Impacts of a PBM-Based Disease Management Program on Asthma Medication Use

OBJECTIVE: To evaluate the impact of an asthma disease management program conducted by a pharmacy benefit management (PBM) organization.

DESIGN: A prospective analysis of the outcomes of an education-based disease management program for a large population of asthma medication users, compared to the outcomes for a matched longitudinal control group.

SETTING: Merck-Medco Managed Care, L.L.C., a national PBM that manages prescription benefits and provides mail-service and online pharmacy services.

PATIENTS: The intervention group consisted of 19,289 patients with asthma, aged 6 and older, divided into high-risk, low-risk, and maintenance subgroups based on history of asthma medication use. The control group consisted of 19,253 asthma patients matched on age and gender.

INTERVENTIONS: Patients in the intervention group received asthma education program. The control group consisted of 19,253 asthma patients matched on age and gender.

CONCLUSION: A PBM-based asthma-education program can improve asthma therapy by increasing usage of inhaled corticosteroids and reducing reliance on quick-relief medications. These treatment changes are consistent with clinical practice guidelines, and are associated with improved symptom control and reduced health care utilization and costs.

KEYWORDS: Asthma, Disease management, Primary care

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by Richard A. Feifer,
Benjamin Gutierrez, and Robert R. Verbrugge

Asthma is a major health problem in the United States, affecting an estimated 26 million people at some point in their lives. It accounts for approximately 9.8 million physician office visits and more than 1.6 million hospitalization days each year. The disease costs an estimated $12.7 billion annually, including direct health care costs and lost productivity. In spite of improved understanding of the disease and the availability of effective medications, asthma prevalence and mortality have increased over the past two decades.

In an effort to improve the health outcomes for patients with asthma, a series of clinical practice guidelines were issued during the 1990s by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and by the World Health Organization (WHO). The most recent guidelines were issued by the National Asthma Education and Prevention Program (NAEPP) in 1997, under the sponsorship of the NHLBI. The NAEPP guidelines stress the value of daily use of anti-inflammatory controller medications for long-term preventive control of persistent asthma, along with the use of quick-relief medications for the treatment of occasional bronchospasm. The guidelines also emphasize the need to educate patients in self-management skills and encourage a close partnership between patients and their health care professionals to develop and maintain effective treatment plans.

In spite of these national and international efforts, adherence to guidelines is often suboptimal. Population studies have identified patterns of underuse of inhaled corticosteroids (ICCs) and overuse of quick-relief medications in asthma patients. These patterns have been observed in prescribing practices and in patient compliance. In one study, one-third of patients with moderate to severe asthma reported not having an ICS inhaler, even though ICS medications are recommended as first-line therapy in national clinical guidelines. Compliance with therapy was also a factor in the underuse of ICS medications, among patients who had an ICS inhaler, fewer than 50% reported using it daily. The overuse of quick-relief medications also reflects both patient behavior and physician practice. Overuse of quick-relief medications may indicate poor long-term control of a patient's asthma, providing an opportunity for the patient's physician to prescribe a more effective regimen of long-term controller medications.
Impacts of a PBM-Based Disease Management Program on Asthma Medication Use

between guidelines and practice, including patients’ inadequate skills in disease self-management and proper medication use.\(^{11,12}\) Also, the national guidelines call for a redirection of some traditional clinical practices, focusing more on long-term control through the use of anti-inflammatory controller medications and less on episodic symptom management using inhaled short-acting beta-agonists. This “paradigm shift” has required a reeducation process for both physicians and patients.\(^{12}\)

Asthma disease management programs can be effective in altering clinical practice and improving patient outcomes.\(^{14–19}\) These programs have been conducted in a variety of formats, including individual or group training sessions and population-based initiatives where educational materials and counseling are made available to a broad population.\(^{16,17}\) The interventions may be directed primarily to asthma patients (education in self-management skills), their health care professionals (education in the guidelines), or both. Interventions can be conducted in person, by mail, by telephone, via the Internet, or using a combination of these educational channels. Asthma disease management programs have demonstrated many benefits, including reductions in asthma symptoms, improved patterns of medication use, reductions in hospitalization and absenteeism, and reduced health care costs.\(^{14–16,21}\)

