Communication, Compliance, and Concordance between Physicians and Patients with Prescribed Medications

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Abstract: Forty-six practicing physicians and 357 patients with diabetes mellitus or congestive heart failure were the subjects for this study, which focuses on the impact of medication regimen and doctor-patient communication in affecting patient medication-taking behavior and physician awareness of these behaviors.

Four types of medication errors were defined: omissions, commissions, scheduling misconceptions and scheduling non-compliance. The average error rates were 19 per cent, 19 per cent, 17 per cent and 3 per cent, respectively. The combined average error was 58 per cent; scheduling non-compliance on the part of the patient was a minor component.

Specific aspects of the medication regimen were associated with increased errors: (1) the more drugs involved between the doctor-patient pair, the greater the errors of omission and commission; and (2) the greater the complexity of the scheduling, the greater the errors of commission and scheduling misconceptions. If the patient did not know the function of all his drugs, errors of commission and scheduling misconception increased.

Neither characteristics of patients nor the severity of disease were influential in determining the extent of medication errors. For patients with congestive heart failure, good communication of instructions and information from physician to patient was associated with low levels of all types of errors. (Am. J. Public Health 66:847–853, 1976)

Introduction

The use of drugs by patients is firmly controlled through a variety of mechanisms initiated by the search for active chemotherapeutic agents, followed by animal studies, experimental studies in humans, controlled clinical trials, regulation and release of pharmaceuticals on the commercial market by the Food and Drug Administration, and finally, controlled distribution by physician prescription through licensed pharmacies. The purpose of these successive steps is to increase the likelihood that the patient receives the most appropriate and efficacious medication for specified indications. However, the final steps in the drug dispensing and consumption process are intimately involved with human factors, such as the prescribing practices of the physician and the memory and motivation of the patient. These human factors may be of sufficient magnitude to distort and even negate the effectiveness of the entire process which precedes the interaction of patient, physician, and medication.

Many studies of patient compliance have made comparisons between patient medication-taking behaviors and medications prescribed in medical records, assuming that the patient is non-compliant if behavior does not conform with the record. This conceptualization of the problem is distorted in that the role of the physician in affecting non-compliance has been inadequately defined. A portion of what has been labeled patient non-compliance may be inadequate communication between physician and patient and insufficient awareness on the part of the physician as to which drugs his patients are taking. The dual issues of physician awareness and patient compliance are of particular concern among patients with chronic diseases who are frequently confronted with multiple drugs and changing drug regimens. The consequences of inappropriate drug use are inadequate control of the disease process, as well as excess morbidity attributable to the drugs themselves.

The intent of this paper is two-fold: (1) to focus on those factors associated with inappropriate drug use; and (2) to emphasize those areas in which modification of current practice by physicians and patients may lead to improved patterns of medication use. The factors selected for study include characteristics of the medication regimen and communication from doctor to patient, each of which may influence medication errors and may also be subject to modification.

Background

Since the spring of 1971, representatives from the American Academy of Family Physicians and from the Department of Epidemiology at the University of North Carolina have been engaged in a study of the organization, utilization,
and assessment of primary medical care.\textsuperscript{4,5} The objectives of this study were: (1) to identify the barriers and stimulants to the use of health care services; and (2) to determine the impact of medical care on patients who have entered and are using the health care system. One area for assessment focuses on patient compliance with taking prescribed medication and physician awareness of drugs being taken by their patients. The desired outcome was agreement between physician and patient on drugs to be taken and schedule to be followed.

The study was undertaken in Fort Wayne, Indiana, a city of almost 200,000 people including contiguous urbanized townships. Primary medical care was provided by physicians in private practice supplemented by active emergency rooms in three voluntary hospitals. The organizational patterns of practice included solo practitioners, two or three man associations, and two loosely organized multispecialty groups.

\section*{Methods}

\subsection*{Physician Participants}

A stratified random sampling procedure was used to select physician participants for the study. The sampling frame was composed of all internists and family physicians listed in the Fort Wayne-Allen County Medical Society Directory. The sampling unit was the individual practitioner or the group of practitioners, depending on the type of practice in which the physician was engaged. A table of random numbers was used to sequence physicians and practices in the order in which they would be asked to participate. Sixty-eight percent of the physicians contacted participated fully in the study.

