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PRESCRIBING PATTERNS AND CLINICAL OUTCOMES IN ASTHMATIC CHILDREN: A HISTORICAL COHORT STUDY

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PRESCRIBING PATTERNS AND CLINICAL OUTCOMES IN ASTHMATIC CHILDREN: A HISTORICAL COHORT STUDY

BY

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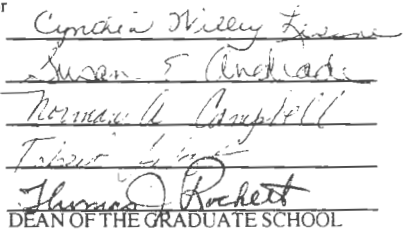

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ABSTRACT

NIH guidelines recommend treatment of moderate or severe childhood asthma with preventive anti-inflammatory medication (inhaled corticosteroids, cromolyn or nedocromil). The guidelines also emphasize providing patient education.

The study objectives were a) to determine if the NIH guidelines for the treatment of childhood asthma were implemented by prescribing preventive medication, b) to determine if the NIH guidelines for the treatment of childhood asthma were implemented by providing patient education and c) to measure the influence of primary care physicians prescribing in accordance with the NIH guidelines on adverse clinical outcomes. Adverse clinical outcomes were measured by severe asthma exacerbations resulting in : hospital admissions, emergency department visits or a course of oral steroids from the primary care physicians.

The data were collected from primary-care physicians in nine managed care plans in the northeastern USA. 311 children enrolled in Medicaid (aged 2-19 years) were identified as having a diagnosis and treatment for asthma during the period January through December 1994. Detailed clinical and pharmacy data were extracted from medical records by nurse reviewers for the period January 1993 through March 1995.

The NIH guidelines for the use of preventive anti-inflammatory medication were implemented on at least one occasion for 61.1% of the children with moderate or severe asthma in this Medicaid population during 1994. Patient education was provided to 41.8% of the children. Cox regression analyses showed prescribing preventive medication for moderate to severe asthmatics in accordance with the NIH guidelines was associated with a reduced risk of receiving a course of oral steroids.

The findings of the present study suggest that many children with moderate or severe asthma were not prescribed preventive medication or provided education by primary care providers as recommended in the NIH guidelines. Inadequate implementation of the NIH guidelines for prescribing preventive medications was associated with adverse clinical outcomes.

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PREFACE

This dissertation is organized using the manuscript format. Part 1 consists of the three manuscripts that form the main body of the dissertation. Part 2 contains the appendices which provide the details required by the University but are not usually presented in a published paper.

Part 1 includes the following manuscripts:

Study 1: Medications prescribed to asthmatic children :
a historical cohort study of the implementation of NIH recommendations

Study 2 : Patient education provided to asthmatic children :
a historical cohort study of the implementation of NIH recommendations

Study 3 : Divergence from NIH guidelines for pharmacologic therapy and risk of adverse outcomes in asthmatic children : a historical cohort study

Part 2 includes the following appendices:

Appendix A. Introduction and review of the problem

Appendix B. Details of the methods

Appendix C. Overview of major findings

TABLE OF CONTENTS

TABLE OF CONTENTS continued

TABLE OF CONTENTS continued

LIST OF TABLES

PART 1

Study 1: Medications prescribed to asthmatic children :
a historical cohort study of the implementation of NIH recommendations

Study 2: Patient education provided to asthmatic children :
a historical cohort study of the implementation of NIH recommendations

LIST OF TABLES continued

LIST OF TABLES continued

LIST OF FIGURES

Study 3 : Divergence from NIH guidelines for pharmacologic therapy and risk of adverse outcomes in asthmatic children : a historical cohort study

PART I

Part 1 includes the following manuscripts:

Study 1: Medications prescribed to asthmatic children :
a historical cohort study of the implementation of NIH recommendations

Study 2 : Patient education provided to asthmatic children :
a historical cohort study of the implementation of NIH recommendations

Study 3 : Divergence from NIH guidelines for pharmacologic therapy and risk of adverse outcomes in asthmatic children : a historical cohort study

Medications prescribed to asthmatic children : a historical cohort study of the implementation of NIH recommendations

ABSTRACT

Background: NIH guidelines recommend treatment of moderate or severe childhood asthma with preventive anti-inflammatory medication (inhaled corticosteroids, cromolyn or nedocromil).

Objective: To determine if the NIH guidelines for the treatment of childhood asthma were implemented by examining the prevalence of prescribing preventive medication. We also examined clinical and demographic predictors of receiving preventive medication.

Design: Non-concurrent cohort study.

Setting: 9 managed care plans in the northeastern USA.

Subjects: 311 children (aged 2 to 19 years) who were treated for asthma between January and December 1994.

Main outcome: Prescribing preventive medication.

Results: Preventive medications were prescribed at least once to 61.1% and more than once to 27.0% of the children with moderate or severe asthma during 1994. Preventive medication was prescribed at least once to 27.1% of the children with mild asthma during 1994.

Logistic regression analyses indicated that preventive medication was more likely to be prescribed for those with moderate or severe compared with mild asthma (aOR 5.34, 95% CI 3.22-8.83) and for older children, (age 5 to 19 years compared with 2 to 4 years, aOR 2.11, 95% CI 1.19-3.72). Prescribing preventive medication was also associated with a prior emergency department visit (aOR 2.27, 95% CI 1.24-4.16), after adjusting for age.

Conclusions: The NIH recommendations were implemented by prescribing preventive medication for 66.7% of the moderate or severe asthmatics over 4 years old during 1994. This study suggests there may be a need for interventions to increase the implementation of the NIH guidelines by primary care physicians and improve the treatment of childhood asthma.

INTRODUCTION

In 1991 an Expert Panel prepared NIH guidelines for the diagnosis and management of asthma.[1] The Expert Panel updated the recommendations in 1997 and continued to emphasize the role of inflammation in the pathogenesis of asthma.[2] The panel outlined an approach to asthma therapy that has four components : patient education, environmental control, comprehensive pharmacologic therapy and objective monitoring measures to monitor the severity of disease and course of therapy.

Daily long term preventive anti-inflammatory medications (such as inhaled corticosteroids, cromolyn sodium or nedocromil) are recommended for persistent asthma.[2] Children consistently requiring symptomatic treatment more than twice a week (classified as moderate or severe asthmatics) should be given daily anti-inflammatory therapy. In addition, appropriate medications to manage acute asthma exacerbations (beta-agonists and oral corticosteroids) should also be prescribed.

This study determines the extent to which the NIH guidelines for the treatment of childhood asthma were implemented by examining the prevalence of prescribing preventive medication by primary care physicians. In addition, this study identifies the demographic characteristics, clinical characteristics or events that are predictors of prescription of preventive medication to children. Evidence that guidelines influence patient care is needed because the effectiveness of guidelines in changing practice behaviors and improving health outcomes is widely questioned.[3 4 5]

METHODS

Data source and study population

The data analyzed were from a sample of 311 children (aged 2 to 19 years) treated for asthma during 1994 in a Medicaid program in the northeastern USA.

Pharmacy and clinical data were requested from nine managed care plans. Each plan was requested to identify all Medicaid members who were diagnosed and treated for asthma during 1994 (International Classification of Diseases, Ninth Revision, Clinical modification code ICD-9=493) and select a random sample of 50 children (aged 2 to 19 years in 1994) to study. The plans provided 388 medical records and 347 were eligible after verifying the patient's age on 1st January 1994 was between 2 to 19 years old (41 were less than 2 years old). 311 were eligible after confirming there was a visit with documentation of a prescription for an asthma medication during 1994 (36 out of 347 did not have documentation of a visit during 1994).

The data abstracted on asthma treatment provided by plan physicians between 1st January 1993 and 31st March 1995 were abstracted from the medical records. Medication data abstracted included all the asthma medications prescribed (product name, route, directions, days supply), date prescribed and prescriber (primary care physician or other). The clinical data included the date of each physician visit, an assessment of the asthma severity at each visit, date of birth, gender, date of initial asthma diagnosis, date of latest theophylline level, date of latest influenza vaccination, and types of patient education provided at each visit (ability to use peak flow meter, ability to use inhaler, how to use inhaler, side effects of medication, avoidance of triggers, action plan for exacerbations, use of diaries, and goals of treatment). For each visit there was also a record of height, weight, blood pressure, a physical examination, medical history (symptoms and functional status), objective

measures of lung function (peak expiratory flow rates, home use of a peak flow meter, spirometry results) and referrals to specialists (dates, type of specialist, reason).

The clinical outcomes extracted from the medical records included asthma-related hospital admissions or emergency department visits (admission dates, discharge dates and reason for visit or admission). A physician visit resulting in the prescription of a course of oral steroids was also considered as an outcome.

Procedures

A data collection instrument and abstracting instructions were provided to nurses who reviewed the members' medical records, and hospital or emergency department encounter files. For each physician visit the nurse reviewer recorded the pharmacy and clinical data requested, such as asthma severity, patient education and asthma medications prescribed. The nurse used the information in the medical records and the NIH guidelines to classify the asthma severity at each visit as mild, moderate or severe asthma.

Statistical analyses

Descriptive statistics were used to document the age, gender, asthma severity, medications prescribed, and clinical outcomes for the 311 children treated for asthma during 1994.

On each date when asthma medications were prescribed these were coded as beta-agonists (oral or inhaled), preventive anti-inflammatory medications (inhaled corticosteroids, inhaled cromolyn or nedocromil), oral theophylline or oral corticosteroids. The children were coded as receiving undertreatment at a visit where the disease severity was recorded to be moderate or severe and no preventive medications were prescribed. The maximum asthma severity recorded in 1994 was used to code the children as mild, moderate or severe asthmatics.

Preventive medication and undertreatment ever being prescribed during the study were used as dichotomous dependent variables in bivariate analyses (Mantel-Hanszel chi square tests) and in multivariate logistic regression. Independent variables in these models included age, gender, asthma severity, prescribing a course of oral steroids at the same visit or a prior visit, prior admission to hospital or a prior emergency department visit. Multivariate adjusted odds ratio, 95% Wald confidence interval (CI), Wald chi-square statistic and the p-value for a two sided significance test were calculated for each independent variable.

Age was coded as a dichotomous variable (2 to 4 years and 5 to 19 years) after establishing that the associations were not linear for each dependent variable. Asthma severity was coded categorically as mild (1), moderate (2), or severe (3). In addition, for the multivariate model for prediction of prescribing preventive medication, asthma severity was coded as a dichotomous variable mild (0) and moderate or severe asthma (1).

RESULTS

Descriptive and bivariate analyses

Frequency distributions of demographic characteristics, asthma severity, medications prescribed, emergency department visits and hospitalizations are summarized in Tables 1-2. Moderate or severe asthma was experienced by 49.4% (126) of the children. 20.9% (65) were prescribed oral steroids, 18.7% (58) made an emergency department visit and 6.8% (21) were admitted to a hospital. During 1994, amongst the children with moderate or severe asthma, 27.0% (21) experienced severe asthma exacerbations, 44.4% (56) were prescribed oral steroids, 28% (35) made an emergency department visit and 11.9% (15) were admitted to a hospital.

During 1994, the overall percentages of children prescribed asthma medications on at least one occasion were as follows : theophylline 4.8% (15), an inhaled steroid 17.7% (55), cromolyn or nedocromil 27.3% (83) and a beta-agonist 86.5% (269).

Preventive medication (cromolyn, nedocromil or inhaled steroid) was prescribed on at least one occasion to 61.1% (77) and more than once to 27.0% (34) of the children with moderate or severe asthma. Preventive medication was prescribed on at least one occasion during 1994 to 27.1% (35) of the children with mild, 60.9% (56) with moderate and 61.8% (21) with severe asthma (Table 1). The results from the bivariate analyses showed that children were more likely to be prescribed preventive medication if they were aged 5 to 19 years, male, or experienced moderate or severe asthma exacerbations. The results of this study indicated that the NIH guidelines for the use of preventive medications were implemented on at least one occasion for 66.7% of the children aged 5 to 19 years old with moderate or severe asthma during 1994.

A course of oral steroids at the same or prior visit or a prior emergency department visit were significantly associated with a subsequent prescription of preventive medication, but a prior hospital admission was not significantly associated with preventive medications subsequently being prescribed.

65.9% (83) of the children with moderate or severe asthma were undertreated on at least one visit when other asthma medications were prescribed (Table 2). 38.9% (49) of the children with moderate or severe asthma were undertreated on 50% or more visits when other asthma medications were prescribed. A course of oral steroids was associated with an increased risk of undertreatment either at the same visit or subsequent visits. A prior emergency department visit was significantly associated with a reduced risk of undertreatment at subsequent visits, but a prior hospital admission was not significantly associated with undertreatment at subsequent visits.

Multivariate analyses

Multivariate odds ratios are presented in Table 3 for the independent associations between asthma severity, an oral steroid course and a prior emergency department visit and prescribing preventive medication, after adjusting for age. The children were significantly more likely to be prescribed preventive medication if they had moderate or severe compared to mild asthma exacerbations (aOR 5.34, 95% CI 3.22-8.83) and were age 5 to 19 years compared to 2 to 4 years old (aOR 2.11, 95% CI 1.19-3.72).

The independent associations between prescribing a course of oral steroids or a prior emergency department visit and subsequently prescribing preventive medications were also evaluated (without adjusting for asthma severity due to multicollinearity) (Table 3). A course of oral steroids being prescribed at the same or prior visit (aOR 2.79, 95% CI 1.57-4.93) or a prior emergency department visit (aOR 2.27, 95% CI 1.24-4.16) was associated

with prescribing preventive medication, after adjusting for age (Table 3). Gender was not significantly associated with preventive medication once age and asthma severity were included in the model.

Multivariate odds ratios for the association between undertreatment of children with moderate or severe asthma and age, asthma severity, an oral steroid course, a prior emergency department visit or a prior hospital admission are presented in Table 4. Moderate compared to severe asthma was not a significant predictor of undertreatment (Table 4). A prior emergency department visit significantly reduced the risk of subsequent undertreatment by the primary care physician (aOR 0.24, 95% CI 0.10-0.60) but a course of oral steroids was associated with an increased risk (aOR 2.23, 95%CI 1.01-4.89) of undertreatment at the same visit or subsequent visits, after adjusting for age. Age 5 to 19 years compared to 2 to 4 years was associated with less risk of undertreatment on 50% or more of the visits (aOR 0.44, 95% CI 0.19-1.02) , after adjusting for prior hospitalization, a prior emergency department visit and an oral steroid course.

DISCUSSION

Asthma is the most common chronic illness in children and has been studied frequently as an indicator of the adequacy and appropriateness of ambulatory care.[1-8] The impact of asthma on the health of children experiencing moderate or severe asthma in this study was reflected in the number admitted to a hospital (11.9%) or attending the emergency department (27.8%) during 1994.

The results of this study suggest that the NIH guidelines for the use of preventive medications were implemented on at least one occasion for 66.7% of the children aged 5 to 19 years old with moderate or severe asthma during 1994, in this Medicaid population. However, amongst children with moderate or severe asthma only 27.0% had more than one prescription for preventive medication documented in the medical records during 1994. Amongst the children with moderate or severe asthma, 38.9% were undertreated on 50% or more physician visits when other asthma medications were prescribed, and 65.9% were undertreated on at least one occasion. Thus, although the majority of patients with moderate or severe asthma were prescribed preventive medication at least once during 1994, regular prescribing of preventive medication was not evident. The pattern of prescribing in this study is not consistent with full implementation of the NIH guidelines, which support regularly prescribing preventive anti-inflammatory medication to children with moderate or severe asthma.

The NIH guidelines recommend anti-inflammatory medications but indicate that theophylline can be prescribed for childhood asthma. Theophylline has a narrow therapeutic index. For a child over 5 years old who needs maintenance medication, an inhaled steroid or cromolyn is considered the simplest and safest regimen.[9] Slow-release theophylline does offer an alternative to inhaled corticosteroids when a patient complies poorly with a maintenance regimen of inhaled steroids or cromolyn and is judged more

likely to adhere to an oral regimen. In this study the prevalence of prescribing theophylline was very low (4.8%), and cannot therefore account for the apparent undertreatment of moderate or severe asthmatics with anti-inflammatory products.

The low overall prevalence of prescribing of preventive medications (cromolyn 27.3% and inhaled steroids 17.7%) and theophylline (4.8%) are comparable with those recorded in other studies of children in different health care settings.[10 11] Friday et al [9] studied children treated for asthma in the emergency department and calculated the percentages of children prescribed asthma medications before the visit were : cromolyn (35%), inhaled steroids (22%) and theophylline (6%). Donahue et al [10] analyzed the percentage of prescriptions for privately insured children and found a similar trend : 16% for cromolyn, 11% inhaled steroids and 6% theophylline.

