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Patterns of Inhaled Antiinflammatory Medication Use in Young Underserved Children With Asthma

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Abstract

BACKGROUND—Asthma guidelines advocate inhaled corticosteroids as the cornerstone treatment of persistent asthma, yet several studies report underuse of inhaled corticosteroids in children with persistent asthma. Moreover, few studies use objective pharmacy data as a measure of drug availability of asthma medications. We examined factors associated with the use of inhaled corticosteroids in young underserved children with persistent asthma using pharmacy records as their source of asthma medications.

METHODS—This was a cross-sectional analysis of questionnaire and pharmacy record data over a 12-month period from participants enrolled in a randomized clinical trial of a nebulizer educational intervention.

RESULTS—Although exposure to ≥ 1 inhaled corticosteroids refill was high at 72%, 1 of 5 children with persistent asthma had either no medication or only short-acting β agonist fills for 12 months. Only 20% of children obtained ≥ 6 inhaled corticosteroids fills over 12 months. Obtaining ≥ 3 inhaled corticosteroids fills over 12 months was significantly associated with an increase in short-acting β agonist fills and receiving specialty care in the regression models while controlling for child age, asthma severity, number of emergency department visits, having an asthma action plan, and seeking preventive care for the child's asthma.

CONCLUSIONS—Overreliance on short-acting β agonist and underuse of inhaled corticosteroid medications was common in this group of young children with persistent asthma. Only one fifth of children obtained sufficient controller medication fills.

Keywords

asthma; children; preventive care; antiinflammatory

Asthma is the leading chronic illness among US children,^{1–3} with the youngest children consistently having the highest emergency department (ED) visit rates.⁴ Airway inflammation

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occurs early in the clinical stages of asthma,⁵ and inhaled corticosteroids (ICSs) have been demonstrated to decrease bronchial hyperreactivity and inflammation, as well as reduce asthma morbidity and mortality.^{6–9} National and international asthma guidelines advocate ICS as the cornerstone of treatment for persistent asthma,^{10–12} yet several studies demonstrate underuse of ICS in children.^{13–16} Reasons for nonadherence to ICS therapy include health care system factors, such as lack of follow-up care,^{17–19} physician underdiagnosis of asthma severity,²⁰ and lack of specialty care.²¹ Social, psychological, and economic factors include young child age, parental distrust and worry about adverse effects of medications,^{22,23} parental misunderstanding of the role of antiinflammatory agents in treating asthma, overreliance on short-acting β -agonist (SAB) medications to relieve acute symptoms,²⁴ and medication costs. Although these social, psychological, and economic factors may be modifiable for medication adherence, they require behavioral, as well as educational, interventions for patients to change their medication use patterns.²⁵ Despite multiple reports of nonadherence to ICS in children, few studies have used objective pharmacy data to measure drug availability of preventive, as well as quick relief, medication use in these children.^{24,26–28} The aim of this article was to describe factors associated with use of ICS in young under-served children with persistent asthma using pharmacy records as the source of their medication use. We hypothesized that low SAB use, receiving specialty care, older child age, and decreased parental concern about ICS adverse effects would be associated with increased ICS use.

METHODS

Participants

Child study participants were recruited from pediatric practices affiliated with 2 urban university hospitals, including pediatric primary care (30%), pulmonary/allergy (50%), and ED (20%) practices between October 2001 and May 2003. Inclusion criteria were children aged 2–9 years with persistent asthma, regular nebulizer use, and ≥ 1 ED visit or hospitalization within 12 months of enrollment. All of the participants were enrolled in a randomized clinical trial to evaluate the effectiveness of an educational intervention focused on parent and child symptom recognition, appropriate home treatment of symptoms, and nebulizer practice on asthma morbidity, medication use, and health care use outcomes.²⁹ Parents were administered a questionnaire face to face in the ED or clinic at the time of recruitment and via telephone at 6 and 12 months. For this analysis, we pooled all of the participants and examined ICS use by parent self-report and review of pharmacy records. The institutional review boards of the Johns Hopkins University Medical Institutions and the University of Maryland School of Medicine approved the study protocols. We obtained informed consent from all of the participating parents, including consent for collection of the child's pharmacy records, and obtained child assent from children ≥ 7 years of age.

Measures

Asthma Severity—Children were assigned an asthma severity level based on national guidelines^{10–12} using frequency of day and night symptoms based on responses to specific questions: “During the past 6 months on average, how many days per week did your child cough, wheeze or experience shortness of breath to limit exercise, ability to play sports or play with friends?” and “During the past 6 months on average, how many nights per month did your child wake up at night with cough, wheeze, shortness of breath, or tightness in chest?” Children who met enrollment criteria for mild, moderate, or severe persistent asthma based on daytime symptoms (>2 times per week) or nighttime symptoms (>2 times per month)^{10,11} were included in the study. Ten children originally classified as mild intermittent by symptom report were reclassified as mild persistent based on premedication severity, for example, symptom frequency and daily antiinflammatory medication use.¹²

