence to support using written materials in addition to verbal consultation.

Pharmacy practitioners should consider the use of written drug information materials an essential component of programs aimed at enabling patients to respond appropriately to experienced drug-related side effects.

BIBLIOGRAPHY

1. Anon. Prescription Drug Products; Patient Package Insert Requirements. Fed Regist. 1982; 47(8):1773-1775.

2. Ley P. Complaints made by Hospital Staff and Patients: A Review of the Literature. Bull Br Psychol Soc. 1972; 25:115-20.

3. Ley P. Towards Better Doctor-Patient Communications. In Communication Between Doctors and Patients, edited by Bennett, A.E. London: Oxford University Press; 1976:75-98.

4. Hulka B Cassel JC, Kupper LL. et al. Communication, Compliance and Concordance Between Physicians and Patients with Prescribed Medications. Am J Pub Health. 1976; 66:847-853.

5. Svarstad BL. Physician-Patient Communication and Patient Conformity With Medical Advice. In the Growth of Bureaucratic Medicine, edited by Mechanic, D. New York, NY: John Wiley and Sons; 1976:220-237.

6. Consumers Union of the United States, Inc. Petition to the FDA to Require More Adequate Patient Labeling of Prescription Drugs. FDA Trac 1975 (Mar); No. 7500769.

7. Anon. Fed Regist. 1968; 33:8812.

8. Anon. Prescription Drug Products. Patient Package Insert Requirements. Fed Regist. 1980; 45:60754-84.

9. Joint Commission of Pharmacy Practitioners. Action on Patient Package Insert Study by Rand Corporation. J.C.P.P. News Release. 1981; (Oct 5).

10. United States Pharmacopeial Convention, Inc. Patient Package Insert Meeting Presentation. USP Docket. 1981; (Sept): No. 79N-0186.

11. American Medical Association. Patient Medication Instruction Sheets. Washington, DC: American Medical Association; 1982.

12. U.S. Dept. of Commerce National Technical Information Center, Springfield, VA. Final Report of the FDA Study of the Nature of Prescription Drug Information Obtained by Patients. Am J Hosp Pharm. 1984; 41:230.

13. Anon. Patient Information and Education About Drugs. A.A.C.P. News Release 1982; Vol. 11, No. 10.

14. Morris LA, Halperin JA. Effects of Written Drug Information on Patient Knowledge and Compliance: A Literature Review. Am J Pub Health. 1979; 69:47-52.

15. George CF, Waters WE, Nicholas JA. Prescription Information Leaflets: A Pilot Study in General Practice. Br Med J. 1983; 287:1193-1196.

16. Wielderholt JB, Kotzan JA. Effectiveness of the FDA-Designed Patient Package Insert for Benzodiazepines. Am J Hosp Pharm. 1983; 40:828-34.

17. McBean BJ, Blackburn JL. Evaluation of Four Methods of Pharmacist-Conducted Patient Education. Can Pharm J.

1982; 115:167-72.

18. Garnett WR, Davis LJ, McKenney JM et al. Effect of Telephone Follow-up on Medication Compliance. Am J Hosp Pharm. 1981; 38:676-9.

19. Gotsch AR, Liquori S. Knowledge, Attitude and Compliance Dimensions of Antibiotic Therapy with PPI's. Med Care. 1982; 20:581-95.

20. Eraker SA, Kirscht JP, Becker MH. Understanding and Improving Patient Compliance. Ann Int Med. 1984; 100:258-268.

21. Ley P. Memory for Medical Information. Br J Soc Clin Psy. 1979; 18:244-255.

22. Hermann F. Information for Patients - What Can Package Inserts Do? Pharm Int. 1980:118-121.

23. American Society of Hospital Pharmacists. Medication Teaching Manual. 3rd Edition. p. 97. Bethesda: American Society of Hospital Pharmacists, 1983.

24. Nu NH, Hull CH, Jenkins, JG et al. S.P.S.S.: Statistical Package for the Social Sciences, 2nd ed., McGraw-Hill Book Company, New York, 1975.