The results from three recent studies of children with moderate or severe asthma have also suggested that the NIH guidelines recommending the use of preventive medication have not been fully implemented. Eggleston at al [12] collected questionnaires completed by the families of 166 asthmatic children requiring an emergency room visit in the past six months, and found less than 50% were receiving preventive medication. Lieu et al [13] studied 508 children hospitalized or attending the emergency department as a result of severe asthma and 990 asthmatic controls. The study reviewed the medications prescribed to the children attending a physician within 30 days before either the hospital admission or emergency department visit and reported up to 49% were prescribed cromolyn or inhaled steroids. Homer et al [6] found that at most 33% of the children hospitalized for asthma had received cromolyn or inhaled steroids before admission.

Low rates of repeat prescriptions for preventive medications were also obtained in other studies, including both adults and children. A study of moderate or severe asthmatics [14]

(adults and children over 7 years old), showed 63% were dispensed preventive medications (but only 32% were receiving preventive medications regularly). Another study[15] also suggested less than 54% of the patients (adults and children over 12 years) prescribed anti-inflammatory medications were refilling the medications regularly. A study of British children indicated[16] very few (less than 15%) were dispensed preventive medications regularly.

Inadequate attendance for primary care physician follow up visits were shown by a study in asthmatic children in the Medicaid program in Massachusetts [17] and similarly less continuous treatment[18] has been noted for asthmatic adults from lower socioeconomic groups. Focus groups of urban minority asthmatic children in New York[19] showed many parents and children had very modest expectations of symptom control. Asthma was viewed by the families as "episodic" increasing their emphasis on symptomatic treatment rather than seeing the need for preventive visits. In our study, lack of continuity of care cannot completely explain the results because 38.9% of the children with moderate or severe asthma attended the primary care physician more than once and were not prescribed preventive medications.

We examined five factors associated with prescribing preventive medication, including age, asthma severity, a prior emergency department visit or hospital admission or prescribing a course of oral steroids at the same or prior physician visit. The multivariate and bivariate analyses suggested that physicians were more likely to prescribe preventive medication for children aged 5 to 19 years old than younger children with moderate or severe asthma. These results were consistent with implementation of the NIH guidelines. Children younger than 5 years of age are recommended to be given courses of oral steroids for chronic severe asthma because they may be unable to use inhalers effectively.[1] Children

with moderate asthma were at a similar risk to children with severe asthma for undertreatment, after adjusting for age.

The physicians prescribed preventive medications to the children experiencing acute asthma exacerbations as indicated by an increased association between an emergency department visit or a course of oral steroids and subsequent prescribing of preventive medication, after adjusting for age. Amongst the children with moderate or severe asthma, there was also a reduced risk of subsequent undertreatment among those with an emergency department visit, after adjusting for age. However, in contrast, a course of oral steroids, after adjusting for age, was associated with undertreatment either at the same or subsequent physician visits. Thus, the prescribing was not consistent with implementing the NIH guidelines for children attending with moderate or severe asthma; even after taking into account the difficulty of treating children under 5 years old with inhaled medications.

The study design did not include a sample size large enough to allow comparisons between the different managed care plans or profile the prescribing practices of individual prescribers. Asthma specialists have been shown to be more likely to prescribe preventive medications than primary care physicians[20 21] and access to or co-ordination of care by specialists[22 23] may have facilitated implementation of the NIH guidelines by some plans.

It was not possible to compare the results from this Medicaid group with other patients attending these plans. Access to Medicaid for children is generally related to low family income, therefore this study selected children with a low socioeconomic status. The information collected from this Medicaid asthmatic population may not be generalizable to other children. There could be differences in prescribing practices or attendance at the physician office for preventive care visits by Medicaid patients.

In the present study medications were free for the patients; thus there was no cost incentive for patients to avoid having prescriptions dispensed for preventive medications. The managed care plans guarantee access for these Medicaid patients but there are many differences between poor minority families and health care providers that may influence prescribing practices for example language, cultural barriers, or literacy levels.[19]

Hospitalization was not found to be associated with subsequent prescribing of preventive medications. However, the frequency of hospitalization showed a seasonal variation. This variation, in combination with the small sample size and the variability of asthma severity, may have limited the ability of this study to detect an association.

An unusual aspect of this study was the collection of clinical data from primary care physician medical records. The asthma diagnoses were confirmed from the medical records and therefore the study did not have to rely solely on the ICD 9 coding for the diagnosis. Using the medical records also allowed the classification of children as mild, moderate or severe asthmatics at each physician visit when an asthma medication was prescribed. The maximum severity recorded during 1994 was used to code the children as mild, moderate or severe asthmatics for the entire study period. The analyses were then able to address confounding by asthma severity. Most previous studies focused on severe asthmatics or did not use the NIH guidelines to assign a clinical assessment of asthma severity. A limitation of this study was that the information about medications prescribed was also collected from the medical records rather than a separate medication claims database; consequently, not all the prescriptions may have been dispensed or refills may not have been documented.

There are many challenges to moving patients away from episodic attendance at the primary care physician's office or emergency department for crisis orientated care and provision of

fragmented care for asthma exacerbations.[24,25] The lack of regular prescribing of preventive medications for some children in our study may show a need for more patient education, provider training, and alternative disease management approaches to introduce asthma prevention strategies.[26,27,28]

Studies of the impact of the NIH guidelines on the emergency department management of childhood asthma have suggested that implementation of the guidelines may be limited.[29,30] Lantner et al [29] surveyed physicians at academic medical centers with a pediatric residency program and found that at most half of those surveyed believed their emergency management of asthma was influenced by the NIH guidelines. Crain et al [30] surveyed physicians based at a sample of children's emergency departments and found that 45.5% had heard of the guidelines and 24% had read them. Crain et al also reported under-use of steroids in the emergency departments and a wide variation in practices.

Preventive medication was prescribed for 66.7% of the moderate or severe asthmatics over 4 years old, which indicates there could be a substantial improvement in the management of childhood asthma by primary care physicians. Our study suggests that for some children prescribing of preventive anti-inflammatory medications was subsequent to an emergency department visit and that the NIH recommendations were not always routinely implemented by primary care providers for children with moderate or severe asthma. This study supports the need for interventions to increase implementation of the NIH guidelines by primary care physicians and improve the treatment of childhood asthma.

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Table 1 Descriptive statistics and bivariate relationships between demographic characteristics, asthma severity or prior clinical events and prescribing of preventive medication, (n=311)

Characteristics		Total		Preventive medication prescribed		
		n	%	n	%	p
Total		311		121	38.9	
Age (years)	2-4	92	29.6	27	29.4	.03
	5-19	219	70.4	94	42.9	
Gender	Female	146	47.3	47	32.2	.03
	Male	163	52.8	72	44.2	
Asthma severity						
	Mild	129	50.6	35	27.1	.00
	Moderate	92	36.1	56	60.9	
	Severe	34	13.3	21	61.8	
Oral steroid course	0	246	79.1	84	34.2	.00
	>=1	65	20.9	37	56.9	
Emergency visit	0	253	81.4	88	34.8	.03
	>=1	58	18.7	29	50.0	
Hospital admission	0	290	93.3	111	38.3	.65
	>=1	21	6.8	7	33.3	

Table 2 Descriptive statistics and bivariate relationships between demographic characteristics, asthma severity or prior clinical events and prescribing of preventive medication or undertreatment for children with moderate or severe asthma, (n=126)

Characteristics		Total		Preventive medication prescribed			Undertreatment			Undertreatment 50% of visits		
		n	%	n	%	p	n	%	p	n	%	p
Total		126		77	61.1		83	65.9		49	38.9	
Age (years)	2-4	39	31.0	19	48.7	.06	28	71.8	.35	18	46.2	.27
	5-19	87	69.1	58	66.7		55	63.2		31	35.6	
Gender	Female	54	43.2	29	53.7	.16	40	74.1	.08	22	40.7	.76
	Male	71	56.8	47	66.2		42	59.2		27	38.0	
Severity	Moderate	92	73.0	56	60.9	.93	60	65.2	.80	35	38.0	.75
	Severe	34	27.0	21	61.8		23	67.7		14	41.2	
Oral steroid	0	70	55.6	43	61.4	.94	40	57.1	.02	25	35.7	.31
course	>=1	56	44.4	34	60.7		43	76.8		25	44.6	
Emergency visit	0	91	72.2	50	55.0	.28	61	67.0	.00	40	44.0	.06
	>=1	35	27.8	23	65.7		13	37.1		9	25.7	
Hospital	0	111	88.1	68	61.3	.12	70	63.1	.09	41	36.9	.79
admission	>=1	15	11.9	6	40.0		6	40.0		5	33.3	

Table 3 Multivariate adjusted Odds Ratios and 95% confidence intervals (CI) for predictors of receiving a prescription for preventive medication, (n=311)

Characteristics	Preventive medication prescribed		
	aOR	p	CI
Model 1:			
Moderate or severe compared to mild asthma	5.34	.00	3.22-8.83
Age >=5 years	2.11	.01	1.19-3.72
Model 2:			
Prior oral steroid courses compared with none	2.79	.00	1.57-4.93
Age >=5 years	2.02	.01	1.18-3.47
Model 3:			
Prior emergency department visits compared with none	2.27	.01	1.24-4.16
Age >=5 years	2.13	.01	1.22-3.70

Table 4 Multivariate adjusted Odds Ratios and 95% confidence intervals (CI) for predictors of undertreatment of children with moderate or severe asthma, (n=126)

Characteristics	Undertreatment			Undertreatment >=50% of visits		
	aOR	p	CI	aOR	p	CI
Model 1:						
Prior emergency visits compared with none	0.24	.00	0.10-0.60	0.30	.02	0.11-0.79
Prior hospital admissions compared with none	0.52	.29	0.15-1.75	0.79	.72	0.22-2.80
Prior oral steroid courses compared with none	2.23	.05	1.01-4.89	2.00	.08	0.91-4.38
Age >=5 years	0.74	.48	0.33-1.70	0.44	.05	0.19-1.02
Model 2:						
Severe compared to moderate asthma	1.14	.76	0.49-2.65	1.12	.79	0.50-2.50
Age >=5 years	0.67	.34	0.29-1.53	0.67	.31	0.31-1.45

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Patient education provided to asthmatic children : a historical cohort study of the implementation of NIH recommendations

ABSTRACT

Background: NIH guidelines for the treatment of childhood asthma emphasize the importance of educating the patient and their family about avoiding triggers and providing information to support self-management of asthma therapy.

Objective: To determine if the NIH guidelines for the treatment of childhood asthma were implemented by examining the prevalence of patient education provision by primary care physicians. We also examined clinical and demographic predictors of providing patient education.

Design: Non-concurrent cohort study.

Setting: 9 managed care plans in the northeastern USA.

Subjects: 311 children (aged 2 to 19 years) who were treated for asthma between January and December 1994.

Main outcomes: Patient education on the potential benefits from avoidance of environmental triggers. Provision of a written action plan for the treatment of acute exacerbations, explaining the goals of treatment and checking the ability to use an inhaler appropriately.

Results: Patient education was provided at least once to 41.8% of the children during 1994. Logistic regression analyses indicated that two predictors of providing information

about avoidance of triggers were severe compared to mild or moderate asthma (aOR 3.61, 95% CI 1.69-7.72) and being prescribed inhaled anti-inflammatory medications (aOR 2.38, 95% CI 1.37-4.12), after adjusting for age. Inhaled anti-inflammatory medications were prescribed for 61.1% of the children with moderate or severe asthma, and 27.1% of the children with mild asthma.

Conclusions: The NIH recommendations to provide patient education were not implemented for at least half of the children during 1994. In addition, less than half of the children prescribed preventive medications or a course of oral steroids were also provided information about avoidance of triggers. We conclude therefore that the limited implementation of the NIH recommendations by primary care physicians in our study has substantially reduced the impact of the NIH guidelines on the management of poorly controlled childhood asthma.

INTRODUCTION

In 1991 an Expert Panel prepared NIH guidelines for the diagnosis and management of asthma.[1] The Expert Panel updated the recommendations in 1997 and continued to emphasize the role of inflammation in the pathogenesis of asthma.[2] The expert panel outlined an approach to asthma therapy that has four components : patient education, environmental control, comprehensive pharmacologic therapy and objective monitoring measures to monitor the severity of disease and course of therapy.

The guidelines emphasize the importance of patient education in the management of asthma and the potential benefits from environmental control. The guidelines specifically recommend provision of action plans, information on avoidance of triggers, goals of treatment and ability to use an inhaler, use of diaries and side effects of medications.

A written action plan to guide patient self-management is especially important for patients with moderate or severe persistent asthma and patients with a history of severe exacerbations. Asthma severity is highly variable and may change over time so assessment is recommended at least biannually. Routine assessment allows the physician to check that treatment goals are being met and that the patient is on appropriate pharmacotherapy with up to date self management and action plans. The ability to use the inhalers correctly should also be checked to ensure maximum benefit from the medication prescribed, especially if asthma control is not achieved.

Exposure of an asthmatic patient to inhalant allergens to which the patient is sensitive increases airway inflammation and symptoms. Substantially reducing such exposure will result in significantly reduced inflammation, symptoms and need for medication. The NIH guidelines recommend that patients with asthma at all levels of severity receive education about the importance of minimizing exposure to inhalant triggers. The counseling should

include how to control and avoid exposure to known allergens, cigarette smoke and to make reasonable attempts to reduce exposure to respiratory viruses.

This study determines the extent to which the NIH recommendations have been implemented by the primary care physicians for children with asthma in a randomly selected population of Medicaid patients enrolled in managed care plans. The study summarizes provision of patient education and information about environmental control. In addition, the study identifies demographic characteristics, clinical characteristics or events that are predictors of primary care physicians providing patient education to children.

METHODS

Data source and study population

The data analyzed were from a sample of 311 children (aged 2 to 19 years) treated for asthma during 1994 in a Medicaid program in the northeastern USA.

Pharmacy and clinical data were requested from nine managed care plans. Each plan was requested to identify all Medicaid members who were diagnosed and treated for asthma during 1994 (International Classification of Diseases, Ninth Revision, Clinical modification code ICD-9=493) and select a random sample of 50 children (aged 2 to 19 years in 1994) to study. The plans provided 388 medical records and 347 were eligible after verifying the patient's age on 1st January 1994 was between 2 to 19 years old (41 were less than 2 years old). 311 were eligible after confirming there was a visit with documentation of a prescription for an asthma medication during 1994 (36 out of 347 did not have documentation of a visit during 1994).

The data abstracted on asthma treatment provided by plan physicians between 1st January 1993 and 31st March 1995 were abstracted from the medical records. Medication data abstracted included all the asthma medications prescribed (product name, route, directions, days supply), date prescribed and prescriber (primary care physician or other). The clinical data included the date of each physician visit, an assessment of the asthma severity at each visit, date of birth, gender, date of initial asthma diagnosis, date of latest theophylline level, date of latest influenza vaccination, and types of patient education provided at each visit (ability to use peak flow meter, ability to use inhaler, how to use inhaler, side effects of medication, avoidance of triggers, action plan for exacerbations, use of diaries, and goals of treatment). For each visit there was also a record of height, weight, blood pressure, a physical examination, medical history (symptoms and functional status), objective

measures of lung function (peak expiratory flow rates, home use of a peak flow meter, spirometry results) and referrals to specialists (dates, type of specialist, reason).

Clinical outcomes extracted from the medical records included asthma-related hospital admissions or emergency department visits (admission dates, discharge dates and reason for visit or admission). A physician visit resulting in the prescription of a course of oral steroids was also considered an outcome.

Procedures

A data collection instrument and abstracting instructions were provided to nurses who reviewed the members' medical records, and hospital or emergency department encounter files. For each physician visit the nurse reviewer recorded the pharmacy and clinical data requested, such as asthma severity, type of patient education provided and asthma medications prescribed. The nurse used the information in the medical records and the NIH guidelines to classify the asthma severity at each visit as mild, moderate or severe asthma. If patient education was provided this was classified by the nurse reviewer in accordance with the recommendations in the NIH guidelines as providing an action plan for exacerbations, information on avoidance of triggers, goals of treatment and ability to use inhaler, medication side effects or use of diaries to record asthma exacerbations.

Statistical analyses

Descriptive statistics were used to document the age, gender, asthma severity, medications prescribed, clinical outcomes and the type of patient education provided for the 311 children treated for asthma during 1994.

On each date when patient education was provided the four types of information were coded as provision of an action plan, information on avoidance of triggers, goals of

treatment and ability to use the inhaler. On each date when asthma medications were prescribed these were coded as beta-agonists (oral or inhaled), preventive anti-inflammatory medications (inhaled corticosteroids, inhaled cromolyn or nedocromil), oral theophylline or oral corticosteroids.

Each type of education was used as dichotomous dependent variables in bivariate analyses (Mantel-Haenszel chi square tests) and in multivariate logistic regression models. Independent variables in these models included age, gender, asthma severity, prescribing preventive medication or a course of oral steroids at the same visit or a prior visit, prior admission to hospital or a prior emergency department visit. Multivariate adjusted odds ratio, 95% Wald confidence interval (CI), Wald chi-square statistic and the p-value for a two sided significance test were calculated for each independent variable. The Bonferroni correction was used to calculate the appropriate significance level for the p-values ($p=<0.0125$).