Most disease management programs reported in the literature have used face-to-face training methods or are part of broader case management programs for asthma patients.\(^{14–17,21}\) A few population-based disease management programs have been implemented by large managed care organizations (MCOs).\(^{18,19}\) Some of these have been successful in improving patient outcomes and reducing health care expenses.\(^{18–20}\) Pharmacy benefit management (PBM) organizations are well-positioned to have a similar impact on health outcomes. They serve a broad population and their unique access to recent prescription claims data enables them to selectively focus their educational messaging. This study assesses whether a disease management program initiated by a large national PBM can have a favorable impact on clinical practice and patient medication use.

### Methods

#### Identification and Stratification

Participants were members of prescription plans sponsored by large employers, MCOs, Blue Cross and Blue Shield organizations, and government programs; Merck-Medco provided PBM services for these prescription plans. Participants were drawn from plans whose sponsors had chosen to have the asthma program made available to their members. Participants were enrolled in the program from April 1998 through June 1999, based on their retail-pharmacy and mail-service prescription drug claims during the preceding six months. Patients were identified for the program if they were age 6 or older and had received medications typically used for asthma treatment. This included one or more prescriptions for an anti-inflammatory controller medication (inhaled corticosteroid, leukotriene modifier, or mast cell stabilizer), or two or more prescriptions for bronchodilators or theophylline. Patients who had used ipratropium during the preceding year were excluded from the program, since this medication is predominantly prescribed for chronic bronchitis and emphysema.\(^{12}\) Patients were given the opportunity to opt out of the program (by telephone or reply card) if they were being treated for another condition.

Program participants were stratified into three intervention groups based on their pattern of asthma medication use. Patients who had received a prescription for one or more anti-inflammatory controller medications (AICMs) during the prior six months were assigned to a maintenance group; AICMs are the preferred class of first-line controller medication in national guidelines.\(^1\) All other patients (i.e., those who had not received an AICM during the prior six months) were assigned to one of the two primary intervention groups, high-risk or low-risk (see below). These two groups included patients receiving theophylline or long-acting beta-agonists (in the absence of AICMs), since these are not preferred controllers in national guidelines.\(^1\)

High-risk group. Patients were assigned to the high-risk group if their medication use during the prior six months indicated suboptimal therapy, placing them at higher risk for poor symptom control. This included patients who showed excessive reliance on bronchodilators (more than eight puffs per day of inhaled short-acting beta-agonists), exclusive use of salmeterol or theophylline, or combined use of theophylline and beta-agonists (short-acting or long-acting). The high-risk group also included patients who had used oral corticosteroids for more than 30 days in conjunction with bronchodilators. All of these high-risk profiles are inconsistent with the NAEPP guidelines, which discourage reliance on bronchodilators (without anti-inflammatory controllers) for the control of persistent asthma.\(^5\) The guidelines also discourage the use of oral corticosteroids, except as a short course to gain symptom control, or in some cases of severe persistent asthma.

Low-risk group. The remaining patients were assigned to the low-risk group. As in the high-risk group, these patients had not used AICMs during the prior six months. Unlike the high-risk group, however, they did not demonstrate overreliance on bronchodilators or oral corticosteroids for asthma control. Patients in the low-risk group received a brief questionnaire by mail shortly after program enrollment. The questionnaire asked about the types and frequency of their asthma symptoms and the types of medications they were using. The primary objective was to identify patients who might be experiencing a more persistent form of asthma and receiving suboptimal therapy. Physicians caring for these patients were informed of the questionnaire results and were asked to review their patients’ therapy in the context of national guidelines. Questionnaire responses
Impacts of a PBM-Based Disease Management Program on Asthma Medication Use