25. Campbell OT, Fiske DW. Convergent and Discriminant Validation by the Multi-trait Multi-method Matrix. Pych Bull. 1959, 56:81-105.

APPENDIX

APPENDIX A: PERSONAL IDENTIFICATION DATA.

	DATE	NAME	ADDRESS	TEL. NO.	METHOD
1.					OW
2.					OW
3.					W
4.					O
5.					W
6.					W
7.					W
8.					O
9.					OW
10.					W
11.					O
12.					W
13.					OW
14.					W
15.					W
16.					OW
17.					O
18.					O
19.					W
20.					OW
21.					O
22.					O
23.					W
24.					W
25.					OW
26.					W
27.					O
28.					O
29.					O
30.					OW

APPENDIX B

OREGON HEALTH SCIENCES UNIVERSITY

Study Title: Evaluation of the Effectiveness of Three Methods Designed to Inform Patients About Side Effects

Principal Investigator: Michael J. Regner R.Ph.

The general purpose of this study is to evaluate three methods of informing patients about their medication(s). Upon consenting to participate in this study, you will be given either verbal and/or written information about one of your drugs from the pharmacist at the time you receive your medication. Approximately 1 to 2 weeks after this, you will be contacted by telephone and asked some questions about your medication. Each patient participating in this study will have the benefit of receiving more information about their medication. This study is designed to enable pharmacists and other health care providers to more effectively instruct their patients about their medication. This study is designed to enable pharmacists and other health care providers to more effectively instruct their patients about medications, and thereby facilitate greater effectiveness and safety in the use of drugs.

Dr. Tom Vorce-West has offered to answer any questions you may have. (Pharmacy Dept. (503) 225-8007).

It is not the policy of the Department of Health and

Human Services, or any other agency funding the research project in which you are participating to compensate or provide medical treatment for human subjects in the event the research results in physical injury. The Oregon Health Sciences University, as an agency of the State, is covered by the State Liability Fund. If you suffer any injury from the research project, compensation would be available to you only if you establish that the injury occurred through the fault of the University, its officers or employees. If you have further questions please call Dr. Michael Baird, M.D., at (503) 225-8014.

I understand I may refuse to participate or withdraw from this study at any time without affecting my relationship with, or treatment at the Oregon Health Sciences University.

APPENDIX C: DIGOXIN VERBAL CONSULTATION

Your doctor has prescribed digoxin for you. Digoxin, also called Lanoxin®, helps increase the force of your heart's pumping action and regulates its beat. It is a very strong and effective drug, and should be taken exactly as directed, at the same time(s) each day. If you should forget to take a dose, omit it and take only your regular dose at the next scheduled time. Do not take a double dose. If you forget to take two or more doses in a row, contact your doctor or pharmacist. Patients taking this medication in the amounts prescribed by their doctors usually do not experience side effects. However, you should contact your doctor at once if you have any loss of appetite, upset stomach, or change in vision. Be sure to keep your digoxin out of reach of children.

APPENDIX D: A.S.H.P. Digoxin Leaflet

DIGOXIN

(di jox' in)

OTHER NAMES: Lanoxin^{R}

WHY is this drug prescribed?

Digoxin is prescribed for persons with irregular heartbeats or those whose hearts have become ineffective in pumping blood throughout the body. Although it does not cure these problems, it does help control them by increasing the force of the heart's pumping action and regulating its beat. It is a very strong and effective drug and should be used only under the close supervision of a doctor.

WHEN should it be used?

This drug usually is taken once a day. However, your doctor will determine how often you should take it. Follow carefully the instructions on your prescription label, and ask your doctor or pharmacist to explain any part that you do not understand. It is extremely important that this medication be taken on a regular schedule. For example, if you are to take the drug once a day, the medication should be taken at the same time each day. It is a good idea to take your medication at the same time you do something regularly each day, such as brushing your teeth in the morning or

going to bed at night.

HOW should it be used?

Digoxin comes in tablets and as an elixir that are taken by mouth. Your doctor has chosen the form that is best for you. Your prescription label tells you how much to take at each dose. You may be instructed to take a larger dose at first and reduce it after a few days. Be sure to follow the instructions carefully. Ask your doctor or pharmacist if you are using the elixir and do not understand how to measure your dose. Usually the drug should be taken on an empty stomach. Contact your doctor or pharmacist if you have any questions regarding how much medication to take or whether to have your prescription refilled when it is gone.

