Effectiveness of Pharmacist Care for Patients With Reactive Airways Disease
A Randomized Controlled Trial

Morris Weinberger, PhD
Michael D. Murray, PharmD
David G. Marrero, PhD
Nancy Brewer
Michael Lykens, MD
Lisa E. Harris, MD
Roopa Seshadri, PhD
Helena Caffrey, MS
J. Franklin Roesner, MD
Faye Smith, MS
A. Jeffrey Newell, RPh
Joyce C. Collins, RPh
Clement J. McDonald, MD
William M. Tierney, MD

Context  It is not known whether patient outcomes are enhanced by effective pharmacist-patient interactions.

Objective  To assess the effectiveness of a pharmaceutical care program for patients with asthma or chronic obstructive pulmonary disease (COPD).

Design, Setting, and Participants  Randomized controlled trial conducted at 36 community drugstores in Indianapolis, Ind. We enrolled 1113 participants with active COPD or asthma from July 1998 to December 1999. Outcomes were assessed in 947 (85.1%) participants at 6 months and 898 (80.7%) at 12 months.

Interventions  The pharmaceutical care program (n=447) provided pharmacists with recent patient-specific clinical data (peak expiratory flow rates [PEFRs], emergency department [ED] visits, hospitalizations, and medication compliance), training, customized patient educational materials, and resources to facilitate program implementation. The PEFR monitoring control group (n=363) received a peak flow meter, instructions about its use, and monthly calls to elicit PEFRs. However, PEFR data were not provided to the pharmacist. Patients in the usual care group (n=303) received neither peak flow meters nor instructions in their use; during monthly telephone interviews, PEFR rates were not elicited. Pharmacists in both control groups had a training session but received no components of the pharmaceutical care intervention.

Main Outcome Measures  Peak expiratory flow rates, breathing-related ED or hospital visits, health-related quality of life (HRQOL), medication compliance, and patient satisfaction.

Results  At 12 months, patients receiving pharmaceutical care had significantly higher peak flow rates than the usual care group (P = .02) but not than PEFR monitoring controls (P = .28). There were no significant between-group differences in medication compliance or HRQOL. Asthma patients receiving pharmaceutical care had significantly more breathing-related ED or hospital visits than the usual care group (odds ratio, 2.16; 95% confidence interval, 1.76-2.63; P = .001). Patients receiving pharmaceutical care were more satisfied with their pharmacist than the usual care group (P = .03) and the PEFR monitoring group (P = .001) and were more satisfied with their health care than the usual care group at 6 months only (P = .01). Despite ample opportunities to implement the program, pharmacists accessed patient-specific data only about half of the time and documented actions about half of the time that records were accessed.

Conclusions  This pharmaceutical care program increased patients’ PEFRs compared with usual care but provided little benefit compared with peak flow monitoring alone. Pharmaceutical care increased patient satisfaction but also increased the amount of breathing-related medical care sought.

JAMA. 2002;288:1594-1602

For editorial comment see p 1642.
Identify and resolve patients’ medication-related problems; (2) patients often have several physicians but frequently patronize a single pharmacy; (3) pharmacists are often the last health professional whom patients see before taking their medication; and (4) pharmacists are trusted by patients.

Literature reviews suggest that enthusiastic reports about the effectiveness of pharmaceutical care are often plagued by serious methodological flaws. Although inpatient pharmaceutical care may be effective, there is less evidence of its effectiveness in outpatient settings and no rigorous studies have been performed in community pharmacies. As the largest provider of prescription services in the United States, community pharmacies provide an important venue for improving patients’ lives via pharmaceutical care. However, substantial barriers to implementing such programs exist.

We conducted a randomized controlled trial to assess the effectiveness of pharmaceutical care for adults with reactive airways disease. Primary outcomes were patients’ peak expiratory flow rate (PEFR), health-related quality of life (HRQOL), medication compliance, and breathing-related emergency department (ED) or hospital visits. Secondary outcomes were patient satisfaction with care and with their pharmacist.

