RESEARCH

The Asheville Project: Long-Term Clinical, Humanistic, and Economic Outcomes of a Community-Based Medication Therapy Management Program for Asthma

Barry A. Bunting and Carole W. Cranor

ABSTRACT

Objective: To assess clinical, humanistic, and economic outcomes of a community-based medication therapy management (MTM) program for 207 adult patients with asthma over 5 years.

Design: Quasi-experimental, longitudinal pre–post study.

Setting: 12 pharmacy locations in Asheville, N.C.

Patients/Other Participants: Patients with asthma covered by two self-insured health plans; professional educator at Mission Hospitals; 18 certificate-trained community and hospital pharmacists.

Interventions: Education by a certified asthma educator; regular long-term follow-up by pharmacists (reimbursed for MTM by health plans) using scheduled consultations, monitoring, and recommendations to physicians.

Main Outcome Measures: Changes in forced expiratory volume in 1 second (FEV_1), asthma severity, symptom frequency, the degree to which asthma affected people's lives, presence of an asthma action plan, asthma-related emergency department/hospital events, and changes in asthma-related costs over time.

Results: All objective and subjective measures of asthma control improved and were sustained for as long as 5 years. FEV_1 and severity classification improved significantly. The proportion of patients with asthma action plans increased from 63% to 99%. Patients with emergency department visits decreased from 9.9% to 1.3%, and hospitalizations from 4.0% to 1.9%. Spending on asthma medications increased; however, asthma-related medical claims decreased and total asthma-related costs were significantly lower than the projections based on the study population's historical trends. Direct cost savings averaged $725/patient/year, and indirect cost savings were estimated to be $1,230/patient/year. Indirect costs due to missed/nonproductive workdays decreased from 10.8 days/year to 2.6 days/year. Patients were six times less likely to have an emergency department/hospitalization event after program interventions.

Conclusion: Patients with asthma who received education and long-term medication therapy management services achieved and maintained significant improvements and had significantly decreased overall asthma-related costs despite increased medication costs that resulted from increased use.

Keywords: Asheville Project, medication therapy management, asthma, health care costs, health outcomes.

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Despite effective treatment modalities, asthma continues to be a major problem in the United States. According to the American Lung Association, more than 20 million Americans had asthma in 2002 and the incidence was rising. In 2001 asthma was the reason for 1.9 million ED visits. Direct costs in 2002 were estimated at $9.4 billion, with an additional $4.6 billion in indirect costs related to loss of work, lost school days, and mortality.[1]

In 1991 the National Asthma Education and Prevention Program (NAEPP), coordinated by the National Heart, Lung, and Blood Institute, published the *Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma,* which was updated it in 1997 and 2002.[2–4] However, Legorreta and colleagues[5] found the original guidelines to have minimal effect on routine care of patients with asthma in a study conducted 7 years following their publication. Studies conducted before and after the issuance of the guidelines demonstrated ongoing problems with underprescribing of controller medications, nonadherence to medications, inability to correctly administer medications including improper inhaler technique, poor patient understanding of their disease, poor understanding of appropriate treatment during acute episodes, and overuse of quick-reliever medications.[6–18]

Different approaches to the care of patients with asthma are necessary. The need to improve patients' knowledge, more frequent patient monitoring, and targeting the behavior of both prescribers and patients in ways that result in more appropriate medication use are highlighted in the literature. Because medications are critical in the management of asthma and pharmacists are highly educated and knowledgeable about medications, pharmaceutical care models might reasonably be considered to determine whether they could provide effective approaches in the improvement of asthma outcomes.

A Medline search revealed 18 asthma outcomes studies that reported on pharmaceutical care interventions for asthma patients and published subsequent to the original 1991 NAEPP guidelines.[19–36] Improved outcomes, indicated by objective measures, were reported in 13 of these studies, and negative or equivocal outcomes were reported in 5 studies. Negative or equivocal reports shared a common theme: a variety of factors led to minimal pharmacist interaction with patients and other types of participation, most commonly because of a lack of time and reimbursement for such interactions.

Previous experience of the authors with a community-based pharmacist-driven diabetes care model, The Asheville Project, led to consideration of the application of this model to an asthma population.[37]

A program based on this model was implemented for asthma patients in January 1999 for employees of the City of Asheville and Mission Hospitals. As in the diabetes program, the employers agreed to waive disease-related medication copayments, pay for self-care education, and compensate pharmacists and an educator for their cognitive services.

Objective

The objective of this study was to assess the clinical, humanistic, and economic outcomes of a pharmacist-driven medication therapy management (MTM) model for patients with asthma. These patients were employees, spouses, or covered dependents of two large employers that together have approximately 12,000 covered lives in their self-insured health plans.

Methods

Two employers who offered MTM services for employees with diabetes began offering a similar service to their employees with asthma. The unique components of the program were self-care education provided by a certified asthma educator at the Mission Hospitals' Health Education Center, MTM services by community and hospital pharmacists, and financial incentives consisting of waived medication copayments on asthma-related medications.

AT A GLANCE

Synopsis: Significantly improved health and economic outcomes were realized by participants in this extension of the Asheville Project, one that involved 207 employees with asthma. Education and medication therapy management (MTM) services, along with incentives such as copayment waivers and payment for MTM services by the health plans, were provided for 5 years. All measures of asthma control—clinical and humanistic—improved significantly and were sustained for the duration of the study. Emergency department visits and hospitalizations decreased significantly. Health plan provider spending for asthma-related medications increased, but spending for other medical claims decreased, and actual spending was significantly lower than projected. Indirect costs of absenteeism and lost productivity significantly decreased.

Analysis: These results demonstrate that the model of care for patients with diabetes successfully implemented in the Asheville Project can be used to design MTM programs for patients with a second chronic disease, asthma. These results add to the mounting evidence that MTM programs produce overall cost savings despite increased medication use. The Asheville Project—a simple community-based model that uses readily available resources to improve health outcomes for patients with diabetes and asthma—is a cost-effective model and should be considered for populations with other chronic medical conditions in which appropriate medication use and self-care are important.

All services and incentives were paid by the employer's health plan. Participating pharmacists received asthma certificate training recognized by the North Carolina Center for Pharmaceutical Care, a service of the North Carolina Association of Pharmacists.

This study was approved by the Institutional Review Board (IRB) of Mission Hospitals. Informed consent was obtained and Authorization for the Use and Disclosure of Protected Health Information was obtained per IRB-approved processes.

Intervention

All patients in the study agreed to receive one-on-one asthma education provided by a certified asthma educator in one or two individual sessions for 60–90 minutes and to be matched with a participating care manager/coach with whom they would meet on a regular, long-term basis. Patients chose their care manager from a list of participating pharmacist providers in the community. Patients agreed to meet with their care manager as frequently as once a month, however, the frequency of counseling sessions was ultimately determined by the care manager. During the study period these counseling sessions averaged 30 minutes every 3 months. These one-on-one, appointment-based encounters were conducted in a semiprivate or private counseling area. Patients could disenroll at any time, but doing so would forfeit future medication copayment waivers.

Patients who had not been provided an asthma action plan by their physician were provided one based on NAEPP guidelines and their current prescribed medications. This action plan was regularly reviewed with patients and updated at subsequent care manager sessions. Medication assessments were provided, including a review of patterns of reliever and controller medication use. Inhaler technique was consistently assessed by having patients demonstrate their administration technique. Symptom frequency was regularly assessed and spirometry and/or peak flow meter results were reviewed with the patient. A review of known triggers and environmental control measures was also conducted. Recommendations were made to patients' physicians, most commonly via faxes, when problems or the potential for improvements in therapy were identified.

