

SUPPLEMENT TO

**M A N A G E D**

# Care

## **Reversing Asthma-Related Morbidity and Mortality Through Patient Persistency And Compliance**

Based on a symposium in San Francisco, March 31, 2004

### **HIGHLIGHTS**

- Underestimating Asthma Severity –  
Variability of Classifications and Outcomes

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- The Truth About SABA Pharmacy Claims –  
Results From a Prospective Study

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- Guidelines, Treatment Options, and Outcomes Data –  
A Health Plan's Perspective

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### **ROUNDTABLE DISCUSSION**

- Challenges: Classification, Persistency, and Perceptions  
Of Disease Control

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## INTRODUCTION

ROBERT P. NAVARRO, PHARM D

President, NavarroPharma LLC

### Facing Challenges in Asthma Management: Compliance and Appropriate Disease Classification

On March 31, 2004, a panel of experts convened to discuss challenges in the management of asthma, such as disease variability, appropriateness of the National Asthma Education and Prevention Program (NAEPP) guidelines, patient compliance, and accuracy of pharmacy claims data as a basis of severity classification. Chronic and potentially debilitating, asthma earns its place among the priority diseases specified by the Institute of Medicine. Despite advances in the pathophysiology, diagnosis, and treatment of asthma, morbidity and mortality have increased — along with its associated financial burden. One reason for this is the condition's variability. Therapy necessitates careful individualization, which ultimately leads to improved compliance and, in turn, better clinical outcomes.

Richard O'Connor, MD, examines asthma's historical prevalence and comparative data pertaining to refill persistence for controller medications and the use of short-acting beta<sub>2</sub> agonists (SABAs). He also examines misclassification of asthma patients relative to the current NAEPP guidelines and patient and physician perceptions of disease control. Helen O. Chernicoff, MD, MSHS, discusses results of the REACH (Registry for the Enhancement of Asthma Control and Health) study — a retrospective analysis of pharmacy claims data versus patient self-reports, evaluating use of SABAs. H. Eric Cannon, PharmD, examines data on refill persistence and the incidence of asthma exacerbations. He represents Intermountain Health Care, which collected data to correlate controller medication utilization and emergency room visits, hospitalizations, and costs. Compared with other treatment, combination therapy with fluticasone/salmeterol consistently showed greater decreases in rates and costs of acute and inpatient care.

Revising the asthma classification system and initiating corresponding changes in treatment recommendations can positively affect asthma management. The urgency for change is particularly relevant to patients with mild disease who have potentially life-threatening exacerbations. All the data support the need to increase efforts to educate patients and the health care community about effective disease control.



ROBERT P. NAVARRO,  
PHARM D

SUPPLEMENT TO  
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**Care**

July 2004

**Reversing Asthma-Related Morbidity and Mortality  
 Through Patient Persistency and Compliance**

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## Self-Study Continuing Education Activity

### ABOUT THIS PUBLICATION

Even with treatment advances and an increased understanding of the pathogenesis of asthma, the related morbidity, mortality, and financial burdens present management and control challenges. In particular, asthma's variability presents a challenge for providers when assessing disease severity. An understanding of the variability of asthma severity and classification, combined with improved provider and patient education, resulting in improved patient compliance, can positively affect asthma-associated morbidity and mortality.

This publication is derived from a symposium in San Francisco on March 31, 2004. The symposium faculty, whose presentations form the basis of the articles herein, provided a comprehensive explanation of the variability of asthma severity and classification. Data were presented regarding the effect on compliance of differing asthma pharmacotherapy options, as measured by refill persistence and the use of reliever medications. Results of a recent retrospective cohort claims study using routinely collected patient data to examine the associations between treatment and outcomes (e.g., use of specific drug regimens and prescription claims) were presented. Data also were presented on the effects of medication compliance and refill persistence on the incidence of asthmatic exacerbations as measured by the use of rescue inhalers, emergency department visits, and hospitalizations. Additionally, data from an innovative prospective study using patient registry information addressed baseline asthma disease control and quality-of-life issues for patients prescribed differing initial maintenance therapies and the effect of nonreported short-acting beta<sub>2</sub> agonist (SABA) use on asthma classifications and outcomes data. The faculty discussed methods of analyzing data from individual health plans to evaluate asthma management efforts and how other health plans can apply these insights.

Program release date: July 15, 2004  
Program expiration date: July 15, 2005

### Target audience

This program has been designed to educate managed care pharmacists,

pharmacy directors, and managed health plan medical directors on recent and upcoming changes in asthma management guidelines, and to help them improve quality of care through examples of progressive and innovative asthma management programs.

### Learning objectives

After reading this publication, the participant should be able to:

1. Compare current asthma management practice patterns and related outcomes.
2. Explain the variability of asthma severity and classifications and how this variability relates to patient-treatment decision making.
3. Evaluate the refill persistency and medication compliance of asthma therapies and the impact on morbidity and mortality.
4. Describe the role of nonreported SABA use in outcomes data and classifications.
5. Utilize current outcomes data to maximize asthma control.
6. Analyze health plan pharmacy data relating to asthma.

### To receive credit

The physician or pharmacist must read the material on pages 3 to 19 of this publication, successfully complete the post-test and evaluation form, and mail the completed form with a check for \$10 to:

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The faculty declared the following:

Robert P. Navarro, PharmD, has reported that he has served as a consultant for GlaxoSmithKline.

Richard D. O'Connor, MD, reports that he has served on the speakers' bureaus for Aventis, AstraZeneca, GlaxoSmithKline, Pfizer, and UCB Pharma.

H. Eric Cannon, PharmD, and Helen O. Chernicoff, MD, MSHS, have reported no relationships with commercial companies having products that are mentioned in their articles.

# Underestimating Asthma Severity – Variability of Classifications and Outcomes

RICHARD D. O'CONNOR, MD

*Director, Department of Quality Management; Director, Department of Clinical Research; Staff Physician, Sharp Rees-Stealy Medical Group, San Diego  
Clinical Professor of Pediatrics, University of California–San Diego School of Medicine*

**F**or nearly two decades, mortality associated with asthma steadily increased. In 1979, the annual number of deaths was 2,598, peaking in 1996 at 5,667. What is especially disturbing is that the number more than doubled — despite better understanding of the disease process and the availability of presumably improving therapy.

The news is not all bad. Since 1996, asthma mortality has declined. In 2000, the number of deaths was 4,487, a decrease of approximately 20 percent compared with 1996. This trend also has been apparent in hospitalizations due to asthma-related symptoms. The number peaked at more than 500,000 in 1994, but then stabilized and gradually decreased during the last few years. In 2000, there were 465,000 asthma-related hospitalizations. Similarly, visits to the emergency room (ER) for acute care fell below 2 million in 2000, with approximately 1.8 million visits (ALA 2004).

Increased prevalence of asthma also accompanied the increase in mortality. Prevalence increased significantly, growing from 3.1 percent of the U.S. population between 1979 and 1981 to 4.6 percent between 1990 and 1992 (NCHS 1997). In 2000, the Centers for Disease Control and Prevention conducted the Behavioral Risk Factor Surveillance System survey, a state-based, random-digit-dialed survey of the noninstitutionalized U.S. population aged 18 or older. Information was collected about modifiable risk factors for chronic diseases and other leading causes of death. The response rate was 51.3 percent, with 182,293 respondents included in the data set. Results indicated that lifetime and current prevalence rates for asthma are 10.5 percent and 7.2 percent, respectively (CDC 2001).

Increased prevalence and mortality of asthma in the United States also impose a significant financial burden on society. These have significant effects among working adults with asthma and cause more school absenteeism than any other chronic illness. Annually, 14.5 million workdays and 14 million school days are lost due to asthma.

## NAEPP responds

In response to the changes in mortality due to asthma and its rising prevalence, the National Asthma Education and Prevention Program (NAEPP) of the National Heart, Lung, and Blood Institute (NHLBI) convened a panel of experts who published guidelines for asthma management in 1991 (NAEPP 1991). Theophylline, not inhaled

corticosteroids (ICSs), was listed among the controller medications recommended for mild persistent asthma. In 1997, when the second Expert Panel Report (EPR-2) was issued, theophylline was removed from the preferred controller category and recommended only as an alternative treatment (NAEPP 1997). ICSs were recommended for mild, moderate, and persistent asthma in adults. The use of ICSs for children, however, was not included in the recommendations until 2002 (Table 1, page 4). In addition, leukotriene receptor antagonists were finally included in the guidelines. In 1997, they were not covered

to any significant degree and, in 2002, were positioned as alternative treatment along with theophylline, nedocromil, and cromolyn.

The 2002 recommendations applied to adults and children as young as 1 year. The preferred treatment for both groups included low-dose ICSs for mild persistent asthma; low- to medium-dose ICSs and long-acting beta<sub>2</sub> agonists (LABAs) for moderate persistent asthma; and high-dose ICSs and LABAs for severe persistent asthma (NAEPP 2002).

