Original Article

Development of the Asthma Impairment and Risk Questionnaire (AIRQ): A Composite Control Measure

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What is already known about this topic? Despite the importance of using asthma control tools to measure symptom control and risk for future exacerbations in patients with uncontrolled asthma, most tools only assess impairment.

What does this article add to our knowledge? This article describes the validation of a novel composite asthma control measure, the Asthma Impairment and Risk Questionnaire (AIRQ), which includes both impairment and risk domains of control.

How does this study impact current management guidelines? The AIRQ may complement current guidelines by facilitating the identification of asthma morbidity that currently goes unrecognized in clinical practice.

BACKGROUND: Asthma exacerbation risk increases with worsening asthma control. Prevailing numerical control tools evaluate only current symptom impairment despite the importance of also assessing risk based on exacerbation history. An easy-to-use questionnaire addressing impairment and risk domains of control is needed.

OBJECTIVE: To validate a composite asthma control tool that includes impairment and risk assessments (Asthma Impairment and Risk Questionnaire [AIRQ]).

METHODS: Four-hundred forty-two patients aged ≥12 years with physician-diagnosed asthma who were followed in specialty practices completed 15 impairment and risk questions with dichotomized yes/no responses. Patients spanned all Global Initiative for Asthma severities and were classified as well-controlled, not well-controlled, or very poorly controlled according to a standard of Asthma Control Test (ACT) score plus prior-year exacerbations. Logistic regression analyses identified questions with the greatest predictive validity to discriminate among patients and determine cut points for these 3 classifications.

RESULTS: The final AIRQ comprises 10 equally weighted yes/no impairment and risk questions. The final 10-item models yielded receiver operating characteristic curves of 0.94 to identify well-controlled versus not well-/very poorly controlled and 0.93

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Conflicts of interest: K. R. Murphy has served as a consultant and is a speaker for AstraZeneca, Boehringer Ingelheim, Genentech, Greer, Merck, Mylan, Novartis, Regeneron, Sanofi, Optinose, and Teva. B. Chipps has served as an advisor, consultant, and as a speaker for AstraZeneca, Boehringer Ingelheim, Circassia, Genentech, Novartis, Regeneron, and Sanofi. D. A. Beuther has participated in advisory boards for AstraZeneca and GlaxoSmithKline. R. A. Wise has received consultant fees and honoraria from AstraZeneca, GlaxoSmithKline, Novartis, Boehringer Ingelheim, Contrafect, Pulmonx, Roche, Regeneron, AbbVie, Spiration, Sunovion, Merck, Circassia, Pneuma, Verona, Bonti, Denali, Aradigm, Mylan, Theravance, Propeller Health, Kiniksa, and Syneos. W. McCann has served as a consultant and speaker for AstraZeneca; has served as a speaker for Regeneron; and has served as a consultant for Aimmune. I. Gilbert, J. M. Eudicone, and H. N. Gandhi are employees of AstraZeneca. G. Harding and K. S. Coyne 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 grants from Aerocrine, Genentech, MedImmune/AstraZeneca, Merck, GlaxoSmithKline, ALK Pharma, Teva, and the National Heart, Lung, and Blood Institute; and has received consultant fees from AstraZeneca, Genentech/Novartis, GlaxoSmithKline, Merck, Regeneron, and Teva.

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Abbreviations used
ACQ- Asthma Control Questionnaire
ACT- Asthma Control Test
AIRQ- Asthma Impairment and Risk Questionnaire
ATS- American Thoracic Society
ERS- European Respiratory Society
FeNO- Fraction of expired nitric oxide
FEV_1- Forced expiratory volume in the first second of expiration
GINA- Global Initiative for Asthma
ICS- Inhaled corticosteroid
ROC- Receiver operating characteristic

to identify well-/not well-controlled versus very poorly controlled asthma, as reflected by the ACT plus prior-year exacerbations standard. Cut points of 0-1, 2-4, and 5-10 best represented well-, not well-, and very poorly controlled asthma.