TABLE 1  Baseline Characteristics of Intervention and Control Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention Group (n=19,289)</th>
<th>Control Group (n=19,253)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>0.98</td>
</tr>
<tr>
<td>6-17</td>
<td>17.3%</td>
<td>17.3%</td>
<td></td>
</tr>
<tr>
<td>18-34</td>
<td>11.9%</td>
<td>11.7%</td>
<td></td>
</tr>
<tr>
<td>35-64</td>
<td>50.2%</td>
<td>50.3%</td>
<td></td>
</tr>
<tr>
<td>65+</td>
<td>20.7%</td>
<td>20.7%</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td>0.87</td>
</tr>
<tr>
<td>Male</td>
<td>42.5%</td>
<td>42.6%</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>57.5%</td>
<td>57.4%</td>
<td></td>
</tr>
</tbody>
</table>

Note: Percentages do not all sum to 100 because of rounding.
*Age at end of baseline period.

were designed to aid physicians in making individual treatment decisions and were not aggregated across patients for analysis.

Control group. In order to control for other factors that might influence changes in patients’ pharmacetical therapy, a comparison group of asthma patients was identified for the analysis. The control group was drawn from Merck-Medco clients that chose not to offer the asthma program to their plan members. Patients were identified for the control group and stratified into high-risk, low-risk, and maintenance groups using the same criteria as those used for the program participants. Control-group patients were selected randomly and matched to the intervention groups on age, gender, and date of entry into the study. The distribution of intervention and control group patients by age and gender is shown in Table 1, above. Patients in both groups were well represented in all parts of the country and in a wide range of benefit plan types.

Intervention and control groups differed somewhat in baseline use of AICMs; for this reason, the outcomes analysis focused on changes in medication use relative to baseline. Patients in the high-risk intervention group showed lower use of AICMs during the year prior to program entry, compared to controls (10.0% versus 14.6%, p<0.01). There was no difference in baseline AICM use between low-risk program participants and controls (p=0.98); both groups showed 6.0% use during the year prior to program entry.

Interventions
Program participants enrolled in the intervention groups all received educational materials by mail on a quarterly basis. For patients under the age of 18, these mailings were addressed to the parent or guardian. The educational materials stressed the role of anti-inflammatory controller medications in maintaining long-term control of asthma. They also provided self-management tips in such areas as inhaler use, peak-flow meter use, and trigger avoidance. Participants were encouraged to work with their health care professionals to develop asthma action plans and discuss the best therapy for their condition. All participants had access to a toll-free telephone counseling service staffed by licensed pharmacists who had received specialized training in asthma and its treatment. Participants in the high-risk group were offered opportunities to receive a free peak-flow meter, which was mailed with instructions for use.

After high-risk and low-risk patients had participated in the program for six months, a monthly retrospective review was initiated on their pharmacy claims since program enrollment. The purpose of this review was to identify patients who had begun using an AICM while enrolled in the program and to encourage them to continue with their therapy as directed by their physician. In addition to the other program interventions, these patients received refill reminders if they were more than 30 days late in refilling an AICM prescription.

Physicians were notified that their patients had been enrolled in the program, and they were offered samples of the same educational materials that their patients received. Physicians of high-risk patients were sent a summary of the NAEPP guidelines outlining optimal medication management for asthma patients. This summary was also sent to the physicians of low-risk patients whose questionnaire responses indicated that a patient’s therapy might be suboptimal relative to the guidelines.

Patients with allergic rhinitis comorbidity received some additional interventions to help them manage their condition. They were identified for these allergy interventions if they had two or more prescription claims for allergy medications during the six months prior to program enrollment. Allergy medications included nasal corticosteroids, nasal mast cell stabilizers, and antihistamines (oral or nasal). All patients with allergic rhinitis comorbidity were offered the opportunity to request a complimentary educational video on controlling environmental triggers. These patients were also sent seasonal pollen alerts, encouraging them to be prepared with appropriate medications and other control measures as necessary. Patients in both the high-risk and low-risk groups were eligible to receive these interventions. Assessing the effects of these specific interventions was outside the scope of the present study.