**Methods**

**Design and Setting**

The study, approved by the Indiana University-Purdue University at Indianapolis institutional review board, was conducted in 36 Indianapolis CVS drugstores. The 36 drugstores were divided into 12 clusters of 3 geographically proximal drugstores (“triplets”). The 3 drugstores within each triplet were matched on percentage of Medicaid-insured adults with reactive airways disease (to control for customers’ socioeconomic status) and number of prescriptions filled (high vs low volume). Within each triplet, we used a random-number chart to assign drugstores to 1 of 3 study groups. Each patient was followed up for a year. Face-to-face interviews at baseline, 6, and 12 months were conducted to assess primary and secondary outcomes (FIGURE).

**Study Groups**

**Pharmaceutical Care Program**. A detailed description of the pharmaceutical care program appears elsewhere. Briefly, the program included (TABLE 1) the following:

- **Pharmacist Training**. Investigators representing several backgrounds presented: (1) an overview of pharmaceutical care and its application to reactive airways disease; (2) an orientation to the study computer and available patient-specific data; (3) explanation for interpreting and using these data for pharmaceutical care; (4) appropriate techniques for measuring PEFR; (5) study materials, resources, and handouts when interacting with patients; and (6) strategies to implement the program.

- **Computer Display of Patient-Specific Data**. When a study patient filled any prescription (not only breathing medications), the drugstore computer alerted pharmacists to review patient-specific data contained in a separate study computer behind the counter. To safeguard patients’ confidentiality, access to patient-specific data required pharmacists’ individualized passwords. Study computers contained: (1) contact information for patients and 1 to 2 physicians caring for their breathing problem; (2) graphical display of all PEFR data gathered during monthly interviews; (3) dates and locations of recent ED visits and hospitalizations; and (4) breathing medications (including compliance rates and refill histories). These data were obtained during monthly telephone interviews. Pharmacists were encouraged to document their pharmaceutical care activities at the bottom of the screen.

- **Written Patient Educational Materials**. We developed 1-page handouts corresponding to specific problems associated with clinical data stored in the study computer. Handouts, designed to be easily understood by patients, used mnemonic devices and color coding to facilitate distribution by pharmacists.

- **Resource Guide**. Attached to the study computer, guides contained laminated pages with practical suggestions to help pharmacists implement the program in a busy practice.

COPD indicates chronic obstructive pulmonary disease.

---

**Figure. Study Flow**

![Study Flow Diagram](image-url)
Control Groups. Patients in the pharmaceutical care group received a peak flow meter, instruction about its use, and monthly calls from research personnel to obtain current PEFR results. We were concerned that these activities could be an active treatment by increasing patients' self-monitoring. So, the peak flow meter monitoring control group also received a peak flow meter, instructions about its use, and monthly calls to elicit PEFRs. However, PEFR data were not provided to the pharmacist. Patients in the usual-care group received neither peak flow meters nor instructions in their use; during monthly telephone interviews, PEFR rates were not elicited. Pharmacists in both control groups also had a 4-hour training session although the topics were different and they received no components of our pharmaceutical care protocol (Table 1).

Procedures
Customers were eligible if they (1) filled a prescription for methylxanthines, inhaled corticosteroids, inhaled or oral sympathomimetics, inhaled parasympathetic antagonists, or inhaled cromolyn sodium during the preceding 4 months; (2) reported having COPD or asthma as an active problem; (3) were 18 years or older; (4) received 70% or more of their medications from a single study drugstore; (5) reported no significant impairment in vision, hearing, or speech that precluded participation; (6) did not reside in an institution (eg, nursing home); and (7) provided written informed consent.

