

Studies Demonstrating Improved Outcomes in Patients with Asthma: A 10-Year Review

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AUDIENCE

This activity is designed for pharmacists, pharmacy directors, managed care organization medical directors and administrators, and payers for health services.

GOAL

To describe clinical trials that have demonstrated a decreased number of emergency department visits and hospitalizations in patients with asthma.

OBJECTIVES

1. Discuss clinical trials that have demonstrated improved outcomes in patients with asthma.
2. Explain principles of optimal long-term asthma management to help ensure excellent outcomes.
3. Describe the role of the pharmacist in working with patients and other healthcare professionals so that optimal outcomes are achieved.

Asthma is an inflammatory airway disease that affects 14 to 15 million Americans and over 100 million people worldwide.^{1,2} It is a costly disease in terms of human suffering and in economic terms, with estimated annual costs of \$6.2 billion in the United States.³ High costs are associated with unnecessary emergency department (ED) visits and hospitalizations. Roughly 10 million missed school days by children are associated with lost work productivity in parents of nearly \$1 billion.²

Morbidity and mortality are greatest among inner city minority populations, with about 5000 deaths in the United States each year.¹ Recent evidence indicates that among the diverse US Hispanic population, Puerto Ricans (especially in the northeast) have the greatest annual asthma mortality (40.9 per million), followed by Cuban Americans (15.8 per million) and Mexican Americans (9.2 per million).⁴ In comparison, non-Hispanic whites had an annual asthma mortality of 14.7 per million, and non-Hispanic blacks had a mortality rate of 38.1 per million.⁴

Diminished quality of life is a major consequence of poorly managed asthma, including nocturnal awakenings or awakening in the early morning with symptoms. Poor sleep quality from asthma or concomitant allergic rhinitis can affect functional status, such as reduced performance at school.^{5,6} Improving asthma control is helpful not only to the patient, but



CONTINUING EDUCATION CREDIT

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also to the parents of children with asthma.⁵ Poor exercise tolerance, interference with social life (eg, for teenagers, dating, and parties), and numerous other factors also are associated with poorly controlled asthma.

Many patients with asthma suffer because of inadequate care provided by healthcare professionals,^{7,8} poor adherence by the patient to prescribed management,⁹ lack of access to care, or a combination of these problems. However, patients who receive evidence-based management as recommended by the National Institutes of Health (NIH) guidelines¹ and other current literature and adhere to such long-term therapy most likely will have excellent outcomes.

The purpose of this paper is to describe studies that demonstrated improved outcomes (eg, fewer ED visits) in patients with asthma. To that end, we performed a MEDLINE search of the English literature for the past decade, looking for relevant studies in asthma patients using the term "asthma outcomes." We defined "improved outcomes" as a reduction in the number of ED visits and hospitalizations. A review of the literature shows clearly that comprehensive long-term management is essential to achieve these goals.

Although studies that primarily examined improvement in the quality of life are of great importance, discussions of these trials are not within the scope of this paper. Similarly, to limit the scope of this paper, studies that examined the effect of patient education only (ie, without any attempt to optimize drug therapy) are not included.

... ESSENTIAL QUALITIES OF PROGRAMS THAT IMPROVE ASTHMA OUTCOMES ...

Application of the 1997 NIH guidelines for the management of asthma is essential to improving outcomes. The 4 major components of long-term management are listed below¹:

- Objective assessment and monitoring
- Control of factors contributing to asthma severity
- Pharmacologic therapy
- Education for a partnership in asthma care.

These 4 components must be combined to achieve optimal outcomes. Excessive attention to drug therapy without adequate, persistent, and caring patient education as a partnership, environmental control, and objective monitoring will likely be associated with inadequate therapeutic

response. Similarly, competent patient education without attention to individualized pharmacologic therapy and appropriate environmental control frequently will result in suboptimal outcomes. Objective assessment and monitoring are also important for achieving fewer acute care visits. **Tables 1-3** and the **Appendix** address each of the 4 major components of the long-term care of asthma as found in the NIH guidelines. Application of the major principles in these guidelines was the basis of the success of the clinical trials described in this review.

... CLINICAL TRIALS DEMONSTRATING IMPROVED OUTCOMES IN INNER CITY POPULATIONS ...

Adult Trials

Mayo et al evaluated 104 patients with very poor asthma control (≥ 5 ED visits in past 24 months or ≥ 2 hospitalizations in the past 12 months).¹⁰ The study was conducted in New York City at the Bellevue Hospital Center chest clinic. Most patients were Hispanic (80%) with some African Americans (15.4%) and Caucasians (3.8%). Forty-seven patients were randomly assigned to an intensive outpatient treatment clinic (intervention group), and 57 patients continued to receive their prior long-term care ("usual care" group). After 8 months of usual care, 19 patients with multiple hospitalizations were subsequently crossed over to the intensive treatment group (crossover group). The mean numbers of hospital admissions before randomization were as follows: intervention group (4.4), usual care group (4.5), and crossover group (6.6).