Asthma Medication Use—Medication use was measured by: (1) examining parental self-report of medication use at baseline, 6, and 12 months; and (2) pharmacy records across the 12-month follow-up. Pharmacy records were obtained from all of the pharmacies used per child as reported by the care-giver over the 12-month period.²⁷ At each of the 3 data collection points, caregivers were asked to identify any pharmacy used in the previous 6 months. Every pharmacy identified at any data collection point was contacted by faxing a copy of the consent forms requesting a complete list of all asthma medications dispensed during the study period. Pharmacies not responding within 1 week were contacted by telephone or in person. Pharmacy records were considered complete if every pharmacy identified by caregivers submitted data for the specified period, indicated that they had no record of the child, or had no prescriptions during the specified period requested. The number of asthma-related prescriptions filled or refilled, including the number of metered dose inhalers, dry powder inhalers, nebulizer ampules and oral medications, was used to examine the actual pattern of asthma medication availability by child over the 12-month period. The pharmacy database captured the dispensing date, product name, strength, dosage form, and quantity dispensed. Before double key entry in the database, all of the pharmacy records were reviewed by an asthma nurse specialist (K.M.) to ensure that complete data retrieval and discrepancies in data entries were adjudicated. Quick relief medications were defined as SABs, whereas controllers included ICSs, leukotriene modifiers, mast cell stabilizers, and long-acting β -agonists. Common ICS medications encountered were fluticasone (Flovent), budesonide (Pulmicort Turbuhaler and Respules), and fluticasone/salmeterol (Advair) inhalers. Oral corticosteroid (OCS) prescription fills were analyzed separately.

For children included in the final analysis ($N = 180$), we analyzed the frequency and amount of medication dispensed as conducted in previous studies³⁰ and chose not to adjust for relative potency or the number of canisters dispensed per prescription fill. Correlation between the number of ICS prescriptions and the amount of ICS medications (ie, number of canisters dispensed) was high (Spearman coefficient = 0.95; $P < .0001$), indicating that each ICS prescription fill represented 1 canister of ICS dispensed. ICSs were selected as the outcome medication, because ICSs were the most frequently reported antiinflammatory medications (51% of all controller prescriptions) and are the recommended therapy for persistent asthma.^{10,11} Multivariate models excluded children only on leukotriene modifiers, mast cell stabilizers, or long-acting β agonists because of low use of these medications in this sample.

Parental worry about adverse effects of asthma medications was ascertained on a Likert scale by asking “How worried are you about side effects of asthma medications?” with responses of very, very worried, very worried, fairly worried, somewhat worried, a little worried, hardly worried, or not worried. Responses were coded as no for “not worried” and yes for all of the other responses.

Asthma Morbidity, Health Care Use, and Asthma Care—Parents were administered questionnaires at baseline and 6 and 12 months after random assignment to ascertain symptom frequency, activity limitation, health care use, and type of asthma care received in the previous 6 months. Symptom frequency was based on responses noted under asthma severity. Activity limitation was ascertained by asking, “Has your child’s activities been limited due to asthma symptoms of cough, wheeze, shortness of breath or chest tightness/discomfort over last 6 months?” and coded as yes or no. Number of hospitalizations, ED, preventive asthma care, and specialty care visits; difficulty paying for medications; and having an asthma action plan during the previous 6 months were ascertained at each time point.

Treatment Group—Children were randomly assigned into 2 groups defined as receiving the nebulizer educational intervention (“intervention”) or standard asthma education (“control”).

As reported previously, there was no treatment effect noted on asthma morbidity, health care use, or medication use by group assignment.²⁹

Data Analysis

Subjects were categorized into 2 groups based on their number of ICS fills over 12 months: 0–2 vs ≥ 3 fills. Based on National Asthma Education and Prevention Program guidelines, we aimed to dichotomize using ≥ 6 ICS prescriptions; however, only 20% of children obtained ≥ 6 , and 40% had ≥ 3 ICS fills over the 12-month study period. Based on this distribution of ICS fills, we chose to dichotomize using 0–2 vs ≥ 3 ICS fills. Differences between ICS groups were examined using standard χ^2 tests, and relative risks were calculated for categorical variables (asthma severity and caregiver educational level). One-way analysis of variance was used to examine group differences for continuous variables (number of SAB fills). Multivariate logistic regression was used to assess independent effects in models for obtaining ≥ 3 ICS fills over 12 months. Variables significant at the .05 level in the bivariate analysis and those with theoretical importance (ie, treatment group, child age, and asthma severity) were entered simultaneously into the multiple logistic regression models. Several logistic regression models were run to adjust for potential confounders. The models were examined for goodness of fit using the Hosmer and Lemeshow test. Two-sided tests were used, and P values $\leq .05$ were considered significant. All of the data analyses were performed using SAS V.8.0³¹ and Stata V.7.0³² software.

RESULTS

Characteristics of Patient Population

A total of 513 children were recruited, with 254 children eligible, 33 parents refused to participate, and 221 (85%) consented and were randomly assigned into the study (Fig 1). At the 12-month follow-up, 180 children (81%) had complete interview and follow-up pharmacy record data for analysis. Most children excluded from follow-up analysis had incomplete pharmacy records ($N = 30$). Children excluded from follow-up ($N = 40$) did not significantly differ from children with complete data ($N = 180$) by age, gender, race/ethnicity, parental education level, or baseline asthma severity.