\subsection*{Patient Participants}

Patients with either congestive heart failure or diabetes mellitus were the subjects for this aspect of the study, since these conditions are seen frequently in the offices of primary care physicians, and they usually require the continued use of one or more medications for their control. Only adult onset diabetics with disease duration of 10 years or less were eligible. Congestive heart failure patients between the ages of 50 and 75 were admissible, with almost all cases being due to either arteriosclerotic or hypertensive heart disease.

Patients were enrolled into the study at the time of an office visit to a participating physician. Patient enrollment from each practice continued over a four-month period. A member of the physician's office staff introduced the study to each eligible patient, and a patient participation rate of eighty-four percent was achieved.

\subsection*{Data Collection}

Within the two weeks following identification at the doctor's office, the patient was visited in his or her home by a nurse-interviewer. At that time, the patient was asked to display current medications, indicate the function of each, repeat the scheduling recommendations of the physician, and indicate whether or not he or she was taking the drug as directed.

Since drug names were infrequently recorded on the bottle, the pharmacy name and address, and prescription number were transcribed from each bottle. A subsequent check of prescriptions at the pharmacy provided the name and schedule for each medication presented by the patient. Of the 76 pharmacies used by patients in the study, only one pharmacy refused to provide the information requested.

From the patient's medical record in the physician's office, the study nurse-interviewer abstracted data on medications prescribed, and not discontinued, during the year prior to the home visit with the patient. These drug data were submitted to the physician for review and any necessary modifications. Drugs for which dose or schedule were unavailable were specifically called to the physician's attention and he was encouraged to supplement the medical record data with his own knowledge of the patient's current medications. Thus, any inaccuracies or omissions in the record could be corrected, giving as complete a picture as possible of the drugs the physician believed his patient to be taking.

Prescription drugs only were included in the analysis, since over-the-counter medications taken by patients may not be known to their physicians. Similarly, patients may be unreliable in producing such drugs.

\section*{Computation of Drug Error Rates}

Since data were collected from doctor-patient pairs, comparison could be made of drugs consumed by patients with drugs prescribed by their doctors, as well as drug schedules recommended by physicians with the patient's perception of the recommended schedule. In addition, the patient's verbal statement of whether or not he or she was taking each drug as prescribed was noted. With this data set, it was possible to formulate four distinctive types of medication errors for each doctor-patient pair:

- \textit{omission rate} = proportion of drugs the patient was \textit{not} taking of those prescribed by the physician;
- \textit{commission rate} = proportion of the drugs the patient \textit{was} taking which the physician had not prescribed;
- \textit{scheduling misconception rate} = proportion of prescribed drugs taken by the patient for which the patient did \textit{not} know the correct schedule;
- \textit{scheduling non-compliance} = proportion of prescribed drugs taken by the patient for which the patient knew the correct schedule but did \textit{not} take as prescribed.

Scheduling was defined in terms of frequency of consumption per 24 hours and number of units (pills, spoonfuls, etc.) to be taken each time.

For each error rate a score was computed for each doctor-patient pair. Each score was a proportion ranging from 0 to 1. The lower the score the smaller the error; the larger the proportion the greater the error. The mathematical properties of these error rates have been discussed previously.\textsuperscript{6,7}

\section*{Doctor-Patient Communication Scores}

A measure of the physician's success in communicating instructions and information to his patients was devised sepa-
rately for diabetic patients and those with congestive heart failure. For each condition the physician was asked to respond to a series of items, which had previously been identified as covering topics which were pertinent to the particular disease process and the patient's management of his condition. For each patient, the physician indicated whether or not the patient had been instructed or informed in each area. The patient was subsequently presented with a corresponding series of questions to determine whether or not the information had been transmitted.

A communication score was devised to measure the proportion of information retained by the patient of the total amount provided by the physician. Communication scores could range from 0 to 1 with higher scores indicating a better level of communication.

Results

Study Group

Forty-six physicians contributed 357 patients to the study. Among these physicians, 33 were in family practice and 13 were internists. Each physician category was approximately equally divided between solo and group practitioners.

Of the patients, 234 were diabetics and 123 had congestive heart failure. These diagnoses were not mutually exclusive, since several heart failure patients also had diabetes and some diabetics had cardiac conditions (but not congestive failure). The mean age of the diabetics was 53 as compared to 63 for congestive failure patients. Approximately 55 per cent of both patient groups were women. Fifty-eight per cent of diabetics were high school graduates compared to forty-two per cent of heart failure patients; more than two-thirds of both patient groups represented the middle or working classes.

