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Outcomes of stepping down asthma medications in a guideline-based pediatric asthma management program

Matthew A. Rank, MD^{*}; Megan E. Branda, MS[†]; Deborah B. McWilliams, MD[‡];
Shirley K. Johnson, MSN, RN, CPNP[‡]; Shefali A. Samant, MD[§]; Jenna C. Podjasek, MD[§];
Miguel A. Park, MD[§]; and Gerald W. Volcheck, MD[§]

^{*} Division of Allergy, Asthma, and Immunology, Mayo Clinic, Scottsdale, Arizona

[†] Division of Healthcare Policy and Research, Mayo Clinic, Rochester, Minnesota

[‡] Division of Community Pediatric and Adolescent Medicine, Mayo Clinic, Rochester, Minnesota

[§] Division of Allergic Diseases, Mayo Clinic, Rochester, Minnesota

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ABSTRACT

Background: Little is known about outcomes after stepping down asthma medications within an asthma management program.

Objective: To determine outcomes of stepping down asthma medications in a pediatric asthma management program.

Methods: We performed a retrospective study of 5- to 18-year-old children with asthma in an integrated primary care practice in the United States. Data were included on participants from March 1, 2009, until December 31, 2011. We first determined whether a child was eligible for step down and next recorded whether a step-down attempt was made and if the attempt was successful. In addition to descriptive statistics for the sample demographics and the outcomes of stepping down, univariate and multivariate analyses were performed to determine predictors of successful asthma medication step-down attempts.

Results: Of the 477 children sampled for this study, 264 (55.3%) had a guideline-eligible opportunity to step down asthma medications. An attempted step down occurred in only 89 (33.7%) of children who had guideline-eligible opportunities. A total of 166 children (34.8%) attempted a step down of asthma medication at least once (including those guideline ineligible to step down). Of children with follow-up, 96 (71.6%) of step-down attempts were successful. Time of year (any season except fall) when the step down was attempted predicted successful step down in univariate and multivariate analysis (odds ratio = 3.81; 95% confidence interval, 1.23–11.85; $P = .02$). Being guideline eligible for step down predicted successful step down in univariate analysis only (odds ratio = 2.51; 95% confidence interval, 1.16–5.43; $P = .02$).

Conclusion: Our findings from this sample of children participating in an asthma management program suggest that stepping down asthma medication based on National Asthma Education and Prevention Program 3 guidelines is frequently successful.

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Introduction

Asthma is a common chronic disease in the pediatric population; most children who have asthma require ongoing disease management. Identifying strategies to adjust medications when managing chronic diseases poses a challenge to health care systems, which may not be designed for addressing such issues when a patient is doing well or is symptom free. For busy patients and health care professionals, the path of least resistance may be to

continue the use of medications when their use may be discontinued or could be stepped down. Stepping down asthma medications may benefit individuals by decreasing adverse effects, treatment burden, and costs. However, stepping down asthma medications also may lead to an increased risk of asthma exacerbations. The most recent national asthma guidelines (National Asthma Education and Prevention Program [NAEPP] 3 from 2007) suggest stepping down asthma medications when asthma is stable for 3 months.¹ In this report, we describe the frequency and success of stepping down asthma medication in a cohort of pediatric patients enrolled in a pediatric asthma management program (PAMP) modeled on the NAEPP-3 guidelines.

Several studies provide preliminary information about outcomes of stepping down asthma medications. Clinical trials suggest that

Reprints: Matthew A. Rank, MD, Mayo Clinic, 13400 E Shea Blvd, Scottsdale, AZ 85259; E-mail: rank.matthew@mayo.edu.

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many patients currently treated with inhaled corticosteroids (ICSs) and long-acting β -agonists or ICSs alone can be successfully stepped down.^{2–16} Use of a multidisciplinary care management team incorporating frequent patient contact has been another strategy associated with successfully stepping down asthma medications.^{17–20} Another type of asthma step down is nonadherence. Individuals who are encouraged to take asthma controller medications may not take them regularly (they forget) or intentionally decide to no longer take them (because of adverse effects, cost, or improvement in symptoms). A recent study suggests that approximately 25% of all asthma exacerbations can be attributed to poor adherence to asthma controller medications.²¹ High levels (>75%) of adherence are needed to prevent asthma exacerbations; most studies of adherence to long-term asthma medications find low adherence rates (range, 21%–70%).^{22–25} The preliminary data suggest many individuals can safely step down their asthma controller medications. However, determining which patients may be safest for stepping down and how to effectively do this in a clinical practice setting is not well established.

