
Asthma-related medication use among children in the United States

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Background: Asthma is one of the most common chronic conditions in children and has a major impact on health care use and quality of life. The Best Pharmaceuticals for Children Act mandates the federal government to sponsor pediatric studies of drugs approved for use in the United States but lacking evaluation in the pediatric population and lacking interest of commercial sponsors. As input into the drug selection and prioritization process, information is needed on the percentage of children who receive asthma-related medications.

Objective: To estimate the percentage of children who receive asthma-related medications.

Methods: Retrospective analysis of outpatient medical and drug claims from members of commercial health care insurance plans enrolled any time from January 1, 2004, through December 31, 2005. The study population included 4,259,103 children throughout the United States aged birth through 17 years.

Results: Fifteen percent of all children were dispensed an asthma-related medication. Among 218,943 children with an asthma diagnosis, 188,286 (86%) had a dispensed asthma-related medication at any time during the 2-year study period. Among children without any asthma diagnoses, 398,880 (10%) had a dispensed medication. Fifty-nine percent of children with an asthma diagnosis were dispensed an anti-inflammatory medication within 90 days after a claim with a diagnosis of asthma.

Conclusions: Asthma-related medications are dispensed to a large percentage of the pediatric population, including many who do not have claims with asthma diagnoses listed. Data on the pharmacokinetics and safety of these drugs in children are largely unknown and difficult to obtain. Clinical studies that use new tools and approaches are needed to resolve this information gap.

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INTRODUCTION

Asthma is one of the most common chronic conditions in children in the United States and the most prevalent cause of childhood disability.¹ There was a steady increase in asthma prevalence among children 0 to 17 years of age during the 1980s and 1990s in the United States. Recent estimates based on parental reports from the National Health Interview Survey have shown that the prevalence of children with asthma has stabilized at approximately 8% to 9%.² Similar patterns have been observed in children worldwide.³

Asthma has a major impact on health care use and quality of life.⁴ It is the third leading cause of hospitalization of children in the United States.⁵ Annually, asthma is related to more than 10 million missed school days, 200,000 hospitalizations, and \$400 million spent on direct medical services.^{6–8}

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Asthma drugs, like most medicines for treating pediatric diseases, have not been adequately studied in children to characterize dosing, efficacy, and safety.^{9–12} In 2002, Congress enacted the Best Pharmaceuticals for Children Act (BPCA) to address this issue of insufficient pediatric information in general. The BPCA mandates the National Institutes of Health (NIH) to sponsor pediatric studies of drugs approved for use in the United States but lacking evaluation in the pediatric population if requests by the Food and Drug Administration to the New Drug Application holder are declined.¹³ The selection of drugs is based on the frequency of use in the pediatric population, the prevalence and severity of the condition being treated, and the potential for providing a health benefit in the pediatric population. It is not clear how often such drugs are dispensed specifically for asthma diagnoses, at what ages, and whether this varies by region. This study was undertaken to provide input into the prioritization process for federal support of pediatric drug studies by evaluating asthma-related medication use among children in the United States.

METHODS

Estimates of the prevalence of asthma and percentage of children with a dispensed asthma-related medication were derived from administrative claims data for children enrolled in commercial insurance plans. The Ingenix LabRx Database was used. These data include claims for health care utilization

for members of one insurer's large national managed care plans for an employed, commercially insured population and their dependents with both medical and pharmacy benefit coverage. Thus, the data are derived from outpatient visit claims and do not represent uninsured children. The deidentified database complies with the Health Insurance Portability and Accountability Act of 1996. The Westat institutional review board reviewed and approved the study.

A medical claims file contained information on up to 5 diagnoses recorded with the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* diagnosis codes. The pharmacy claims file included the National Drug Code and fill date for outpatient prescription medications. Children aged birth through 17 years who were enrolled in the plans at any time from January 1, 2004, through December 31, 2005, were included.