Information regarding the benefits of ICS therapy has accumulated since the 1997 iteration of the guidelines. In a Canadian study by Suissa (2000), the number of canisters of ICSs dispensed on an annual basis was correlated with the risk ratio of death from asthma. Results showed that when 3 to 6 canisters are used consistently per year, the level of risk declines sharply — demonstrating the importance of persistence.

In a retrospective cohort study, 180 patients with asthma who had been given their first prescription for an ICS were matched to more than 223 controls on the basis of age, gender, and previous disease severity and fol-



RICHARD D.  
O'CONNOR, MD

**TABLE 1** NAEPP classification of disease severity

Disease Severity	Symptoms/day Symptoms/night	Peak flow or FEV <sub>1</sub> (%) Peak flow variability (%)
<b>Mild intermittent</b>	≤2 days per week ≤2 nights per month	≥80 <20
<b>Mild persistent</b>	>2/week but <1/day >2 nights per month	≥80 20–30
<b>Moderate persistent</b>	Daily >1 night per week	>60–<80 >30
<b>Severe persistent</b>	Continual Frequent	≤60 >30

Classification is determined using the most severe finding prior to treatment. Three or more exacerbations in children place them in the persistent category.

FEV<sub>1</sub>=forced expiratory volume in 1 second.

SOURCE: NAEPP 2002

lowed for 12 months. There were significant ( $P<.01$ ) reductions of 50 percent in the need for hospitalization, 26 percent in the likelihood of being seen in the ER, and 15 percent in the likelihood of being seen in the physician's office. Costs declined 23.6 percent per patient per month in the patients who received an ICS compared with the matched control population (Balkrishnan 1998).

Since the introduction of the NAEPP guidelines, medications have been the focus of attention and fundamental to most subsequent revisions. The constant, however, has been the classification system for asthma severity. This article will address the need for a new perspective on how asthma is classified.

### NAEPP classification: Time for a modification?

According to current guidelines, asthma severity is classified using the most severe finding prior to initiating therapy. This strategy is in contrast to classification of other chronic conditions, such as diabetes, hypertension, and congestive heart failure; severity for these diseases is categorized after therapy initiation and based on the level of response or lack of response to medication. In fact, asthma is the only chronic condition that is classified before therapy is initiated.

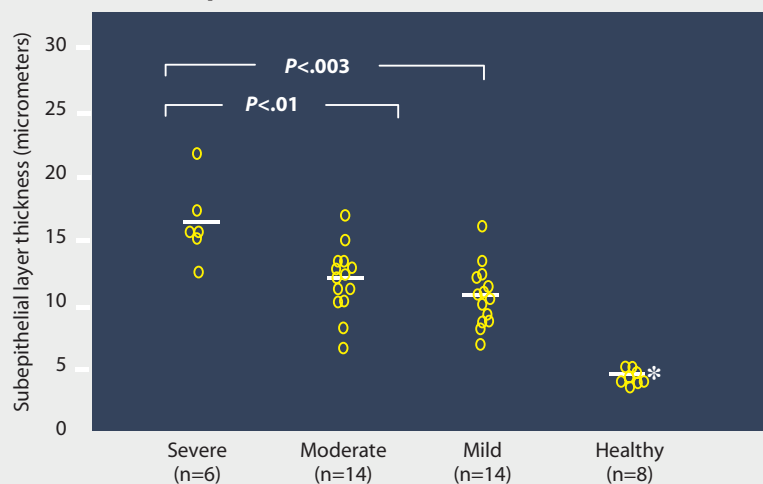
The category of mild disease, compared with moderate or severe, is the first area in need of reconsideration, particularly because these patients can suffer catastrophically

severe exacerbations. Although patients who have mild disease generally have normal or near-normal lung function, results from methacholine tests consistently demonstrate airway hyperreactivity. Also, alveolar lavage or biopsy of the airways in these patients shows evidence of inflammatory cell infiltration, epithelial cell disruption, and airway remodeling that has been found to begin extremely early in mild asthmatics (Figure 1).

Well-characterized asthmatics with mild and moderate persistent disease were subjected to an allergen challenge to evaluate possible physiologic differences. Total and differential cell counts were assessed at baseline and 24 hours following exposure to the allergen. Pathologically, there was no distinction between patients with mild and moderate persistent asthma. Furthermore, the degree of postchallenge response in patients with mild and moderate persistent asthma was identical (Moore 2001).

Based on evidence of airway remodeling and examination of subepithelial layer thickness, asthmatics can be differentiated from controls and severe asthmatics can be differentiated from patients with mild or moderate disease. Nevertheless, no distinction can be made between mild and moderate asthmatics on the basis of airway remodeling. Therapeutic categories have been developed that separate these two groups, however.

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**FIGURE 1** Airway remodeling in patients with mild persistent asthma

\* $P<.001$ , healthy subjects vs. patients with asthma.

SOURCE: CHETTA 1997

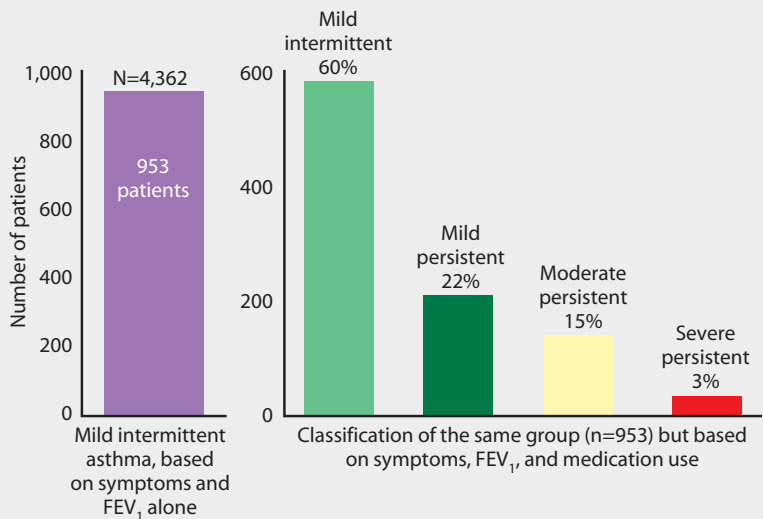
A study by Robertson that was published in 1992 strongly illustrates the need to revisit classification of asthma severity. Pediatric asthma-related deaths during a 3-year period were reviewed in the state of Victoria, Australia, based on interviews with the parents of 51 children who had died. The investigators inquired about the symptoms the children had in the 6 months prior to the acute event. Surprisingly, one third of the children had mild disease, described in the report as “trivial asthma.” One third were categorized as moderate, and only one third were considered severe (Robertson 1992). Mild disease is misleading in the sense that death is a possible outcome.

A study by Fuhlbrigge (2001) examined the relationship between pulmonary function and disease severity in a pediatric cohort of approximately 3,500 children. Children with asthma were followed prospectively for a year after baseline pulmonary function testing. It was concluded that a low forced expiratory volume in 1 second ( $FEV_1$ ) is a predictor of the likelihood of an acute episode of asthma within 12 months. This applied, however, to a very small proportion of the patients in the study. Of greater importance, children who had  $FEV_1$ s of 80 to 100 percent of predicted values, and indeed children who had  $FEV_1$ s well above 100 percent of predicted values, still required acute care visits between one fifth to one third of the time.

In a European study of 4,300 adults, approximately 950 were classified as mild intermittent asthmatics based on symptoms and pulmonary function as suggested by the NAEPP guidelines. When medication use was added as a variable, there was a migration of 40 percent of patients into a persistent category, including 18 percent who fell into the moderate or severe category (Figure 2).

Fuhlbrigge conducted the first critical examination of the current asthma-severity classification system by investigating how questions are asked and the effect this has on classification of disease severity. Using short-term symptom recall, patients were asked how often they experienced chest tightness, wheezing, shortness of breath, or cough throughout the past 4 weeks due to asthma. Based on their responses, 44 percent were classified as mild intermittent asthmatics, 20 percent as mild persistent asthmatics, and 36 percent as moderate or severe. When investigators asked patients about the effects of their disease on functional capacity (e.g., activities of daily living), however, the mild intermittent category fell to 11 percent; the mild persistent category stayed at about

**FIGURE 2 Misclassification of intermittent asthma**



$FEV_1$ =forced expiratory volume in 1 second.

SOURCE: LIARD 2000

20 percent. Nonetheless, there was a dramatic rise in the proportion of patients who were now classified as moderate or severe, which jumped to 70 percent (Fuhlbrigge 2002).

Further evidence demonstrating the variability of asthma was provided by a study by Calhoun and colleagues of steroid-naïve patients who were enrolled in two double-blind, randomized, controlled trials. At baseline, all patients were required to meet the criteria established by NAEPP guidelines for moderate or severe persistent asthma. Symptoms, albuterol use, and morning peak flow were analyzed weekly. Approximately 30 percent of patients stayed in the class they were assigned at the beginning of the study. Yet, 70 percent — based upon peak flow alone — changed classification on multiple occasions (Calhoun 2003).

Asthma is not a static disease. Patients are seen at a point in time, and it is impossible to classify disease severity on that basis. The effect our classification system has on patients and providers is equally disturbing.

