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JACE Management Control of Management Contro

PII: S2213-2198(25)00631-2

DOI: https://doi.org/10.1016/j.jaip.2025.06.039

Reference: JAIP 6110

To appear in: The Journal of Allergy and Clinical Immunology: In Practice

Received Date: 21 February 2025

Revised Date: 9 June 2025 Accepted Date: 26 June 2025

Please cite this article as: Murphy KR, Chipps B, Lanz MJ, Bacharier LB, Guilbert TW, George M, Mohammad A, Winders T, LeNoir M, Gilbert IA, Eudicone JM, Coyne KS, Harding G, Zeiger RS, Pediatric Asthma Impairment and Risk Questionnaire: A Control Assessment for Children Aged 5-11 Years, *The Journal of Allergy and Clinical Immunology: In Practice* (2025), doi: https://doi.org/10.1016/j.jaip.2025.06.039.

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# Pediatric Asthma Impairment and Risk Questionnaire: A Control Assessment for Children Aged 5-11 Years

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# **Funding statement**

This work was supported by AstraZeneca (Wilmington, Del, USA).

# **Conflicts of interest**

**K. R. Murphy** has served as a consultant and speaker for AstraZeneca, Boehringer Ingelheim, Genentech, Merck, Mylan, Novartis, OptiNose, Regeneron, Sanofi, Stallergenes Greer, and Teva.

- **B. Chipps** has served as an advisor, consultant, and speaker for AstraZeneca, Boehringer Ingelheim, Circassia, Genentech, Novartis, Regeneron, and Sanofi.
- M. J. Lanz has served as a consultant or speaker for Amgen, AstraZeneca, Cogent, Genentech, Grifols, Novartis, and Sanofi/Regeneron, and has received grant funding from AstraZeneca, Genentech/Roche, Regeneron, and Sanofi.
- L. B. Bacharier has served as a consultant for AstraZeneca, Avillion Life Sciences, GSK, Recludix Pharma, Regeneron, and Sanofi; has received speaker fees from Regeneron and Sanofi; is a member of the data and safety monitoring board for Aravax, AstraZeneca, Cystic Fibrosis Foundation Therapeutics/Vertex Pharmaceuticals, and DBV Technologies; and has received research support from the National Institutes of Health and Sanofi.
- T. W. Guilbert has received grants and personal fees from AstraZeneca, OM Pharma, and Sanofi/Regeneron/Amgen; has received grants from GSK; has received personal fees from Advent.com, AiCME, Genentech, PlatformQ Health, and Polarean; and has received royalties from UpToDate.
- **M. George** has served as a consultant for AstraZeneca, Genentech/Roche and Verona, and has served as a speaker for AstraZeneca and Regeneron.
  - **A. Mohammad** has served on an advisory board for AstraZeneca.
- T. Winders has served as a consultant and speaker for ALK-Abelló A/S, AstraZeneca, Chiesi, Genentech, GSK, Regeneron, Roche, and Sanofi.

M. LeNoir has served on an advisory board for AstraZeneca and is a board

member for the African American Wellness Project and the Digital Health for

Equitable Health Alliance

I. Gilbert and J. M. Eudicone are employees of AstraZeneca and may hold

stock or stock options.

K. S. Coyne and G. Harding are employees of Evidera, which was contracted

by AstraZeneca for study design and to collect and analyze data for this study.

R. S. Zeiger has received grant support from ALK-Abelló A/S, AstraZeneca,

Blueprint Technologies, Merck & Co., the National Heart, Lung, and Blood Institute,

and Sanofi; has received consultant fees from AstraZeneca, Bayer, Merck & Co.;

has received royalties from UpToDate; and has warrants from DBV Technologies

during the conduct of the present study.

Article type: original article

Abstract: 246 words [max: 250 words]

Body of manuscript: 4953 words

Tables/figures: 8 [max 8]

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# ABSTRACT [246/250 WORDS]

**BACKGROUND**: Uncontrolled asthma in childhood is associated with exacerbations and impaired health-related quality of life. Commonly used control tools for children aged 5-11 years assess asthma symptoms but not exacerbations, potentially leading to overestimation of control and suboptimal management.

**OBJECTIVE**: This cross-sectional observational study aimed to validate the Pediatric Asthma Impairment and Risk Questionnaire (Peds-AIRQ), a novel control tool assessing symptom impairment and exacerbation risk.

**METHODS**: A total of 399 children aged 5-11 years with physician-diagnosed asthma were recruited from 1 primary care and 7 specialty care sites across the United States. Parents/caregivers, with input from their child, answered 18 yes/no questions about asthma symptoms and exacerbations. Children were categorized as having well-controlled (WC), not well-controlled (NWC), or very poorly controlled (VPC) asthma according to a validation standard using Global Initiative for Asthma symptom control questions plus prior-year exacerbations. Items with the greatest ability to discriminate among control categories and cut points were determined through logistic regression analyses.

**RESULTS**: Models yielded a Peds-AIRQ comprising 5 impairment-based and 3 risk-based questions. The Peds-AIRQ yielded areas under receiver-operating characteristic curves of 0.85 to differentiate WC versus NWC/VPC asthma and 0.83 to differentiate WC/NWC versus VPC asthma. Score cut points of 0-1, 2-4, and 5-8 "yes" responses were determined to best represent WC, NWC, and VPC asthma, respectively.

**CONCLUSIONS**: The Peds-AIRQ is a validated numerical assessment tool for children aged 5-11 years that can be used at point-of-care to evaluate asthma control based on current symptoms and exacerbation history.

# **HIGHLIGHTS**

What is already known about this topic? Asthma control assessment tools are available for children with asthma aged 5-11 years; however, the most commonly used tools for this age group measure only symptom impairment and not the exacerbation-based risk domain.

What does this article add to our knowledge? This article describes the validation of the Pediatric Asthma Impairment and Risk Questionnaire (Peds-AIRQ), a novel asthma control tool developed to assess impairment and risk in a single point-of-care tool.

How does this study impact current management guidelines? The low-literacy-demand, 8-item, equally weighted, yes/no Peds-AIRQ can serve as a shared decision-making tool to identify uncontrolled asthma in children aged 5-11 years.

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Keywords (up to 10): Asthma; Control; Uncontrolled; Impairment; Risk;

Exacerbation; Questionnaire; Validation; Pediatric

## **Abbreviations used**

AIRQ: Asthma Impairment and Risk Questionnaire

AUC: Area under the curve

BMI: Body mass index

C-ACT: Childhood Asthma Control Test

CI: Confidence interval

GED: General Equivalency Diploma

GINA: Global Initiative for Asthma

GINA SCT: Global Initiative for Asthma 4-question, symptom control tool

ICS: Inhaled corticosteroid(s)

LABA: Long-acting β<sub>2</sub>-agonist

LAMA: Long-acting muscarinic antagonist

NAEPP: National Asthma Education and Prevention Program

NWC: Not well-controlled

OCS: Oral corticosteroid(s)

OR: Odds ratio

Peds-AIRQ: Pediatric Asthma Impairment and Risk Questionnaire

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PedsQL: Pediatric Quality of Life Inventory

ROC: Receiver-operating characteristic

SABA: Short-acting β-agonist

SCS: Systemic corticosteroid(s)

SD: Standard deviation

TRACK: Test for Respiratory and Asthma Control in Kids

VPC: Very poorly controlled

WC: Well-controlled

# INTRODUCTION

Asthma is one of the most common chronic diseases in children and a leading cause of missed school days, emergency room (ER) visits, and hospitalizations.<sup>1, 2</sup> An estimated 2 million children aged 5-11 years have asthma in the United States.<sup>3</sup> Approximately half of these children have uncontrolled disease,<sup>2</sup> which is associated with exacerbations, disability, impaired health-related quality of life, and increased healthcare utilization.<sup>4-6</sup> To improve outcomes, children with uncontrolled asthma must be identified and monitored for disease progression and treatment effectiveness.

The US National Asthma Education and Prevention Program (NAEPP)<sup>7</sup> and the Global Initiative for Asthma (GINA)<sup>8</sup> recommend the use of validated numerical impairment questionnaires, such as the Childhood Asthma Control Test (C-ACT)<sup>9</sup> and the Asthma Control Questionnaire (ACQ) for children,<sup>10</sup> or the consensusdeveloped, 4-question GINA symptom control tool (GINA SCT).<sup>8</sup> Although these tools measure symptom impairment, they do not include exacerbation history. In our qualitative study examining the need for a composite control tool, 48% of children aged 5-11 years assessed by a clinician and 28% by the GINA SCT were rated as having well-controlled asthma despite experiencing prior-year exacerbations.<sup>11</sup> Failure to include exacerbation history leads to overestimation of control, resulting in suboptimal treatment and poorer outcomes.<sup>12</sup>

The Asthma Impairment and Risk Questionnaire (AIRQ) is a 10-item, equally weighted, yes/no, low-literacy-demand, composite tool developed and validated to assess control in adolescents and adults aged ≥12 years.<sup>13</sup> The AIRQ has been

shown to be superior to expert physician opinion and impairment-based tools at differentiating levels of asthma control and risk of future exacerbations. <sup>14, 15</sup> The AIRQ also better predicts future exacerbations than a combination of biomarkers and demographic and clinical features univariately associated with increased exacerbation risk. <sup>16</sup> Although the Test for Respiratory and Asthma Control in Kids (TRACK), a validated tool that measures asthma symptom impairment and exacerbation risk, is available for use with children aged <5 years <sup>17</sup>, there remains an unmet need for a composite measure of asthma control for children aged 5-11 years. Additionally, there is a need to validate assessment tools in populations most affected by asthma and its associated morbidity, such as in Black or African American, and Hispanic or Latino children.

