The Impact of a Pharmacotherapy Consultation on the Cost and Outcome of Medical Therapy

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Background. One important task for physicians is to optimize their patients' medication regimen. Involvement of clinical pharmacists who have specific training in drug regimen design has been associated with improved patient outcomes for specific medical conditions, eg, hypertension and anticoagulation. This prospective, randomized trial investigated whether a single consultation by a clinical pharmacist with high-risk patients and their primary physicians would result in improved prescribing outcomes.

Methods. Patients at risk for medication-related problems were identified and randomized to receive a pharmacotherapy consultation (consult group) or usual medical care (control group). Outcomes, including the number of drugs, number of doses per day, cost of medications, and patient reports of adverse effects, were recorded at baseline and at 6 months following the intervention.

Results. Fifty-six subjects were evaluable: 29 in the control group, and 27 in the consult group. Six months after the consultation, the number of drugs, the number of doses, and the 6-month drug costs all decreased in the consult group and increased in the control group; the net difference was 1.1 drugs (P=.004), 2.15 doses per day (P=.007), $586 per year ($P$=.008). The side effects score improved by 1.8 points more in the consult group compared with the control group (P=NS). Similarly, the prescribing convenience score in the consult group improved by 1.4 points more than that of the control group (P=NS).

Conclusions. This study demonstrates several important benefits of integration of a clinical pharmacist into a primary care setting, including improvement in cost and simplification of the medication regimen with no reduction in quality of care.

Key words. Pharmacists; clinical pharmacist; drug therapy; family practice; cost.
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Among the most critical tasks of primary care physicians is to optimize their patients' drug regimens. An optimal drug regimen is one that produces the desired benefits while minimizing the number of drugs, doses per day, cost, and adverse effects. To improve compliance, patients should also perceive that their medication regimen is convenient. Both drug-related hospital admissions and compliance are associated with the number of medications prescribed.[1,2]

The clinical pharmacist is a potentially valuable resource in this process. Clinical pharmacists are pharmacists who have obtained specific training in providing patient care in the area of pharmacotherapy.

The impact of a clinical pharmacist's services on outcomes for specific diseases has been evaluated in a controlled fashion. At least three separate studies on the control of hypertension have shown improved blood pressure control with the use of a pharmacotherapy consultation.[3-5] Anticoagulation therapy managed by clinical pharmacists has also demonstrated favorable results.[6] Studies have demonstrated that collaboration between a clinical pharmacist and the treating physician benefits pa-

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tients with multiple medical problems; however, these studies have not been conducted in a randomized, controlled fashion.[5,7–10]

In this randomized clinical trial conducted in a primary care practice, we tested the hypothesis that a brief in-office pharmacotherapy consultation involving a clinical pharmacist, at-risk patients, and treating physicians would be associated with improved outcomes including: decreased number of medications; decreased cost of medications; decreased number of doses per day; improvement in reported adverse effects; and improvement in patient understanding and compliance with their medication regimens. Further, it was hypothesized that these improvements would persist for 6 months.

Methods

Description of the Study

From a primary care patient population, we identified patients at risk for medication-related problems using the instrument validated by Koecheler et al.[11] We randomly assigned patients to intervention and control groups and measured the outcomes for each group at baseline and after 6 months. We measured the following outcomes by means of chart review and questionnaires*: (1) the number of chronic prescription medications in the regimen; (2) the number of individual doses per day; (3) monthly cost of prescription drugs, based on "maximum allowable cost" for Medicaid reimbursement; (4) patient self-reports of compliance and of the drug regimen convenience using a scale developed by the authors*; and (5) side effects and problems, based on self-reports using a scale developed by the authors.*

Intervention

Each patient in the intervention group was given a 45- to 60-minute pharmacotherapy consultation. The consultation was provided by a clinical pharmacist with a post-baccalaureate PharmD degree and experience in ambulatory care. The goals of the consultation were to simplify the regimen, improve the effectiveness of the regimen, and decrease adverse effects. A secondary goal was to decrease cost if this could be accomplished without adversely affecting the first three goals.

Patients were asked to bring in all their medicines in a "brown bag." After performing a chart review, the pharmacist conducted a medication history. This was a focused interview based on the current regimen and the side-effects questionnaire described above. The pharmacist evaluated the medication regimen for the following drug-related problems: drug interactions, unneeded drugs, adverse drug reactions, therapeutic duplication, suboptimal drug selection, inappropriate dosage interval, and cost. The pharmacist then met with the treating physician to discuss his findings. A new regimen was developed by a collaborative dialogue between the physician and the pharmacist. Finally, the pharmacist conducted a brief educational session with the patient to explain any changes in the regimen and to improve the patient's understanding of their drug therapy.

One month after the intervention, the pharmacist contacted the patient by telephone (5 to 10 minutes) to reinforce the treatment plan. Six months after the intervention, the five outcomes were again measured.