### Undertreatment

Because physicians underestimate underlying asthma severity, patients are undertreated. Medication use was analyzed and asthma severity estimated by 4,005 patients and their physicians. Patients were provided with a copy of the national guidelines and asked to categorize their disease severity. Physicians were asked to do the same for these patients. Approximately 10.5 percent of patients described their disease as mild and 50.1 percent as severe. In direct contrast, physicians classified 44.6 with mild disease and 10.9 with severe asthma. Using the same clas-

sification scheme, patients and providers point in opposite directions (Wolfenden 2003).

How, then, did these discrepancies of severity assessment affect treatment? In patients who reported moderate symptoms, 35 percent received ICSs if the physician classified their asthma as mild, 53 percent if the physician classified their asthma as moderate, and 68 percent if the physician classified their disease as severe. Therefore, all interpretations of the data point to the same conclusion — one to two thirds of these patients are being undertreated. They should *all* be on an ICS.

Equally disturbing is the tendency of patients to underestimate the potential impact of this disease on their health and well-being. Surprisingly, among 2,500 asthmatic patients categorized with moderate persistent disease, 60 percent with daily symptoms report that they are completely controlled or well controlled (Asthma in America 1998). Of those with severe persistent asthma, 32 percent report that their symptoms are completely controlled or well controlled. This is a classic case of denial and potentially dangerous situation: patients overestimating their level of control in the face of ongoing symptoms.

Consistent with these findings are results from the OPTIMA study by O'Byrne. The effects of adding formoterol, a LABA, to low doses of budesonide, an ICS, for 1 year were evaluated in patients with mild asthma. Group B of this study included 1,272 corticosteroid-treated patients who were assigned to twice daily treatment with 100 mcg budesonide, 100 mcg budesonide plus 4.5 mcg formoterol, 200 mcg budesonide, or 200 mcg budesonide plus 4.5 mcg formoterol. Baseline characteristics showed that FEV<sub>1</sub>s in these patients with mild persistent disease averaged approximately 85 percent of predicted values. Adding formoterol reduced the risk for the first severe exacerbation and for poorly controlled days by 43 percent and 30 percent, respectively. Furthermore, adding formoterol was more effective than doubling the corticosteroid dose (O'Byrne 2001).

Thus, mild persistent asthma shows substantial improvement when combination therapy is recommended versus what is currently recommended — use of an ICS alone. In fact, O'Byrne showed that both groups that received steroids with a LABA did substantially better than the groups that used an ICS alone.

### **Clinical/economic consequences of utilization**

Thirteen randomized controlled trials (12 in adults, 1 in children) around the world compared ICSs with leukotriene receptor antagonists (LTRAs) and the rate of exacerbations. Patients with mild and moderate asthma allocated to treatment with an LTRA were 60 percent more likely to have suffered an exacerbation of asthma than patients who were allocated to treatment with an ICS. Also, all secondary measures — pulmonary func-

tion parameters, nighttime asthma symptoms, albuterol use as rescue medication, days without asthma, and treatment failure rates — favored ICS therapy. The risk of treatment failure was 2.5 times higher for patients receiving an LTRA (Ducharme 2003).

A number of studies have examined the cost of care between patients treated with an ICS versus a leukotriene modifying agent (LTM). A meta-analysis of these studies showed that annual pharmacy costs of LTM treatment is significantly higher: \$1,062 versus \$807 for ICS ( $P<.05$ ). There was even a greater difference in annual total asthma cost (ICS pharmacy plus utilization) between the two drugs: \$1,393 versus \$882 ( $P<.005$ ). Furthermore, although there was no difference between the drugs relative to hospitalization rates for the year prior to therapy initiation, there was a significant ( $P<.005$ ) drop after therapy with an ICS, from 4.7 percent to 2.2 percent versus only the change following treatment with an LTM from 4.8 percent to 4.3 percent (not significant). Similarly, use of an ICS resulted in a significant ( $P<.005$ ) decline in ER visits, from 10.8 to 6.2 percent; the change in the LTM group was not significant (Halpern 2003).

### **Medication persistence**

A Health Benchmarks analysis evaluated medication persistence. Refill rates for first-line combination therapy with fluticasone propionate/salmeterol as a single inhaler and fluticasone inhaler alone were compared. In the preindex period, patients were identified based on use of albuterol inhalers. The index was based on the date the patient filled a prescription for either the fluticasone/salmeterol combination as a single inhaler ( $n=1,013$ ) or fluticasone ( $n=1,130$ ). There was a significant ( $P<.05$ ) difference between the two groups in the number of refills dispensed in the 1 year follow-up period; the fluticasone/salmeterol group refilled the prescription 4.04 times versus 2.19 times for the fluticasone metered-dose inhaler group. Refill persistence, therefore was approximately 80 percent greater in the combination therapy group. Similarly, there was a greater reduction in ER visits or hospitalizations in the group using fluticasone/salmeterol; 44 percent versus 28 percent in the fluticasone group. In fact, an odds ratio showed that the fluticasone/salmeterol combination product resulted in a 41 percent lower risk of an asthma-related emergency room/hospital event compared with fluticasone alone.

These findings were consistent with another Health Benchmarks analysis using fluticasone/salmeterol (group A) as a single inhaler ( $n=1,101$ ) versus fluticasone and salmeterol (group B) simultaneously in separate inhalers ( $n=321$ ). Group A showed significantly ( $P<.05$ ) improved persistence, refilling the product 4.04 times in a year versus 2.37 times by those in group B. Furthermore, group A required significantly ( $P<.01$ ) less albuterol than

group B. Notably, group A showed a significant ( $P<.05$ ) reduction of 60 percent in the number of required ER visits or hospitalizations: 2.6 percent versus 8.4 percent. Difference in odds ratio for risk of an asthma-related ER visit or hospitalization was even more dramatic in this analysis, with group A showing a 71 percent lower risk of an asthma-related event compared with patients given prescriptions for the identical components requiring two separate inhalers (HBI 2001).

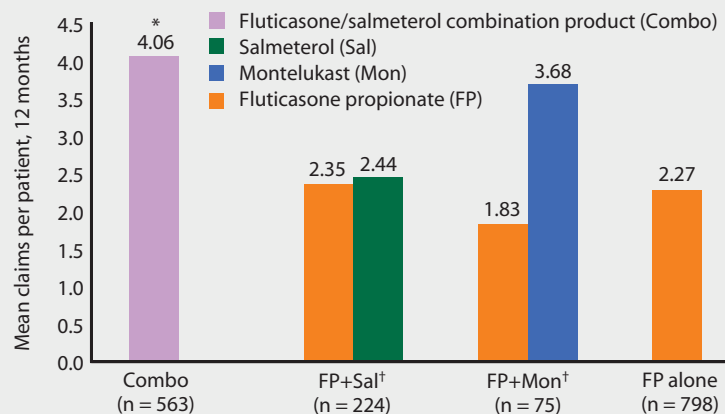
The key finding in the Health Benchmarks studies is that increased persistence is associated with a reduction in ER visits and hospitalizations. A retrospective study by Stoloff supports this finding. Refill persistence was evaluated in patients using (1) fluticasone/salmeterol as a single device; (2) fluticasone and salmeterol as two separate devices; (3) fluticasone and montelukast as two controller medications; (4) fluticasone alone; and (5) montelukast alone. The fluticasone/salmeterol combination in a single inhaler showed significantly ( $P<.05$ ) greater persistence compared with all groups using fluticasone as a component (Figure 3).

In addition to improved persistence and outcomes with fluticasone/salmeterol as combination therapy, the product also has been shown to be more cost-effective versus fluticasone plus montelukast. In randomized, controlled, double-blind, prospective trials, patients received fluticasone 100 mcg twice daily during the run-in period. Subsequently, they were allocated to receive either fluticasone/salmeterol combination therapy 100/50 mcg bid ( $n=222$ ) versus fluticasone 100 mcg bid plus montelukast 10 mg qd ( $n=225$ ) and followed for 12 weeks. Cost of daily treatment was \$1 more (\$4.64 vs. \$3.64) for patients allocated to fluticasone plus montelukast (O'Connor in press).

Cost-effectiveness was evaluated in another study using first-line maintenance therapy with fluticasone/salmeterol combination, fluticasone alone, or montelukast alone. Clinically important parameters including peak expiratory flow rates and rescue-free days also were examined. For both measures, the fluticasone/salmeterol combination product showed better results compared with both treatment groups, with a significant ( $P<.001$ ) difference compared with montelukast alone.

The average cost per patient with an exacerbation was approximately \$29 for those receiving the fluticasone/salmeterol combination product versus the substantially higher expense of more than \$150 for the montelukast group.

**FIGURE 3** Persistence: combination vs. monotherapies



\*The fluticasone/salmeterol combination product showed significantly greater persistence ( $P<.05$ ) compared with the FP components of FP+SAL, FP+MON, and FP alone. Comparisons controlled for demographics, physician specialty, chronic disease score, and pre-index medication use.

†FP+Sal and FP+Mon prescribed in combination but taken as separate products.