Data from clinical practice suggest that asthma step-down attempts are few and that most decisions to step down asthma medications are not made during a traditional outpatient visit.²⁶ In our study, an active management program reached out to children and their families, usually by telephone, which allowed for step-wise adjustments if deemed guideline appropriate by the management team. Also in this study, we are able to distinguish between step-down attempts that were guideline appropriate and those that were not (patient or family initiated without being eligible for step down based on the guideline recommendations). Data from this study will help guide health care professionals who consider stepping down asthma controller medication for children in their practice.

Methods

Study Design, Setting, and Participant Identification

This study was a retrospective sample of children aged 5 to 18 years who were enrolled in a PAMP. The PAMP was set in the employee and community health practice, an integrated primary care medical practice with 6 clinic sites in Rochester, Minnesota, serving a patient panel of approximately 140,000 including approximately 40,000 children receiving primary care from 18 pediatricians, 57 family medicine physicians, 8 pediatric nurse practitioners, 20 family medicine nurse practitioner or physician assistants, and 65 pediatric and family medicine residents. Prevalence of pediatric asthma in this population is estimated to be 12%. This study was performed with approval from the Mayo Clinic Institutional Review Board in accordance with federal regulations.

Children were identified for the study using a database of participants in the PAMP. Only children and their families who provided consent for medical record review were included in the sample. Children eligible for enrollment in care management had either persistent asthma (requiring daily ICSs), a history of an emergency department or hospital visit for asthma during the past 12 months, or uncontrolled asthma symptoms per the NAEPP guidelines. Eligible children could agree to have a nurse care manager aid their primary care provider in the care of asthma until they were doing well enough to “graduate” from the program. At any time, approximately 25% of the pediatric asthma population in the employee and community health practice is actively enrolled in the PAMP. Care managers would meet with patients who had appointments in the office, but almost 90% of the care provided by care managers was by telephone following the NAEPP-3 recommendations for appropriate timing of follow-up (with a mean of 4 care manager contacts per patient per year).

Description of Program

The PAMP was developed with an interdisciplinary team of primary care providers with enrollment of the first child in March 2009. The PAMP has a medical director (D.B.M.), with 4 other primary care providers (physician or nurse practitioner) and a nursing supervisor providing oversight, as well as a team of 8 nurses acting as “care managers” for asthma. Care manager competencies included training in triage/assessment, knowledge, documentation, patient education, facilitation, and communication. The training followed standard algorithms derived from the NAEPP-3 guidelines, including decisions about when to consider stepping down asthma medications based on symptom control and objective measures such as spirometry. The goals of the PAMP are as follows: (1) follow evidenced-based guidelines (NAEPP-3) to provide consistent care within/across sites; (2) provide proactive, longitudinal nonvisit care as opposed to reactive, episodic care, including more frequent assessment of symptom control and barrier assessment (medication adherence, concern of adverse effects, trigger identification and environmental control, need for education such as inhaler technique, and issues affecting self-efficacy); (3) generate and use an electronic medical record–based registry for population management, which includes providing care for those patients not contacting the health care system on their own; and (4) provide support for busy primary care providers via completion of forms. The PAMP is an ongoing practice initiative, and for the purposes of this study, data were included on participants from March 1, 2009, until December 31, 2011.

The main assessment tool used in the PAMP is the Asthma Control Assessment (ACA), a questionnaire adapted from NAEPP-3 to target both the risk and impairment domains of asthma (see eFig 1 for the questions included in the ACA). In addition to questions focusing on risk and impairment, the ACA had questions about adherence (with 5 discreet choices to estimate how frequently scheduled asthma medications were taken), confidence (with 5 discreet choices estimating self-efficacy of patients and their families), and smoke exposure (firsthand or secondhand).

