A Randomized Controlled Trial of Facilitating Information Giving to Patients with Chronic Medical Conditions
Effects on Outcomes of Care

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BACKGROUND. The purpose of this study was to assess the impact of an intervention to facilitate information giving to patients with chronic medical conditions on outcomes of care.

METHODS. A consecutive sample of 276 eligible patients with chronic medical conditions at a family medicine clinic was randomized to control and experimental interventions. A total of 205 completed the study. Experimental group patients received copies of their medical record progress notes, and they completed question lists for physician review, while control group patients received health education sheets and completed suggestion lists for improving clinic care. Self-reported physical functioning, global health, and patient satisfaction and adherence were measured at enrollment and after the interventions. Visit lengths and patient response to medical record sharing after the interventions were also measured.

RESULTS. After the intervention, experimental group patients reported 3.7% better overall physical functioning than did control patients (mean = 83.6, standard deviation [SD] = 17.6 vs mean = 79.9, SD = 25.3; P = .005 after adjusting for covariates). The experimental group was more satisfied with their physician's care (mean = 31.4, SD = 4.6 vs mean = 31.3, SD = 5.2; P = .045 after adjusting for covariates). They were also more interested in seeing their medical records than were control patients (mean = 12.0, SD = 2.8 vs mean = 11.2, SD = 2.8; P = .002 after adjusting for covariates). Experimental group patients also reported an 8.3% improvement in overall health status (postintervention mean = 3.0, SD = 1.1) compared with their pre-intervention health status (mean = 2.8, SD = 1.0; P =.001). Visit lengths for patients in the experimental group did not differ from those of the control group.

CONCLUSIONS. A simple patient-centered intervention to facilitate information giving in the primary health care of patients with chronic medical conditions can improve self-reported health, physical functioning, and satisfaction with care.

KEY WORDS. Communication; physician-patient relations; patient participation; medical records. *(J Fam Pract 1999; 48:356-363)*

Health care delivery in the United States is undergoing dramatic changes in response to cost-containment efforts. Many of these changes emphasize efficiency and give insufficient attention to the physician-patient relationship.[1,2] There is growing evidence to suggest, however, that medical outcomes may be improved substantially by changes in the process of care itself, including the physician-patient interaction.[3-5]

The exchange of information is central to an effective physician-patient encounter. Most patients want more extensive, detailed medical information than they routinely receive.[6,7,8] Empiric evidence suggests that information giving is associated with many desirable outcomes, including reduced postoperative pain and hospital stays,[9,10,11] improved functional[12,13] and physiologic outcomes,[12,14,15] and patient satisfaction with[16-18,19] and adherence to medical care.[17,20-23] Despite these broad findings, studies of physician-patient interactions confirm that physicians spend relatively little time giving information to the patient,[24,25] and they underestimate patients' needs and desires for information and discussion about the patients' medical problems.[26]

Several systemic and sociocultural aspects of health care delivery in the United States hinder patient-centered approaches to health care. First, the agenda of the physician-patient encounter is typically controlled by physicians;[4,27] most physicians are not specifically

trained to elicit the patient's point of view,[28] and physicians may discourage questions with behavioral cues.[20] Second, frequent use of medical jargon by physicians serves as a barrier to information exchange.[29-31] Third, the health care system has traditionally prohibited patient access to one of the richest sources of personal medical information: the medical record.[32,33] Finally, patients are reluctant to challenge physicians and spend little time asking questions.[34,35] These inhibiting influences may pose special risks to patients with chronic medical conditions who especially need informational tools to effectively manage their conditions.

A number of intervention studies have addressed some of these barriers and have resulted in improved outcomes of care, including health and functioning.[12,13,36-40] But some interventions[12,13,38,39] required sufficient time and effort to make implementation under cost-containment difficult. In studies of simpler interventions,[36,37,40] health outcomes were not addressed.

A simple patient-centered intervention was designed to be incorporated in the primary health care of patients with a wide range of chronic medical conditions. This included strategies to overcome barriers to patient access to information, including patient inhibitions about asking questions, deficits in information provided by physicians, and restrictions on patients' access to medical records. A randomized controlled trial was conducted to measure the effect of the experimental intervention on self-reported health and functional status and on patient satisfaction with and adherence to medical care.