Children included in this analysis were primarily black (89%), male (64%), received Medicaid (82%), lived with their biological mother (91%), and were young, with a mean age of 4.5 years (SD: 2.1; Table 1). Most caregivers reported a high school education or higher (76%) and employment outside the home (53%), and 47% reported household incomes of less than \$20 000. Few families (11%) reported any problems paying for their child's asthma medications at baseline or at the 12-month follow-up.

Asthma morbidity in this group was high (Table 1), with most children classified with mild (63%) or moderate-to-severe persistent (32%) asthma. ED visits and hospitalizations were high, yet confined to a small proportion of the sample (ED visits: 38%; hospitalizations: 8%) with an overall mean of 1.83 ED visits and a mean of 0.36 hospitalizations during the previous 6 months. Almost two thirds (64%) of parents reported asthma-related activity limitation in their child, half received asthma specialty, and less than half (41%) reported having a written asthma action plan in the home. No significant differences were noted for sociodemographic and health characteristics between children with complete follow-up data ($N = 180$) and the total baseline sample ($N = 221$; Table 1).

Mortality—Three deaths occurred in study children (ages 4, 6, and 9 years) because of asthma complications, and 2 of the deaths occurred in children categorized with severe persistent asthma. All of these children received Medicaid insurance and reported ≥ 1 ED visit within 6

months of enrollment, and only 1 received specialty care. All of the children had been hospitalized once, including 1 child hospitalized 5 times within 6 months of study enrollment. Excessive quick relief medication use (9 fills over 6 months) was noted in 1 child. Only 1 of the 3 children received antiinflammatory medication over the 12 months.

Relationship Between Prescribed Asthma Medication Filled and Asthma Severity

Specific asthma medication fill regimens are shown in Table 2 for a subset of children ($N = 174$; 97%) with complete pharmacy data and severity assignment at 12 months. Six children had incomplete severity data at 12 months. Most children (78%) had a combination of ≥ 1 antiinflammatory and a quick relief medication (SAB) available at some point during the 12-month study period (Table 2). Although exposure to ≥ 1 ICS medication was high at 72%, 1 of 5 children had either no medication or only SAB medication available during the 12-month follow-up. OCS medication availability was high, with 59% of children obtaining ≥ 1 OCS medication fill over the 12-month study period, and children classified with mild persistent asthma had an increased number of OCS fills as compared with children with moderate-to-severe but not significant asthma (mild persistent: 63%; moderate/severe: 50%; $P > .05$; Table 2).

As shown in Fig 2, only 20% of children obtained ≥ 6 , and 40% obtained ≥ 3 ICS fills over 12 months. The frequency of SAB fills ranged from 0 to 26 fills with 20% of children obtaining ≥ 6 SAB fills over 12 months. Sample medications were reported by 38 parents (21%), primarily for Albuterol or Xopenex (32%), Flovent or Pulmicort (29%), or Singulair (29%).

There was a trend in the correlation between the average total number of ICS and SAB prescriptions filled over the 12 months (total ICS prescriptions: mean: 43.3; SD: 8.4; total SAB prescriptions: mean: 54.8; SD: 11.9; Spearman's coefficient: 0.52; $P = .09$).

Factors Associated With ICS Use

The unadjusted relative risks and 95% confidence interval (CI) for factors associated with ≥ 3 ICS fills are shown in Table 3. Factors significantly associated with ≥ 3 ICS fills were older child age, receiving specialty care, having an asthma action plan, making a physician appointment even when the child is well (seeking preventive care), decreased number of ED visits during the previous 6 months at baseline, and increased number of SAB fills over the 12-month study period. The number of care-givers reporting "worry about side effects of asthma medicines" did not differ by number of ICS fills ($P = .54$) or by child age ($P = .44$). Treatment group assignment within the original study was not associated with ≥ 3 ICS fills over the 12 months in the bivariate analysis or logistic models. In the multivariate logistic regression models, obtaining ≥ 3 ICS fills over 12 months was independently predicted by increased use of SAB medication and receipt of specialty care within the past 12 months after controlling for child age, gender, number of ED visits during the last 6 months, having an asthma action plan, and asthma severity (Table 4). A trend was noted in seeking preventive care for the child (range odds ratios: 2.15–2.25; CI: 0.9–5.3). The Hosmer and Lemeshow test demonstrated reasonable goodness of fit for both models presented.