The intervention group received long-term asthma management consistent with the original 1991 NIH guidelines, although this study was conducted and published before those guidelines were released.¹¹ Key features of the intensive management program included the following:

- Two initial visits lasting at least 1 hour each, including detailed repetitive discussion of asthma and its treatment as well as self-management techniques;
- Tailored drug regimens, emphasizing inhaled corticosteroids with a spacer device and a simplified schedule as well as short-acting inhaled β_2 -agonists on an as-needed basis;
- An emergency supply of prednisone (40 mg daily for 3 days) to use based on peak expiratory flow values and severity of symptoms;

Table 1. Stepwise Approach to Managing Asthma in Adults and Children Over 5 Years Old: Treatment[†]

Classification	Long-Term Control	Quick Relief	Education
Step 4 Severe persistent	Daily medications: <ul style="list-style-type: none"> • Anti-inflammatory: inhaled corticosteroid (high dose) AND <ul style="list-style-type: none"> • Long-acting bronchodilator: long-acting inhaled β_2-agonist, sustained-release theophylline, or long-acting β_2-agonist tablets AND <ul style="list-style-type: none"> • Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg/day) 	<ul style="list-style-type: none"> • Short-acting bronchodilator: inhaled β_2-agonist as needed for symptoms • Intensity of treatment will depend on severity of exacerbation • Use of short-acting inhaled β_2-agonists on a daily basis, or increasing use, indicates the need for additional long-term-control therapy 	Steps 2 and 3 actions PLUS <ul style="list-style-type: none"> • Refer to individual education/counseling
Step 3 Moderate persistent	Daily medication: EITHER <ul style="list-style-type: none"> • Anti-inflammatory: inhaled corticosteroid (medium dose) OR <ul style="list-style-type: none"> • Inhaled corticosteroid (low to medium dose) and add a long-acting bronchodilator, especially for nighttime symptoms: long-acting inhaled β_2-agonist, sustained-release theophylline, or long-acting β_2-agonist tablets If needed: <ul style="list-style-type: none"> • Anti-inflammatory: inhaled corticosteroid (medium or high dose) AND <ul style="list-style-type: none"> • Long-acting bronchodilator, especially for nighttime symptoms: long-acting inhaled β_2-agonist, sustained-release theophylline, or long-acting β_2-agonist tablets 	Same as for step 4	Step 1 actions PLUS <ul style="list-style-type: none"> • Teach self-monitoring • Refer to group education if available • Review and update self-management plan
Step 2 Mild persistent	One daily medication: <ul style="list-style-type: none"> • Anti-inflammatory: either inhaled corticosteroid (low doses) or cromolyn sodium or nedocromil (children usually begin with a trial of cromolyn sodium or nedocromil) OR <ul style="list-style-type: none"> • Sustained-release theophylline to serum concentration of 5-15 mg/mL is an alternative, but not preferred, therapy; zafirlukast or zileuton also may be considered for patients ≥ 12 years of age, although the position of these agents in therapy is not fully established[‡] 	Same as for step 4	Step 1 actions PLUS <ul style="list-style-type: none"> • Teach self-monitoring • Refer to group education if available • Review and update self-management plan

(continued on next page)

***Boldface** indicates preferred treatment.

[†]*Step down:* Review treatment every 1-6 months; a gradual stepwise reduction in treatment may be possible. *Step up:* If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control (avoidance of allergens or other factors that contribute to asthma severity).

[‡]Montelukast was not available at the time the 1997 National Institutes of Health guidelines were released.

Table 1. (Continued)

Classification	Long-Term Control	Quick Relief	Education
Step 1 Mild intermittent	No daily medication needed	<ul style="list-style-type: none"> • Short-acting bronchodilator: inhaled β_2-agonists as needed for symptoms • Intensity of treatment will depend on severity of exacerbation • Use of short-acting inhaled β_2-agonists more than 2 times a week may indicate the need for additional long-term-control therapy 	<ol style="list-style-type: none"> 1. Teach basic facts about asthma 2. Teach inhaler/spacer/holding chamber technique 3. Discuss roles of medications 4. Develop self-management plan 5. Develop action plan for when and how to take rescue actions, especially for patients with a history of severe exacerbations 6. Discuss appropriate environmental control measures to avoid exposure to known allergens and irritants

***Boldface** indicates preferred treatment.

[†]*Step down*: Review treatment every 1-6 months; a gradual stepwise reduction in treatment may be possible. *Step up*: If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control (avoidance of allergens or other factors that contribute to asthma severity).

*Montelukast was not available at the time the 1997 National Institutes of Health guidelines were released.

Notes

The stepwise approach presents general guidelines to assist clinical decision making; it is not intended to be a specific prescription.

Asthma is highly variable; clinicians should tailor specific medication plans to the needs and circumstances of individual patients.

Gain control as quickly as possible; then decrease treatment to the least medication necessary to maintain control. Gaining control may be accomplished by either starting treatment at the step most appropriate to the initial severity of the condition or starting at a higher level of therapy (eg, a course of systemic corticosteroids or a higher dose of inhaled corticosteroids).

A rescue course of systemic corticosteroids may be needed at any time and at any step.

Some patients with intermittent asthma experience severe and life-threatening exacerbations separated by normal lung function and no symptoms. This may be especially common with exacerbations provoked by respiratory infections. A short course of systemic corticosteroids is recommended.

At each step, patients should control their environment to avoid or control factors that make their asthma worse (eg, allergens, irritants); this requires specific diagnosis and education.

Source: Reference 1.

- Repetitive education, including observation of the patient's use of a metered-dose inhaler (MDI) and spacer device; and
- Easy access to the clinic (patients could phone or come to the clinic if their asthma was not well controlled).

Mayo et al used hospital readmission rate and number of hospital days as their main outcome measures.¹⁰ During a 32-month follow-up period, the intervention group had a 3-fold reduction in readmissions and hospital days ($P < .003$) compared

with retrospective data (patients were used as their own controls). Likewise, there was a 3-fold reduction in the readmission rate for the intervention group versus the usual care group ($P < .004$). Similar reductions were seen for the patients who were crossed over from the usual care group to the intervention group ($P < .004$).