Study Design

This was a quasi-experimental, longitudinal, pre–post study. Patients were City of Asheville or Mission Hospitals employees and covered spouses and dependants with asthma who agreed to participate in an asthma wellness program sponsored by their employer. The providers were community and hospital pharmacists and a professional educator. A total of 18 pharmacists at 12 community pharmacy locations and a hospital-based education center clinic participated. Approximately 75% of patients were followed in community pharmacy settings and 25% in a hospital clinic setting. Approximately 50% of the community settings were independent pharmacies, 45% were regional chains, and 5% were national chains. Pharmacists received certificate training and provided MTM services to study participants. The asthma educator was trained in the National Respiratory Training Centers certificate program, which is an established United Kingdom training program that is now being used in the United States to train asthma educators.[a]

Inclusion and Eligibility Criteria

All patients covered by the participating employers' health plans with a diagnosis of asthma, regardless of their baseline control or severity, were eligible for enrollment. This program differs from many disease management programs in that patients were not specifically targeted because of a history of emergency department (ED) visits, hospitalizations, or high utilization of health plan dollars. Participation in this asthma care program was voluntary and enrollment occurred continuously from January 1, 1999, to December 31, 2003.

A total of 207 adults aged 19 or older and 45 children participated in the program. Because a majority of our outcomes data were on the adult population and children's data could not be consistently grouped with adult data due to differences in some key outcome indicators (e.g., spirometry is unreliable in young children, schooldays missed versus workdays), the pediatric data will be analyzed separately at a later date.

Patients were eligible for inclusion in the clinical analysis if they received any program intervention and if data were available to classify the patient's asthma severity using forced expiratory volume in 1 second (FEV_1) and/or NAEPP symptom criteria. Patients were eligible for humanistic analysis if they received any intervention and gave baseline and postintervention responses to a standardized asthma questionnaire, the Asthma Outcomes Monitoring System (AOMS) (Lincoln, R.I., QualityMetric Inc.). Patients were eligible for economic analysis if they received any interventions, asthma-related health care costs were available from insurance and prescription claims for at least 6 months preceding their enrollment in the study, and for as long as data were available postintervention. When financial data were available for a period of less than 1 year, but greater than 6 months, the data were annualized.

Outcome Definitions

The clinical outcomes assessed in this study were changes in FEV_1 over time, mean study group FEV_1 at baseline and at the most recent annual follow-up, percentage of patients with normal FEV_1 (80% or above) at baseline and the most recent annual follow-up, percentage of patients with severe asthma (FEV_1 of 60% or less) at baseline compared with most recent annual follow-up, changes in asthma severity classification over time, comparison of objective versus self-reported changes in severity, frequency of asthma symptoms at night, frequency of asthma attacks or episodes, and other key NAEPP symptom indicators.

Humanistic outcomes were defined as changes in responses to

statements that described how asthma was affecting patient's lives (e.g., "Asthma has limited my performance at work, school, or other activities"). Patients were asked to rank the degree to which asthma had affected them using standard AOMS questions. Subsequently, a Likert-type numeric rank score was assigned to responses, converting them into a summated scale that could be statistically analyzed.

For the bivariate analyses, the outcomes were expressed as the mean change over time. Severity classification was based on NAEPP guidelines.[3] For example, *normal* was defined as an FEV_1 $\geq 80\%$ relative to reference or predicted values, and *severe persistent asthma* was defined as an $FEV_1 \leq 60\%$. NAEPP classification criteria, FEV_1 and/or symptom criteria, were used to classify patient's asthma as severe persistent, moderate persistent, mild persistent, or mild intermittent.[3]

We examined the number of ED visits and hospitalization, and asthma-related health care costs over time. Economic outcomes and ED/hospital event records were obtained from medical and prescription claims provided by the employers through their claims processing organizations.[b] The mean annual expenditures were compared over time. Specifically, direct medical costs were defined as the amount paid by the employer (as the payer) for asthma-related physician visits, ED visits, hospitalizations, prescription drugs, cognitive MTM services, educator fees, and medication copayment waivers.

Indirect costs were defined as the cost to the employer of lost work hours due to absenteeism and presenteeism. We assessed absenteeism by asking patients to report the average number of workdays per year they missed due to their asthma before and after entering the program. We assessed presenteeism by asking patients to report the average number of hours per year that were totally lost or wasted while at work because they were not able to do their normal amount of work due to their asthma before and after they entered the program.

Data Sources

Demographic data were obtained from enrollment questionnaires and medical records. Clinical and humanistic data were gathered from spirometry testing and a standardized asthma questionnaire. Data regarding direct costs of care were obtained from patient's medical records, insurance and prescription claims, and employer records. Indirect costs were calculated based on self-reported patient data.

Data Measurement

In this intention-to-treat study, all patients enrolled in the program who received any intervention were included in the analyses whenever data were available. In some cases, patients had no historical cost data because they were new employees at the time of enrollment, however, we were able to include them in the clinical group because baseline and follow-up clinical data were available.

Similarly, patients for whom baseline and follow-up cost data were available but were missing clinical data were included in the cost analysis but not the clinical analyses. Spirometry was performed at baseline and approximately annually thereafter using the same spirometer and the same tester.

Direct medical costs were determined from all available claims data, including post-dropout data for as long as it was available. A minimum of 6 months of preintervention insurance claims were required; when a patient's cost data was available for at least 6 months but less than a full year, we annualized costs for that year. This adjustment applied to patients who enrolled but had not been employed for a full year and those who left the health plan and had less than a year's worth of claims data available. We determined asthma-related costs per patient per year and adjusted to 2003 U.S. dollars using the U.S. Consumer Price Index for Medical Care.

Since this was an open-enrollment study of usual patient care rather than a protocol-driven evaluation, the timing of baseline and follow-up spirometry measurements was not standardized. Additionally, since some patients had more than one follow-up FEV_1 measurement during the year, we used the follow-up FEV_1 values closest to each patient's anniversary enrollment date in the analyses. Despite the decreased number of evaluable FEV_1 measurements afforded by this decision, some patients have seasonal variation, and we thought the value of annual comparisons outweighed the loss of some data points.

Data Analysis

Nonparametric statistics were performed on paired data to analyze outcomes of the intervention. We compared preintervention baseline data with data for each available follow-up date. For continuous data, we used the Wilcoxon signed rank test, and for counts, we used the McNemar chi-square test. Because multiple comparisons were involved, we adjusted critical P values for statistical tests under the assumption that a critical value of P is .05 for only one test of significance. We used the Bonferroni correction, the most conservative of the adjustment methods. Our major endpoints for comparison were the 1-year follow-up from baseline, although we displayed the 6-month follow-up if these were the only available data. Using the Bonferroni correction, the equivalent critical P value is .01 for five follow-up comparison time periods. We did not use repeated-measures analysis of variance because of variation in population size and composition at each follow-up.

We are reporting three sets of data over time: changes in FEV_1, changes in asthma severity classification, and changes in economic outcomes. Other data presented are baseline compared with the most recent follow-up. Because of the open-enrollment format with patients entering the program at different times, we needed to determine each patient's individual baseline year in a consistent and systematic way. For the clinical and humanistic data this was easily established by using their enrollment date and subsequent annual evaluation dates thereafter. However, since the financial

data were based on medical and prescription claims that were only available by calendar year, it was necessary to establish a convention for assigning a calendar year enrollment date to each individual. We assumed that if patients enrolled during the latter half of a year (July 1 or later) they would have minimal opportunity for program interventions to affect their financial outcomes that year, so that year was considered their baseline financial year. If they enrolled early in a year (before July 1) the program interventions would have been in place long enough to have an opportunity to influence their financial outcomes during that calendar year, and their baseline year was then defined as the prior calendar year. We were thus able to group all data into preintervention baselines and to group patients by time in the program, irrespective of when they enrolled. For the financial cost analysis we examined 3 years of historical financial data and designated the year before enrollment as baseline year 1 (BY1), data from 2 years prior as BY2, and data from 3 years prior as BY3. Postintervention years were simply designated as program years 1, 2, 3, 4, and 5.

Results

Demographics

A total of 207 patients, 58 (28%) men and 149 (72%) women participated in this project during the study period. Of these, 24 (12%) were black and 183 (88%) were white. The mean age of participants was 41.7 years (men, 40 years; women, 42 years).