CONCLUSIONS: AIRQ is a rigorously validated composite measure designed to identify adults and adolescents with varying degrees of asthma control. Ongoing investigations will determine test-retest reliability, responsiveness to change, and predictive ability for future exacerbations. **(J Allergy Clin Immunol Pract 2020;■:■-■)**

Key words: *Asthma; Control; Uncontrolled; Impairment; Risk; Exacerbation; Instrument; Validation*

Patients with asthma in the United States suffer with an unacceptably high burden of disease[1,2]; among these, the Centers for Disease Control and Prevention found that 60% of adults (2016) and 50% of children (2012-2014) had uncontrolled asthma.[3] Patients with very poorly controlled asthma are at increased risk for frequent exacerbations, greater health care resource utilization, and limitations in activities compared with those with well-controlled disease.[3-6] From 2019 to 2038, uncontrolled asthma in patients aged ≥15 years is projected to cost the US economy $963.5 billion and result in a loss of 15.5 million quality-adjusted life-years.[1] Despite the prevalence and morbidity of uncontrolled disease, health care providers and patients overestimate control.[7,8] Consequently, there is a need to change how uncontrolled asthma is identified and monitored.

The Global Initiative for Asthma[6] (GINA) defines uncontrolled asthma in terms of poor symptom control (daytime symptoms, night waking due to asthma, reliever use, and activity limitations) and future risk of adverse outcomes (exacerbations, persistent airflow limitation, and side effects of medications).[6] Despite asthma control comprising both impairment and risk domains, commonly used numerical asthma control tools for adults and adolescents such as the Asthma Control Test (ACT)[9,10] and Asthma Control Questionnaires (ACQ)[11] only evaluate impairment.[9,11] Although the Asthma Control and Communications Instrument,[12] Pediatric Asthma Control and Communications Instrument,[13] Test for Respiratory and Asthma Control in Kids,[14] and Composite Asthma Severity Index[15] do evaluate impairment and risk, they are not validated as single control measures for both adults and adolescents. A selection of asthma control measures and their properties can be found in Table E1 (available in this article's Online Repository at www.jaci-inpractice.org).

The Asthma Impairment and Risk Questionnaire (AIRQ) is a new composite (impairment and risk) measure designed to address the gaps in questionnaires used to evaluate control. The primary objective of this cross-sectional study was to develop and validate the AIRQ relative to a composite of ACT score and medical record–documented prior-year exacerbations (ACT + exacerbations).

METHODS

Validation process

This planned cross-sectional analysis of 442 patients aged ≥12 years with physician-diagnosed asthma and varying levels of control and severity is part of a larger longitudinal study to validate AIRQ. Institutional review boards from each of the 12 participating specialty care study sites provided protocol approval.

AIRQ development process

AIRQ was designed, refined, and tested from August 2017 to December 2018 by a network of 190 US scientific experts and primary and specialty care clinicians with diverse practice experiences in geographic areas representing a high burden of disease.[16-18] Teams of 65 advisors met face to face and virtually to discuss how to identify and remediate morbidity associated with uncontrolled asthma and reached consensus to develop a screening questionnaire for uncontrolled disease. Advisors reviewed the literature on asthma control, existing diagnosis and management guidelines, and current control questionnaires to determine impairment and risk questions.

A series of modified Delphi panels with 140 advisors resulted in agreement on the number and content of proposed questions. Items were phrased in a simple yes/no response format and worded to have low literacy demand.[19] Each yes response was given a value of 1; yes responses were summed to provide an overall score, with higher scores indicating worse asthma control. Cognitive interviewing and observation of questionnaire completion were performed to evaluate and establish comprehension and user experience (n = 30 adults and adolescents with asthma; electronic, paper-and-pencil, and interviewer administration; English and Spanish translation).[20]

Cross-sectional validation patients

Patients were recruited from 12 geographically diverse US allergy/immunology and pulmonology clinics from May to August 2019. A representative sample of patients with various levels of control based on screening ACT score before enrollment was sought. Sites were required to have access to patient records spanning 12 months before enrollment to provide objective documentation of exacerbations.

Patients were excluded based on diagnosis of any other non-asthma chronic lower respiratory condition, prior bronchial thermoplasty, ≥3 months of continuous oral corticosteroid use ≥10 mg/day at entry, or currently or actively planning to become pregnant.

After an explanation of the study, interested adults and parents of adolescents provided written informed consent, with adolescents providing assent.