A diagnosis of asthma was defined as an outpatient or ambulatory medical service claim (eg, office visit, urgent care or emergency department visit) with an *ICD-9-CM* code beginning with 493 in any of the 5 available diagnosis fields. Asthma-related drugs included anti-inflammatories (oral inhalation or oral corticosteroids, leukotriene modifiers, or mast cell stabilizers) or bronchodilators (anticholinergics, sympathomimetics, or xanthine derivatives). These drugs are not necessarily used exclusively for the treatment of asthma. However, they will be referred to as asthma-related medications in this report. The combination of fluticasone and salmeterol was classified as an anti-inflammatory, and the combination of albuterol and ipratropium was classified as a sympathomimetic. The use of each drug was analyzed individually. For example, if a child reported using fluticasone, that child was included in the group of children who used fluticasone. If this same child also reported using albuterol, the child was also included in the group of children who used albuterol.

The prevalence of asthma was calculated as the probability of a medical claim containing a diagnosis of asthma within a 12-month period. The probability was computed using time to first asthma diagnosis (based on the first date during the 2004–2005 enrollment period of a submitted asthma claim) for all children in a life table analysis.¹⁴ This approach enables children not continuously enrolled throughout the study period to be included in the calculation. It yields an estimate that is comparable to a 12-month period prevalence typically obtained from a survey (eg, response to the question, “Have you visited a doctor due to asthma during the past 12 months?”).

To summarize the total burden of drug use, we calculated the percentage of all children with a dispensed asthma-related medication during a standardized 1-year period using the life table approach described herein. The percentage of children with a dispensed asthma-related medication was also calculated among the subgroup of children with an asthma diagnosis. However, the medical claim does not include information on medications specifically prescribed for the condition, and the pharmacy claims record does not include the indica-

tion for use. Therefore, to increase the specificity of the association between the diagnosis and medication, we included only asthma-related medications prescribed within 90 days after a diagnosis of asthma. For rescue medications, the temporal relation between diagnosis and medication use may not be as straightforward or as limited. Therefore, we also calculated the percentage of children with an asthma diagnosis who had an asthma-related medication dispensed at any time during our 2-year study period.

Finally, because children with no claims for asthma-related care during the study period may also be prescribed an asthma-related medication, we calculated the percentage of these children (ie, children presumably without asthma) with a dispensed asthma-related medication during the 2-year study period.

SAS statistical software, version 9 (SAS Institute Inc, Cary, North Carolina), was used for all statistical analyses. Statistical confidence intervals are not presented, since the large samples produced narrow ranges. For example, among children with asthma in our study population, the width of the 95% confidence interval for an estimate of the percentage with a dispensed medication will be approximately 0.4% (ie, the estimate $\pm 0.2\%$). Therefore, even differences of 1 percentage point (eg, 20% vs 21%), which are not clinically important, will be statistically significant at $P < .05$ and should be interpreted cautiously.

RESULTS

A total of 4,259,103 children were enrolled in the insurance plan during at least part of 2004–2005, with slightly more boys enrolled (51.2%) than girls (48.8%). The age distribution by sex is given in Table 1, and the enrollment numbers by geographic area are given in Table 2. Children from all 50 states and the District of Columbia are represented in the study population. The age distribution of the study population was similar to that of the US pediatric population (<http://www.census.gov/popest/national/asrh/NC-EST2006-sa.html>). Proportionately more children were from the Midwest and South than in the US pediatric population (31% vs 22% and 43% vs 36%, respectively). Conversely, fewer children were from the Northeast and West than in the US pediatric population (11% vs 17% and 15% vs 24%, respectively). The mean number of days of enrollment during the 2-year study period was 426 days, and 60% of children were enrolled for at least 12 months.

Table 1. Pediatric Study Population by Age and Sex^a

Age, y	Male, No.	Female, No.	Total, No. (%)
0–4	717,030	682,694	1,399,724 (32.9)
5–11	822,543	784,373	1,606,916 (37.3)
12–14	366,825	350,801	717,626 (16.8)
15–17	272,409	262,428	534,837 (12.6)
Total	2,178,807	2,080,296	4,259,103 (100.0)

^a Data are from administrative claims files from a national managed care organization with both medical and pharmacy benefit coverage for commercial insurance plans for calendar years 2004–2005.

Table 2. Pediatric Study Population by Geographic Area^a

Geographic area	No. (%) of children
Northeast region	459,771 (10.8)
New England	146,221
Middle Atlantic	313,550
Midwest region	1,323,523 (31.1)
East North Central	813,143
West North Central	510,380
South region	1,835,977 (43.1)
South Atlantic	932,323
East South Central	227,352
West South Central	676,302
West region	639,832 (15.0)
Mountain	406,638
Pacific	233,194
Total	4,259,103 (100.0)

^a Data are from administrative claims files from a national managed care organization with both medical and pharmacy benefit coverage for commercial insurance plans for calendar years 2004–2005.