Patient's Baseline Characteristics

Inclusion criteria were met by 207 adult patients. Patients were eligible for the clinical group when data were sufficient to classify their asthma severity using NAEPP criteria at baseline and at least one follow-up point (paired comparison); 126 patients were eligible for one or more of the clinical comparisons. Patients were eligible for the humanistic cohort if they completed an AOMS questionnaire at baseline and at least one follow-up; 76 patients eligible for one or more of the humanistic comparisons. Patients were eligible for the economic cohort if they had at least 6 months of historical medical or prescription claims data; 202 patients met inclusion criteria using insurance and prescription claims for one or more of the economic comparisons.

Severity Classification

Using NAEPP classification criteria, we classified patients into one of four standard asthma severity categories—severe persistent, moderate persistent, mild persistent, or mild intermittent—and made comparisons of baseline with follow-up intervals.

Of the 207 study patients, 103 were in the program for at least 1 year and had sufficient data to allow paired pre–post comparisons of severity. At baseline, 82% of patients were classified with severe or moderate persistent asthma and 18% were classified with
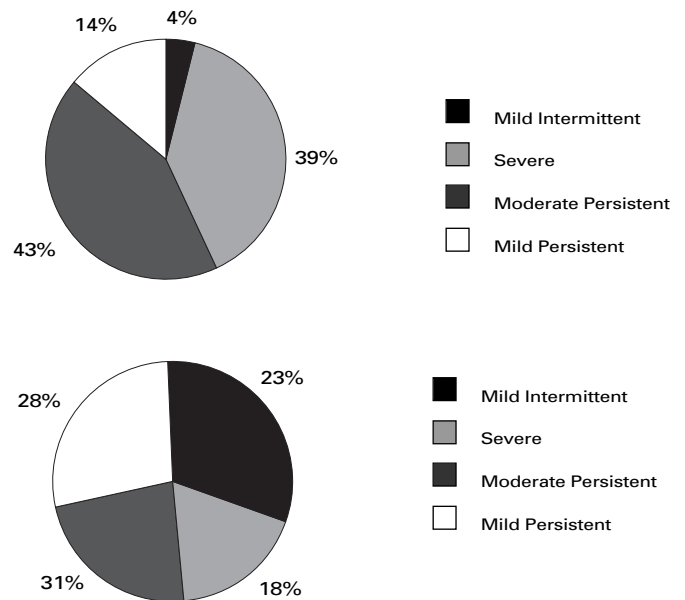

Figure 1. NAEPP Asthma Severity Classification at Baseline Versus Last Follow-up (n = 103; paired data)

mild persistent or mild intermittent asthma. These percentages were similar to general population proportions reported by NAEPP in 1997, when 77% of patients with asthma were in the severe or moderate persistent categories and 23% were categorized as mild. After participation in the current program for 1 year or longer, the percentage of study patients in the severe or moderate persistent categories decreased to 49%, and those in the mild categories increased to 51%. Figure 1 illustrates the shifts in severity categories.

Figure 2 shows the change in severity classification over time using paired data at 12, 24, 36, 48, and 60 months. To allow statistical comparisons, we assigned a numeric scale as follows: mild intermittent, 1; mild persistent, 2; moderate persistent, 3; and severe, 4. At every interval severity classifications improved significantly ($P < .0008$). Comparing pre–post severity classifications, 55% of patients improved, 37% had no change, and 8% were worse.

Patients' Perception of Asthma Severity

We compared patients' perceptions of the severity of their asthma with an objective assessment. Patients were asked to self-categorize the severity of their asthma into mild intermittent, mild persistent, moderate persistent, or severe persistent at baseline and at follow-up. We compared this self-assessment with objective assessments based on NAEPP criteria using the above numeric scale. At baseline the average self-ranked score was significantly lower (less severe) at 2.6, compared with 3.2 using objective criteria. After participation in the program patients accurately assessed the degree to which they
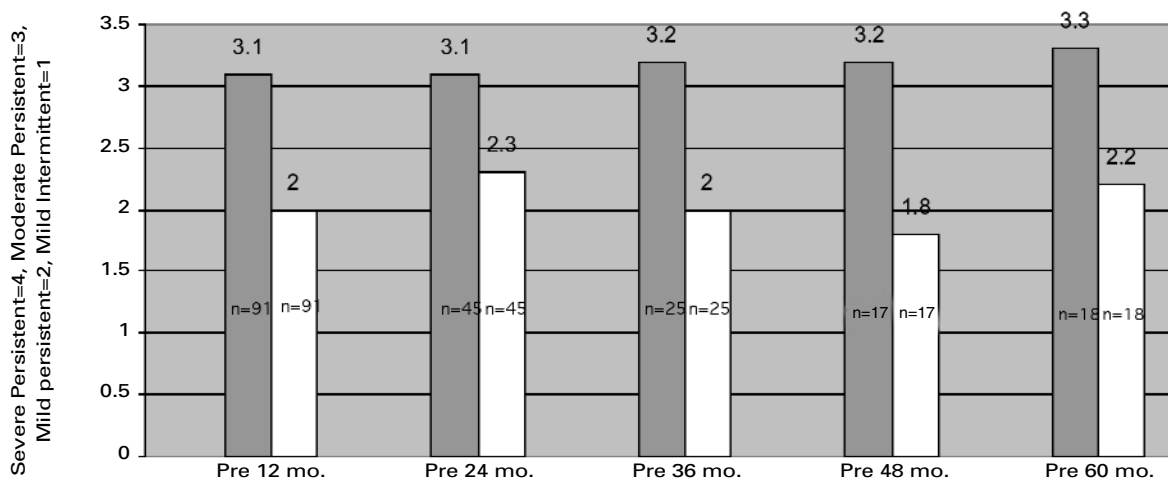
Figure 2. Change in Asthma Severity Score Over Time

Bars indicate the average score of the group on a severity score range of 1–4.

"Pre" indicates severity at the time the person entered the program (before any interventions).

P < .0008 for all comparisons using the Wilcoxon signed rank test.

improved over time (the self-assessment score and objective scores both improved by 0.7); however, they continued to underestimate the severity of their asthma to the same degree.

Physician-Related Factors

We were interested in knowing how baseline asthma control compared for patients managed by primary care physicians versus specialists and if patients benefited differently from the program interventions based on physician type. After determining that these two groups were comparable, we examined severity scores based on the same 4-point severity scale described above.

Patients who were being followed by a specialist had an average baseline score of 3.0 and improved after program interventions to a score of 2.5 (P = .0003, Wilcoxon signed rank test). Patients who were being followed by nonspecialists had an average baseline score of 3.3 and improved after program interventions to a score of 2.5 (P < .00001, Wilcoxon signed rank test).

Spirometry Results

A total of 84 patients who were in the program for at least 1 year and had both a baseline and at least one annual follow-up FEV_1 result. The average preenrollment FEV_1 was 81% of predicted; this improved to 90% during the program. Only 50% of patients had a normal FEV_1 at the time they enrolled, but after being in the program for 1 year or longer this proportion increased to 75%. At the time of enrollment, 17% of patients had FEV_1 results in the

severe persistent range; after being in the program for 1 year or longer this decreased to only 4%. Figure 3 shows the change in FEV_1 over time using paired data at 12, 24, 36, 48, and 60 months. Statistically significant changes in FEV_1 were observed at 12 and 48 months using a conservative P value of .01. If a P value of .05 had been used, the 60-month comparison would have also been statistically significant. A comparison of baseline to latest annual FEV_1 results indicated that 70% of patients improved, 24% were worse, and 6% were unchanged.

Symptom Frequency

A standardized asthma questionnaire was used to determine the frequency of key asthma symptoms patients were experiencing at baseline and annually after program intervention. We report here the results of responses to eight key questions related to asthma symptoms.

At baseline 28% of patients indicated being awakened frequently at night by their asthma (≥ 2 times/week). This decreased to 12% after being in the program for 1 year or longer. At baseline 55% of patients indicated a low frequency (< 2 times/month). This increased to 81% after being in the program for 1 year or longer.