In a study of 25 African Americans and Caucasians with 3 or more ED visits for asthma in the past 12 months, Pauley et al applied the principles described in the NIH guidelines in an effort to

reduce the number of ED visits.¹² After seeing the clinic physician, patients were educated in groups of 3 by the clinical pharmacist investigator. The education session emphasized asthma as an inflammatory condition of the airways, avoidance of triggers, self-management of acute exacerbations (including an emergency supply of prednisone), the role of each medication (stressing inhaled corticosteroids twice daily), and correct use of inhalers. Subsequent to group sessions, patients were encouraged to contact the investigators at any time. These individual patient-initiated encounters to reinforce education and appropriate self-management were considered critical to the clinic's success.

Each patient served as his or her own control. During the 6-month intervention period, total ED visits (all patients combined) decreased dramatically from 47 (December to June the year before the intervention) to 6 (December to June the year of the intervention). The mean number of ED visits per patient for these time periods was 1.88 versus 0.24 ($P = .006$).

Because many inner city indigent patients unfortunately view the ED as their primary site of medical care, Kelso et al conducted a trial aimed at initiating long-term intervention in the ED.¹³ They evaluated a group of 30 African Americans who had 5 or more ED visits for asthma in the past 2 years, 3 or more ED visits in the past year, or 2 or more hospitalizations in the past 2 years. Clinical pharmacist investigators provided 1 hour of individual education regarding asthma and its treatment after the patients had responded to ED therapies. Patient education included stressing the role of airway inflammation and inhaled corticosteroids, avoiding triggers, and use of MDIs and MDIs plus spacer devices. In addition, correct use of

peak flow meters and colored zone management was reviewed. All patients received demonstrations on how to use the devices, and patient use was observed. At the completion of the education session, patients were given asthma clinic appointments and encouraged by the investigators to keep appointments. Patients were scheduled to see the same clinical pharmacist and physician investigators for follow-up visits.

These 30 intervention patients were compared with a retrospective control group of inner city indigent patients ($n = 22$) for 1 year before and after the intervention in the ED. In addition, ED visits for intervention patients were compared with their own prior 2-year record. Intervention group ED visits decreased from a mean 4.4 to 2.6 ($P < .01$), but the control group had no decrease (3.4 visits before and 3.5 visits after).

Table 2. Summary of Control Measures for Environmental Factors That Can Make Asthma Worse

<p>Allergens Reduce or eliminate exposure to the allergen(s) the patient is sensitive to, including:</p> <ul style="list-style-type: none"> ■ Animal dander: Remove animal from house or, at a minimum, keep animal out of patient's bedroom and seal or cover with a filter air ducts that lead to bedroom. ■ House dust mites: Essential: Encase mattress in an allergen-impermeable cover; encase pillow in an allergen-impermeable cover or wash it weekly; wash sheets and blankets on the patient's bed in hot water weekly (water temperature of $\geq 130^{\circ}\text{F}$ is necessary for killing mites). Desirable: Reduce indoor humidity to less than 50%; remove carpets from the bedroom; avoid sleeping or lying on upholstered furniture; remove carpets that are laid on concrete. ■ Cockroaches: Use poison bait or traps to control. Do not leave food or garbage exposed. ■ Pollens (from trees, grass, or weeds) and outdoor molds: To avoid exposure, adults should stay indoors with windows closed during the season in which they have problems with outdoor allergies, especially during the afternoon ■ Indoor mold: Fix all leaks and eliminate water sources associated with mold growth; clean moldy surfaces. Consider reducing indoor humidity to less than 50%. <p>Tobacco smoke Advise patients and others in the home who smoke to stop smoking or smoke outside the home. Discuss ways to reduce exposure to other sources of tobacco smoke, such as from day care providers and in the workplace.</p> <p>Indoor/outdoor pollutants and irritants Discuss ways to reduce exposures to the following:</p> <ul style="list-style-type: none"> ■ Wood-burning stoves or fireplaces ■ Unvented stoves or heaters ■ Other irritants (eg, perfumes, cleaning agents, sprays)

Source: Reference 1.

Pediatric Trials

Greineder et al studied 53 patients with asthma (aged 1-17 years) in an asthma outreach program aimed at reducing the number of ED visits and hospitalizations.¹⁴ Seventy percent of these children and adolescents were African American. Patients and their caregivers received individual instruction regarding asthma and its treatment, triggers, and use of inhalers as well as peak flow meters. This initial educational session lasted 1 to 2 hours. Drug therapy was tailored for each patient based on the NIH guidelines.¹¹ A key feature of this program was that the study outreach nurse persisted in telephoning the family to ensure clinic appointments were kept (frequency of clinic visits varied depending on the patient's clinical status). For most patients continuing weekly telephone contact established rapport and was important in the study's success.

Hospitalizations and ED visits were followed for a period of 6 to 24 months before and after the inter-

vention. Emergency department visits were decreased by 79% ($P < .0001$), and hospital admissions were decreased by 86% ($P < .001$).

In a follow-up pediatric outreach program study, Greineder et al randomized 57 patients to a usual care group or an intervention group after a single intensive asthma education session.¹⁵ Both groups had drug therapy prescribed per NIH guidelines.¹¹ The intervention group received consistent follow-up via the study outreach nurse, as in the prior study by this group.¹⁴ Emergency department visits and hospitalizations were compared for 1 year before and 1 year after intervention for all patients. Although the usual care group patients had significant reductions in the number of ED visits (39%) and hospitalizations (43%), the intervention group had greater reductions: a 73% decrease in ED visits ($P = .0002$) and an 84% decrease in hospitalizations ($P = .0012$). The intervention group decreases were significantly greater ($P < .05$). In addition, estimated cost savings were \$11.67 for every dollar spent on the outreach nurse's salary. Since there was a reduction in the number of acute care visits in the usual care group, a more conservative estimate of savings was \$7.69 for every dollar spent on the outreach nurse's salary.