The recruitment protocol 27 was designed to maximize customers' confidentiality (Figure). Patients were enrolled between July 1998 and December 1999. In July 1998, drugstore programmers queried their database to identify all customers 18 years or older who, during the preceding 4 months, filled a prescription for 1 of the above breathing medications at any study pharmacy. Corporate personnel mailed letters to these individuals stating that: (1) they were working with Indiana University School of Medicine (IUSM) to develop programs to improve the health of its customers; (2) IUSM was evaluating these programs by talking to customers; (3) customers would be paid up to $60 for participating in the evaluation; and (4) they could page an investigator with questions about the project. Subjects were asked to sign and return a form providing permission in order to release their names to IUSM investigators or that they were uninterested in participating. A drugstore employee attempted to telephone persons who failed to return a signed form to verify that they received the letter, determine their interest in participating, and offer to send them another form. Only after receiving a signed form indicating a person's willingness to be contacted was the name released to the IUSM project manager.

The project manager then conducted a telephone screening interview to describe the study, review patient eligibility, and, for eligible patients, arrange a face-to-face baseline interview (Figure). All interviewers

---

**Table 1. Components of Intervention**

<table>
<thead>
<tr>
<th>Pharmaceutical Care Program Group</th>
<th>Peak Flow Meter Monitoring Control Group</th>
<th>Usual Care Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer display of patient-specific data</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Background and contact information</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Peak flow rates</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Emergency department visits or hospital admissions</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Medications/medication possession ratio</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Tailored patient education materials</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Resource guide</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Pragmatic strategies to facilitate implementation of pharmaceutical care</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Pharmacist training</td>
<td>Overview on pharmaceutical care</td>
<td>Overview on pharmaceutical care</td>
</tr>
<tr>
<td>Overview on pharmaceutical care</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Pharmaceutical care in reactive airways disease</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Interpreting and using patient-specific data</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Techniques to measure peak flow</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Study materials, handouts, and resources</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Strategies to implement program</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Instruction on counseling techniques</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

*Patients in both the pharmaceutical care program and peak flow meter monitoring group received free peak flow meters and instructions on their use. In both these groups, peak flow results were obtained during monthly telephone calls. These results were shared with pharmacists in the pharmaceutical care program group only.
completed training on the study protocol, interviewing techniques, asthma and COPD, proper peak flow meter technique. Interviewers were instructed to ensure that the proper peak flow meter technique was used during face-to-face interviews.

Interviewers, blinded to study group assignment, obtained informed consent and conducted baseline interviews. After completing an interview, the laptop computer used to administer interviews revealed the patient’s study group assignment. At that time, interviewers distributed a Personal Best peak flow meter (Health Scan Product, Inc, Cedar Grove, NJ) and reviewed proper meter technique for patients in the pharmaceutical care program and peak flow monitoring control groups. Following the baseline interview, we sent letters notifying physicians treating the patient’s breathing problem and advised them that the patient was participating in a study in which a pharmacist might receive PEFR, medication compliance, and health services utilization data. The letter stressed that the pharmacist would make no treatment decisions but may educate patients about their breathing problem and reinforce compliance with the physician’s prescribed treatment regimen.

Patients were censored from the study if they died, were placed in a nursing home, moved away permanently from Indianapolis, their insurance no longer covered using these drugstores, or they lost telephone access. For patients not censored, we attempted to conduct in-person follow-up interviews at 6 and 12 months to assess outcomes by individuals blinded to study group. Patients in all 3 groups received a $20 gift certificate for each interview completed.

Monthly telephone interviews were conducted with all patients to ascertain ED or hospital use, breathing medications not contained in the pharmacists’ database (ie, over-the-counter, prescriptions from other drugstores, samples), and frequency with which they had spoken to a pharmacist about their breathing medications during the previous month. In addition, patients receiving peak flow meters were asked to use their meters and report their PEFR while on the telephone. Patients are capable of reliably recording PEFR readings.

Measures

Peak expiratory flow rate, the maximum velocity of exhalation that can be generated by patients, correlates highly with parameters of pulmonary function and clinical outcomes of patients with asthma and COPD. For this study, we transformed PEFRs into the percentage of maximum predicted value based on patients’ sex, age, and height.