At baseline 35% of patients indicated a high frequency of asthma episodes, flare-ups, attacks (≥ 2 times/week). This decreased to 16% of patients after being in the program for 1 year or longer. At baseline 50% indicated a low frequency of asthma episodes (≤ 1 time/week). This increased to 75% of patients after being in the program for 1 year or longer.
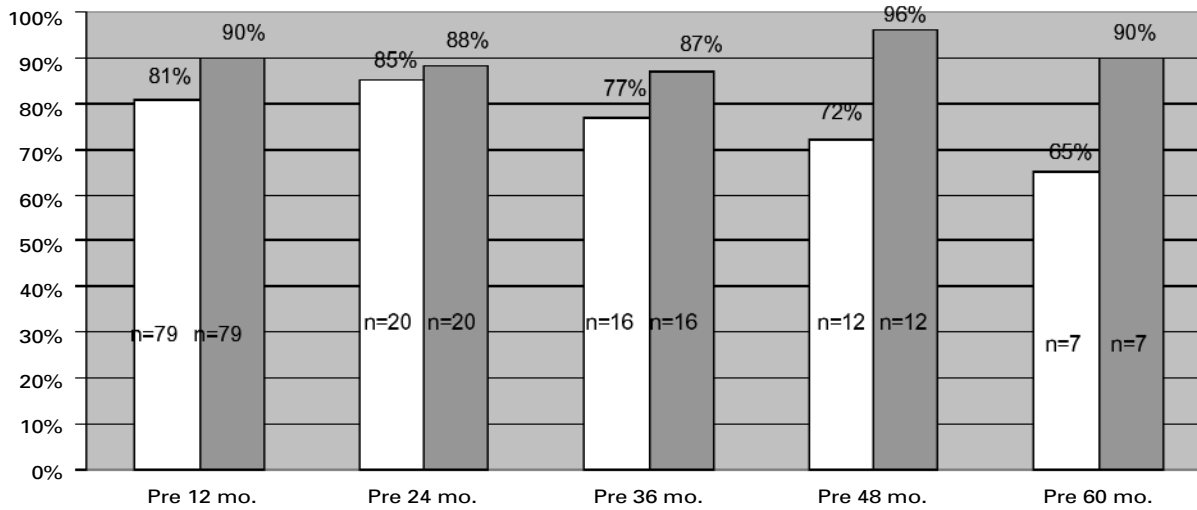
Figure 3. Change in Mean FEV$_1$ of Study Participants Over Time

Bars indicate forced expiratory volume in 1 second (FEV$_1$) expressed as a percentage of predicted based on patient age, weight, height, and gender.

"Pre" indicates FEV$_1$ at the time the person entered the program (before any interventions).

$P < .00001$, 0.5, 0.07, 0.0068, and 0.028, respectively, using the Wilcoxon signed rank test.

Figures 4–6 summarize patients' responses to all eight of these key questions regarding the frequency of specific asthma symptoms, including the two elaborated on above. To analyze the data statistically, a numeric scale was assigned to patient's responses, based on how frequently they were experiencing these symptoms. In every case reported symptoms decreased significantly.

Humanistic/Quality of Life/Functional Status

Using the standardized AOMS questionnaire, a series of questions were also asked regarding how asthma affected people's lives. Figure 7 summarizes patients' responses for five humanistic measures. Shortness of breath was ranked as the most problematic, and a sense that asthma was controlling the patient's life was ranked as the least problematic. Every category improved significantly at follow-up.

Asthma Treatment (Action) Plans

All patients were asked upon entry into the program whether they had an asthma treatment plan. Using paired data on the 73 patients who were in the program 1 year or longer and answered this question at both baseline and at follow-up, we found that 63% indicated at baseline that they had an asthma treatment plan. This increased to 99% at follow-up ($P < .0001$ McNemar's chi-square test).

ED Visits and Hospitalizations for Asthma

From insurance claims records we were able to determine the number of asthma-related ED events and hospitalizations for up to 3 years before patient enrollment and up to 5 years after enrollment. We were able to determine the rates of ED events and hospitalizations for 272 patient–years before enrollment and 320 patient–years following enrollment. Results were as follows:

■ *ED visits:* 46 ED visits (range 0–5/patient/year) in 272 patient–years before enrollment were observed, an average of 16.9 ED visits/100 patients/year. After program enrollment, only 6 ED events (range 0–1/patient/year) in 320 patient–years were recorded, an average of 1.9 ED visits/100 patients/year. Patients with an ED event decreased from an average of 9.9% annually before the program to 1.3% after the program.

■ *Hospitalizations:* 14 hospitalizations (range 0–4/patient/year) in 272 patient–years before enrollment were observed, an average of 5.1 hospitalizations/100 patients/year. After program enrollment, only 6 hospitalizations (range 0–1/patient/year) in 320 patient–years were recorded, an average of 1.9 hospitalizations/100 patients/year. Patients with a hospitalization decreased from an average of 4% annually before the program to 1.9% after the program.

■ *Combined inpatient events:* Grouping ED and hospitalization events to analyze all asthma-related inpatient events resulted in a total of 60 events (range 0–7/patient/year) in 272 patient–years before enrollment, an average of 22.0 events/100 patients/year. After program enrollment, only 12 events (range of 0–2/patient/year) in 320 patient–years were observed, an average
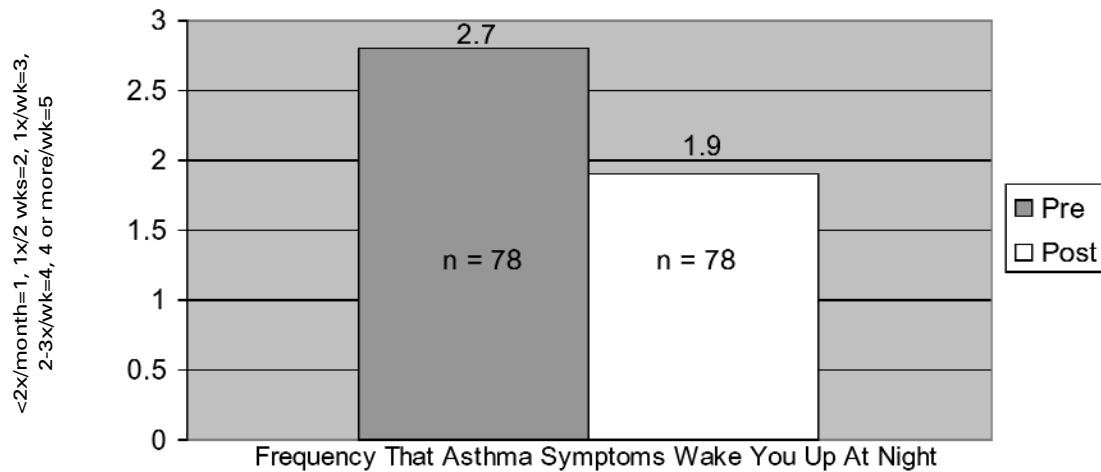
Figure 4. Change in Asthma Symptom Frequency During Prior 4 Weeks

Bars indicate the average score of the group on a symptom frequency scale of 1 to 5.
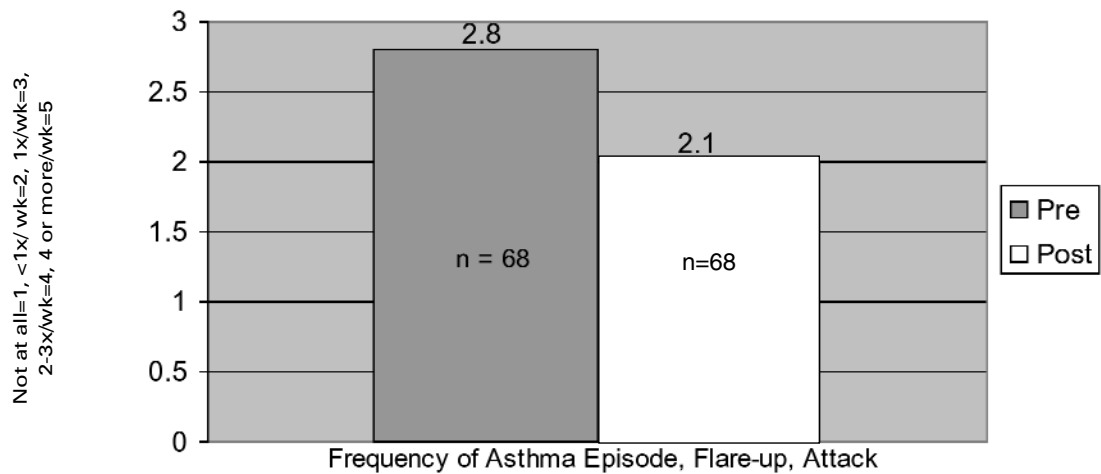*P* = .01 using the Wilcoxon signed rank test.