DISCUSSION

Despite the majority of study children with persistent asthma receiving some exposure to ICS, 60% received substandard, non-National Asthma Education and Prevention Program guideline-based care defined as < 3 ICS fills over 12 months comparable to the 39% reported in a previous study of low-income, non-Medicaid uninsured children with asthma,³³ yet considerably lower than other claims-based studies of Medicaid insured children³⁴ or children presenting to EDs³⁵. This study confirms the overreliance of young children with persistent

asthma on quick relief medication for asthma treatment reported in children with asthma-related ED visits²⁴ and the low use of ICS medications as noted in several studies.^{36–39}

Although children with asthma may go through periods of controlled and uncontrolled disease based on exposures to allergens and pollutants, exercise, and respiratory infections, early identification and treatment of symptoms in young children is critical to prevent exacerbations and reduce morbidity.⁴⁰ Although more than half of parents reported activity limitation in their child because of asthma, fewer than half obtained adequate ICS fills to prevent symptoms. Parents may be either tolerating a substandard level of symptom control or inaccurately reporting their child's level of asthma control.⁴⁰ Alternatively, the low ICS use may reflect reluctance of providers to prescribe antiinflammatory medication for young children, reluctance of parents to fill an ICS prescription, or both, particularly if the child is asymptomatic.^{16,41} Identification of children requiring controller medication relies on an accurate diagnosis of asthma severity, including functional effect,^{38,42,43} and may improve control of symptoms.⁴⁴ Misclassification of severity by physicians in children with moderate disease may also have contributed to the underuse of antiinflammatory medication in this sample and is not uncommon.^{45,46} Most children in this sample had ≥ 2 opportunities (ie, nonurgent care visits) to be evaluated by health care providers and to receive a prescription for controller medication.

Explanations for the low ICS fills found in this sample include parents opting to use ICS medications appropriately on a short-term/sporadic basis for symptom relief or consistent use at a low dose over a 12-month period,²⁵ scenarios we were unable to determine with our data. Either scenario implies that parents adhere to regimens that accommodate their social, psychological, and economic values.²⁵ Parental worry about adverse effects was not associated with number of ICS fills or child age; however, there were significantly fewer ICS fills noted in the younger age group (age <6 years).

Contrary to our hypothesis, higher quick relief medication fills were significantly associated with increased ICS fills in this sample. Perhaps there is a subgroup of children with appropriate ICS use who remain symptomatic and require increased β -agonist use (eg, children with improper administration technique, frequent pre-treatment for exercise, or exposure to viral illness or allergens) resulting in concurrent use of quick relief and preventive medications. Parental misunderstanding of quick relief medication use, overtreatment of mild symptoms, and family sharing of asthma medicines by relatives who lack health insurance³⁷ may also explain overreliance on quick relief medicines. Health care provider factors contributing to overuse of quick relief medication include lack of awareness of increased number of SAB fills because of multiple prescribers, long-term re-fills, or telephone refills provided by nonmedical office or pharmacy staff.⁴⁷ In addition, more than half of all children filled ≥ 1 OCS prescription over the 12-month period, with a slightly higher number of children with mild persistent asthma obtaining an OCS fill as compared with children with more severe disease. This may be a marker for uncontrolled asthma or may represent misclassification of children with mild persistent asthma.

One notable result is the level of asthma mortality (1.4%) in this group of inner-city children as compared with the national asthma mortality rate of 0.7/100 000 in all children with asthma <18 years old.¹ Misuse of quick relief medications has been associated with increased morbidity and mortality^{6,48}; however, excessive use was only noted in 1 of the 3 asthma deaths in this study. One of 4 children with moderate-to-severe persistent asthma was undertreated for asthma either by obtaining no asthma medication or obtaining only SAB fills, and only 1 of the 3 children who died received any antiinflammatory medication fills over 12 months.

We are unable to rule out poor access to quality care as a major factor associated with inappropriate ICS fill rates in this study as noted in other large inner city child samples.⁴⁹ However, access to specialty care was significantly associated with increased ICS fills consistent with a recent study demonstrating that specialty care among a privately insured cohort and a population-based sample was associated with increased use of antiinflammatory medications, as well as quality of life.^{21,50} Although specialty care has been associated with less overuse of β -agonists⁵⁰ and reduced ED care,⁴² this was not evident in our data.

Limitations

There are some elements of the study design that may limit our findings. Because asthma severity was based on parent recall of symptoms and antiinflammatory medication use, severity may be imprecise, and there may be some misclassification of asthma severity. However, the severity classifications were consistent for persistent asthma at baseline and 12 months. If severity misclassification did occur, severity was most likely underestimated, resulting in an underestimation of the association between severity and medication use in this study. Although we were able to obtain pharmacy records regarding the number of prescriptions dispensed over a 12-month period, we are limited in determining actual medication use by the child or sharing of medication among household members. Prescription records do indicate drug availability and have been shown to be a reliable source of drug exposure.⁵¹ Moreover, pharmacy data do not account for samples provided to the parent; thus, our data may underestimate the amount of albuterol use but is less likely to underestimate the low ICS use in this sample. Last, generalizability beyond this group of children is limited because of the selection bias in this sample. We purposely recruited children with more severe or uncontrolled asthma to maximize our ability to detect a difference in the original educational intervention trial. This sample was selected from a base of high-risk, inner-city children with persistent asthma who attended both primary and specialty care sites.

Implications

Despite these limitations, there are several important study implications. In our sample, overreliance on SABs and underuse of ICS medications was common and is substandard asthma care for children. One of 5 children with persistent asthma had either no medication or only SAB medication available during the 12-month follow-up. Routine asthma care visits incorporating use of pharmacy records to monitor overuse of SAB and underuse of ICS medications, ascertaining parental symptom recognition skills, and referral to asthma specialist when indicated may enhance child adherence to antiinflammatory medication to improve daily asthma management.