Disease-specific HRQOL was assessed during the baseline and 6- and 12-month interviews using asthma- and COPD-specific measures developed to detect clinically important changes within randomized trials. Both questionnaires use analogous 7-point Likert scales for categorical variables and analysis of variance for continuous variables. When assumptions for these parametric tests were not met, we used the Fisher exact and Kruskal-Wallis tests, respectively. When between-group baseline differences were significant (P<.05), we controlled for those variables in all subsequent analyses. We used χ² tests and t tests to compare baseline characteristics of patients who did and did not complete 12-month interviews. During the study period, 2 drugstores (both control) were closed. In both cases, all study patients transferred to another study drugstore. Patients’ original study group was retained for all analyses.

Consistent with our hypotheses, we compared the pharmaceutical care...
group with each of the 2 control groups using an intent-to-treat analysis. Sample size was based on our ability to detect a 10% difference in breathing-related ED or hospital visits (25% vs 15%) between the pharmaceutical care group and each control group with 80% power and α = .025 (using Bonferroni correction for 2 pairwise comparisons). For an estimated 15% attrition, we enrolled approximately 1100 patients.

To test for differences in intervention group means for continuous outcomes measured at 6 and 12 months, we used repeated measures analysis of variance models, with baseline scores as covariates. This model makes no assumption about outcome measures in intervention groups’ being linear over time. Random effects corresponding to intervention groups were included. However, because variation due to pharmacy was consistently nonsignificant, we excluded the effect of pharmacy from the final models. For binary outcomes (compliance, proportion with a breathing-related ED or hospital visit), we used logistic regression. For compliance, we used a repeated measures approach. For breathing-related ED or hospital visits, we weighted each person’s contribution by the amount of time in the study. Because HRQOL had different items depending on disease group (asthma vs COPD), separate models were constructed. For all other outcomes, interaction effects of disease with intervention group were investigated. If the interaction was not significant, we analyzed COPD and asthma patients together, including disease group as a covariate. Separate models were analyzed for patients with COPD and for patients with asthma if the interaction was significant. Treatment by time interactions were also tested and, if significant, tests of intervention effect were done separately for 6- and 12-month outcomes. We also examined temporal trends by comparing 6- and 12-month outcomes to baseline measures, accounting for multiple comparisons using Holm procedures. If the overall effect of intervention group was significant from tests described above, change from baseline was analyzed separately for each intervention group. For all repeated measures analyses, compound symmetry variance-covariance structure was used to specify the correlation between responses for the same individual. For all pairwise comparisons, we reported unadjusted P values.

As a secondary analysis, we used data from the pharmaceutical care pro-

### Table 2. Baseline Characteristics of Patients With Reactive Airways Disease

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Chronic Obstructive Pulmonary Disease</th>
<th>Asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacological Care Program (n = 185)</td>
<td>Usual Care Control (n = 138)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>62.2 (11.0)</td>
<td>62.2 (11.9)</td>
</tr>
<tr>
<td>White, No. (%)*</td>
<td>149 (80.5)</td>
<td>116 (89.2)</td>
</tr>
<tr>
<td>Women, No. (%)†</td>
<td>118 (63.8)</td>
<td>86 (66.2)</td>
</tr>
<tr>
<td>Education, mean (SD), y</td>
<td>12.6 (3.2)</td>
<td>12.0 (2.4)</td>
</tr>
<tr>
<td>Smoking status, No. (%)</td>
<td>72 (38.9)</td>
<td>47 (36.2)</td>
</tr>
<tr>
<td>Past</td>
<td>107 (57.8)</td>
<td>81 (62.3)</td>
</tr>
<tr>
<td>Current</td>
<td>6 (3.2)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Breathing medications, No. (%)</td>
<td>58 (31.3)</td>
<td>39 (30.0)</td>
</tr>
<tr>
<td>Inhalers of corticosteroids</td>
<td>14 (7.6)</td>
<td>14 (10.8)</td>
</tr>
<tr>
<td>Leukotriene inhibitors</td>
<td>28 (15.1)</td>
<td>19 (14.6)</td>
</tr>
<tr>
<td>Methylxanthines</td>
<td>110 (59.5)</td>
<td>76 (58.5)</td>
</tr>
<tr>
<td>Sympathomimetics</td>
<td>40 (21.6)</td>
<td>33 (25.4)</td>
</tr>
<tr>
<td>Inhaled parasympathetic antagonists</td>
<td>4 (2.2)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Systemic corticosteroids</td>
<td>37 (20.0)</td>
<td>33 (25.4)</td>
</tr>
<tr>
<td>Medication compliance, No. (%)</td>
<td>34 (18.4)</td>
<td>28 (21.5)</td>
</tr>
</tbody>
</table>