Data Abstraction

The data were abstracted by the authors from the medical record, which included asthma management flow sheets, notes from providers and nurse care managers, and pulmonary function testing. The data were entered into a database using REDCap software, an electronic data capture tool hosted at Mayo Clinic.

Definitions

A step-down attempt was defined as any decrease in an asthma controller medication and was classified into the following categories based on the NAEPP-3 guidelines: a decrease in inhaled corticosteroids but not enough to change the step-level of treatment, step 2 to 1, step 3 to 1, step 3 to 2, and so on. A step-down attempt could be based on the recommendation of the provider/nurse manager or a choice made independently by the patient and their family. A guideline-eligible step-down opportunity was based on the definition of stable asthma put forward by the NAEPP-3 and for the purposes of this study was as follows: green zone (“well-controlled” asthma symptom frequency per NAEPP-3) on ACA for 3 months or more, no abnormal pulmonary function test results for 3 months (defined as forced expiratory volume in 1 second [FEV₁] out of normal predicted range, a decreased FEV₁ to forced vital capacity ratio based on predicted range, or an elevated oral exhaled nitric oxide level), no systemic corticosteroids for 3 months, and no emergency department or hospital visits for asthma in the past 12 months. Therefore, a step-down attempt either met all of these conditions (guideline eligible) or did not (guideline ineligible).

Successful step down of asthma medications, for the purposes of this study, was defined as being in the green zone on the ACA, normal pulmonary function test results, no systemic corticosteroid use, and no emergency department or hospital visits for asthma for at least 3 months after the attempt. The timing of the step-down attempt was divided into these categories: fall (September–November), winter (December–February), spring (March–May), and summer (June–August).

Statistical Analysis

Descriptive terms were used for demographics (age, sex, smoke exposure, FEV₁, NAEPP level on entering the program, and confidence and adherence to treatment). We described the proportion of individuals with a step-down opportunity and the total number of step-down opportunities (including multiple opportunities for any one individual). The frequency of successful step down was calculated based on the first step-down attempt and then calculated by category (NAEPP-3 guidelines followed or not followed). We performed both univariate and multivariate analysis based on the outcome of successful or unsuccessful step down using the following variables: age, sex, adherence, FEV₁, smoking exposure, type of step down (eg, step 2 to step 1), and whether the stepdown was guideline eligible. In the multivariate analysis, we imputed missing values for smoking exposure based on age and sex and FEV₁ based on age, sex, and smoking status. These values were found to be missing at random and were imputed 5 times to populate the missing values. No model findings were affected by the different imputations, and for ease of presentation only one imputation results are presented. Statistical analysis was performed using SAS statistical software, version 9.2 (SAS Institute Inc, Cary, North Carolina).

Results

We identified 898 children who were enrolled in the program and randomly sampled 477 children for this study. The mean age of children in the sample was 11 years, 41.9% were female, the mean FEV₁ percent predicted was in the normal range, most did not have regular tobacco exposure (78.0%), and most reported high self-efficacy and adherence. The mean time in the PAMP was 15 months, with a mean of 4 assessments. Most children entered the program with asthma medications placing them at NAEPP treatment level 1, 2, or 3. The demographics of the sample are summarized in Table 1.

Table 1
Demographics of the study sample

Demographic	No. (%) of participants ^a (N = 477)
Age, mean (SD), y	11.0 (3.7)
Female	200 (41.9)
Prebronchodilator FEV ₁ , mean (SD), % predicted	97.8 (14.1)
No tobacco exposure	372 (78.0)
Adherence to medications >90%	359 (75.3%)
Confidence/self-efficacy very high	343 (71.9%)
Length of program enrollment, mean (range), mo	14.8 (1–37)
No. of assessments, mean (SD)	4.3 (2.5)
NAEPP level on enrollment, n (%) ¹	
1	119 (24.9%)
2	210 (44.0%)
3	105 (22.0%)
4	29 (6.1%)
5	14 (2.9%)
6	0 (0%)

Abbreviations: FEV₁, forced expiratory volume in 1 second; NAEPP, National Asthma Education and Prevention Program.

^aData are presented as number (percentage) of participants unless otherwise indicated.