Prevalence of Asthma Diagnoses

The prevalence of asthma by age, sex, and geographic region is given in Table 3 and Table 4. The prevalence of asthma (based on the probability of having a medical claim with an asthma diagnosis within a 12-month period) was 6.2%. The prevalence of asthma decreased by age group (from 7.0% in 0- to 4-year-olds to 4.3% in 15- to 17-year-olds; $P < .001$) and was overall 41% greater in boys than girls (7.2% vs 5.1%; $P < .001$). However, the sex difference was most pronounced in the younger age groups and diminished with age to the point where the prevalence was approximately the same among 15- to 17-year-olds. The prevalence of asthma was highest in the Northeast (7.8%), an estimate that is 43% greater than the Midwest, 23% greater than the South, and 35% greater than the West ($P < .001$).

Dispensed Asthma-Related Medications

The last column of Table 5 gives the percentage of all children who were dispensed an asthma-related medication in

Table 3. One-Year Period Prevalence of Asthma (per 100 Children) by Age and Sex^a

Age, y	Male	Female	Total	Male-female ratio
0–4	8.57	5.39	7.02	1.59
5–11	7.79	5.20	6.53	1.50
12–14	5.56	4.72	5.15	1.18
15–17	4.14	4.52	4.33	0.92
Total	7.17	5.09	6.15	1.41

^a Data are from administrative claims files from a national managed care organization with both medical and pharmacy benefit coverage for commercial insurance plans for calendar years 2004–2005. Prevalence of asthma per 100 children based on the probability of a claim with a diagnosis of asthma within a 12-month period after January 1, 2004, or date of enrollment (whichever is later) using a life table analysis. Diagnosis of asthma defined as a claim with an *International Classification of Diseases, Ninth Revision, Clinical Modification* code starting with 493.

Table 4. One-Year Period Prevalence of Asthma (per 100 Children) by Geographic Region^a

Geographic area	Prevalence of asthma	Ratio
Northeast region	7.83	Reference
New England	7.32	
Middle Atlantic	8.07	
Midwest region	5.46	0.70
East North Central	5.33	
West North Central	5.66	
South region	6.36	0.81
South Atlantic	6.31	
East South Central	5.13	
West South Central	6.83	
West region	5.80	0.74
Mountain	5.67	
Pacific	6.01	
Total	6.15	

^a Data are from administrative claims files from a national managed care organization with both medical and pharmacy benefit coverage for commercial insurance plans for calendar years 2004–2005.

1 year. Approximately 15% of all children were dispensed an asthma-related medication within 1 year, with 10% receiving an anti-inflammatory and 10% receiving bronchodilator medication.

The use of asthma-related outpatient prescription medications among children with and without an asthma diagnosis is also given in Table 5. Among the 218,943 children with an asthma diagnosis, 75% had at least 1 asthma-related medication dispensed within 90 days after the asthma claim. For drugs likely to be used as asthma episode controllers, 37% of children with asthma were dispensed at least 1 inhaled corticosteroid, and 26% were dispensed a leukotriene modifier. Mast cell stabilizers and xanthine derivatives were dispensed infrequently (<1%). Oral corticosteroids were dispensed to 30% of children with asthma. Sympathomimetics were dispensed to 58% of children with asthma. Most sympathomimetics were for short-acting β_2 -agonist inhalers, used primarily as rescue medications, which were dispensed to 56% of children.

Table 5 also gives the number and percentage of children with asthma who were dispensed an asthma-related medication at any time during the study period. Eighty-six percent of children with asthma were dispensed at least 1 asthma-related medication at any time during the study period. The percentage of children with asthma who had a dispensed medication for a short-acting β_2 -agonist inhaler increased from 56% (dispensed within 90 days) to 72% (dispensed at any time during the 2-year study period; $P < .001$).