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Abbreviations

ED	emergency department
ICS	inhaled corticosteroid
SAB	short-acting β -agonist

OCS

oral corticosteroid

CI

confidence interval

References

- Centers for Disease Control and Prevention. Asthma mortality and hospitalization among children and young adults-United States, 1980–1993. *MMWR Morb Mortal Wkly Rep* 1996;45:350–353. [PubMed: 8604212]
- Newacheck PW, Budetti P, Halfon N. Trends in activity limiting chronic conditions among children. *Am J Public Health* 1986;76:178–184. [PubMed: 2936257]
- Benson V, Marano MA. National Center for Health Statistics. Current estimates from the National Health Interview Survey, 1995. *Vital Health Stat* 1998;10:1–428.
- Centers for Disease Control and Prevention. Surveillance for asthma-United States, 1980 –1999. *MMWR Surveill Summ* March 2002;51:1–13.
- Dixon AE, Irvin CG. Early intervention of therapy in asthma. *Curr Opin Pulm Med* 2005;11:51–55. [PubMed: 15591888]
- Lara, M.; Nicholas, W.; Morton, S.; Vaiana, ME.; Genovese, B.; Rachelefsky, G. A Blueprint for Policy Action. Santa Monica, CA: Rand; 2001. Improving Childhood Asthma Outcomes in the United States.
- 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. [PubMed: 10922423]
- Blais L, Suissa S, Boivin JF, Ernst P. First treatment with inhaled corticosteroids and the prevention of admission to hospital for asthma. *Thorax* 1998;53:1025–1029. [PubMed: 10195073]
- Donahue JG, Weiss ST, Livingston JM, Goetsch M, Greinder DK, Platt R. Inhaled steroids and the risk of hospitalization for asthma. *JAMA* 1997;277:887–891. [PubMed: 9062326]
- US Department of Health and Human Service. Expert Panel Report #2. Guidelines for the Diagnosis and Management of Asthma; NIH Publication No. 97-4051. Bethesda, MD: National Asthma Education and Prevention Program; 1997. Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute.
- US Department of Health and Human Service. Guidelines for the Diagnosis and Management of Asthma: Update on Selected Topics, 2002; NIH Publication No. 97-4051. Bethesda, MD: National Asthma Education and Prevention Program; 2002. Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute.
- National Heart, Lung and Blood Institute, National Institutes of Health. Global Initiative for Asthma: Global Strategy for Asthma Management and Prevention; Revised 2002. Bethesda, MD: National Heart, Lung and Blood Institute, National Institutes of Health; 2002.
- Lieu TA, Lozano P, Finkelstein JA, et al. Racial/ethnic variation in asthma status and management practices among children in managed Medicaid. *Pediatrics* 2002;109:857–865. [PubMed: 11986447]
- Diette GB, Skinner EA, Markson LE, et al. Consistency of care with national guidelines for children with asthma in managed care. *J Pediatr* 2001;38:59–64. [PubMed: 11148513]
- Diaz T, Sturm T, Matte T, et al. Medication use among children with asthma in East Harlem. *Pediatrics* 2000;105:1188–1193. [PubMed: 10835056]
- Halterman JS, Yoos HL, Sidora K, Kitzman H, McMullen A. Medication use and health care contacts among symptomatic children with asthma. *Ambul Pediatr* 2001;1:275–279. [PubMed: 11888415]
- Farber HJ, Capra AM, Finkelstein JA, et al. Misunderstanding of asthma controller medications: association with nonadherence. *J Asthma* 2003;40:17–25. [PubMed: 12699208]
- Bender B, Milgrom H. Compliance with asthma therapy: A case for shared responsibility. *J Asthma* 1996;33:199–202. [PubMed: 8707774]
- David C. Preventive therapy for asthmatic children under Florida Medicaid: Changes during the 1990s. *J Asthma* 2004;41:655–661. [PubMed: 15584315]