In a study of children enrolled in Medicaid (aged 2-16 years), patients were assigned to a control group or an intervention group.¹⁶ An asthma outreach nurse maintained monthly contact with the intervention group after extensive individual asthma education and treatment per NIH guidelines. The control group received usual care from a primary care clinician and no outreach. At the time of enrollment in the study, a higher proportion of patients in the control group (60%) than in the outreach group (34%) were receiving anti-inflammatory therapy.

For a period of 1 year before study initiation, there were no differences between the control group ($n = 40$) and the intervention group ($n = 38$) in the number of ED visits or hospitalizations. One year after the intervention, the mean number of ED visits decreased from 3.5 to 1.7 ($P < .05$) in the intervention group versus a decrease from 3.5 to 2.4 visits in the control group. Decreases in hospitalizations were also significant in the intervention group (0.6 to 0.2 per child; $P < .001$). Average asthma

Table 3. Key Educational Messages for Patients

<p><i>Check off or document that the following key messages have been covered.</i></p> <p>Basic facts about asthma</p> <ul style="list-style-type: none"> ■ The contrast between asthmatic and normal airways ■ What happens to the airways in an asthma attack <p>Roles of medications</p> <ul style="list-style-type: none"> ■ How medications work <ul style="list-style-type: none"> Long-term control: Medications that prevent symptoms, often by reducing inflammation Quick relief: Short-acting bronchodilator relaxes muscles around airways ■ Stress the importance of long-term-control medications and not to expect quick relief from them <p>Skills</p> <ul style="list-style-type: none"> ■ Inhaler use (patient demonstrates) ■ Spacer/holding chamber use ■ Symptom monitoring, peak flow monitoring, and recognizing early signs of deterioration <p>Environmental control measures</p> <ul style="list-style-type: none"> ■ Identifying and avoiding environmental precipitants or exposures <p>When and how to take rescue actions</p> <ul style="list-style-type: none"> ■ Responding to changes in asthma severity (daily self-management plan and action plan)

Source: Reference 1.

healthcare charges per year were reduced by \$721 per child in the intervention group versus \$178 per child in the control group.

In a pilot program to improve outcomes in children with asthma, Stout et al emphasized home visits by community-based lay workers collaborating with a pediatrician, pharmacist, and public health nurse.¹⁷ Twenty-three children were evaluated for 1 year before and after the intervention. Eighty-seven percent of the children were African American, and two thirds were younger than 5 years of age. Initial intervention included asthma evaluation and treatment by a physician, pharmacist review of medication use, peak expiratory flow assessment, and training in the use of inhalation devices. After the study nurse trained the lay outreach workers, they visited the patients at least monthly for the first 6 months of the program and then at least quarterly. The outreach workers reinforced the comprehensive asthma management plan, including control of environmental triggers in the home.

Emergency department visits the year before study enrollment totaled 20, compared with only 7 in the year after the intervention. Feedback from the families indicated that while they trusted the health professionals who were the study investigators, they felt more comfortable sharing information and concerns with the lay outreach workers.

... CLINICAL TRIALS DEMONSTRATING
IMPROVED OUTCOMES IN NON-INNER
CITY POPULATIONS ...

Zeiger et al evaluated outcomes in 309 patients (aged 6-59 years) who were members of the Kaiser Permanente Health Plan HMO in San Diego, California, and who had received ED or hospital care for asthma in the late 1980s.¹⁸ Patients were alternately assigned to an intervention group (facilitated referral to an allergist; $n = 149$) or control group (routine generalist care; $n = 160$). As in other successful programs, the intervention group received detailed asthma education, treatment emphasizing anti-inflammatory therapy, and training in peak flow meter use, inhaler use, and environmental control.

Over a 6-month period after enrollment in the study, the intervention group had an almost 50% reduction in the number of ED visits compared with the control group ($P = .017$) and a 75% decrease in nocturnal awakenings compared with the control group ($P < .0001$). A much higher percentage of the intervention group (36.5%) than the control group

(13.9%) used inhaled anti-inflammatory agents such as inhaled corticosteroids.

In another evaluation of asthma outcomes in patients enrolled in Kaiser Permanente, Im described the initiation of a pharmacist-managed Asthma Therapeutic Clinic at Bellflower Medical Center in California.¹⁹ The clinic was approved by the allergy, internal medicine, family practice, and emergency room departments. The pharmacist saw patients individually to educate them about asthma and goals of treatment. Each patient's drug therapy was monitored, including dose, schedule, drug interactions, cost effectiveness, and adverse effects. Patients received instruction regarding correct use of inhalation devices and maintaining a symptom diary. Reports of patient education and medication adjustments were sent to the primary physician for review and authorization. In the early 1990s, 75 patients were evaluated, comparing ED visits and hospitalizations for 1 year before and 1 year after enrollment in the clinic. There was a 66% reduction in ED visits ($P = .0001$) and a 48% reduction in hospitalizations ($P = .0079$).