Among the 188,286 children with asthma who were dispensed an asthma-related medication, 37.2% were dispensed a single type of anti-inflammatory and 43.7% were dispensed 2 or more different types of anti-inflammatories (the remaining 19.1% were dispensed bronchodilators only). Among these same children, 72.6% were dispensed a single broncho-

Table 5. Dispensed Asthma-Related Medications Among Children With and Without an Asthma Diagnosis^a

Therapeutic category ^b	Asthma-related drug use among children with a diagnosis of asthma, No. (%) ^c		Asthma-related drug use among children without a diagnosis of asthma but with a dispensed medication at any time, No. (%) ^d	Asthma-related drug use among all children with a dispensed medication during 1 year, % ^e
	Children with a dispensed medication within 90 days after diagnosis	Children with a dispensed medication at any time ^d		
Any asthma-related drug	164,904 (75.32)	188,286 (86.00)	398,880 (10.05)	14.58
Anti-inflammatory	130,174 (59.46)	152,302 (69.56)	267,481 (6.74)	10.18
Corticosteroids	111,965 (51.14)	135,632 (61.95)	220,820 (5.56)	8.58
Inhalation	80,554 (36.79)	98,005 (44.76)	44,959 (1.13)	3.69
Beclomethasone	1,392 (0.64)	1,785 (0.82)	538 (0.01)	0.05
Budesonide	30,587 (13.97)	39,527 (18.05)	18,027 (0.45)	1.53
Fluticasone	23,417 (10.70)	29,983 (13.69)	12,078 (0.30)	1.06
Fluticasone-salmeterol	32,334 (14.77)	39,058 (17.84)	15,027 (0.38)	1.30
Triamcinolone	504 (0.23)	669 (0.31)	413 (0.01)	0.02
Oral	66,010 (30.15)	88,266 (40.31)	186,502 (4.70)	6.32
Dexamethasone	938 (0.43)	1,945 (0.89)	11,711 (0.29)	0.28
Methylprednisolone	2,435 (1.11)	4,371 (2.00)	22,318 (0.56)	0.53
Prednisolone	44,479 (20.32)	59,608 (27.23)	107,695 (2.71)	4.01
Prednisone	21,026 (9.60)	28,302 (12.93)	49,717 (1.25)	1.66
Leukotriene modifiers	57,005 (26.04)	69,435 (31.71)	64,858 (1.63)	3.26
Montelukast	56,923 (26.00)	69,346 (31.67)	64,813 (1.63)	3.26
Mast cell stabilizers	1,142 (0.52)	1,632 (0.75)	773 (0.02)	0.06
Inhalation	1,141 (0.52)	1,630 (0.74)	771 (0.02)	0.06
Cromolyn	1,063 (0.49)	1,538 (0.70)	748 (0.02)	0.06
Bronchodilators	127,369 (58.17)	163,723 (74.78)	210,682 (5.31)	9.62
Anticholinergics	1,967 (0.90)	2,586 (1.18)	615 (0.02)	0.08
Inhalation	1,965 (0.90)	2,584 (1.18)	614 (0.02)	0.08
Ipratropium	1,891 (0.86)	2,502 (1.14)	596 (0.02)	0.08
Sympathomimetics	127,084 (58.04)	163,503 (74.68)	210,234 (5.30)	9.60
β_2 -Agonists, oral	6,688 (3.05)	12,295 (5.62)	44,429 (1.12)	1.41
Albuterol	6,654 (3.04)	12,239 (5.59)	44,107 (1.11)	1.40
Inhalation, long-acting	2,258 (1.03)	2,946 (1.35)	1,011 (0.03)	0.10
Formoterol	1,507 (0.69)	1,870 (0.85)	525 (0.01)	0.06
Salmeterol	772 (0.35)	1,110 (0.51)	488 (0.01)	0.04
Inhalation, short-acting	122,075 (55.76)	157,784 (72.07)	171,218 (4.31)	8.47
Albuterol	104,042 (47.52)	137,848 (62.96)	146,858 (3.70)	7.21
Albuterol-ipratropium	1,280 (0.58)	1,732 (0.79)	684 (0.02)	0.06
Levalbuterol	22,265 (10.17)	30,507 (13.93)	24,447 (0.62)	1.45
Pirbuterol	4,120 (1.88)	5,626 (2.57)	3,451 (0.09)	0.21
Xanthine derivatives	147 (0.07)	206 (0.09)	369 (0.01)	0.01

^a Data are from administrative claims files from a national managed care organization with both medical and pharmacy benefit coverage for commercial insurance plans for calendar years 2004–2005.