20. Halterman JS, Yoos HL, Kaczorowski JM, et al. Providers underestimate symptom severity among urban children with asthma. *Arch Pediatr Adolesc Med* 2002;156:141–146. [PubMed: 11814375]
21. Vollmer WM, O'Hollaren M, Ettinger KM, et al. Specialty differences in the management of asthma. A cross-sectional assessment of allergists' patients and generalists' patients in a large HMO. *Arch Intern Med* 1997;157:1201–1208. [PubMed: 9183231]
22. Bender BG, Bender SE. Patient-identified barriers to asthma treatment adherence: response to interviews, focus groups and questionnaires. *Immunol Allergy Clin N Am* 2005;25:107–130.
23. Conn KM, Halterman JS, Fisher SG, Yoos HL, Chin NP, Szilagyi PG. Parental beliefs about medications and medication adherence among urban children with asthma. *Ambul Pediatr* 2005;5:306–310. [PubMed: 16167856]
24. Stempel DA, McLaughlin TP, Stanford RH. Treatment patterns for pediatric asthma to and after emergency department events. *Pediatr Pulmonol* 2005;40:310–315. [PubMed: 16010682]
25. Adams RJ, Weiss ST, Fuhlbrigge A. How and by whom care is delivered influences anti-inflammatory use in asthma: Results of a national population survey. *J Allergy Clin Immunol* 2003;112:445–450. [PubMed: 12897755]
26. Sherman J, Patel P, Hutson A, Chesrown S, Hendeles L. Adherence to oral montelukast and inhaled fluticasone in children with persistent asthma. *Pharmacotherapy* 2001;21:1464–1467. [PubMed: 11765298]
27. Mudd K, Bollinger ME, Hsu VD, Donithan M, Butz A. Pharmacy Fill Patterns in Young, Urban Children with Persistent Asthma. *J Asthma* 2006;43:597–600. [PubMed: 17050224]
28. Sherman J, Hutson A, Baumstein S, Hendeles L. Telephoning the patient's pharmacy to assess adherence with asthma medications by measuring refill rate for prescriptions. *J Pediatr* 2000;136:523–526.
29. Butz AM, Tsoukleris MG, Donithan M, et al. Effectiveness of home nebulizer education intervention in young minority children with asthma. *Arch Pediatr Adolesc Med* 2006;160:622–628. [PubMed: 16754825]
30. Farber HJ, Chi FW, Capra A, et al. Use of asthma medication dispensing patterns to predict risk of adverse health outcomes: A study of Medicaid-insured children in managed care programs. *Ann Allergy Asthma Immunol* 2004;92:319–328. [PubMed: 15049395]
31. SAS Institute. SAS/STAT User's Guide. Version 8.0. Cary, NC: SAS Institute, Inc; 2000.
32. Stata Corporation. Stata Statistical Software. Release 7.0. College Station, TX: Stata Corporation; 2001.
33. Szilagyi PG, Dick AW, Klein JD, et al. Improved asthma care after enrollment in the state children's health insurance program in New York. *Pediatrics* 2006;117:486–496. [PubMed: 16452369]
34. Shields AE, Comstock C, Finkelstein JA, Weiss KB. Comparing asthma care provided to Medicaid-enrolled children in a primary care case manager plan and a staff model HMO. *Ambul Pediatr* 2003;3:253–262. [PubMed: 12974661]
35. Lenhardt RO, Catrambone CD, McDermott MF, Walter J, Williams SG, Weiss KB. Improving pediatric asthma care through surveillance: The Illinois emergency department asthma collaborative. *Pediatrics* 2006;117:S96–S105. [PubMed: 16777837]
36. McQuaid EL, Kopel SJ, Klein RB, Fritz GK. Medication adherence in pediatric asthma: reasoning, responsibility, and behavior. *J Pediatr Psychol* 2003;28:323–333. [PubMed: 12808009]
37. Walders N, Kopel SJ, Koinis-Mitchell D, McQuaid EL. Patterns of quick-relief and long-term controller medication use in pediatric asthma. *J Pediatr* 2005;146:177–182. [PubMed: 15689902]
38. Anis AH, Lynd LD, Wang X, et al. Double trouble: Impact of inappropriate use of asthma medication on the use of health care resources. *Can Med Association J* 2001;164:625–631.
39. Goodman DC, Lozano P, Stukel TA, Chang C, Hecht J. Has asthma medication use in children become more frequent, more appropriate, or both? *Pediatrics* 1999;104:187–194. [PubMed: 10428993]
40. Carlton BG, Lucas DO, Ellis EF, Conboy-Ellis K, Schoheiber O, Stempel D. The status of asthma control and asthma prescribing practices in the United States: Results of a large prospective asthma control survey of primary care practices. *J Asthma* 2005;42:529–535. [PubMed: 16169784]
41. Handelman L, Rich M, Bridgemohan CF, Schneider L. Understanding pediatric inner-city asthma: an explanatory model approach. *J Asthma* 2004;41:167–177. [PubMed: 15115169]

42. Schatz M, Cook EF, Nakahiro R, Petitti D. Inhaled corticosteroids and allergy specialty care reduce emergency hospital use for asthma. *J Allergy Clin Immunology* 2003;111:503–508. [PubMed: 12642829]
43. Fuhlbrigge AL, Adams RJ, Guilbert TW, Grant E, Lozano P, Janson SL. The burden of asthma in the United State. Level and distribution are dependent on interpretation of the National Asthma Education and Prevention Program guidelines. *Am J Respir Crit Care Med* 2002;166:1044–1049. [PubMed: 12379546]
44. Cabana, M.; Sligh, KK.; Nan, B.; Leo, H.; Bratton, SL.; Dombkowski, KJ. Outcomes associated with spirometry for pediatric asthma in a managed care organization. *Pediatrics*. 2006. Available at: www.pediatrics.org/cgi/content/full/118/1/e151
45. Van den Berg NJ, Hagmolen W, Nagelkerke AF, Bindels PJE, van der Palen J, van Aalderen WMC. What general practitioners and paediatricians think about their patients' asthma. *Patient Educ Couns* 2005;59:182–195. [PubMed: 16257623]
46. Calhoun WJ, Sutton LB, Emmett A, Dorinsky PM. Asthma variability inpatients previously treated with B_2 -agonist alone. *J Allergy Clin Immunol* 2003;112:1088–1094. [PubMed: 14657863]
47. Ferrell CW, Aspy CB, Mold JW. Management of prescription refills in primary care: an Oklahoma physicians resource/research network (OKPRN) study. *J Am Board Fam Med* 2006;19:31–38. [PubMed: 16492003]
48. Stempel DA, McLaughlin TP, Stanford RH, Fuhlbrigge AL. Patterns of asthma control: A 3-year analysis of patient claims. *J Allergy Clin Immunol* 2005;115:935–939. [PubMed: 15867848]
49. Kattan M, Mitchell H, Eggleston P, et al. Characteristics of inner-city children with asthma: The National Cooperative Inner-City Asthma Study. *Pediatr Pulmonol* 1997;24:253–262. [PubMed: 9368259]
50. Schatz M, Zeiger RS, Mosen D, et al. Improved asthma outcomes from allergy specialist care: A population-based cross-sectional analysis. *J Allergy Clin Immunol* 2005;116:1307–1313. [PubMed: 16337464]
51. Grymonpre R, Cheang M, Fraser M, Metge C, Sitar DS. Validity of prescription claims database to estimate medication adherence in older persons. *Med Care* 2006;44:471–477. [PubMed: 16641666]