METHODS

SETTING AND PATIENT SAMPLE
The study site was a university hospital family medicine continuity clinic. Patients aged 19 to 75 years were eligible if they had been seen twice at the clinic in the previous 6 months or once in the previous month for a chronic medical condition. A "chronic medical condition" was defined as one that required ongoing medical attention, persisted or was likely to persist for a long time, and either resulted in limitations in everyday functioning (eg, arthritis) or had the potential of poor medical outcome if untreated (eg, hypertension or diabetes). Patient exclusion criteria included: (1) inability to read, write, or speak English; (2) pregnancy; (3) diagnoses of alcohol or substance abuse, or major psychiatric disorder; or (4) active evaluation or treatment for cancer.

STUDY DESIGN
After randomization using a card-shuffling technique, self-administered baseline questionnaires were completed in the clinic waiting room. The experimental and control interventions were then administered by research assistants. All 35 clinic physicians (13 faculty and fellows, 22 residents) saw patients from both groups and were not apprised of the study design or

purpose. At the next regularly scheduled clinic visit (the second after study enrollment) the experimental and control interventions were repeated. Two weeks later participants were mailed a follow-up questionnaire to be returned by mail.

INTERVENTIONS
The experimental intervention consisted of 2 components administered before each physician-patient encounter. The first was the patient question list. Patients were asked to record the 2 main questions they would like answered during that visit on a "Patient Note," which was then attached to the front of the patient's medical chart for the physician's review. The second component was medical record sharing. Patients were given a copy of their physician's previous progress note (routinely dictated and rarely exceeding 1 page) and a 14-page "Glossary of Common Medical Terms and Abbreviations" as an aid in interpretation.

To ensure the study's external validity,[41] the control intervention was designed to mirror the experimental intervention in attention given to the patient. The control intervention also consisted of 2 components administered before each physician-patient encounter. The first of these was the patient suggestion list. Patients were asked to anonymously write down 2 suggestions for improving clinic services on a "Patient Suggestion Form," which was not seen by the patient's physician. The second component was health education. Patients were given a 1-page "Health Information Sheet" containing standard health educational information about diet and nutrition.

MEASURES
Outcome measures (including general health, physical functional status, patient satisfaction with care, and patient adherence) were collected both at baseline and postintervention; visit lengths were measured postintervention only. Internal consistency reliability, or the degree to which all items in a scale consistently measure the same underlying phenomenon, was measured in the final study sample of 205 using Cronbach's alpha[42] (and is listed for each instrument in Table 3). Cronbach's alpha values can range from 0 to 1.0, with 1.0 indicating perfect reliability; values >0.50 are considered adequate for group comparisons.[43]

Self-reported health was measured by a global health rating item,[44,45,46] and by the number of disability days in the previous month. Physical functional status was measured using the 10-item Physical Functioning scale (PF-10) from the Short Form-36 Health Survey (SF-36),[46] and by a RAND Health Insurance Experiment 4-item mobility scale.[47-49] These items were combined into an aggregate physical functional status (PFS) scale. All functional status scales were standardized to a 0 to 100 scale, with higher scores indicating better functioning.

Patient satisfaction with their physician's interper-

sonal care (such as listening carefully) was measured using 7 items from the American Board of Internal Medicine.[50] General adherence to recommended medical care was measured with the 5-item General Adherence Scale from the Medical Outcomes Study[51,52]; this was reduced to a single item at baseline.

Patients' attitudes toward seeing their medical records were measured by items used in previous studies of medical-record sharing.[12,13] Factor analysis, with principal components extraction and varimax rotation, indicated 2 underlying constructs: the interest index (the patient's curiosity about their medical record) and the apprehensiveness index (the patient's fearfulness about finding something unknown in the chart). The Health Information Propensity Scale consisted of 6 items developed for our study to measure subjects' propensity for pursuing and obtaining medical information on their own. Experimental group patients also were asked about their experiences with seeing their medical records. Finally, after each intervention was administered, the duration of the physician-patient encounter was approximated by measuring the total time the patient spent in the examination room.

STATISTICAL ANALYSIS

The experimental and control groups were compared at baseline, using one-way analysis of variance for continuous variables and chi-square tests for categorical variables. Analysis of covariance was used to compare postintervention means between experimental and control groups, using the baseline value as the covariate. Where interaction between covariate and treatment group was statistically significant, regression coefficients were fit for each group. In addition, within each group, paired t tests were used to compare baseline and postintervention self-reported global health, as well as to compare baseline and postintervention health information propensity. Independent t tests with pooled variance were used to compare mean experimental and control visit lengths. The relationships of attitudinal variables to postintervention physical functional status were examined using Pearson's product-moment correlations. Ordinary least squares regression procedure was used to predict the PFS after the intervention. For all statistical tests, a value of $P < .05$ was considered statistically significant.

