

Validation of Parental Reports of Asthma Trajectory, Burden, and Risk by Using the Pediatric Asthma Control and Communication Instrument

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What is already known about this topic? National asthma guidelines recommend that clinicians routinely assess multiple dimensions of asthma morbidity. Patient-reported outcomes are emerging as an important clinical measure. Most asthma questionnaires measure only asthma control.

What does this article add to our knowledge? The Pediatric Asthma Control and Communication Instrument domains of Direction, Bother, and Risk are valid and discriminating measures of parent-reported asthma morbidity. A brief questionnaire can be used by clinicians to simultaneously measure multiple dimensions of asthma morbidity.

How does this study impact current management guidelines? The Pediatric Asthma Control and Communication Instrument offers clinicians a new means to meet guideline recommendations to assess multiple dimensions of asthma health.

BACKGROUND: Despite a growing interest, few pediatric asthma questionnaires assess multiple dimensions of asthma morbidity, as recommended by national asthma guidelines, or use patient-reported outcomes.

OBJECTIVE: To evaluate a questionnaire that measures multiple dimensions of parent-reported asthma morbidity (Direction, Bother, and Risk).

METHODS: We administered the Pediatric Asthma Control and Communication Instrument (PACCI) and assessed asthma

control (PACCI Control), quality of life, and lung function among children who presented for routine asthma care. The PACCI was evaluated for discriminative validity.

RESULTS: A total of 317 children participated (mean age, 8.2 years; 58% boys; 44% African American). As parent-reported PACCI Direction changed from “better” to “worse,” we observed poorer asthma control ($P < .001$), mean Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) scores ($P < .001$), and FEV₁% ($P = .025$). Linear regression showed that, for each change in PACCI Direction, the mean PACQLQ score decreased by -0.6 (95% CI, -0.8 to -0.4). As parent-reported PACCI Bother changed from “not bothered” to “very bothered,” we observed poorer asthma control ($P < .001$) and lower mean PACQLQ scores ($P < .001$). Linear regression showed that, for each change in PACCI Bother category, the mean PACQLQ score decreased by -1.1 (95% CI, -1.3 to -0.9). Any reported PACCI Risk event (emergency department visit, hospitalization, or use of an oral corticosteroid) was associated with poorer asthma control ($P < .05$) and PACQLQ scores ($P < .01$).

CONCLUSIONS: PACCI Direction, Bother, and Risk are valid measures of parent-reported outcomes and show good discriminative validity. The PACCI is a simple clinical tool to assess multiple dimensions of parent-reported asthma morbidity, in addition to risk and control. © 2014 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2014;2:186-92)

Key words: Risk; Children; Burden; Trajectory; Survey; Validation; PACCI; Patient-reported outcomes

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Abbreviations used

ANOVA-Analysis of variance

FEV₁-Forced expiratory volume in the first second

FEV₁%-FEV₁ percent predicted

NIH-National Institutes of Health

PACCI-Pediatric Asthma Control and Communication Instrument

PACQLQ-Pediatric Asthma Caregiver Quality of Life Questionnaire

Asthma guidelines published by the National Institutes of Health (NIH) suggest that health care providers assess multiple dimensions of patient asthma morbidity, including the signs and symptoms of asthma, quality of life and/or functional status, history of exacerbations, pharmacotherapy (adherence, adverse effects), lung function, and patient-provider communication.¹ The guidelines encourage clinicians to use patient self-assessment questionnaires as a means of obtaining information on these dimensions of asthma control from the perspective of the patient and/or the patient's family. However, most currently available self-assessment questionnaires evaluate just one or two of these dimensions of morbidity,²⁻⁵ always impairment, and rarely risk. Furthermore, these questionnaires do not capture the patient or parent perspectives regarding quality of life or changes (improvements or worsening) in disease morbidity.⁶

We have shown that clinicians do use multiple dimensions of asthma health to assess and treat asthma,⁷⁻⁹ including disease trajectory (eg, direction of asthma getting worse or better), burden (bother), and risk for poor outcomes. Analysis of those findings, along with asthma guidelines and other published work, suggests that the treatment decisions made by health care providers involve a multiplicity of clinical assessments and cognitive tasks.¹⁰ Therefore, if clinicians are truly to provide care consistent with national asthma guidelines, then there may be a benefit to development and validation of tools that facilitate the work of clinicians to successfully carry out as many of these clinical assessments and tasks as possible.

The Pediatric Asthma Control and Communication Instrument (PACCI) is a parent-completed assessment questionnaire that assesses 5 dimensions of asthma health. The PACCI has previously been validated as a measure of asthma control,¹¹ as has the adult version, the Asthma Control and Communication Instrument.¹² The purpose of this study was to evaluate the validity of 3 other PACCI domains unique from control: disease trajectory (Direction [eg, asthma getting worse or better], burden [Bother], and Risk domains [systemic use of corticosteroids, emergency department (ED) visits, hospitalizations]) in a diverse pediatric sample, including black, Latino, and Spanish-speaking children, across the age spectrum (0-21 years).

METHODS

Questionnaire development and content

The development of the PACCI has been previously described.¹¹ It is written at a fifth-grade reading level, has been validated to measure asthma control among diverse, English- and Spanish-speaking patient populations, and is intended to help clinicians better use patient-parent reported information to guide asthma treatment. The PACCI is a 12-item parent-completed questionnaire (see Figures E1 and E2 in this article's Online Repository at www.jaci-inpractice.org) that assesses 5 conceptual

domains of asthma morbidity (direction, bother, risk, adherence, and control). The assessments are based on parental report of the child's asthma since the last visit with the physician (or over the past 2 months if the child has not previously seen the physician). The current analysis focuses on 3 of the 5 domains:

1. Direction: the trajectory of how the child's asthma has changed (better, the same, or worse).
2. Bother: how much the parent is bothered by the child's asthma (not bothered, somewhat bothered, very bothered) as an indication of how burdensome asthma has been on the child's parents.
3. Risk: the occurrence of ED visits, hospitalizations, and/or oral corticosteroid use for asthma.

Procedures

This was a cross-sectional study that took place between July 2007 and September 2010. This study was approved by the Johns Hopkins University and University of California, San Francisco, institutional review boards. Before seeing a clinician, the parents completed the following: the PACCI; established questionnaires that measure asthma morbidity (described below); and a demographic questionnaire. Spirometry was obtained only at the Johns Hopkins Children's Center, at the discretion of the treating clinician.

Sample

A convenience sample of subjects was recruited among patients who presented for outpatient asthma care at Johns Hopkins Children's Center or the University of California, San Francisco, in established asthma specialty care clinics with practices modeled after NIH guidelines. The patients were seen by pediatric pulmonologists, general pediatricians, and nurse practitioners. Subjects were eligible if they (1) had self-reported physician-diagnosed asthma, (2) were accompanied by a caregiver who could give consent, and (3) spoke English or Spanish. Caregivers provided informed consent, and children older than 8 years of age provided assent in their preferred languages.

Established asthma morbidity measures

Asthma control was measured by using the PACCI Control domain, which has been validated previously.¹¹ For this analysis, control was scored in 2 ways:

1. Sum score is a summation of the score assigned to each response option (0-5 for questions 7, 8, 10, 11; 0-4 for question 9), which range from 0 (best asthma control) to 19 (worst asthma control).
2. Problem index dichotomously scores each of the 5 Control items (questions 7-11) as 0 ("green" responses) or 1 (all other responses), which are then summed and which range from 0 (no control problems) to 5 (5 control problems).

The Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ)¹³ consists of 13 questions that assess the impact of asthma on activity limitation (4 questions) and emotional function (9 questions) during the previous week. Each question is scored on a 7-point scale. The final PACQLQ score is a mean of the 13 scores, with higher scores indicating better quality of life. The PACQLQ has been shown to be a valid measure of asthma-specific quality of life for children with stable and unstable asthma, and with different levels of asthma severity.¹⁴⁻¹⁶ The emotional function domain of the PACQLQ is designed to

TABLE I. Sociodemographic and asthma morbidity characteristics of participants (n = 317)

Sociodemographic Characteristics	
Age (y), mean $\pm$ SD (range)	8.2 $\pm$ 4.8 (0.48-20.54)
Girls, %	42
Ethnicity, %	
African American	42.6
White	31.2
Latino	15.5
Other	5.4
Unknown	4.4
Parental education, %	
Less than 12th grade	7.3
High school graduate	19.8
Some college or technical school	25.8
College graduate	14.5
Postcollege graduate	17.9
Unknown	14.5
Asthma morbidity indicator, % patients	
Level of asthma control by PACCI controlled	39.1
Partly controlled	25.2
Uncontrolled	25.6
Poorly controlled	10.1
Parent-reported disease trajectory, % patients	
Better	50.8
Same	40.6
Worse	8.6
Parent-reported disease burden, % patients	
Not bothered	40
Somewhat bothered	51
Very bothered	9
PACQLQ score, mean (95% CI)	
Overall	5.5 (5.3-5.6)
Emotional function	5.5 (5.3-5.6)
Activity limitation	5.1 (4.9-5.3)
Asthma control, PACCI Sum Score, mean (95% CI)	4.3 (3.9-4.8)
PACCI Problem Index, mean (95% CI)	1.7 (1.5-1.8)

capture a range of possible parental feelings that may be present due to the child's asthma, including feeling "helpless or frightened," frustrated or impatient," "upset," "bothered," and "worried or concerned." The total score for the emotional function domain is the mean of the item scores that make up that domain. The activities limitation domain inquires about the frequency of changed family plans, missed work, sleepless nights, and nocturnal awakenings due to the child's asthma. We examined the total PACQLQ score as well as total scores for the activity limitation and emotional function domains separately. Spirometry was obtained at Johns Hopkins Children's Center at the discretion of the clinician for the 79 children (25% of the participants) who were able to perform the spirometry due to age (ie, those who were ≥ 5 years of age).