The objective of this cross-sectional study was to derive and validate the final items for a Pediatric AIRQ (Peds-AIRQ) in a demographically and clinically diverse group of children to achieve the best fit model against a validation standard of impairment (symptom control) and risk (chart-documented prior-year exacerbations).

## **METHODS**

## Study design

This validation study included 399 child and parent/caregiver dyads enrolled from 1 primary care and 7 specialist clinics across diverse geographic regions in the United States between October 2023 and July 2024.

The study protocol was approved by a central institutional review board (Western Institutional Review Board-Copernicus Group, Princeton, NJ; protocol number: 20234200) for all sites, and the study was conducted in accordance with the ethical principles of the International Committee on Harmonisation's Good Clinical Practice guidelines. Parents and caregivers provided written informed consent; children provided verbal assent.

# Participant eligibility

Children aged 5-11 years with a physician-confirmed asthma diagnosis and parent-/caregiver-reported use of ≥1 asthma medications in the prior 6 months were enrolled. Parents/caregivers had to be the child's primary caregiver and aged ≥18 years. Children and their parents/caregivers had to speak and understand English or Spanish to participate. Dyads were excluded if the child or their parent/caregiver had a cognitive impairment, hearing difficulty, visual impairment, or a medical condition that might interfere with their ability to agree to participate and/or complete study questionnaires. Additional exclusion criteria included having a pre-existing, non-asthma lung or medical condition with symptoms that could be confused with asthma, or a gestational age at birth of <35 weeks.

Study recruitment efforts prioritized enrolling roughly equivalent proportions of children from age groups 5-6, 7-8, and 9-11 years and ensuring diversity of race, ethnicity, and socioeconomic status that was reflective of the US childhood population with asthma. The primary care study site was a Federally Qualified Healthcare Center (FQHC) site serving minority and economically disadvantaged

populations. The study team evaluated and provided feedback to sites on the sociodemographic composition of the enrolled children on a weekly basis.

Enrollment aimed for 30% of children using a short-acting β-agonist (SABA) only (intermittent disease); 20% using only low-dose inhaled corticosteroids (ICS) or montelukast for maintenance and SABA as rescue therapy (mild persistent disease); and ≥50% utilizing medication appropriate for moderate-to-severe persistent asthma. Up to 25% of children could have experienced an exacerbation within the prior 4 weeks.

#### **Assessments**

Peds-AIRQ. The draft Peds-AIRQ was developed by adapting the 10 yes/no items from the AIRQ.<sup>11</sup> Following evaluation through cognitive interviews with 60 child and parent/caregiver dyads and expert clinician feedback, items were refined for clarity, added to explore alternate wordings for pertinent concepts, or removed due to perceived lack of relevance or ambiguity, resulting in the inclusion of 8 additional items containing wording or control-threshold variations. The 18-item draft Peds-AIRQ comprised impairment and risk questions addressing asthma symptoms, activity impairment, medication use, and asthma-related exacerbations, unscheduled medical visits, and hospitalizations.

Child- and parent-/caregiver-completed assessments. Parents/caregivers completed the following questionnaires at the baseline clinic visit, with input from their children: (1) 18-item draft Peds-AIRQ; (2) C-ACT (7-item asthma symptom impairment-based control tool for children aged 4-11 years);<sup>9</sup> (3) a sociodemographic questionnaire; and (4) Pediatric Quality of Life Inventory

(PedsQL) Acute Version (Parent Proxy Report for children aged 5-7 years<sup>18</sup> and Child Self-Report for children aged 8-11 years<sup>19, 20</sup>). Participants and the physicians evaluating the children were blinded to the scores of all participant-completed questionnaires.

The draft Peds-AIRQ included images of demographically diverse children at the top of the questionnaire and images of rescue therapies for the two relevant draft questions. The authors felt that rescue inhaler images were necessary for the parents/caregivers and children to facilitate understanding of which of their medications the two draft questions referred to. All images were included based on expert input that the images would facilitate shared decision-making conversations between the clinicians, parents/caregivers, and children being assessed with the final Peds-AIRQ.

Method of assessment completion. Sites were provided with a tablet (iPad) for participants to complete assessments during their clinic visit. The first 84 dyads completed all questionnaires on paper due to delays in the launch of the web-based survey. A mode-of-administration sub-study was conducted at 3 sites in which participants were assigned via block randomization to complete the Peds-AIRQ electronically (via tablet), on paper, or via interviewer (ie, site staff) administration.

Physician-completed assessments. At baseline, physician investigators completed a chart review, medical history intake form with the dyads, a physical examination of the child, and a clinical information form regarding the child's asthma clinical history, current medications, exacerbations, and systemic corticosteroid (SCS) use.

Physicians asked the 4 GINA SCT questions addressing impairment from daytime

symptoms, night awakenings, rescue use, and activity.<sup>8</sup> Upon completion of the visit, physicians provided their expert assessment of each child's level of asthma control using a 5-point Likert scale: completely controlled, well-controlled, somewhat controlled, partly controlled, and not controlled.

Composite GINA SCT plus exacerbations outcome measure. The prespecified primary outcome measure was level of asthma control relative to baseline C-ACT score (impairment) plus chart-documented prior-year exacerbations (risk). However, based on recent literature demonstrating that the GINA SCT performs better than the ACT in identifying current asthma control in adolescents and adults, 15, 21 GINA SCT score plus exacerbation history was identified by the authors as being a more discriminating composite outcome measure than C-ACT plus exacerbation history to validate the Peds-AIRQ items. To confirm this selection, an interim examination of baseline data was conducted to verify the performance of the GINA SCT versus the C-ACT.

Exacerbations were defined as a change in asthma symptoms requiring a course of SCS (oral corticosteroids [OCS] for ≥3 days and/or steroid injection); or an ER, urgent care, walk-in clinic, or unplanned office visit for an asthma exacerbation; or a hospital admission for asthma of >24 hours. Asthma control relative to the Peds-AIRQ validation standard was stratified into 3 levels based on a composite score of GINA SCT plus exacerbations: well-controlled (WC), not well-controlled (NWC), and very poorly controlled (VPC) (Figure 1).

# Statistical analysis and model selection

The analysis set was defined as all child and parent/caregiver dyads who completed the baseline visit and potential Peds-AIRQ questions and had GINA SCT plus prior-year exacerbation data. Sociodemographic and clinical characteristics data were summarized using descriptive statistics. All analyses were conducted using SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

Multivariable logistic regression analyses were used to determine which of the 18 draft Peds-AIRQ items provided the greatest validity in discriminating among children with varying levels of asthma control, as defined by the validation standard. Two dichotomous models were run against the validation standard by changing the dependent-variable group as follows: Model 1: WC versus NWC/VPC asthma; Model 2: WC/NWC versus VPC asthma. Initially, the models included only the first 10 items from the Peds-AIRQ to evaluate model fit, potential score cut points, receiver operating characteristic (ROC) curves, and item performance; 5 additional impairment items were added and evaluated as described above. Additional models were run to evaluate the model fit for different symptom thresholds (eg. "any night" vs "≥2 nights"). Items with the best model fit were retained, and logistic regressions were performed using age group, sex, race, ethnicity, and body mass index (BMI) percentile group (reference group: healthy weight 5th to <85th percentile) as covariates. After initial item selection, the 3 exacerbation risk-related items with a 3month recall period were evaluated in place of the exacerbation risk-related items with a 12-month recall period.

After completing all model runs, the overall performance and fit were compared. Items that were significant and complementary to each dependent variable were retained. The final selection of items for the Peds-AIRQ was made based on retention of well-performing items, balancing among items strongly identifying WC asthma versus all others and VPC asthma versus all others, and lack of redundancy with items that differed only by event frequency.

For the primary outcome measure, the predictive model used two separate logistic regression models to discriminate between asthma control groups. This approach was selected in favor of an ordinal or multinomial logistic regression based on previous validation work on the AIRQ.<sup>13</sup> In that study, it was found that ordinal and multinomial models were not constant across outcome levels, indicating that the proportional odds assumption did not hold for the data. The AIRQ questions performed differently when identifying the WC vs NWC/VPC control groups compared to when identifying the WC/NWC vs VPC control groups. Consequently, separate dichotomous models were required to discriminate among the asthma control groups.

After final item selection, sensitivity and specificity were calculated to determine cut points for Peds-AIRQ score ranges best representing WC versus NWC/VPC asthma and WC/NWC versus VPC asthma. High sensitivity was prioritized for identifying WC asthma, and high specificity was prioritized for VPC asthma. As such, control cut points would maximize identification of children with WC asthma who likely would not need further intensive assessments and management plan updates and minimize any overidentification of children with VPC asthma who would need

prioritization for accelerated evaluations and advanced and potentially high-cost treatments.

Correlations (Spearman rank coefficients) were evaluated between the final scores of the Peds-AIRQ and C-ACT, GINA SCT, PedsQL, and physician assessment. Final Peds-AIRQ scores across C-ACT and physician assessment of asthma control groups were analyzed using general linear models and Scheffe's post hoc adjustment for pairwise comparisons. Chi-square tests were used to compare Peds-AIRQ asthma control categories by physician assessment and C-ACT control groups.