RESULTS

Two hundred and seventy-six consecutive patients were determined eligible by chart review and face-to-face assessment; 265 agreed to participate in the study (4% refusal rate) and were randomly assigned to the control (n = 131) or experimental (n = 134) groups. A total of 205 (103 in the experimental group, 102 in the control group; 77%) completed the study. Fifty-six patients did not return during the study period for a second regularly scheduled clinic visit (29 experimental group patients,

27 control group patients); 2 patients in each group returned for a second visit but did not return the follow-up questionnaire. The mean number of days between clinic visits was 51.2 (SD = 39.4).

SAMPLE CHARACTERISTICS

Sociodemographic characteristics of the final sample of 205 appear in Table 1; there were no statistically significant differences between groups. Mean baseline physical functioning measured by the PF-10 for the entire sample was 77.0 (SD = 25.5), as compared with 84.2 reported for the PF-10 in the general US population.[53] Sixty-nine percent reported limitations in vigorous physical activities, such as lifting heavy objects. Frequencies of diagnostic types of chronic medical conditions by group appear in Table 2. The most common diagnosis was hypertension, but this was the sole chronic condition in only 19% of the sample.

Table 3 presents baseline measures of functional status, health, attitudes, and adherence by intervention group. Only 1 statistically significant difference was observed: the experimental group perceived their global health to be worse ($P = .04$).

ANALYSIS OF BASELINE DATA FROM PATIENTS LOST TO FOLLOW-UP

The 205 patients who completed the study ("completers") were compared with the 60 patients who failed to complete the study ("noncompleters"). Patients assigned to either experimental or control groups were equally likely to be lost to follow-up ($\chi^2 = 0.002$; $P = .96$). There were no statistically significant differences between completers and noncompleters in sociodemo-

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TABLE 1

Sociodemographic Characteristics of Study Sample, by Group

	Experimental Group (n=103)	Control Group (n=102)
Age, mean years (SD)	54.3 (1.4)	52.8 (1.6)
Women, %	59.2	56.9
Education, % with less than college	58.8	60.2
Ethnicity, %		
African American	24.3	26.5
Hispanic	6.8	7.8
White	57.3	49.0
Other	11.7	16.7

Note: All differences statistically nonsignificant with $P > .40$ for each test. SD denotes standard deviation.

TABLE 2

Chronic Medical Condition Diagnoses of Study Sample, by Group

Condition	Experimental Group (n=103)	Control Group (n=102)
Hypertension	66	64
Diabetes mellitus	21	16
Arthritis	18	22
Chronic pain (eg, low back pain)	20	19
Heart disease (eg, angina, heart failure)	17	10
Chronic lung disease (eg, COPD, asthma)	9	9
Stroke	3	3
Peptic ulcer disease	3	3
Collagen-vascular disease	1	3
Chronic renal failure	1	2
Seizure disorder	1	1
Parkinson's disease	1	0

Note: Numbers do not add up to total number of study subjects in group because many patients had multiple diagnoses.
COPD denotes chronic obstructive pulmonary disease.

graphic characteristics, functional status, patient satisfaction, and attitudes toward medical records, with the exception of noncompleters being older (mean age = 53.5 years vs 46.8 years; P = .002) and more likely to be female (χ^2 = 5.38; P = .02).

INTERVENTION EFFECTS

Functional Status and Health Small but statistically significant differences favoring the experimental group over the control group were observed after the intervention in aggregate PFS, the PF-10, and mobility scales (Table 3). Participants' assessment of their global health is also shown in this table. Since the means for the experimental group were lower than for the control group both before and after intervention, paired t tests were used to measure improvement. The improvement in the means for global health was statistically significant for experimental group patients (from 2.78 to 3.02; paired t = 3.30; P = .001), but not for control patients (from 3.07 to 3.13; paired t = 0.86; P = .39).

Correlation coefficients for attitudinal variables, both pre- and postintervention, (ie, medical records attitudes, health information propensity, adherence, and patient satisfaction, with postintervention PFS) were all less than 0.05 and statistically nonsignificant.