Cheng et al conducted a follow-up evaluation of the pharmacist-run clinic at Bellflower Medical Center.²⁰ In a retrospective chart review of 58 patients (17 patients were lost to follow-up) over 7 years, the reduction in number of ED visits was sustained (7.83 visits per patient per year before the clinic to 0.74 visits 7 years after the clinic began). Hospitalizations also were reduced from 0.53 to 0.16 per patient per year. In yet another evaluation of the Kaiser Bellflower pharmacist-run asthma clinic, Wan and Kurohara reported that for 195 asthma patients enrolled from November 1995 to August 1997, the ED visits per patient per year were reduced from 1.97 to 0.68 over a period of 12 to 33 months of follow-up.²¹

Kelso et al evaluated outcomes over a 2-year period for a group of middle-class and low-income employed adult African Americans with poorly controlled asthma (≥ 5 ED visits in past 2 years or ≥ 2 hospitalizations in past 2 years).²² This study was initiated and managed by a clinical pharmacist in collaboration with a pulmonologist. The intervention group ($n = 21$) received initial detailed patient education in a 1-hour session (asthma as inflammatory airway disease, triggers, medications, use of peak flow meters and colored zones, MDI and spacer use, written crisis plan). Special emphasis was given to showing genuine concern for the patient as part of the partnership in education described in the 1997 NIH guidelines.¹ Easy access to the investiga-

tors was stressed, and frequent phone contact was made. Treatment was tailored per NIH guidelines, emphasizing inhaled corticosteroids. As in the Mayo et al trial,¹⁰ an emergency supply of prednisone (40 mg daily for 3 days) was given to each patient in the intervention group. During each clinic visit, the investigators observed the patient using the MDI with a spacer and the peak flow meter and gave reminders about the importance of inhaled corticosteroids. The control group (n = 18) received usual care.

The mean number of ED visits for the intervention group decreased significantly from 2.3 to 0.6 per year ($P = .0001$) versus the control group decrease of 2.6 to 2.0 per year ($P = .11$). Sixty-two percent of the intervention group had complete elimination of ED visits and hospitalizations.

Table 4. Role of the Pharmacist in Improving Asthma Outcomes

- Ensure use of the principles in the NIH guidelines¹
- Work in partnership with patients and other health professionals
- Patient education, including demonstrations and observation of peak flow meters, MDI and MDI plus spacer device, breath-activated dry powder inhalers
- Patient education regarding environmental control, controllers vs "quick relievers," asthma as an inflammatory airway disease, prevention of exercise-induced asthma, action plan for acute exacerbations, including colored zone management with PEF
- Ensure adequate anti-inflammatory therapy (doses, etc)
- Ensure appropriate use of long-acting bronchodilators
- Encourage outreach programs, including consistent telephone contact and home visits by health professionals or trained community health workers
- Monitor for adverse drug effects and drug interactions
- Ensure optimal management of concomitant allergic rhinitis, sinusitis, GERD, and perimenstrual asthma to improve outcomes
- Ensure appropriate use of systemic corticosteroids in home management of acute exacerbations per NIH guidelines
- Track ED visits, hospitalizations, quality-of-life measures, lost school or work days

ED = emergency department; GERD = gastroesophageal reflux disease; MDI = metered-dose inhaler; NIH = National Institutes of Health; PEF = peak expiratory flow.

... OTHER CLINICAL TRIALS
DEMONSTRATING IMPROVED
OUTCOMES ...

George et al assessed the effect of a comprehensive educational program on outcomes in 77 adults with asthma.²³ Patients hospitalized for asthma were randomized either to receive detailed, repetitive education and subsequent referral to a university asthma clinic (n = 44) or to receive usual care (n = 33). Over the subsequent 6 months, intervention patients (inpatient education and referral to university asthma clinic) had significantly fewer ED visits (a total of 27 visits for 6 months before enrollment vs a total of 3 visits after; $P = .04$). Control patients (usual care) had a total of 17 visits in the preintervention period and 15 visits in the postintervention period. Although this study emphasized patient education, we included it briefly in our review because patients were referred to a university asthma clinic for comprehensive care.

McGill et al evaluated the effect of an educational and therapeutic intervention program in Head Start children using clinical pharmacists as asthma counselors.²⁴ The intervention consisted of personalized education, management skill training, development of an asthma management plan, and family empowerment to use healthcare resources. Interventions were done in partnership with the child's physician and Head Start personnel. The intervention group (n = 33) had a 66% reduction in ED visits in the year after the intervention versus the year before; the control group (n = 51) had a 33% reduction in ED visits ($P = .03$).

Buchner et al examined the effect of patient education and training primary care providers in use of the NIH guidelines on outcomes in children and adults with asthma enrolled in a managed care organization.²⁵ Patients received education via direct patient contact, home nurse care visits, or telephone. Booklets and videos also were sent to patients. Medical and pharmacy administrative claims data were reviewed for 1 year before and 1 year after the intervention for 6698 patients. The number of patients receiving chronic inhaled corticosteroid therapy increased 25% after the educational sessions for clinicians. There was an 18% reduction in the number of hospitalizations for asthma in the year after the intervention ($P < .01$) and a 39% reduction in the number of patients with multiple hospital admissions ($P < .05$).

Higgins et al evaluated outcomes for 61 pediatric patients who received asthma education classes;

there were 2 sessions covering the disease, triggers, medication use, and peak flow meters.²⁶ Patients then were assigned to a primary care provider who was trained in use of the NIH guidelines. Although ED visits and hospitalizations were not reduced to a statistically significant degree, there was a trend toward a reduction, and annual savings were highest for inpatient admissions: \$4348 per patient.