Age was coded as a dichotomous variable (2 to 4 years and 5 to 19 years) after establishing that the associations were not linear for each dependent variable. The maximum asthma severity recorded in 1994 was used to code the children as mild, moderate or severe asthmatics. For the multivariate analyses, the categories of asthma severity were collapsed, as appropriate, according to the associations found for each type of education.

RESULTS

Descriptive and bivariate analyses

The relationships between provision of patient education and demographic characteristics, asthma severity, medications prescribed, emergency department visits and hospitalizations are summarized in Tables 1-2. The Bonferroni correction was used to calculate the appropriate significance level for the p-values ($p=<0.0125$).

Patient education was documented for less than 50% of the children during 1994, regardless of the type of education. Specifically, action plans were provided on at least one occasion to 41.8% (130) of the children during 1994. Information on the importance of avoiding triggers was provided to 24.4% (76) of the children. Limited patient education was provided to support self-management of asthma by using the medications prescribed appropriately; 13.5% (42) of the children received information on the goals of the treatment and 15.8% (49) had their ability to use the inhaler checked.

Applying the criteria in NIH guidelines for asthma severity classified 50.6% (129) as mild asthmatics, 36.1% (92) experienced at least one moderate and 13.3% (34) at least one severe asthma exacerbation during 1994. Action plans were provided to 76.5% (26) of the children with severe asthma, 55.4% (51) with moderate asthma and 40.3% (52) with mild asthma. Information on avoidance of triggers was provided to 52.9% (18) of the children with severe asthma, 29.4% (27) with moderate asthma and 23.3% (30) with mild asthma. Bivariate analyses showed that children with moderate or severe asthma were more frequently provided an action plan for exacerbations, and information on avoidance of triggers or goals of treatment.

Fewer than 25% of the children with moderate or severe asthma were documented in the medical records as being provided either : information on the goals of treatment or having

the ability to use the inhaler correctly confirmed. Fewer than 10% of children with moderate or severe asthma were provided information about medication side effects or used diaries. However, children prescribed a course of oral steroids were significantly more likely to be provided two types of patient education at the same or subsequent visits : information on avoidance of triggers (p-value =0.003) or a review of the treatment goals (p-value=0.01).

Prescribing preventive medications was associated with providing three types of patient education. Preventive anti-inflammatory medication (inhaled corticosteroids, cromolyn or nedocromil) were prescribed by the primary care provider for 38.9% (121) of the children. The children prescribed preventive medication, were significantly more frequently provided three types of patient education : goals of treatment (p-value=0.001), action plan (p-value=0.001), and avoidance of triggers (p-value=0.001). Prescribing preventive medication was not significantly associated with confirmation of the ability to use an inhaler.

Adverse clinical events were not associated with subsequent provision of patient education by the primary care providers. Bivariate analyses did not show either emergency department visits or hospitalization to be significantly associated with subsequent provision of patient education.

Multivariate analyses

Multivariate odds ratios for the association between receiving four types of patient education and asthma severity, preventive medication, and age are presented as Model 1 (Table 3). Multivariate odds ratios for the independent associations between an oral steroid course (Model 2), or an emergency department visit (Model 3) and the four types of patient education provided are presented in Table 3. The associations between hospitalizations and

provision of patient education were not estimated using multivariate analyses because of the small number of children admitted to hospital. The Bonferroni correction was used to calculate the appropriate significance level for the p-values ($p=<0.0125$).

Multivariate analyses showed that asthma severity was significantly associated with the provision of three types of patient education: an action plan, information on avoidance of triggers and a review of treatment goals (after adjusting for age and prescribing preventive medication) (Table 3). The adjusted odds ratios for an action plan for exacerbations were as follows: moderate compared to mild asthma aOR 1.85 (95% CI 1.25-2.75), and severe compared to mild asthma aOR 3.43 (95% CI 2.32-5.09). The adjusted odds ratio for provision of information on avoidance of triggers to children with severe asthma compared to mild or moderate asthma was aOR 3.61 (95% CI 1.69-7.72). The adjusted odds ratio for a review of the treatment goals for moderate or severe compared to mild asthma was aOR 3.12 (95% CI 1.45-6.72).

Associations between prescribing preventive medications and providing patient education are presented in Table 3. Children prescribed preventive medication were significantly more likely to receive two types of patient education at subsequent visits (after adjusting for age and asthma severity) : avoidance of triggers (aOR 2.38, 95% CI 1.37-4.12), and a review of the treatment goals (aOR 3.14, 95% CI 1.46-6.75) but not ability to use an inhaler. Children prescribed a course of oral steroids were also significantly more likely to be provided two types of patient education at the same or subsequent visits (after adjusting for age) : avoidance of triggers (aOR 2.62, 95% CI 1.43-4.77) and a review of the treatment goals (aOR 2.63, 95% CI 1.29-5.36).

Emergency department visits were not associated with the subsequent provision of patient education by the primary care providers. A prior emergency department visit was not a significant predictors (after adjusting for age) for primary care providers subsequently providing an action plan (aOR 0.79, 95% CI 0.42-1.49), information about avoidance of triggers (aOR 0.84, 95% CI 0.39-1.80), a review of treatment goals (aOR 2.49, 95%CI 1.11-5.55), or confirming the ability to use an inhaler (aOR 1.21, 95% CI 0.54-2.74).

DISCUSSION

The NIH guidelines recommend that all asthmatic children receive education about asthma and avoidance of triggers. However, provision of patient education was not documented in the medical records for the majority of children in our study. Action plans for severe exacerbations were the most frequent form of patient education provided and were given to 41.8% of the children. Action plans were provided to the majority of children with moderate (55.4%) or severe asthma (76.5%). Multivariate analyses showed that asthma severity was significantly associated with provision of three types of patient education. However, fewer than 25% of the children with moderate or severe asthma were documented in the medical records as being provided either information on the goals of treatment or having the ability to use the inhaler correctly. Less than 10% of children with moderate or severe asthma were provided information about medication side effects or use of diaries.

Preventive medication was prescribed for 61.1% of the children with moderate or severe asthma and 27.1% of the children with mild asthma. Children who were prescribed preventive medication were more likely to be provided information about avoidance of triggers aOR 2.38 (95% CI 1.37-4.12), or education about treatment goals aOR 3.14 (95% CI 1.46-6.75), after adjusting for age and asthma severity. 39.9% of children with moderate or severe asthma were not prescribed preventive medication and were also less likely to receive information about the importance of avoiding triggers or education about asthma. There was no significant association between a prior emergency department visit or hospitalization and patient education being provided by the primary care providers.

This study indicates a need for more patient education, provider training, and new approaches to ensure widespread implementation of the NIH recommendations by primary care providers.[3,4,5] Other studies of the impact of the NIH guidelines on the emergency

department management of childhood asthma have also suggested that implementation of the guidelines may be limited.[6,7]

The study design did not include a sample size large enough to allow comparisons between the different managed care plans or profile the prescribing practices of individual prescribers. Asthma specialists prescribe preventive medications more frequently than primary care physicians[8,9] and access to or co-ordination of care by specialists[10,11] may have facilitated implementation of the NIH guidelines by some of the plans.

This population-based study of Medicaid eligible children is restricted to children from low income families. It was not possible to compare the results from this Medicaid group with other patients attending these plans. The present study suggests there is limited implementation of the NIH recommendations even for a group known to be at particularly high risk of asthma-related hospitalization [12] or mortality.[13,14]

The NIH guidelines advocate providing education to the patients and their family but there are some conflicting results about the effectiveness of providing very limited education to patients. One systematic review and meta-analysis of the published literature on adults concluded that limited asthma education (information only) for adults reduced emergency department visits and improved knowledge but did not reduce hospitalizations or physician visits.[15]

One limitation of our study was the use of medical records to evaluate patient education as the quality of the education routinely provided could not be assessed. The extent of the education provided may also have been underestimated; for example the ability to use an inhaler may be checked by pharmacists and not recorded in the medical records. In addition, education may be provided to the patient but not documented in the medical

records by the health care provider. This study may have underestimated the amount of patient education provided, which could have biased the estimates of the associations towards the null value.

The potential impact of providing appropriate patient education for children has been demonstrated.[16] A randomized control trial studied the impact over 12 months of an initial training program comprising five 1 hour sessions for the parents and children. This study found an increase in knowledge, compliance and reduced emergency room visits and days of hospitalization.

Poor knowledge about asthma will make self-management difficult and lack of parental knowledge has been associated with readmission to hospital [17 18 19] or emergency department visits.[20 21] For example, if the patients start or increase steroid medication at the onset of a cold or flu this has been shown to reduce the odds of an emergency department visit.[22] There is also evidence to suggest that co-operation between health care providers, parents and children is essential to achieve optimal management.[23]

Patient education was documented for less than half of the children during 1994, regardless of the type of education. The findings of the present study suggest that provision of patient education by primary care providers was associated with asthma severity. However, less than a quarter of the children with moderate or severe asthma were documented in the medical records as being provided information on the goals of treatment or having the ability to use the inhaler correctly confirmed. In addition, over half of the children prescribed inhaled anti-inflammatory medication were not provided information about avoidance of triggers. Poorly controlled asthma is estimated to account for approximately 30% of the direct medical costs of asthma[24] and also results in many social costs to the children and their family, for example by causing absenteesim from school.[25] Nearly two

thirds of the ambulatory care visits for asthma are to primary care providers rather than asthma specialists.[26] We conclude therefore that the limited implementation of the NIH recommendations by primary care physicians in our study has substantially reduced the impact of the NIH guidelines on the management of poorly controlled childhood asthma.

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Table 1 Descriptive statistics and bivariate relationships between demographic characteristics, asthma severity, prior clinical events or medication prescribed and providing action plans or advice on avoidance of triggers

Characteristics		Total		Action plan for exacerbations			Avoidance of triggers		
		n	%	n	%	p	n	%	p
Total		311		130	41.8		76	24.4	
Age (years)	2-4	92	29.6	31	33.7	.06	15	16.3	.03
	5-19	219	70.4	99	45.2		61	27.9	
Gender	Female	146	47.3	60	41.1	.74	32	21.9	.30
	Male	163	52.8	70	42.9		44	27.0	
Asthma severity									
	Mild	129	50.6	52	40.3	.00	30	23.3	.00
	Moderate	92	36.1	51	55.4		27	29.4	
	Severe	34	13.3	26	76.5		18	52.9	
Preventive medication	0	190	61.1	59	31.1	.00	32	16.8	.00
	>=1	121	38.9	71	58.7		44	36.4	
Oral steroid course	0	246	79.1	95	38.6	.03	51	20.7	.00
	>=1	65	20.9	35	53.9		25	38.5	
Emergency visit	0	253	81.4	97	38.3	.20	57	22.5	.38
	>=1	58	18.7	17	29.3		10	17.2	
Hospital admission	0	290	93.3	122	42.1	.10	70	24.1	.13
	>=1	21	6.8	5	23.8		2	9.5	

Bonferroni test for significance p-value=<0.0125

Table 2 Descriptive statistics and bivariate relationships between demographic characteristics, asthma severity, prior clinical events or medication prescribed and reviewing the treatment goals or ability to use an inhaler

Characteristics		Total		Goals of treatment			Ability to use inhaler		
		n	%	n	%	p	n	%	p
Total		311		42	13.5		49	15.8	
Age (years)	2-4	92	29.6	8	8.7	.11	16	17.4	.61
	5-19	219	70.4	34	15.5		33	15.1	
Gender	Female	146	47.3	16	11.0	.20	21	14.4	.50
	Male	163	52.8	26	16.0		28	17.2	
Asthma severity									
	Mild	129	50.6	11	8.5	.00	18	13.6	.12
	Moderate	92	36.1	22	23.9		23	25.0	
	Severe	34	13.3	8	23.5		7	20.6	
Preventive medication	0	190	61.1	12	6.3	.00	23	12.1	.03
	>=1	121	38.9	30	24.8		26	21.5	
Oral steroid course	0	246	79.1	27	11.0	.01	35	14.2	.15
	>=1	65	20.9	15	23.1		14	21.5	
Emergency visit	0	253	81.4	27	10.7	.08	33	13.0	.62
	>=1	58	18.7	11	19.0		9	15.5	
Hospital admission	0	290	93.3	36	12.4	.80	47	16.2	.16
	>=1	21	6.8	3	14.3		1	4.8	

Bonferroni test for significance p-value=<0.0125

Table 3 Multivariate adjusted Odds Ratios and 95% confidence intervals (CI) for the association between asthma severity, age, prescribing preventive medication and receiving patient education

Characteristics	Action plan			Avoidance of triggers			Treatment goals			Ability to use inhaler		
	aOR	p	CI	aOR	p	CI	aOR	p	CI	aOR	p	CI
Model 1:												
Preventive medication	1.88	.02	1.09-3.24	2.38	.00*	1.37-4.12	3.14	.00*	1.46-6.75	1.49	.25	0.76-2.93
Severity	1.85 [a]	.00*	1.25-2.75	3.61 [b]	.00*	1.69-7.72	3.12 [c]	.00*	1.45-6.72	2.35 [c]	.01*	1.20-4.61
Age >=5 years	1.77	.05	1.00-3.16	1.81	.08	0.94-3.48	1.78	.19	0.76-4.18	0.81	.54	0.41-1.59
Model 2:												
Oral steroid course	1.97	.02	1.13-3.45	2.62	.00*	1.43-4.77	2.63	.01*	1.29-5.36	1.64	.17	0.82-3.27
Age >=5 years	1.73	.04	1.03-2.89	2.20	.02	1.16-4.19	2.13	.07	0.93-4.88	0.88	.69	0.45-1.69
Model 3:												
Emergency visit	0.79	.47	0.42-1.49	0.84	.66	0.39-1.80	2.49	.03	1.11-5.55	1.21	.64	0.54-2.74
Age >=5 years	2.22	.01*	1.27-3.88	2.18	.03	1.09-4.33	2.99	.02	1.17-7.65	0.96	.91	0.47-1.97

Asthma severity code : [a] 0=Mild 1=Moderate 2= Severe [b] 0=Mild & moderate 1= Severe [c] 0=Mild 1=Moderate & severe

*Bonferroni test for significance p-value=<0.0125

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Divergence from NIH guidelines for pharmacologic therapy and risk of adverse outcomes in asthmatic children : a historical cohort study

ABSTRACT

Objective: To determine if the implementation of NIH guidelines for the treatment of moderate or severe childhood asthma with preventive anti-inflammatory medication (inhaled corticosteroids, cromolyn or nedocromil) reduced the risk of severe asthma exacerbations.

Design: Non-concurrent cohort study.

Setting: 9 Medicaid managed care plans in the northeastern USA.

Subjects: 311 children (aged 2-19 years) who were treated for asthma during the period January 1993 to December 1994.

Main outcomes: Admission to hospital, emergency department visit or a course of oral corticosteroids.

Results: Cox regression analyses were conducted with time dependent covariates for being prescribed preventive medications and adjusting for asthma severity (mild, moderate or severe), with a fixed covariate for age. Children diagnosed with moderate or severe asthma at least once who were prescribed preventive medication were less likely to require a course of oral steroids (Hazard Ratio 0.42 95% CI 0.19-0.95), after adjusting for age and asthma severity. No significant association was found between prescribing preventive medications and hospital admission or an emergency department visit.

Conclusions: Prescribing preventive medication to children with moderate or severe asthma reduced the risk of exacerbations requiring a course of oral steroids. This study suggests that primary care physicians prescribing anti-inflammatory medication in accordance with the NIH guidelines may improve the clinical outcomes for children with moderate or severe asthma.

INTRODUCTION

Asthma is the most common chronic childhood illness in the US [1] affecting 6.9% of children and is the fourth leading cause of disability in children.[2] In 1991 an Expert Panel prepared NIH guidelines for the diagnosis and management of asthma.[3] The Expert Panel recommendations were updated in 1997 and continued to emphasize the role of inflammation in the pathogenesis of asthma.[4] The panel outlined an approach to asthma therapy that has four components: patient education, environmental control, comprehensive pharmacologic therapy and objective monitoring of the asthma severity.

Daily long term preventive anti-inflammatory medications (such as inhaled corticosteroids, cromolyn sodium or nedocromil) are recommended by the NIH guidelines for persistent asthma . Children consistently requiring symptomatic treatment more than twice a week (classified as moderate or severe asthmatics) should be given daily anti-inflammatory therapy. In addition, appropriate medications to manage acute asthma exacerbations (beta-agonists and oral corticosteroids) should also be prescribed.

Primary care physicians have multiple opportunities to implement the NIH guidelines, to monitor asthma severity, and adjust the pharmacotherapy. This study determined whether the implementation of NIH guidelines for the treatment of moderate or severe childhood asthma by primary care physicians prescribing preventive anti-inflammatory medication (inhaled corticosteroids, cromolyn or nedocromil) reduced the risk of severe asthma exacerbations. Severe asthma exacerbations were measured by a hospital admission, emergency department visit or a course of oral steroids from the primary care physician.