^b Drug name listed if percentage is greater than 0.1% for any category.

^c Diagnosis of asthma defined as a claim with an *International Classification of Diseases, Ninth Revision, Clinical Modification* code starting with 493.

^d Drugs dispensed at any time while child was enrolled in insurance plan during 2004–2005.

^e Based on the probability of a claim for the medication within a 12-month period using a life table analysis.

dilator, and 14.4% were dispensed 2 or more different types of bronchodilators (the remaining 13.0% were dispensed anti-inflammatories only).

Among children without a claim for asthma during the 2-year study period, 10% were dispensed an asthma-related

medication (Table 5). Although this percentage is lower than the 86% estimate observed among children with an asthma claim, it represents more than twice as many children (398,880 vs 188,286). This excess in the absolute number of children without an asthma diagnosis who were dispensed an

asthma-related medication was most pronounced for oral corticosteroids and albuterol (oral). Among the 398,880 children without a diagnosis of asthma who were dispensed an asthma-related medication, 59.0% were dispensed a single type of anti-inflammatory and 8.0% were dispensed 2 or more different types of anti-inflammatories (the remaining 32.9% were dispensed bronchodilators only). Similarly, 50.1% were dispensed a single bronchodilator, and 2.8% were dispensed 2 or more different types of bronchodilators (the remaining 47.2% were dispensed anti-inflammatories only). Among these 398,880 children, 81% had a diagnosis of another respiratory illness or related condition. The most common other conditions (and *ICD-9-CM* codes) were acute respiratory infection (465), acute pharyngitis (462), and acute bronchitis and bronchiolitis (466).

Variations by Sex, Region, and Age

The remaining analyses focus on children with an asthma diagnosis and examined the percentage who were dispensed an asthma-related medication within 90 days of a diagnosis. No large differences were observed among males and females with asthma. However, for several medications the percentage of males with asthma who were dispensed an asthma-related medication was slightly greater than the corresponding percentage in females with asthma (data not shown).

When variations by geographic region were examined, the percentages of children with asthma-related dispensed medications were similar across regions. The percentage for any asthma-related medication in the Northeast, the region with the greatest asthma prevalence, was slightly less than the other regions (73% in the Northeast vs 75% to 76% in other regions). Inhaled corticosteroids were dispensed almost equally among regions (36% to 37%), but the percentage of leukotriene modifier use in the West (21%) was below the percentages in the other regions (26% to 28%). By contrast, the West region had a slightly higher percentage of dispensed short-acting inhaled β_2 -agonists (58% in the West vs 55% to 56% in other regions). These relatively small differences were statistically significant (ie, $P < .05$) because of the large samples sizes involved in the comparisons.

Asthma-related medications dispensed to children with asthma varied by age (Table 6). The percentage of children with at least 1 asthma-related medication dispensed within 90 days after an asthma diagnosis decreased from 77% among 0- to 4-year-olds to 69% among 15- to 17-year-olds ($P < .001$). Among 67,932 0- to 4-year-olds with an asthma diagnosis, 9,173 were younger than 1 year, and 7,613 (83.0%) were dispensed an asthma-related medication. The trend of decreasing percentages of dispensed medications by age was more evident among anti-inflammatories than bronchodilators. In particular, the percentages of children with dispensed inhaled corticosteroid and leukotriene modifier controller medications were lowest in the 15- to 17-year-old group. The use of several individual drugs followed an age pattern expected by their formulation. Budesonide was most common among 0- to 4-year-olds, fluticasone-salmeterol was more

Table 6. Dispensed Asthma-Related Medications Among Children With Asthma by Age^a