Figure 5. Change in Asthma Symptom Frequency During Prior 4 Weeks

Bars indicate the average score of the group on a symptom frequency scale of 1 to 5.
P = .0011 using the Wilcoxon signed rank test.

of 3.8 events/100 patients/year. Patients with an ED event and/or hospitalization decreased from an average of 13.9% annually before the program to 3.2% after the program.

Figure 8 shows the percentage of patients with any ED/hospital event by year and the event rates expressed as rates per 100 patients. The inpatient event rates per year for the 3 years before enrollment were much higher at 21.3, 22.2, and 22.3 events/100 patients/year than during the 5 years of the program, which averaged 5.4, 2.6, 1.9, 5.4, and 0 events/100 patients/year.
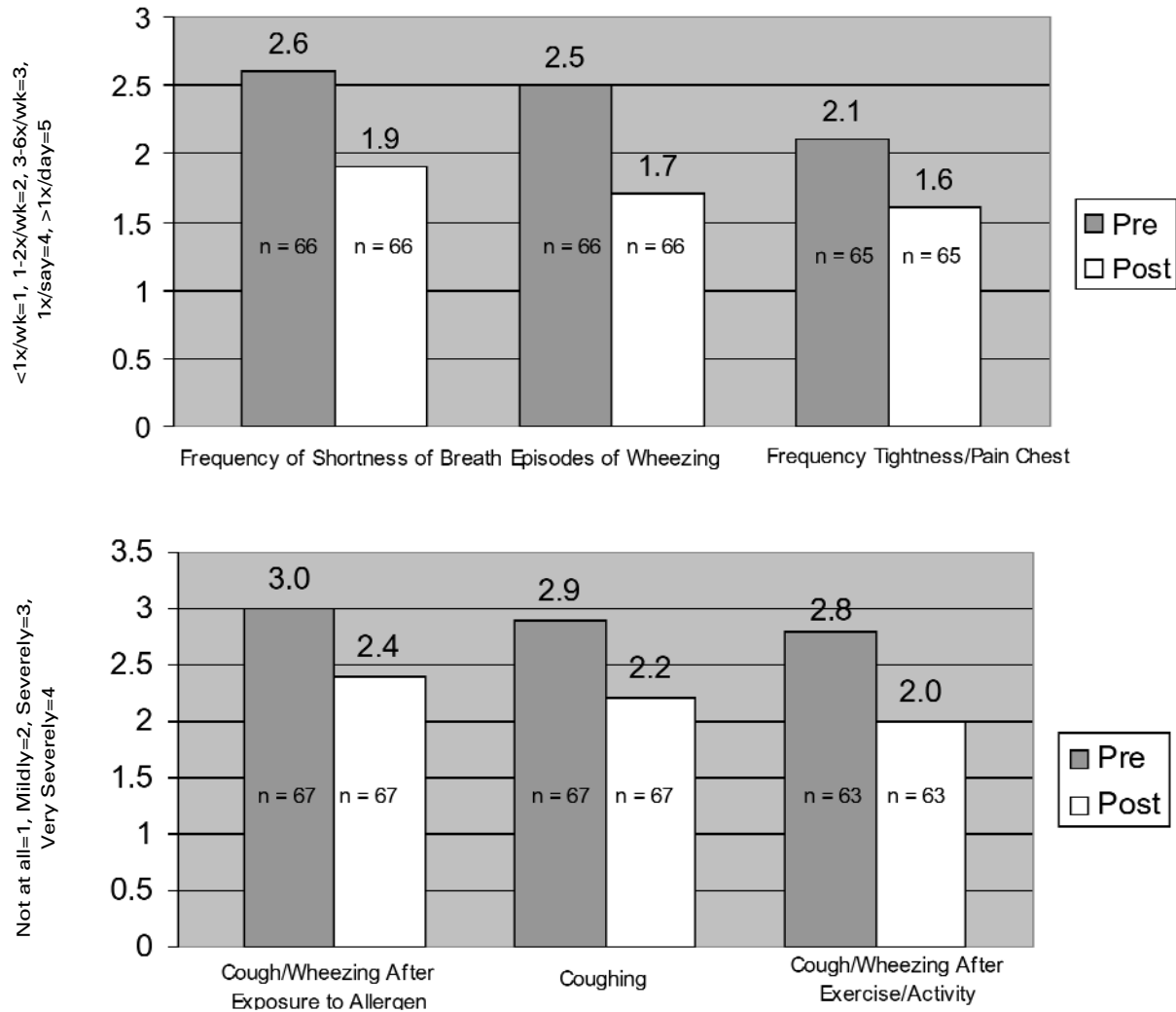
Figure 6. Change in Asthma Symptom Frequency During Prior 4 Weeks

Bars indicate the average score of the group on a symptom frequency scale of 1 to 5 (first graph) and 1 to 4 (second graph)
P < .003 for all six pre–post comparisons using the Wilcoxon signed rank test.

Financial Outcomes

From medical claims and prescription claims we were able to examine direct asthma-related costs for up to 3 years before patient enrollment and up to 5 years after program enrollment. Financial trends were consistent from year to year (with no large peaks or valleys) and sufficient historical data was available (at least 118 historical records/year) to be reasonably confident that the observed financial trends were real (see Figure 9). After program interventions, direct asthma-related costs leveled off in absolute terms and decreased relative to the projected trend. The difference between projected and actual direct costs for each year multiplied by the number of participants in the program each year resulted in a calculated cost savings of $161,187 in reduced direct costs over

the 5 years of the study. In Figure 9 financial data for the 5 program years include program costs (education, counseling sessions, reduced medication copayments), so the savings calculated are net savings. The numbers above the bars in this figure are the number of financial records (medical and prescription) used to compute the average cost and not the number of patients.