What SPECIAL INSTRUCTIONS should I follow while using this drug?

Be sure to take only the exact amount of medication prescribed by your doctor at each dose. Your doctor may ask you to check your pulse daily while taking this medication and will teach you how to do so. If your pulse is slower than the number of beats per minute your doctor tells you to check for, contact your doctor about taking the drug that day.

What STORAGE CONDITIONS are necessary for this drug?

Keep this medication in the container it came in.

Keep this medication out of the reach of children.

What should I do IF I FORGET to take a dose?

Do not take a missed dose when you remember it. Omit it and take only your regular dose at the next scheduled time. Do not take a double dose. If you forget to take two or more doses in a row, contact your doctor or pharmacist.

What SIDE EFFECTS can this drug cause? What can I do about them?

Patients taking this medication in the amounts prescribed by their doctors usually do not experience side effects. However, you should contact your doctor at once if you have loss of appetite, nausea, vomiting, or diarrhea; changes in vision, such as blurring, color changes or seeing spots; or irregular heartbeats or changes in pulse rate.

What OTHER PRECAUTIONS should I follow while using this drug?

Before you begin to take digoxin, tell your doctor about any other medications you are taking, including nonprescription medications.

Keep in touch with your doctor and pharmacist while taking this medication.

Do not allow anyone else to take this medication.

APPENDIX E: OUTLINE OF DIGOXIN ORAL CONSULTATION

KEY WORD		ABBREVIATED TEXT
1.	Name	Digoxin/Lanoxin®
2.	Purpose	Improves pumping force/regularity of heart beat
3.	Compliance	Very strong/effective drug
4.	Directions	As directed, at same time(s) each day
5.	Missed dose	Omit/take only your regular dose at next scheduled time. Don't take double dose.
	Missed doses	Contact MD or R.Ph.
6.	Side effects	Contact MD at once if you experience A. upset stomach B. loss of appetite D. change in vision
7.	Storage	Keep out of reach of children

APPENDIX F: POSTCARD

Dear

Sometime within the next 10 days an interviewer from the Pharmacy School at Oregon State University will telephone to ask you some questions about a medication you may be taking. The survey, as a part of a research project, will provide a better understanding of the type of information people should recieve about their medication(s). All the information given us is strictly confidential and will be reported as a summary for a group only, not for any one individual.

Thank you for your courtesy and help.

Very truly yours,

Michael J. Regner, R.Ph.
Team Leader Pharmacist
University Hospital Pharmacy
Oregon Health Sciences University

College of Pharmacy
Oregon State University
Corvallis, OR 97331

Address Correction Requested

APPENDIX G

QUESTIONNAIRE INFORMATION: O/W/OW (circle one)

DATE: _____ TELEPHONE: _____

Hello, my name is Mike Regner, and I'm calling for the pharmacy school at Oregon State University in cooperation with the Oregon Health Sciences University. The person in your household I would like to speak to is _____. (If respondent not home, ask when) _____. You may recall receiving a postcard from us about this survey. We are currently working on a study regarding information presented to patients concerning medications they receive.

We want everyone we interview to know that answers to all questions on this survey are strictly confidential and will be summarized as a group, but not for any one person. Also, we want you to know that your name has been randomly selected from a list of patients receiving digoxin medication from the pharmacy at the Oregon Health Sciences University. If, during this interview, I should come to any question that you don't want to answer, just let me know and I'll go on to the next question. However, I do want you to know that your responses to this interview are a very important part of our study, and we can not substitute others' responses for yours. Okay?

I'd like to begin by asking you some questions regarding your digoxin medication which was given to you by the phar-

macy at the Oregon Health Sciences University approximately one week ago.

1. Are you currently taking digoxin, or not?

    1. YES (Go on to Q1b)
    2. NO (Go on to Q1a)
    3. DK/NA

- -

1a. May I ask why you stopped taking this medication?