Analysis

Descriptive statistics (means and proportions) were used to characterize the sociodemographic and clinical characteristics of the study population. To test for discriminative properties, we

examined mean asthma PACCI Control (sum score, problem index), PACQLQ, and lung function (FEV₁ percent predicted [FEV₁%] and FEV₁:FVC ratio) values across the PACCI domains of Direction (better, same, worse), Bother (not bothered, somewhat bothered, very bothered), and Risk (yes vs no for reports of ED visits, hospitalization and/or use of oral corticosteroids for asthma) by using ANOVA. To further explore the relationship of the parent-reported outcomes and quality of life, we created simple linear regression models to examine how quality of life scores (and subdomain scores) varied across the categories of Direction and Bother. Because there were few hospitalizations reported among the participating subjects, a *post hoc* Any Risk variable was constructed to further evaluate the discriminative properties of the PACC Risk domain. Any Risk is a composite measure that combines all 3 Risk indicators. A "yes" response for the Any Risk variable is based upon parental report of the occurrence of at least 1 of the 3 indicators of risk, whereas a "no" response is based upon the absence of the occurrence of all 3 risk indicators. We used χ^2 analyses to examine the associations of Direction, Bother, and Risk domains to each other. Specifically, we looked at the proportion of patients reporting (1) a given level of Direction by levels of Bother and Risk; (2) a given level of Bother by levels of Risk. Analyses were performed by using STATA 11 (Stata Corp, College Station, Tex). All analyses were 2-sided, and a *P* value of less than .05 was considered to be statistically significant.

RESULTS

Respondent characteristics

There were a total of 317 participants, who represented a variety of ethnicities and parental education levels (Table I), of whom 79 patients performed spirometry. Parents reported that, during the prior 2 months, or since their child's most recent asthma outpatient visit, 33% of study participants used oral corticosteroids (95% CI, 28%-38%), 20% had an ED visit for asthma (95% CI, 15%-24%), and 10% were hospitalized for asthma (95% CI, 6%-13%) (Table I). In terms of parent-reported outcomes: (1) half of the parents reported that their child's asthma had improved ("better"), whereas fewer than 10% reported that their child's asthma had declined ("worse"), the remainder reported their child's asthma as being unchanged; (2) for the Bother domain, 60% of parents reported being "bothered" about their child's asthma, with most being "somewhat bothered" rather than "very bothered." Mean scores and 95% CIs were similar among overall quality of life (PACQLQ) and the emotional function and activity limitation subdomains.

Discriminative properties

In general, we observed significant associations of each PACC domain with various valid indicators of asthma morbidity, particularly, the indicators of asthma control and quality of life. More detailed findings are described below.

Direction. Parents' reports of the direction of their child's asthma were associated with indicators of asthma morbidity (Table II). More specifically, as parent-reported PACC Direction varied from "better" to "worse," mean PACC Sum Scores and PACC Problem Index scores increased (which indicated poorer asthma control) (*P* < .001), whereas we observed decreased mean overall PACQLQ scores (*P* < .001) and FEV₁% (*P* = .025) (Table II). A similar association was observed with

TABLE II. Discriminant properties of PACCI Direction domain: mean values (95% CI) of asthma control, quality of life, and lung function values across PACCI Direction categories by using ANOVA

Measures of asthma morbidity	PACCI direction categories			P value
	Better (n = 159)	Same (n = 127)	Worse (n = 27)	
PACCI Sum Score	2.8 (2.3-3.4)	5.3 (4.6-6)	8.2 (7-9.4)	<.0001
PACCI Problem Index	1 (0.8-1.2)	2.1 (1.8-2.4)	3.5 (2.9-4)	<.0001
Quality of Life, Overall (PACQLQ)	5.8 (5.6-6.0)	5.2 (4.9-5.4)	4.7 (4.2-5.3)	<.0001
Quality of Life, Emotional Function (PACQLQ)	5.8 (5.6-6.0)	5.2 (5.0-5.5)	4.7 (4.2-5.3)	<.0001
Quality of Life, Activity Limitation (PACQLQ)	5.7 (5.4-5.9)	4.6 (4.3-4.9)	4.6 (3.9-5.3)	<.0001
FEV ₁ %	90 (90-100) (n = 28)	80 (80-90) (n = 47)	80 (60-110) (n = 4)	.025
FEV ₁ :FVC, %	90 (80-90) (n = 28)	80 (80-90) (n = 47)	80 (70-90) (n = 4)	.7744

TABLE III. Discriminant properties of PACCI Bother domain: mean values (95% CI) of asthma control, quality of life, and lung function values across PACCI Bother categories by using ANOVA

Measures of asthma morbidity	PACCI bother category			P value
	Not bothered (n = 126)	Somewhat bothered (n = 160)	Very bothered (n = 29)	
PACCI Sum Score	1.7 (1.3-2.2)	5.2 (4.7-5.8)	10.1 (8.9-11.2)	<.0001
PACCI Problem Index	0.6 (0.4-0.8)	2.1 (1.8-2.3)	3.9 (3.4-4.4)	<.0001
Quality of Life, Overall (PACQLQ)	6.2 (6.1-6.4)	5.1 (4.9-5.3)	4.2 (3.6-4.7)	<.0001
Quality of Life, Emotional Function (PACQLQ)	6.3 (6.1-6.4)	5.1 (4.9-5.3)	4.3 (3.7-4.9)	<.0001
Quality of Life, Activity Limitation (PACQLQ)	6.1 (5.9-6.4)	4.6 (4.4-4.9)	3.8 (3.1-4.5)	<.0001
FEV ₁ %	90 (80-100) (n = 33)	80 (80-90) (n = 44)	80 (60-100) (n = 2)	.1372
FEV ₁ :FVC, %	90 (80-90) (n = 33)	80 (80-90) (n = 44)	80 (70-90) (n = 2)	.6022

the PACQLQ emotional function and activity limitations subdomains but, more consistently, with the emotional function domain. Linear regression showed that, for each change in PACCI Direction category (from “better” to “same” to “worse”), the mean PACQLQ change was -0.6 (95% CI, -0.8 to -0.4), whereas the mean emotional function score decreased by -0.6 (95% CI, -0.8 to -0.3), and the activities limitation score decreased by -0.8 (95% CI, -1.0 to -0.5). There was no significant association with mean FEV₁:FVC as parent-reported asthma direction varied from “better” to “worse” ($P = .8$).

Bother. The mean PACCI Sum Score and the PACCI Problem Index increased significantly (which indicated poorer asthma control) as parent-reported PACCI Bother varied from “not bothered” to “very bothered” ($P < .001$) (Table III). Mean PACQLQ values significantly decreased (which indicated poorer quality of life) as parent reports of PACCI Bother varied from “not bothered” to “very bothered” ($P < .001$). This pattern of findings held true for both the emotional function and activity limitations PACQLQ subdomains. Linear regression showed that, for each change in PACCI Bother category (from “not bothered” to “somewhat bothered” to “very bothered”), the mean PACQLQ change was -1.1 (95% CI, -1.3 to -0.9) whereas the mean emotional function score decreased by -1.0 (95% CI, -1.3 to -0.8), and the activities limitation score decreased by -1.3 (95% CI, -1.6 to -1.0). There was no significant change in FEV₁% and FEV₁:FVC across categories of PACCI Bother ($P > .1$ for both lung function measures).

Risk. Each PACCI Risk measure was significantly associated with asthma control and quality of life scores (Table IV). Specifically, the mean PACCI Sum Score and Problem Index scores

increased significantly for those who reported any occurrence of an ED visit, hospitalization or use of an oral corticosteroid ($P < .05$). Similarly, quality of life scores (PACQLQ: overall; emotional function and activity limitations subdomains) decreased significantly in the presence of any reported indicator of risk ($P < .01$). There were no significant associations between the individual PACCI measures of risk and the lung function measures ($P > .05$), although significant associations were observed between the Any Risk composite variable and mean values for FEV₁% ($P < .0001$), FEV₁:FVC ratio ($P < .05$) as well as the measures of asthma control (PACCI Sum Score and Problem Index) ($P < .0001$) and quality of life (PACQLQ) ($P < .0001$).

Associations of Direction with Bother and Risk.