Logistic regressions were performed using Peds-AIRQ, physician assessment, and C-ACT control levels as independent variables and ≥1 prior-year exacerbation as the dependent variable (odds ratios [ORs] and 95% Wald confidence intervals [CIs]). Chi-square tests compared area under the ROC curves for Peds-AIRQ regression models versus those for physician assessment and C-ACT to predict prior-year exacerbations and the comparative frequencies of ≥1 and ≥2 prior-year exacerbations. Peds-AIRQ scores were compared across mode-of-administration groups using general linear models.

# **RESULTS**

#### **Cohort characteristics**

Mean (standard deviation [SD]) age of the children was 7.9 (1.9) years. Most children were male (62.9%), White (68.9%), and not of Hispanic/Latino ethnicity

(66.4%); 26.3% were obese, 22.8% had intermittent asthma, and 9.0%, 60.2%, and 8.0% had mild, moderate, or severe persistent asthma based on pharmacologic treatment, respectively; and 39.1% had public or no health insurance (**Table I**). Mean (SD) age of the parents/caregivers was 39.8 (7.4) years, and 12.8% were male. Almost all participating adults were parents (96.7%); most were employed full time (60.7%), 52.6% reported at least a college degree, and 41.4% reported a household annual income above \$100,000. Sites served children from 12 different states, and almost half of the children resided in large central metropolitan areas.

The FQHC primary care site was in a central-city urban environment and saw more economically disadvantaged children than other sites, and the 60 children recruited from this site contributed significantly to the diversity of the study population. Notably, the recruited children were less likely to be White (11.7% vs 79.1%), more likely to be Hispanic or Latino (83.3% vs 24.5%) and more likely to have public health insurance (91.7% vs 29.2%) compared with children recruited at other study sites (all comparisons P < .001). In addition, the parents/caregivers of the children at this site tended to be slightly younger (mean age 37.3 years vs 40.3 years; P = .004), less likely to be employed full-time (43.3% vs 63.7%; P < .001), and less likely to have a college education or post-graduate degree (6.7% vs 60.8%; P < .001) than parents/caregivers of children recruited at other sites.

At baseline, 47.4% of children had WC asthma according to GINA SCT score, 28.8% had partly controlled asthma, and 23.8% had uncontrolled asthma. Based on C-ACT scores, 69.2% had WC, 25.6% NWC, and 5.0% VPC asthma. Physicians assessed 64.9% of children as having asthma that was completely/well-controlled,

21.3% as somewhat controlled, and 13.8% as partly/not controlled. Overall, 45.9% of children had ≥1 and 34.1% had ≥2 prior-year exacerbations.

# Outcome measure, logistic regression analyses, and model selection

An interim examination of baseline data showed that 27.1% of children enrolled in the Peds-AIRQ study were classified as having WC asthma by the C-ACT despite having had prior-year exacerbations, whereas only 16.5% were similarly assessed by the GINA SCT. These results were congruent with the findings of Chipps et al<sup>15, 21</sup>; therefore, the composite GINA SCT plus prior-year exacerbations outcome measure was used for logistic regression analyses and models.

Multivariable logistic regression analyses were used to determine which of the 18 draft Peds-AIRQ items provided the greatest ability to discriminate among children with varying levels of asthma control (**Table II**). Items that were significant in ≥1 model were retained. Items significant in both models included symptoms on ≥5 days and rescue medication use for ≥2 days over the prior 2 weeks, as well as prioryear SCS use, and ER, urgent care, or unplanned visits to a health care provider due to asthma symptoms. Items that were significant only in Model 1 (WC vs NWC/VPC asthma) were asthma symptoms limiting physical activities and awaking from sleep on any night over the prior 2 weeks due to symptoms. Asthma symptoms limiting planned activities in the prior 2 weeks was significant only in Model 2 (WC/NWC vs VPC asthma). Hospitalization was not significant in either model but was retained due to clinical relevance. The 3-month recall period for the exacerbation items regarding SCS use and ER, urgent care, or unplanned visits to a health care provider were significant in both models; however, the items with a 12-month recall

period were retained due to better item performance and model fit. Eighty-seven participants reported "no" to the 3-month exacerbation recall items but reported "yes" to one or more of the 12-month recall items. Online Repository **Table E1 (A, B, C, and D)** shows iterations of Model 1 and Model 2. The final 8-item Peds-AIRQ (**Figure E1**) includes 5 impairment and 3 risk items.

The dependent-variable models performed well, with an area under the ROC curve of 0.86 for the individual item model (0.85 for the 0-8 summed score model) to identify WC versus NWC/VPC asthma and 0.85 for the individual item model (0.83 for the 0-8 summed score model) to identify WC/NWC vs VPC asthma (**Figure 2**). The sensitivity and specificity of each model were examined to select cut points to identify control levels using the Peds-AIRQ 0-8 summed score, prioritizing sensitivity to identify WC asthma and specificity to identify VPC asthma. A Peds-AIRQ cut point of ≥2 to separate WC asthma versus all others yielded a sensitivity of 0.79, specificity of 0.81, and positive and negative predicted values of 0.90 and 0.63, respectively (**Figure 2A**). A cut point of ≥5 to separate VPC asthma from all others showed a specificity of 0.95, sensitivity of 0.38, and positive and negative predictive values of 0.87 and 0.65, respectively (**Figure 2B**).

A final series of logistic regressions was performed to examine the control groups as defined by the above cut points, controlling for covariates of age group, sex, BMI percentile group, race, and ethnicity. These yielded model area under the ROC curves of 0.85 for WC versus NWC/VPC asthma and 0.84 for WC/NWC versus VPC asthma.

# Peds-AIRQ and construct validity

The mean (SD) Peds-AIRQ score was 2.4 (2.2). Cut points of 0-1, 2-4, and 5-8 resulted in 159 children (39.8%) being assessed as having WC asthma, 161 (40.4%) as having NWC asthma, and 79 (19.8%) having VPC asthma, respectively. Of note, there were no differences in Peds-AIRQ scores and control groups between the FQHC site and other sites (*P* >.05 for both). The distribution of total Peds-AIRQ scores (**Figure E2 A**) ranged from 26.6% of the children having a score of 0 to 1.5% of the children having a score of 8. The Peds-AIRQ item with the greatest proportion of children having a "yes" response was ER, urgent care, or unplanned visits to a health care provider due to asthma symptoms (43.6%), whereas hospitalizations for asthma symptoms had the lowest proportion of "yes" responses (4.0%) (**Figure E2 B**).

Significant correlations were observed between the Peds-AIRQ score and C-ACT (r=-0.67), GINA SCT (r=0.66), physician assessment of control (r=0.48) and PedsQL (r=-0.43 for parent-proxy; r=-0.37 for child self-report) scores (P<.001 for all). Mean Peds-AIRQ score increased significantly with worsening C-ACT and physician assessment control category, and pairwise comparisons were significant for both measures, except mean Peds-AIRQ score for C-ACT VPC versus NWC asthma (**Table III**).

The proportion of children experiencing  $\geq 1$  prior-year exacerbation increased within each worsening Peds-AIRQ control category (20.8% WC, 54.7% NWC, and 78.5% VPC, P < .001, **Table IV**). Similarly, within each worsening control level, the proportion of children experiencing SCS courses (P < .001), ER visits (P < .001), and

hospitalizations (P=.03) for asthma also increased. Both NWC and VPC asthma were significantly associated with ≥1 prior-year exacerbation vs WC asthma: OR [95% CI] 4.55 [2.78-7.44] and 13.49 [7.00-25.99], respectively, P<.001 for both) (**Figure 3**). Physician assessment and C-ACT control levels were also significantly associated with ≥1 prior-year exacerbations, with the area under the curve (AUC) for Peds-AIRQ (0.74) being higher than that for C-ACT (0.60, P<.001) and numerically, but not statistically, greater than physician assessment (AUC=0.69, P=.09).

Overall, the Peds-AIRQ classified a significantly lower proportion of children as having controlled or WC asthma who had  $\geq 1$  (8.3%) and  $\geq 2$  (4.8%) prior-year exacerbations than physician assessment (20.8% and 13.8%) and C-ACT (27.1% and 18.3%), P < .001 for all comparisons (**Figure 4**). Similarly, the proportion of children categorized as having uncontrolled asthma who had  $\geq 1$  and  $\geq 2$  prior-year exacerbations was significantly greater for Peds-AIRQ (37.6% and 29.3%) than the physician assessment (25.1% and 20.3%) and C-ACT (18.5% and 15.5%), all P < .001.

#### Mode of administration

The mode-of-administration sub-study included 165 dyads (tablet, n = 53; paper, n = 57; interviewer, n = 55) across 3 sites (2 specialty, 1 primary care). Mean (SD) Peds-AIRQ scores were 2.2 (1.86) for tablet, 2.2 (2.14) for paper, and 3.0 (2.19) for interviewer-administered. Although the overall general linear model was significant (P=.05), no pairwise comparisons were significant between the mode-of-administration groups.