*P<.05 for both conditions.

†P<.05 for chronic obstructive pulmonary disease only.

©2002 American Medical Association. All rights reserved.
pharmacist documented his/her actions on the study computer.

**RESULTS**

Letters were mailed to 14 195 persons meeting initial eligibility criteria: 3019 returned forms (2193 were interested; 824 refused). Of those not returning a form, follow-up telephone calls identified 756 additional persons interested in participating. Of 2951 interested patients screened by the project coordinator, 1202 were ineligible, 492 refused, and 136 could not be contacted. After excluding 8 pilot study participants, 1113 were enrolled. Table 2 presents baseline characteristics for 453 patients with COPD and 660 patients with asthma. We completed interviews with 947 patients (85.1%) at 6 months and patients 898 patients (80.7%) at 12 months. Completion rates did not differ significantly by disease or study group. Patients not completing 12-month interviews were more likely to report a hospital or ED visit during the month prior to enrollment (9.8% vs 5.9%, P = 0.04), less education (13.1 vs 13.6 years, P = 0.04), and, for COPD patients only, lower HRQOL. Unadjusted outcome data across time are presented in Table 3.

Study groups were comparable at baseline (P > 0.05), except for race (both diseases) and PEFR (COPD only). To account for these differences, we controlled for race in all analyses and for baseline PEFR among COPD patients only. Except for satisfaction with health care, for which the intervention group by time interaction was significant, intervention effects were reported across 6 and 12 months together. Disease groups were tested in the same model for all outcomes except breathing-related ED or hospital visits, for which the effect of the intervention groups differed significantly by disease.

Across 6 and 12 months, there was a significant (P = 0.006) overall difference in PEFR among the 3 study groups (Table 4). Specifically, the pharmaceutical care group had higher PEFR than usual care (P = 0.02) but was not different from the peak flow meter monitoring group (P = 0.28). Time contrasts showed significant (P < 0.01) increases in PEFR in the pharmaceutical care group from baseline to 12 months and in the peak monitoring group from baseline to both 6 and 12 months.

Table 2. Baseline Characteristics for 453 COPD Patients and 660 Asthma Patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>Peak Flow Meter Monitoring Control</th>
<th>Pharmaceutical Care Program</th>
<th>Usual Care Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (n = 446)</td>
<td>6 Months (n = 369)</td>
<td>12 Months (n = 356)</td>
</tr>
<tr>
<td>Peak flow rate, mean (SD), % predicted</td>
<td>63.8 (21.6)</td>
<td>65.5 (19.5)</td>
<td>65.5 (19.5)</td>
</tr>
<tr>
<td>No. with COPD</td>
<td>185</td>
<td>146</td>
<td>149</td>
</tr>
<tr>
<td>Overall HRQOL, mean (SD)</td>
<td>4.0 (1.0)</td>
<td>4.5 (1.0)</td>
<td>4.4 (1.1)</td>
</tr>
<tr>
<td>No. with asthma</td>
<td>262</td>
<td>225</td>
<td>207</td>
</tr>
<tr>
<td>Overall HRQOL, mean (SD)</td>
<td>4.5 (1.2)</td>
<td>5.0 (1.3)</td>
<td>5.0 (1.2)</td>
</tr>
<tr>
<td>Medication compliance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not compliant, %</td>
<td>34.9</td>
<td>27.0</td>
<td>22.5</td>
</tr>
<tr>
<td>4-Item measure, mean (SD)</td>
<td>1.3 (1.2)</td>
<td>1.0 (1.1)</td>
<td>0.8 (1.1)</td>
</tr>
<tr>
<td>Hospital or ED visits, %†††</td>
<td>...</td>
<td>...</td>
<td>22.9</td>
</tr>
<tr>
<td>COPD</td>
<td>...</td>
<td>...</td>
<td>15.7</td>
</tr>
<tr>
<td>Asthma</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