METHODS

Data source and study population

The data analyzed were from a sample of 311 children (aged 2-19 years) treated for asthma during 1994 in a Medicaid program in the northeastern USA.

Medication and clinical data were requested from 9 managed care plans. Each plan was requested to identify all Medicaid members who were diagnosed and treated for asthma during 1994 (International Classification of Diseases, Ninth Revision, Clinical modification code ICD-9=493), and select a random sample of 50 children (aged 2 to 19 years in 1994) for study. The plans provided 388 medical records and 347 were eligible after verifying the patient's age on 1st January 1994 was between 2 to 19 years old (41 were less than 2 years old). 311 were eligible after confirming there was a visit with documentation of a prescription for an asthma medication during 1994 (36 out of 347 did not have documentation of a visit during 1994).

The data on asthma treatment provided by plan primary care physicians between 1st January 1993 and 31st March 1995 were abstracted from the medical records. Medication data abstracted included all the asthma medications prescribed (product name, route, directions, days supply), date prescribed and prescriber (primary care physician or other). The clinical data included the date of each physician visit, an assessment of the asthma severity at each visit, date of birth, gender, date of initial asthma diagnosis, date of latest theophylline level, date of latest influenza vaccination, and types of patient education provided at each visit (ability to use peak flow meter, ability to use inhaler, how to use inhaler, side effects of medication, avoidance of triggers, action plan for exacerbations, use of diaries, and goals of treatment). For each visit there was also a record of height, weight, blood pressure, a physical examination, medical history (symptoms and functional status),

objective measures of lung function (peak expiratory flow rates, home use of a peak flow meter, spirometry results) and referrals to specialists (dates, type of specialist, reason).

The clinical outcomes extracted from the medical records included asthma-related hospital admissions or emergency department visits (admission dates, discharge dates and reason for visit or admission). A primary care physician visit resulting in the prescription of a course of oral steroids was also considered.

Procedures

A data collection instrument and abstracting instructions were provided to nurses who reviewed the members' medical records, and hospital or emergency department encounter files. For each primary care physician visit the nurse reviewer abstracted the data requested, such as asthma severity, patient education and asthma medications prescribed. The nurse used the information in the medical records and the NIH guidelines to classify the asthma severity at each physician visit as mild, moderate or severe asthma. According to the clinical characteristics described in the NIH guidelines, mild asthmatics have infrequent, mild exacerbations which can be up to twice a week which are generally of brief duration. Moderate asthmatics have symptoms twice or more per week, the exacerbations may last several days and occasionally require emergency care. Severe asthmatics have continuous symptoms, limited activity levels, frequent nocturnal symptoms, and occasional hospitalization and emergency treatment.

Asthma severity was coded as mild (1), moderate (2) or severe (3) at each physician visit. The maximum asthma severity recorded before the first event of the outcome under evaluation was used to divide the children into mild, moderate and severe asthmatics.

Asthma medications were coded as beta-agonists (oral or inhaled), preventive anti-inflammatory medications (inhaled corticosteroids, inhaled cromolyn or nedocromil), oral theophylline or oral corticosteroids. The children were coded as receiving undertreatment at a visit where the asthma severity was moderate or severe and no preventive medications were prescribed.

Prescribing anti-inflammatory medications in accordance with the NIH guidelines was determined by the following dichotomous variables: preventive medication (prescribed at least once), preventive medication prescribed at 50% or more of the visits when other asthma medications were prescribed, undertreatment (preventive medication was not prescribed at least once when the children visited the primary care physician with moderate or severe asthma) or undertreatment at 50% or more of the visits when other asthma medications were prescribed.

The age on 1st January 1994 was calculated and coded in four categories (2 to 4 years, 5 to 7 years, 8 to 11 years and 12 to 19 years). In addition the multivariate analyses included age coded as two dichotomous variables. After establishing that the associations were not linear for each outcome, age was coded as 2 to 4 years and 5 to 19 years for an emergency department visit and a course of oral steroids or 2 to 7 years and 8 to 19 years for a hospital admission.

The seasons were coded as a dichotomous variable for each physician visit. The fall-winter season was coded as 1st October to 31st March.

For the descriptive analyses the beginning of person-time for an individual was defined as the date of the first physician visit when an asthma medication was prescribed between 1st January 1993 and 31st December 1994. The end of person-time was defined as the first

date for the outcome under evaluation after the first physician visit (either a hospital admission or an emergency department visit for asthma or a course of oral steroids) or the end of the study period (31st December 1994). Person-time and events after the first event of the outcome under evaluation were therefore censored and not evaluated.

STATISTICAL ANALYSES

Descriptive statistics and bivariate analyses

Descriptive statistics were used to document the age, gender, asthma severity, medications prescribed and clinical outcomes for these 311 children treated for asthma during 1994.

Emergency department visits, hospital admissions or course of oral steroids

Hospital admission, emergency department visit or course of oral steroids per person-year were calculated and documented by the following independent variables: age group, gender and asthma severity before the outcome under evaluation. The incidence density ratio (IDR) was calculated for each age group relative to the 2 to 4 year olds. The IDR were calculated for each asthma severity relative to the mild asthmatics.

In addition the bivariate relationship was evaluated between the event rates and prescribing preventive medication to children with moderate or severe asthma before each outcome. The IDR were calculated for each outcome relative to the children that received no preventive medication or no undertreatment.

Preventive medication and undertreatment

Preventive medication and undertreatment (for moderate and severe asthmatics) per person-year were calculated and documented by the following independent variables: age group, gender and asthma severity before each outcome. The incidence density ratio (IDR) was calculated for each age group relative to the 2 to 4 year olds. The IDR were calculated for each asthma severity relative to the mild asthmatics for preventive medication and moderate asthmatics for undertreatment. For each outcome children were identified who had a visit with moderate or severe asthma before the event. The IDR were calculated relative to the children that had no event for each outcome.

Multivariate analyses

For each outcome, Cox's regression method[5] was used to determine adjusted hazard ratios and 95% confidence intervals (CI) for exposure to preventive medication or undertreatment, both when coded as fixed covariates or as time-dependent covariates.

The fixed covariates were exposure to preventive medication or undertreatment, or a fixed covariate for exposure to preventive medication or undertreatment at the last visit in the study or before the event as appropriate. The fixed covariate analyses selected children with moderate or severe asthma before the outcome and used the time from the first visit when asthma medication was prescribed to the event or 31st December 1994.

The analyses also included time dependent covariates for preventive medication, undertreatment, asthma severity (mild=1, moderate=2 or severe=3), and season. The time dependent analyses used the time from the first visit with moderate or severe asthma when asthma medication was prescribed to the event or 31st December 1994.

Multivariate adjusted hazard ratios and 95% confidence intervals (CI) were calculated for each clinical outcome. The analyses all included a fixed covariate for age.

RESULTS

Descriptive and bivariate results

Emergency department visits, hospital admission or course of oral steroids

Frequency distributions of demographic characteristics, asthma severity, medications prescribed, emergency department visits, hospital admissions and a course of oral steroids are summarized in Tables 1-2.

Emergency department visits were made at a rate of 0.260 per person-year, with a significantly higher rate for children with severe compared to mild asthma (0.573 per person-year) and for children aged 2 to 4 years when compared to older age categories (0.437 per person-year). The results from the bivariate analyses showed that children were more likely to make an emergency department visit if they were aged 2 to 4 years (Table 1) or experiencing severe compared to mild asthma exacerbations (IDR 2.2 95% CI 1.2-3.9, p-value 0.00).

Hospital admissions were at a rate of 0.094 per person-year and did not change significantly with disease severity or decreasing age group.

Oral steroid courses were prescribed to children with severe asthma exacerbations at a rate of 0.217 per person-year and the rates did not significantly differ between mild or moderate asthmatics. Oral steroid courses were prescribed at a significantly higher rate to children aged 8 to 11 years old (IDR 1.8 95% CI 1.1-3.5, p-value 0.04).

Prescribing preventive medication to children with moderate or severe asthma was associated with a significantly reduced risk of being prescribed a course of oral steroids, (IDR 0.4 95% CI 0.2-0.7, p-value 0.00) (Figure 1, Table 2). The rates were also reduced although not significantly for hospital admissions, (IDR 0.5 95% CI 0.2-1.2, p-value

0.06) and emergency department visits (IDR 0.7 95% CI 0.4-1.4, p-value 0.17), (Figure 1, Table 2).

Undertreatment at 50% or more of the visits was associated with a significantly increased rate of prescribing a course of oral steroids (IDR 2.6 95% CI 1.0-6.4, p-value 0.02) (Table 2). Undertreatment was not associated with significantly increased emergency department visit rates or hospital admission rates (Figure 2, Table 2). Gender was uniformly not a significant predictor of the clinical outcomes.

Preventive medication and undertreatment

Preventive medication was prescribed at a rate of 0.828 per person-year to the children with severe asthma, 0.614 per person-year to the children with moderate asthma and 0.270 of the children with mild asthma (Table 3). The results from the bivariate analyses showed that moderate or severe asthma exacerbations before each outcome were significant predictors of preventive medication being prescribed (Table 3). Moderate asthmatics were not significantly more likely to be undertreated than severe asthmatics (Table 4). Gender and age were not significant predictors of prescribing preventive medication or undertreatment (Tables 3-4).

The preventive medication prescribing rates for children with moderate or severe asthma before the event were not significantly lower before an emergency department visit, hospitalization or a course of oral steroids (Table 5). The analyses suggest that there was significantly more undertreatment amongst children with moderate or severe asthma before an emergency department visit (IDR 1.8 95% CI 1.2-2.8, p-value 0.01) or a course of oral steroids (IDR 2.6 95% CI 1.6-4.3, p-value 0.00) but not before hospitalization (Figure 3, Table 5).

Multivariate analyses

Hazard Ratios (HR) for the association between preventive medication and an emergency department visit, hospital admission or a course of oral steroids for children with moderate or severe asthma are presented in Table 6.

Prescribing preventive medication to children with moderate or severe asthma was associated with a significantly reduced risk of a course of oral steroids in both a) the fixed covariate analyses for prescribing preventive medication at the last visit before the event (HR 0.26 95% CI 0.09-0.77, p-value 0.02), after adjusting for age and b) the time dependent covariate analyses for prescribing preventive medication (HR 0.42 95% CI 0.19-0.95, p-value 0.04), after adjusting for age and asthma severity (Figure 4).

Prescribing preventive medication was not associated with a significantly reduced risk of an emergency department visit after adjusting for age, asthma severity and an interaction with season. Periods of moderate or severe asthma were associated with a significantly higher risk for an emergency department visit (moderate asthma HR 1.96, 95% CI 1.11-3.47, and severe asthma HR 3.86 95% CI 2.88-5.16, p-value 0.03, after adjusting for age and preventive medication).

A course of oral steroids (unadjusted HR 2.4, 95% CI 1.3-4.4, p-value 0.01) and asthma severity (unadjusted HR 2.1, 95% CI 1.2-3.7, p-value 0.01) when coded as time-dependent covariates, were also associated with a significantly increased risk of an emergency department visit.

The multivariate analyses of children with moderate or severe asthma indicated a significantly increased risk of an emergency department visit or a course of oral steroids with undertreatment (Table 7). Undertreatment was associated with a significantly

increased risk of a course of oral steroids in both a) the fixed covariate analyses for undertreatment at the last visit prior to an event if one occurred (HR 5.01, 95% CI 1.99-12.65, p-value 0.00), after adjusting for age and b) the time dependent covariate analyses (HR 2.53, 95% CI 1.15-5.58, p-value 0.02), after adjusting for age and asthma severity (Figure 5).

Undertreatment was associated with a significantly increased risk of an emergency department visit in the fixed covariate analyses for undertreatment at the last visit prior to an event if one occurred (HR 2.08, 95% CI 1.03-4.20, p-value 0.04). The time dependent analyses showed asthma severity was associated with an increased risk for an emergency department visit (moderate asthma HR 2.12, 95% CI 1.20-3.72, and severe asthma HR 4.48, 95% CI 3.36-5.97, p-value 0.01 after adjusting for age and undertreatment).

No significant results were obtained for an association between prescribing preventive medication and reducing the risk of hospital admission (Table 6). There was an increased but not significant association between undertreatment at the last visit prior to an event if one occurred and hospitalization (HR 2.45, 95% CI 0.91-6.62, p-value 0.08) (Table 7).

DISCUSSION

The results of this study suggest that the NIH guidelines for the use of preventive medications were implemented by the primary care physicians on at least one occasion to 39.9% of the children in this study. Amongst the children with moderate or severe asthma during this study, 65.4% were not prescribed preventive medication on at least one occasion when they attended the primary care physician with moderate or severe asthma. The pattern of prescribing in this study is not consistent with full implementation of NIH guidelines, which support regularly prescribing preventive anti-inflammatory medication to children with moderate or severe asthma.

This study shows that prescribing preventive medications by primary care physicians in accordance with NIH guidelines was associated with improved clinical outcomes in this study population. Severe asthma exacerbations requiring treatment with a course of oral steroids were reduced by more than half amongst the children prescribed preventive medication HR 0.42 (95% CI 0.19-0.95) (Figure 4). Multivariate analyses also showed that there was 2.5 times the risk of a subsequent course of oral steroids, among those with undertreatment (Figure 5). Undertreatment at the last primary care physician visit before an emergency department visit or a course of oral steroids was also associated with a significantly increased risk of both these adverse outcomes.

Undertreatment on at least one primary care physician visit was approximately twice as common in children attending the primary care physician with moderate or severe disease before an emergency department visit or before receiving a course of oral steroids (Figure 3). This study did not show a significant association between undertreatment and either a hospital admission or an emergency department visit (Figures 2 and 5). This study did however indicate that the primary care physicians could be prescribing preventive medications to more of the moderate or severe asthmatics. The high rates of emergency

department visits, hospital admissions and courses of oral steroids showed the impact of severe asthma exacerbations on the health of these children. Undertreatment is a modifiable risk factor for acute asthma exacerbations that could be successfully changed by the primary care physicians fully implementing the NIH guidelines.

Other studies of asthmatic children have reported more under-use of preventive medication. A study was conducted by Kaiser Permanente Medical Care Program in California of children hospitalized or attending the emergency department as a result of severe asthma between January-July 1995. The study reviewed the medications prescribed to children attending a physician within 30 days of the hospital admission or emergency department visit: over 73% were prescribed a beta-agonist, 47% a course of oral steroids but only up to 49% were prescribed cromolyn or inhaled steroids.[6] Under-use of preventive medications was also found amongst asthmatic children (48% were Medicaid patients) attending the emergency department of an inner city academic pediatric hospital in Pennsylvania during 1994: 35% were previously ever prescribed cromolyn and 22% ever prescribed inhaled steroids.[7] A questionnaire completed by the families of 392 asthmatic children living in the inner city, revealed that only 11% were receiving preventive medication. Selecting 166 children with more severe asthma exacerbations requiring an emergency room visit in the past six months, the authors found that even in 1992 over 50% were under-treated and were not receiving preventive medication.[8]

The results from the current study are also consistent with two studies using claims data bases which supported the suggestion that inhaled corticosteroid therapy caused a significant reduction in health care service use by asthmatic children, including Medicaid enrollees. One study reported asthma medication claims data from 6035 insured (non-Medicaid) asthmatic children, the study was published by a New England based health maintenance organization, Harvard Pilgrim Health Care (HPHC). The HPHC results

showed the percentage of asthma prescriptions dispensed for preventive medications between October 1991 and September 1994 was respectively as follows: beta-agonists 67%, cromolyn 16% and inhaled steroids 11%, theophylline 6%." The study by HPHC demonstrated that preventive medications confer significant protection against exacerbations of asthma leading to hospitalization, but did not investigate other clinical outcomes.

A retrospective case-control study of asthmatic Medicaid children (less than 12years old) used a North Carolina claims database to follow the health care costs of 85 cases and 72 controls for 1year.[10 11] The cases began inhaled corticosteroid therapy between March 1994 to 1995. The controls were on asthma therapy other than steroids for a continuous 2-year period between March 1993 to March 1996. The study demonstrated that the introduction of inhaled corticosteroid therapy to Medicaid children was associated with a significant reduction in the total health care costs (hospitalizations, physician visits, outpatient visits and the cost of medications).

Many of the drugs for asthma can appear to increase risk of adverse outcomes because the patients for whom asthma medications are prescribed may have an increased risk of frequent and severe asthma exacerbations.[12] The benefits of prescribing preventive medication were not always evident in the current study if the analyses did not adjust for asthma severity. Consequently to address confounding by asthma severity, the multivariate analyses used Cox regression which provided flexibility in the way the asthma severity and preventive medication were coded. The analyses could select the children attending with either moderate or severe asthma before the outcome and include severity as a time dependent covariate. The Cox regression analyses used both fixed covariates and time dependent covariates to measure exposure to preventive medication or undertreatment of children with moderate or severe asthma before each event. Cox regression also allowed the models to include time dependent variables recorded at irregular intervals for preventive

medication and severity recorded before the outcome being evaluated.