    1. NEVER STARTED TAKING IT.
    2. OTHER, _____
    3. DK/NA

    (Skip to Q3)

1b. Could you tell me about how long you have been taking digoxin?

    1. LESS THAN ONE MONTH
    2. ONE MONTH TO ONE YEAR
    3. LONGER THAN ONE YEAR

    (Go on to Q2)

---

2. While you have been taking this medication, have you noticed any bothersome effects?

    1. YES (Go on to Q2a)
    2. NO (Skip to Q3)
    3. DK/NA

- -

2a. Could you please describe what this was?

2b. What, if anything, did you do to deal with this?

---

3. I have a list of some of the ways people may hear about possible bothersome effects from their medications. Could you please tell me whether or not you have received any such information about your digoxin from any of the following sources. First...

	YES	NO	DK/NA
a. A DOCTOR	1	2	3
b. A FRIEND/RELATIVE	1	2	3
c. A PHARMACIST	1	2	3
d. WRITTEN (eg. books, leaflets, magazines)	1	2	3
e. OTHER, _____	1	2	3

---

4. Could you tell me, whether or not, you received any written information about your digoxin, at the time you received your medication?

1. YES (Go on to Q4a)
2. NO (Skip to Q5)
3. DK/NA

- -

4a. Did you happen to read the written material given to you about your digoxin?

1. YES (Go on to Q4b)
2. NO (Skip to Q5)
3. DK/NA

- -

4b. Do you have it available to you now?

1. YES
2. NO
3. DK/NA

(Go on to Q4c)

4c. How well did you understand this written material?

1. VERY WELL
2. FAIRLY WELL
3. NOT TOO WELL
4. NOT AT ALL
5. DK/NA

---

5. Could you tell me, whether or not, the parmacist talked to you about your digoxin at the time he gave it to you?

1. YES (Go on to Q5a)
2. NO (Skip to cases)
3. DK/NA

5a. How well did you understand what you were told by the pharmacist?

1. VERY WELL
2. FAIRLY WELL
3. NOT TOO WELL
4. NOT AT ALL
5. DK/NA

At this time, I would like to talk to you about a few

problems which some people might have while taking their medication. I will read six examples of possible situations, and I would like you to place yourself in each of these. After each example, I will give you three choices, and I would like you to tell me which of the choices describes what you would have actually done while taking digoxin. Please use any written material given to you at the time you received your medication to help you answer these questions. If you wish, I will pause now until you are ready.

1. If, a few days after starting on this medication, you had a day when you just didn't feel like eating, but you were sure you hadn't eaten anything that didn't agree with you. You ate a very light breakfast that morning, but by noon you didn't care for anything at all. Would you have

    1. Called your doctor right away?

    2. Waited and called your doctor only if you hadn't felt better by the end of the week?

    3. Done something else_____?

2. If, one day last week, you had found yourself having trouble reading and watching TV because your vision was blurry, would you have

    1. Made an appointment with your eye doctor?

    2. Thought that this may be caused by your medication and called your doctor right away?

3. Done something else_____?

3. If, sometime last week, you suddenly developed a dry red rash that itched miserably, would you have

1. Thought that this was caused by the medication and called your doctor?

2. Thought that it probably was caused by something else and treated it with a home remedy?

3. Done something else_____?

4. If, one evening, you discovered that you had missed taking your morning dose of digoxin, would you have

1. Taken the missed dose immediately upon remembering it?

2. Called your doctor immediately?

3. Omitted it, and resumed taking your regular dose at the next scheduled time?

5. If, you had taken your medication one morning, eaten breakfast, and enjoyed a good lunch, then suddenly felt nauseated that afternoon, would you have

1. Called your doctor right away?

2. Cut down on your food or gone on a bland diet until you felt better?

3. Done something else_____?

6. Lastly, please indicate how you are taking your digoxin by choosing the following statement which is most correct.

1. I take my medication only once daily, at the same time each day.

2. I take my medication only once daily, but not necessarily at the same time each day.

3. Something other, _____.

Thats all the questions I have for you. I just want to thank you for your time and cooperation in answering the questions. I would be glad to answer any questions you might have about this survey.