Significant associations were observed between responses to the Direction and the Bother and Risk domains (Table V; see Table E1 in this article’s Online Repository at www.jaci-inpractice.org). More specifically, we observed a higher proportion of parents reporting “better” asthma among those not reporting an ED visit or oral corticosteroid use for asthma than among those who did report such an occurrence (Table V). A similar but statistically insignificant trend was observed for hospitalizations due to asthma. Conversely, a higher proportion of parents reported their child’s asthma as “the same” or “worse” if their child had an ED visit or oral steroid use for asthma compared with parents who did not report these 2 types of events. A similar but statistically insignificant trend was observed for asthma-related hospitalizations. In terms of the PACCI Bother domain, a higher proportion of parents reported not being bothered about their child’s asthma if they also did not report an ED visit, hospitalization, or oral corticosteroid use for

TABLE IV. Discriminant properties of PACC I Risk domain: mean values (95% CI) of asthma control, quality of life, and lung function values across PACC I Risk categories by using ANOVA*

Measures of asthma morbidity	PACC I risk category									
	ED visit		Hospitalization		Prednisone use		Any risk†		No (n = 196)	Yes (n = 121)
	No (n = 252)	Yes (n = 62)	No (n = 284)	Yes (n = 31)	No (n = 211)	Yes (n = 103)	No (n = 196)	Yes (n = 121)		
PACC I Sum Score	3.9 (3.5-4.4)	5.8 (4.8-6.8)‡	4.1 (3.7-4.6)	5.8 (4.6-7.1)§	3.3 (2.8-3.8)	6.3 (5.5-7.1)	3.2 (2.7-3.6)	6.1 (5.4-6.8)		
PACC I Problem Index	1.5 (1.3-1.7)	2.3 (1.9-2.7)	1.6 (1.4-1.8)	2.3 (1.7-2.8)§	1.2 (1.0-1.5)	2.5 (2.1-2.8)	1.2 (1.0-1.4)	2.5 (2.1-2.8)		
Overall Quality of Life PACQLQ	5.6 (5.4-5.8)	4.8 (4.4-5.1)	5.5 (5.4-5.7)	4.6 (4.0-5.1)‡	5.8 (5.6-5.9)	4.8 (4.6-5.1)	5.8 (5.7-6.0)	4.8 (4.6-5.1)		
Emotional Function Quality of Life PACQLQ	5.6 (5.4-5.8)	4.9 (4.6-5.3)	5.5 (5.4-5.7)	4.7 (4.0-5.3)‡	5.7 (5.6-5.9)	4.9 (4.6-5.2)	5.8 (5.6-6.0)	4.9 (4.6-5.1)		
Activity Limitation Quality of Life PACQLQ	5.4 (5.1-5.6)	4.2 (3.8-4.6)	5.2 (5.0-5.5)	4.0 (3.3-4.6)‡	5.6 (5.4-5.8)	4.1 (3.8-4.4)	5.7 (5.5-5.9)	4.2 (3.9-4.5)		
FEV ₁ %	90 (80-90) (n = 64)	80 (70-90) (n = 15)	90 (80-90) (n = 64)	90 (70-100) (n = 15)	90 (80-90) (n = 64)	80 (70-90) (n = 15)	90 (80-90) (n = 64)	80 (70-90) (n = 15)§		
FEV ₁ :FVC, %	80 (80-90) (n = 64)	80 (70-90) (n = 15)	90 (80-90) (n = 64)	80 (80-90) (n = 15)	90 (80-90) (n = 64)	80 (80) (n = 15)§	90 (80-90) (n = 64)	80 (80-90) (n = 15)§		

*For statistical comparisons in mean values between those who answered "yes" and those who answered "no."

†Any Risk is a composite variable that indicates that a parent responded "yes" to any one of the PACC I Risk measures (an ED visit for asthma, a hospitalization for asthma, or prednisone use for asthma).

‡ $P < .01$.§ $P \leq .05$.|| $P < .0001$.

asthma ($P < .005$) (Table V). Conversely, a higher proportion of parents reported being "somewhat bothered" or "very bothered" about their child's asthma if they also had reported an ED visit, hospitalization, or oral steroid use for asthma. Lastly, a decreasing proportion of parents reported that their child's asthma was "better" as the level of "bother" from asthma increased from "not bothered" to "somewhat bothered" to "very bothered" ($P < .001$) (Table E1). Conversely, an increasing proportion of parents reported that their child's asthma was "worse" as the level "bother" from asthma increased from "not bothered" to "very bothered" ($P < .001$).

DISCUSSION

The PACC I is a valid means of measuring multiple indicators of asthma morbidity, including disease trajectory (Direction), disease burden (Bother), and indicators of Risk (ED visits, hospitalizations, and use of prednisone for asthma). Therefore, the PACC I should facilitate the comprehensive collection of asthma morbidity data meaningful to parents of children with asthma and their health care providers. The collection of information regarding multiple dimensions of asthma morbidity is suggested in the NIH asthma guidelines, although no tools currently exist that capture more than 2 dimensions of asthma morbidity, typically asthma control and/or risk. Because the Direction, Bother, and Risk domains of the PACC I have already been shown to be important to medication treatment decision-making,^{8,9} it is reasonable to systematically incorporate these domains into a parent or patient questionnaire for routine clinical use by pediatric health care providers.

Although we observed an association of the PACC I Direction, Bother, and Risk domains with asthma control and quality of life, we believe that the PACC I domains are unique constructs to be assessed in addition to asthma control and quality of life. Previous research in our group has shown that the PACC I Direction, Bother, and Risk constructs modify physician perceptions of asthma control and severity.⁷ The PACC I allows for the assessment of asthma control, risk, and 2 parent-reported outcomes indicative of quality of life (Direction, Bother) by using a single questionnaire, a feasible advantage over other currently available questionnaires that tend to measure only control. For the purposes of validity testing, we were obligated to examine how the Direction, Bother, and Risk dimensions of asthma morbidity relate to established measures of asthma morbidity (eg, asthma control). However, we do not believe that simply measuring asthma control alone would provide insight into these dimensions of asthma morbidity. Focusing exclusively on asthma control does not get at unique perspectives of disease morbidity from the patient and/or parent point of view. This is indeed the purpose of developing patient-reported outcomes as well as developing patient-centered means of clinical evaluation, as promoted in asthma guidelines,¹ and by the NIH,⁶ the Patient Centered Outcomes Research Institute,^{17,18} and the Food and Drug Administration.¹⁹

Direction (ie, trajectory of asthma status) is not an NIH asthma-guideline-based criterion for determining asthma morbidity. However, we propose that Direction should be considered because it is a dimension of disease activity provided from the parent and/or patient's perspective, and it is consistent with the evolving interests for using patient-reported outcomes to evaluate patient response(s) to treatment.¹⁹⁻²¹ Although not

TABLE V. Discriminant properties of PACCI Direction and Bother domains: categories of PACCI Risk across levels of Direction and Bother by using the χ^2 test for trend

Risk categories	ED visit		Hospitalization		Prednisone use		Any risk	
Direction categories	No (n = 252)	Yes (n = 62)	No (n = 284)	Yes (n = 31)	No (n = 211)	Yes (n = 103)	No (n = 196)	Yes (n = 121)
Better (n = 159), %	54	37	52	35	58	36	58	39
Same (n = 127), %	38	50	39	55	35	52	35	50
Worse (n = 26), %	8	13	8	10	7	12	7	11
P value	.05*		.2*		.002*		.005*	
Bother categories	No (n = 252)	Yes (n = 62)	No (n = 284)	Yes (n = 31)	No (n = 211)	Yes (n = 103)	No (n = 196)	Yes (n = 121)
Not bothered (n = 124), %	45	16	43	13	51	15	54	17
Somewhat bothered (n = 159), %	47	69	48	77	42	70	40	69
Very bothered (n = 29), %	8	14	9	10	7	15	6	14
P value	<.001*		.004*		<.001*		<.001*	

*Statistical comparison is proportions of those who answered “yes” compared with those who answered “no.”

evaluated in this study, analysis of additional data within our group suggests that the Direction domain is (1) associated with longitudinal changes in other measures of asthma morbidity,²² and (2) a meaningful determinant of treatment decisions by pediatricians to step-down controller medication therapy.^{8,9,23}

The NIH asthma guidelines recommend that “perceptions and experiences of patients must be assessed directly and not imputed from measures of clinical status.”¹ The PACCI Bother dimension is an indicator of disease burden as perceived by the family and appears to be a valid indicator of quality of life. The Bother construct has previously been incorporated into a published patient-reported outcome measurement tool.²⁴ The Bother construct is influential in pediatrician ratings of asthma severity and decisions to step-up and step-down treatment.^{7,9} Given that the Bother construct also is based on parent and/or patient perceptions, the PACCI offers 2 patient-reported outcomes (Bother and Direction) that could be useful in evaluating changes over time in patient clinical status from the patient’s and/or parent’s perspective.²² Notably, there are no asthma quality of life measures that meet this criterion because they are primarily focused on symptom assessment.⁶

The NIH asthma guidelines suggest that health care providers routinely assess patient risk for poor outcomes as a component of asthma control or severity evaluations. The guidelines characterize risk as “exacerbations requiring oral systemic corticosteroids.” The PACCI provides for the assessment of 3 indicators of asthma exacerbations, ED visits, hospitalizations, and oral corticosteroid use, each of which independently should be of clinical importance to a health care provider who elicits a history of such an occurrence. Results from evaluation of the Any Risk variable (defined as a “yes” response to any one of the 3 risk indicators) suggests that these items could be collapsed into a single question, although further exploration of other measurement properties (eg, predictive validity) is needed before doing so. We previously observed how reports of a recent hospitalization result in more severe asthma ratings, poorer asthma control ratings, and an increased likelihood of stepping up asthma treatment by pediatricians.^{7,9} More information is needed on the effect of reports of ED visits and/or oral corticosteroid use on the clinical evaluations and treatment decisions by pediatricians.

There are several limitations to this study. First, these findings have been observed among children seeking care in asthma specialist settings, so these results may not be generalizable to children cared for in other settings. However, we included a broad cross-section of sociodemographic groups, including children seen at a federally qualified health center. Second, our data are based on parent self-report and so are subject to recall bias and reporting bias. However, parent report is a widely used clinical and research approach, and oftentimes is the primary means to obtaining clinical information. Any reporting bias would likely be non-differential toward the null. Third, this was a cross-sectional study, so we do not know the predictive validity of the Direction, Bother, and Risk domains of the PACCI in identifying patients at higher risk for poor outcomes in the future. This lack of information regarding the predictive ability of morbidity assessments is a common limitation among pediatric asthma questionnaires. Fourth, some of the comparisons used were limited by small numbers of participants (eg, there are only 4 and 2 subjects in the “Worse” and “Very Bothered” subpopulations, respectively, who performed pulmonary function tests). Lastly, we do not know the impact of routine assessment of PACCI Direction, Bother, and Risk on asthma care and asthma outcomes. However, there is a significant gap in the literature regarding the usefulness of any of the asthma assessment questionnaires in improving care and helping clinicians to provide care more consistent with national asthma guidelines.