Outcome Measures
The primary program objective was to increase the use of AICMs by patients in the high-risk and low-risk intervention groups. Patients in the maintenance group were excluded from further analysis. The percentage of patients receiving an AICM prescription was measured for the 12-month period prior to program enrollment (the baseline period) and the 12 months following program enrollment (study period). The primary measure was the change in percentage AICM use between the
Impacts of a PBM-Based Disease Management Program on Asthma Medication Use

Baseline period and study period. This was computed for all AICMs in aggregate, and then separately for each class of AICM (inhaled corticosteroids, leukotriene modifiers, and mast cell stabilizers). Although the program used six months of drug claims data to identify asthma patients and to stratify them into groups, 12-month baseline and study periods were used for program evaluation. Because patients with asthma may have seasonal fluctuations in their medication use, a 12-month analysis window was used to mitigate the impact of seasonal fluctuations on the analysis. Only patients with continuous benefits eligibility throughout the baseline and study periods were included in the analysis.

One expected impact of increased AICM use is a reduction in the reliance on inhaled short-acting beta-agonists for asthma control. To assess this, the use of inhaled short-acting beta-agonists was measured for the six-month period prior to getting an AICM, and compared to their usage during the six-month period starting 30 days after they began AICM therapy. The 30-day period is a start-up period to allow the controller medication to have an effect on symptom control. Usage was measured in average puffs per day, calculated by adding the number of puffs (doses) in all of the inhaled short-acting beta-agonist canisters dispensed during a time period, and dividing by the number of days in the time period. Because of differences in canister capacity across manufacturers, this analysis was conducted individually for each product. The measure may be affected by multiple, overlapping purchases of canisters (e.g., separate canisters for school and home use). However, this potential complication would apply to both of the analysis periods (pre and post); when averaged over a large population and a long time period, it is unlikely to be a source of confounding.

### TABLE 2 Impact of Program on Use of Anti-inflammatory Controller Medications (AICMs)

<table>
<thead>
<tr>
<th>Type of Medication</th>
<th>Subgroup</th>
<th>Intervention Group (% Use)</th>
<th>Control Group (% Use)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline Period</td>
<td>Study Period</td>
<td>Change*</td>
</tr>
<tr>
<td>All anti-inflammatory controllers (combined)</td>
<td>High-risk</td>
<td>10.0</td>
<td>27.8</td>
<td>17.8</td>
</tr>
<tr>
<td></td>
<td>Low-risk</td>
<td>6.0</td>
<td>18.7</td>
<td>12.7</td>
</tr>
<tr>
<td>Inhaled corticosteroids</td>
<td>High-risk</td>
<td>4.8</td>
<td>19.8</td>
<td>15.0</td>
</tr>
<tr>
<td></td>
<td>Low-risk</td>
<td>3.8</td>
<td>14.4</td>
<td>10.6</td>
</tr>
<tr>
<td>Leukotriene modifiers</td>
<td>High-risk</td>
<td>5.9</td>
<td>13.1</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td>Low-risk</td>
<td>2.0</td>
<td>5.9</td>
<td>3.9</td>
</tr>
<tr>
<td>Mast cell stabilizers (cromolyn, nedocromil)</td>
<td>High-risk</td>
<td>0.3</td>
<td>1.2</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>Low-risk</td>
<td>0.5</td>
<td>1.8</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Note: Table shows the percentage of patients who received at least one prescription for the specified type of medication. Usage is shown both before (Baseline) and after (Study) program entry. For the Intervention Group, High-risk n=4,216 and Low-risk n=4,591. For the Control Group, High-risk n=3,830 and Low-risk n=2,291.