SOURCE: STOLOFF 2004

## Conclusion

Asthma care today has fallen short of the NHLBI goals. Although great strides have been made in therapeutic options for asthma, many challenges remain. We need to revisit our classification system for asthma and understand better the issues surrounding drug persistence. Substantial numbers of patients with asthma are undertreated. The results reviewed in this article underscore the urgent need to improve patient and provider education if we are to reverse these trends in asthma care.

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# The Truth About SABA Pharmacy Claims – Results from a Prospective Study

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Asthma affects more than 17 million Americans, resulting in a loss that exceeds 10 million school days, more than 1.5 million emergency room visits, approximately 500,000 hospitalizations, and more than 5,000 deaths annually (HBI 2002). Health Benchmarks Inc. (HBI) is a health services research company that converts health care data, such as these pertaining to asthma, into clinically and scientifically meaningful information, with the goal to improve health care delivery. Toward this end, HBI conducts health outcomes analysis and management, pharmacoeconomic evaluations, and clinical research.

HBI conducted a large observational study called REACH<sup>1</sup> — Registry for the Enhancement of Asthma Control and Health. REACH was conducted using an observational registry. That is, physicians were asked to recruit and enroll patients with asthma and simply conduct their daily clinical practice, providing usual care. The study required no additional follow-up visits or special care by the physician. This protocol had the advantage of ensuring the external validity of the findings and maximizing the ability of investigators to apply the information to the general public.

REACH was a 12-month, prospective, observational outcomes study of patients with persistent asthma. One objective was to examine disease control and quality of life (QOL) in two groups of patients: one group that previously used a short-acting beta<sub>2</sub> agonist (SABA) but not an inhaled corticosteroid (ICS) and then was started on a fluticasone propionate/salmeterol (100/50mcg) combination product that was provided in a single inhaler (initial maintenance therapy cohort); and a second group that previously used an ICS and then had therapy augmented to fluticasone propionate/salmeterol combination monotherapy (switched cohort). An additional analysis was conducted to compare self-reported use of SABAs with pharmacy claims data from designated health plans, which generates a key baseline finding of the REACH study.

## Retrospective analysis of pharmacy claims

Four hundred ninety-four physicians, representing 17 physician groups from 14 states throughout the country

were recruited and trained to participate in REACH. To be included in the study, physicians had to have treated at least 10 patients with asthma within the previous year. The majority were primary care physicians (48 percent); however, a number of specialties were included, such as allergy and immunology (25 percent), internal medicine (17 percent), pulmonology (6 percent), pediatrics (2 percent), and critical care (1 percent).

The REACH observational registry enrolled patients in eight designated managed care plans, including HMOs and PPOs. On a quarterly basis, administrative claims data were accessed with patient permission and updated. Participants had to be at least 15 years old with a current diagnosis of asthma and able to speak English so that they could complete the study questionnaires. Three months prior to enrollment, patients had to have used either a SABA or an ICS. If patients had concurrent respiratory disease (e.g., chronic obstructive pulmonary disease, pneumonia, atelectasis, chronic bronchitis, or emphysema), they were excluded from the study. Those receiving fluticasone/salmeterol or single-controller agents other than a single ICS within 3 months prior to the study also were excluded. Patient data were determined based on surveys pertaining to disease control and asthma-related QOL. Administrative claims data were collected prospectively (12 months post-enrollment) and retrospectively (6 months pre-enrollment).

The 6-item modified Asthma Control Questionnaire (ACQ) measured adequacy of asthma control as defined by international guidelines, which recommend minimization of day and nighttime symptoms, activity limitation, bronchoconstriction, and use of short-acting bronchodilators (adapted from Juniper 2003). The 32-item modified Asthma Quality of Life Questionnaire (AQLQ) was developed to measure functional impairments most important to adults (age 17–70 years) with asthma. It covered four domains: symptoms, emotions, exposure to environmental stimuli, and activity limitation (adapted from Juniper 2003). Both instruments can be administered by the interviewer or self-administered and have been validated in clinical trials (Juniper 1993, 1999).

This paper focuses on the retrospective analysis. The 12-month prospective study is ongoing, and results will be available in the near future.

<sup>1</sup> REACH is a trademark of Health Benchmarks Inc.

**Results: claims data vs. self-reported SABA use**

REACH included 1,061 patients: 686 in the initial maintenance therapy cohort and 375 in the switched cohort. Sixty-two percent of patients were females and 42 percent were 21 to 40 years of age. Compared with the switched cohort, patients in the initial maintenance therapy cohort tended to be younger, less likely to belong to a staff-physician group model, less likely to belong to an

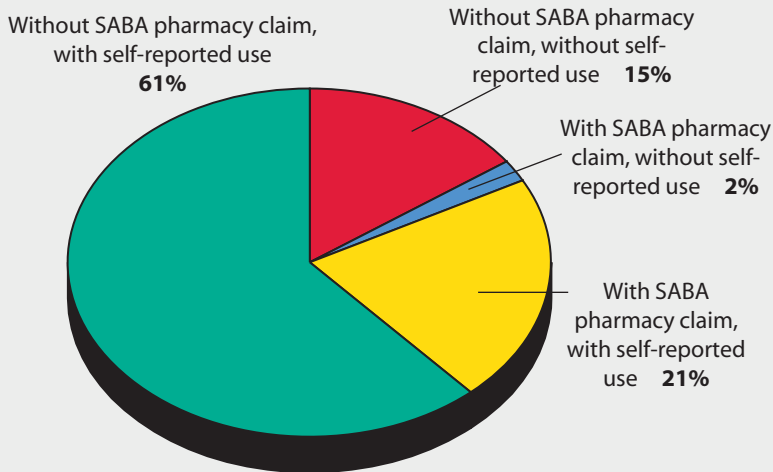
HMO, and more likely to live outside of California.

Global scores for asthma control on a 7-point scale (with 7 representing greatest severity) for the two cohorts were not significantly different at baseline. For the individual domains, the asthma control questionnaire included, there was one difference: compared with the switched cohort, the initial maintenance therapy cohort showed significantly ( $P<.05$ ) less control over awakenings at night. Similarly, baseline data for the two cohorts in QOL measures were comparable, with the exception of environment-related QOL: Compared with the initial maintenance therapy cohort, the switched cohort indicated significantly ( $P<.05$ ) greater impairment. Thus, despite the difference in therapies, baseline results were markedly similar between the two cohorts. Although there were statistically significant differences, these differences were clinically small.

Additionally, survey results for average daily frequency of SABA use during the week prior to enrollment overall did not show differences between the two cohorts. About 20 percent of each cohort reported no use during this time — 30 percent, 1 to 2 puffs; 25 to 30 percent, 3 to 4 puffs; and 25 percent more than 4 puffs. A slightly higher percentage of initial maintenance therapy patients used 3 to 4 daily puffs in the week prior to enrollment compared with the switched cohort, which was considered statistically significant ( $P<.05$ ). This does not represent a clinically meaningful difference, however. It also is notable that approximately a quarter of the study population at baseline reported more than 4 puffs per day of a SABA in the prior week, suggesting insufficient asthma control in a surprisingly large proportion of the study population.

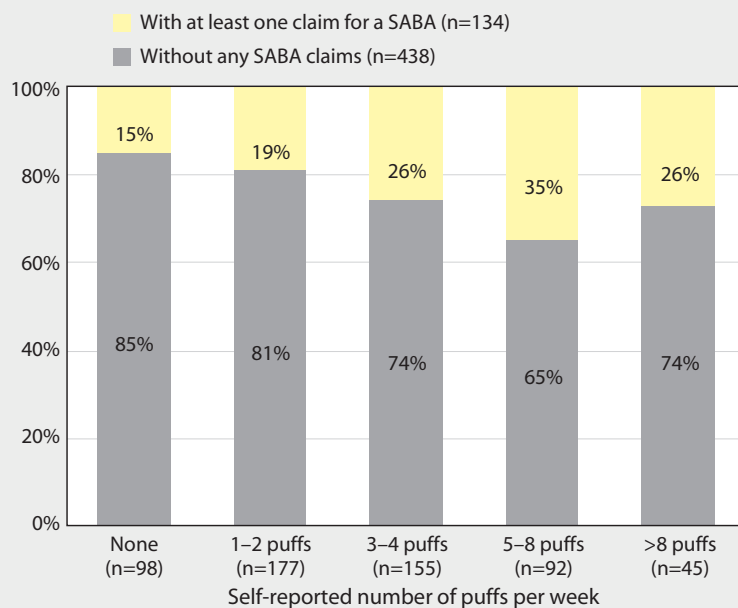
A critical finding related to the comparison between pharmacy administrative claims for SABAs per the health plans' administrative claims data and patients' self-reported data (Figure 1). A dramatic discordance was noted between the two data sets. A striking 61 percent of patients self-reported SABA use during the 3 months prior to the beginning of the study, but the administrative claims

**FIGURE 1 Pharmacy claims data versus self-reported use of SABAs**



SOURCE: HBI 2002

**FIGURE 2 Self-reported use of SABAs by patients with and without a retrospective pharmacy claim**



SABA=short-acting beta<sub>2</sub> agonist.