In summary, the Direction, Bother, and Risk domains of the PACCI are valid measures of asthma morbidity. Further research is needed to learn (1) about the predictive and longitudinal implications of parent-reported Direction, Bother, and Risk; and (2) if routine assessment of these dimensions of asthma morbidity by pediatric health care providers results in improved asthma patient care and outcomes. The PACCI offers pediatric health care providers a comprehensive measure of asthma morbidity and parent-reported measures of pediatric asthma morbidity that should be useful in clinical care and research settings.

REFERENCES

1. National Asthma Education and Prevention Program. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma-Summary Report 2007. *J Allergy Clin Immunol* 2007;120(Suppl):S94-138.

2. Schatz M, Sorkness CA, Li JT, Marcus P, Murray JJ, Nathan RA, et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol* 2006;117:549-56.
3. Murphy KR, Zeiger RS, Kosinski M, Chipps B, Mellon M, Schatz M, et al. Test for respiratory and asthma control in kids (TRACK): a caregiver-completed questionnaire for preschool-aged children. *J Allergy Clin Immunol* 2009;123:833-9.
4. Skinner EA, Diette GB, Algatt-Bergstrom PJ, Nguyen TT, Clark RD, Markson LE, et al. The Asthma Therapy Assessment Questionnaire (ATAQ) for children and adolescents. *Dis Manag* 2004;7:305-13.
5. Liu AH, Zeiger R, Sorkness C, Mahr T, Ostrom N, Burgess S, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *J Allergy Clin Immunol* 2007;119:817-25.
6. Wilson SR, Rand CS, Cabana MD, Foggs MB, Halterman JS, Olson L, et al. Asthma outcomes: quality of life. *J Allergy Clin Immunol* 2012;129(Suppl):S88-123.
7. Demissie S, Riekert KA, Eakin MN, Bilderback A, Diette GB, Okelo SO. How do perceptions of asthma control and severity relate to indicators of asthma status and treatment recommendations by pediatricians? *Pediatr Allergy Immunol Pulmonol* 2012;25:17-23.
8. Diette GB, Patino CM, Merriman B, Paulin L, Riekert KA, Okelo SO, et al. Patient factors that physicians use to assign asthma treatment. *Ann Intern Med* 2007;167:1360-6.
9. Okelo SO, Patino CM, Riekert KA, Merriman B, Bilderback A, Hansel NN, et al. Patient factors used by pediatricians to assign asthma treatment. *Pediatrics* 2008;122:e195-201.
10. Bracha Y, Brottman G, Carlson A. Physicians, guidelines, and cognitive tasks. *Eval Health Prof* 2011;34:309-35.
11. Okelo SO, Eakin MN, Patino CM, Teodoro AP, Bilderback AL, Thompson DA, et al. The Pediatric Asthma Control and Communication Instrument asthma questionnaire: for use in diverse children of all ages. *J Allergy Clin Immunol* 2013;132:55-62.
12. Patino CM, Okelo SO, Rand CS, Riekert KA, Krishnan JA, Thompson K, et al. The Asthma Control and Communication Instrument: a clinical tool developed for ethnically diverse populations. *J Allergy Clin Immunol* 2008;122:936-43.
13. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in the parents of children with asthma. *Qual Life Res* 1996;5:27-34.
14. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in children with asthma. *Qual Life Res* 1996;5:35-46.
15. Tauler E, Vilagut G, Grau G, Gonzalez A, Sanchez E, Figueras G, et al. The Spanish version of the Paediatric Asthma Quality of Life Questionnaire (PAQLQ): metric characteristics and equivalence with the original version. *Qual Life Res* 2001;10:81-91.
16. Reichenberg K, Broberg AG. Quality of life in childhood asthma: use of the Paediatric Asthma Quality of Life Questionnaire in a Swedish sample of children 7 to 9 years old. *Acta Paediatr* 2000;89:989-95.
17. Selby JV, Beal AC, Frank L. The Patient-Centered Outcomes Research Institute (PCORI) national priorities for research and initial research agenda. *JAMA* 2012;307:1583-4.
18. Barr P. Collaborative efforts: PCORI comparative-effectiveness awards add a new twist: patient input. *Mod Healthc* 2012;42:12-3.
19. Speight J, Barendse SM. FDA guidance on patient reported outcomes. *BMJ* 2010;340:c2921.
20. Frampton GK, Shepherd J. Patient-reported outcomes in clinical trials of inhaled asthma medications: systematic review and research needs. *Qual Life Res* 2011;20:343-57.
21. Rothman ML, Beltran P, Cappelleri JC, Lipscomb J, Teschendorf B. Patient-reported outcomes: conceptual issues. *Value Health* 2007;10(Suppl 2):S66-75.
22. Demissie SM, Bilderback A, Eakin MN, Riekert KA, Rand CS, Okelo SO. How well do parental reports of interval changes in well-being relate to traditional indicators of asthma morbidity? *Am J Respir Crit Care Med* 2011;183:A3784.
23. Okelo SO, Siberry GK, Solomn BS, Yamazaki M., Hetzler T, Ferrell CL, et al. Survey of Pediatric Asthma Care Education in Residency (SPACER) Study. *Pediatric Academic Society Abstracts2View Online Archives E-PAS2009:3685.1. 2009.*
24. Yeatts KB, Stucky B, Thissen D, Irwin D, Varni JW, Dewitt EM, et al. Construction of the Pediatric Asthma Impact Scale (PAIS) for the Patient-Reported Outcomes Measurement Information System (PROMIS). *J Asthma* 2010;47:295-302.

Pediatric Asthma Control & Communication Instrument

Asthma also includes reactive airway disease, regular coughing, wheezing, or difficulty breathing with or without colds.

Your child's name: _____ Today's Date: _____

When was your child's last asthma visit? _____ If your child has never had an asthma visit, check here ☐

Please check ☒ one answer for each of the following questions.

Your answers will help your doctor give you the best asthma care.

Direction

1. Since your child's last visit to **this** doctor's office, how has your child's asthma been?

Better



Same



Worse



If your child has not seen a doctor, please answer about the past 2 months.

Bothered

2. Since your child's last visit to **this** doctor's office, how much have you been bothered by your child's asthma?

Not
bothered



Somewhat
bothered



Very
bothered



If your child has not seen a doctor, please answer about the past 2 months.

Risk

- 3-5. Since your child's last visit to **this** doctor's office, has your child:

If your child has not seen a doctor, please answer about the past 2 months.

3. Been to the emergency room for asthma?

No



Yes



4. Been hospitalized for asthma?



5. Used prednisone (Orapred, steroid pill, steroid liquid or steroid syrup) for asthma?



Forget to take medicine

6. How often do you **forget** to give your child's **daily** asthma medicine when he/she feels fine?

Daily asthma medicines include: Aerobid, Advair, Asmanex, Azmacort, Budesonide, Flovent, QVAR, Pulmicort, Singulair, Symbicort

My child is not supposed to take a daily asthma medicine



None of the time



Some of the time
1-2 days/week



Most of the time
3-4 days/week



All of the time
5-7 days/week



FOR CLINICIAN USE

If any of the answers farthest to the right or in red ☒ are selected, this may be consistent with poorly controlled and/or undertreated asthma. Further assessment and **follow-up in 2-6 weeks** is recommended.

(OVER)

FIGURE E1. This is the English version of the Pediatric Asthma Control and Communication Instrument. Pages 1 and 2 are parent completed; page 3 is a treatment algorithm for the health care provider.

Asthma Symptoms					
7. Over the past week , how many days has your child had asthma symptoms? For example:					
▪ Cough ▪ Chest tightness ▪ Shortness of breath ▪ Sputum (spit, mucous, phlegm when coughing) ▪ Difficulty taking a deep breath ▪ Wheezy or whistling sound in the chest	0	1-2	3-6	Every day (not all day long)	Every day (all day long)
8. Over the past week , how many days have you had to give your child medicine to quickly relieve asthma symptoms? For example:					
▪ Albuterol/Proventil/Proair/Ventolin/Xopenex via Inhaler/Spray/Pump or Machine/Nebulizer	0	1-2	3-6	Every day (not all day long)	Every day (all day long)
9. Over the past week , how many days did your child have an asthma attack? For example:					
▪ When it is harder to breathe for your child ▪ When you give your child more quick-relief asthma medicine (e.g., Albuterol) ▪ When the asthma medicine does not work	0	1	2-3	4-7	
10. Over the past week , how much does asthma limit your child's activities?					
	Not at all	Slightly	Moderately	Very much	Completely
11. Over the past TWO weeks , how many nights did your child's asthma keep your child from sleeping or wake him/her up?					
	0	1	2	3-7	8-14
12. Please write down any concerns or anything else you would like your doctor to know about your child's asthma.					

PLEASE GIVE THIS TO YOUR PROVIDER. Thank you.