Drug Error Rates

Drug error rates were reported previously for diabetic and congestive failure patients. Both types of patients were on the average, omitting 18–19 per cent of drugs prescribed, and taking 19–20 per cent more drugs than their physicians realized, and making scheduling errors on about 17 per cent of drugs. When all types of medication-taking errors were combined, the average total error for all doctor-patient pairs was 58 per cent. Scheduling non-compliance has not been subject to further analysis since the mean rate was low (about 3 per cent), and it exhibited only minor variability.

Factors Associated with Medication Errors

Four categories of variables were reviewed in relation to the drug error rates. These included patient characteristics, measures of disease severity, complexity of the medication regimen, and communication from physician to patient. If characteristics of patients and their diseases were associated with drug error rates, a descriptive profile could be developed which would be useful to physicians and other providers in helping to predict patients at high risk for making drug errors. Various aspects of the medication regimen and the level of communication may themselves influence medication errors, and these factors have the potential for modification within the process of medical care.

Patient Characteristics: These factors can be summarily reviewed, since their association with drug error rates was minimal. The characteristics analyzed included: age, sex, marital status, education, current activity, number of people in household, and social class (Hollingshead two factor index based on occupation and education). There were no statistically significant associations (p ≤ .05) between any of these variables and the drug error rates. *

Disease Severity: Several measures of disease severity were available. Duration of disease and number of other concurrent diseases might be expected to influence the medical status of the patient. Neither factor, however, was associated with drug errors.

For heart failure patients there were two additional measures of disease severity—the New York Heart Association Classification of functional impairment and number of prior hospitalizations for congestive heart failure. Neither variable was associated with drug error rates.

A rather consistent pattern appeared among the diabetic patients, when the insulin dependent were compared with those using oral agents or diet alone. Patients requiring insulin had higher drug error rates than those not requiring insulin. However, the association was based on a small number of insulin dependent patients (23) and was statistically significant for scheduling misconceptions only.

Medication Regimen: (a) Number of drugs involved between the doctor-patient pair. The number of drugs consumed by patients ranged from 0 to 14 and prescribing patterns showed a similar variation. Our previous analysis demonstrated an association between number of drugs involved between the doctor-patient pair and errors of omission and commission. * * The errors increased with increasing number of drugs prescribed and consumed. Error rates for scheduling misconception showed a fairly even pattern (.17), whether one or seven or more drugs were involved.

(b) Knowledge of drug function. Another feature of the drug regimen was whether or not the patient knew the function of each medication he was taking. A tenable hypothesis might be that the greater the proportion of drugs for which the patient knew the function the less likely he would be to make errors.

Drugs were assigned to the "function known" category, if the patient displayed a reasonable knowledge of their function. For example, if a diuretic was taken "to get rid of water" or digitalis was taken "for the heart," these were considered acceptable responses. Only when the stated function was inconsistent with known pharmacologic and clinical properties or the patient denied knowledge of the function was the response categorized as incorrect. Overall, patients were reasonably knowledgeable about drug function; 69 per

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* The Statistical tests used in this paper are the usual analysis of variance F-tests for comparing the means of two or more populations. The assumptions of normality and homogeneity of variance associated with these tests have been examined and have been found to hold to a reasonable degree of approximation.
cent of patients knew the function of all drugs they were taking.

Graphic presentations correlating error rates with knowledge of drug function controlling for number of drugs involved are shown in Figures 1 and 2. In both figures, there are two categories of function knowledge: function known for 100 per cent of drugs and less than 100 per cent. Figure 1 shows that mean commission rates are high among those patients who did not know the function of all their drugs, irrespective of the number of drugs being taken. With the exception of patients taking six or more drugs, commission rates are higher for patients who did not know the function of all their medications than for those who did. This association reaches statistical significance, (p < .005) only for the 2-3 drug category.

A similar finding for scheduling misconception rates is shown in Figure 2. The scheduling misconception rates are higher for patients without function knowledge on all their drugs as compared to those with 100 per cent knowledge. This association is consistent for each category of number of drugs with the exception of 6 or more. Statistical significance is reached at the .05 level for the 2-3 and 4-5 drug categories.

Omission rates were not associated with per cent of drugs with known function.

(c) Complexity of medication schedule. Another area in which medication regimen might be expected to affect error rates is in the complexity of scheduling medications. Specifically, increased complexity may be associated with increased error. The per cent of drugs scheduled once-a-day was selected as a measure of scheduling complexity, assuming that it is easier to remember the schedule for medications taken only once-a-day as opposed to those scheduled more frequently.