Physicians and other patient caregivers were specifically excluded from knowledge that patient outcomes were being studied. They were aware only that the office's clinical pharmacist was performing pharmacotherapy consultations on selected patients. Similarly, we did not interfere in normal physician-patient assignments. As a result, some physicians cared for patients in both groups.

Patient Selection

All patients seen in the Family Health Center of the Grand Rapids Family Practice Residency were placed on a sequentially numbered list each month. Charts were selected for review using a computer program designed to randomly select from the list. These randomly selected charts were reviewed by a research assistant for the presence of two or more risk factors for adverse consequences of medication therapy as defined by Koecheler et al.[11] Patients were enrolled from June 1991 to December 1992. The risk factors included: (1) five or more medications in current regimen; (2) 12 or more daily doses; (3) four or more medication changes in the last 12 months; (4) more than three concurrent disease states; (5) documentation of medication noncompliance in the medical record; and (6) drugs that require therapeutic monitoring, eg, digoxin, theophylline.

Patients were not eligible for enrollment if they: (1) had evidence in the medical record of active alcohol or illicit drug abuse; (2) were unwilling or unable to return for a pharmacotherapy consultation; (3) had their regimen primarily managed by an outside consultant; (4) were terminally ill; or (5) were less than 18 years of age.

Eligible patients were randomly assigned to intervention or control group using a random number table.

**Copies of the questionnaires and scales used in this study are available from the authors.*

Statistical Analysis

Demographic data were analyzed with Student's *t* test for continuous data and Fisher's exact test for categorical data. Baseline outcome variables and within-group changes from baseline were compared using Fisher's exact test for categorical data and the Mann-Whitney *U* test for continuous data. This comparison of within-group changes using the Mann-Whitney *U* test was necessary, rather than the usual two-way ANOVA because the frequency distribution was skewed with outliers. The only two-way ANOVA available for non-normal data is the Friedman's test for matched samples, which did not apply to our data.

Results

Of 749 patients initially randomized to be screened, two or more risk factors were identified for 98 patients. Of these 98, 25 refused to participate, seven were active alcohol abusers, and two were not expected to live for 6 months. The remaining 64 patients were randomly assigned to intervention or control. Thirty-four were randomized to receive a consultation; 30 were randomized to the control group. One patient in each group died during the 6-month period following enrollment. Four of the consult group were lost to follow-up, and two were discovered to have their medications managed by an outside consultant. This left 27 evaluable patients in the consult group and 29 evaluable patients in the control group. The two groups did not differ with respect to race, sex, or age (all *P* values >.45). The average age for evaluable patients was 60.5 years. Black patients and women comprised 28% and 80% of the total, respectively.

There were no differences in screening risk factors between the two groups at baseline except for a higher percentage of monitored drugs, such as theophylline or anticonvulsants, in the control group (Table 1). Likewise, there were no statistically significant differences in outcome variables between the two groups at baseline.

There were significant differences between the two groups with regard to within-group changes in outcome variables from baseline to 6 months (Table 2). The number of drugs, number of doses, and the 6-month cost all decreased in the intervention group and increased in the control group; the net difference was 1.1 drugs (*P*=.004), 2.15 doses (*P*=.007), and $293 per 6 months (*P*=.008).

The change in the composite score of side effects showed improvement in both groups over the 6 months, with the improvement in the consult group being 1.8 points greater than the that in the control group (*P*=NS). Similarly, the "understanding and compliance" composite scores improved in both groups with the change in the consult group being greater by 1.4 points (*P*=NS).

Table 1. Presence of Screening Risk Factors at Baseline

Risk Factor	Consult Group, % (n=27)	Control Group, % (n=29)
5 or more long-term medications	89	90
12 or more doses per day	26	28
4 or more medication changes in the past year	59	52
More than 3 chronic diseases	70	76
Documented noncompliance	18	21
Monitored drug	26	52

NOTE: There were no statistical differences between the consult and control groups with regard to risk factors except for monitored drug (P=.04).

Discussion

Thirteen percent (98/749) of our ambulatory population were at risk for negative consequences of drug therapy as defined by our entry criteria. The 64 participating patients entered the study taking an average of six medications with almost 10 doses per day. The annual drug costs at entry averaged $1800 per person.

The patients randomized to the consult group benefited significantly more than did the control group in the the number of drugs, the number of doses per day, and the total cost of medications for the 6 months. The cost difference for within-group changes from baseline was $293 over 6 months (*P*=.008). This would extrapolate to $586 in savings per year. The number of drugs and their cost, however, are not the only consideration. For example, simplifying the medication regimen and reducing cost at the expense of good medical care would be inappropriate. Our study addressed this by evaluating patient-reported outcomes. The results of the questionnaire suggested at least no worsening of these outcomes and a nonsignificant trend toward beneficial effect on both adverse effects and on understanding and compliance (Table 2).