*Change=Percentage for study period-Percentage for baseline period.

### TABLE 3 Impact of Program on New Medication Starts and Returns to Therapy

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Measure</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>p value</th>
</tr>
</thead>
</table>
|          | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starts | % returning | % new starters and returns to therapy.

Note: Table shows the percentage of patients in each group who received at least one prescription for an anti-inflammatory controller medication (AICM) during the study period. Results are shown for patients who had no prior use of AICMs during the preceding 12-month period (% new starts), and for patients who had prior use of AICMs during that period (% returning to therapy).
Impacts of a PBM-Based Disease Management Program on Asthma Medication Use

Statistical Methods
Changes in AICM use between baseline and study periods, comparing intervention and control groups, were tested for statistical significance using a chi-square test as described in Fleiss. Chi-square tests were also used to evaluate differences between intervention and control groups in baseline age and gender, baseline AICM use, and study-period AICM use. Differences in beta-agonist use were evaluated using paired t-tests.

Results

Use of Anti-inflammatory Controllers
The primary outcome of interest was the impact of the program on the use of AICMs among people who had not used them during the six months prior to program entry. These results are summarized in Table 2, page 463. The table shows the percentage of patients using AICMs during the baseline and study periods, for both intervention and controls. Results are shown for all AICMs combined and for each of the three subtypes of AICM (inhaled corticosteroids, leukotriene modifiers, and mast cell stabilizers). The primary measure is the change in AICM use between baseline and study periods.

Both intervention and control groups showed increases in AICM use, but the increases were significantly greater for participants in the intervention groups (both high-risk and low-risk). The absolute levels of AICM use tended to be higher for high-risk patients than for low-risk patients, across both baseline and study periods.

Among the three subtypes of AICM, only inhaled corticosteroids showed a statistically significant increase in use by program participants compared to controls. This effect was observed for both high-risk and low-risk patients in the intervention group. Leukotriene modifiers and mast cell stabilizers showed trends in the direction of increased use by program participants, but the changes were not significant when compared to the control group.

Most patients had not used AICMs during the 12 months prior to program entry, but some patients had used AICMs at some point during the prior year (see the percentages for the baseline period in Table 2). To determine which patients were more strongly influenced by the program, the high-risk and low-risk groups were broken into two subgroups for analysis purposes. One subgroup had no AICM claims during the 12 months prior to program entry. Patients in this subgroup were considered “new starts” if they received an AICM during the 12 months after they entered the program. The second subgroup had received at least one AICM during the baseline period (specifically, between 6 and 12 months prior to program entry). Patients in this subgroup were considered to be “returning” to therapy if they received an AICM during the 12 months after they entered the program.

The results for patients with and without prior AICM use are shown in Table 3, page 463. Among prior users in the high-risk group, the program had a strong impact on returning patients to AICM therapy; the percentage returning to therapy was significantly higher for the intervention group than for controls. There was no significant difference between intervention and control groups in the percentage of high-risk users who were new to AICM therapy. In the low-risk group, the program had a strong and consistent influence on patients with and without prior AICM use. Compared to controls, the percentage of low-risk patients receiving AICMs was significantly higher for both types of program participants, those returning to therapy and those who were new to therapy.

Use of Inhaled Beta-agonists
The use of inhaled short-acting beta-agonists was tracked for program participants who began using AICMs during the study period. Usage was compared before and after AICM therapy began. The pre-AICM period was the six months prior to getting the first AICM prescription. The post-AICM period started 30 days after getting the first AICM prescription, and extended for six months. The results are displayed in Figure 1, this page, for patients in the high-risk and low-risk intervention groups, and for the two groups combined. The use of inhaled short-acting beta-agonists dropped significantly among program participants who began using AICMs; overall usage dropped 11%. The reduction was stronger for participants in the low-risk group, where usage dropped 18%. For participants in the high-risk group, usage dropped 8%.
group, the reduction was of borderline significance.

