

Pharmaceutical Care and Health Care Utilization in an HMO

CONTEXT. The belief that expanding the role of pharmacists in patient care could improve the safety and efficacy of drug therapy is growing. Specifically, pharmaceutical care programs through which pharmacists provide direct and ongoing counseling to patients have been introduced. Whether such programs reduce medication-related problems or health care utilization is unknown.

OBJECTIVE. To assess whether a pharmaceutical care program decreases health care utilization, medication use, or charges.

DESIGN. Nonrandomized, controlled trial.

SETTING. Staff clinic and freestanding contract pharmacies affiliated with a large HMO in greater Minneapolis–St. Paul (6 intervention pharmacies, 143 control pharmacies).

STUDY POPULATION. Adult HMO enrollees ($n = 921$) with heart or lung disease who used one of the selected pharmacies.

INTERVENTION. Patients at intervention pharmacies were invited to participate in the pharmaceutical care program. The protocol-based program consisted of scheduled meetings between trained pharmacists and patients to assess drug therapy, plan goals, and intervene through counseling and/or consultation with other health professionals.

OUTCOME MEASURES. Change in number of outpatient clinic visits, unique medications dispensed, and total charges over 1 year of follow-up.

RESULTS. In an intention-to-treat analysis (after adjustment for gender, age, Charlson Comorbidity Index, disease category, and the baseline value of the utilization measure), the number of unique medications for patients in the pharmaceutical care group increased more than in the usual care group (1.0 vs. 0.4 unique medications; $P = 0.03$). There was no difference between the two groups in the change in total number of clinic visits or total costs. In secondary adherence analyses, participants were more likely than the usual care group to increase the number of clinic visits (1.2 vs. -0.9 ; $P = < 0.01$) and number of unique medications (1.0 vs. 0.2; $P = 0.02$).

CONCLUSION. Pharmaceutical care for patients with chronic health conditions appears to be associated with a modest increase rather than a decrease in health care utilization.

Pharmaceutical care programs, in which pharmacists work directly with patients to assess, monitor, and modify their pharmaceutical regimens, are an increas-

ORIGINAL ARTICLE

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Eff Clin Pract. 2002;5:49-57.

Edited by Brenda E. Sirovich,
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See related editorial on
pages 91-94.

ingly common health care model. In fact, the American College of Physicians–American Society of Internal Medicine recently announced support for an expanded role for pharmacists, including direct patient education through pharmaceutical care programs.¹ In these programs, pharmacists address such issues as drug side effects, drug–drug interactions, incorrect administration, and potentially inappropriate medications during scheduled patient visits. Pharmacists may also initiate consultations with other health professionals.^{2–5} These programs aim to reduce adverse events associated with inappropriate prescription and/or administration of medical therapies. Pharmaceutical care may be particularly beneficial for patients with chronic diseases who require ongoing therapeutic monitoring.

While such interventions have the potential to be cost-effective (i.e., benefiting patients while reducing health care utilization and costs associated with medication-related problems),² research findings to date on the effects of pharmaceutical care conflict. Some studies report that pharmaceutical care dramatically decreases health care utilization, some find no effect, and others report a decrease only in selected utilization measures.^{6–14} One reason for these disparate findings may be the difference in what constitutes pharmaceutical care. Despite extensive documentation of the components of pharmaceutical care in the literature, a recent review concluded that its “practice is neither uniform nor universal.”¹⁵

In addition, until recently much of the research on the outcomes of pharmaceutical care was methodologically flawed—in a review of economic studies on pharmaceutical care published through 1997, Plumridge and Wojnar-Horton¹⁵ did not find a single research project that met their stringent criteria for study design and analytic method. Since this review, the results of a large randomized trial conducted at Kaiser Permanente in California were published. This study found that, among 6000 patients on multiple medications, pharmaceutical care had no effect on outpatient encounters or drug utilization, although it did result in a small (2% to 3%) relative decrease in the risk for hospitalization.¹⁶

We sought to test the hypothesis that pharmaceutical care reduces utilization, medication use, and health care charges of patients with heart and lung disease in a controlled trial conducted at HealthPartners, an HMO in Minnesota.