Of the 477 children included in our sample, 264 (55.3%) had an opportunity (based on NAEPP-3 guideline eligibility) to step down asthma medications. Of the guideline-eligible opportunities to step down asthma medications (n = 264), there were 89 guideline-eligible step-down attempts (33.7%) (see Fig 1 for summary). Of those who were not guideline eligible to step down asthma medication (n = 213), 76 (35.7%) attempted stepping down asthma medications.

Of the 477 children, 166 (34.8%) attempted to step down their asthma medication at least once, regardless of guideline eligibility for step down (31 made 2 attempts, 5 made 3 attempts, and 1 made 4 attempts). We analyzed the first step-down attempt for each child and found 96 (57.8%) were successful, 38 (22.9%) not successful, and 32 (19.3%) we were unable to judge because of inadequate follow-up during the study period. Thus, when follow-up was available, first time step down was successful 72% of the time for children in this asthma management program. Of attempts with follow-up available, there were 74 guideline-eligible step-down attempts and 60 non-guideline-eligible step-down attempts. Fifty-nine of 74 guideline eligible steps were successful (79.7%) compared with 37 of 60 non-guideline-eligible attempts (61.7%). Children guideline eligible and guideline ineligible for step down had similar proportions of follow-up data available: 74 of 89 (83.1%) and 61 of 76 (80.3%), respectively.

Odds ratios were calculated with 95% confidence intervals for predictors for successful step down of asthma medications and revealed that being guideline eligible and making the attempt during spring, summer, or winter (as opposed to fall) were significantly associated with successful step down ($P < .05$ for both, see Table 2 for univariate analysis summary results). In a multivariate model that included age, sex, tobacco exposure, and FEV₁, stepdown type, stepdown eligibility, and time of season were significantly associated with successful step down of asthma medication. However, being guideline eligible for step down, which was found to be significant in univariate analysis, demonstrated a trend toward significance, with an odds ratio of 2.18 (95% confidence interval, 0.93–5.08, $P = .07$). Table 3 summarizes the results from the multivariate analysis.

Discussion

We found that children participating in an asthma management program frequently have step-down opportunities (55.3% of

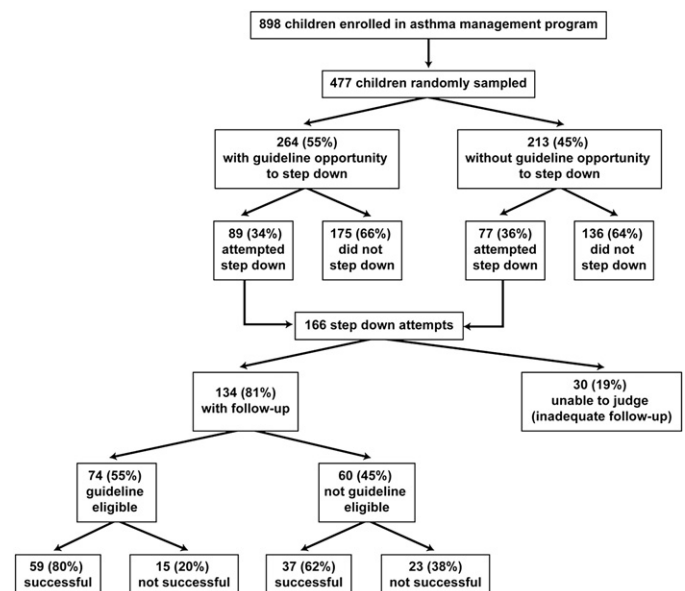


Figure 1. Step down attempts and outcomes.