*COPD indicates chronic obstructive pulmonary disease; HRQOL, health-related quality of life; ED, emergency department; and ellipses, not applicable. Values were missing from 1 patient in the baseline and in 2 patients at the 12-month follow-up in the pharmaceutical care program and from 1 patient in the 6-month follow-up in the peak flow monitoring control group.

†Proportion of patients with at least 1 breathing-related hospital or emergency department (ED) visit during the 12 months.
greater satisfaction with their pharmacist than did patients in either the usual care (P < .02) or peak flow monitoring (P = .01) control group. Moreover, the pharmaceutical care group reported greater satisfaction with their health care compared with the usual care group at 6 months (P = .01); this difference was not sustained at 12 months (P = .14). There was no difference in satisfaction with health care between the pharmaceutical care and peak flow monitoring groups at 6 months (P = .08) or 12 months (P = .14). During monthly interviews, 49.3% of patients in the pharmaceutical care group reported having discussions with their pharmacists about their breathing problems while 24.3% of patients in the peak flow meter monitoring and 24.2% in the usual care control groups reported having discussions with their pharmacists (P < .001). Patients in the pharmaceutical care group reported a mean (SD) rate of speaking to their pharmacist during the previous month 1.17 (1.77) times compared with 0.51 (1.19) times in the peak flow monitoring and compared with 0.40 (0.89) in the usual care group (P < .001). Frequency of interactions with the pharmacist was correlated with patient satisfaction with their pharmacist (r = .12; P < .001).

There were ample visits during which pharmacists had opportunities to implement the pharmaceutical care program for patients with both asthma (mean [SD], 19.4 [16.8] visits) and COPD (22.4 [17.7] visits). However, they only accessed data from the computer about half the time (asthma, 10.3 [7.5] visits; COPD, 11.8 [10.5] visits) and documented actions only about half the time these records were accessed (asthma, 6.2 [5.8] visits; COPD, 6.2 [7.0] visits). Using documentation to assess dose of the intervention, we observed no statistically significant dose-response effect for PEFR or HRQOL. Notably, when pharmacists documented more pharmaceutical care actions, patients exhibited less noncompliance with their breathing medications (OR, 0.96; 95% CI, 0.92-0.99; P = .02) and had more breathing-related ED or hospital visits (OR, 1.06; 95% CI, 1.04-1.07; P < .001).

**COMMENT**

We examined the effectiveness of a pharmaceutical care program designed to improve patients’ clinical status, HRQOL, and medication compliance. At 12 months, patients in the pharmaceutical care group had significantly higher PEFRs than those receiving usual care; however, our program offered no advantage compared with monitoring patients’ PEFRs monthly. Moreover, patients participating in our program were significantly more satisfied with their pharmacists than the other 2 groups; they were also more satisfied with their health care than the usual care group. Although we observed a substantial improvement in both medication compliance and HRQOL among patients in the pharmaceutical care program at 6 months that was sustained at 1 year, similar improvement was observed in both control groups.