Methods

Overview

Figure 1 shows the overall design and patient recruitment for the Pharmaceutical Care Project at HealthPartners in the Twin Cities metropolitan area

(which had about 750,000 enrollees at the time of the study, 1997 to 1998). We designed a nonrandomized controlled trial and included both pharmacies located in HMO-owned clinics and free-standing pharmacies. Within each pharmacy, on the basis of recent medication use, we randomly selected patients with heart or lung disease. To evaluate the effect of pharmacy care, we compared change in health care utilization (clinic visits, medications, and total costs) in control vs. intervention clinics before and after implementation of the pharmacy care.

Intervention

Pharmaceutical care is a protocol-based program originally developed by the University of Minnesota. It includes ongoing scheduled meetings between patients and pharmacists at which drug therapy is reviewed and assessed and the goals of drug therapy are planned.² For each patient, the protocol began with a 20- to 30-minute patient interview. At this initial interview, the patient was asked to bring all medications (both prescription and over-the-counter) to the pharmaceutical care sessions, which took place in a room or area other than the pharmacy window. The pharmaceutical care intervention also included communication with the patient’s physician about drug therapy problems that had been identified by the pharmacist. Follow-up meetings with patients were supposed to occur with each subsequent prescription filled for the patient at that pharmacy. However, the protocol did not define specific patient follow-up schedules.

Participating pharmacists were all trained in the Encara Practice System. This system was developed by the Peters’ Institute of Pharmaceutical Care at the University of Minnesota and has been used by the Minnesota Pharmaceutical Care Project.^{2, 5} Encara, a for-profit organization, provided a 1-day training program specially designed for participating staff pharmacists to cover patient interview techniques and use of the company’s data collection and assessment tool for medication management (MedAssess software).

Pharmacy Selection

Six pharmacies participated in the intervention—three were located within staff clinics and three were free-standing pharmacies serving patients in contract clinics. The three intervention pharmacies were selected to include different population sizes—each served 7000 to 15,000 patients. The three freestanding pharmacies volunteered to participate in the intervention and had pharmacists who were already trained and certified in the pharmaceutical care system used in the study.