# **DISCUSSION**

This cross-sectional validation study identified 5 impairment-based and 3 risk-based items for inclusion in the final Peds-AIRQ. The questions are equally weighted, with 0-1 "yes" responses representing WC, 2-4 NWC, and 5-8 VPC asthma. The Peds-AIRQ items are strongly associated with the GINA SCT plus prior-year exacerbation validation standard and differentiated with high sensitivity for identifying WC versus NWC/VPC asthma and high specificity for identifying WC/NWC versus VPC asthma.

The included items address parent/caregiver and child recall of asthma-related daytime and nighttime symptoms, physical limitations, ability to participate in activities, and medication use over the previous 2 weeks, and exacerbations and healthcare resource utilization over the previous 12 months. Although there is no consensus on the optimal recall period of symptoms, with validated control tools for children utilizing anywhere from 1- to 4-week recall periods, 9, 10, 22 the Peds-AIRQ employs a 2-week recall period to enhance memory of the events and to exclude symptoms that may have resolved. With respect to a 12-month recall period for the risk items, although prior 3-month SCS use and ER visits for asthma contributed significantly to the models, the models did not perform as well as those with the 12-month recall period items. Moreover, as asthma exacerbations are often seasonal, a 12-month recall period best captures all exacerbations that could place children at risk of subsequent exacerbations.

The construct validity of the Peds-AIRQ was demonstrated by significant correlations of the Peds-AIRQ score with C-ACT, GINA SCT, physician assessment,

and PedsQL scores. Peds-AIRQ control categories were significantly related to C-ACT and physician assessment control groups. The proportion of children who experienced prior-year asthma exacerbations or asthma-related OCS courses, ER visits, and hospitalizations, increased with worsening Peds-AIRQ control level.

The burden of exacerbations and resultant adverse health conditions that can be associated with SCS treatment is unacceptably high in children with asthma. In the current study, almost half of the children had ≥1 exacerbation in the prior year. Childhood asthma is associated with multiple comorbidities later in life, including obesity, diabetes, hypertension, and cardiovascular disease, which may be partly attributed to childhood SCS exposure and exercise and normal physical activity limitations due to uncontrolled disease.<sup>23-25</sup> Of note, 26% of children in the current study were categorized as obese, and another 16% as overweight based on BMI.

For almost two decades, epidemiologists have recognized that uncontrolled asthma and a history of prior exacerbations are the strongest predictors of future exacerbations in children.<sup>26-28</sup> However, recent analyses have questioned the ability of impairment-only control tools to predict future exacerbations in children.<sup>29</sup> Exacerbation history and number of prior-year exacerbations contribute to the risk for subsequent exacerbations.<sup>30-33</sup> Moreover, although the Peds-AIRQ item on prior-year hospitalization for asthma did not contribute significantly to the validation models, it was retained due to the morbidity of the event and studies in children showing that a hospitalization for asthma increases the risk for any severe exacerbation over the subsequent 4 years.<sup>27, 34</sup> The scoring and cut points of the Peds-AIRQ ensure that no child who has had a prior-year hospitalization for asthma

would be placed in the WC category. Hospitalizations for worsening asthma symptoms are almost universally treated with SCS, as recommended by NAEPP<sup>7</sup> and GINA,<sup>8</sup> thus resulting in a Peds-AIRQ score of ≥2. Although prior-year hospitalization for asthma was a rare event in our study, occurring in only 8 (2.0%) of the 399 children, as the Peds-AIRQ control category worsened, the proportion of children with a hospitalization increased significantly: 0% of those with WC, 2.5% of those with NWC, and 5.1% of those with VPC asthma (*P*=.027).

In the present study, the composite Peds-AIRQ was more strongly associated with prior-year exacerbations than the C-ACT, the asthma control assessment for children commonly used in clinical practice.<sup>34, 35</sup> Moreover, the Peds-AIRQ categorized a significantly lower proportion of children with ≥1 and ≥2 exacerbations in the prior year as having WC asthma and a significantly higher proportion as having uncontrolled asthma than the C-ACT and physician assessment. These findings support the need for a point-of-care tool that can evaluate current symptoms and exacerbation history in a single instrument, so that overestimation of control is minimized, and children at potential risk of exacerbations can be identified and management plans adjusted as appropriate.

The Peds-AIRQ is pictorial, includes only equally weighted yes/no items validated for both parent/caregiver and child responses, and is at a sixth grade reading level (Flesch-Kincaid Readability Test). The validity of the tool was maintained whether administered via a tablet, on paper, or verbally. Equal weighting of each question was selected for clinical and statistical reasons and did not include scoring based on a value of the coefficient for each question in the logit model. The

goal was to develop a tool that children and parents/caregivers could easily understand, complete, and score, and equal weighting allows for the total score to be calculated based on simple addition. The models performed very well using individual scores with equal weighting; thus, weighted scoring was not necessary. Furthermore, because the Peds-AIRQ items are intended to capture the spectrum of asthma control, items needed to be equally weighted to avoid favoring any control group. Taken together, these features of the Peds-AIRQ decrease the cognitive burden on respondents, which may facilitate shared decision-making conversations between clinicians, parents/caregivers, and children.

The questions included in the Peds-AIRQ were developed through a needs-assessment process aided by a qualitative study that included testing and refinement of each of the AIRQ items. This process was undertaken to ensure that the voices of children and parents/caregivers most affected by asthma in the US were considered during the development and validation of the Peds-AIRQ. The number of parent/caregiver-child dyads who participated in this process was informed by a recent systematic review that assessed saturation strategies in qualitative research. This research identified a sample size of 9 to 17 interviews as being sufficient to reach saturation. By including 60 parent/caregiver-child dyads, saturation across the age groups of interest could be achieved and would sufficiently represent sociodemographic subgroups of children most impacted by asthma morbidity. In the qualitative study, 20% of children were aged 5-6 years, 28% were aged 7-8 years, and 42% were aged 9-11 years. Twenty-five percent were Black/African American

children, 32% were Hispanic or Latino children, 40% were on public insurance, and at least 15% were living in households at or below the federal poverty level.<sup>37</sup>

This study aimed to recruit a population representative of children with asthma in the US. The most recent demographic data for all children in the US<sup>38</sup> are based on individuals aged ≤19 years. Over this period, 51% of children were male; 59% White, 17% Black, African American, or Black/African American-mixed race; and 26% Hispanic or Latino. The latest Centers for Disease Control and Prevention (CDC) data (2022)<sup>3</sup> on the sociodemographic characteristics of children with asthma are based on individuals aged ≤18 years. Based on these CDC data, the statistics that can be derived for the demographics of children with asthma are approximately 58% (n/N: 2,614,618/4,529,232) male, 46% (n/N: 2,060,007/4,529,232) White, 22% (n/N: 989,470/4,529,232) Black; and 45% (n/N: 2,044,667/4,529,232) Hispanic or Latino. The participants included in the present study were aged 5-11 years; thus, a fully accurate comparison of this study population to the national statistics, which are relative to children aged ≤19 or ≤18 years, cannot be made. However, our study population was reflective of children in the US and children in the US with asthma: 63% were male; 69% were White; 15% Black/Black-mixed race; and 33% were Hispanic. Of note, the developmental study for the C-ACT included children aged 5-11 years, of which 61% were male; 68% White; 11% Afro-Caribbean/African American; and 6% Hispanic/Latino/Spanish American.9

There are several validated asthma control tools for children (Online Repository **Table E2**). A strength of the Peds-AIRQ is the diversity of age, sex, race, ethnicity, and socioeconomic profiles of the children who participated in this

validation study. Furthermore, 8.0% of the Peds-AIRQ validation population had severe persistent asthma based on pharmacologic therapies they were receiving, which strengthens the ability of the model to identify children with VPC asthma compared with tools such as C-ACT, for which only 2.1% of the validation study population were identified with severe asthma. Unlike the Pediatric Asthma Control and Communication Instrument, the ACQ, C-ACT, and Asthma APGAR, the yes/no format of the Peds-AIRQ makes it simple to administer and score, allowing definitive answers to each question.

The limitations of this study include the generalizability of results to the most atrisk children with asthma. Despite the validation population including children from high-morbidity populations, a lower proportion of children in the current study (38.6%) compared with the general population of children with asthma (47.6%) were covered by Medicaid.<sup>39</sup> Additionally, only 45.4% of parents/caregivers had less than a 4-year college degree, and only 39.1% of the families had household incomes <\$100,000. Most children were enrolled from specialty clinics, so findings may not be applicable to all primary care settings. Although a small number of participants completed the Peds-AIRQ in Spanish, most completed it in English, and there was low representation of children living in rural areas. Future studies in more socioeconomically disadvantaged children should be undertaken to evaluate the validity of the Peds-AIRQ for those who are most at risk of adverse outcomes from asthma.

A longitudinal study of the Peds-AIRQ will determine whether a composite control tool for children aged 5-11 years will be predictive of future exacerbation occurrence and health-related quality of life.

# CONCLUSION

Use of the Peds-AIRQ in clinical practice can facilitate the identification of children with uncontrolled asthma and promote shared decision-making to optimize management and reduce morbidity.