Therapeutic category ^b	Children with a dispensed medication among children with a diagnosis of asthma, % ^c			
	0-4 y	5-11 y	12-14 y	15-17 y
Any asthma-related drug	76.86	76.23	71.99	69.20
Anti-inflammatory	62.92	62.16	52.93	48.55
Corticosteroids	57.07	51.88	43.58	40.43
Inhalation	38.58	37.95	33.66	30.38
Beclomethasone	0.58	0.70	0.55	0.54
Budesonide	28.16	10.49	3.78	2.59
Fluticasone	12.25	12.31	6.80	5.25
Fluticasone-salmeterol	1.01	18.26	24.22	23.04
Triamcinolone	0.05	0.23	0.35	0.45
Oral	38.69	29.33	20.11	19.11
Dexamethasone	0.65	0.35	0.20	0.34
Methylprednisolone ^d		0.53	2.36	3.72
Prednisolone	37.91	19.59	1.64	0.38
Prednisone	0.67	10.67	16.86	15.71
Leukotriene modifiers	23.32	30.81	23.55	19.80
Montelukast	23.32	30.78	23.45	19.69
Zafirlukast	0.00	0.04	0.12	0.12
Mast cell stabilizers	0.30	0.50	0.71	0.79
Inhalation	0.30	0.50	0.71	0.79
Cromolyn	0.29	0.46	0.65	0.72
Bronchodilators	59.70	56.97	55.05	53.65
Anticholinergics	1.12	0.82	0.76	0.64
Inhalation	1.11	0.82	0.76	0.64
Ipratropium	1.11	0.80	0.69	0.51
Tiotropium ^d		0.02	0.07	0.13
Sympathomimetics	59.53	56.86	54.93	53.48
β_2 -Agonists, oral	6.55	2.06	0.55	0.35
Albuterol	6.52	2.05	0.54	0.35
Inhalation, long-acting	0.34	1.11	1.55	1.71
Formoterol	0.30	0.79	0.93	0.97
Salmeterol	0.04	0.33	0.62	0.75
Inhalation, short-acting	55.13	55.14	54.15	52.75
Albuterol	41.00	48.29	49.85	49.13
Albuterol-ipratropium	0.44	0.54	0.69	0.82
Levalbuterol	18.28	8.81	3.46	2.17
Pirbuterol	0.09	2.14	3.30	3.03
Xanthine derivatives	0.04	0.05	0.12	0.13
Oral	0.04	0.05	0.12	0.13
Theophylline ^d		0.03	0.10	0.11

^a Data are from administrative claims files from a national managed care organization with both medical and pharmacy benefit coverage for commercial insurance plans for calendar years 2004–2005.

^b Drug name listed if percentage is greater than 0.1% for any category.

^c Diagnosis of asthma defined as a claim with an International Classification of Diseases, Ninth Revision, Clinical Modification code starting with 493. Includes medications dispensed within 90 days after an asthma diagnosis.

^d Fewer than 10 children in category; percentage not calculated.

common among 5- to 17-year-olds, prednisolone use decreased with age (possibly because prednisolone is a liquid formulation), and use of prednisone, which is available as a liquid and tablet, increased with age. The percentages of children dispensed short-acting β_2 -agonists were similar across age groups, although albuterol was mainly used among the older age groups, whereas both albuterol and its single isomer levalbuterol were dispensed to the younger age groups. An analogous pattern was observed when asthma-related medications dispensed at any time were examined, although all percentages were proportionally higher (data not shown).

DISCUSSION

Medical and pharmacy claims data were used to estimate the prevalence of asthma and the percentage of children with dispensed asthma-related medications in a pediatric population of more than 4.2 million children enrolled in commercial insurance plans throughout the United States. These data are derived from outpatient visit claims and do not represent uninsured children. Rather than limiting our analysis to children continuously enrolled, we included all children and used a life table approach to account for varying lengths of enrollment. This produced an asthma prevalence estimate based on the probability of a claim with a diagnosis of asthma within a 12-month period (asthma outpatient claim prevalence). Our asthma outpatient claim prevalence was 6.2%, compared with a 5.2% asthma attack prevalence (percentage of children with at least 1 attack during the past 12 months) and 8.9% current asthma prevalence (percentage of children with asthma at time of interview) from the National Health Interview Survey.² The prevalence of asthma outpatient claims decreased with age. Higher prevalence was observed in males than females, but this sex difference diminished with age, and prevalence estimates were higher in the Northeast region. All of these findings are consistent with reports from national surveys^{2,15} and suggest that the asthma experience of our study population is comparable to the US pediatric population.