The observed confidence intervals for associations were often wide because the sample of patients with a moderate or severe asthma before the emergency department visit or hospital admission was small. In the bivariate analyses emergency department visit rates were much higher in the group with outbreaks of severe disease. There were about 40 children in our sample classified as experiencing severe exacerbations and 56 that received a course of oral steroids and this therefore limited our analyses.

A course of oral steroids is recommended by the NIH guidelines for the acute treatment of severe asthma exacerbations and therefore may have compensated for the risk of adverse outcomes from undertreatment with inhaled anti-inflammatory medication. For example, one study showed starting or increasing steroid medications at the onset of a cold or flu reduced the odds of asthmatic children making an emergency department visit.[9] Emergency department visits were shown in our multivariate analyses to be consistently associated with prior severe asthma exacerbations or a course of oral steroids. If a course of oral steroids is considered a surrogate marker for an exacerbation of asthma severity, as preventive medication reduces the number of severe exacerbations there may also be a substantially greater potential to reduce emergency department visits than has been evident in this small sample.

In our study emergency department visits were more common amongst 2 to 4 year olds. The NIH guidelines recognize this age group is less likely to be able to successfully co-ordinate inhaling preventive medication, and may have to rely instead on courses of oral steroids for acute exacerbations. The 0 to 4 year age group has been found to exhibit higher hospitalization rates for asthma than other age groups[13, 14] and there is an association between children aged 2 to 4 years old making more emergency department visits.[15, 16]

Hospital admission was less common than an emergency department visit and the rates appear not to be associated with severity, thus in this small sample the children were not always attending the primary care physician with moderate or severe disease before being admitted. The complexity of asthma risk factors may have prevented the association between undertreatment and admissions to hospital being detected in this sample size and duration. The triggers for each patient may be different and asthma severity fluctuates, there may be many periods when although preventive medication is not prescribed the asthma severity may not deteriorate to require an emergency department visit or hospitalization. In addition, if the children are taken to the physician with severe asthma a course of oral steroids will in many instances prevent hospitalization or an emergency department visit being necessary. Hospital admissions in this study were also seasonal (zero between July and September) and this may also explain the lack of association with undertreatment in this study.

One predisposing factor for emergency department visits or hospital admissions seems to be the season of the year as more events were recorded during fall or winter. Similar results have also been recorded in other studies and viral infections have been suggested as a possible explanation for these seasonal trends.[17] Viral infections aggravate clinical asthma and increase airway responsiveness that may persist for weeks after the infection.[18] For example, two studies on asthmatic children reported the most common symptom experienced prior to the emergency department visit was wheezing induced by respiratory infections (over 75%).[7 19] In our study, the reasons for the emergency department visits and hospital admissions were not recorded in detail. For example, it was not known whether a viral infection was considered the trigger for the acute exacerbation or an indoor allergen.

The information collected from this Medicaid asthmatic population may not be generalizable to other children. There could be differences in prescribing practices or attendance at the physician office for preventive care visits by Medicaid patients. The managed care plans guarantee access for these Medicaid patients but there are many differences between poor minority families and health care providers that may influence prescribing practices for example language, cultural barriers, or literacy levels.[20] Asthma may be viewed by families as "episodic" rather than needing regular attendance at the physician for preventive medications. The study design did not include a sample size large enough to allow comparisons between the prescribing practices and outcomes from each of the nine different managed care plans or profile individual primary care prescribers.

The race of the children in the current study was not known but it is possible some of the minority children are under-utilizing the primary care physicians. Studies of Medicaid asthmatic children have showed that African-American children have significantly fewer primary care physician visits than their white counterparts even after adjusting for potential confounding variables, suggesting under -use of preventive services for asthma.[21 22] A racial disparity may therefore exist in access to effective management of chronic asthma.

Indoor allergens, such as cockroaches as well as dust mites or pets are now recognized as important triggers, which may be important amongst children living in poor housing conditions.[23] It was not known whether these children were living in inner city homes or rural conditions.

A disproportionate number of poor children have been shown to rely on the emergency department instead of primary care providers for their asthma care.[7 22 24] Higher hospitalization rates for asthma have been recorded for poor or minority children.[25 26] For example, a study of hospital discharge data from asthmatics less than 25 years old showed

that black patients were five times more likely than white to be hospitalized for asthma and 50% more likely to be readmitted.[27] These patient and various health care system characteristics all pose challenges to Medicaid patients moving away from episodic attendance at the primary care physician's office or emergency department for crisis orientated, fragmented care for asthma exacerbations.[21 28 29 30]

Rates for asthma prevalence are highest among children residing in inner cities and important risk factors for asthma-related mortality includes being poor or black.[1 31 32 33] The Medicaid eligibility criteria for this study means all the children were from poor families. It was not possible to compare the results from this Medicaid group with other patients attending these plans. In the present study medications were free for the patients: thus there was no cost incentive for patients to avoid having prescriptions dispensed for preventive medications. In addition, a study of asthmatic Medicaid recipients showed that trends in prescribing anti-inflammatory medications were consistent and parallel with changes observed in the general population.[34] However, two cross-sectional studies of medication claims data have shown an association between underuse of inhaled steroids and lower income.[35 36] This population based study of Medicaid eligible children provides valuable information about the effectiveness of the NIH recommendations in a sample from the group of children known to be at a high risk of adverse outcomes.

An unusual aspect of this study was the collection of clinical data from primary care physician medical records. The asthma diagnoses were confirmed from the medical records and therefore the study did not have to rely solely on the ICD 9 coding for the diagnosis. In the past the diagnosis criteria have varied for classifying asthma severity but the NIH guidelines include a working definition of mild, moderate and severe asthma severity. Access to the medical records allowed the NIH guidelines to be used to classify the children as mild, moderate or severe asthmatics at each physician visit when an asthma

medication was prescribed. The analyses were then able to address confounding by asthma severity by stratified analyses and including a time dependent covariate for asthma severity in the model. Most previous studies focused on severe asthmatics or did not use either the NIH criteria or a clinical assessment of severity, relying instead on medication claims data to calculate beta-agonist use rates of children treated by primary care physicians.

The information about prescribing medications was collected from the medical records rather than a separate medication claims database, consequently not all the prescriptions may have been actually dispensed or administered regularly as directed. Patient compliance is important for preventive medications to be beneficial and for children it may be especially complex as parents, school nurses and other carers may have to administer the medication. Many studies have identified poor compliance with preventive medication amongst preschool [37] and school children [38] as well as with adult asthmatics.[39,40] Patient compliance was not measured in this study, therefore these data may underestimate the value of prescribing preventive medication to these children.

The low socioeconomic status of these children means they might be unable to avoid some environmental triggers, have a higher frequency of severe asthma, and experience a lack of continuity of care more than insured children. The effectiveness of prescribing in accordance with the NIH guidelines was still however clearly demonstrated as preventive medication significantly reduced, and undertreatment of moderate or severe asthma significantly increased the risk of prescribing a course of oral steroids.

Asthma is the most common chronic illness in children[13] and is the most frequent cause of hospitalization among children[41] and one of the leading causes of absenteeism from school.[42] Mortality rates are low for asthma but poorly controlled asthma results in many social costs to the children in addition to the medical costs associated with high rates of

physician consultations and hospital admissions. This population-based study supports the effectiveness of prescribing preventive anti-inflammatory medication under conditions of actual use by a Medicaid population. This study shows that primary care physicians can improve the control of asthma by implementing the NIH guidelines and regularly prescribing anti-inflammatory medication for moderate or severe asthma.

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Figure 1 Bivariate relationship between preventive medication and clinical outcomes for children with moderate or severe asthma

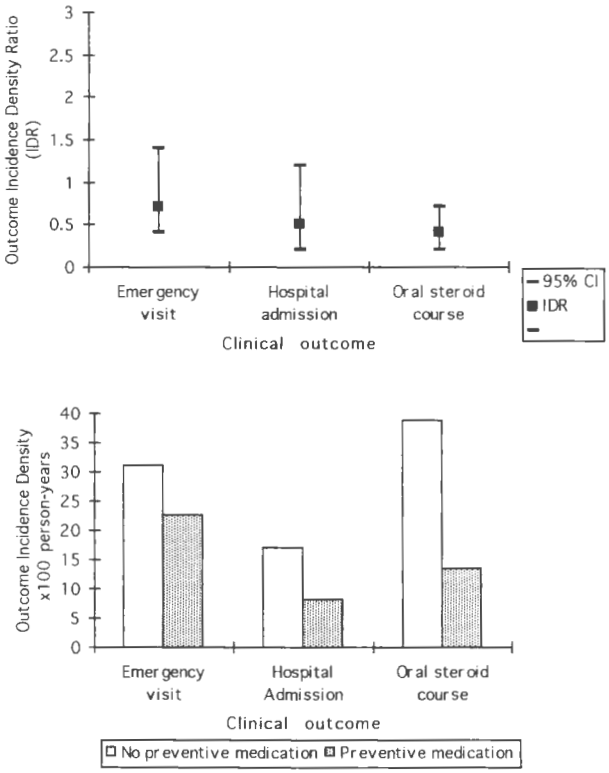


Figure 2 Bivariate relationship between undertreatment and clinical outcomes for children with moderate or severe asthma

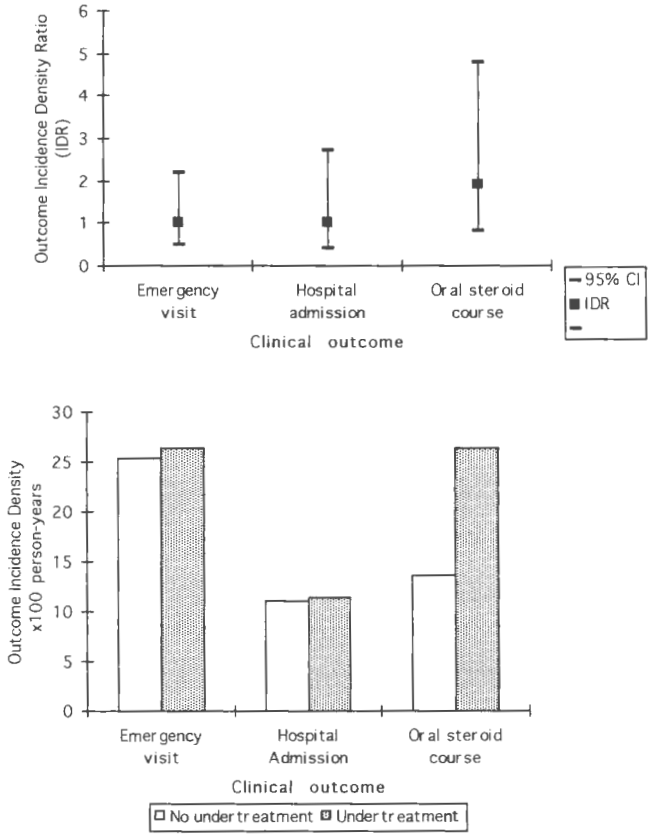
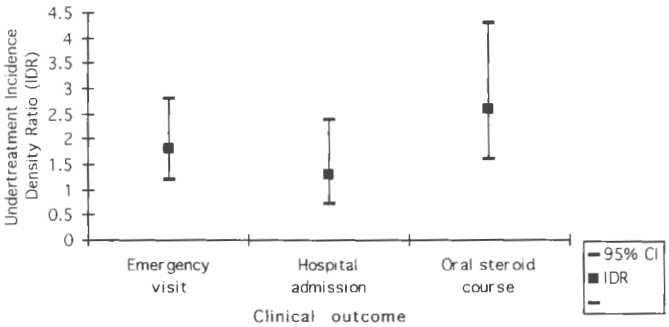


Figure 3 Bivariate relationship between clinical outcomes and undertreatment of children visiting the primary care physician with moderate or severe asthma before the event



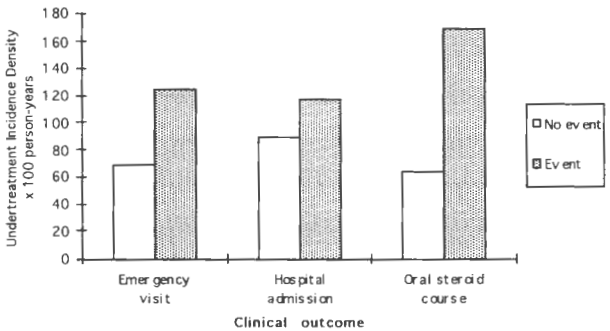


Figure 4 Adjusted Hazard Ratios (aHR) for preventive medication and clinical outcomes for children with moderate or severe asthma

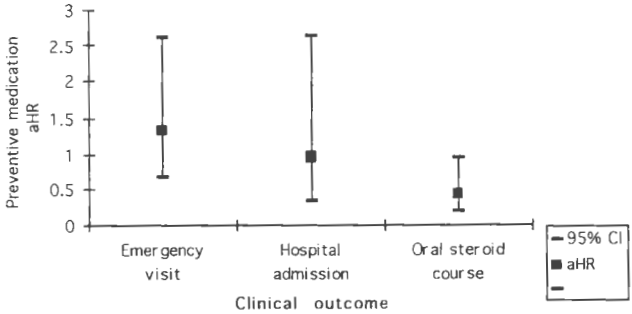


Figure 5 Adjusted Hazard Ratios (aHR) for undertreatment and clinical outcomes for children with moderate or severe asthma

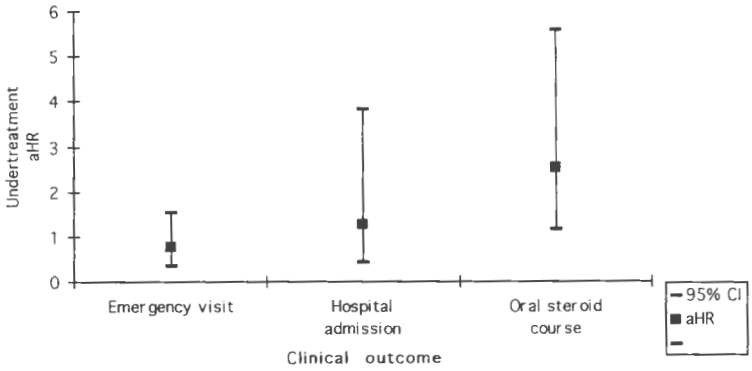


Table 1 Descriptive statistics and bivariate relationships between demographic characteristics, asthma severity and clinical outcomes

ID = Incidence Density x 10^2 (person-years) IDR=Incidence Density Ratio C=Cases

Characteristics	Emergency department visit					Hospital admission					Oral steroids course				
	n (person-years)	C	ID	IDR (95% CI)	p	n (person-years)	C	ID	IDR (95% CI)	p	n (person-years)	C	ID	IDR (95% CI)	p
Total	311(254.03)	66	26.0			311(277.83)	26	9.4			311(257.97)	56	21.7		
Age 2-4 years	92(70.98)	31	43.7			92(82.59)	11	13.3			92(82.33)	16	19.4		
5-7 years	82(72.49)	14	19.3	0.4 (0.2-0.8)	.00	82(77.65)	8	10.3	0.8 (0.4-1.8)	.29	82(69.18)	15	21.7	1.1 (0.5-2.4)	.38
8-11 years	76(61.46)	9	14.6	0.3 (0.2-0.6)	.00	76(64.83)	4	6.2	0.5 (0.2-1.4)	.09	76(54.25)	19	35.0	1.8 (1.1-3.5)	.04
12-19 years	61(49.09)	12	24.4	0.6 (0.3-1.1)	.04	61(52.77)	3	5.7	0.4 (0.1-1.5)	.09	61(52.21)	6	11.5	0.6 (0.2 1.5)	.13
Gender															
Female	146(118.25)	28	23.7			146(125.82)	13	10.3			146(118.10)	24	20.3		
Male	163(133.19)	38	28.5	1.2 (0.8-1.9)	.23	163(149.42)	13	8.7	0.9 (0.4-1.8)	.33	163(138.11)	31	22.5	1.1 (0.6-1.9)	.36
Asthma severity															
Mild	144(110.80)	29	26.2			136(114.13)	8	7.0			151(122.93)	21	17.1		
Moderate	108(99.40)	16	16.1	0.6 (0.3-1.1)	.06	113(106.65)	12	11.3	1.6 (0.7-3.9)	.15	105(92.61)	24	25.9	1.5 (0.9 2.7)	.08
Severe	40(31.40)	18	57.3	2.2 (1.2-3.9)	.00	44(43.72)	5	11.4	1.6 (0.5-4.9)	.19	31(27.36)	2	7.3	0.4 (0.2-1.2)	.12

Table 2 Descriptive statistics and bivariate relationships between preventive medication or undertreatment and clinical outcomes for children with moderate or severe asthma