Limitations

There are some inherent limitations to a population-based study of this kind. Participants are drawn from a population defined by the plan members of client companies, rather than drawing from the national population as a whole. A sample of this type can be broad in its demographic composition (see Table 1, page 462), but it may not match the frequency distribution of the population as a whole. It is also likely that the sample includes some patients who were being treated for conditions other than asthma (such as chronic bronchitis or emphysema), in spite of the opportunities they had to opt out of the program. This is a challenge for any program that identifies patients based on their history of prescription drug use, since some medications are not uniquely prescribed for a specific condition. However, the effect of including some patients with other conditions would typically be to dilute the measured impact of a condition-specific program. The positive results presented here may therefore underestimate the full impact of the program on enrolled asthma patients.

A related limitation derives from the process of stratifying patients into groups based on their patterns of medication use. This is appropriate for a study that seeks to measure changes in medication use as its primary dependent variable. However, it can be problematic to infer disease severity or day-to-day usage from a patient’s medication purchases, so the subgroups are likely to be somewhat heterogeneous in severity and compliance. For example, patients in the high-risk group share a set of clinical indicators of suboptimal therapy and greater disease severity, but their baseline medications vary, and their baseline levels of compliance may vary as well. The heterogeneity in the intervention groups requires some caution when drawing generalizations from the study.

Finally, the educational interventions in this study were directed to patients and their physicians, in parallel. This is probably the most effective means of influencing treatment changes, and the strategy is consistent with the NAEPP guidelines for improving physician-patient partnership in asthma care. A disadvantage of this approach is that it makes it difficult to separate the effects of the patient-directed and physician-directed interventions. This exemplifies a more general limitation of programs with multiple interventions (newsletters, telephone counseling, pollen count alerts, physician mailings, etc.); it is difficult to determine which of the interventions had the strongest influence in achieving program outcomes.

Discussion

Over the past few decades, there has been a significant shift in the relative importance ascribed to bronchoconstriction and inflammation in the pathophysiology of asthma. Asthma has been considered historically to be an episodic disorder characterized by acute bronchoconstriction. It is now understood to be a long-term inflammatory condition that makes the airways more reactive to stimuli such as allergens, airborne irritants, and other triggers. This change in the medical view of asthma has required a significant shift in treatment strategies. Historically, treatment often focused on the use of bronchodilators to control episodes of asthma symptoms. More recent guidelines, like those issued by NAEPP in 1997, have advocated a long-term, preventive approach to the disease, including increased use of anti-inflammatory medications to control the underlying condition. The long-term use of AICMs has been shown to improve asthma symptoms and reduce the need for bronchodilators for episodic symptom relief.

Translating national guidelines into changes in clinical practice and patient behavior can take many years. Population-based studies continue to find significant patterns of underuse of controller medications and overreliance on bronchodilators for symptom control. In the present study, 22% of participants (those assigned to the high-risk group) had a pattern of medication use indicative of more severe asthma symptoms and suboptimal therapy. Patients in this subpopulation had no recent use of AICMs, generally relied on bronchodilator medications for asthma control, and showed a pattern of suboptimal therapy compared to guidelines. Patients in the low-risk group (24% of participants) were similar in that they showed no recent use of AICMs to manage their asthma; for patients with persistent asthma, this also represents suboptimal therapy. Overall, up to 46% of patients with asthma were likely receiving suboptimal therapy compared to national guidelines.

In this program, an educational intervention aimed at both patients and physicians had a significant impact on the pattern of prescribed medications. The program increased the overall use of AICMs in both intervention groups. The program was effective in stimulating new or renewed usage of controller medications by many patients who had not recently been using them. These changes are consistent with national guidelines and represent a more optimal therapeutic regimen for long-term control. In other population-based and clinic-based studies, increased use of AICMs has been associated with improved symptom control, improved lung function, reduced hospitalization, and an overall reduction in health care costs.