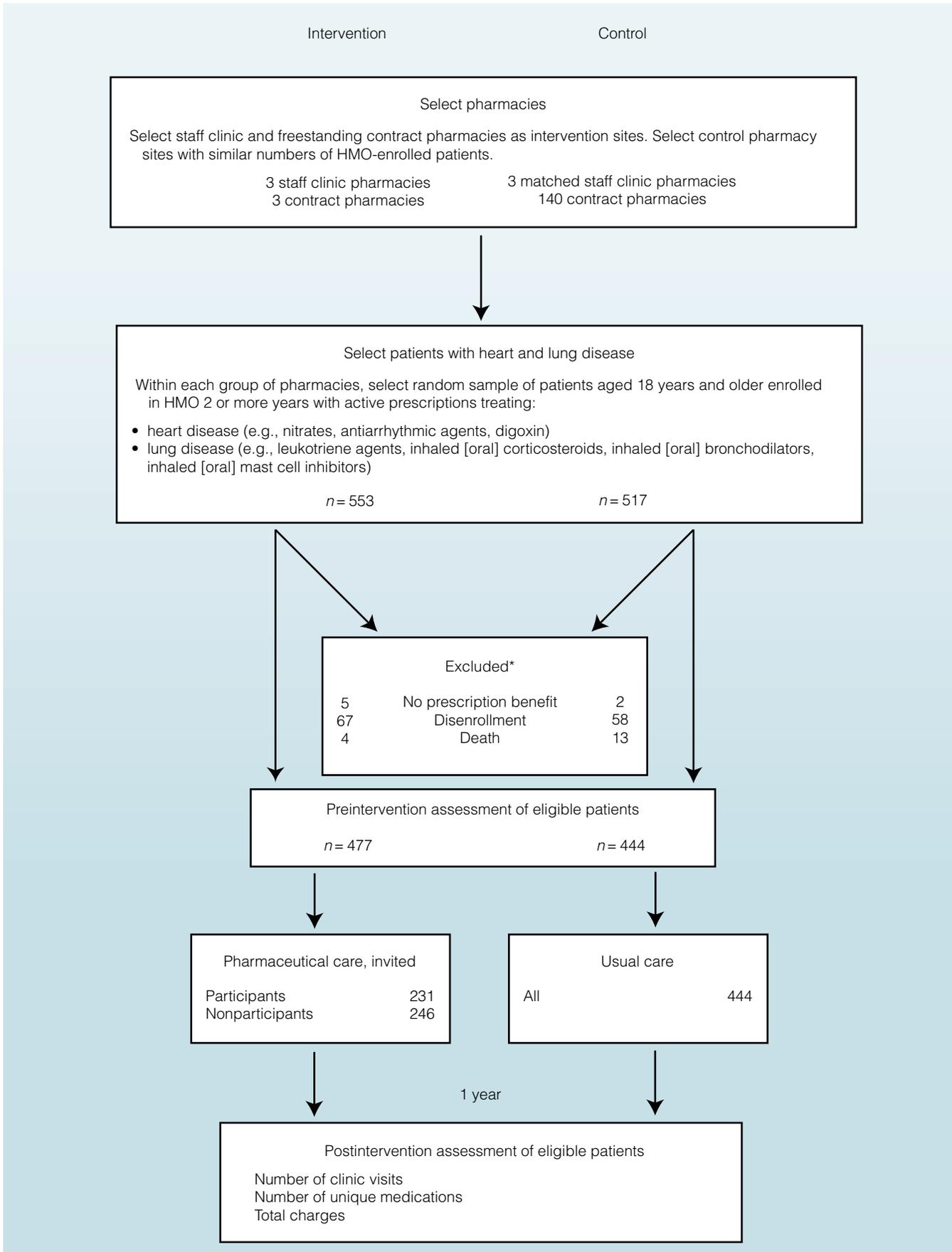


FIGURE 1. Study design. Patients in the contract pharmacy control group were randomly selected from all patients using nonintervention contract pharmacies. *Patients were excluded if they met any criteria noted before completion of the study.

We selected control pharmacies as follows. For staff clinic pharmacies, we chose three control pharmacies similar in terms of enrollment size and age composition to the three staff clinic intervention pharmacies. To select contract pharmacies, we randomly chose patients from among those using nonintervention contract pharmacies. The 140 contract pharmacies used by these patients make up the control contract pharmacy sample.

Patient Selection

The intervention group consisted of a random sample of HMO enrollees aged 18 years or older who were patients at one of the six intervention pharmacies and who had heart or lung disease ($n = 477$). Patients were eligible for the heart disease group if they had filled prescriptions for nitrates, antiarrhythmic agents, or digoxin during the 6 months before the study began. Patients were eligible for the lung disease group if they had filled prescriptions for leukotriene agents, oral inhaled corticosteroids, oral inhaled bronchodilators, or oral inhaled mast cell stabilizers during the same period. Control group patients met the same criteria and were randomly selected from among patients at control pharmacies ($n = 444$).

People who died, disenrolled, or discontinued their pharmacy benefit before the end of the study period were excluded. One hundred forty six (14%) of the 1070 people in the original study sample were excluded from the analyses due to disenrollment, death, or discontinuation of pharmacy benefits before the end of their 2-year period. Persons in the inclusion and exclusion groups were generally similar; those in the control sample were slightly more likely to be excluded because of death (2.5% vs. 0.7%; $P < 0.05$).

Outcome Measures

The three primary outcome measures were the number of outpatient clinic visits (professional and urgent care), number of unique medications dispensed (as measured by distinct generic code numbers), and total charges (inpatient, outpatient, and pharmacy charges). We calculated the change in each measure between the baseline and postintervention years. We also examined the total number of medications, the proportion of patients with at least one hospital admission, and the mean number of hospital days. Data on clinic visits and charges were extracted from the medical claims database at HealthPartners; data on filled prescriptions and medications were extracted from the health plan's pharmacy claims database. Because the enrollees in our study had a pharmacy benefit, data were available on all filled prescriptions paid by the health plan. The only exceptions

were inexpensive medications for which the drug cost was lower than the co-pay.