However, contrary to our hypothesis, asthma patients in the pharmaceutical care group had more breathing-related ED or hospital visits. Notably, we are observing care-seeking behavior and did not examine the appropriateness of visits although observed PEFRs suggest poor function. Interestingly, although our a priori hypotheses did not involve comparing the 2 control groups with each other, breathing-related ED or hospital visits in the peak flow monitoring control group (14.6%) was twice that of usual care (7.3%). Increased visits may have resulted from patients associating their PEFR values with symptoms, which could have resulted in more care seeking. That simple monitoring could have measurable effects on clinical outcomes is consistent with our previous study of regular telephone calls from non–health care professionals. These findings suggest that strategies to increase patient involvement in care of their chronic conditions (especially

---

**Table 4. Outcomes Over 12 Months**

<table>
<thead>
<tr>
<th>Event</th>
<th>No. of Events</th>
<th>Pharmaceutical Care Program</th>
<th>Peak Flow Monitoring Care Control</th>
<th>Usual Care</th>
<th>Comparisons Across Treatment Groups</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak flow rate, mean (SE)</td>
<td>995</td>
<td>63.72 (0.58)</td>
<td>64.56 (0.65)</td>
<td>61.82 (0.71)</td>
<td></td>
<td>.006</td>
</tr>
<tr>
<td>Overall HRQOL, mean (SE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>400</td>
<td>4.42 (0.06)</td>
<td>4.30 (0.08)</td>
<td>4.31 (0.08)</td>
<td>.31</td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>595</td>
<td>4.97 (0.08)</td>
<td>4.93 (0.85)</td>
<td>4.83 (0.07)</td>
<td>.23</td>
<td></td>
</tr>
<tr>
<td>Medication compliance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not compliant, %</td>
<td>993</td>
<td>.04 (0.05)</td>
<td>.05 (0.05)</td>
<td>.09 (0.05)</td>
<td>.22</td>
<td>.81 (0.58-1.12) 1.09 (0.80-1.49)</td>
</tr>
<tr>
<td>4-Item measure</td>
<td>995</td>
<td>0.87 (0.05)</td>
<td>0.85 (0.05)</td>
<td>0.92 (0.06)</td>
<td>.57</td>
<td>.90 (0.76-1.06) 0.90 (0.76-1.06)</td>
</tr>
<tr>
<td>Hospital or ED visit COPD</td>
<td>447</td>
<td>.04 (0.05)</td>
<td>.07 (0.05)</td>
<td>.11 (0.06)</td>
<td>.34</td>
<td>.09 (0.36-2.63) 1.08 (0.93-1.25)</td>
</tr>
<tr>
<td>Asthma</td>
<td>653</td>
<td>.04 (0.06)</td>
<td>.08 (0.06)</td>
<td>.12 (0.06)</td>
<td>.24</td>
<td>.03 (0.03-1.20) 0.98 (0.65-1.49)</td>
</tr>
</tbody>
</table>

*Ellipses indicate that the least squares mean from repeated measures analysis of variance was adjusted for baseline and averaged across follow-up times. Means and odds ratios (ORs) are also adjusted for race and pharmacy triplet and, if chronic obstructive pulmonary disease (COPD) is separated, for baseline peak flow rate. CI indicates confidence interval; HRQOL, health-related quality of life; and ED, emergency department.

P value for intervention vs control group contrast is statistically significant accounting for multiple comparisons.
enhancing self-efficacy for monitoring) may increase health services utilization.

The most likely explanation for our findings was that despite our efforts to design a pragmatic program and reinforce its use, it was not used consistently. Notably, pharmacists only viewed data in the study computer half the time patients filled prescriptions, and they documented their actions only 50% of the time those data were viewed. There are several possible explanations for this. First, our intervention was cumbersome and required pharmacists to access data on a separate study computer. When this investigation began, it was not possible to integrate patient-specific data into the regular drugstore computer. Now, those options exist through the intranet. Second, implementation of the program may require release time or other incentives for the pharmacists. Third, although all pharmacists participated in our program, they were not universally enthusiastic about this expanded role. In retrospect, a better strategy may have been to identify 1 enthusiastic pharmacist per store to be responsible for implementing the program in his/her drugstore. Indeed, a recent randomized trial found that an intervention delivered by highly motivated and selected community pharmacists in Canada improved the process of cholesterol risk management; interestingly, unlike our results, patients were not more satisfied with this program.13