ID = Incidence Density x 10^2 (person-years) IDR=Incidence Density Ratio C=Cases

Characteristics	Emergency department visit					Hospital admission					Oral steroids course				
	n (person-years)	C	ID	IDR	p	n (person-years)	C	ID	IDR	p	n (person-years)	C	ID	IDR	p
Total	148(130.8)	34	26.0			157(150.4)	17	11.3			136(120.0)	26	21.7		
Preventive medication No	61(51.12)	16	31.3			58(52.58)	9	17.1			54(38.75)	15	38.7		
Yes	87(79.68)	18	22.6	0.7 (0.4-1.4)	.17	99(97.79)	8	8.2	0.5 (0.2-1.2)	.06	82(81.22)	11	13.5	0.4 (0.2 0.7)	.00
>=50% visits	64(55.43)	14	25.3	0.8 (0.4-1.7)	.28	73(70.24)	6	8.5	0.5 (0.2-1.4)	.09	67(62.83)	10	15.9	0.4 (0.2 0.9)	.01
Undertreatment No	47(39.46)	10	25.3			52(45.52)	5	11.0			47(44.13)	6	13.6		
Yes	101(91.35)	24	26.3	1.0 (0.5-2.2)	.46	105(104.85)	12	11.4	1.0 (0.4-2.7)	.47	89(75.84)	20	26.4	1.9 (0.8-4.8)	.07
>=50% visits	60(50.69)	15	29.6	1.2 (0.5-2.6)	.35	56(55.61)	6	10.8	1.0 (0.3-3.7)	.49	56(45.88)	16	34.9	2.6 (1.0-6.4)	.02

Table 3 Descriptive statistics and bivariate relationships between demographic characteristics or asthma severity before the event and preventive medication

ID=Incidence Density x 10^2 (person-years) IDR=Incidence Density Ratio

Characteristics		Preventive medication				
		n (person-years)	Cases	ID	IDR	p
Total*		311 (257.97)	124	48.1		
Age*	2-4 years	92 (82.33)	32	38.9		
	5-7 years	82 (69.18)	34	49.2	1.3 (0.8-2.1)	.17
	8-11 years	76 (54.25)	30	55.3	1.4 (0.9-2.3)	.08
	12-19 years	61 (52.21)	28	53.6	1.4 (0.1-1.7)	.11
Gender *	Female	146 (118.10)	50	42.3		
	Male	163 (138.11)	72	52.1	1.2 (0.9-1.8)	.13
Emergency visit						
	Mild	144 (110.80)	30	27.1		
	Moderate	108 (99.40)	61	61.4	2.3 (1.5-3.5)	.00
	Severe	40 (31.40)	26	82.8	3.1 (1.9-5.0)	.00
Hospital admission						
	Mild	136 (150.37)	31	20.6		
	Moderate	113 (106.65)	69	64.7	3.1 (2.1-4.7)	.00
	Severe	44 (43.72)	30	68.6	3.3 (2.1-5.3)	.00
Oral steroids course						
	Mild	151 (122.93)	36	29.3		
	Moderate	105 (92.61)	60	64.8	2.2 (1.5-3.3)	.00
	Severe	31 (27.36)	22	80.4	2.7 (1.7-4.6)	.00

*Calculated before oral steroids course

Table 4 Descriptive statistics and bivariate relationships between demographic characteristics or asthma severity before the event and undertreatment for children with moderate or severe asthma

ID = Incidence Density x 10^2 (person-years)

IDR= Incidence Density Ratio

Characteristics	Undertreatment				
	n (person-years)	Cases	ID	IDR	p
Total*	136 (119.98)	89	74.2		
Age*					
2-4 years	44 (41.72)	32	76.7		
5-7 years	34 (27.71)	21	75.8	1.0 (0.6-1.7)	.48
8-11years	30 (26.87)	21	78.2	1.0 (0.6-1.9)	.48
12-19 years	28 (23.66)	15	63.4	0.8 (0.4-1.6)	.30
Gender *					
Female	61 (53.52)	42	78.5		
Male	74 (65.56)	47	71.7	0.9 (0.6-1.4)	.33
Emergency visit					
Moderate	108 (99.40)	74	74.5		
Severe	40 (31.40)	27	86.0	1.2 (0.8-1.8)	.26
Hospital admission					
Moderate	113 (106.65)	75	70.3		
Severe	44 (43.72)	30	68.6	1.0 (0.7-1.5)	.46
Oral steroids course					
Moderate	105 (92.61)	71	76.7		
Severe	31 (27.36)	18	65.8	0.9 (0.5-1.4)	.28

*Calculated before oral steroids course

Table 5 Descriptive statistics and bivariate relationships between an emergency department visit, hospital admission or course of oral steroids and preventive medication or undertreatment of children visiting the primary care physician with moderate or severe asthma before the event

ID = Incidence Density x 10^2 (person-years) IDR= Incidence Density Ratio

Characteristics		Preventive medication				Undertreatment			
	n (person-years)	Cases	ID	IDR	p	Cases	ID	IDR	p
Emergency visit									
No	114 (111.59)	69	61.8			77	69.0		
Yes	34 (19.21)	18	93.7	1.5 (0.9-2.6)	.06	24	124.9	1.8 (1.2-2.8)	.01
Hospital admission									
No	140 (104.07)	91	87.4			93	89.4		
Yes	17 (10.30)	8	77.7	0.9 (0.4-1.8)	.38	12	116.5	1.3 (0.7-2.4)	.19
Oral steroids course									
No	110 (108.08)	71	65.7			69	63.8		
Yes	26 (11.88)	11	92.6	1.4 (0.8-2.7)	.14	20	168.4	2.6 (1.6-4.3)	.00

Table 6 Hazard Ratios (HR) and 95% Confidence Intervals (CI) describing the association between preventive medication and an emergency department visit, hospital admission or course of oral steroids for children with moderate or severe asthma

Variable	Emergency department visit			Hospital admission			Oral steroids course		
	HR	p	CI	HR	p	CI	HR	p	CI
Preventive medication	1.83	.14	0.82-4.06	3.40	.10	0.78-14.97	1.71	.34	0.56-5.22
Age*	0.42	.01	0.21-0.84	0.61	.32	0.22-1.64	0.66	.38	0.27-1.65
Preventive medication at last visit before event	1.34	.40	0.68-2.65	0.63	.36	0.23-1.70	0.26	.02	0.09-0.77
Age*	0.44	.02	0.22-0.86	0.63	.36	0.23-1.70	0.83	.69	0.34-2.04
Preventive medication prior to event**	1.31	.44	0.66-2.61	0.93	.89	0.33-2.64	0.42	.04	0.19-0.95
Severity** Moderate	1.96	.02	1.11-3.47	1.02	.99	0.45-2.32	1.11	.74	0.60-2.07
Severe	3.86	.02	2.88-5.16						
Age *	0.59	.15	0.29-1.22	0.55	.28	0.19-1.61	1.32	.52	0.57-3.07

* Age coding: >=5 years for emergency department visits and oral steroids & >=8 years for hospital admissions

** Time dependent covariate

Table 7 Hazard Ratios (HR) and 95% Confidence Intervals (CI) describing the associations between undertreatment and an emergency department visit, hospital admission or a course of oral steroids for children with moderate or severe asthma

Variable		Emergency department visit			Hospital admission			Oral steroids course		
		HR	p	CI	HR	p	CI	HR	p	CI
Undertreatment		1.15	.73	0.52-2.55	1.10	.87	0.36-3.38	8.13	.04	1.09-60.79
Age*		0.46	.02	0.23-0.90	0.63	.37	0.23-1.71	0.79	.60	0.32-1.93
Undertreatment at last visit before event		2.08	.04	1.03-4.20	2.45	.08	0.91-6.62	5.01	.00	1.99-12.65
Age*		0.54	.09	0.27-1.09	0.72	.53	0.26-1.99	0.82	.66	0.33-2.00
Undertreatment prior to event**		0.75	.42	0.36-1.53	1.27	.68	0.42-3.84	2.53	.02	1.15-5.58
Severity**	Moderate	2.12	.01	1.20-3.72	0.94	.90	0.38-2.32	0.76	.47	0.37-1.59
	Severe	4.48	.01	3.36-5.97						
Age *		0.59	.15	0.29-1.22	0.56	.28	0.19-1.63	1.33	.51	0.57-3.09

* Age coding: >=5 years for emergency department visits and oral steroids & >=8 years for hospital admissions

** Time dependent covariate

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PART 2

Part 2 includes the following appendices:

Appendix A. Introduction and review of the problem

Appendix B. Details of the methods

Appendix C. Overview of major findings

APPENDIX A INTRODUCTION AND REVIEW OF THE PROBLEM

CHILDHOOD ASTHMA

Studies of childhood asthma indicate a prevalence range of between 0.5 to 6.3% in the USA.[1] Asthma is the fourth leading cause of disability[2] and the most common chronic disease of childhood.[3] Mortality rates are low for asthma but poorly controlled asthma results in many social costs to the children in addition to the medical costs.[4] For example, asthma is one of the leading causes of absenteeism from school : a loss of more than 10 million school days was estimated for 1990, resulting in lost productivity costs for the caregivers of $726 million.[5] Asthma is the most frequent cause of hospitalization among children and over the last 20 years pediatric hospitalization rates for asthma doubled.[6] Asthma also leads to high rates of primary care physician consultations and emergency room visits.[5] According to the 1988 National Health Interview Survey (NHIS) in a sample of children less than 18 years old, asthma was rated as severe, moderate and mild for 10%, 32% and 59% of the children.[7] However, the children with severe asthma account for 27% of the days missed from school, 35% of the hospitalizations and 77% of the days in hospital.[7]

Rates for asthma prevalence are highest among children residing in inner cities and important risk factors for asthma-related mortality include being poor or black.[8,9,10] Higher hospitalization rates for asthma have also been recorded for poor or minority children.[7,11] For example, a study of hospital discharge data from asthmatics less than 25 years old showed that black patients were five times more likely than white to be hospitalized for asthma and 50% more likely to be readmitted.[12] Studies of Medicaid asthmatic children have shown that African-American children have significantly fewer primary care physician visits than their white counterparts, even after adjusting for potential confounding

variables, suggesting under-use of preventive services for asthma.[13 14] A racial disparity may therefore exist in access to effective management of chronic asthma.

A disproportionate number of poor children have been shown to rely on the emergency department instead of primary care providers for their asthma care.[14 15 28] Many aspects of poverty may be increasing the risk of mortality, such as: lack of access to high quality health care, lack of continuity of care, decreased use of anti-inflammatory medications, housing with high levels of cockroach or dust mite antigens, poor systems of social support, and low education levels.[10 16] Both patient and various health care system characteristics all pose challenges to moving low income patients away from episodic attendance at the primary care physician's office or emergency department for crisis orientated, fragmented care for asthma exacerbations.[13 17 18 19] The inner city in the US is inhabited by impoverished people who are disproportionately nonwhite so separating these risks has proved difficult, however some evidence currently suggests socioeconomic status is the more important risk factor than race for asthma morbidity.[10]

Studies of the prevalence of childhood asthma have shown that the prevalence of asthma changes during childhood with age and gender.[1] The prevalence of asthma is higher in boys less than 5 years old, with the distribution becoming more equal later in childhood, and among adults asthma is more common in women than men.[20 21] Amongst children with mild episodic asthma up to 60% will have an improvement in symptoms by adulthood, although less than 20% of chronic asthmatics will become asymptomatic.[22]

The management of chronic asthma has changed in recent years with the increased recognition of the important role of the inflammatory component in the pathogenesis of asthma. The management of asthma currently includes both drug therapy and the avoidance of known allergens, monitoring lung function with peak flow meters and a

greater emphasis on the importance of educating the patient and their family about asthma.[23] Indoor allergens, such as cockroaches, dust mites, pets or cigarette smoke are now recognized as important triggers for asthma.[24,25]

Viral infections aggravate clinical asthma and increase airway responsiveness that may persist for weeks after the infection.[22,26] Consequently there are seasonal increases in the frequency of asthma attacks when the epidemic respiratory virus infections are in the community in the fall or when there are higher concentrations of airborne allergens. For example, studies on asthmatic children reported the most common symptom experienced prior to the emergency department visit was wheezing induced by respiratory infections (over 75%)[27,28] and starting or increasing steroid medication at the onset of a cold or flu have been shown to reduce the odds of an emergency department visit.[29]

Research indicates approximately 30% of the direct medical costs of asthma are attributable to inadequately controlled disease.[30] Nearly two thirds of ambulatory care visits for asthma do not involve asthma specialists but physicians from family medicine or general practice, pediatrics or internal medicine.[5] Opportunities exist to optimize the treatment of asthma by primary care physicians and improve the patients quality of life, minimize the impact of the disease on the family and reduce the frequency and severity of acute exacerbations leading to hospitalization or emergency room visits.

NIH GUIDELINES FOR THE TREATMENT OF CHILDHOOD ASTHMA

Summary of recommendations

In 1991 an Expert Panel prepared NIH guidelines for the diagnosis and management of asthma.[23] The expert panel outlined an approach to asthma therapy that has four components: patient education, environmental control, comprehensive pharmacologic therapy and objective monitoring measures to monitor the severity of disease and course of therapy. The Expert Panel updated the recommendations in 1997 and continued to emphasize the role of inflammation in the pathogenesis of asthma.[31] The guidelines issued in 1997 advocated a stepwise approach, linking asthma severity with treatment alternatives and put an even stronger emphasis on anti-inflammatory medication.

The NIH guidelines issued in 1991 defined three categories of asthma severity: mild, moderate or severe (Table 1). The NIH classification of asthma severity is based on severity before optimal therapy is initiated. Asthma is highly variable, so the characteristics of each class are general and may overlap plus individuals can switch between categories over time. The updated guidelines issued in 1997 expanded the categories to four by dividing mild asthmatics into patients with mild intermittent asthma or mild persistent asthma. The data extracted from the medical records related to the period between 1993 and 1994 therefore this study used the criteria published in 1991 to categorize the asthma severity and assess the appropriateness of the therapy prescribed.

Daily long term preventive anti-inflammatory medications (such as inhaled corticosteroids, cromolyn sodium or nedocromil) are recommended for persistent asthma.[23] Children consistently requiring symptomatic treatment more than twice a week (classified as moderate or severe asthmatics) should be given daily anti-inflammatory therapy. In addition, appropriate medications to manage acute asthma exacerbations (beta-agonists and

oral corticosteroids) should also be prescribed. The treatment recommended by the 1991 guidelines can be summarized as follows:

Mild asthma:

Beta-agonist alone

Cromolyn alone

Beta-agonist and cromolyn

Moderate asthma: Anti-inflammatory agents and bronchodilators

Beta-agonist and inhaled steroid

Beta-agonist, cromolyn and inhaled steroid

Beta-agonist and theophylline

Severe asthma:

As for moderate asthma with addition of oral steroids and spacer device.

The NIH guidelines recommend anti-inflammatory medications but indicate that theophylline can be prescribed for childhood asthma. Theophylline has a narrow therapeutic index so for a child over 5 years old who needs maintenance medication, an inhaled steroid or cromolyn is considered the simplest and safest regimen.[32] Slow-release theophylline does offer an alternative to inhaled corticosteroids when a patient complies poorly with a maintenance regimen of inhaled steroids or cromolyn and is judged more likely to adhere to an oral regimen. The NIH guidelines recognize the younger age group is less likely to be able to successfully co-ordinate inhaling preventive medication, and may have to rely instead on courses of oral steroids for acute exacerbations.

Oral steroids are very effective anti-inflammatory medications but are reserved for severe asthma because of the risk of suppressing pituitary adrenal function and causing iatrogenic Cushings syndrome with the associated impairment of growth, bone formation and bone density. There is evidence to suggest that children receiving oral therapy also benefit from inhaled steroids.[35] The regular prophylactic use of inhaled steroids is the recommended therapy for moderate asthma, reducing the extent to which theophylline and oral steroids are prescribed.[33] [34] There is substantial evidence to show that moderate doses of inhaled steroids do not impair growth and maturation because there is such a weak systemic effect.[35]

Beta-agonist medications have been associated with controversy over whether high use was associated with an increased risk of fatal asthma. There have been numerous headlines about whether beta-agonists are associated with an increase in asthma deaths, however a full review of the evidence did not eventually support the initial concerns.[36] The studies concluded that the increased risk of fatal or near fatal asthma was clinically important for adult patients who used >1-2 cans of inhaler per month[37] or for hospitalization for children using >8 inhalers per person-year.[38] There is also evidence that in patients with mild asthma, neither deleterious nor beneficial effects derive from regular use of inhaled albuterol beyond those derived from use of the drug as needed.[39]

The guidelines also emphasize the importance of patient education in the management of asthma and the potential benefits from environmental control. The guidelines recommend provision of action plans, information on avoidance of triggers, goals of treatment and ability to use an inhaler, use of diaries and side effects of medications.

A written action plan to guide patient self-management is especially important for patients with moderate or severe persistent asthma and any with a history of severe exacerbations.

Asthma severity is highly variable and may change over time so assessment is recommended at least biannually. This allows the physician to check that treatment goals are being met and that the patient is on appropriate pharmacotherapy with up to date self management and action plans. The ability to use the inhalers correctly should also be checked to ensure maximum benefit from the medication prescribed, especially if asthma control is not achieved.