From patient questionnaires we were also able to estimate indirect costs of asthma based on self-reported missed workdays and hours of lost productivity due to asthma (Figure 10). We asked patients to report the number of workdays they missed annually due to their asthma (absenteeism) and the number of work hours annually that were totally lost or wasted at work because they were not able to do their normal amount of work due to their asthma
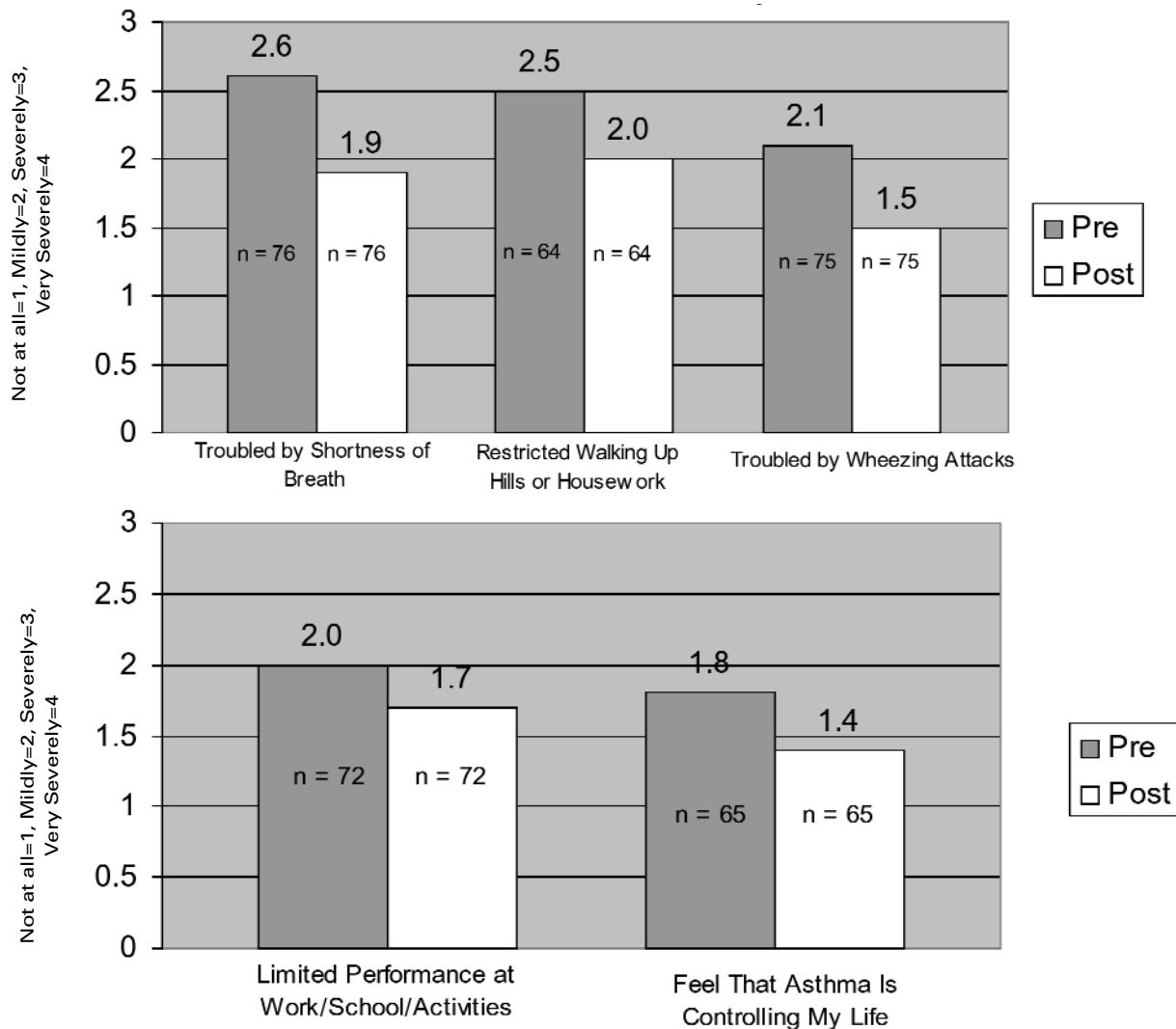
Figure 7. Change in Asthma's Effect on Patient's Lives

Bars indicate the average score of the group on a humanistic scale of 1 to 4.

$P < .01$ for all five pre–post comparisons using the Wilcoxon signed rank test.

(presenteeism). Patients reported missing an average of 2.5 work-days annually due to asthma before entering the program and 0.5 workdays annually after enrollment. They reported an average of 66.5 hours per year missed due to presenteeism before entering the program, and 16.8 hours per year after enrollment. To be included in the indirect cost comparison, the participant had to be an employee, as opposed to being a spouse, and they had to have been in the program for at least 1 year and have answered absenteeism and presenteeism questions. Spouses were not included in this analysis because we did not have access to their hourly wages. A total of 42 patients fit the inclusion criteria. Combining both absen-teeism and presenteeism hours resulted in an average gain of 66

hours/patient/year. With an hourly average rate of $18.64/hour (provided by the employers), this calculation resulted in an aver-age of $1,230/patient/year savings in indirect costs. If these data were extrapolated to the entire study population the savings due to indirect cost reduction would total $423,120 over the 5 years of the study.

Combined direct and indirect savings for the 5 years of the study equaled $584,307 (direct savings of $161,187 plus indirect savings of $423,120). The estimated annual net savings were $1,955/patient/year with $725/patient/year being net hard dollar direct costs.
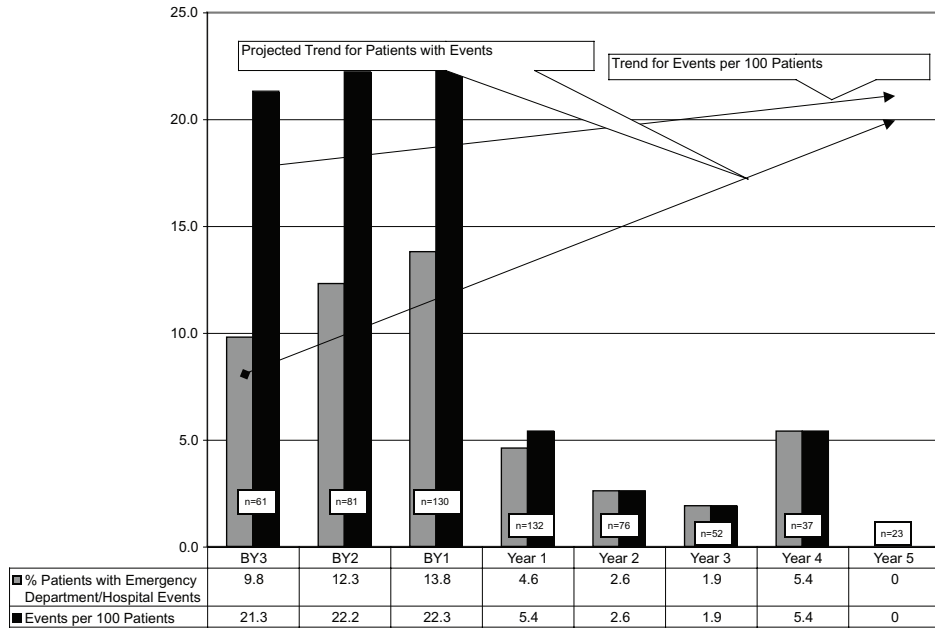
	BY3	BY2	BY1	Year 1	Year 2	Year 3	Year 4	Year 5
▣ % Patients with Emergency Department/Hospital Events	9.8	12.3	13.8	4.6	2.6	1.9	5.4	0
■ Events per 100 Patients	21.3	22.2	22.3	5.4	2.6	1.9	5.4	0

Figure 8. Asthma Care Events (Emergency Department and Hospitalization) Per Patient Per Year Versus Projected Totals

BY3 is the baseline year 3 years before the patient's enrollment. BY2 is baseline year 2, BY1 is the year before enrollment, Year 1 is the first year of the program intervention, and so forth.

The gray bars indicate the percentage of patients in that year that had any emergency department/hospital events.

The black bars indicate the number of events/100 patients (e.g., BY3 bar indicates an event rate of 21.3 per 100 patients).

Discussion

In the March/April 2003 issue of the *Journal of the American Pharmacists Association (JAPhA),*[37] we published the results of a 5-year study on the long-term outcomes of a diabetes education and MTM program involving 194 patients. Significant clinical, humanistic, and economic improvements following intervention were demonstrated in that population. Since that time, a number of diabetes programs based on our model have begun in other states and a recent publication in *JAPhA*[38] reported similar positive first-year outcomes from five other communities. Our purpose in the present study was to determine whether our model could work for another chronic illness, asthma.

We report here for the first time the results of a 5-year study on the long-term outcomes of this model for asthma in 207 adults, which also found significant clinical, humanistic, and economic improvement in this chronic illness.

With the advent of MTM as a reimbursable service under Medicare in 2006, comparing the value of MTM approaches to chronic illnesses, including diabetes and asthma, with those outcomes currently being achieved with routine care is important.

This is the only study of which we are aware that has examined the effects of asthma education and MTM services on FEV_1, asth-ma severity, humanistic measures, and direct and indirect medical costs over a period as long as 5 years.