Two years of utilization and charge data were extracted—one at baseline and one at follow-up. For participants, the baseline period was defined as 1 year before their initial appointment for pharmaceutical care and the follow-up period was 1 year after. For refusers and controls, the baseline and follow-up years were defined around hypothetical appointment dates that were within similar periods of the actual pharmaceutical care appointments.

Covariates

We included gender, age, chronic disease (heart vs. lung), and the Charlson Comorbidity Index because they are covariates known to impact health care utilization and charges. The Charlson Comorbidity Index is constructed from inpatient and outpatient diagnostic (ICD-9) codes in the HMO electronic database (measured during the baseline year). This index has been shown to predict mortality, morbidity, and resource use.^{17–20} For each regression equation, the specific outcome variable from the baseline year was included as a covariate to control for possible differences at baseline.

Analysis

We conducted bivariate analyses to compare the baseline characteristics of the intervention and control groups. In these bivariate analyses, we used chi-square tests for dichotomous variables and t tests for continuous variables. We used multiple linear regression analyses to test the substitution hypothesis—that pharmaceutical care is associated with reduced outpatient clinic visits, medications, and total medical charges. We performed an intention-to-treat analysis to compare the change in each outcome variable between baseline and postintervention years in the pharmaceutical care and control groups. Because intention-to-treat analysis dilutes any potential effect from the intervention, we also conducted an adherence analysis. Differences were considered to be statistically significant ($P \leq 0.05$).

Results

Baseline Characteristics

As **Table 1** shows, about half of each sample was female, their mean age was 57 to 58 years, and about 40% were in the heart disease group. Patients averaged 14 clinic visits a year and 9 unique medications and had \$10,000 to \$11,000 in annual health care charges at baseline. The intervention and control groups did not differ significantly in any of these baseline variables.

TABLE 1
Baseline Characteristics

VARIABLES	INTERVENTION (n = 477)	CONTROL (n = 444)
Background		
Female	50%	51%
Heart disease	43%	40%
Age (mean), yr	57	58
Charlson Comorbidity Index (mean)	1.2	1.3
Outcome		
Number of clinic visits (mean)	14.4	14.9
Number of unique medications (mean)	9.1	9.4
Total charges (mean)	\$9600	\$11,000

* $P > 0.05$ for all variables.

Pharmaceutical Care

Of the 477 patients invited to participate in the intervention group, 231 actually participated in pharmaceutical care (participation rate 48%). Table 2 gives an overview of pharmaceutical care activities based on information tracked by the participating pharmacists in the MedAssess database. The pharmacists identified at least one drug therapy problem for 69% of the patients. For one third of the patients, they observed an adverse reaction to at least one medication; for about one fourth, they noted that additional medical therapy was needed. Many patients were found to be on doses that were too high (12%) or too low (34%). Pharmacists provided some form of intervention for a large majority of patients (87%). For 70% of participating patients, the pharmacist contacted a physician, often about a potential medication change.²¹

Intention-To-Treat Analysis

Figure 2 shows the crude change in the three primary outcome variables (clinic visits, unique medications, and charges) in the pharmaceutical and usual care (control) groups, and Figure 3 presents the corresponding results adjusted for gender, age, Charlson Comorbidity Index, disease category, and baseline value of the utilization measure. The only utilization measure that showed a significant difference between the pharmaceutical care and usual care groups, in both crude and adjusted analyses, was the number of unique medications. After adjustment, the average increase in the number of unique med-

ications was 0.6 higher for the pharmaceutical care group than for the usual care group ($P = 0.03$). Additional analyses showed no difference between pharmaceutical care and control groups in total number of prescriptions dispensed, proportion with one or more hospital admissions, and mean number of hospital days (data not shown).

Adherence Analysis

Table 3 presents findings from the adherence analyses, which compared the subset of patients who participated in the pharmaceutical care program with the control group. Contrary to our predicted substitution hypothesis, pharmaceutical care patients had a statistically significant increase in numbers of clinic visits and unique medications compared with patients in the control group. There was no significant difference in total charges.