Table 2

ORs for successful step down of asthma medications: univariate analysis

Variable	OR (95% CI)	P value
Age	1.06 (0.94–1.19)	.35
Sex (female vs male)	1.05 (0.48–2.29)	.91
FEV ₁	1.03 (1.00–1.06)	.07
Smoking status (exposure vs no exposure)	0.56 (0.18–1.69)	.30
Time of year (all other seasons vs fall season)	3.90 (1.3–11.4)	.02
Type of step down (decrease in dose not enough for step down vs all others)	0.70 (0.24–2.04)	.51
Guideline eligible	2.51 (1.16–5.43)	.02

Abbreviations: CI, confidence interval; FEV₁, forced expiratory volume in 1 second; OR, odds ratio.

children) based on the current NAEPP-3 guidelines but that step-down attempts occurred only 33.7% of the time when such an opportunity existed. Step-down attempts were successful 71.6% of the time, and step-down attempts were frequently successful even when not guideline eligible (61.7% of the time). The single strongest predictor we identified for successful step down of asthma medication was the time of year when the step down was attempted. The next notable predictor of successful step down was being guideline eligible, which was significant in univariate but not multivariate analysis. These findings suggest that step-down opportunities are frequently available and are frequently successful; extra caution should be considered during the fall season and when a child is not guideline eligible to step down.

The rates of successful step down are similar to previous clinical trials in which specific step-down attempts were made.^{2–16} Our data suggest that clinical practice, when supported by a disease management team, can likely accomplish successful asthma step down in a large number of asthma patients. Active disease management may differ from usual clinical practice. In a year-long study of children and adults in 2002–2003 by Yawn et al,²⁶ only 78 step-down attempts in 397 individuals occurred (34 of which were patient initiated). This finding compares with our data where 208 total attempts (including first and additional attempts) were made in 477 individuals over a mean of 15 months (almost double the rate seen in the report from Yawn et al). These results are not surprising, given the structure of the PAMP, but are important when considering health system changes that may facilitate successful step down of asthma medications. Another key finding from this study is that only 34% of guideline-eligible attempts were acted on, which suggests there may be several barriers to attempting step down even in an actively managed program. The reasons for not stepping down when there appeared to be opportunities were not identified based on the current study design. Studies designed to understand the reasons that children, their families, and health care providers elected not to step down when an opportunity appeared to exist will shed further light on the decision-making behind stepwise asthma medication adjustments. Additional

Table 3ORs for successful step down of asthma medications: multivariate analysis^a

Variable	OR (95% CI)	P value
Age	1.06 (0.93–1.21)	.41
Sex (female vs male)	0.93 (0.39–2.23)	.87
FEV ₁	1.02 (0.99–1.05)	.27
Smoking status (exposure vs no exposure)	0.67 (0.20–2.29)	.52
Time of year (fall season vs all other seasons)	3.81 (1.23–11.85)	.02
Type of step-down (decrease in dose not enough for step down vs all others)	0.85 (0.26–2.75)	.78
Guideline eligible	2.18 (0.93–5.08)	.07

Abbreviations: CI, confidence interval; FEV₁, forced expiratory volume in 1 second; OR, odds ratio.^aVariables included were age, sex, FEV₁, smoking exposure, time of year, type of step down, and guideline eligibility.

studies testing novel health care systems may be needed to optimize stepwise medication adjustments for asthma.

There are several limitations to consider in this study. First, there is no control group of children enrolled who were under usual care (ie, not enrolled in the PAMP); therefore, the applicability of our findings to practices without such a program are unknown. Second, this was a retrospective, noncontrolled study, and decisions about stepping down were made by many different health care providers. Interpreting data collected retrospectively introduces the possibility of bias. This is also a strength of the study by serving as evidence that stepping down asthma medications can be successful outside the setting of clinical trials. Third, we defined successful step down based on a 3-month follow-up interval. It will be important to determine outcomes of step down for a longer period, such as 1 year. Fourth, the predictors of successful asthma step down are only preliminary and need to be validated in other samples. The development of a predictive model for asthma step down may prove useful for health care providers discussing the option of stepping down asthma medications with children and their families. Fifth, the study may be underpowered to find significant differences for all of the factors we tested; for example, our finding that guideline eligibility was not associated with a statistically significant increase in step down success needs to be studied in larger and separate samples before we consider abandoning such guidelines.

In summary, we have extended the findings from clinical trials that report results from specific medication step-down strategies to outcomes from a disease management program that includes multiple step-down types. Our findings from this sample of children participating in an asthma management program suggest that guideline-based stepping down of asthma medication is an option that should be frequently considered and will be frequently successful.