The goal of this MTM program was to overcome barriers to care and improve asthma outcomes by improving patient self-care knowledge, increasing access to medications by lowering medication copayments, and providing access to underutilized, but knowledgeable, health care resources, educators, and pharmacists. Patients in this study received asthma education and met on a long-term, regular basis with an assigned care manager/coach for face-to-face counseling. Participants qualified for waived asthma medication copayments. The cost of the education, medication copayment waivers, and care manager service fees were paid by two health plans with a total of 12,000 insured lives.

Despite being gainfully employed, under the care of a physician, and having a health plan that included good prescription and medical benefits, only 50% of our study patients had a normal FEV_1 at the time they enrolled. After being in the program for 1 year or longer, 75% of program participants had normal FEV_1 values, and 70% of patients had improved. The number of patients with severe and moderate persistent asthma decreased from 82% to 49%. Also, the number of patients in the severe category decreased from 39% to 18%. All of these clinical improvements persisted over time. Patients with more severe asthma, and those
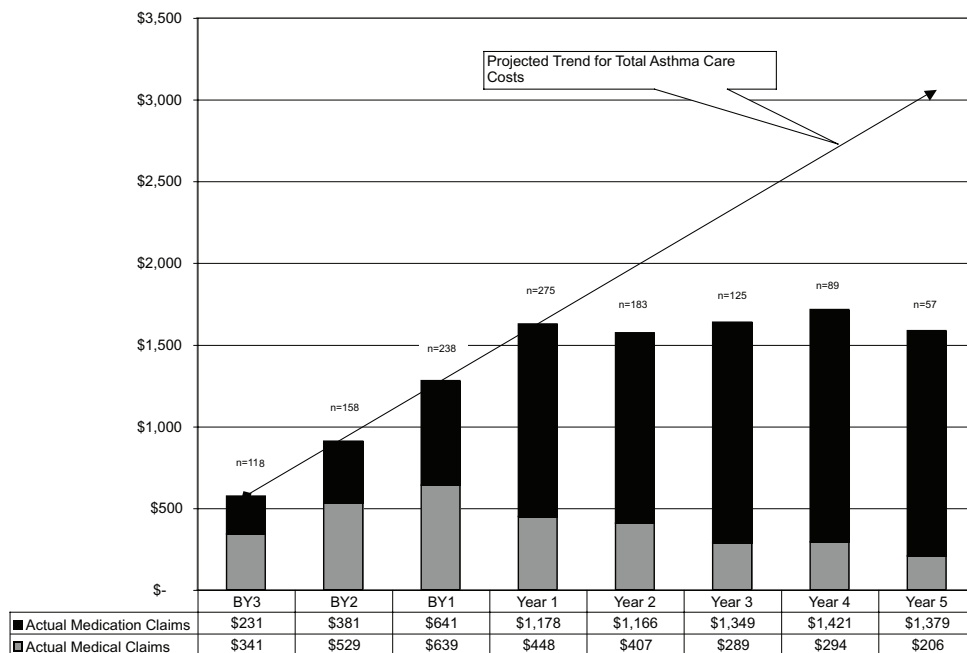
Figure 9. Average Direct Asthma Care Costs (Medical and Medication) Per Patient Per Year Versus Projected Totals

BY3 is the baseline year 3 years before the patient's enrollment. BY2 is baseline year 2, BY1 is the year before enrollment, Year 1 is the first year of the program intervention, and so forth.

The gray bars indicate the average direct cost of asthma medications ($/patient/year).

The black bars indicate the average direct cost of asthma-related medical claims (emergency department visits, hospitalizations, physician office visits). Total direct asthma-related costs are indicated by the combined bars.

The sample sizes above the bars are the number of medical and prescription claims records available for analysis that year, upon which the averages were calculated.

who were in the program longer, benefited more from the intervention. Patients with severe or moderate persistent asthma at baseline had a greater than sixfold improvement in FEV_1 compared with those with mild persistent or mild intermittent asthma. All these findings were both statistically and clinically significant.

Before entering the program patients consistently underestimated their asthma severity compared with objective measures such as FEV_1 and symptom frequency. After participation they accurately assessed their degree of improvement but continued to underestimate their actual severity. These findings support the NAEPP recommendation that objective measures of asthma, such as peak flow meter measurements, are important for many patients. The need for regular objective assessment, such as this program provides, is also reinforced by our findings.

We found that patients of primary care physicians scored higher (worse) than patients of specialists at baseline on an asthma severity score, although both groups on average were categorized with moderate persistent asthma at baseline. After participation in the program both groups on average improved one category level to mild persistent and ended up with the same final average severity score. Therefore, both groups improved through program inter-

ventions, but the patients of nonspecialists were less well controlled at baseline and benefited more from the intervention.

Two hallmark asthma symptoms are the frequency which asthma causes the patient to wake up at night and the frequency of episodes/flares/attacks (Figures 4 and 5). According to 1997 NAEPP guidelines, many of these episodes are avoidable with appropriate management. At baseline 28% of study patients were being awakened at night two or more times per week, and 35% were having two or more attacks per week. After being in the program for 1 year or longer, only 12% indicated they were still being awakened two or more times per week and only 16% were having asthma attacks two or more times a week, 57% and 54% decreases, respectively. These findings were statistically and clinically significant.

Other symptom parameters, including episodes of wheezing, tightness or pain in chest, shortness of breath, coughing, cough/wheezing after exposure to airborne allergens, and cough/wheezing after exercise/activity, all decreased significantly after program interventions (Figure 6). Also, all evaluated humanistic and functional parameters improved significantly (Figure 7).

This program was remarkably successful in achieving the NAEPP recommendation that all patients with asthma have an
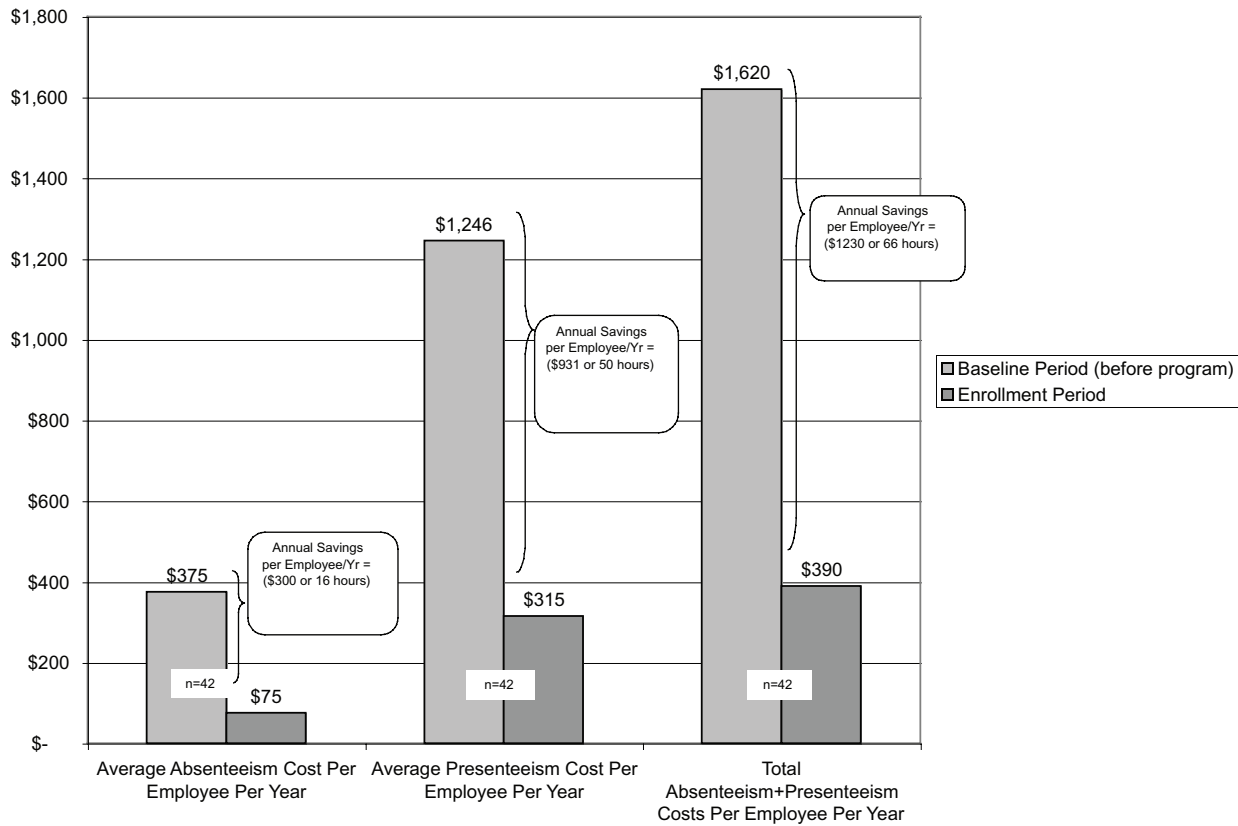
Figure 10. Average Indirect Costs (and Savings) for Total Work Hours Lost Annually Due to Asthma