Discussion

Our study does not provide evidence that pharmaceutical care decreases health care utilization or charges in

TABLE 2
Reported Pharmacists' Activities for Pharmaceutical Care Participants (n = 231)*

PHARMACIST ACTIVITY	PERCENTAGE OF PATIENTS
Identified drug therapy problem	
Any problem identified	69%
Unnecessary drug therapy	8%
Need additional drug therapy	25%
Wrong drug	12%
Dose too low	34%
Dose too high	12%
Adverse drug reaction	34%
Provided one or more intervention for patient	
Any intervention provided	87%
Contacted physician	70%
Corrected problem	42%
Followed up with patient	39%
Consulted literature, specialist, or manufacturer	8%
Gave information to patient	72%

*Percentages do not add up to 100% because participants could have several or no drug therapy problems and/or pharmaceutical care interventions.

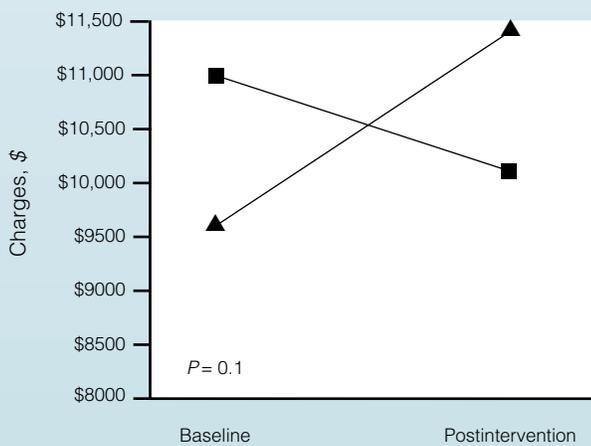
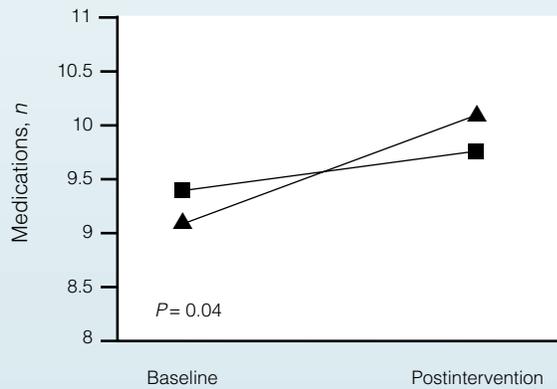
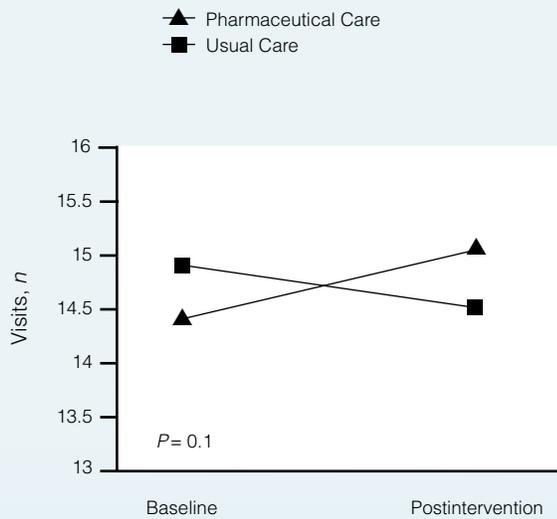


FIGURE 2. Crude change in utilization for the pharmaceutical care and usual care groups: intention-to-treat analysis.