One of the strengths of our intervention method was the step requiring patients to bring in their medicines to a personal interview with the clinical pharmacist. Recommendations after the interview were often quite different than would be expected from the profile alone.

Limitations of this study include small sample size and lack of blinding. The sample size prevented us from showing statistical significance in the adverse effect and "understanding and compliance" questionnaire outcomes. Regarding the lack of blinding, every effort was

Table 2. Change in Outcome Variables from Baseline to 6 Months

Variable	Consult Group			Control Group			Net Difference*	*P* Value
	Baseline	6 Months	Change	Baseline	6 Months	Change		
No. of drugs	5.6	5.0	−0.6	5.7	6.2	0.5	1.1	.004
No. of doses/day	9.5	7.9	−1.6	9.9	10.5	0.6	2.2	.007
6-month cost of medications, $	929	799	−130	889	1052	163	293	.008
Understanding and compliance†	2.3	0.6	−1.6	2.3	2.1	−0.2	1.4	NS
Side effects score‡	8.4	4.7	−3.7	7.9	5.9	−1.9	1.8	NS

**Net difference is the difference in change between the consult group and the control group.*
†Total score on a scale of 0 to 12.
‡Total score on a scale of 0 to 32.

made to reduce investigator bias by rigid adherence to data collection criteria. When arbitrary definitions, such as for "drug," "chronic disease," and "noncompliance," were required, these assignments were made before randomization and consistently applied to all subjects. There was also a risk of the Hawthorne effect occurring, in which physicians may have changed their clinical behavior because of being observed. We deliberately did not inform physicians caring for patients in either group that they were part of a study measuring outcomes. Nonetheless, it is possible that physicians could have realized they were being observed. Conversely, some physicians whose patients received a consult may have transferred the principles from the consult to a control patient. If this had happened, it would have had the effect of diminishing the observed difference between the consult and control groups.

The vagaries of randomization resulted in more patients who were receiving monitored drugs being in the control group. We believe that this difference did not affect our measured outcomes, since the baseline measures of outcome, including adverse effects, were no different between the two groups.

The results of this study raise several questions. Could simpler, easier-to-use measures be used to identify patients at risk? Would a periodic "tune-up" of the consultation enhance or prevent fading of the benefits? Would a larger, wider study be able to demonstrate beneficial effects on outcomes such as hospitalizations, emergency room visits, and physician office visits? Further investigations are needed to address these and other questions.

Conclusions

Pharmacotherapy consultation in this study was associated with simplified, less expensive medication regimens. The intervention also resulted in reductions in side effects and improvements in understanding and compliance, although these changes were not statistically significant. Because the study used an existing health care professional (clinical pharmacist with a doctorate in pharmacy) in a primary care ambulatory setting, using a standardized risk-assessment tool, the results of this study should be generalizable to other primary care or managed care settings.

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References

1. Hallas J, Harvald B, Gram LF, et al. Drug related hospital admissions: the role of definitions and intensity of data collection, and the possibility of prevention. J Intern Med 1990; 228:83–90.
2. Meichenbaum D, Turk D. Facilitating patient adherences. New York, NY: Plenum Press, 1987.
3. Bond CA, Monson R. Sustained improvement in drug documentation, compliance, and disease control: a four-year analysis of an ambulatory care model. Arch Intern Med 1984; 144:1159–62.
4. McKenney JM, Slining JM, Henderson HR, et al. The effect of clinical pharmacy services on patients with essential hypertension. Circulation 1973; 48:1104–11.
5. Morse GD, Douglas JB, Upton JH, et al. Effect of pharmacist intervention on control of resistant hypertension. Am J Hosp Pharm 1986; 43:905–9.
6. Conte RR, Kehoe WA, Nielson W, et al. Nine-year experience with a pharmacist-managed anticoagulation clinic. Am J Hosp Pharm 1986; 43:2460–4.
7. Monson R, Bond CA, Schuna A. Role of the clinical pharmacist in improving drug therapy: clinical pharmacists in outpatient therapy. Arch Intern Med 1981;141:1441–4.
8. Linkewich JA, Catalano RB, Flack HL. The effect of packaging and instruction on outpatient compliance with medication regimens. Drug Intell Clin Pharm 1974; 8:10–5.
9. Chrischelles EA, Helling DK, Aschoff CR. Effect of clinical pharmacy services on the quality of family practice physician prescribing and medication costs. Drug Intell Clin Pharm 1989; 23:417–21.
10. Lobas NH, Lepinski PW, Abramowitz PW. Effects of pharmaceutical care on medication cost and quality of patient care in an ambulatory-care clinic. Am J Hosp Pharm 1992;49:1681–8.
11. Koecheler JA, Abramowitz PW, Swim SE, Daniels CE. Indicators for the selection of ambulatory patients who warrant pharmacist monitoring. Am J Hosp Pharm 1989; 46:729–32.