#### **ACKNOWLEDGMENTS**

We are grateful to the children and their parents and caregivers who enrolled in the Pediatric AIRQ studies for their graciousness in advancing research into the identification of uncontrolled asthma. We thank Niladri Aichbhaumik, MD; Nicole Chase, MD; David Cypcar, MD; Nabeel Farooqui, MD; Derek Johnson, MD; Jeanne M Lomas, DO; Neha Reshamwala, MD; Derrick Ward, MD; and Matthew Wilson, MD for their participation as Pediatric AIRQ study investigators. We also thank Mary Kate Ladd, MA, of Evidera, for project management and Ren Yu, MA, of Evidera for statistical programming. Medical writing support was provided by Sarah E. Shires, PhD, of Oxford PharmaGenesis Inc. (Newtown, PA, USA), and was in accordance with Good Publication Practice (GPP 2022) guidelines and funded by AstraZeneca (Wilmington, DE, USA).

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# **TABLES**

**TABLE I.** Baseline characteristics of participant dyads (N = 399)

Child sociodemographic characteristics	
Age (years), mean (SD)	7.9 (1.9)
5-6 years, n (%)	107 (26.8)
7-8 years, n (%)	136 (34.1)
9-11 years, n (%)	156 (39.1)
Male, n (%)	251 (62.9)
Ethnicity, n (%)	
Not Hispanic or Latino	265 (66.4)
Hispanic or Latino	133 (33.3)
Missing	1 (0.3)
Race, n (%)	
African American, Black, African American/Black-Mixed	61 (15.3)
Asian	8 (2.0)
American Indian or Alaska Native	0 (0.0)
Native Hawaiian or Other Pacific Islander	2 (0.5)
White	275 (68.9)
Other	52 (13.0)
Missing	1 (0.3)
Health insurance, n (%)	
Private/commercial	225 (56.4)
Public (eg, Medicaid)	154 (38.6)
Both private/commercial and public coverage	16 (4.0)

None	2 (0.5)
Missing	2 (0.5)
Physician-reported clinical characteristics	
BMI percentile, mean (SD)	71.1 (27.4)
Underweight (<5th percentile), n (%)	11 (2.8)
Healthy weight (5th to <85th percentile), n (%)	218 (54.6)
Overweight (85th to <95th percentile), n (%)	65 (16.3)
Obesity (≥95th percentile), n (%)	105 (26.3)
Positive family history of asthma, n (%)	265 (66.4)
Time since asthma diagnosis (years), mean, SD	3.9 (2.56)
Second-hand smoke exposure, n (%)	44 (11.0)
Maintenance pharmacologic therapy class, n (%)*	
ICS	109 (27.3)
ICS/LABA	160 (40.1)
LAMA	5 (1.3)
Leukotriene modifier	114 (28.6)
Biologic	19 (4.8)
SABA only	73 (18.3)
Fixed-dose combination fast-acting LABA/ICS	10 (2.5)
Asthma severity based on pharmacologic therapies, n (%) <sup>†</sup>	
Intermittent asthma	91 (22.8)
Mild persistent asthma	36 (9.0)
Moderate persistent asthma	240 (60.2)
Severe persistent asthma	32 (8.0)

Parent/caregiver sociodemographic characteristics	
Age (years), mean (SD)	39.8 (7.4)
Male, n (%)	51 (12.8)
Relationship to child, n (%)	
Parent	386 (96.7)
Grandparent	12 (3.0)
Missing	1 (0.3)
Employment status, n (%)	
Full time	242 (60.7)
Part time	52 (13.0)
Homemaker	58 (14.5)
Student	3 (0.8)
Unemployed	23 (5.8)
Retired	6 (1.5)
Disabled	9 (2.3)
Other	5 (1.3)
Highest education level, n (%)	
Less than high school	8 (2.0)
High school or GED	110 (27.6)
Associate degree	63 (15.8)
College/university degree	117 (29.3)
Postgraduate school	93 (23.3)
Other	7 (1.8)
Missing	1 (0.3)

Household income, n (%)	
≤ \$15,000	12 (3.0)
\$15,000 to \$29,999	24 (6.0)
\$30,000 to \$44,999	33 (8.3)
\$45,000 to \$59,999	32 (8.0)
\$60,000 to \$74,999	26 (6.5)
\$75,000 to \$99,999	29 (7.3)
≥\$100,000	165 (41.4)
Prefer not to say	77 (19.3)
Missing	1 (0.3)

BMI, body mass index; GED, General Equivalency Diploma; ICS, inhaled corticosteroid(s); LABA, long-acting β2-agonist; LAMA, long-acting muscarinic antagonist; NAEPP, National Asthma Education and Prevention Program; SABA, short-acting β2-agonist; SD, standard deviation.

<sup>\*</sup>Not mutually exclusive.

<sup>&</sup>lt;sup>†</sup>Classification based on 2020 NAEPP Stepwise Approach for Management of Asthma.

**TABLE II.** Peds-AIRQ items evaluated for inclusion

	Model 1:	Model 2:						
	WC vs NWC/VPC	WC/NWC vs VPC						
	asthma*	asthma*						
In the past 2 weeks, has your child's coughing, wheezing, shortness of breath, or chest tightness:								
1. Occurred during the day on 5 or more days?	X	X						
2. Woke you or your child up from sleep on 2 or more	_	_						
nights?	K							
3. Caused your child to use rescue medication (inhaler or	X	X						
nebulizer) on 2 or more days?	(0)							
In the past 2 weeks:								
4. Did your child limit or stop planned activities because of	_	X						
their asthma symptoms?								
5. Did your child need to stay home because of their asthma	_	_						
symptoms?								
6. Did asthma symptoms limit your child from being	Х	_						
physically active?								
7. Did you feel that it was difficult to take care of your child's	_	_						
asthma?								
In the past 12 months, has coughing, wheezing, shortness of b	preath, or chest tight	ness:						
8. Caused your child to take steroid pills, liquids, or shots	Х	Х						
such as prednisone or Medrol®?								
9. Caused your child to go to the emergency room, urgent	X	X						
care, or have unplanned visits to a health care provider?								
10. Caused your child to stay in the hospital overnight?	Retained <sup>†</sup>	Retained <sup>†</sup>						
In the past 2 weeks, has your child's coughing, wheezing, sho	tness of breath, or c	chest tightness:						
11. Woke you or your child up from sleep on any night?	Х	_						

12. Caused your child to use rescue medication (inhaler or	_	_
nebulizer) on 5 or more days?		
In the past 2 weeks:		
13. Did you feel that it was difficult to keep your child's	_	_
asthma symptoms under control?		
14. Did you lack confidence in taking care of your child's	_	_
asthma?		
15. Did you feel uncertain about taking care of your child's	_	_
asthma?		
In the past 3 months, has coughing, wheezing, shortness of broad	eath, or chest tightne	ess:
16. Caused your child to take steroid pills, liquids, or shots	+ ‡	+ ‡
such as prednisone or Medrol®?	9.	
17. Caused your child to go to the emergency room, urgent	+ ‡	+ ‡
care, or have unplanned visits to a health care provider?		
18. Caused your child to stay in the hospital overnight?	_	_

AIRQ, Asthma Impairment and Risk Questionnaire; ER, emergency room; NWC, not well-controlled; Peds-AIRQ, Pediatric Asthma Impairment and Risk Questionnaire; VPC, very poorly controlled; WC, well-controlled.

\*"X" represents a significant variable in the logistic regression model; "—" represents nonsignificant questions.

<sup>†</sup>Item 10 was retained in final Peds-AIRQ despite being nonsignificant in both models due to the clinical significance of hospitalization for asthma and low prevalence of this event in the validation sample.

<sup>‡</sup>"+" represents a significant variable in the logistic regression model that was not retained. The 3-month recall questions were significant in models; however, the questions assessing 12-month steroid use and ER/unplanned visits performed better and with better model fit; thus the 12-month recall items were retained over the 3-month recall items.

**TABLE III.** Relationship between Peds-AIRQ score and physician and C-ACT assessments of asthma control at baseline

Peds-AIRQ	Physician assessment of asthma control at baseline							
score/asthma control	Completely/	Somewhat	Partly/not	Overall F	Pairwise			
	well-controlled	controlled	controlled	P value	comparisons <sup>†</sup>			
category	(n = 259)	(n = 85)	(n = 55)	X <sup>2</sup> *	P values			
Peds-AIRQ score, mean	1.5 (1.7)	3.7 (2.0)	4.5 (2.1)	85.01 (< .001)	a: < .001 b: < .001 c: .025			
Well-controlled (0-1), n (%)	145 (56.0)	12 (14.1)	2 (3.6)	)				
Not well-controlled (2-4), n (%)	93 (35.9)	43 (50.6)	25 (45.5)	< .001				
Very poorly controlled (5-8), n (%)	21 (8.1)	30 (35.3)	28 (50.9)					
Peds-AIRQ	C-ACT asthma control category at baseline							
score/asthma control	Well-controlled	Not well-	Very poorly Overall <i>F</i>		Pairwise			
		controlled	controlled	P value	comparisons <sup>†</sup>			
category	(n = 276)	(n = 102)	(n = 20)	X <sup>2</sup> *	P values			
Peds-AIRQ score, mean	1.52 (1.6)	4.32 (2.0)	5.00 (2.5)	122.21 (< .001)	a < .001 b: < .001 c: .278			
Well-controlled (0-1), n (%)	147 (53.3)	9 (8.8)	2 (10.0)	< .001				
Not well-controlled (2-4), n (%)	115 (41.7)	41 (40.2)	5 (25.0)					

Very poorly controlled				
(5-8), n (%)	14 (5.1)	52 (51.0)	13 (65.0)	
(5 5), (75)				

*C-ACT*, Childhood Asthma Control Test; *Peds-AIRQ*, Pediatric Asthma Impairment and Risk Questionnaire; *SD*, standard deviation.