FIGURE 1.
Flow diagram of subject progress through randomized trial.

FIGURE 2.
Frequency of asthma medication prescriptions filled over 12 months by type of medication.

TABLE 1

Baseline Sociodemographic Health Characteristics for Children With Complete Follow-up Data ($N = 180$) Compared With Total Sample at Baseline ($N = 221$)

Sociodemographic Characteristic	Children With Complete Pharmacy and Questionnaire Data at Follow-up ($N = 180$), n (%)	Total Sample at Baseline ($N = 221$), n (%)
Ethnicity		
Black	160 (88.9)	197 (89.1)
White	18 (10.0)	22 (10.0)
Other	2 (1.1)	2 (0.9)
Gender		
Male	115 (63.9)	145 (65.6)
Child age (range: 2–9 y), mean (SD)	4.5 (2.1)	4.5 (2.1)
Parent/guardian educational level		
Some HS	42 (23.3)	53 (23.9)
HS graduate or GED	65 (36.1)	85 (38.5)
Some college/trade school	58 (32.2)	68 (30.8)
4 y of college or college graduate	15 (8.3)	15 (6.8)
Household Income		
Less than \$20 000	84 (46.7)	106 (48.0)
More than \$20 000	70 (38.9)	89 (40.3)
Missing	26 (14.4)	26 (11.7)
Type of medical insurance for child		
Medical assistance	147 (82.1)	176 (79.6)
Private	31 (17.3)	40 (18.1)
Self-pay	1 (0.6)	5 (2.3)
Problems paying for asthma medications in last 6 mo	20 (11.1)	22 (10.0)
Asthma morbidity and health care use characteristics		
Severity level		
Mild intermittent	8 (4.4)	10 (4.5)
Mild persistent	114 (63.3)	134 (60.6)
Moderate persistent	33 (18.3)	46 (20.8)
Severe persistent	25 (13.9)	31 (14.0)
No. of ED visits (range: 0–20 visits) during last 6 mo, mean (SD)	1.83 (2.55)	1.95 (2.7)
No. of hospital admissions for asthma during last 6 months, mean (SD)	0.36 (0.67)	0.38 (0.71)
Written plan for asthma care in home	74 (41.1)	85 (38.5)
Limitation of activity because of asthma	116 (64)	148 (67)
Receives specialty care	90 (50.0)	107 (48.4)
SAB fills past 6 mo	1.67 (1.8)	1.75 (1.9)

HS indicates high school.

TABLE 2

Specific Asthma Medication Regimens Over Follow-up by Severity Level (≥ 1 Prescription Filled Over 12 Months; $N = 174$)

Asthma Medication Regimen	Severity Level		Total ($N = 174$), n (%)
	Mild Persistent ($N = 114$), n (%)	Moderate/Severe Persistent ($N = 60$), n (%)	
No medication	6 (5.3)	6 (10.0)	12 (6.9)
Quick relief medication only (SAB)			
SAB only fills	18 (15.8)	9 (15.0)	27 (15.5)
Antiinflammatory controller + quick relief use ^a			
ICS + quick relief fills ^b	26 (22.8)	17 (28.3)	43 (24.7)
LM + quick relief fills	9 (7.9)	1 (3.1)	10 (5.8)
ICS + LM or mast cell stabilizer + quick relief fills ^b	55 (48.2)	27 (45.0)	82 (47.1)
OCS use			
OCS bursts (≥ 1) fills	72 (63.2)	30 (50.0)	102 (58.6)

Data exclude 6 children with incomplete severity data at follow-up. LM indicates leukotriene modifier.

^a Any antiinflammatory use + quick relief medication: 135 of 174 (78%).

^b Any ICS use alone or in combination: 125 of 174 (72%).