Assessments

Participants answered a series of questionnaires on a tablet, in the clinic, during the single index visit. They were also administered a fraction of expired nitric oxide (FeNO) test,[21] pre- and post-bronchodilator spirometry,[6] and a blood eosinophil test. Serum

ACT + exacerbations outcome[a]	ACT score		OCS use or ED/unplanned visits in past 12 months		Hospitalizations in past 12 months
Well-controlled	≥20	AND	0	AND	0
Not well-controlled	16-19	OR	1	AND	0
Very poorly controlled	≤15	OR	≥2	OR	≥1

FIGURE 1. ACT plus prior-year exacerbations. *ACT*, Asthma Control Test; *ED*, emergency department; *OCS*, oral corticosteroid. [a]Well-controlled: ACT ≥20 *and* no OCS use, ED or unplanned visits, or hospitalizations. Not well-controlled: ACT of 16-19 *or* 1 burst of OCS *or* 1 visit to the ED/unplanned visit due to asthma in the past 12 months with no hospitalizations in the past 12 months. Very poorly controlled: ACT ≤15 *or* ≥2 bursts of OCS *or* ED/unplanned visits *or* hospitalized due to asthma in the past 12 months.

IgE and skin and/or serum specific IgE testing from within the prior year were recorded. IgE levels at baseline were determined if the prior-year value was unavailable.

Patient-completed assessments

Questionnaires were completed in the following order. Patients received no interpretations of assessments:

(1) The initial 10 yes/no impairment and risk questions previously developed through the modified Delphi process and evaluated in the patient cognitive interviewing study.
(2) Five additional yes/no impairment questions reflecting new concepts or frequencies of symptom occurrence. The questions were developed through literature review and expert opinion to determine whether alternative items or ways of expressing the content of the initial questions would better discriminate between patients with differing levels of asthma control.
(3) ACT.[9]
(4) A 5-point Likert scale question on self-perceived global asthma control. This item was evaluated previously with patients in the cognitive interviewing study.
(5) Sociodemographic questionnaire.

Physician-completed assessments

Physician investigators had access to clinical records and baseline study spirometry but were blinded to all patient study questionnaires and test data:

(1) Chart abstraction form for clinical, physiologic, and biomarker data. Content was informed by the GINA report and National Asthma Education and Prevention Program guidelines.
(2) After chart review and patient interview and examination, physicians completed a 5-point Likert scale question on global asthma control.

Defining outcomes of ACT + exacerbations

To achieve the study's primary objective, the 15 candidate impairment and risk questions were evaluated against a criterion composite measure of asthma control defined as baseline ACT score (impairment) and chart-documented prior-year exacerbations (risk) (Figure 1). Exacerbation was defined as a change in asthma clinical status requiring a course of systemic corticosteroids (oral steroids for ≥3 days) OR an emergency department, urgent care, or unplanned office visit for an asthma exacerbation (not associated with a hospitalization) OR hospital stay for asthma for >24 hours. ACT + exacerbations determined 3 levels of control (well-controlled, not well-controlled, and very poorly controlled). These control levels were based on the validated control levels of the ACT and the American Thoracic Society/European Respiratory Society (ATS/ERS) severe exacerbation criteria.[22]

Statistical analysis and model selection

Descriptive statistics were used for patient sociodemographic and clinical characteristics and to present results from AIRQ, ACT, and patient and physician global assessments of control.

Multivariable logistic regression analyses were used to determine which of the 15 questions and cut points had the greatest validity in discriminating between patients of varying levels of control, as defined by ACT + exacerbations. These identified questions comprised the final AIRQ. Two dichotomous comparisons were made by changing the dependent variable groups as follows: model 1, well-controlled versus not well-/very poorly controlled; model 2, well-/not well-controlled versus very poorly controlled. Criteria for final AIRQ question selection were based on 3 complementary objectives: (1) retention of well-performing items; (2) balancing among items that strongly identify well-controlled versus all others and very poorly controlled versus all others; and (3) avoiding redundancy of similar items that differed only by event frequencies.

For each dependent variable, the first model included only the initial 10 items as covariates, whereas the next model series included all 15 items. After the initial analyses, age, sex, and GINA step-therapy (GINA 1-3 vs 4/5) were entered into the models as covariates. Models were evaluated for best model fit using R^2, Hosmer and Lemeshow, and Akaike information criterion; receiver operating characteristic (ROC) curves; and individual item performance. Items that did not consistently perform well in the models (eg, due to lack of significance) were removed. After completion of all model runs, the overall model performance and fit were compared; items that were significant and complementary to each dependent variable model were retained to capture the full range of impairment and risk for all patients with asthma.