Our investigation had several limitations. First, although our overall dropout rate was relatively low (18%), those not completing 12-month interviews appeared to have worse breathing problems, worse HRQOL scores, and less education. These are characteristics of patients who might have benefitted most from our program. Indeed, the rate of breathing-related ED or hospital visits, particularly among patients with asthma, was lower than expected from our previous work.14 Second, the recruitment protocol required to safeguard patient confidentiality resulted in our inability to contact more than half the patients, thus compromising generalizability. Third, several important questions are beyond the scope of this study: Was the observed increase in visits due to increases in ED or hospital use? Were the increased visits clinically appropriate? Was there an effect on the appropriateness of medication regimens? Could the increase in ED visits have accounted for improvements in PEFR (eg, by alterations in medications)? Finally, we cannot determine whether patients’ knowledge that they were being observed influenced self-reported outcomes.

Pharmaceutical care can play an important role in patient care, as supported by a recent American College of Physicians position paper.55 However, data from this study suggest that implementation of the pharmacy care program was poor, perhaps due to limited time or lack of incentives to use the resources provided, and resulted in limited benefits in terms of clinical end points. Given the poor implementation, it is not surprising that our program provided little benefit compared with peak flow monitoring alone. Additional research is needed to determine whether other approaches using pharmaceutical care will improve patients’ outcomes. Such evaluations should be conducted in “real-world” community pharmacies using strategies that are pragmatic in busy retail pharmacies, even though randomized trials conducted in real world settings present methodological and pragmatic challenges.

Author Affiliations: Regenstrief Institute for Health Care (Drs Weinberger, Murray, Harris, McDonald, and Tierney, and Ms Brewer and Smith), Roudebush Veterans Affairs Medical Center (Drs Weinberger and Tierney), Department of Health, Indiana University School of Medicine (Drs Weinberger, Murray, Marrero, Lykens, Harris, Seshadri, Roesner, McDonald, and Tierney, and Ms Caffrey), Indianapolis; and Purdue University School of Pharmacy, West Lafayette, Ind (Dr Murray); CVS Pharmacy, Woodsock R (Mr Newell and Ms Collins). Dr Weinberger is now the Vergil N. See Distinguished Professor of Healthcare Quality Management of Health Policy, University of North Carolina at Chapel Hill.

Author Contributions: Study concept and design: Weinberger, Murray, Lykens, Harris, McDonald, Tierney. Acquisition of data: Weinberger, Murray, Marrero, Brewer, Smith, Newell, Collins, Tierney. Analysis and interpretation of data: Weinberger, Murray, Marrero, Lykens, Harris, Seshadri, Caffrey, Roesner, Newell, Tierney. Drafting of the manuscript: Weinberger, Murray, Brewer, Seshadri, Caffrey, Smith, Tierney. Critical revision of the manuscript for important intellectual content: Murray, Marrero, Brewer, Lykens, Harris, Seshadri, Caffrey, Roesner, Newell, Collins, McDonald, Tierney. Statistical expertise: Seshadri, Caffrey. Obtained funding: Weinberger, Murray, Harris, Tierney. Administrative, technical, or material support: Weinberger, Murray, Marrero, Brewer, Lykens, Smith, Newell, McDonald, Tierney. Study supervision: Weinberger, Murray, Brewer, Collins, McDonald, Tierney.

Funding/Support: Financial support for this project was provided by grant 5 R01 HS09083 from the Agency for Healthcare Research and Quality and the Health Services Research and Development (HSR&D) Service, Department of Veterans Affairs (Research Career Scientist Award to Dr Weinberger). This material is based on work supported in part by the Office of Research and Development, HSR&D Service, Department of Veterans Affairs.

Acknowledgment: We thank Marina Weisburd, CVS District Managers and Supervisors, CVS support staff, the many pharmacists who participated in this study, and our interviewers for their contributions.

REFERENCES
14. Singhal PK, Raish DW, Gupchup CV. The impact of pharmaceutical services in community and ambulatory care setting: evidence and recommenda-

©2002 American Medical Association. All rights reserved.

(Reprinted) JAMA. October 2, 2002—Vol 288, No. 13 1601