The primary impact of the program was an increase in the use of inhaled corticosteroids. Other classes of AICM (leukotriene modifiers and mast cell stabilizers) showed trends in the direction of increased use, but the changes were not significant when compared to the control group. It is worth noting that there were substantial increases in the use of leukotriene modifiers during the study period, for both the intervention and control groups (see Table 2). These increases reflect the emerging acceptance of these agents in asthma therapy during the period of the study, which began shortly after this new class of controller medications was introduced.
Impacts of a PBM-Based Disease Management Program on Asthma Medication Use

There were some notable differences in program impacts across subgroups. The program was more consistent in influencing the therapy of participants with prior AICM use, compared to participants with no prior AICM use during the preceding year. For participants with prior use, the program stimulated increased use of controllers by participants in both the high- and low-risk subgroups. For participants with no prior use, only the low-risk subgroup showed a significant number of new medication starts as a result of the intervention. The stronger impact of the program on those who have prior control experience suggests that an educational intervention of this type may be especially effective in motivating people to return to therapy.

The lack of a significant effect on "new starts" for the high-risk subgroup is somewhat surprising, given that this group is characterized by suboptimal therapy and presumably has more incentive to achieve better control. It is worth noting that high-risk participants (across both intervention and control groups) showed a much higher frequency of new controller starts than low-risk participants. This suggests that the patients at greatest need for improved therapy were often getting the clinical attention they needed, for reasons beyond the program intervention itself.

A desirable outcome of increased controller use is a reduction in patients' reliance on bronchodilators for symptom control. One of the guiding principles of the NAEPP therapy guidelines is to achieve control of the inflammatory process through consistent use of controller medications, thereby reducing acute flare-ups and the need for quick-relief medications. In this study, there was a significant overall decrease in the use of inhaled beta-agonists among people who started using controller medications. This provides strong validation that the program was effective in shifting therapy in the direction associated with more optimal health outcomes.

The impacts on beta-agonist use were stronger for the low-risk group than for the high-risk group, for reasons that are unclear. The high-risk group was heterogeneous—not all of the participants were heavy users of inhaled beta-agonists during the baseline period—which may have reduced sensitivity to the program's impact on beta-agonist use in that group.

A primary objective of population-based disease management programs is to produce changes in clinical practice that improve health outcomes for patients. The strategy includes educating patients to take an active role in managing their condition, and motivating them to work with their health care professionals to develop the most effective treatment plan. The results of this study demonstrate that a PBM-based disease management program can be very effective in stimulating changes to therapy in a favorable direction. Increasing patients' awareness of their condition and their treatment options can have a beneficial effect on their therapeutic regimen. Since these changes can only be accomplished in partnership with their health care professionals, education of physicians is also an important part of the program.

When implementing a disease management program, a PBM has the advantage of being able to track medication use closely, both what is dispensed and when it is dispensed. This enables a PBM to focus its messaging on a patient's specific medication regimen and refill activity. On the other hand, a PBM does not have the kind of face-to-face interaction that is possible in a clinic-based program. For reasons of scale, it is generally limited to educational mailings, telephone counseling services, and Internet-based interventions. Also, unlike many managed care environments, a PBM cannot directly influence the broader treatment decisions made for a patient. As this study demonstrates, a PBM can have a significant impact on these decisions, but the impact comes more indirectly through education and motivation.

Conclusion

This study demonstrates that a PBM-based disease management program can produce favorable changes in asthma medication therapy, including increased use of AICMs and decreased reliance on inhaled beta-agonists. These changes are associated with improvements in asthma control and reductions in overall health care expenses. Educational interventions appear to be especially effective in motivating people with some controller experience to return to therapy.

References

11. Legorreta AP et al. Compliance with national asthma management guide-
Impacts of a PBM-Based Disease Management Program on Asthma Medication Use