The graphs in Figures 3 and 4 illustrate this point. Mean commission rates are shown in Figure 3 for patients taking one to four drugs by the per cent of drugs scheduled once-a-day. Per cent scheduled once-a-day has been divided into 100 per cent and less than 100 per cent; that is, all drugs are scheduled once-a-day as opposed to some or all drugs being scheduled more than once-a-day. In general, commission errors are lower when all drugs are scheduled once-a-day, although this association is not statistically significant.

Scheduling misconceptions appear in Figure 4, where at each level of number of drugs involved, the error rate is lower when all drugs are scheduled for once-a-day. This association is significant (p < .05) when the number of drugs being taken is 1, 2, or 3. In both Figures 3 and 4, the number of drugs is limited to four, since above that number almost no patients had 100 per cent of drugs scheduled once-a-day.

Doctor-Patient Communication: The distribution of communication scores was reviewed separately for diabetic and congestive heart failure patients, followed by an analysis of the relationship between these scores and the drug error rates. No association was found for the diabetic patients, whereas the pattern for congestive heart failure patients was clear.
Communication scores were grouped in tertiles, and the mean drug error rates computed for each of the three levels of communication. The graphed results are shown in Figure 5 for congestive heart failure patients. For each of the three drug error rates, a pattern of increased error with decreased level of communication is evident. The differences are significant at a p value less than .001 for omissions and p values between .05 and .10 for commissions and scheduling misconceptions.