SOURCE: HBI 2002

data from their health plan held no record of SABA prescription fills during the 6 months prior to the beginning of the study.

The retrospective data were analyzed from yet a different perspective (Figure 2). Patients were asked to report the number of puffs used in the week prior to enrollment. Among those who reported using more than 8 puffs (n=45), 74 percent had no pharmacy administrative claims for SABA in the 6-month period prior to being enrolled in the study. Only 26 percent of this group who used more than 8 puffs had at least one corresponding SABA claim. The Kappa statistic was used to establish concordance between the different data sets. Overall, the Kappa statistic for evidence of SABA use generated by self-reports versus retrospective claims was 0.06 (95 percent confidence interval: 0.03, 0.09). Because the range of the Kappa statistic is 0 to 1, a finding of 0.06 is markedly low, indicating that there was virtually no concordance between the two parameters.

### REACH conclusions and limitations

There were a number of important findings generated by the REACH study. Patients in the initial maintenance therapy and switched cohorts showed similar asthma control and asthma-related QOL at baseline. Asthma severity, as indicated by self-reported SABA use, also was extremely similar between the two cohorts. The percentage of patients who reported frequent use of SABAs (>4 puffs per day in the prior week) at baseline was nearly equivalent in the two cohorts, which was approximately 25 percent. Another important outcome was the extreme discordance between the administrative claims data and self-reports of SABA use. A large proportion of patients (61 percent) reported use of a SABA but had no accompanying pharmacy claims.

These findings were significant but the study had some limitations. Although the patient population represented

more than 14 states, most were residents of California, which can limit the applicability of the data to other geographic regions. Second, this study followed patients retrospectively for only 6 months. A future study of retrospective claims for longer periods may show a greater correlation between claims data and self-reported medication use. Further, REACH restricted the patient population to commercial health plan members, excluding Medicaid or uninsured patients with asthma. These patients may not be as well managed and, therefore, many have less disease control.

Nevertheless, the results of REACH underscore the importance of reevaluating the classification of asthma that may otherwise be based solely on SABA pharmacy claims data. Given the significant gap seen in the REACH study between such data and self-reported data, health care providers and investigators should reconsider the reliability of SABA pharmacy claims as a tool for categorizing disease severity. Patients who previously used an ICS demonstrated similar disease severity to those who did not. Furthermore, the lack of agreement between pharmacy claims and self-reported data on SABA use suggests a need for caution in the interpretation of asthma severity studies based solely on these claims.

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# Responding to New Guidelines, Treatment Options, and Outcomes Data – A Health Plan’s Perspective

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Intermountain Health Care (IHC) is a not-for-profit, vertically integrated health care system that has been distinguished by *Modern Healthcare* as the nation’s top integrated health care network. IHC’s clinical integration and Care Process Models (CPMs) are nationally recognized. The company is a full-service organization that includes 21 hospitals and 150 medical facilities, with physician offices throughout Utah and Idaho. There are 450 physicians in the Intermountain Physician Group (350 are primary care practitioners) and another 2,500 who are affiliated with the system. Further, IHC has 480,000 enrollees in its health plans and is affiliated with 500,000 others that lease our network.

The integration of physician, hospital, and health plan services is fundamental to the IHC mission and is what makes it unique among health care organizations. What allows IHC to implement successful clinical integration is, in part, its prime location. The majority of the population is consolidated along a 90-mile corridor north and south of Salt Lake City, facilitating efforts to collaborate with physicians, hospitals, and patients in the surrounding area. Without data from the hospitals and physician clinics, and without having care managers in the plan who can access the data, IHC would not be able to accomplish all that it has; integration of these components in the system is the root of our success in disease management.

Our primary goal is to improve the quality of the health care system using evidence-based medicine and sophisticated information systems, as recommended by the Institute of Medicine (IOM). For example, our advanced information technology ensures that our health plans can coordinate National Committee on Quality Assurance or HEDIS (Health Plan Employer Data and Information Set) initiatives on a systemwide basis and track compliance. Our health plans also are responsible for provider relations, which are enhanced through education and distribution of CPMs to physicians. The plans have a role as advocates, which includes scheduling appointments for preventive care and channeling members

to appropriate providers. IHC facilities participate in the management of acute and chronic care, including medical, surgical, and pharmacologic care; providing discharge planning; and education and coordination of census reports. Care managers in both the facilities and health plan work together to ensure that all patients receive the best possible care. IHC physicians oversee the development of CPMs, implement standard physician orders, and provide physician communications, education, and monitoring.

Although cost control is a secondary objective at IHC, the company recognizes that if health care is delivered through best practices based on appropriate care of patients, cost-effective management will follow.

## Goals of the asthma clinical program

To address the chasm in the American health care system, the IOM identified 15 conditions that should be a priority, including asthma (IOM 2000). Asthma management, therefore, is a priority for Intermountain. A coordinated, integrated, multidisciplinary system of care for asthma patients is our first objective. Toward this goal, IHC reviews and summarizes the literature so that our disease management programs are founded on evidence-based medicine, as recommended by the IOM. Clinical data and research are key to identifying issues that must be addressed to ensure optimum care. They provide the mechanism to disseminate this information to physicians caring for patients with asthma and are the basis of educational materials developed by our hospitals and health services. At IHC, we believe “You can only manage what you measure,” which is our fundamental philosophy governing much of what we do. If we achieve that, we know we are well on our way to realizing another important objective—helping patients maintain near-normal lung function and activity levels.

All physicians share this goal. As one said, “If my patients were runners before asthma, I want them to feel secure enough to become runners again.” Similarly, we want to be able to return patients to normal levels of their



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**TABLE 1 Intermountain Health Care therapy guidelines for asthma management**

<b>Daily long-term control therapy</b>	No daily medication	<b>Low-dose inhaled corticosteroids (preferred)</b> or Consider LTRA	<b>Low-to medium-dose inhaled corticosteroids</b> <i>plus</i> Long-acting beta <sub>2</sub> agonist <i>and/or</i> Consider LTRA to improve control	<b>High-dose inhaled corticosteroids</b> <i>plus</i> Long-acting beta <sub>2</sub> agonist <i>and/or</i> LTRA <i>and/or</i> Oral corticosteroids p.m.
<b>Quick-relief therapy</b>	Short-acting inhaled beta <sub>2</sub> agonist	Short-acting inhaled beta <sub>2</sub> agonist	Short-acting inhaled beta <sub>2</sub> agonist	Short-acting inhaled beta <sub>2</sub> agonist
<b>Other</b>		Consider asthma specialist consultation; assess for allergy triggers	Asthma specialist consultation; allergy evaluation	Ongoing comanagement with an asthma specialist; allergy evaluation
<b>Nonmedical therapy</b>	Education    Action plan    Trigger elimination    Immunizations    Smoking-cessation program			

LTRA=leukotriene receptor antagonist.

SOURCE: NAEPP 2002

daily activities by controlling and preferably preventing chronic and troublesome exacerbations. To accomplish this, we aim for optimal pharmacotherapy with minimal or no adverse effects, resulting in the limited use of short-acting bronchodilators (i.e., no more than twice weekly). Finally, we strive to minimize the need for emergency room (ER) visits and hospitalizations and educate patients to participate in their disease management. We provide this guidance through educational pamphlets and brochures that are posted on our Web site.

### Information systems and optimal patient care

A review of the literature has shown that combination therapy using inhaled corticosteroids (ICSs) plus long-acting beta<sub>2</sub> agonists (LABAs) is effective for asthma control. This information is consistent with the most recent guidelines issued by the National Asthma Education and Prevention Program, which supports the use of ICSs as first-line therapy (Table 1). We educate patients about this preferred treatment and how to use it correctly for maximum efficacy.