FOR CLINICIAN USE ONLY: Control/Severity Assignment

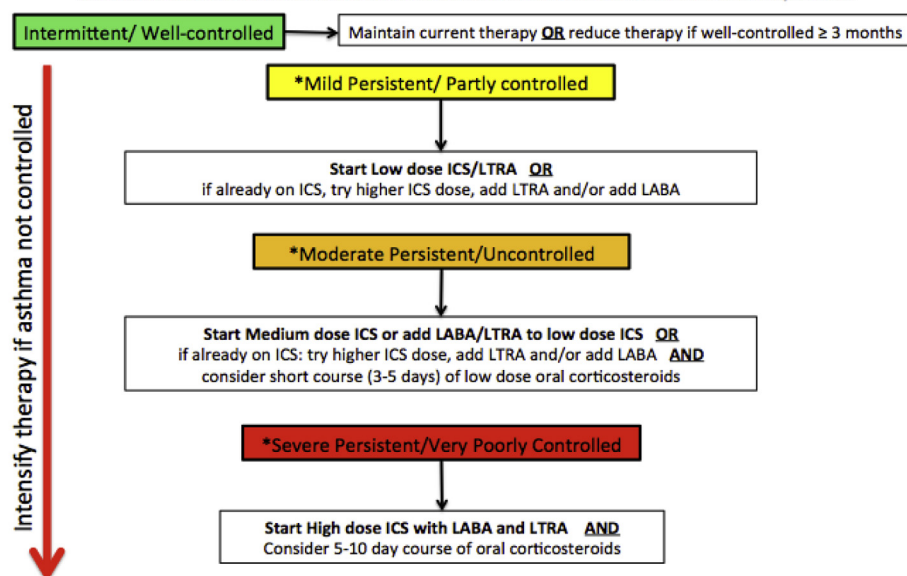
Assign patient's current level of asthma control by looking at the box checked *farthest to the right* on questions 7-11 and match the box color to the level of asthma control in this section.

The goal for all patients is to have controlled/intermittent asthma. If asthma is uncontrolled/persistent, possible explanations include: under-treatment, poor inhaler technique, poor adherence, environmental allergies and/or exposures, comorbid conditions (see treatment algorithm). **Follow-up in 2 – 6 weeks** is recommended.

Controlled/ Intermittent	Partly Controlled/ Mild Persistent	Uncontrolled/ Moderate Pers.	Poorly Controlled Severe Pers.

FIGURE E1. (Continued.)

Treatment Recommendations Based on Asthma Control or Severity Level



Inhaled Corticosteroids (ICS)		Child 0-4 years old			Child 5-11 years old			>12 years old		
		Low Dose	Medium	High Dose	Low Dose	Medium	High Dose	Low Dose	Medium	High Dose
Beclomethasone/QVar MDI	40mcg 80mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	>2-4 puffs	>4 puffs	2-4 puffs 1-3 puffs	>3-6 puffs	>6 puffs
Budesonide/Pulmicort DPI Flexhaler	90mcg 180 mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	>2-4puffs	>4 puffs	2-6 puffs 1-3 puffs	4-6 puffs	>6 puffs
Budesonide/Pulmicort Respule	0.25mg neb 0.5mg neb	2 nebs 1 neb	>2 nebs 2 neb	>2 nebs	2 nebs 1 neb	4 nebs 2 nebs	4 nebs	N/A	N/A	N/A
Fluticasone/Flovent MDI	44 mcg 110 mcg 220 mcg	4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puff	2-4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puffs	2-6 puffs 2 puffs 1 puff	6-10 puffs 2-4 puffs 1-2 puffs	>10 puffs >4 puffs >2 puffs
Fluticasone/Flovent Diskus DPI	50 mcg 100 mcg 250 mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	3-4 puffs 1 puff	>4 puffs >2 puffs	2-6 puffs 1-3 puffs 1 puff	6-10 puffs 4-5 puffs 2 puffs	>10 puffs >5 puffs >2 puffs
Mometasone/Asmanex Twisthaler DPI	200mcg	N/A	N/A	N/A	N/A	N/A	N/A	1 puff	2 puffs	>2 puffs
Combination Drugs—ICS + LABA: patient should not take more than: 2 puffs per dose of the combo MDI or 1 puff per dose of the combo DPI										
Fluticasone/Salmeterol (Advair) MDI	45/21 mcg 115/21 mcg 230/21 mcg	N/A	N/A	N/A	1-2 puffs	2-4 puffs 1-2 puffs	2 puffs 1 puff	1-3 puffs 1 puff	3-4 puffs 2-3 puffs 1 puff	3-4 puffs 1-2 puffs
Fluticasone/Salmeterol Diskus (Advair) DPI	100/50 mcg 250/50 mcg 500/50 mcg	N/A	N/A	N/A	1 puff	1-2 puffs 1 puff	1 puff	1 puff	1-2 puffs 1 puff	1-2puffs 1 puffs
Budesonide/Formoterol (Symbicort)	80/4.5mcg MDI 160/4.5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	1-3 puffs 1-2 puffs	4 puffs 2-3puffs	3-4 puffs
Mometasone/Formoterol (Dulera)	100/5mcg MDI 200/5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1 puff	2 puffs

Notes: Medication doses of puffs or nebs in the chart are for total doses per day (e.g., 2 puffs = 2 total puffs). Combination drugs are assumed to be equivalent to doubling of the ICS dose alone (e.g., 1 puff of Fluticasone/Salmeterol 45/21 = 2 puffs of Fluticasone). N/A and blank areas indicate that there is no on-label recommended dosing available.
ICS: inhaled corticosteroid; **LTRA:** leukotriene receptor antagonist; **LABA:** long acting -agonist; **MDI:** metered dose inhaler; **DPI:** dry powder inhaler

FIGURE E1. (Continued.)

Instrumento de Comunicación y Control del Asma

Nombre de su niño: _____ Fecha: _____

¿Cuándo fue la última visita por asma de su niño(a) con su doctor regular? _____

Si su niño(a) nunca ha tenido una visita por asma con un doctor, marque aquí ☐

Por favor marque una respuesta ☒ para cada una de las siguientes preguntas. Sus respuestas ayudan al doctor a darle a su niño un mejor cuidado de asma.

Dirección					
1. Desde la última visita de su hijo(a) al doctor, ¿como ha estado el asma de su hijo(a)?	Ha estado mejorando	Está igual	Ha estado empeorando		
Si su hijo(a) no ha sido evaluado por un doctor, por favor conteste sobre los últimos dos meses.	☐	☐	☐		
Molestias					
2. Desde la última visita de su hijo(a) al doctor, ¿qué tan molesto para usted ha sido el asma de su hijo(a)?	Nada molesto	Algo molesto	Muy molesto		
Si su hijo(a) no ha sido evaluado por un doctor, por favor conteste sobre los últimos dos meses.	☐	☐	☐		
Riesgo					
3-5. Desde la última visita de su hijo(a) al doctor, su hijo(a):	No	Sí			
Si su hijo(a) no ha sido evaluado por un doctor, por favor conteste sobre los últimos dos meses.	☐	☐			
3. ¿Ha requerido atención por su asma en el servicio de <u>urgencias</u> ?	☐	☐			
4. ¿Ha sido <u>hospitalizado</u> por su asma?	☐	☐			
5. ¿Ha usado <u>prednisona</u> /prednisone/prednisolone (pastille o jarabe que contiene esteroides) para su asma?	☐	☐			
Olvida tomar medicina					
6. Cuando su niño se encuentra bien ¿qué tan frecuente olvida darle su medicina <u>diaria</u> para el asma?	Mi hijo no debe de tomar medicina diaria para el asma	Nunca lo olvido	Lo olvido en algunas ocasiones 1 a 2 días por semana	Lo olvido mayor parte del tiempo 3 a 4 días por semana	Lo olvido todo el tiempo 5 a 7 días por semana
Las medicinas diarias para el asma incluyen: Aerobid, Advair, Asmanex, Azmacort, Budesonide, Flovent, QVAR, Pulmicort, Singulair,.	☐	☐	☐	☐	☐

FOR CLINICIAN USE

If any of the answers farthest to the right or in red ☒ are selected, this may be consistent with poorly controlled and/or undertreated asthma. Further assessment and **follow-up in 2-6 weeks** is recommended.

(OVER)

FIGURE E2. This is the Spanish version of the Pediatric Asthma Control and Communication Instrument. Pages 1 and 2 are parent completed; page 3 is a treatment algorithm for the health care provider.

Síntomas de asma					
En la última semana , ¿cuántos días su hijo(a) presentado síntomas de asma? *Por ejemplo: tos, presión o dolor de pecho, falta de aire, flema (escupe, moco, flema al toser), dificultad para respirar profundo, tiene silbidos o hace día)	Días				
	0	1-2	3-6	Todo los días (no todo el día)	Todos los días (todo el día)
					
7.					
Medicamentos de rescate					
8. En la última semana , ¿cuántos días le ha dado a su hijo(a) medicamento para alivio rápido de los síntomas de asma? Por ejemplo: Albuterol, Inhalador, spray, Bomba,	Días				
	0	1-2	3-6	Todo los días (no todo el día)	Todos los días (todo el día)
					
Ataques o Crisis					
9. En la última semana , ¿cuántos días su hijo(a) ha tenido ataques de asma? Por ejemplo: cuando le cuesta trabajo respirar; cuando usted tiene que darle más medicamento cuando las medicinas no funcionan	Días				
	0	1	2-3	4-7	
					
Limitación a la actividad física					
10. En la última semana , el asma de su hijo(a) ¿qué tanto ha limitado su actividad física?	Nada	Ligeramente	Moderadamente	Mucho	Completamente
					
Síntomas nocturnos					
11. En las últimas dos semanas , ¿cuántas noches el asma de su hijo(a) lo ha despertado o no lo ha dejado dormir?	Noches				
	0	1	2	3-7	8-14
					
12. Por favor escriba cualquier otra información que a usted le interese que su doctor sepa acerca del asma de su hijo(a).					

FOR CLINICIAN USE ONLY: Control/Severity Assignment

			
Controlled/ Intermittent	Partly Controlled/ Mild Persistent	Uncontrolled/ Moderate Persistent	Poorly Controlled/ Severe Persistent

Assign patient's current level of asthma control/severity by looking at the box checked *farthest to the right* on questions 7-11 and match the box color to the level of asthma control/severity in this section.

Severity categories are for patients not on controller therapy. Control categories are for patients currently taking controller therapy.