Attitudinal and Behavioral Measures Experimental group patients reported more interest in and less apprehension about seeing their medical records than did the control group after the intervention, which remained statistically significant for interest in medical records. Patients in the experimental group reported more satisfaction with their medical care after the intervention than did control group patients (P = .045). Within the experimental group, the increase in propensity for health-information seeking after the intervention was statistically significant (paired t = 2.95; P = .004), but not for the control group. Finally, there was no statistically significant difference between groups after the intervention in general adherence to medical care.

Visit Length The experimental intervention did not significantly increase the length of the experimental group's visits after the interventions (first postintervention visit mean = 29.9 minutes; second visit = 31.4 minutes) as compared with the control group's visits (first postintervention visit mean = 40.5 minutes; second visit = 27.3 minutes). Because visit lengths were approximated by the total time the patient spent in the examination room, these times were necessarily longer than actual physician-patient encounters.

Administering the entire experimental intervention before each physician-patient encounter took no more than 20 seconds per patient; study patients asked few questions of the staff members who administered the interventions with regard to the materials.

Relative to Other Health Status Determinants Treatment group, PFS at baseline, age, adherence to medical treatment, sex, education, and ethnicity, were entered into a multiple regression equation with postintervention physical functioning as the dependent variable (Table 4). Better physical functioning at baseline, younger age, and experimental group status were most strongly predictive of improved postintervention functional status (P <.01).

EXPERIMENTAL GROUP RESPONSE TO MEDICAL-RECORD SHARING

Eighty-three percent of experimental group patients reported that the information learned from their medical records made their visits with the doctor "go smoother," and 80% felt "better prepared" for their visit. Although 16% reported finding incorrect or inaccurate information, 89% of the experimental group reported being "not at all" upset by the information in their records.

DISCUSSION

This randomized controlled trial demonstrates that a simple patient-centered intervention to facilitate information giving in the primary health care of patients with chronic medical conditions is feasible and can improve physical functioning and patient satisfaction with care. The experimental intervention performed better in predicting functional status than other demonstrated predictors of health outcomes, such as socioeconomic status (as measured by educational level), ethnicity, and sex.[54-58] The experimental intervention also resulted in improvements in self-reported health and increased

interest in health-related information, including the medical record. This intervention differed from previous attempts to involve patients in the health care process in that it required little time and effort to implement[12,13,38,39] and addressed multiple barriers to information giving.[36-38]

The magnitude of improvement in patient outcomes here was small—approximately 4% for self-reported functioning and 8% in overall health—when compared with effect sizes in trials of disease-specific drugs or procedures in which discrete physiologic outcomes (eg, blood pressure) are measured. In any individual patient, such small changes may not be clinically tangible. Demonstrating large improvements in broad outcomes, such as overall functioning and health, in a population of patients with diverse chronic illnesses is difficult at best. Trials of more intensive interventions on processes of care of patients with chronic conditions have also yielded either small effect sizes in physical functioning or have simply prevented functional decline.[13,59] However, maintenance of or even slight improvement in functioning in a population that would otherwise decline may have substantial societal significance, especially when the effort required is small.

Several considerations support the notion that our findings are conservative. The study duration was short, and despite their chronic diseases, the study population was generally highly functional. It is possible that in a less functional

patient population with interventions carried out over a longer term, larger and more clinically significant improvements in health and functioning may be demon-

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TABLE 3

Baseline and Postintervention Health-Related and Attitudinal Measures in the Randomized Controlled Trial of a Patient-Centered Intervention