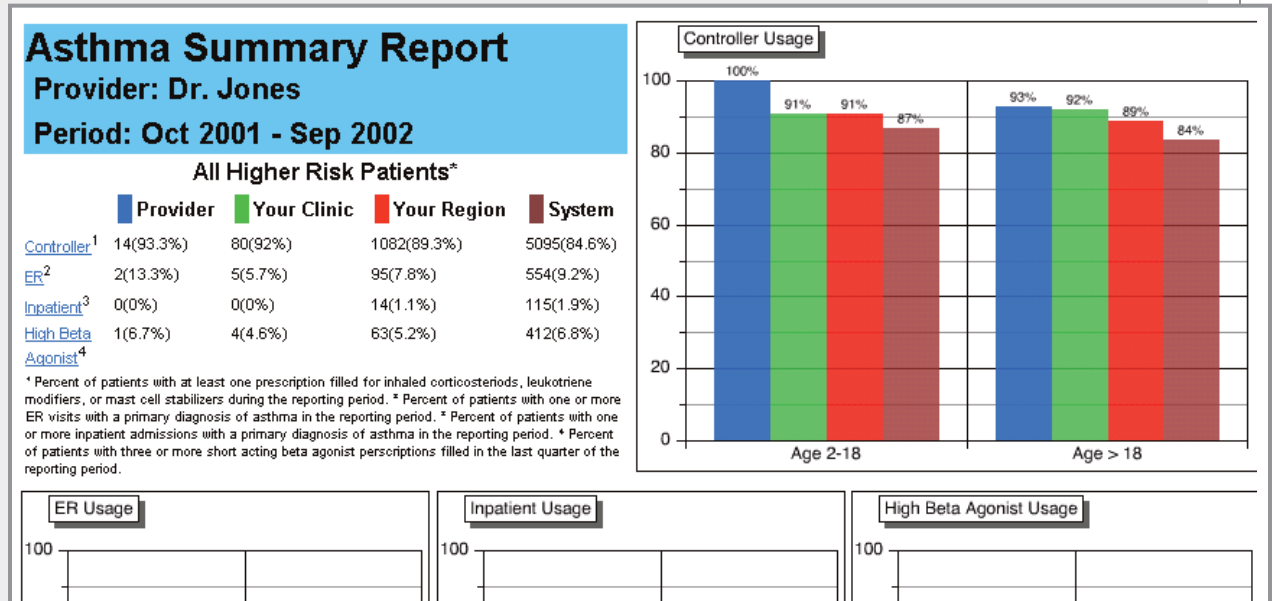
In addition, IHC focuses on identifying the level of risk in patients with asthma in an effort to provide optimal pharmacotherapy. Through our special data collection processes, we have found that patients who fill more than 14 short-acting beta<sub>2</sub> agonist (SABA) prescriptions in a 1-year period have a 50 to 60 percent increase in the likelihood of being seen in the ER in the subsequent 12 months. Risk stratification ensures appropriate treatment, which translates into more cost-effective treatment and more satisfied employers because their employees are maintaining control over their disease.

Through our secure Web server, physicians are asked to review asthma summary reports (Figure 1, page 14). Our physicians can access these reports at any time and use them to evaluate the progress they have made in managing their patients with asthma. Information provided includes controller medication utilization, frequency of SABA use, visits to the ER, and hospitalizations. Furthermore, a global summary is included so that physicians have a basis of comparison with their clinic, peers throughout the region, or providers with similar practices across the system.

Consistent with our clinical integration program, our medical directors have access to this information, providing them with the opportunity to oversee the practice patterns of the physicians who report to them. Likewise, members of the care management staff and pharmacy staff have access to these reports. Therefore, if clinical pharmacists are given a field assignment for academic detailing on specific diseases or drugs, they can refer to these disease-specific reports to obtain important information. Toward gaining needed feedback to improve care, they may initiate a discussion with a physician or hospital by saying: "We notice that a lot of your patients are not using controller therapy," or "We notice that you've got a lot of patients using high doses of short-acting beta<sub>2</sub> agonists."

When we do find that patients have been to the ER, the IHC disease management program ensures that a care manager contacts them subsequent to the visit, which is generally within a day. The care manager could then access scheduling software at the hospitals or within our physician division and schedule either a follow-up ap-

**FIGURE 1 Intermountain Health Care asthma summary report**



pointment with the primary care physician or an educational appointment with a respiratory therapist. The data also are used to generate information from ambulatory medical records available at physician clinics or within the hospitals for our care managers to ask, “Has this patient had a pulmonary function test?” Care managers have found that as many as 85 percent of their patients have not had a pulmonary function test. Without this form of screening, it is difficult to know whether disease severity is classified appropriately for these patients.

Our data have shown that generally 50 to 80 asthma patients visit the ER in 1 month. One-month IHC results showed that 80 patients required acute care in the ER. We therefore strive to reduce future exacerbations by offering follow-up assistance and educational services. Surprisingly, 29 percent of patients who have been seen in the ER reject this opportunity that could potentially improve their disease control.

In an effort to prevent visits to the ER, IHC also collects data on patients who have used urgent care facilities when their physician is not available. Based on this information, we develop a report that is distributed to the care managers of these patients. In February, they contacted 78 patients who were seen in the preceding month in these facilities. Of those patients contacted, only 10 patients actually said, “I want to follow up and have more education on my asthma.” Clearly, more effort is needed in encouraging physicians who practice in these facilities to educate their patients — increase their awareness of asthma as a severe disease and of the benefits and importance of complementary services.

Currently, all our patients — including those who have been seen in the ER, urgent care facility, and/or a physician’s office in the preceding month for asthma — receive a letter from a care manager along with an educational brochure. IHC is making every effort to disseminate information to physicians and patients about asthma care.

### Pharmacy management

Our approach to pharmacy management and the basic philosophy that governs our formulary decisions are reflected in the words of John F. Kennedy: “There are risks and costs to a program of action, but they are far less than the long range risks and costs of comfortable inaction.”

When the combination fluticasone/salmeterol product became available, IHC adopted the product early in its introduction into the market, recognizing that its potential benefits outweighed the risks of prolonging the decision to include it in our formulary. Indeed, long-range risks and costs of comfortable inaction are issues that we all need to think about. Often in managed care, we have the mandatory 6-month period before reviewing a product. Many times, we’ll hesitate and wait for a contract to expire. Instead, when innovative therapies are introduced, we need to be prepared to say: “We’re willing to take that risk; we’re willing to take action early based on the scientific evidence and what is best for our patients.” When IHC initially reviewed the fluticasone/salmeterol combination product, patients annually filled approximately three prescriptions a year for their controller medications and only 1.5 for a SABA.

A cost analysis demonstrated that fluticasone/salmeterol also reduced our costs compared with fluticasone/leukotriene and fluticasone/leukotriene/salmeterol (Table 2). Notably, in treating an equal number of patients with fluticasone, leukotriene, and salmeterol in combination versus fluticasone and leukotriene, our costs were markedly higher, increasing from approximately \$500 to \$900 a year.

We then evaluated the cost of the combination product fluticasone/salmeterol on a per-dose basis. Results showed that even at the highest dose (500 mcg/50 mcg), this dual agent in a single inhaler was still cost-effective, at a cost of \$147.84 per unit (n=426). This was not much more compared with 250 mcg/50 mcg (n=708) and 100 mcg/50 mcg (n=317), which were \$108.59 per unit and \$86.62 per unit, respectively. Considering our average annual cost for these patients of \$459.10, it was easily decided that even based on the highest cost for this product with an average of three refills, the product would not cost much more than what we were already spending per year for these patients.

Furthermore, the use of fluticasone/salmeterol provides the opportunity for patients to gain better control of their disease, therefore providing us with an opportunity to reduce our overall costs. IHC also conducted an analysis of medication trends and corresponding costs from January 2000 through July 2003. We projected that if current patients were switched to fluticasone/salmeterol, IHC could reduce costs by almost \$500,000 (Figure 2).

**TABLE 2 Internal experience: Cost comparisons of asthma agents**

Drug	Patients	Cost/Year
Fluticasone/salmeterol	911	\$459.10
Fluticasone/leukotriene	550	\$556.83
Fluticasone/leukotriene/salmeterol	540	\$892.47

SOURCE: INTERMOUNTAIN HEALTH CARE

### Impact of controller medication utilization

Through effective clinical integration programs and sophisticated information technology, IHC strives to increase use of controller medications in their patients with asthma. Our educational programs and care management intervention via contacts with our patients have resulted in an increase in the number of our patients using controller medications from approximately 78 percent to 88 percent. The benefits have been obvious. According to our trends analyses, there were decreases in ER visits, hospitalizations, and use SABAs between all patients with asthma and those on controller medications, with the greatest difference noted in ER visits (Figure 3).

These clinical outcomes corresponded with benefits in costs. From the last quarter of 1999 through the second and third quarters of 2000, IHC showed dramatic savings in per-member, per-month charges. Although there were increased costs in pharmacy, they were offset by reductions in costs correlating with less ER and inpatient care. We, therefore, succeeded in improving the health of our patients with asthma and their productivity in the workplace at almost no additional overall medical expense. As recently as last year, our cost for a patient with asthma

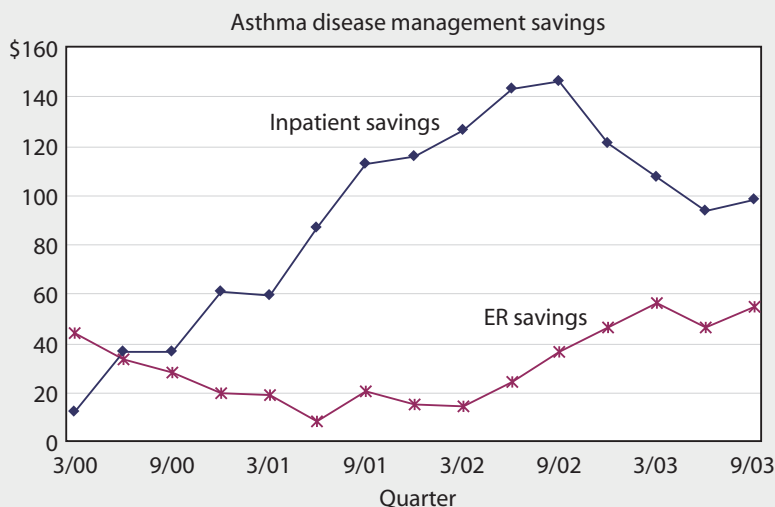
who needed acute care in the ER was on average \$518 and \$2,234 for a patient who needed hospitalization. In comparison, the national cost estimates are \$234 for a visit to the ER and \$3,103 for a patient who is hospitalized (Stanford 1999). When we factor in acute events avoided in those average costs, there is a quarterly savings in excess of \$150,000, and in some quarters in 2002, we saved substantially more than that.