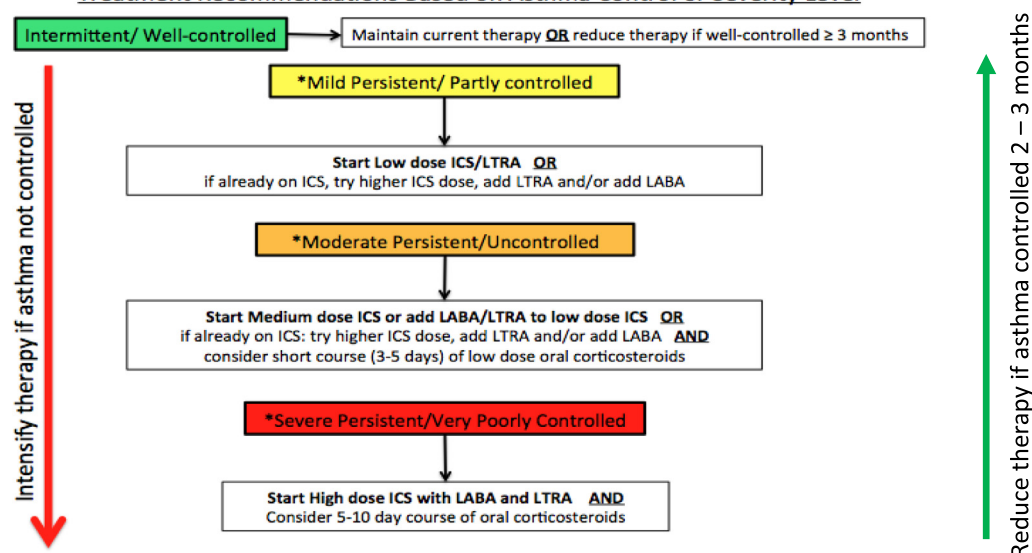
The goal for all patients is to have controlled asthma with the least amount of medication and no side effects.

If asthma is not controlled, possible explanations include: acute respiratory infection, under-treatment with daily controller medications, poor inhaler technique, poor adherence, environmental allergies and/or exposures, comorbid conditions (see treatment algorithm on page 3).

Follow-up in 2 – 6 weeks is recommended.

FIGURE E2. (Continued.)

Treatment Recommendations Based on Asthma Control or Severity Level

*** IF ASTHMA IS NOT CONTROLLED, ALSO CONSIDER EACH OF THE FOLLOWING:**

Acute Respiratory Infection: □ patient may benefit from regular use of Albuterol (e.g., 4 times a day) during the acute illness

Inhaler technique: □ is patient using spacer with MDI? □ have patient demonstrate inhaler technique

Medication adherence: □ review patient response to PACCI adherence question □ review pharmacy record of filled medications

Environmental allergies and exposures: □ has patient been allergy tested? □ is there secondhand smoke exposure?

Comorbid conditions: □ allergic rhinitis □ sinusitis □ obesity □ gastro-esophageal reflux

Asthma specialist referral: □ systemic steroids ≥ 2 times/year □ intubation/ICU admit □ uncontrolled asthma on high dose ICS

Inhaled Corticosteroids (ICS)		Child 0-4 years old			Child 5-11 years old			>12 years old		
		Low Dose	Medium	High Dose	Low Dose	Medium	High Dose	Low Dose	Medium	High Dose
Beclomethasone/QVar MDI	40mcg 80mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	>2-4 puffs	>4 puffs	2-4 puffs 1-3 puffs	>3-6 puffs	>6 puffs
Budesonide/Pulmicort DPI Flexhaler	90mcg 180 mcg	N/A	N/A	N/A	2-4 inhal 1-2 inhal	>2-4 inhal	>4 inhal	2-6 inhal 1-3 inhal	4-6 inhal	>6 inhal
Budesonide/Pulmicort Respule	0.25mg neb 0.5mg neb	2 nebs 1 neb	>2 nebs 2 neb	>2 nebs	2 nebs 1 neb	4 nebs 2 nebs	4 nebs	N/A	N/A	N/A
Fluticasone/Flovent MDI	44 mcg 110 mcg 220 mcg	4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puff	2-4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puffs	2-6 puffs 2 puffs 1 puff	6-10 puffs 2-4 puffs 1-2 puffs	>10 puffs >4 puffs >2 puffs
Fluticasone/Flovent Diskus DPI	50 mcg 100 mcg 250 mcg	N/A	N/A	N/A	2-4 inhal 1-2 inhal	3-4 inhal 1 inhal	>4 inhal >2 inhal	2-6 inhal 1-3 inhal 1 inhal	6-10 inhal 4-5 inhal 2 inhal	>10 inhal >5 inhal >2 inhal
Mometasone/Asmanex Twisthaler DPI	200mcg	N/A	N/A	N/A	N/A	N/A	N/A	1 inhal	2 inhal	>2 inhal
Combination Drugs—ICS + LABA: patient should not take more than: 2 puffs per dose of the combo MDI or 1 puff per dose of the combo DPI										
Fluticasone/Salmeterol (Advair) MDI	45/21 mcg 115/21 mcg 230/21 mcg	N/A	N/A	N/A	1-2 puffs	2-4 puffs 1-2 puffs	2 puffs 1 puff	1-3 puffs 1 puff	3-4 puffs 2-3 puffs 1 puff	3-4 puffs 1-2 puffs
Fluticasone/Salmeterol Diskus (Advair) DPI	100/50 mcg 250/50 mcg 500/50 mcg	N/A	N/A	N/A	1 inhal	1-2 inhal 1 inhal	1 inhal	1 inhal	1-2 inhal 1 inhal	1- inhal 1 inhal
Budesonide/Formoterol (Symbicort)	80/4.5mcg MDI 160/4.5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	1-3 puffs 1-2 puffs	4 puffs 2-3puffs	3-4 puffs
Mometasone/Formoterol (Dulera)	100/5mcg MDI 200/5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1 puff	2 puffs

Notes: **MEDICATION DOSES** of puffs or nebs in the chart are for **TOTAL DOSES PER DAY** (e.g., 2 puffs = 2 total puffs per day).

Combination drugs are assumed to be equivalent to doubling of the ICS dose alone (e.g., 1 puff of Fluticasone/Salmeterol 45/21 = 2 puffs of Fluticasone)

N/A and blank areas indicate that there is no on-label recommended dosing available. **INHAL:** inhalation of DPI

ICS: inhaled corticosteroid; **LTRA:** leukotriene receptor antagonist; **LABA:** long acting beta₂-agonist; **MDI:** metered dose inhaler; **DPI:** dry powder inhaler

FIGURE E2. (Continued.)

TABLE E1. Discriminant properties of PACCI Direction domain: levels of disease burden (PACCI Bother) across levels of PACCI Bother by using the χ^2 test for trend

Bother category	PACCI direction category, %			P value
	Better (n = 159)	Same (n = 127)	Worse (n = 26)	
Not bothered (n = 124)	72	26	2	<.001
Somewhat bothered (n = 159)	42	52	6	
Very bothered (n = 29)	10	41	48	

Pediatric Asthma Control & Communication Instrument

Asthma also includes reactive airway disease, regular coughing, wheezing, or difficulty breathing with or without colds.

Your child's name: _____ Today's Date: _____

When was your child's last asthma visit? _____ If your child has never had an asthma visit, check here ☐

Please check ☒ one answer for each of the following questions.
Your answers will help your doctor give you the best asthma care.

Direction

- | | | | |
|--|---|---|--|
| 1. Since your child's last visit to <u>this</u> doctor's office, how has your child's asthma been? | Better
 | Same
 | Worse
 |
|--|---|---|--|

If your child has not seen a doctor, please answer about the past 2 months.

Bothered

- | | | | |
|--|---|--|--|
| 2. Since your child's last visit to <u>this</u> doctor's office, how much have you been bothered by your child's asthma? | Not bothered
 | Somewhat bothered
 | Very bothered
 |
|--|---|--|--|

If your child has not seen a doctor, please answer about the past 2 months.

Risk

- | | | |
|---|---|---|
| 3-5. Since your child's last visit to <u>this</u> doctor's office, has your child: | No | Yes |
| 3. Been to the emergency room for asthma? |  |  |
| 4. Been hospitalized for asthma? |  |  |
| 5. Used prednisone (Orapred, steroid pill, steroid liquid or steroid syrup) for asthma? |  |  |

If your child has not seen a doctor, please answer about the past 2 months.

Forget to take medicine

- | | | | | | |
|---|---|---|--|--|---|
| 6. How often do you <u>forget</u> to give your child's <u>daily</u> asthma medicine when he/she feels fine? | My child is not supposed to take a daily asthma medicine
 | None of the time
 | Some of the time
1-2 days/week
 | Most of the time
3-4 days/week
 | All of the time
5-7 days/week
 |
|---|---|---|--|--|---|

Daily asthma medicines include: Aerobid, Advair, Asmanex, Azmacort, Budesonide, Flovent, QVAR, Pulmicort, Singulair, Symbicort

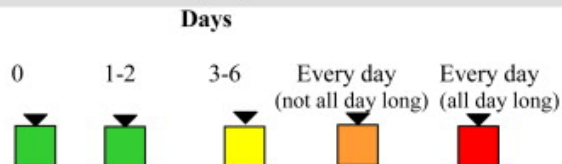
FOR CLINICIAN USE

If any of the answers farthest to the right or in red ☒ are selected, this may be consistent with poorly controlled and/or undertreated asthma. Further assessment and **follow-up in 2-6 weeks** is recommended.