Exposure of an asthmatic patient to inhalant allergens to which the patient is sensitive increases airway inflammation and symptoms. Substantially reducing such exposure will result in significantly reduced inflammation, symptoms and need for medication. Patients with asthma at all levels of severity are recommended in the NIH guidelines to receive education about the importance of minimizing exposure to inhalant triggers. The counseling should include how to control and avoid exposure to known allergens, cigarette smoke and to make reasonable attempts to reduce exposure to respiratory viruses.

Implementation of recommendations for childhood asthma

This study determines the extent to which the NIH recommendations have been implemented by the primary care physicians for children with asthma in a randomly selected population of Medicaid patients. The study summarizes prescribing of preventive medication, provision of patient education and information about environmental control. In addition the study identifies the demographic characteristics, clinical characteristics or events that are predictors of prescription of preventive medication or provision of patient education to children.

Primary care physicians have multiple opportunities to implement the NIH guidelines and optimize the treatment by monitoring the asthma severity, pharmacotherapy and providing counseling on self-management of asthma. Evidence that guidelines influence patient care

is needed because their effectiveness in changing practice behaviors and improving health outcomes is widely questioned. [40 41 42] Physician performance has been shown to be improved by providing feedback on prescribing practice patterns which can also be used to support quality improvement initiatives targeting potential areas for change.[43 44]

The impact of the guidelines on clinical outcomes will depend on the effectiveness of the treatment recommended but also on the dissemination of the recommendations from the specialists to the primary care physicians. For example, asthma specialists have been shown to be more likely to prescribe preventive medications than primary care physicians[45 46] and access to or co-ordination of care by specialists[47 48] may facilitate implementation of the NIH guidelines.

The results from four recent studies focused on children with moderate or severe asthma have indicated that the NIH guidelines recommending the use of preventive medication have not been fully implemented. A study was conducted by Kaiser Permanente Medical Care Program in California of children hospitalized or attending the emergency department as a result of severe asthma between January through July 1995. The study reviewed the medications prescribed to children attending a physician within 30 days of the hospital admission or emergency department visit: over 73% were prescribed a beta-agonist, 47% a course of oral steroids but only up to 49% were prescribed cromolyn or inhaled steroids.[29]

Under-use of preventive medications was also found amongst asthmatic children (48% were Medicaid patients) attending the emergency department of an inner city academic pediatric hospital in Pennsylvania during 1994: 35% were previously ever prescribed cromolyn and 22% ever prescribed inhaled steroids.[28] Similarly, a study of children hospitalized as a result of an asthma exacerbation found that at most 33% of the children hospitalized for asthma had received cromolyn or inhaled steroids before admission. [49]

A questionnaire completed by the families of 392 asthmatic children living in the inner city, revealed that only 11% were receiving preventive medication. Selecting 166 children with more severe asthma exacerbations requiring an emergency room visit in the past six months, the authors found that even in 1992 over 50% were under-treated and were not receiving preventive medication.[50]

The impact of guidelines on the treatment of a chronic disease such as asthma is dependent on sustained compliance with the recommendations. Low rates of repeat prescriptions for preventive medications have been detected in studies of adults and children. A study of moderate or severe asthmatics [51] (adults and children over 7 years old), showed 63% were dispensed preventive medications (but only 32% were receiving preventive medications regularly). Another study[52] also suggested less than 54% of the patients (adults and children over 12 years) prescribed anti-inflammatory medications were collecting the medications regularly. A study of British children indicated[53] very few (less than 15%) were dispensed preventive medications regularly.

The impact of these NIH guidelines on the emergency department management of childhood asthma has also been studied[54, 55] and also revealed that implementation may be limited. A survey of physicians at academic medical centers with a pediatric residency program found that at most half of those surveyed believed their emergency management of asthma was influenced by the NIH guidelines.[54] A survey of physicians based at a sample of children's emergency departments showed that 45.5% had heard of the guidelines and 24% had read them.[55]

There are many challenges to moving towards providing preventive care for asthmatics and persuading patients not to only attend either the primary care physician's office or

emergency department for urgent care for acute asthma exacerbations.[56, 57] The lack of regular prescribing of preventive medications for some children may show a need for more patient education, provider training, and alternative disease management approaches to introduce the asthma treatment strategies recommended in the NIH guidelines.[58, 59, 60]

Effectiveness of the NIH recommendations for the treatment of childhood

The efficacy of anti-inflammatory medications at reducing airway hyperresponsiveness was demonstrated in clinical trials and these results were the basis for development of the NIH guidelines.[23] Few population based studies have been published on the effectiveness of anti-inflammatory medications for the treatment of childhood asthma. Many researchers have focused on severe asthmatics rather than the population treated by primary care physicians. This population based study reviews the effectiveness of primary care physicians prescribing preventive anti-inflammatory medications under conditions of actual use.

Two studies using claims data bases have shown that inhaled corticosteroid therapy caused a significant reduction in health care service use by asthmatic children. One study reported asthma medication claims data from 6035 insured (non-Medicaid) asthmatic children, at Harvard Pilgrim Health Care (HPHC). The HPHC results showed the percentage of asthma prescriptions dispensed for preventive medications between October 1991 and September 1994 was respectively as follows: beta-agonists 67%, cromolyn 16% and inhaled steroids 11%, theophylline 6%.[38] The study by HPHC demonstrated that preventive medications confer significant protection against exacerbations of asthma leading to hospitalization, but did not investigate other clinical outcomes.

A retrospective case-control study of asthmatic Medicaid children (less than 12 years old) used a North Carolina claims database to follow the health care costs of 85 cases and 72

controls for 1 year.[61,62] The cases began inhaled corticosteroid therapy between March 1994 to 1995. The controls were on asthma therapy other than steroids for a continuous 2-year period between March 1993 to March 1996. The study demonstrated that the introduction of inhaled corticosteroid therapy to Medicaid children was associated with a significant reduction in the total health care costs (hospitalizations, physician visits, outpatient visits and the cost of medications).

A cohort study of the relative risk of readmission to hospital by severe asthmatic patients (age 5-54 years) showed that using inhaled steroids reduced the risk of readmission during the period 16 days to 6 months after the first admission[63] or of fatal or near fatal asthma.[33] The studies have not however always demonstrated a protective effect for severe asthmatics of steroids from readmission of children[64] or patients age (5-45 years) [65] to hospitals.

The NIH guidelines recommend education to support self-management, although there are some conflicting results exist about the efficacy of providing very limited education. Many of the education studies are however difficult to compare as there are few patients studied, and the nature of the intervention and duration all vary considerably. Positive effects on outcomes were found from some programs for children which were designed to promote knowledge and self-management in asthma. For example, a randomized control trial studied the impact over 12 months of an initial training program comprising five 1 hour sessions for the parents and children. This study found an increase in knowledge, compliance and reduced emergency room visits and days of hospitalization.[66] Reductions in hospitalizations and emergency room visits have also been obtained from introducing a pediatric outreach program for an inner city population that were identified as having a history of using these services.[48] Another study of the benefits of introducing a program for inner city children only showed a significant effect of the program on children whose episodes of asthma were severe enough to have been hospitalized in the previous year.[67] A

systematic review and meta-analysis of the published literature on adults concluded that limited asthma education(information only) for adults reduced emergency department visits and improved knowledge but did not reduce hospitalizations or physician visits.[68]

There is evidence to suggest that co-operation between health care providers, parents and children is essential to achieve optimal management.[69] Poor knowledge about asthma will make self-management difficult and lack of parental knowledge has been associated with readmission to hospital [70 71] or emergency department visits.[72 73] Focus groups of urban minority asthmatic children in New York showed many parents and children had very modest expectations of symptom control.[74] Asthma was viewed by the families as "episodic" increasing their emphasis on symptomatic treatment rather than for preventive visits. Many studies have identified poor compliance with preventive medication amongst preschool [75] and school children [76] as well as with adult asthmatics.[53 77 78] Consequently some organizations are experimenting with approaches to implementing the NIH guidelines which integrate patient education with careful co-ordination of medical management for acute and ambulatory care.[57 58 79]

Table 1 NIH guidelines (1991) criteria for classification of asthma by severity of disease

Characteristics	Mild	Moderate	Severe
A. Pretreatment			
Frequency of exacerbations	Exacerbation of cough and wheezing no more often than 1-2 times per week	Exacerbation of cough and wheezing on a more frequent basis than 1-2 times per week. Could have history of severe exacerbations, but infrequent. Urgent care treatment in hospital emergency department or doctor's office <3 times per year.	Virtually daily wheezing. Exacerbations frequent, often severe. Tendency to have sudden severe exacerbations. Urgent visits to hospital emergency departments or doctor's office >3 times per year. Hospitalization >2 times per year, perhaps with respiratory insufficiency or, rarely, respiratory failure and history of intubation. May have had cough syncope or hypoxic seizures.

Table 1 (continued) NIH guidelines (1991) criteria for classification of asthma by severity of disease

Characteristics	Mild	Moderate	Severe
Frequency of symptoms	Few clinical signs or symptoms of asthma between exacerbations.	Cough and low grade wheezing between acute exacerbations often present.	Continuous albeit low grade cough and wheezing almost always present.
Degree of exercise tolerance	Good exercise tolerance but may not tolerate vigorous exercise, especially prolonged running.	Exercise tolerance diminished.	Very poor exercise tolerance with marked limitation of activity.
Frequency of nocturnal asthma	1-2 times per month maximum	2-3 times per week	Considerable, almost nightly sleep interruption due to asthma. Chest tight in early morning.
School or work attendance	Good school or work attendance	School or work attendance may be affected	Poor school or work attendance.

Table 1 (continued) NIH guidelines (1991) criteria for classification of asthma by severity of disease

Characteristics	Mild	Moderate	Severe
Pulmonary function			
a) Peak expiratory flow rate (PEFR)	PEFR>80% predicted. Variability*<20%	PEFR 60-80% predicted Variability 20-30%	PEFR <60% predicted Variability >30%
b) Spirometry	Minimal or no evidence of airway obstruction on spirometry. Normal expiratory flow volume curve; lung volumes not increased. Usually a >15% response to acute aerosol bronchodilator administration, even though baseline near normal.	Signs of airway obstruction on spirometry are evident. Flow volume curve shows reduced expiratory flow at low lung volumes. Lung volumes often increased. Usually a >15% response to acute aerosol bronchodilator administration.	Substantial degree of airway obstruction on spirometry. Flow volume curve shows marked concavity. Spirometry may not be normalized even with high dose steroids. May have substantial increase in lung volumes and marked unevenness of ventilation. Incomplete reversibility to acute aerosol bronchodilator administration
c)Methacholine sensitivity	Methacholine PC20>20mg/ml	Methacholine PC20 2-20mg/ml	Methacholine PC20 <2mg/ml

*Variability: the difference between a morning and evening measure or among morning measurements each day for a week.

Table 1 (continued) NIH guidelines (1991) criteria for classification of asthma by severity of disease

Characteristics	Mild	Moderate	Severe
B. After optimal therapy is established			
Response to and duration of therapy	Response to bronchodilators in 12-24 hours, regular drug therapy is not usually required except for short periods of time.	Periodic use of bronchodilators required during exacerbations fro a week or more. Systemic steroids also usually required for exacerbations. Continuous around the clock drug therapy required. Regular use of anti-inflammatory agents may be required for prolonged periods of time.	Requires continuous around the clock drug therapy including daily corticosteroids, either aerosol or systemic, often in high doses.

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APPENDIX B DETAILS OF THE METHODS

Data source and study population

The data analyzed were from a sample of children (aged 2 to 19 years) treated for asthma during 1994 by the Medicaid program in Pennsylvania, USA. The data were collected during a medical care evaluation for the Department of Public Welfare of the Commonwealth of Pennsylvania.

Medicaid is a program financing medical care for qualifying low-income patients. The eligibility for treatment of children under a Medicaid program is influenced by the parents' income and employment status. A substantial loss of patients due to changes in enrollment status have been reported in a 5 year period.[2] This study was restricted to children eligible for Medicaid enrollment as a minimum for 1994. This time frame is appropriate for studying the outcomes of treatment of childhood asthma because the study was evaluating medication effects which have a rapid onset of action and a reduction in acute asthma exacerbations could be expected to be observed in this time frame.[1]

The data sources for the analyses were the primary care medical records and hospital and emergency department encounter files. Automated medication claims records were provided for comparison with the medical records of 106 patients.

The data elements in Medicaid files that are required for claims payment are considered to have generally good accuracy.[2] However data that are not directly related to claims payment, may be of poorer quality and should be verified. This study included a check of the reliability of the primary care medical records as a source of information on asthma medications by comparing the agreement with medication claims.

Sample size and sampling strategy

Each plan was requested to identify all Medicaid members who were diagnosed and treated for asthma during 1994 (International Classification of Diseases, Ninth Revision, Clinical modification code ICD-9=493) and select a random sample of 50 children (aged 2 to 19 years in 1994) for study.

The asthma diagnoses were confirmed by nurse reviewers checking the primary care medical records and therefore the study did not rely solely on the ICD 9 coding for the asthma diagnosis. Patients without a diagnosis of asthma in the medical records were not included in the study.

The NIH guidelines include an algorithm for differential diagnosis of asthma and recommend a detailed medical history checking for key indicators for a possible diagnosis of asthma, physical assessment and then pulmonary function testing(spirometry) to establish the diagnosis.[3] Mild to moderate cases of asthma may be difficult to diagnose, especially among young children. The guidelines summarize differential diagnosis of asthma and indicate that wheezing by children due to asthma is often confused with wheezing due to recurrent respiratory infections. Reliance on the ICD-9 code alone without verification with the medical records would have been inappropriate for identification of a sample of asthmatic children.

The age of the children 1st January 1994 was calculated from the date of birth. The age range of children included in the cohort was verified to be 2 to 19 years old. Children younger than 2 years old or over 19 years were excluded from the study.

The plans provided 388 medical records and 347 were eligible after verifying the patient's age on 1st January 1994 was between 2 to 19 years old (41 were less than 2 years old).

311 were eligible after confirming there was an asthma visit date with documentation of a prescription for an asthma medication during 1994 (36 out of 347 did not have documentation of a visit during 1994).

Data collection

A data collection instrument was created and abstracting instructions were provided to the nurse reviewers. The data collection was conducted on-site, with a separate data collection instrument for each patient. No data was collected directly from the physicians or patients. The data on asthma treatment provided by plan physicians between 1st January 1993 and 31st March 1995 were abstracted from the medical records.

The nurse reviewers were asked to abstract data on the five most recent asthma related hospital admissions and emergency department visits from January 1993 through March 1995. For each hospitalization or emergency department visit the nurse reviewer documented the admission dates, discharge dates and reason for visit or admission. The reasons listed on the data collection instrument included patients lack of compliance, wrong treatment plan, unusual exposure to trigger, lack of guidance for medication late notification, other and not documented.

For each primary care physician visit the nurse reviewer was asked to abstract from the medical record all the asthma related medications prescribed on each visit date between January 1993 through March 1995. Medication data abstracted from the medical records included details of the asthma medications prescribed (product name, route, directions, days supply), date prescribed and prescriber (primary care physician or other).

The clinical data abstracted included date of birth, gender, date of initial asthma diagnosis, date of latest theophylline level, date of latest influenza vaccination. The data also included

the date of each physician visit (up to 10 visits), the types of patient education provided at each visit (ability to use peak flow meter, ability to use inhaler, how to use inhaled medications, side effects of medication, avoidance of triggers, action plan for exacerbations, use of diaries, and goals of treatment). For each visit there was a record of height, weight, blood pressure, a physical examination, medical history (symptoms and functional status), objective measures of lung function (peak expiratory flow rates, home use of a peak flow meter, spirometry results) and referrals to specialists (dates, type of specialist, reason). These were all recorded for each visit as " yes", "no" or "not documented in the record". In addition the instrument allowed "not applicable " to be recorded for ability to use peak flow meter, ability to use inhaler, how to use inhaled medications, or side effects of medications.

The nurse used the information in the medical records and the NIH guidelines(1991)[3] to classify the asthma severity at each primary care visit as mild, moderate or severe asthma. In the past the diagnosis criteria have varied for classifying asthma severity but the NIH guidelines include a working definition of mild, moderate and severe asthma severity. Access to the medical records allowed the NIH guidelines to be used to classify the children as mild, moderate or severe asthmatics at each physician visit when an asthma medication was prescribed. The analyses were then able to address confounding by asthma severity for example by stratified analyses and including a time dependent covariate for asthma severity in the Cox regression model.

Medication claims from 4 managed care plans were also provided for a sample of 106 of the children (aged 2 to 19 years) treated for asthma during 1994. The medication claims data included all the asthma medications dispensed (product name) and date dispensed.

The data recorded on the instrument were entered into a database and transferred with the automated medication claims records to the Department of Applied Pharmaceutical Sciences at the University of Rhode Island.