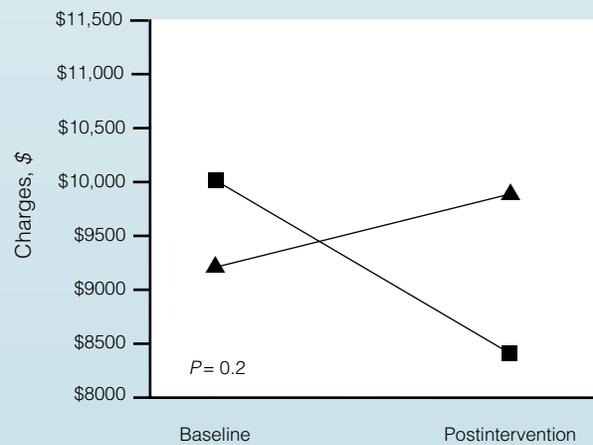
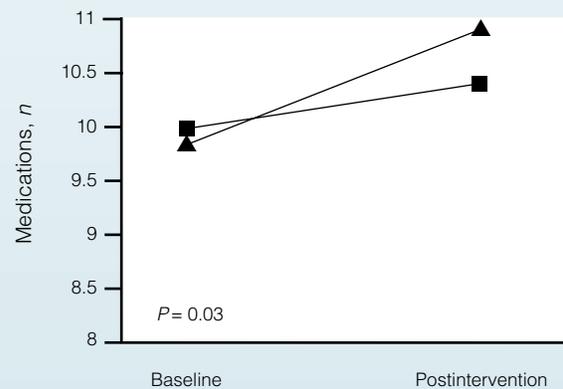
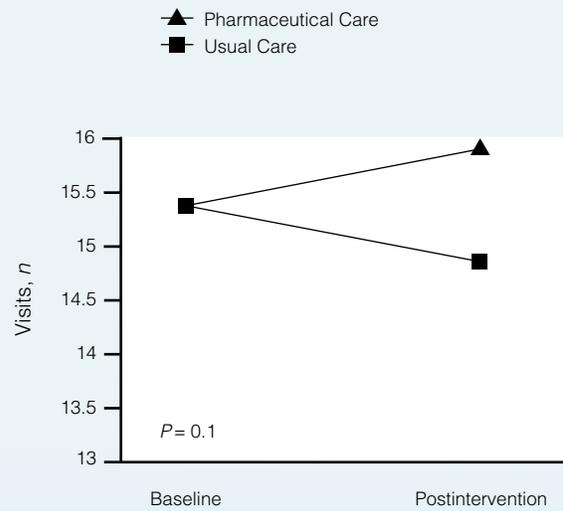


FIGURE 3. Adjusted change in utilization for the pharmaceutical care and usual care groups: intention-to-treat analysis. Data adjusted for gender, age, chronic condition group (heart vs. lung), comorbid conditions, and the outcome variable at baseline.

TABLE 3

Change in Utilization among Participants in Pharmaceutical Care vs. Usual Care: Adherence Analysis

VARIABLE	PHARMACEUTICAL CARE PARTICIPANTS (n = 231)			USUAL CARE (n = 444)			P VALUE*
	BASELINE	CRUDE CHANGE	ADJUSTED CHANGE	BASELINE	CRUDE CHANGE	ADJUSTED CHANGE	
Number of clinic visits	16	1.5	1.2	14.9	-0.4	-0.9	<0.01
Number of unique medications	10	1.1	1.0	9.4	0.3	0.2	0.02
Total charges	\$9500	\$1100	-\$900	\$11,000	-\$900	-\$2000	NS

* P value for the difference between the adjusted change in the pharmaceutical care group vs. the usual care group. NS = not significant.

this HMO setting. To the contrary, pharmaceutical care for this sample of patients with heart and lung diseases appeared to be associated with a modest increase in certain components of medical utilization, specifically prescription medications and possibly outpatient clinic visits. We did not find any statistically significant differences between pharmaceutical care and usual care in total charges, in either the intention-to-treat or adherence analyses. However, it should be noted that we did not include any program costs in these analyses.

Our findings on clinic utilization and costs are similar to those of the randomized trial done by McCombs and colleagues¹⁶ at Kaiser Permanente in California. While the Kaiser study concluded, “Much of the value of these consultations may reside in the avoidance of catastrophic events that result in hospital admissions,” we did not have sufficient power given our sample size and 2-year time frame to detect a difference in hospitalization between the two groups. Of note, the mortality difference observed between control and intervention patients (2.5% vs 0.7%; $P < 0.05$) could reflect the effect of pharmaceutical care; however, it more likely represents unmeasured baseline differences in health.