### Advantages of disease management programs

Consistent with our philosophy of disease management, we generate clinical programs according to scientific evidence, including the evidence presented in this article.

We have established via our own best practices. Our disease manage-

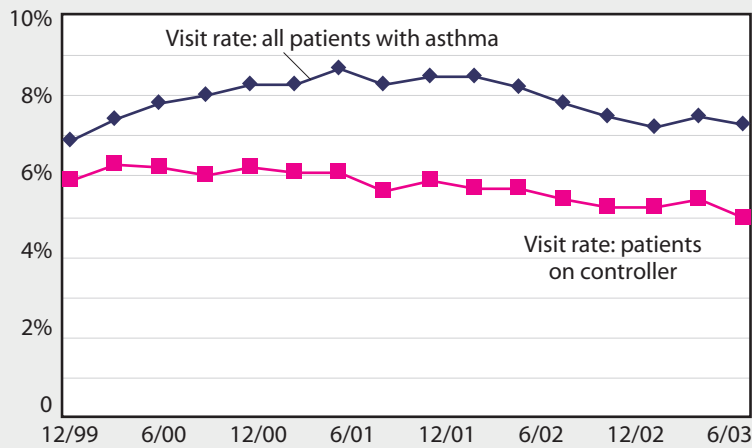
**FIGURE 2 Cost savings for acute care and hospitalizations**



SOURCE: INTERMOUNTAIN HEALTH CARE

**FIGURE 3** Emergency room visit rates

Total asthma patient population vs. patients on controller medications



SOURCE: INTERMOUNTAIN HEALTH CARE

ment programs have demonstrated value in improving clinical outcomes cost-effectively. IHC programs are designed through integration of physician, hospital, and care manager services; they are physician driven and administered through a physician leader (primarily one of our employees), however, in conjunction with our clinical programs. A full-time nurse administrator assists our physicians in the design and implementation of these programs. CPMs and patient education materials are developed by Clinical Programs in cooperation with treating physicians. These are a few of the many advantages of our current programs. Others include collection of claims and laboratory data to define opportunities, provide operational triggers for patient management, and evaluate outcomes. Furthermore, our disease management program is not imposed on our physician offices by the health plan, thus improving physician interaction.

What is particularly important is our system of obtaining feedback from the health care community. We routinely solicit responses from the treating physicians who receive our reports, often asking such questions as: "Is there an area of management of this disease that we need to change?" "Are there questions about how we are delivering the information to care management?" "Is there any issue regarding how we administer pharmacy?" "Does patient education need improvement?" These are just a few key questions that we would use to obtain the essential information to continue meeting the needs of our patients and health care providers.

## Key challenges

We face one of the biggest challenges today in managing disease states within an employer group. This is because large national employer groups are taking the pie and carving out pieces. For example, pharmacy, mental health, and health and wellness are all pieces that they may decide to manage by establishing relationships with different health plans. As soon as an employer carves out a benefit, we no longer have all the pieces of the pie we need to provide effective disease management. For best results, disease control can be realized only through consistent integration of claims data, pharmacy data, and laboratory data. If an employer carves out pharmacy benefits, it becomes extremely hard for a company like IHC to classify patients at risk without the

pharmacy data. We know now that well-integrated disease management programs will provide us with the evidence base needed to confirm improvements in our patients' quality of life. We are confident that we have a valid, active mechanism through which we can disseminate guidelines to our physicians and improve care.

In summary, most important has been IHC's awareness of the urgent need to educate not only patients with asthma but also the health care community. Our mission is to provide the best clinical practice and to deliver it in a consistent and integrated way (IHC 2004).

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# Challenges in Asthma Management: Classification, Persistency, and Perceptions Of Disease Control

*The three preceding articles and the following panel discussion demonstrate the challenges health care professionals face regarding the clinical and financial implications posed by the morbidity and mortality associated with asthma. Appropriate classification of disease severity is one such challenge. An integrated system of care, based on the collaboration of individual providers, hospitals, and health plans, is fundamental to efforts to achieve positive change in the care of patients with asthma. Finally, results from clinical trials of recent advances in treatment have been encouraging, thus emphasizing the importance of disseminating information about how new therapies improve disease control, reduce the need for acute care and hospitalization and, in turn, decrease costs.*

## PANELISTS

### **Robert P. Navarro, PharmD (moderator)**

President  
NavarroPharma LLC

### **H. Eric Cannon, PharmD**

Director, Pharmacy Services  
Intermountain Health Care

### **Helen O. Chernicoff, MD, MSHS**

Vice President, Research and Development  
Health Benchmarks Inc.

### **Richard D. O'Connor, MD**

Director, Department of Quality Management  
Director, Department of Clinical Research  
Staff Physician  
Sharp Rees-Stealy Medical Group  
Clinical Professor of Pediatrics  
University of California–San Diego School of Medicine

**ROBERT P. NAVARRO, PHARM.D:** Dr. Chernicoff, if short-acting beta<sub>2</sub> agonists [SABA] claims are under-reported, what additional claims data can be used to identify asthma severity?

**HELEN O. CHERNICOFF, MD, MSHS:** Self-reports, physician reports, or chart abstractions are important tools. If resources are limited to administrative pharmacy claims data, however, various other measures can be used, such as ER visits, hospitalizations, and outpatient visits. Although we based our study on claims data, I believe it's unusual to assess only SABA usage through administrative pharmacy claims. Many medications, especially used for asthma, may be stockpiled in the

home. Or, patients may be receiving samples from their physicians.

**RICHARD D. O'CONNOR, MD:** We have to understand that although the data suggest that looking at albuterol use is necessary, it may not be sufficient. It may be a starting point, but that's all. If you're measuring administrative data, certainly hospitalizations, ER visits, urgent care, use of prednisone, which is not likely to be stockpiled, might be more reflective of asthma severity. The message is not that claims data are insufficient, but that patients report using much more albuterol than the health care system believes they're using.

**NAVARRO:** Eric, you also evaluated SABA use. Do some of these findings influence the way you may view SABA use as you monitor your patients?

**H. ERIC CANNON, PHARM.D:** We measured SABA use to determine level of risk in our patients with asthma. We believe SABA use is effective in identifying a large percentage of, though not all, patients at risk. We have a few risk-stratification tools now in predictive modeling, so that if we look at health care as a continuum, we can determine if a low-risk patient today may become a high-risk patient in 12 months. By looking at a combination of SABA overuse, repeated visits to a physician's office, and steroid use, we believe we can capture most, though not all, these patients. Administrative claims data may underestimate severity, yet it's one tool we need to take maximum advantage of, keeping in mind the limitations.

**NAVARRO:** Basically then, we can agree that using a variety of data sources is probably the best strategy for identifying patients at risk and monitoring outcomes. Based on disease variability, which patients are appropriate for monotherapy with inhaled cortico-

steroids [ICSs] and which for combination therapy?

**O'CONNOR:** I'm waiting for confirmation of Anne Fuhlbrigge's study before reaching any conclusions on this issue. Her results suggest that 75 to 80 percent of patients with asthma have moderate or severe disease. Therefore, 80 percent probably deserve to be on combination therapy and 20 percent on ICSs. Paul O'Byrne's study raises the key question regarding appropriate therapy for mild disease. His data show clearly that even mild persistent asthmatics may be candidates for combination therapy. But this change in treatment recommendations is not going to occur in the next iteration of our guidelines. A lot of evidence would have to be generated before that recommendation would be made. I believe the changes we can look forward to in the next guidelines update relates to how we classify disease severity, which will shift populations. Currently, 45 percent of patients are considered intermittent mild, and they use only albuterol. That's a huge mistake. Most asthmatics have much more significant disease than we recognize.

**NAVARRO:** Dick, based on the studies you discussed, patients refill the fluticasone/salmeterol combination product more often than other controller medications. Can you comment on why that might be?

**O'CONNOR:** I believe, in part, because it's used only once in the morning and once in the evening. Also, importantly, it appears to work better. Ease of use and increased effectiveness may account for improved refill persistency is better. Once patients initiate combination therapy, albuterol use diminishes. This change can be dramatic.

**CANNON:** Dick, I'd like your opinion on an important issue. According to manufacturers, patients are more compliant when using leukotrienes versus an ICS or combination therapy. Is that an argument to keep patients on this therapy even though it may not be as effective?

**O'CONNOR:** First of all, results with LTRAs [leukotriene receptor antagonists] have shown that approximately 30 percent of patients are true responders and 70 percent don't respond at all to these medications. A medication that helps only one quarter to one third of patients, I would suggest, is not a good choice. Second, you've raised a good example of a case when compliance isn't associated with improved outcomes. An ICS consistently has shown substantially better outcomes than LTRAs. So, from a clinical and economic perspective, I wouldn't recommend an LTRA. Further, most of the market for LTRAs in the world exists in the United States. They're not used to any significant degree in the United Kingdom or elsewhere in Europe.