\*Interval data evaluated using general linear models with overall F reported; categorical data evaluated by  $\chi^2$  with P value reported.

<sup>†</sup>Pairwise comparisons between means were performed using Scheffe's *post hoc* test, adjusting for multiple comparisons. Comparisons: a: completely/well-controlled versus somewhat controlled asthma; b: completely/well-controlled versus poorly/not controlled asthma; and c: somewhat controlled versus poorly/not controlled asthma.

**TABLE IV.** Relationship between prior-year exacerbations and Peds-AIRQ control category

Clinical Characteristic	WC asthma	NWC asthma	VPC asthma	P value*
	(n = 159, 39.8%)	(n = 161, 40.4%)	(n = 79, 19.8%)	
Children with ≥1				
exacerbation in the	33 (20.8%)	88 (54.7%)	62 (78.5%)	< .001
past 12 months, n (%)				
No. of ER/urgent care	0.4 (0.33)	0.2 (0.06)	4.4.(4.50)	. 001
visits, mean (SD)	0.1 (0.32)	0.3 (0.96)	1.1 (1.58)	< .001
No. of ER/urgent care	0 (0, 3)	0 (0 5)	0 (0, 10)	
visits, median (range)	0 (0, 3)	0 (0, 5)	0 (0, 10)	
0	150 (94.3%)	129 (80.1%)	38 (48.1%)	< .001 <sup>†</sup>
≥1	9 (5.7%)	32 (19.9%)	41 (51.9%)	
≥2	1 (0.6%)	7 (4.3%)	17 (21.5%)	< .001 <sup>‡</sup>
No. of unplanned clinic	0.2 (0.52)	0.7 (1.17)	1.1 (1.46)	< .001
visits, mean (SD)	0.2 (0.32)	0.7 (1.17)	1.1 (1.40)	< .001
No. of unplanned clinic	0 (0, 3)	0 (0, 9)	1 (0, 9)	
visits, median (range)	0 (0, 3)	0 (0, 9)	1 (0, 9)	
0	140 (88.1%)	97 (60.2%)	34 (43.0%)	< .001 <sup>†</sup>
≥1	19 (11.9%)	64 (39.8%)	45 (57.0%)	< .001
≥2	6 (3.8%)	30 (18.6%)	20 (25.3%)	< .001 <sup>‡</sup>
No. of hospitalizations	1			
0	159 (100.0%)	157 (97.5%)	75 (94.9%)	.027
1	0 (0%)	4 (2.5%)	4 (5.1%)	.021

No. of OCS courses				
0	139 (87.4%)	109 (67.7%)	34 (43.0%)	
1	15 (9.4%)	29 (18.0%)	22 (27.8%)	< .001
≥2	5 (3.1%)	23 (14.3%)	23 (29.1%)	

ANOVA, analysis of variance; ER, emergency room; NWC, not well-controlled; OCS, oral corticosteroid(s); Peds-AIRQ, Pediatric Asthma Impairment and Risk Questionnaire; SD, standard deviation; VPC, very poorly controlled; WC, well-controlled.

Note: Only the highest utilization for each exacerbation was recorded (eg, a hospitalization was not also recorded as an SCS course).

\*Chi-square test is used to compare frequencies by groups, and ANOVA (general linear model) is used to compare mean scores across groups.

<sup>†</sup>Chi-square test was used to compare ER/urgent care and unplanned clinic visits (0 vs ≥1) across AIRQ control categories.

<sup>‡</sup>Chi-square test was used to compare ER/urgent care and unplanned clinic visits (0 vs ≥2) across AIRQ control categories.

## **FIGURES**

## FIGURE 1. The Peds-AIRQ validation standard\*.

ER, emergency room; GINA SCT, Global Initiative for Asthma symptom control tool; NWC, not well-controlled; Peds-AIRQ, Pediatric Asthma Impairment and Risk Questionnaire; SABA, short-acting beta-agonist; SCS, systemic corticosteroid, VPC, very poorly controlled; WC, well-controlled.

\*GINA SCT includes the following questions: Over the past 4 weeks, has the child had 1) Daytime asthma symptoms more than twice/week?; 2) Any night waking due to asthma?; 3) SABA reliever for symptoms more than twice/week?; 4) Any activity limitation due to asthma?<sup>8</sup> Zero "yes" responses to the 4 GINA SCT questions represent well-controlled, 1-2 "yes" responses not well-controlled, and 3-4 "yes" responses very poorly controlled asthma.

**FIGURE 2.** ROC curves for (A) Peds-AIRQ Model 1: WC versus NWC/VPC asthma and (B) Peds-AIRQ Model 2: WC/NWC versus VPC asthma.

AUC, area under the curve; LR, likelihood ratio; NWC, not well-controlled; Peds-AIRQ, Pediatric Asthma Impairment and Risk Questionnaire; ROC, receiver-operating characteristic; VPC, very poorly controlled; WC, well-controlled.

<sup>a</sup>AUC = 0.85 for 0-8 summed score (0.86 for individual items).

<sup>b</sup>AUC = 0.83 for 0-8 summed score (0.85 for individual items).

**FIGURE 3.** Odds ratios (95% CIs) for the occurrence of prior-year exacerbations relative to asthma control category (N = 399).

Percentages are based on the number of children in each asthma control category.

*C-ACT*, Childhood Asthma Control Test; *CI*, confidence interval; *NWC*, not well-controlled; *Peds-AIRQ*, Pediatric Asthma Impairment and Risk Questionnaire; *WC*, well-controlled; *VPC*, very poorly controlled.

**FIGURE 4.** Prior-year exacerbations in children categorized as having (A) completely or well-controlled and (B) uncontrolled asthma<sup>a</sup> (N = 399).

*C-ACT*, Childhood Asthma Control Test; *Peds-AIRQ*, Pediatric Asthma Impairment and Risk Questionnaire.

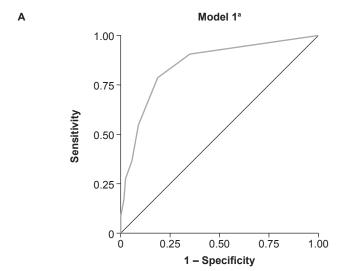
<sup>a</sup>Uncontrolled asthma includes somewhat controlled, not well-controlled, partly controlled, very poorly controlled, and not controlled asthma.

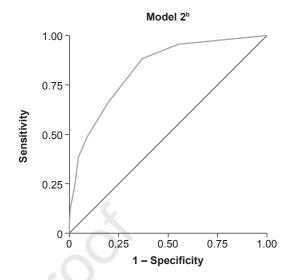
 ${}^{\rm b}P$  < .001 comparison to Peds-AIRQ.

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Peds-AIRQ asthma control category	GINA SCT score*		SCS use or ER/unplanned hospital visits in the past 12 months		Hospitalizations in the past 12 months
Well-controlled	0	AND	0	AND	0
Not well-controlled	1-2	OR	1	AND	0
Very poorly controlled	3-4	OR	≥2	OR	≥1

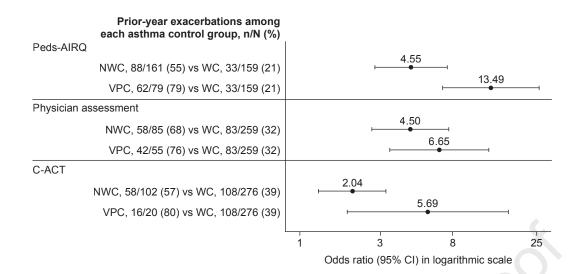
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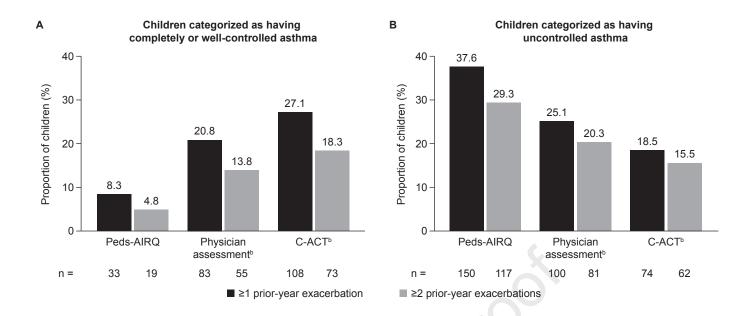




Peds-AIRQ score cut-off	LR+	LR-	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Area under the ROC curve
≥1	2.60	0.14	0.91	0.65	0.85	0.75	0.78
≥2	4.16	0.26	0.79	0.81	0.90	0.63	0.80
≥3	6.11	0.49	0.55	0.91	0.93	0.47	0.73
≥4	6.17	0.67	0.37	0.94	0.94	0.40	0.66
≥5	14.00	0.73	0.28	0.98	0.96	0.38	0.63
≥6	8.50	0.85	0.17	0.98	0.96	0.35	0.58

Peds-AIRQ score					Positive predictive	Negative predictive	Area under the
cut-off	LR+	LR-	Sensitivity	Specificity	value	value	ROC curve
≥1	1.75	0.09	0.96	0.45	0.59	0.92	0.70
≥2	2.38	0.19	0.88	0.63	0.66	0.87	0.76
≥3	3.30	0.43	0.66	0.80	0.73	0.74	0.73
≥4	5.44	0.56	0.49	0.91	0.81	0.68	0.70
≥5	7.60	0.65	0.38	0.95	0.87	0.65	0.67
≥6	8.00	0.78	0.24	0.97	0.88	0.61	0.61





## Pediatric AIRQ

(Asthma Impairment and Risk Questionnaire)



For use by health care providers for their patients 5 to 11 years old who have been diagnosed with asthma. Pediatric AIRQ® is intended to be part of an asthma clinic visit.