Discussion

Although a large literature exists on the subject of patient compliance with therapeutic regimens, some conceptual and methodologic constraints have limited the potential impact of the findings. First, the implicit assumptions underlying much of this research have been that compliance and non-compliance are patient related phenomena, and that non-compliant behavior represents the patient's volitional choice. Rarely have researchers and practitioners seriously studied the extent to which apparent non-compliance is merely the lack of congruity between what the patient thinks he is supposed to do and what the physician thinks the patient is doing. Just as it is the patient's responsibility to follow the physician's instructions, it should also be the physician's responsibility to know if and how often the patient takes his drugs. Recognition of this interaction broadens the con-
cept of patient compliance to one of physician-patient concorde-
ance.
A second problem with concordance research has been
the lack of data on physician-patient pairs. Even when the
opportunities for using paired data have existed, the analy-
ses have not exploited the potential. Without paired analy-
ses, insights as to the nature and types of problems surround-
ing medication use are limited.
As a sequel to the previous issues lies the problem of
measurement and quantification. If we accept the concept of
concordance as opposed to compliance and the analysis of
data by doctor-patient pairs, then the specific types of dis-
cordant behaviors become more clearly defined, and meas-
urement of these behaviors in a quantitative fashion can fol-
low.8
Other research has focused on compliance with taking
one particular medication or pharmacologic class of
drugs.14-17 Although research designs of this type eliminate
or avoid many potentially confounding variables, such as the
use of additional medications or the presence of co-morbid
conditions, the results are rarely generalizable or applicable
to the usual adult patient who is plagued with more than one
medical diagnosis and subject to a number of specific and
non-specific therapeutic interventions. The findings and in-
terpretations might be different if the constraints of patient
selection were removed and if the total rather than partial
pattern of medication prescribing and consuming were re-
viewed.
The intent of this paper has been to identify modifiable
features of the medication regimen and doctor-patient com-
munication which were correlated with medication-taking er-
ror. Certain characteristics of the medication regimen bear a
significant relationship to the types and amount of error ob-
served. The number of drugs involved between the doctor-
patient pair is clearly associated with errors of omission and
commission. The more drugs the doctor prescribes, the more
the patient omits; the more drugs the patient takes, the greater
the number about which the physician is uninformed.
This simple information should have important applica-
tions to both medical practice and patient performance. Re-
duce the number of drugs prescribed and consumed to the
minimum number consistent with the therapeutic goals.
The finding that increased frequency of scheduling medi-
cations was associated with an increased rate of scheduling
misconceptions by the patient should hardly be surprising.
However, scheduling non-compliance was low (.034), which
suggests that patients tend to be compliant to the best of
their knowledge, but they are acting on misinformation. Mis-
information can be reduced by reducing the complexity of
medication schedules which the patient is expected to follow
each day.
The low scheduling non-compliance rates are partially a
function of the method of calculation, which is based on the
assumption of availability of correct drugs and correct sched-
uling information. The interpretation of this rate is as fol-
lows: Given that the physician and patient agree on drugs or-
dered and consumed, and that the patient’s scheduling infor-
mation is in accord with the physician, for only a very small
per cent of drugs do patients deny taking their medication as
prescribed. Since other research suggests that patient state-
ments on whether or not drugs are taken as prescribed under-
estimate the true level of non-compliance,18-20 we can dou-
ble or triple the rate obtained to allow for the methodolo-
gic deficiency. A figure three times that noted would produce
an average scheduling non-compliance rate of 10.2 per cent,
which is still lower than the other types of errors observed.
These data suggest that focusing on volitional patient non-
compliance as the target for improving medication taking be-
havior has less potential than review of other aspects of the
patient-provider encounter.
Most compliance studies have focused on low income
patients attending hospital outpatient clinics. The current
study, as well as those of Charney, et al.21 and Neely and
Patrick,22 deals with predominantly middle class patients at-
tending private physicians who provide a regular and contin-
uing source of care. This difference in characteristics of
patients and practice settings may account for the low sched-
uling non-compliance rates. However, average omission and
commission rates of nearly 20 per cent each, and additional
errors of scheduling misconceptions averaging 17 per cent
represents a great deal of misunderstanding and confusion
which has not been alleviated in the private practice setting.
Knowledge of drug function, as opposed to no knowl-
edge or incorrect knowledge, was associated with decreased
error rates of commission and scheduling misconception. Er-
ror rates of both types were reduced when functional knowl-
edge was reasonable for all drugs being taken at each level of
number of drugs involved. Since sociodemographic charac-
teristics of patients did not correlate with per cent of drugs
for which function was known, review of the drug delivery
system to identify critical points where the patient’s learning
could be reinforced may be in order. Opportunities to en-
hance functional knowledge start with the physician at the
time of initial prescribing, can be reinforced by the pharma-
cist at the time the prescription is filled, and should be con-
tinued by the physician or other provider at follow-up visits.
Follow-up visits could be more effective if medication were
physically present in order that both physician and patient
could clearly visualize which drugs were being taken for
which purpose.
No consistent pattern of drug errors in relation to
patient characteristics or measures of disease severity were
found. Other reports have presented variable findings in
these areas, and frequently the results have been negative as
in the current situation.1, 3, 5, 6, 10, 11, 22 It appears unlikely
that any consistent set of demographic descriptors exist
which can differentiate compliant from non-compliant
patients.
Among patients with congestive heart failure, communica-
tion of instructions and information was inversely associat-
ed with drug error rates: the better the communication the
lower the errors. This same relationship had been sought pre-
viously among diabetic patients.8 Although lacking an asso-
ciation between overall communication and drug errors, a
very high correlation was found between specific communi-
cation items and the relevant behaviors. For example, if the
patient knew the correct name of his hypoglycemic medica-
tion, he almost always had the correct medication on hand; if
the name were unknown or in error, he was less likely to have the correct medicine. The same observation pertained to other aspects of therapeutic behavior such as urine testing for glucose or carrying diabetic identification. When patients were informed as to what was expected of them, their behaviors conformed to that expectation more than 85 per cent of the time. The major problem was communication; a third or more of patients were unaware of the expectation in specific instructional areas.

If instructions are to be followed, they must be understood by the patient. This may require written instructions or an additional provider to insure comprehension of the information transmitted.

REFERENCES

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On Conduct In the Sick Room

The physician should enter the sick room with the feeling that he has a serious duty to perform. He must remember that his countenance, and words, and actions are watched by the patient and by his friends in all cases of severe sickness; and, indeed, where, though disease is slight, the apprehension of evil is great.

First of all, his deportment should be calm; he should be sober without solemnity, and civil without formality. He should abstain from all levity. He should, indeed, be cheerful, and, under proper circumstances, he may indulge in vivacity and humor, if he has any. But all this should be done with reference to the actual feeling of the patient and of his friends. He should avoid mannerism; and rather cultivate the feelings which will lead him aright, than be thinking in detail of the particular steps which he should take. The physician should never exact attention to himself. The patient is the central object in the sick room, or should be so. The physician should recognize this, and, if possible, put his patient at ease, so as to facilitate his intercourse with him.

—from "Letters to a Young Physician Just Entering Upon Practice", James Jackson, MD, LLC Phillips Samson & Co. Boston, 1855