Acknowledgments

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Supplementary Data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ana.2013.02.012>

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Adolescent Asthma Control Assessment (Ages 12 and older)

This form collects information that is part of the medical record. **Discard after electronic entry.**

Mayo Clinic Number	Patient Name (First, Middle, Last)	Date Today (Month DD, YYYY)
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These questions will help you describe your asthma and how it is impacting your life. It will help us determine how well controlled your asthma is. Please check ☒ in the one box that best describes your answer.

1. **During the last MONTH**, on average how many days did you have asthma symptoms?
(such as wheezing, coughing, chest tightness, shortness of breath)

Not at all ☐ 0	1-2 times a week ☐ 1	3-6 days a week ☐ 2	Once a day ☐ 3	Throughout the day ☐ 4
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2. **During the last MONTH**, how many times did asthma affect your sleep?
(such as wheezing, coughing, chest tightness, shortness of breath)

Not at all ☐ 0	1-2 times a MONTH ☐ 1	3-4 times a MONTH ☐ 2	2-3 nights a WEEK ☐ 3	4 nights a week or more ☐ 4
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3. **During the last MONTH**, on average how much did asthma limit your normal activity? (such as running, playing, attending school)

Not at all ☐ 0	Almost never ☐ 1	A little ☐ 2	Moderate ☐ 3	A lot ☐ 4
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4. **During the last MONTH**, on average how many times did you use a "rescue medicine" such as Albuterol because of asthma symptoms?
Do not include Albuterol used for pre-treatment. (such as taking Albuterol to prevent symptoms before exercise)

Not at all ☐ 0	1-2 times a week ☐ 1	3-4 times a week ☐ 2	Daily ☐ 3	Several times a day ☐ 4
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5. **During the last YEAR**, did you require a burst of steroids for an asthma flare (pill, liquid, or injection form)?
(such as Prednisone, Prednisolone, Prelone, Dexamethasone, Decadron)

Not at all ☐ 0	1 time this past YEAR ☐ 1	2 times this past YEAR ☐ 2	3 or more times this past YEAR ☐ 3
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6. **How controlled has your asthma been over the last month?**

Completely ☐ 0	Well ☐ 1	Somewhat ☐ 2	Poorly ☐ 3	Not at all ☐ 4
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Determining level of asthma control

Green Zone If all of your answers were 0 or 1, your asthma is likely well controlled.

Yellow Zone If you have any answers of 2 or 3, your asthma is likely not well controlled

Red Zone If you have any answers of 4, your asthma is likely under poor control.

If you are in the **Yellow Zone** or **Red Zone**, please talk with your health care provider.

Please complete back of form.

eFigure 1. Adolescent asthma control assessment.

Adolescent Asthma Management Questionnaire

Mayo Clinic Number	Patient Name <i>(First, Middle, Last)</i>	Date Today <i>(Month DD, YYYY)</i>
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1. How confident are you in your ability to care for your asthma and knowing what to do?

☐ Almost Always (>90%) ☐ Most of the time (>75%) ☐ Sometimes (50%) ☐ Rarely (<25%) ☐ Never (0%)

2. If a daily controller medication is prescribed, how often are you taking your daily medication? (such as Flovent, Asmanex, Advair)

☐ Almost Always (>90%) ☐ Most of the time (>75%) ☐ Sometimes (50%) ☐ Rarely (<25%) ☐ Never (0%) ☐ NA

3. Do you have any concerns about possible side effects of your asthma medications? ☐ Yes ☐ No

If so, what concerns? _____

4. Which of the following seem to trigger your asthma flares?

☐ Yes ☐ No Allergy
☐ Yes ☐ No Sinusitis
☐ Yes ☐ No Acid reflux
☐ Yes ☐ No Respiratory infection
☐ Yes ☐ No Exercise
☐ Yes ☐ No Weather
☐ Yes ☐ No Other _____ (explain)

5. What is your smoke exposure? ☐ family member/caregiver smokes ☐ I/teen smokes ☐ I/teen used to smoke ☐ none**6. In the past 12 months:**

How many times did you go to the Emergency Room for asthma or wheezing? ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4+

How many times were you hospitalized for asthma or wheezing? ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4+

7. In the past 12 months, how many days of school or work were missed because of asthma symptoms?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 or more

eFigure 1. (continued).