TABLE 3

Unadjusted Relative Risks (95% CI) for Health and Sociodemographic Factors Associated With Number of ICS Prescriptions Filled Over 12 Months ($N = 169$)

Characteristics	0–2 ICS Fills ($N = 97$), n (%)	≥ 3 ICS Fills ($N = 72$), n (%)	Total ($N = 169$), n (%)	RR (95% CI)/ ANOVA Test
Sociodemographic characteristics				
Child gender				
Male	68 (70.1)	39 (54.2)	107 (63.3)	1.46 (1.0–2.1)
Child race/ethnicity				
Black	87 (89.7)	63 (87.5)	150 (88.8)	
White/other (ref)	10 (10.3)	9 (12.5)	19 (11.2)	1.13 (0.7–1.9)
Child age				
Mean (SD)	5.04 (1.8)	5.96 (2.1)	5.55 (2.1)	$F = 3.18^a$
Parent educational level				
Less than HS graduate	29 (29.9)	19 (26.4)	48 (28.4)	
HS graduate or higher	68 (70.1)	53 (73.6)	121 (71.6)	1.11 (0.7–1.7)
Income				
Less than \$20 000	43 (63.2)	36 (69.2)	79 (65.8)	
More than \$20 000	25 (36.8)	16 (30.8)	41 (34.2)	1.17 (0.7–1.8)
Type of health insurance				
Medical assistance	79 (81.4)	59 (81.9)	138 (81.7)	
Private insurance/self-pay/other	18 (18.6)	13 (18.1)	31 (18.3)	0.98 (0.6–1.5)
Asthma health characteristics				
Severity				
Mild persistent	60 (65.9)	45 (63.4)	105 (64.8)	
Moderate/severe persistent	31 (34.1)	26 (36.6)	57 (35.2)	1.06 (0.7–1.5)
Activities limited because of asthma within past 6 mo	58 (60.4)	42 (58.3)	100 (59.5)	0.95 (0.7–1.4)
Asthma management				
Specialty care in past 12 mo	37 (38.1)	48 (66.7)	85 (50.3)	0.51 (0.3–0.7) ^a
Asthma action plan in home	64 (66.0)	58 (80.6)	122 (72.2)	1.60 (1.0–2.6) ^a
Make appointment with child's physician even when child well	69 (71.1)	64 (88.9)	133 (78.7)	2.17 (1.1–4.1) ^a
Worried about side effects of asthma medicines	25 (25.8)	20 (27.8)	45 (26.6)	1.06 (0.7–1.6)
Difficulty paying for medications	6 (8.5)	9 (8.3)	15 (8.3)	1.02 (0.5–1.9)
Treatment group Intervention	61 (64.9)	33 (35.1)	94 (52.2)	1.23 (0.9–1.7)
No. of admissions for asthma in last 6 mo, mean (SD)	0.13 (0.4)	0.08 (0.4)	0.11 (0.43)	$F = 0.58$
No. of ED visits in past 6 mo, mean (SD)	1.09 (1.9)	0.59 (1.1)	0.88 (1.6)	$F = 4.11^a$
No. of regular, nonacute care visits to pediatrician in past 12 mo, mean (SD)	2.33 (5.8)	1.94 (1.8)	2.17 (4.5)	$F = 0.31$
No. of OCS courses in past 6 mo, mean (SD)	1.13 (1.7)	0.86 (1.4)	1.02 (1.6)	$F = 1.26$
No. of SAB fills in past 12 mo, mean (SD)	2.19 (1.9)	5.69 (4.9)	3.68 (3.5)	$F = 41.9^a$

RR indicates risk ratio; ANOVA, analysis of variance; ref, reference. Excluded are 11 children with fills for leukotriene modifier, mast cell stabilizer, and long-acting β agonist medications only.

^a $P < .05$.

TABLE 4

Adjusted Odd Ratios (95% CI) for Logistic Regression Model Independently Predicting at Least 3 ICS Prescriptions Filled Over 12 Months

Factor	Model 1 Odd Ratio (95% CI)	Model 2 Odd Ratio (95% CI)
No. of fills for SAB medication in past 12 mo (continuous)	1.46 (1.2–1.7) ^a	1.46 (1.2–1.7) ^a
Specialty care within past 12 mo	2.89 (1.3–6.5) ^b	3.01 (1.3–6.7) ^b
Make appointment with doctor even if child is well (seek preventive care)	2.25 (1.0–5.3) ^c	2.15 (0.9–5.1) ^c
Child Age, y		
6–8 vs 2–5	1.04 (0.9,1.2)	1.04 (0.9–1.2)
No. of ED visits in last 6 mo		
1–2 vs 0	1.20 (0.5–2.8)	1.3 (0.6–3.1)
≥3 vs 0	1.35 (0.5–3.8)	1.6 (0.6–4.3)
Have asthma action plan	0.76 (0.3–1.7)	0.76 (0.3–1.7)
Severity of asthma at baseline		
Mild persistent vs mild intermittent	2.65 (0.3–24.6)	
Moderate/severe persistent vs mild intermittent	5.89 (0.4–37.8)	
Hosmer and Lemeshow goodness of fit	$\chi^2 = 2.74$; $P = .95$	$\chi^2 = 9.62$; $P = .29$

^a $P < .0001$;

^b $P < .01$;

^c $P = .07$ –.08.