Among potential asthma episode controller medications, only 59% of children with asthma were dispensed any anti-inflammatory medication (which includes oral corticosteroids that could be used for prevention, for an acute exacerbation, or for other indications) within 90 days after a medical claim that contained an asthma diagnosis. Although an evaluation of a potential disparity between asthma guidelines and actual treatment patterns is beyond the scope of this analysis, these data are consistent with reports that suggest the use of controller medications may be suboptimal.^{16–18} Previous reports indicate that the cause of underuse of controller medications is less likely underprescribing¹⁹ and more likely parental misunderstanding of asthma therapies.^{20,21} Among children with asthma in our study the percentage who received a dispensed medication for a controller medication decreased with age. A decrease with age, however, was not as pro-

nounced for the short-acting, inhalation rescue medications. These findings may reflect a greater adherence problem among teenagers with asthma who should be using controller medications. Given the established effectiveness of controller medications in reducing emergency department visits and hospitalizations,^{22–24} special efforts in health education may be needed to address adherence issues with teens.

The analyses of data from administrative claims databases are subject to several limitations. We did not have additional clinical information, such as pulmonary function tests, that would be useful to characterize severity of a child's asthma and determine which therapeutic options were appropriate. Also, it was not possible to use a standardized set of criteria for defining and diagnosing asthma by physicians across the nation. The diagnosis of asthma among children younger than 5 years (and especially infants) is particularly problematic. Our definition was based solely on a submitted medical claim that contains an *ICD-9-CM* code of 493 for asthma. Medication use was based on claims submitted for a dispensed medication. Information is not available for medications that may have been obtained without submitting an insurance claim (eg, medications purchased out-of-pocket, drug samples provided). Our study group included only children enrolled in commercial health insurance plans, which accounts for approximately 65% of US children.²⁵ Approximately 25% of children are covered by government plans (eg, Medicaid). However, our estimates of the percentage of children with an asthma diagnosis and the percentage of children with a dispensed asthma-related medication are similar to those found in Medicaid populations.²⁶ Unlike Medicaid data sets, we did not have race/ethnicity information, which has been reported to be associated with asthma and health care use.^{2,27,28}

Our analytic approach for estimating medication dispensing in children with asthma differed from that commonly used with medical and pharmacy claims data.^{26,29,30} Analyses that include definitions for persistent asthma or patterns of drug use (eg, sustained use, order of drug use) require longitudinal data on each child. Therefore, a minimum enrollment period is used as an eligibility criterion for the study, such as requiring a child to be continuously enrolled for a 1- or 2-year period. An enrollment duration requirement will often exclude a large portion of children covered by the insurance plan. We used a more inclusive method to make maximum use of our available data and to minimize potential bias that might arise from excluding children who were not continuously enrolled for a long period.

From a total drug burden perspective, asthma-related medications may be used by children without a diagnosis of asthma. Although the relative percentage is smaller than among children with an asthma diagnosis, the absolute number of children is larger. In our analysis, these children may have asthma but have not submitted a claim for it during the study period or they may have other respiratory-related or other (nonrespiratory) conditions that require these medications. If our estimate that 15% of children are dispensed an

asthma-related medication is applied to the total US pediatric population, then more than 11 million children may be taking asthma-related medications each year.

Four decades ago it was recognized that pediatric therapeutics needed substantial attention to reach the level of evidence required of drugs used in adults.³¹ In 2002 Congress enacted the BPCA to begin work to address this need (and to supplement efforts initiated through section 111 of the Food and Drug Administration Modernization Act and the Food and Drug Administration Pediatric Rule). The legislation specifically directs the NIH to evaluate drugs approved for marketing within the United States to identify those needing further study in children. At a recent NIH meeting to discuss prioritization of drugs for pediatric studies (Annual BPCA Prioritization Meeting, December 5–6, 2006, Bethesda, Maryland), experts in pediatric asthma noted that asthma affects children differently than adults and that data on pharmacokinetics and safety of antiasthmatic drugs are limited. They also noted that in contrast to adults the determination of efficacy in children was difficult, requiring new tools and approaches.³² The management of asthma moves into the hospital as its severity increases. Unfortunately, limited data on pediatric dosing, safety, and efficacy of antiasthmatic drugs produce substantial variation in treatment of these critically ill children.

Given the public health impact of asthma and the lack of information on the relative use of medications, we have analyzed data sets that describe pediatric conditions and medications used for treatment. These data, along with reviews of information describing pediatric dosing, safety, and efficacy, will be used by a National Institute of Child Health and Human Development Asthma Working Group to set priorities for the class of drugs or individual drugs that need further study to improve the therapeutic management of children with asthma.

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