We found that pharmacists discovered medication-related problems and consulted with the patients’ physicians for a substantial majority of these patients with chronic health conditions.²¹ In other analyses, we have reported that pharmaceutical care appears to increase patient awareness about medication side effects.²² In these ways, the pharmaceutical care intervention might have stimulated greater involvement with the health care system, thus increasing utilization and possibly improving the quality of patient care. Because our study was not designed to evaluate the quality of patient care, we cannot assess whether the

increase in medications and clinic visits reflects better quality of care or overtreatment.

Our study has several limitations. First, despite our efforts to adjust for potential confounders in this nonrandomized study, there may still be unmeasured differences between intervention and control sites. We chose to select sites rather than randomly assign patients to pharmaceutical care and control groups for pragmatic reasons. Pharmaceutical care entails substantial training for pharmacists and reorganization for pharmacies. We believed it would be unreasonable to expect pharmacists trained in pharmaceutical care to fully implement a new system with one set of patients and completely refrain from using their enhanced skills with other patients. We did not account for group randomization in our analyses. The statistical significance of any differences reported may be overstated. Second, only about half of those invited to participate in pharmaceutical care actually chose to do so. Thus, the intervention effect is diluted in our intention-to-treat analyses. Our adherence analyses, however, failed to show a beneficial effect of the pharmaceutical care intervention.

Finally, it is possible that the intervention was not sufficiently potent.³ In a focus group, the pharmacists reported inconsistent follow-up consultations with the patients. Although patient monitoring was intended to be a component of pharmaceutical care, the protocol did not provide specific guidelines for follow-up visits.²¹ We were unable to count the actual number of follow-up encounters between pharmacists and patients because of a limitation in the MedAssess tracking software, which merged initial and subsequent encounters into one file.

Our study does not support the concept of a “substitution” effect—that consultation with a pharmacist

supplants other, more costly types of medical services. Our findings will be disappointing both to proponents of pharmaceutical care and to health plans. Even without a cost-substitution effect, however, pharmaceutical care may offer the important benefit of assuring more appropriate use of medications. In an era when medication-dispensing functions are often automated from a central mail-in location, pharmaceutical care may be useful as a way for pharmacists to contribute to the monitoring of patient care.

Take-Home Points

- While many have suggested that an expanded role for pharmacists in direct patient education will improve the safety and efficacy of drug therapy, research is limited and the results conflict.
- We studied the impact of a pharmaceutical care program on health care utilization, medication use, and charges in an HMO-based, nonrandomized, controlled trial.
- Among a group of patients with heart or lung disease, pharmaceutical care was associated with an increase rather than a decrease in health care utilization.
- Further research is needed to understand the long-term effect of pharmaceutical care on the quality of patient care and health care utilization.

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Acknowledgments

We thank the following people for their contributions to this project: Kirsten Hase, BA; Kim Becker, RPh; Tony Grupa, RPh; Peggy Sannes, RPh; Steven Markes, RPh; Deborah Kohlman, RPh; Jean Byun, RPh; Stefanie Michels, RPh; Deborah Schwartz, RPh; Michelle Skoglund, RPh; Judy Sperry, PharmD; Rick Sorensen, RPh; Lowell Anderson, RPh; Willie Wimmer, RPh; Steve Simonson, RPh; Gregory Wedin, PharmD, RPh; Marianne Tomechko, PharmD, RPh; Glen Kegley, RPh; John Loch, RPh. We are also grateful to the reviewers for their comments on an earlier version of our paper and especially to Brenda Sirovich, MD, MS, Associate Editor of *Effective Clinical Practice*, for all her work on editing this manuscript.

Grant Support

This project was funded by a grant from the Pharmaceutical Care Consortium, which included the following members: HealthPartners, Astra Merck, Bristol-Myers Squibb, Dupont, Forest Pharmaceuticals, Hoechst Marion Roussel, Novartis Pharmaceuticals Corporation, Novo Nordisk, Pfizer Pharmaceuticals, Rhone-Polenc Rorer, Schering-Plough, Searle, Wyeth-Ayerst, and Encara.

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