Other studies have demonstrated reduced asthma exacerbations (ie, improved outcomes) as part of an overall evaluation of adding a long-acting inhaled β_2 -agonist to an inhaled corticosteroid.^{27,28} A recent case-control study provided further evidence that low-dose inhaled corticosteroid therapy prevents asthma deaths.²⁹

... ROLE OF THE PHARMACIST IN IMPROVING OUTCOMES ...

Several clinical pharmacist-initiated studies aimed at reducing acute care visits have been cited in this review.^{12,13,19-22,24} Collaboration between clinical pharmacist and physician investigators in applying the principles of the NIH guidelines has been clearly proven to improve outcomes in several settings and regions of the United States. Pharmacist roles that can enhance patient outcomes are summarized in **Table 4**. To achieve competence in these roles, pharmacists are encouraged to become certified in asthma management (via colleges or associations who offer certification programs) as well as self-study of the NIH guidelines and other current literature.

... CONCLUSION ...

Several studies over the past 10 years have demonstrated that patients with asthma can have a reduced number of ED visits and hospitalizations when clinicians manage the disease using current guidelines. Utilizing the 4 major components of the NIH guidelines (objective assessment, environmental control, anti-inflammatory and other controller therapies, and patient education as a partnership) is dramatically effective. For inner city populations, outreach programs are helpful as part of the partnership between patients, families, and clinicians. Optimal long-term management of asthma is cost effective as well as highly efficacious in reducing ED visits and hospitalizations.

... REFERENCES ...

1. *Expert Panel Report II. Guidelines for the Diagnosis and Management of Asthma*. Bethesda, MD: National Institutes of Health; 1997. NIH publication 97-4051.
2. *Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention*. Bethesda, MD: National Institutes of Health; 1995. NIH publication 95-3659.
3. **Weiss KB, Gergen PJ, Hodgson TA**. An economic evaluation of asthma in the United States. *N Engl J Med* 1992;326:862-866.
4. **Homa DM, Mannino DM, Lara M**. Asthma mortality in U.S. Hispanics of Mexican, Puerto Rican, and Cuban heritage, 1990-1995. *Am J Respir Crit Care Med* 2000;161:504-509.
5. **Mahajan P, Pearlman K, Okamoto L**. The effect of fluticasone propionate on functional status and sleep in children with asthma and on the quality of life of their parents. *J Allergy Clin Immunol* 1998;102:19-23.
6. **Craig TJ, Teets S, Lehman ED, Chinchilli VM, Zwillich C**. Nasal congestion secondary to allergic rhinitis as a cause of sleep disturbance and daytime fatigue and the response to topical nasal corticosteroids. *J Allergy Clin Immunol* 1998;101:633-637.
7. **Hartert TV, Windom HH, Peeples RS, et al**. Inadequate outpatient medical therapy for patients with asthma admitted to two urban hospitals. *Am J Med* 1996;100:386-394.
8. **Legorreta AP, Christian-Herman J, O'Connor RD, et al**. Compliance with national asthma management guidelines and specialty care. *Arch Intern Med* 1998;158:457-464.
9. **Milgrom H, Bender B, Ackerson L, et al**. Noncompliance and treatment failure in children with asthma. *J Allergy Clin Immunol* 1996;98:1051-1057.
10. **Mayo PH, Richman J, Harris HW**. Results of a program to reduce admissions for adult asthma. *Ann Intern Med* 1990;112:864-871.
11. *Expert Panel Report. Guidelines for the Diagnosis and Management of Asthma*. Bethesda, MD: National Institutes of Health; 1991. NIH publication 91-3042.
12. **Pauley TR, Magee MJ, Cury JD**. Pharmacist-managed, physician-directed asthma management program reduced emergency department visits. *Ann Pharmacother* 1995;29:5-9.
13. **Kelso TM, Self TH, Rumbak MJ, Stephens MA, Garrett W, Arheart KL**. Educational and long term therapeutic intervention in the ED: Effect on outcomes in adult indigent minority asthmatics. *Am J Emerg Med* 1995;13:632-637.
14. **Greineder DK, Loane KC, Parks P**. Reduction in resource utilization by an asthma outreach program. *Arch Pediatr Adolesc Med* 1995;149:415-420.
15. **Greineder DK, Loane KC, Parks P**. A randomized controlled trial of a pediatric asthma outreach program. *J Allergy Clin Immunol* 1999;103:436-440.
16. **Kelly CS, Morrow AL, Shults J, Nakas N, Strobe GL, Adelman RD**. Outcomes evaluation of a comprehensive intervention program for asthmatic children enrolled in Medicaid. *Pediatrics* 2000;105:1029-1035.
17. **Stout JW, White LC, Rogers LT, et al**. The asthma outreach project: A promising approach to comprehensive asthma management. *J Asthma* 1998;35:119-127.
18. **Zeiger RS, Heller S, Mellon MH, Wald J, Falkoff R, Schatz M**. Facilitated referral to asthma specialist reduces relapses in asthma emergency room visits. *J Allergy Clin Immunol* 1991;87:1160-1168.
19. **Im J**. Evaluation of effectiveness of an asthma clinic managed by an ambulatory care pharmacist. *Calif J Hosp Pharm* 1993;5:5-6.
20. **Cheng B, Paulson Y, Wan H, Mochidome S, Hartman T, Kurohara M**. Evaluation of the long-term outcome of adult patients managed by the pharmacist-run asthma program in a health main-

tenance organization [abstract]. *J Allergy Clin Immunol* 1999;103:S1.