Lighter bars indicate the average cost/patient/year of lost work hours due to asthma (absenteeism, presenteeism, and combined) for the year prior to program enrollment.

Darker bars indicate the average cost/patient/year of lost work hours due to asthma (absenteeism, presenteeism, and combined) for the patients most recent year of program participation.

asthma action plan. Nearly all (99%) patients in this study reported having an asthma action plan after participation in this program, a large increase from the percentage of patients having a plan at the beginning of the program (63% at baseline).

The litmus test for the effectiveness of programs aimed at improving asthma outcomes is to observe decreased ED visits and hospitalizations. We observed a significant decrease in ED and hospitalization events, and patients were six times less likely to have an ED visit or hospitalization after enrolling in the program (Figure 8). The percentage of patients with at least one ED/hospital event was on the rise before the start of the program, but the average number of events per patient were flat. Although these patients overall appeared to have been getting steadily worse, there was no sharp spike in the frequency of events before patient enrollment. Therefore, patients did not enroll because they had just experienced a "bad year" and "would have improved" on average even without program interventions. This speaks against a regression-to-the-mean statistical bias, which is an inherent risk in disease management programs.

The litmus test from the employer/payer perspective is to observe net cost savings from disease management programs. As shown in Figure 9, direct asthma-related costs were steadily rising in the 3 years before the start of the study. The trendline on these historical data shows a consistent upward slope and a 5-year projection of costs rising to approximately $3,000/patient/year for direct asthma-related costs if standard care had continued. Although 3 years of historical data provide a reasonable length of time to establish a trend for these type of data, we believed it was important to know whether this trend was consistent with objective data from an outside source. A comprehensive study done by Cisternas et al.[39] in a general adult asthma population of 401 patients in 2003 found direct medical costs of $4,912/patient, higher than our data projection of $3,000/patient by 2003. Based on these factors we believe it is reasonable to compare our observed postintervention costs with the historical trend line of our population; that is, our cost projections appear conservative.

Using historical trend data we calculated direct cost savings over the 5-year study period of $161,187. During the 3-year histor-

ical period, 55% of all direct asthma-related costs were medical claims, primarily ED visits and hospitalizations; however, during the 5 years of program intervention, medical claims averaged only 20% of direct asthma-related costs. Indirect costs (Figure 10) resulting from absenteeism and presenteeism accounted for an additional $423,120 in savings due to increased productivity. Productivity estimates are most relevant and translatable into dollar savings for production-based employers; however, even in service-based fields, such as municipalities and hospitals, increases in productivity are very important. Combined total direct and indirect cost savings over the 5-year study period were $584,307.

While spending on asthma medications increased significantly, the plans realized a net hard dollar savings of $725/patient/year in direct health care costs and an additional $1,230/patient/year in soft dollar productivity. These financial improvements are even more impressive considering that program interventions were not targeted toward a subset of individuals who had been high utilizers of health plan dollars, as is the approach of most commercial disease management programs. This program was open to all individuals with asthma regardless of the status of their disease control or utilization history.

Disease management programs, whether the more traditional telephonic nurse-driven model, or a community-based pharmacist-driven medication therapy management model, need to demonstrate not only that clinical, humanistic, and financial improvements occur, but that they are sustainable over long periods of time. And although clinical and humanistic improvements are important to employers/payers, what they really want is evidence that these programs save more than they cost. Understandably, many purchasers of health care services will be skeptical of approaches such as MTM, or other disease management approaches, until they see convincing evidence that a return on investment is likely. At a time when rising health care costs threaten the insurability of many Americans, it is extremely important to determine whether preventive approaches are cost-effective. Studies that demonstrate the net financial impact, positive, negative, or neutral, of particular disease management models are critically needed.

Limitations

The longitudinal analysis of data in this study is subject to the limitations that are typical of studies that lack a randomized control group. Any pre–post study must address inherent potential threats to internal and external validity.[40,41] Of particular threat to a study of this type are selection bias and regression-to-the-mean because participation was voluntary. Selection bias from dropouts was addressed by using an intention-to-treat design. Of the 207 patients, 39 (19%) were no longer participating in the program at the end of the 5-year study period. Only 9 of the patients over the 5-year study period dropped out because of a desire to no longer participate or failure to meet the requirements of the program for completing education and keeping care manager appointments. A majority of

dropouts (n = 30) resulted from changes in employment and/or insurance. However, all available data on patients who dropped out were included in the analysis, including post-dropout observations. To address the threat of regression-to-the-mean, we looked at historical trends for 3 years before patient enrollment and determined that the rates of ED visits and hospitalizations were consistent for the 3 years before patient enrollment and there was no spike of inpatient events before patient enrollments.

Other study limitations include missing data and a small sample size for some data points. Some missing annual FEV_1 follow-up data and data needed to make some severity classifications limited comparisons at some time intervals. Although the small sample size for some measures was an issue, we included all eligible patients who received any intervention, and after determining that the two employer groups in the study were similar at baseline, we combined them to increase sample size and statistical power. Another potential limitation was that the unequal data-gathering periods pre- and post-MTM might introduce unaccounted for variance in the data. Because of the real-world nature of this study, unequal data-gathering periods were unavoidable. This pre–post study asserts that patients would not have improved to the extent observed with standard care alone. This is supported by the findings reported in the 1997 NAEPP guidelines, and specifically the study by Legorreta et al.,[5] which found that published asthma guidelines had little impact on standards of care in asthma even after being actively promoted in the medical community for more than 7 years. Our findings that significant improvements occurred within as little as 1 year of program intervention, occurred regardless of which year patients entered the program, and persisted for as long as 5 years supported our conclusion that the observed improvements were not the result of chance.

The introduction of new therapeutic modalities could have accounted for improvement in a population followed over this long a time period. However, during the study, no major new therapeutic drugs for asthma were introduced in the United States; the leukotriene modifiers had been introduced more than 1 year before the beginning of the study.

We did not attempt to determine what part of the observed improvements resulted from the various interventions made (asthma education, long-term follow-up, financial incentives) or to examine and compare the improvements obtained by individual program providers. We can only support the conclusion that a combination of these factors led to the observed outcome improvements.

Conclusion

A community-based asthma disease management program that provided asthma education, financial incentives, and face-to-face counseling by specially trained community pharmacists resulted in significant improvements in clinical, humanistic, and financial outcomes. After participation in the program, patients were significantly less likely to have an asthma-related ED visit or hospital-

ization, and the health plans experienced significant reductions in net health care costs.

This simple community-based model uses resources available in many communities and has now demonstrated long-term effectiveness for two chronic medical conditions, diabetes and asthma. This model should be considered for populations with chronic medical conditions for whom self-care knowledge and appropriate medication use are important.

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[a]National Respiratory Training Center, www.nrtc-usa.org.

[b]Prescription claims were provided by Smith Premier, American Healthcare, Express Scripts; medical claims were provided by Acordia, Kanawha.

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