These questions are about your child's asthma. This form should be completed by parents or caregivers with input from their child.

Please answer all of the questions below.

#### In the past 2 weeks, has your child's coughing, wheezing, shortness of breath, or chest tightness:

1. Occurred during the day on 5 or more days?

Yes No

2. Woke you or your child up from sleep on any night?

Yes No

#### In the past 2 weeks, has coughing, wheezing, shortness of breath, or chest tightness:

3. Caused your child to use rescue medication (inhaler or nebulizer) on 2 or more days?

Yes No



Albuterol sulfate



Proventil® HFA (Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.)



Albuterol sulfate



Xopenex HFA® (Sunovior Pharmaceuticals Inc.) Levalbuterol tartrate



Xopenex\* (Sunovion Pharmaceuticals Inc.) Levalbuterol HCI



Albuterol sulfate

Please see all prescribing information for all products

#### In the past 2 weeks:

4. Did your child limit or stop planned activities because of their asthma symptoms?

Yes No

5. Did asthma symptoms limit your child from being physically active (such as running, playing, gym class, doing sports)?

Yes No

## In the past 12 months, has coughing, wheezing, shortness of breath, or chest tightness:

6. Caused your child to take steroid pills, liquids, or shots such as prednisone or Medrol®?

Yes No

7. Caused your child to go to the emergency room, urgent care or have unplanned visits to a health care provider?

Yes No

8. Caused your child to stay in the hospital overnight?

Yes No

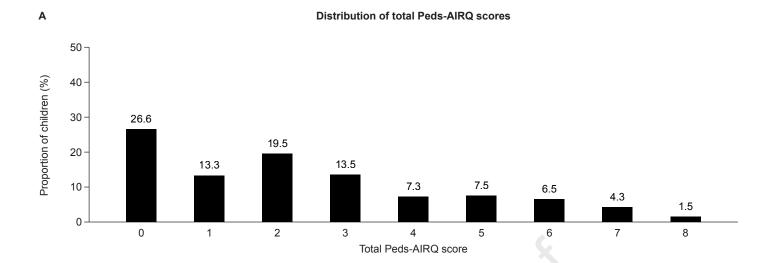
**Total YES Answers** 

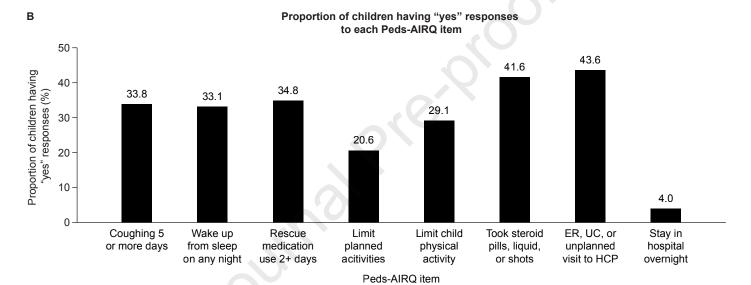
### What Does Your Child's Pediatric AIRQ® Score Mean?

The Pediatric AIRQ® is meant to help your child's health care providers talk with you and your child about your child's asthma control. The Pediatric AIRQ® does not diagnose asthma. Whatever your child's Pediatric AIRQ® score (total YES answers), it is important for your child's health care team to discuss the number and answers to each of the questions with you and your child. All patients with asthma, even those who may be well-controlled, can have an asthma attack. As asthma control worsens, the chance of an asthma attack increases. Only your child's medical provider can decide how best to assess and treat your child's asthma.



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## **ONLINE REPOSITORY**

# Pediatric Asthma Impairment and Risk Questionnaire: A Control Assessment for Children Aged 5-11 Years

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**TABLE E1**. Logistic regression models to identify significant predictors of asthma control (GINA SCT + exacerbation)

A) Model 1 – Peds-AIRQ initial 10 items: Log odds of asthma control (WC [0] vs NWC/VPC [1])

Parameters	B (SE)	p-value	Wald Chi-square	OR	95% CI	for OR
					Lower	Upper
Peds-AIRQ 10 Items (ref = No)						
AIRQ 1: Coughing 5 or more days	1.12 (0.39)	0.005	8.05	3.05	1.41	6.59
AIRQ 2: Woke you from sleep 2+ nights	0.77 (0.47)	0.10	2.68	2.15	0.86	5.38
AIRQ 3: Rescue medication 2+ days	0.75 (0.37)	0.045	4.03	2.12	1.02	4.41
AIRQ 4: Limit planned activities	0.33 (0.67)	0.62	0.24	1.39	0.37	5.16
AIRQ 5: Stay home because of asthma symptoms	-0.03 (0.67)	0.97	0.00	0.97	0.26	3.65
AIRQ 6: Limit child physical activity	0.86 (0.44)	0.050	3.83	2.37	1.00	5.60
AIRQ 7: Difficult to take care of asthma	-0.73 (0.76)	0.34	0.91	0.48	0.11	2.14
AIRQ 8: Took steroid pills or shots	0.85 (0.36)	0.019	5.53	2.34	1.15	4.75
AIRQ 9: ER, UC, or unplanned visit to HCP	1.71 (0.38)	<0.001	20.08	5.54	2.62	11.72
AIRQ 10: Stay in hospital overnight	0.59 (1.59)	0.71	0.14	1.81	0.08	40.90
Model Fit	)					
Number of observations	392					
AIC	334.98					
-2Log likelihood	312.98					
R <sup>2</sup> , Cox-Snell, Max-rescaled	0.3057, 0.4446					
Score, Chi-square (DF, p-value)	116.92 (10, <0.001)					
Wald, Chi-square (DF, p-value)	83.22 (10, <0.001)					
Hosmer-Lemeshow, Chi-square (DF, p-value)	14.66 (7, 0.041)					

Parameters	B (SE)	p-value	Wald Chi-square	OR	95% CI for OR	
					Lower	Upper
C-index (AUC)	0.8591					

# B) Model 2 – Peds-AIRQ initial 10 items: Log odds of asthma control (WC/NWC [0] vs VPC [1])

Parameters	B (SE)		Wald Chi-square	OR	95% CI for OR		
					Lower	Upper	
AIRQ 10 Items (ref = No)							
AIRQ 1: Coughing 5 or more days	0.69 (0.33)	0.035	4.45	1.99	1.05	3.78	
AIRQ 2: Woke you from sleep 2+ nights	0.52 (0.37)	0.16	2.01	1.69	0.82	3.47	
AIRQ 3: Rescue medication 2+ days	0.72 (0.33)	0.027	4.87	2.06	1.08	3.91	
AIRQ 4: Limit planned activities	0.74 (0.48)	0.13	2.36	2.09	0.82	5.34	
AIRQ 5: Stay home because of asthma symptoms	-0.46 (0.48)	0.34	0.90	0.63	0.25	1.62	
AIRQ 6: Limit child physical activity	0.07 (0.38)	0.85	0.03	1.07	0.51	2.26	
AIRQ 7: Difficult to take care of asthma	0.18 (0.53)	0.73	0.12	1.20	0.43	3.37	
AIRQ 8: Took steroid pills or shots	0.92 (0.30)	0.003	9.06	2.50	1.38	4.55	
AIRQ 9: ER, UC, or unplanned visit to HCP	1.66 (0.31)	<0.001	29.46	5.27	2.89	9.61	
AIRQ 10: Stay in hospital overnight	0.11 (0.79)	0.89	0.02	1.12	0.24	5.31	
Model Fit	. 00						
Number of observations	392						
AIC	368.00						
-2Log likelihood	346.00						
R <sup>2</sup> , Cox-Snell, Max-rescaled	0.3439, 0.472						
Score, Chi-square (DF, p-value)	149.48 (10, <0.001)						
Wald, Chi-square (DF, p-value)	104.07 (10, <0.001)						
Hosmer-Lemeshow, Chi-square (DF, p-value)	8.21 (7, 0.31)						
C-index (AUC)	0.8548						

# C) Model 1 – Peds-AIRQ test impairment items: Log odds of asthma control (WC [0] vs NWC/VPC [1])

Parameters	B (SE)	p-value	Wald Chi-square	OR	95% CI for OR		
					Lower	Upper	
AIRQ Items (ref = No)							
AIRQ 1: Coughing 5 or more days	1.07 (0.36)	0.003	8.59	2.90	1.42	5.92	
AIRQ 4: Limit planned activities	0.81 (0.62)	0.19	1.71	2.25	0.67	7.61	
AIRQ 5: Stay home because of asthma symptoms	-0.03 (0.56)	0.96	0.00	0.97	0.32	2.93	
AIRQ 6: Limit child physical activity	0.68 (0.41)	0.10	2.76	1.98	0.88	4.43	
AIRQ 11: Wake up from sleep on any night	0.83 (0.37)	0.027	4.91	2.29	1.10	4.78	
AIRQ 12: Cause to use rescue medication 5 or more times	0.43 (0.45)	0.35	0.89	1.53	0.63	3.73	
Model Fit							
Number of observations	397						
AIC	408.10						
-2Log likelihood	394.10						
R <sup>2</sup> , Cox-Snell, Max-rescaled	0.1796, 0.258						
Score, Chi-square (DF, p-value)	64.97 (6, <0.001)						
Wald, Chi-square (DF, p-value)	47.73 (6, <0.001)						
Hosmer-Lemeshow, Chi-square (DF, p-value)	4.76 (5, 0.45)						
C-index (AUC)	0.7490						