Data coding and screening

The analyses were all performed using SAS 6.12. A SAS program was written to ensure that any duplicates of patient records were deleted. Missing values were changed to be represented by a single code for all the variables. Univariate descriptive statistics were examined using programs such as 'Proc Univariate'. A series of checks were made to ensure codes had been programmed appropriately. For age the range of the values, mean and standard deviations were checked to confirm these were plausible.

Asthma severity was coded as mild (1), moderate (2) or severe (3) at each physician visit. The maximum asthma severity recorded during the study period was used to classify the children into mild, moderate and severe asthmatics.

Asthma medications were coded as dichotomous variables :beta-agonists (oral or inhaled), preventive anti-inflammatory medications (inhaled corticosteroids, inhaled cromolyn or nedocromil), oral theophylline or oral corticosteroids. The asthma medications were recorded by generic or Trade Names, so the coding of the asthma medication variables were carefully checked to ensure none of the medications had been missed and were recoded appropriately. Data on the route of administration was missing for too many patients to code oral or inhaled beta-agonists separately.

The seasons were coded as a dichotomous variable for each physician visit. The fall to winter season was coded as 1st October to 31st March.

The dates for hospital admission and emergency department visits were used to determine whether the patients experienced these outcomes within the defined time period. Each variable was coded 1 for each patient experiencing an event or zero for those not having the event within the defined time period.

The data for each patient was transposed to create a data set containing one record per patient. Each record contained the demographic information, plus asthma severity and medications for each primary care physician visit (maximum 10 visits). If the patient attended less than ten visits the data was coded as missing for the remaining visits. A SAS program was written to code the children as receiving undertreatment at each visit where the asthma severity was moderate or severe and no preventive medications were prescribed. For example; each record contained a unique patient identifier code, age, sex, hospital admission (0,1), emergency department visit (0,1), plus for each visit date asthma severity (coded 1,2,3), preventive medications (0,1), oral steroids (0,1), undertreatment (0,1) or season (0,1) etc.

For all the analyses the data collected was censored for 31st December 1994. All the data collected before 1st January 1993 or after 31st December 1994 were excluded from the analyses. For example, some hospital admissions were documented for patients for before 1st January 1993 and these were excluded form the analyses.

For the analyses using data for the period 1st January 1994 to 31st December 1994 the data before 1st January were excluded from the data set. For the Cox regression analyses the beginning of person-time for an individual was defined as the date of the first physician visit when an asthma medication was prescribed between 1st January 1993 and 31st December 1994. The end of person-time was defined as the first date for the outcome under evaluation after the first physician visit (either a hospital admission or an emergency

department visit for asthma or a course of oral steroids) or the end of the study period (31st December 1994).

Prescribing anti-inflammatory medications in accordance with the NIH guidelines was determined by the following dichotomous variables: preventive medication (prescribed at least once), preventive medication prescribed at 50% or more of the visits when other asthma medications were prescribed, undertreatment (preventive medication was not prescribed at least once when the children visited the primary care physician with moderate or severe asthma) or undertreatment at 50% or more of the visits when other asthma medications were prescribed.

For the reliability assessment, the medication claims data selected included the medication data (using date dispensed) for between January to December 1994. The medical record and medication claims data sets were merged using a unique patient identifier code and any unmatched records were not included in the analyses. The medication claims data before the first physician visit were not included in the analyses. Dichotomous codes were created for oral steroids and preventive medications dispensed using the medication claims records.

In order to have confidence in the reliability of the study results the drug exposure classification using medication claims data was compared with the primary care physician medical records, which were the main source of data for our study. Nondifferential misclassification of dichotomous variables may bias the risk estimates towards the null value.[4] but if there is differential misclassification then the effects on relative risk estimates are unpredictable.[5]

The kappa statistic is commonly published in papers to demonstrate the reliability of a method for dichotomous variables.[6] The agreement between the medical records and

claims for the medication dispensed was evaluated by calculating the percent agreement and kappa statistic for two dichotomous medication exposure variables (oral steroid course and preventive medication). In addition differential misclassification of exposure status was evaluated by calculating the kappa statistics for each group of children divided up by outcome.

Multivariate analyses

The outcomes studied were too infrequent to be analyzed as continuous variables, very few patients had more than one event during the study. The outcomes were therefore coded as dichotomous events. Cox regression was therefore the multivariate methods selected for the analyses of the clinical outcomes. For the logistic regression analyses the data analyzed was collected during 1994. The Cox regression analyses were able to adjust for the person-time contributed to the data set and allowed all the data collected between January 1993 and December 1994 to be included in the analyses. Both methods allowed the creation of models from a combination of independent variables which are continuous, categorical, or discrete. Unlike many of the multivariate methods assumptions of multivariate normality, linearity and homoscedasticity are not required for the predictors included in the models.

The SAS procedure PROC PHREG was used for the Cox regression analyses,[7] and PROC LOGISTIC was used for the logistic regression analyses. The analyses used PROC PHREG so that both fixed and time dependent covariates could be included in the models. The coding of data and programming was complex in order to organize the data appropriately for PROC PHREG. The programs were developed from studying examples provided in SAS users' guides.[8 9 10]

The analyses included fixed covariates for preventive medications and preventive medications prescribed at the last visit before the event, so the proportional hazard assumption was checked. The assumption was examined graphically using PROC LIFETEST by checking the plots of cumulative hazard (i.e. log negative log survival probability) against log survival time can be considered parallel for selected dichotomized covariates.

The linearity of the association of continuous variables with each dependent variable studied were examined and the variables coded appropriately before the analyses were progressed, for example, age was dichotomized for some of the multivariate analyses.

Many of the drugs for asthma can appear to increase risk of adverse outcomes because the patients for whom asthma medications are prescribed may have an increased risk of frequent and severe asthma exacerbations.[11] Consequently to address confounding by asthma severity, the multivariate analyses selected the children attending with either moderate or severe asthma before the outcome, included a covariate for severity or for Cox regression included severity as a time dependent covariate. The logistic regression analyses were able to stratify the patients by the maximum asthma severity recorded during the study. This is in line with NIH guidelines which classify patients as mild, moderate or severe based on the history before the asthma is treated.

The introduction of time dependent covariates allows the status of each individual to vary during the study and the Cox regression model no longer assumed the effect of the covariate was the same at all the time points, even when recorded at irregular intervals. The models were able to include time dependent covariates for asthma severity and preventive medications. The Cox regression analyses used both fixed covariates for age or gender and time dependent covariates.

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APPENDIX C OVERVIEW OF MAJOR FINDINGS

There were three major findings from this study of the impact of the NIH guidelines on the treatment of childhood asthma by primary care providers:

1) primary care providers implemented the NIH recommendations by prescribing inhaled anti-inflammatory medications at least once for 61.1% of the children with moderate or severe asthma during 1994

2) the NIH recommendations to provide patient education were not fully implemented by the primary care providers because only 41.8% of the children received any patient education during 1994

3) prescribing preventive medications to children with moderate or severe asthma reduced the risk of being prescribed courses of oral steroids (HR 0.42, 95% CI 0.19-0.95), after adjusting for age and asthma severity.

The results from this study demonstrate the potential impact of the NIH recommendations on the clinical outcomes of asthmatic children. There may be an opportunity to further improve the outcomes for asthmatic children by supporting physicians and pharmacists to more fully implement the NIH recommendations for all the children with moderate or severe asthma.

NIH guidelines recommend treatment of moderate or severe childhood asthma with preventive anti-inflammatory medication (inhaled corticosteroids, cromolyn or nedocromil). The guidelines emphasize the importance of patient education about avoidance of triggers

and the management of asthma (written action plan for exacerbations, goals of treatment and how to use an inhaler).

Children with moderate or severe asthma during 1994 were prescribed a beta-agonist (96%) and 61.1% were prescribed preventive medications at least once. The NIH recommendations were not followed regularly because only 27.0% of the moderate or severe asthmatics were prescribed preventive medication more than once during the year. In addition, providing patient education was only recorded for 41.8% of the children.

The results suggested that the prescribing of preventive medications is related to sentinel clinical events and the NIH recommendations are not always routinely implemented for children with moderate or severe asthma. Logistic regression analyses indicated prescribing preventive medication was associated with moderate or severe compared to mild asthma (aOR 5.34, 95% CI 3.22-8.83) and age 5 to 19 years compared to 2 to 4 years (aOR 2.11, 95% CI 1.19-3.72). Prescribing preventive medication was also associated with a prior emergency department visit (aOR 2.27, 95% CI 1.24-4.16), after adjusting for age.

Children younger than 5 years of age are recommended to be given courses of oral steroids for chronic severe asthma because they may be unable to use inhalers effectively. The NIH guidelines for the use of preventive medications were implemented on at least one occasion for 66.7% of the children aged 5 to 19years old with moderate or severe asthma during 1994. The prescribing was not therefore consistent with fully implementing the NIH guidelines for all the children attending with moderate or severe asthma; even after taking into account the difficulty of treating children under 5 years old with inhaled medications.

The NIH guidelines recommend anti-inflammatory medications but indicate that theophylline can be prescribed for childhood asthma. In this study the prescribing rates for theophylline were very low (4.8%), and cannot therefore account for the apparent undertreatment of moderate or severe asthmatics with inhaled anti-inflammatory products.

The low rates of repeat prescriptions for antinflammatory products amongst the children with moderate or severe asthma in our study cannot be fully explained by poor patient compliance with follow-up primary care visits. In our study, lack of continuity of care cannot completely explain the results because 38.9% of the children with moderate or severe asthma attended the primary care physician more than once and were not prescribed preventive medications. Low rates of repeat prescriptions for preventive medications were also obtained in other studies, although these included both adults and children.[1 2 3] Inadequate attendance for primary care physician follow up visits were shown by a study in asthmatic children in the Medicaid program in Massachusetts.[4]

The reasons for not prescribing preventive medications to all the patients with moderate or severe asthma are not known in the current study. Under-treatment of asthmatic children has however also been recorded in three other studies which reported that at least 50% of the children were not prescribed preventive medication before either an admission to hospital or attending the emergency department.[5 6 7]

The NIH guidelines on the importance of on-going patient education and self-management of asthma do not appear to have been widely implemented by the primary care physicians during this study period. Patient education was documented for less than 50% of the children during 1994, regardless of the type of education. Action plans for severe exacerbations were the most frequent form of patient education provided and were given to the majority of severe asthmatics. Fewer than 25% of the children with moderate or severe

asthma were documented in the medical records as being provided information on the treatment goals or having the ability to use an inhaler correctly confirmed during 1994. No education on avoidance of environmental triggers was given to at least two thirds of the children with mild or moderate asthma and over a third of the children with severe asthma.

In this study increasing asthma severity was associated with review of treatment goals, an action plan and the avoidance of triggers. There was no indication that children received additional patient education after either an emergency department visit or hospitalization. Prescribing preventive medication was associated with the provision of patient education (after adjusting for age and asthma severity), consequently children without preventive medication were also less likely to receive counseling.

One limitation of our study was the use of medical records to evaluate patient education as the quality of the education routinely provided could not be assessed. The extent of the education provided may also have been underestimated; for example the ability to use an inhaler may be checked by pharmacists and not recorded in the medical records. In addition, education may be provided to the patient but not documented in the medical records by the health care provider.

These results could be explained by differences between physicians or managed care plans in the extent to which NIH guidelines are implemented. The study design did not include a sample size large enough to allow comparisons between the different managed care plans or profile the prescribing practices of individual prescribers. For example, asthma specialists have been shown to be more likely to prescribe preventive medications than primary care physicians[8,9] and access to or co-ordination of care by specialists[10,11] may have facilitated implementation of the NIH guidelines by some plans.

Prescribing preventive medication to children with moderate or severe asthma reduced the risk of being prescribed oral steroid courses. Cox regression analyses were conducted with time dependent covariates for being prescribed preventive medications and adjusting for asthma severity (mild, moderate or severe), with a fixed covariate for age. Children diagnosed with moderate or severe asthma at least once who were prescribed preventive medication were less likely to require a course of oral steroids (Hazard Ratio 0.42 95% CI 0.19-0.95), after adjusting for age and asthma severity. No significant association was found using Cox regression between prescribing preventive medications and hospital admissions or an emergency department visits.

Emergency department visits were shown in our Cox regression analyses to be consistently associated with prior severe asthma exacerbations or a course of oral steroids. The Cox regression models included asthma severity and preventive medications as time dependent covariates but could not also include oral steroids because of multicollinearity with asthma severity. A course of oral steroids is recommended by the NIH guidelines for the acute treatment of severe asthma exacerbations and therefore may have reduced the risk of adverse outcomes from undertreatment with inhaled anti-inflammatory medication. For example, one study showed starting or increasing steroid medications at the onset of a cold or flu reduced the odds of asthmatic children making an emergency department visit.[5]

A disproportionate number of Medicaid children have been shown to rely on the emergency department instead of primary care providers for their asthma care[12] and some parents prefer to use the emergency department.[13 14] These patient and various health care system characteristics all pose challenges to Medicaid patients moving away from episodic attendance for crisis orientated, fragmented care for asthma exacerbations.[15 16 17]

In our study emergency department visits were more common amongst 2 to 4 year olds. The NIH guidelines recognize this age group is less likely to be able to successfully co-ordinate inhaling preventive medication, and may have to rely instead on courses of oral steroids for acute exacerbations. The 0 to 4 year age group has been found to exhibit higher hospitalization rates for asthma than other age groups[18 19] and there is evidence of children aged 2 to 4 years old making more emergency department visits.[20 21]

One predisposing factor for emergency department visits or hospital admissions seems to be the season of the year as more events were recorded during fall or winter. Similar results have also been recorded in other studies and viral infections have been suggested as a possible explanation for these seasonal trends.[22 23] In our study, it was not known whether a viral infection was considered the trigger for the asthma-related emergency department visit or hospital admission. Seasonal influences may explain why undertreatment at the last primary care physician visit before an emergency department visit or a course of oral steroids was associated in the Cox regression analyses with a significantly increased risk of both these adverse outcomes. The Cox regression analyses also included a time dependent covariate for season but the small sample size and low event rates may have prevented the study detecting an association between preventive medications and hospitalization or emergency department visits.

Only a few population based studies have been published on the effectiveness of anti-inflammatory medications for the treatment of childhood asthma, many of which have focused on severe asthmatics. However, a case control study of Medicaid children showed prescribing corticosteroid therapy was associated with a significant reduction in the total health care costs (hospitalizations, physician visits, outpatient visits and the cost of medications).[24] Similarly, two studies of asthmatic children demonstrated preventive

medications confer significant protection against exacerbations of asthma leading to hospitalization.[25 26] A cohort study of the relative risk of readmission to hospital by asthmatic patients (age 5-54years) showed that using inhaled steroids reduced the risk of readmission during the period 16 days to 6 months after the first admission[27] or of fatal or near fatal asthma.[28] Other studies have not however always demonstrated a protective effect for severe asthmatics of steroids from readmission of children[29] or patients age (5-45 years) [30] to hospitals.

The information about prescribing medications was collected from the medical records rather than a separate medication claims database, consequently not all the prescriptions may have been actually dispensed or administered regularly as directed. Patient compliance is important for preventive medications to be beneficial and for children it may be especially complex as parents, school nurses and other carers may have to administer the medication. Many studies have identified poor compliance with preventive medication amongst preschool[31] and school children.[32] Patient compliance was not measured in this study, therefore these data may underestimate the value of prescribing preventive medication to these children.

The information collected from this Medicaid asthmatic population may not be generalizable to other children.[33] The Medicaid eligibility criteria for this study means all the children were from poor families. It was not possible to compare the results from this Medicaid group with other patients attending these plans. In the present study medications were free for the patients; thus there was no cost incentive for patients to avoid having prescriptions dispensed for preventive medications.

The managed care plans guarantee access for these Medicaid patients but there are many differences between poor minority families and health care providers that may influence

prescribing practices for example language, cultural barriers, or literacy levels.[34] Indoor allergens, such as cockroaches, dust mites, pets or cigarette smoke are now recognized as important triggers for asthma, which may be particularly difficult for Medicaid eligible children to avoid.[35 36]

The low socioeconomic status of these children means they might be unable to avoid some environmental triggers, have a higher frequency of severe asthma,[37 38] and experience a lack of continuity of care more than insured children[15 16 17] or under-use preventive services for asthma.[39 4] The effectiveness of prescribing in accordance with the NIH guidelines was still however, clearly demonstrated as preventive medication significantly reduced, and undertreatment of moderate or severe asthma significantly increased the risk of prescribing a course of oral steroids. Reducing the asthma exacerbations requiring oral steroids would be expected to improve the quality of life for the children.

This population-based study supports the effectiveness of prescribing inhaled preventive anti-inflammatory medication under conditions of actual use by a Medicaid population. This study shows that primary care physicians can improve the control of asthma by implementing the NIH guidelines and regularly prescribing anti-inflammatory medication for moderate or severe asthma. Our results also showed there was limited implementation of the NIH recommendations for prescribing preventive medication and providing patient education, which may have reduced the impact of the guidelines on improving the management of childhood asthma. This study supports the need for interventions to increase implementation of the NIH guidelines by primary care physicians and improve the treatment of childhood asthma.

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