21. Wan H, Kurohara M. Utilization outcomes evaluation of a clinical pharmacist run adult asthma management program [abstract]. *J Allergy Clin Immunol* 1999;103:S5.

22. Kelso TM, Abou-Shala N, Heilker GM, Ahreart KL, Portner TS, Self TH. Comprehensive long term management program for asthma: Effect on outcomes in adult African Americans. *Am J Med Sci* 1996;311:272-280.

23. George MR, O'Dowd LC, Martin I, et al. A comprehensive educational program improves clinical outcome measures in inner-city patients with asthma. *Arch Intern Med* 1999;159:1710-1716.

24. McGill KA, Sorkness CA, Decker CA, Havighurst T, Lemanske RF, Busse WW. Improved asthma outcomes in Head Start children using pharmacist asthma counselors [abstract]. *Am J Respir Crit Care Med* 1997;155:A202.

25. Buchner DA, Butt LT, De Stefano A, Edgren B, Suarez, Evans

RM. Effects of an asthma management program on the asthma member: Patient-centered results of a 2-year study in a managed care organization. *Am J Manag Care* 1998;4:1288-1297.

26. Higgins JC, Kiser WR, McClenathan S, Tynan NL. Influence of an interventional program on resource utilization in pediatric asthma. *Am J Manag Care* 1998;4:1465-1469.

27. Pauwels RA, Lofdahl CG, Postma DS, et al. Effect of inhaled formoterol and budesonide on exacerbations of asthma. *N Engl J Med* 1997;337:1405-1411.

28. Shapiro G, Lunry W, Wolfe J, et al. Combined salmeterol 50 mcg and fluticasone propionate 250 mcg in the Diskus device for the treatment of asthma. *Am J Respir Crit Care Med* 2000;161:527-534.

29. Suissa S, Ernst P, Benayoun S, Baltzan M, Cai B. Low-dose inhaled corticosteroids and the prevention of death from asthma. *N Engl J Med* 2000;343:332-336.

Appendix. Asthma Action Plan

Name _____

Date _____

Asthma Action Plan

It is important in managing asthma to keep track of your symptoms, medications, and peak expiratory flow (PEF). You can use the colors of a traffic light to help learn your asthma medications:

- Green means Go—use preventive (anti-inflammatory) medicine.
- Yellow means Caution—use quick-relief (short-acting bronchodilator) medicine in addition to the preventive medicine.
- Red means Stop!—get help from a doctor.

a. Your GREEN ZONE is 80% to 100% of your personal best. GO!

Breathing is good with no cough, wheeze, or chest tightness during work, school, exercise, or play.

ACTION:

- Continue with medications listed in your daily treatment plan.

b. Your YELLOW ZONE is 50% to less than 80% of your personal best. CAUTION!

Asthma symptoms are present (cough, wheeze, chest tightness).

Your peak flow number drops below _____ or you notice:

- Increased need for inhaled quick-relief medicine
- Increased asthma symptoms upon awakening
- Awakening at night with asthma symptoms
- _____

ACTIONS

- Take ____ puffs of your quick-relief (bronchodilator) medicine _____. Repeat ____ times.
- Take ____ puffs of _____ (anti-inflammatory) _____ times/day.
- Begin/increase treatment with oral steroids.
Take ____ mg of _____ every AM _____ and PM _____.
- Call your doctor (phone) _____ or emergency room (phone) _____.

c. Your RED ZONE is 50% or less of your personal best. DANGER!!

Your peak flow number drops below _____ or you continue to get worse after increasing treatment according to the directions above.

ACTIONS

- Take ____ puffs of your quick-relief (bronchodilator) medicine _____. Repeat ____ times.
 - Begin/increase treatment with oral steroids. Take ____ mg now.
 - Call your doctor now (phone) _____.
 - If you cannot contact your doctor, go directly to the emergency room (phone) _____.
- Other important phone numbers for transportation _____.

AT ANY TIME, CALL YOUR DOCTOR IF:

- Asthma symptoms worsen while you are taking oral steroids, or
- Inhaled bronchodilator treatments are not lasting 4 hours, or
- Your peak flow number remains or falls below _____ in spite of following the plan.

Physician Signature _____

Patient's/Family Member's Signature _____

This plan is provided as an example to clinicians.

Source: Reference 1.

CONTINUING PHARMACY EDUCATION



This course has been approved for a total of two (2) contact hours of continuing education credit (0.2 CEUs) by the University of Tennessee College of Pharmacy. The University of Tennessee College of Pharmacy is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. ACPE Program Number: 064-999-01-202-H-01. This course expires February 28, 2003.

Instructions

After reading the article "Studies Demonstrating Improved Outcomes in Patients with Asthma: A 10-Year Review," select the best answer to each of the following questions.

1. How many million people in the United States are estimated to have asthma?

- a) 10-11 million
b) 14-15 million
c) 15-20 million
d) 9-10 million

2. Which inner city ethnic group has the greatest annual mortality from asthma?

- a) Puerto Ricans
b) African Americans
c) Caucasians
d) Mexican Americans

3. According to the National Institutes of Health (NIH) guidelines, which of these is 1 of the 4 components of long-term asthma management?