D) Model 2 - Peds-AIRQ test impairment items: Log odds of asthma control (WC/NWC [0] vs VPC [1])

Parameters	B (SE) p-value		Wald Chi-square	OR	95% CI for OR		
					Lower	Upper	
AIRQ Items (ref = No)							
AIRQ 1: Coughing 5 or more days	0.72 (0.28)	0.011	6.52	2.05	1.18	3.55	
AIRQ 4: Limit planned activities	1.28 (0.42)	0.002	9.42	3.61	1.59	8.18	
AIRQ 5: Stay home because of asthma symptoms	-0.11 (0.41)	0.78	0.08	0.89	0.40	1.98	
AIRQ 6: Limit child physical activity	-0.01 (0.33)	0.98	0.00	0.99	0.52	1.89	
AIRQ 11: Wake up from sleep on any night	0.52 (0.30)	0.08	3.13	1.69	0.94	3.02	
AIRQ 12: Cause to use rescue medication 5 or more times	0.39 (0.33)	0.24	1.40	1.48	0.77	2.84	
Model Fit		9					
Number of observations	397						
AIC	463.60						
-2Log likelihood	449.60						
R <sup>2</sup> , Cox-Snell, Max-rescaled	0.1758, 0.239						
Score, Chi-square (DF, p-value)	74.07 (6, <0.001)						
Wald, Chi-square (DF, p-value)	59.47 (6, <0.001)						
Hosmer-Lemeshow, Chi-square (DF, p-value)	2.70 (5, 0.75)						
C-index (AUC)	0.7189						

AIC, Akaike information criterion; AUC, area under the curve; CI, confidence interval; DF, degrees of freedom; ER, emergency room; GINA, Global Initiative for Asthma; HCP, health care provider; NWC, not well-controlled; OR, odds ratio; Peds-AIRQ, Pediatric Asthma Impairment and Risk Questionnaire; ref, reference value; SCT, symptom control tool; SE, standard error; UC, urgent care; VPC, very poorly controlled; WC, well-controlled.

**TABLE E2.** Pediatric asthma control tools (representative list)

Questionnaire	Items	Control*	Admin†	Literacy	Recall time	Response options	Scoring system	Avail	Age (y)	Exac
				demand‡						
ACQ [E1, E2]	7§	Imp	Self: ≥11 y	NA	1 wk	0-6	Mean of 7 items:	Requires	≥6	No
Asthma Control			Trained			Totally controlled to	0-6	permission		
Questionnaire			interviewer:			severely	Well-controlled:			
			6-10 yll			uncontrolled	≤0.75			
						8	Not well-			
						0,	controlled: ≥1.5			
						10	[E3]			
Asthma APGAR [E4]	6; 5	Imp	Self	NA	2 wk	0-6	Total 6-item	Yes	5-45	No
	dom¶				010	Adequate to	score: 0-100			
						inadequate control				
ATAQ [E5]	20#	Imp	Caregiver	NA	4 wk or 12 mo	0 (no) or 1 (yes)	Total 7-item	Yes	5-17	No
Asthma Therapy						Control problem	score for control			
Assessment				0			scale: 0-7			
Questionnaire (for										
children/adolescents)										

Questionnaire	Items	Control*	Admin†	Literacy	Recall time	Response options	Scoring system	Avail	Age (y)	Exac
				demand‡						
C-ACT [E6]	7	Imp	Child and	NA	4 wk	0-3 (Nos. 1-4); 0-5	Total 7-item	Yes	4-11	No
Childhood Asthma			caregiver			(Nos. 5-7)	score: 0-27			
Control Test							Well-controlled:			
							≥20			
							Not well-			
						Ś.	controlled: 13-19			
						0,	Very poorly			
						(O	controlled: ≤12			
CASI [E7]	8; 5	Both	Clinician	NA	2 wk (exac:	0-3 (Nos. 1-5)	Weighted 5-dom	Yes	6-17	Yes
Composite Asthma	dom**				2 mo)	0-5 (No. 6)	total: 0-20††			
Severity Index						0, 2, 4, 6 (Nos. 7-8)				
LASS [E8]	8	Imp	Clinician	NA	4 wk	1-5	Total 8-item	Yes	3-17;	No
Lara Asthma Symptom						Never, a few days,	score: 8-40		18-64	
Scale						some days, most				
				5		days, every day				

Questionnaire	Items	Control*	Admin†	Literacy	Recall time	Response options	Scoring system	Avail	Age (y)	Exac
				demand‡						
PACCI [E9]	12; 5	Both	Caregiver	5th	Since prior	Sum score: 0-4	Sum score: 0-19	Yes	≤21	Yes
Pediatric Asthma Control	dom‡‡				visit;	(Nos. 7, 8, 10, 11);	Better control to			
and Communication					control	0-3 (No. 9)	worse control			
Instrument					dom: 1 wk	Problem index: 0-1	Problem index: 0-			
					(noct awk:	(5-dom,	5			
					2 wk)	yes/no controlled)	controlled to not			
						Categories:	controlled			
						assigned based on	Categories: 4			
						Nos. 7-11	levels of			
					010		severity/control§§			
TRACK [E10]	5	Both	Caregiver	NA	4 wk (rescue	0-20 (0, 5, 10, 15,	Total 5-item	Yes	<5	Yes
Test for Respiratory and					med: 3 mo;	or 20 points)	score: 0-100			
Asthma Control in Kids					exac: 12 mo)	Worse control to				
				0,,		better control				

Admin, administration; avail, freely available for use; awk, awakening; comb, combination (physician- and child-administered); dom, domain; exac, exacerbation; FEV<sub>1</sub>, forced expiratory volume in 1 second; imp, impairment; med, medication; mo, month(s); NA, not available; NAEPP, National Asthma Education and Prevention Program; No., number; noct, nocturnal; No., numbers; perm, permission; wk, week(s).

\*Questionnaires were categorized as assessing impairment, risk, or both domains of asthma control.

†Questionnaires were categorized as being administered by a clinician, self/caregiver (pediatric), or combination of clinician and self/caregiver (pediatric).

‡Literacy demand was defined by grade level (eg, 5th-grade reading level).

§The ACQ can also be administered in 3 shortened formats: symptom only (ACQ-5), symptoms plus β2-agonist use (ACQ-6), and symptoms plus β2-agonist use and FEV<sub>1</sub> (ACQ-7). [E11]

IlQuestions 1-6 are self-administered by children aged ≥11 years or administered by a trained interviewer for children aged 6-10 years. Question 7 (FEV₁ range) is completed by the clinician.

¶Domains include activity limitations, daytime and nighttime symptom frequency, asthma triggers, adherence to asthma medications, and child-perceived response to therapy.

#Questionnaire consists of a 7-item control scale.

\*\*Domains include daytime symptoms, nighttime symptoms, lung function, treatment, and exacerbations.

††Weighted breakdown: daytime symptoms (15% of the total), nighttime symptoms (15% of the total), lung function (15% of the total), treatment (25% of the total), and exacerbations (30% of the total).

‡‡Domains include direction of change in asthma status, bother, risk, adherence, and control.

§§Intermittent/controlled, mild persistent/partly controlled, moderate persistent/uncontrolled, and severe persistent/poorly controlled.

FIGURE E1. The Pediatric Astrima Impairment and Kisk Questionnaire (Peds-AIRQ).

The final 8-item Pediatric Asthma Impairment and Risk Questionnaire (AIRQ), a composite asthma control tool designed to measure impairment and risk in children aged 5-11 years. The Pediatric AIRQ score is calculated as the sum of the yes responses. © 2024 AstraZeneca. All rights reserved. AIRQ is a registered trademark of AstraZeneca. The Pediatric AIRQ is reproduced with permission from AstraZeneca. AstraZeneca is the copyright owner of the Pediatric AIRQ; however, third parties will be allowed to use the Pediatric AIRQ free of charge. The Pediatric AIRQ must always be used in its entirety. Except for limited reformatting, the Pediatric AIRQ may not be modified or combined with other instruments without prior written approval. The 8 questions of the Pediatric AIRQ must appear verbatim, in order, and together as they are presented and not divided on separate pages. All copyright and trademark information must be maintained as it appears on the bottom of the Pediatric AIRQ and on all copies. The layout of the final authorized Pediatric AIRQ may differ slightly, but the item wording will not change.

FIGURE EZ. DISTRIBUTION OF (A) TOTAL PEAS-AIRQ SCORES and (B) proportion of children naving "Yes" responses to each Peds-AIRQ item.

ER, emergency room; *HCP*, health care provider; *Peds-AIRQ*, Pediatric Asthma Impairment and Risk Questionnaire; UC, urgent care.

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