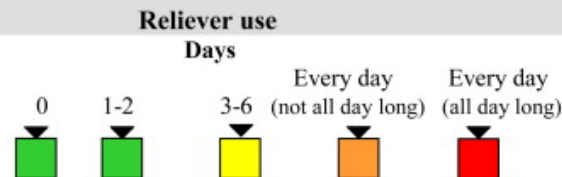
(OVER)

Asthma Symptoms

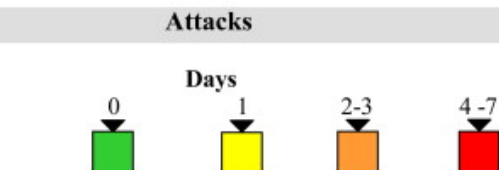
7. Over the **past week**, how many days has your child had asthma symptoms? For example:
- Cough
 - Chest tightness
 - Shortness of breath
 - Sputum (spit, mucous, phlegm when coughing)
 - Difficulty taking a deep breath
 - Wheezy or whistling sound in the chest



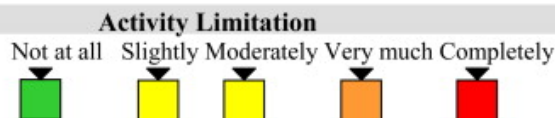
8. Over the **past week**, how many days have you had to give your child medicine to quickly relieve asthma symptoms? For example:
- Albuterol/Proventil/Proair/Ventolin/Xopenex via Inhaler/Spray/Pump or Machine/Nebulizer



9. Over the **past week**, how many days did your child have an asthma attack? For example:
- When it is harder to breathe for your child
 - When you give your child more quick-relief asthma medicine (e.g., Albuterol)
 - When the asthma medicine does not work



10. Over the **past week**, how much does asthma limit your child's activities?



11. Over the **past TWO weeks**, how many nights did your child's asthma keep your child from sleeping or wake him/her up?



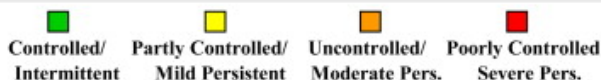
12. Please **write down any concerns or anything else** you would like your doctor to know about your child's asthma.

PLEASE GIVE THIS TO YOUR PROVIDER. Thank you.

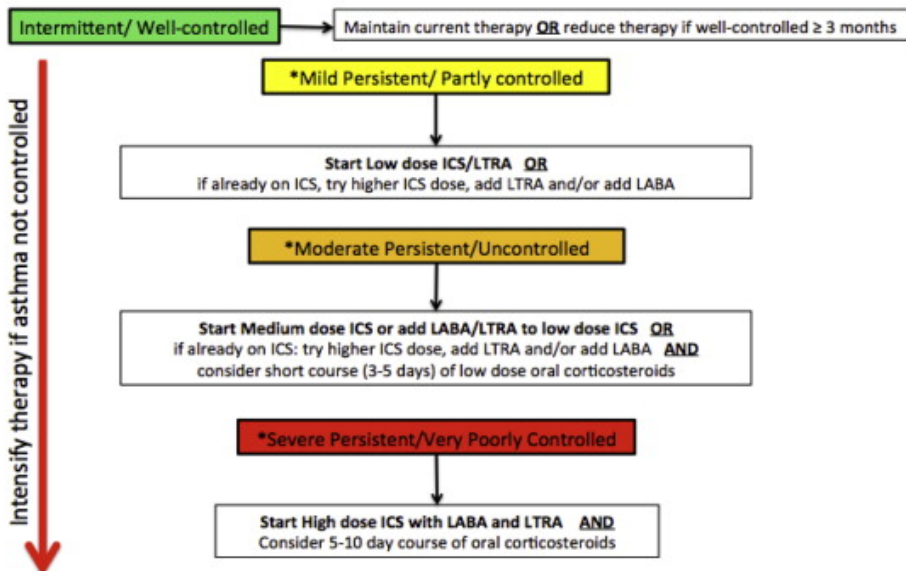
FOR CLINICIAN USE ONLY: Control/Severity Assignment

Assign patient's current level of asthma control by looking at the box checked *farthest to the right* on questions 7-11 and match the box color to the level of asthma control in this section.

The goal for all patients is to have controlled/intermittent asthma. If asthma is uncontrolled/persistent, possible explanations include: under-treatment, poor inhaler technique, poor adherence, environmental allergies and/or exposures, comorbid conditions (see treatment algorithm). **Follow-up in 2 – 6 weeks** is recommended.



Treatment Recommendations Based on Asthma Control or Severity Level



* IF ASTHMA IS NOT WELL-CONTROLLED/INTERMITTENT, ALSO CONSIDER EACH OF THE FOLLOWING:

Inhaler technique: □patient using spacer with MDI? □have patient demonstrate inhaler technique

Medication adherence: □review patient PACCI response to adherence question □review pharmacy record of filled prescriptions

Environmental allergies and exposures: □allergy tested? □secondhand smoke exposure?

Comorbid conditions: □gastro-esophageal reflux □allergic rhinitis □sinusitis □obesity □allergic bronchopulmonary aspergillosis

Asthma specialist referral: □systemic steroids ≥2 times/year □intubation/ICU admit □uncontrolled asthma on high dose ICS

Inhaled Corticosteroids (ICS)		Child 0-4 years old			Child 5-11 years old			>12 years old		
		Low Dose	Medium	High Dose	Low Dose	Medium	High Dose	Low Dose	Medium	High Dose
Beclomethasone/QVar MDI	40mcg 80mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	>2-4 puffs	>4 puffs	2-4 puffs 1-3 puffs	>3-6 puffs	>6 puffs
Budesonide/Pulmicort DPI Flexhaler	90mcg 180 mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	>2-4puffs	>4 puffs	2-6 puffs 1-3 puffs	4-6 puffs	>6 puffs
Budesonide/Pulmicort Respule	0.25mg neb 0.5mg neb	2 nebs 1 neb	>2 nebs 2 neb	>2 nebs	2 nebs 1 neb	4 nebs 2 nebs	4 nebs	N/A	N/A	N/A
Fluticasone/Flovent MDI	44 mcg 110 mcg 220 mcg	4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puff	2-4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puff	2-6 puffs 2 puffs 1 puff	6-10 puffs 2-4 puffs 1-2 puffs	>10 puffs >4 puffs >2 puffs
Fluticasone/Flovent Diskus DPI	50 mcg 100 mcg 250 mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	3-4 puffs 1 puff	>4 puffs >2 puffs	2-6 puffs 1-3 puffs 1 puff	6-10 puffs 4-5 puffs 2 puffs	>10 puffs >5 puffs >2 puffs
Mometasone/Asmanex Twisthaler DPI	200mcg	N/A	N/A	N/A	N/A	N/A	N/A	1 puff	2 puffs	>2 puffs
Combination Drugs—ICS + LABA: patient should not take more than: 2 puffs per dose of the combo MDI or 1 puff per dose of the combo DPI										
Fluticasone/Salmeterol (Advair) MDI	45/21 mcg 115/21 mcg 230/21 mcg	N/A	N/A	N/A	1-2 puffs	2-4 puffs 1-2 puffs	2 puffs 1 puff	1-3 puffs 1 puff	3-4 puffs 2-3 puffs 1 puff	3-4 puffs 1-2 puffs
Fluticasone/Salmeterol Diskus (Advair) DPI	100/50 mcg 250/50 mcg 500/50 mcg	N/A	N/A	N/A	1 puff	1-2 puffs 1 puff	1 puff	1 puff	1-2 puffs 1 puff	1-2puffs 1 puffs
Budesonide/Formoterol (Symbicort)	80/4.5mcg MDI 160/4.5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	1-3 puffs 1-2 puffs	4 puffs 2-3puffs	3-4 puffs
Mometasone/Formoterol (Dulera)	100/5mcg MDI 200/5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1 puff	2 puffs

Notes: Medication doses of puffs or nebs in the chart are for total doses per day (e.g., 2 puffs = 2 total puffs).

Combination drugs are assumed to be equivalent to doubling of the ICS dose alone (e.g., 1 puff of Fluticasone/Salmeterol 45/21 = 2 puffs of Fluticasone)

N/A and blank areas indicate that there is no on-label recommended dosing available.

ICS: inhaled corticosteroid; LTRA: leukotriene receptor antagonist; LABA: long acting -agonist; MDI: metered dose inhaler; DPI: dry powder inhaler

Instrumento de Comunicación y Control del Asma

Nombre de su niño: _____ Fecha: _____

¿Cuándo fue la última visita por asma de su niño(a) con su doctor regular? _____

Si su niño(a) nunca ha tenido una visita por asma con un doctor, marque aquí ☐

Por favor marque una respuesta ☒ para cada una de las siguientes preguntas. Sus respuestas ayudan al doctor a darle a su niño un mejor cuidado de asma.

Dirección

1. Desde la última visita de su hijo(a) al doctor, ¿como ha estado el asma de su hijo(a)?

Si su hijo(a) no ha sido evaluado por un doctor, por favor conteste sobre los últimos dos meses.

Ha estado mejorando



Está igual



Ha estado empeorando



Molestias

2. Desde la última visita de su hijo(a) al doctor, ¿qué tan molesto para usted ha sido el asma de su hijo(a)?

Si su hijo(a) no ha sido evaluado por un doctor, por favor conteste sobre los últimos dos meses.

Nada molesto



Algo molesto



Muy molesto



Riesgo

3-5. Desde la última visita de su hijo(a) al doctor, su hijo(a):

Si su hijo(a) no ha sido evaluado por un doctor, por favor conteste sobre los últimos dos meses.

3. ¿Ha requerido atención por su asma en el servicio de urgencias?

No



Sí



4. ¿Ha sido hospitalizado por su asma?



5. ¿Ha usado prednisona/prednisone/prednisolone (pastille o jarabe que contiene esteroides) para su asma?