- a) utilizing pharmacologic treatment only
b) controlling environmental trigger factors
c) aromatherapy/herbal therapy
d) weekly clinic visits

4. In the inner city trial conducted by Kelso et al, the clinical pharmacist investigator initiated individualized asthma education:

- a) in a physician's office
b) in an asthma clinic
c) in the emergency department
d) in the pharmacy

5. Patients defined as having moderate persistent asthma should receive which long-term control medication?

- a) cromolyn
b) medium-dose inhaled corticosteroid
c) high-dose prednisone
d) inhaled albuterol

6. Estimated costs associated with asthma in the United States are:

- a) \$8.6 billion
b) \$10 billion
c) \$1 billion
d) \$6.2 billion

(CPE questions continued on following page)

Studies Demonstrating Improved Outcomes in Patients with Asthma: A 10-Year Review

ACPE Program Number: 064-999-01-202-H-01

(PLEASE PRINT CLEARLY)

Name

Home Address

City

State/ZIP

Daytime Phone #

States in Which CE Credit is Desired

Social Security #

Please circle your answers:

- 1. a b c d 6. a b c d 11. a b c d 16. a b c d
2. a b c d 7. a b c d 12. a b c d 17. a b c d
3. a b c d 8. a b c d 13. a b c d 18. a b c d
4. a b c d 9. a b c d 14. a b c d 19. a b c d
5. a b c d 10. a b c d 15. a b c d 20. a b c d

Please complete the Program Evaluation on following page, and send with \$15 fee, payable to University of Tennessee, to:

Glen E. Farr, PharmD
University of Tennessee College of Pharmacy
600 Henley Street, Suite 213
Knoxville, TN 37902

...CPE QUIZ...

7. In the trial conducted by Mayo et al, the outcomes measured resulted in:

- a) an increase in albuterol use
- b) a 3-fold decrease in hospital days
- c) an increase in physician office visits
- d) a 2-fold decrease in mortality

8. Many of the studies had educational sessions that described the pathophysiology of asthma as being:

- a) a bronchospastic airway
- b) a hyperreactive airway
- c) an infectious process
- d) an inflammatory process

9. According to the Asthma Action Plan (Appendix), patients whose peak flow response drops into the red zone should begin immediate treatment with:

- a) nebulized albuterol
- b) oral corticosteroids
- c) leukotriene modifiers
- d) cromolyn

10. When educating patients about their asthma, you should always describe which of the following?

- a) the pathways and mediators of the inflammatory process
- b) the roles of medications
- c) the pharmacokinetics of the medications
- d) the value of over-the-counter asthma medications

11. In the first pediatric trial by Greineder et al, emergency department visits were reduced by:

- a) 79%
- b) 39%
- c) 84%
- d) 86%

12. How many days of school are missed annually due to asthma?

- a) 1 million
- b) 6.2 million
- c) 10 million
- d) 500,000

13. In a study of children enrolled in Medicaid, the patients treated according to the NIH guidelines had an average reduction in healthcare charges of:

- a) \$721/child per year
- b) \$178/child per year
- c) \$650/child per year
- d) \$250/child per year

14. Which of the following is an appropriate suggestion when educating patients about the environmental trigger factors that worsen asthma?

- a) stop smoking
- b) wash blankets and sheets daily in bleach
- c) get rid of all pets
- d) wear a mask when outside the home

(CPE questions continued on following page)

CPE PROGRAM EVALUATION (064-999-01-202-H-01)

The University of Tennessee College of Pharmacy would like to have your opinion. Please fill out the questionnaire below, tear off along the dotted line, and mail along with your CPE test form. We thank you for your evaluation, which is most helpful.

Please circle your answers:

My pharmacy practice setting is:	Independent	Chain	Hospital	Consultant
The objectives of the lesson were achieved:	Yes	No		
The quality of presentation of the material was:	Excellent	Good	Fair	Poor
The information presented will be useful to me in my practice.	Strongly agree	Mildly agree	Mildly disagree	Strongly disagree

How long did it take you to read the material and respond to the Continuing Education questions: (Please specify the number of hours.)

Please send this evaluation, along with your answer sheet and \$15 check payable to University of Tennessee, to:

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University of Tennessee College of Pharmacy
600 Henley Street, Suite 213
Knoxville, TN 37902

...CPE QUIZ...

15. The yellow zone on a patient's peak flow meter is what percentage of their personal best value?

- a) 40%-60%
- b) 70%-90%
- c) 50%-80%
- d) 30%-60%

16. Which of the following was a pharmacist intervention in the study by McGill et al?

- a) home follow-up visits
- b) construction of an asthma management plan
- c) providing booklets and videos to the patients
- d) prescribing long-term anti-inflammatory medications

17. Which statement best describes the literature regarding improvement of outcomes in patients with asthma?

- a) cooperation among healthcare professionals has helped reduce emergency department visits
- b) self-education by the patient has proven most beneficial
- c) as physician visits increase, the number of missed school days decreases
- d) annual visits to a pulmonologist has helped decrease emergency department visits

18. According to the NIH guidelines, patients classified as having mild intermittent asthma who are subsequently using their short-acting β_2 -agonist more than 2 times per week may need:

- a) a long-acting β_2 -agonist
- b) an anti-inflammatory medication
- c) more puffs of their short-acting β_2 -agonist
- d) to go to the emergency room

19. Which of the following is a common feature of pediatric asthma outreach programs?

- a) annual visits with a pulmonologist
- b) weekly home visits by a nurse
- c) home visits by the physician
- d) regular follow-up educational sessions

20. The optimal way to reduce asthma-related health-care costs is to:

- a) decrease medication costs by minimizing use of corticosteroids
- b) tell patients to seek medical attention when asthma flares up
- c) implement NIH guidelines for asthma management, emphasizing the patient-provider relationship
- d) reduce medication costs by minimizing β_2 -agonist use

Please fill out the University of Tennessee College of Pharmacy program evaluation that accompanies this quiz (page 199).