**NAVARRO:** I would like to ask about the discrepancy between patient and physician perceptions of mild versus severe disease. Also, *Asthma in America* found that

patients underestimate their disease control. So, what do we do about the difference of opinion between physicians and patients? And, how do we change patient perceptions about their disease control?

**O'CONNOR:** Part of it has to do with changing our guidelines and recommendations on how we classify and treat asthma. For example, even if three hypertension drugs are needed to control a patient who has this condition, these patients are considered controlled but not severe. In this example, hypertension would be considered severe if not controlled despite aggressive treatment. The same approach may be needed for asthma. More aggressive therapy to control a patient's asthma could be recommended to control the disease. Then, therapy should be decreased gradually to maintain control. Present guidelines classify asthma as severe before we initiate therapy. An operational approach to treatment response may be better for asthma. Further, we need to recognize that most patients have moderate to severe disease, not mild disease. Finally, we need aggressive public education campaigns. The data are crystal clear that the more a patient uses an ICS or a combination product, the better the outcome. The challenge for us is to encourage changes in patients' behavior and, just as important, changing physician behavior.

**NAVARRO:** Eric, InterMountain Health Care has good results with its asthma management program. Does that have to do with improvement in physician and patient education?

**CANNON:** When we ask physicians about their patients with asthma, they all say that they are adequately controlled and treated with optimal therapy. We feel that our educational efforts are effective when we show physicians our data that indicate a need to change treatment strategies — and their response is positive. That is, rather than responses such as, "I don't believe the data," or "The data must be flawed," they say, "Maybe I need to look at the guidelines and review how I'm treating my patients with asthma." In terms of patient education, a 5-minute visit with a physician can't be the sole source of information. Education needs to be provided through different media, at different times, and frequently and consistently so that we can raise awareness effectively. For example, I realized the urgency of this need for awareness during a visit with my sister when my 5-year-old niece was having an asthma attack. I asked the question, "Do you have medication for her at home?" And, my sister said, "Yes." I said, "Are you using it on a regular basis?" My sister replied, "Oh no, she only needs it when she has an attack." I realized that she'd had the medications at home to control her daughter's asthma, yet she did not fully understand that the controller therapy needed to be used every day. So, it's obvious that even in highly

educated people, we still aren't doing a good job. At IHC, we're changing our educational brochures annually. Just changing the graphics helps to draw attention to the important information.

**NAVARRO:** Eric, were your data showing increased utilization of montelukast for only asthma or asthma and allergic rhinitis?

**CANNON:** Although we tried to limit the group by requiring that patients be on an ICS or short- or long-acting beta agonist to receive montelukast, we know that some patients were using these medications just for allergies. We know that an ICS is clearly the best therapy. So, within the next 2 or 3 months, we probably will stipulate that a leukotriene cannot be prescribed unless the patient is on an ICS first.

**O'CONNOR:** Let me make one point about LTRAs and their use in allergic rhinitis. Part of the difficulty we have is the commonly held concept that an LTRA is an anti-inflammatory agent. It's not, really, especially in humans. If you use, as the gold standard, a change in inflammatory cell markers either on lavage or biopsy of either the nose or the bronchus, there is not a study done that has ever shown a reduction in inflammatory cell infiltrates associated with an LTRA. In contrast, we have more than 100 studies with an ICS that show anti-inflammatory benefit and 13 studies of intranasal

steroids versus second-generation antihistamines. We now have three randomized, blinded, controlled studies comparing an ICS intranasally with LTRAs. The score is 3 to nothing. If we get another half dozen studies, it will be 9 to nothing. An LTRA is not really an anti-inflammatory agent nor is it as clinically effective as intranasal steroids. It is also significantly more expensive. There is no inflammatory cell biopsy effect of the LTRAs. The predominant effect is bronchodilation. It inhibits one molecule in the leukotriene pathway. So, LTRAs are in a sense a safer version of theophylline. As a pediatrician, I'm extremely concerned about that. Inflammation of the airways is the major danger for a child with asthma. The only way we know to treat or prevent the inflammation is with the use of an anti-inflammatory agent. My concern is that by treating more children with LTRAs — and that's where much of the usage occurs — we're putting children at risk, because we're not providing them effective anti-inflammatory therapy.

**NAVARRO:** Thank you all for your contributions to this important discussion on asthma. I think we agree that although many challenges remain in the management of asthma, we are well on our way to meeting them successfully through meaningful dialogue as we shared today.

## CONTINUING EDUCATION POST-TEST

Please tear out the combined answer sheet/evaluation form on page 21. On the answer sheet, place an X through the box of the letter corresponding with the correct response for each question. There is only ONE correct answer to each question.

- Changes to the NAEPP guidelines for 2002, including use of inhaled corticosteroids (ICSs) in children and adults, were based on a number of studies, such as Suissa (2000). Results showed that annual use of \_\_\_\_\_ canisters of ICSs sharply reduces the risk of death from asthma.**
  - 1–3
  - 2–4
  - 3–6
  - 5–7
- Asthma severity, according to current NAEPP guidelines, is classified using the most severe finding after initiating therapy.**
  - True.
  - False.
- When the current classification guidelines were developed, patients with mild and moderate persistent disease were subjected to an allergen challenge. Results indicated that when comparing the two groups:**
  - There were no similarities in total and differential cell counts.
  - Pathologically, there was no distinction between them.
  - The eosinophil count was higher in patients with moderate disease.
  - The degree of response postchallenge was significantly different.
- A critical study took place in Victoria, Australia, investigating deaths due to asthma in 51 children. What proportion of this group was classified as patients with mild disease?**
  - Three quarters.
  - One quarter.
  - Two thirds.
  - One third.
- Undertreatment is one of the serious consequences of misclassification of asthma. When asthma severity was evaluated by patients and their physicians based on the same classification scheme, 10.5 percent of patients described their disease as mild versus \_\_\_\_\_ of physicians.**
  - 15.3 percent
  - 22.1 percent
  - 44.6 percent
  - 75.2 percent
- Health Benchmarks data suggest that compared with fluticasone alone, a fluticasone/salmeterol combination product showed reductions in emergency room visits and hospitalizations, and improved compliance.**
  - True.
  - False.
- The retrospective analysis of the REACH study showed short-acting beta<sub>2</sub> agonist (SABA) use of 61 percent based on self-reports without pharmacy claims versus \_\_\_\_\_ percent based on self-reports with pharmacy claims.**
  - 21
  - 32
  - 45
  - 51
- In the week prior to enrollment in the REACH study, of patients who reported using more than 8 puffs, 74 percent had no pharmacy claims for the 6 months pre-enrollment, compared with 26 percent who had at least one claim.**
  - True.
  - False.
- The results of REACH underscore the importance of reevaluating the classification of asthma that otherwise may be based solely on SABA pharmacy claims data.**
  - True.
  - False.
- Intermountain Health Care data showed that patients who filled more than 14 SABA prescriptions in 1 year have a \_\_\_\_\_ percent increase in the likelihood of being seen in the emergency room in the subsequent 12 months.**
  - 10–15
  - 20–30
  - 30–40
  - 50–60
- Intermountain care managers found that as many as 85 percent of their patients have not had a(n) \_\_\_\_\_, thus making it difficult to know if their disease severity has been classified appropriately.**
  - Bronchoconstriction test
  - Alveolar lavage
  - Pulmonary function test
  - Test for arterial blood gases
- Based on a cost-effectiveness analysis, it was projected that if current patients were switched to the fluticasone/salmeterol combination product, Intermountain could reduce costs by almost \$500,000.**
  - True.
  - False.

## CONTINUING EDUCATION ANSWER SHEET/CERTIFICATE REQUEST

### Reversing Asthma-Related Morbidity and Mortality Through Patient Persistency and Compliance

## CE Credit for Physicians and Pharmacists

#### Sponsored by Medical Education Resources Inc.

I certify that I have completed this educational activity and post-test credits and claim 2 contact hours.

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**Physician** — Maximum of 2 hours in category 1 credit. This learning module may be used for category 1 credit through July 15, 2005.

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**EXAMINATION:** Place an X through the box of the letter that represents the best answer to each question on page 20. There is only ONE answer per question. Place all answers on this form:

	A.	B.	C.	D.
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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12.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### PROGRAM EVALUATION

To receive continuing education credit, please provide all information requested below. This assures prompt and accurate issuance of your continuing education certificate.

Please rate this program as follows:

	Excellent	Very good	Good	Fair	Poor
Overall quality of program	5	4	3	2	1
Content	5	4	3	2	1
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Effectiveness of this format for learning	5	4	3	2	1
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How long did it take you to complete this continuing education activity? Hours \_\_\_\_\_ Minutes \_\_\_\_\_

Requested topics/skills to address in future programs:

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This program was educational and not promotional.  
Yes \_\_\_\_\_ No \_\_\_\_\_ If no, please explain: \_\_\_\_\_

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