Olvida tomar medicina

6. Cuando su niño se encuentra bien ¿qué tan frecuente olvida darle su medicina diaria para el asma?

Las medicinas diarias para el asma incluyen: Aerobid, Advair, Asmanex, Azmacort, Budesonide, Flovent, QVAR, Pulmicort, Singulair.

Mi hijo no debe de tomar medicina diaria para el asma



Nunca lo olvido



Lo olvido en algunas ocasiones 1 a 2 días por semana



Lo olvido mayor parte del tiempo 3 a 4 días por semana



Lo olvido todo el tiempo 5 a 7 días por semana



FOR CLINICIAN USE

If any of the answers farthest to the right or in red ☒ are selected, this may be consistent with poorly controlled and/or undertreated asthma. Further assessment and **follow-up in 2-6 weeks** is recommended.

(OVER)

Síntomas de asma

En la **última semana**, ¿cuántos días su hijo(a) presentado síntomas de asma?

*Por ejemplo: tos, presión o dolor de pecho, falta de aire, flema (escupe, moco, flema al toser), dificultad para respirar profundo, tiene silbidos o hace día)



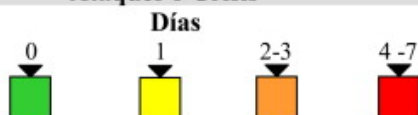
Medicamentos de rescate

8. En la **última semana**, ¿cuántos días le ha dado a su hijo(a) medicamento para alivio rápido de los síntomas de asma? Por ejemplo: Albuterol, Inhalador, spray, Bomba,



Ataques o Crisis

9. En la **última semana**, ¿cuántos días su hijo(a) ha tenido ataques de asma? Por ejemplo: cuando le cuesta trabajo respirar; cuando usted tiene que darle más medicamento cuando las medicinas no funcionan



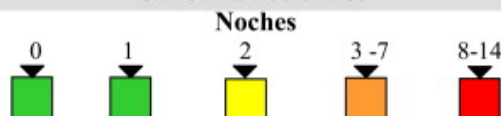
Limitación a la actividad física

10. En la **última semana**, el asma de su hijo(a) ¿qué tanto ha limitado su actividad física?



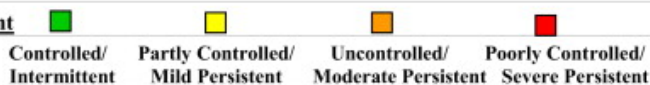
Síntomas nocturnos

11. En las **últimas dos semanas**, ¿cuántas noches el asma de su hijo(a) lo ha despertado o no lo ha dejado dormir?



12. Por favor escriba cualquier otra información que a usted le interese que su doctor sepa acerca del asma de su hijo(a).

FOR CLINICIAN USE ONLY: Control/Severity Assignment



Assign patient's current level of asthma control/severity by looking at the box checked *farthest to the right* on questions 7-11 and match the box color to the level of asthma control/severity in this section.

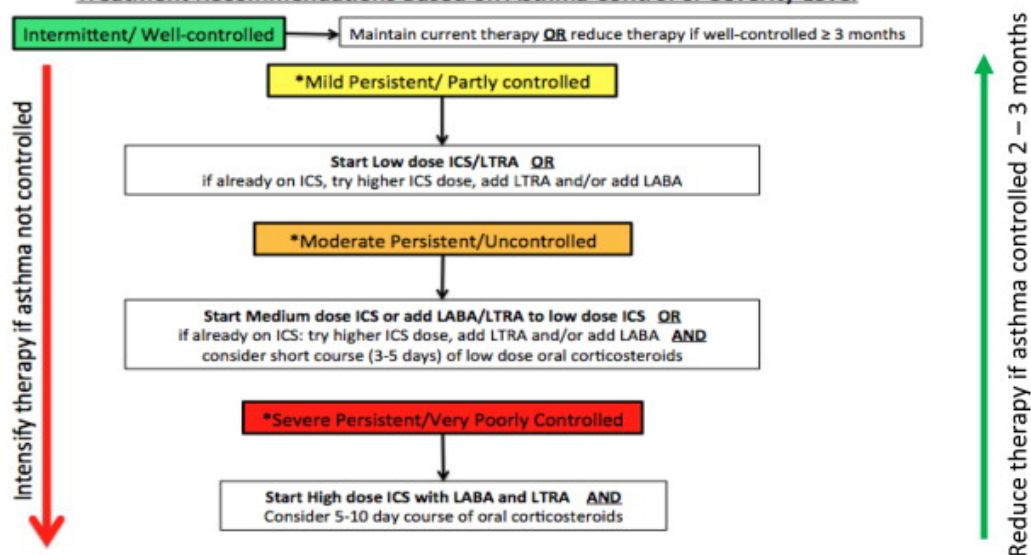
Severity categories are for patients not on controller therapy. Control categories are for patients currently taking controller therapy.

The goal for all patients is to have controlled asthma with the least amount of medication and no side effects.

If asthma is not controlled, possible explanations include: acute respiratory infection, under-treatment with daily controller medications, poor inhaler technique, poor adherence, environmental allergies and/or exposures, comorbid conditions (see treatment algorithm on page 3).

Follow-up in 2 – 6 weeks is recommended.

Treatment Recommendations Based on Asthma Control or Severity Level



* IF ASTHMA IS NOT CONTROLLED, ALSO CONSIDER EACH OF THE FOLLOWING:

- Acute Respiratory Infection:** □ patient may benefit from regular use of Albuterol (e.g., 4 times a day) during the acute illness
- Inhaler technique:** □ is patient using spacer with MDI? □ have patient demonstrate inhaler technique
- Medication adherence:** □ review patient response to PACCI adherence question □ review pharmacy record of filled medications
- Environmental allergies and exposures:** □ has patient been allergy tested? □ is there secondhand smoke exposure?
- Comorbid conditions:** □ allergic rhinitis □ sinusitis □ obesity □ gastro-esophageal reflux
- Asthma specialist referral:** □ systemic steroids ≥ 2 times/year □ intubation/ICU admit □ uncontrolled asthma on high dose ICS

Inhaled Corticosteroids (ICS)		Child 0-4 years old			Child 5-11 years old			>12 years old		
		Low Dose	Medium	High Dose	Low Dose	Medium	High Dose	Low Dose	Medium	High Dose
Beclomethasone/QVar MDI	40mcg 80mcg	N/A	N/A	N/A	2-4 puffs 1-2 puffs	>2-4 puffs	>4 puffs	2-4 puffs 1-3 puffs	>3-6 puffs	>6 puffs
Budesonide/Pulmicort DPI Flexhaler	90mcg 180 mcg	N/A	N/A	N/A	2-4 inhal 1-2 inhal	>2-4 inhal	>4 inhal	2-6 inhal 1-3 inhal	4-6 inhal	>6 inhal
Budesonide/Pulmicort Respule	0.25mg neb 0.5mg neb	2 nebs 1 neb	>2 nebs 2 neb	>2 nebs	2 nebs 1 neb	4 nebs 2 nebs	4 nebs	N/A	N/A	N/A
Fluticasone/Flovent MDI	44 mcg 110 mcg 220 mcg	4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puff	2-4 puffs 1 puff	5-8 puffs 1-3 puffs 1 puff	>8 puffs >3 puffs >1 puffs	2-6 puffs 2 puffs 1 puff	6-10 puffs 2-4 puffs 1-2 puffs	>10 puffs >4 puffs >2 puffs
Fluticasone/Flovent Diskus DPI	50 mcg 100 mcg 250 mcg	N/A	N/A	N/A	2-4 inhal 1-2 inhal	3-4 inhal 1 inhal	>4 inhal >2 inhal	2-6 inhal 1-3 inhal 1 inhal	6-10 inhal 4-5 inhal 2 inhal	>10 inhal >5 inhal >2 inhal
Mometasone/Asmanex Twisthaler DPI	200mcg	N/A	N/A	N/A	N/A	N/A	N/A	1 inhal	2 inhal	>2 inhal
Combination Drugs—ICS + LABA: patient should not take more than: 2 puffs per dose of the combo MDI or 1 puff per dose of the combo DPI										
Fluticasone/Salmeterol (Advair) MDI	45/21 mcg 115/21 mcg 230/21 mcg	N/A	N/A	N/A	1-2 puffs	2-4 puffs 1-2 puffs	2 puffs 1 puff	1-3 puffs 1 puff	3-4 puffs 2-3 puffs 1 puff	3-4 puffs 1-2 puffs
Fluticasone/Salmeterol Diskus (Advair) DPI	100/50 mcg 250/50 mcg 500/50 mcg	N/A	N/A	N/A	1 inhal	1-2 inhal 1 inhal	1 inhal	1 inhal	1-2 inhal 1 inhal	1- inhal 1 inhal
Budesonide/Formoterol (Symbicort)	80/4.5mcg MDI 160/4.5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	1-3 puffs 1-2 puffs	4 puffs 2-3puffs	3-4 puffs
Mometasone/Formoterol (Dulera)	100/5mcg MDI 200/5mcg MDI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1 puff	2 puffs

Notes: **MEDICATION DOSES** of puffs or nebs in the chart are for **TOTAL DOSES PER DAY** (e.g., 2 puffs = 2 total puffs per day).
Combination drugs are assumed to be equivalent to doubling of the ICS dose alone (e.g., 1 puff of Fluticasone/Salmeterol 45/21 = 2 puffs of Fluticasone).
N/A and blank areas indicate that there is no on-label recommended dosing available. **INHAL:** inhalation of DPI
ICS: inhaled corticosteroid; **LTRA:** leukotriene receptor antagonist; **LABA:** long acting beta₂-agonist; **MDI:** metered dose inhaler; **DPI:** dry powder inhaler