Instrument	Baseline*		Postintervention†	
	Experimental n=103	Control n=102	Experimental n=103	Control n=102
Health-Related				
Physical Functional Status (Range: 0-100, 100=highest functioning; Cronbach's alpha=0.92)	82.6 (19.2)	80.8 (22.5)	83.6 (17.6)	79.9 (25.3)§
Physical Functioning-10 (Range: 0-100; Cronbach's alpha=0.93)	78.3 (23.3)	75.7 (27.6)	79.1 (21.7)	75.3(28.4)‡
Mobility (Range: 0-100); Cronbach's alpha=0.77)	93.5 (14.6)	93.4 (14.4)	94.7 (12.0)	91.3 (17.1)‖
Global Health Status (Range: 1-5, 5=best health)	2.8 (1.0)	3.1 (1.0)	3.0 (1.1)	3.1 (1.0)
Number of Disability Days (Range: 0-31 days)	3.0 (7.0)	2.3 (5.4)	2.6 (6.2)	2.3 (5.5)
Attitudinal				
Medical Records Attitudes				
Interest Index (Range: 3-15, 15=most interest; Cronbach's alpha=0.58)	11.6 (2.8)	11.7 (2.8)	12.0 (2.8)	11.2 (2.8)§
Apprehensiveness Index (Range: 2-10, 10=most apprehensive; Cronbach's alpha=0.62)	3.6 (1.3)	3.7 (1.7)	3.3 (1.4)	3.6 (1.7)
Patient Satisfaction (Range: 7-35, 35=most satisfaction; Cronbach's alpha=0.93)	31.0 (4.7)	31.4 (5.0)	31.4 (4.6)	31.3 (5.2)‡
Health Information Propensity (Range: 6-24, 24=most propensity; Cronbach's alpha=0.64)	14.9 (3.4)	14.4 (3.7)	15.6 (3.9)	14.8 (4.1)
Adherence (Baseline range: 1-6, 6=highest adherence; Postintervention range: 5-30, 30=highest; Cronbach's alpha=0.76)	5.0 (1.1)	5.1 (1.0)	24.0 (4.9)	23.8 (4.8)

Note: Data are unadjusted mean scores with standard deviations in parentheses.
*P values are reported for baseline differences in means between experimental and control groups.
†P values are reported for differences in postintervention means between experimental and control groups adjusted for baseline scores, using analysis of covariance.
‡P <.05
§P <.01
‖P <.001

TABLE 4

Predictors of End-of-Study Physical Functional Status*

Variable	Meaning of High Score	Regression Estimates	
		Coefficient (b)	95% Confidence Interval
Physical functional status at baseline	Higher functioning	0.85*	(0.78 to 0.92)
Age	Older	-0.11*	(-0.20 to -0.02)
Intervention group	Experimental group patients	2.77†	(0.22 to 5.33)
Adherence	Greater adherence	-0.93	(-2.18 to 0.32)
Sex	Female	1.63	(-1.10 to 4.36)
Education	Higher education	0.77	(-0.22 to 1.76)
Ethnicity	Nonwhite	0.45	(-2.21 to 3.10)
Constant		13.28	(1.91 to 24.65)

Note: Adjusted R^2 = 0.81; $F_{(7,193)}$ = 125.72; P <.001. Ordinary least squares regression with simultaneous entry of all independent variables
*P <.01.
†P = .03

strated. In addition, because the same physicians cared for patients in both groups, "contamination," or physician-learning, may have contributed to reducing the magnitude of group differences.

The mechanism by which the experimental intervention may have influenced health outcomes is not clear. Neither greater adherence to medical treatment nor interest in health information, including the medical record, appeared to be the basis for the experimental intervention's effects. The explanation may lie in other mediating factors associated with improved health,[60] such as sense of control,[61-65] self-efficacy,[66-68] and informational support as social support.[69-72]

Despite historical physician concerns about medical-record sharing with patients,[73] this aspect of the intervention appeared to be desirable to experimental group patients, as suggested by increased interest in their medical records and in patient satisfaction. Furthermore, medical-record sharing did not seem to be disruptive to the physician-patient interaction. A large majority of experimental group patients reported that their office visits went more smoothly as a result, and there was no significant increase in visit length. These findings suggest that medical records can be safely and beneficially shared with patients with chronic medical conditions.

The results of this study must be interpreted with its limitations in mind. The nature of the intervention prevented the complete blinding of either participating physicians or research assistants to group assignment. Another limitation was that the study was conducted in a universi-ty-based primary care clinic; the generalizability of the results may be limited with regard to other health care delivery settings.

Future research should include measures of possible mediating variables to elucidate the intervention's mechanism of action. In addition, documentation of physician satisfaction with such interventions is needed to assess the relationship of physician attitudes and behavior to the intervention's effect on patients.

The aging of the US population[74] portends a shift from the acute care model to one aimed at maintaining or improving the health and functioning of an increasing number of patients with chronic medical conditions. This shift in focus necessitates increasing emphasis on psychosocial aspects of health care. Simultaneously, the continuing trend toward cost containment mandates efficiency. Therefore, even small improvements in the health of patients with chronic conditions that result from simple changes in the health care delivery process, as observed here, are noteworthy because of their potential population-wide impact. Consideration should be given to incorporating the essential features of this intervention—sharing medical records and formally soliciting patients' questions—into the primary care of patients with chronic medical conditions.

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