After final item selection, sensitivity and specificity were calculated to determine cut points to identify AIRQ score ranges best representing well-controlled versus not well-/very poorly controlled and well-/not well-controlled versus very poorly controlled asthma. Lastly, a multinomial logistic regression was performed to evaluate the concordance index of summed AIRQ score and the 3 levels of control defined by the ACT + exacerbations standard. Age, sex, and GINA step-therapy level were tested as covariates, but not retained in regressions as nonsignificant. The concordance index for the multinomial model was obtained as the weighted average of indices for nested logistic models for the 3 outcome levels. This analysis was conducted to further contribute to the interpretation of AIRQ cut point scores.

Correlations (Spearman rank coefficients) were evaluated between the final AIRQ score, ACT score, and physician and patient global control assessment items to assess concurrent validity. Discriminant validity was evaluated by comparing the final AIRQ score across physician and patient global assessments of control, as well as comparing pulmonary function, biomarkers of

TABLE I. Baseline patient characteristics

	Total (N = 442)
Patient-reported sociodemographic characteristics	
Age (y), mean (SD)	44.0 (20.1)
12-17 y, n (%)	77 (17.4%)
Male sex, n (%)	121 (27.4%)
Ethnicity, n (%)	
Not Hispanic or Latino	420 (95.0%)
Missing	9 (2.0%)
Race, n (%)	
White	373 (84.4%)
Black or African American	36 (8.1%)
Other*	28 (6.3%)
Missing	5 (1.1%)
Highest level of education, n (%)	
Less than high school	52 (11.8%)
Secondary/high school	105 (23.8%)
Associate degree, technical, or trade school	75 (17.0%)
College/university degree	107 (24.2%)
Postgraduate degree	68 (15.4%)
Other†	29 (6.6%)
Missing	6 (1.4%)
Clinician-reported clinical characteristics	
BMI (kg/m^2), mean (SD)	31.3 (9.0)
Asthma diagnosis duration (y), mean (SD)	18.1 (15.2)
Mean FEV_1 pre-bronchodilator, % predicted	85.4 (16.9)
Clinician-reported characteristics: smoking history	
Smoking status	
Never smoked, n (%)	327 (74.0%)
Previous smoker, n (%)	96 (21.7%)
Current smoker, n (%)	13 (2.9%)
Pack years smoked (current smoker), mean (SD)	0.8 (1.1)
Clinician-reported characteristics: maintenance pharmacologic therapies‡	
Drug class, n (%)	
ICS	74 (16.7%)
ICS/LABA	291 (65.8%)
LAMA	59 (13.3%)
Triple therapy (fixed-dose combination)	0 (0%)
Leukotriene modifier	222 (50.2%)
Biologic	40 (9.0%)
SABA only	27 (6.1%)
GINA step 4/5 therapy, n (%)	288 (65.2%)

BMI, Body mass index; *FEV_1*, forced expiratory volume in the first second of expiration; *GINA*, Global Initiative for Asthma; *ICS*, inhaled corticosteroid; *LABA*, long-acting β-agonist; *LAMA*, long-acting muscarinic antagonist; *SABA*, short-acting β-agonist; *SD*, standard deviation.

*Other race includes Asian, American Indian/Alaska Native, African American, and Native Hawaiian/Pacific Islander; Asian and Native Hawaiian/Pacific Islander; Hispanic; Mexican; white and African American (n = 3); white and American Indian (n = 5); white and Asian; white, Asian, and American Indian; white, Spanish, and other.

†Other education includes 5 years of college, no degree; middle school (n = 3); currently in high school (n = 3); GED; high school graduate; master's degree; not in high school or college; some college (n = 6); student.

‡Not mutually exclusive.

inflammation, and medical record–documented numbers and types of exacerbations by AIRQ score groups using general linear models (PROC GLM) and Scheffe's *post hoc* adjustment for pairwise comparisons.

RESULTS

Cohort characteristics

This analysis included 442 patients who completed their enrollment visit by August 9, 2019. Mean (standard deviation) age was 44.0 (20.1) years (range: 12-84 years; 17.4% aged 12-17 years), 27.4% were male, and 84.4% were Caucasian. Slightly more than one-third of patients reported high school or less as their highest education level. Mean pre-bronchodilator forced expiratory volume in the first second of expiration (FEV_1) was 85.4% of predicted (range, 34%-169%), and 65.2% were currently prescribed GINA step 4/5 inhaled corticosteroid (ICS)/long-acting β-agonist (Table I).

At enrollment, 47.1% of patients were well-controlled according to ACT score (≥20), 25.4% were not well-controlled (score, 16-19), and 27.5% were very poorly controlled (score, ≤15); 55.3% of patients had no prior-year exacerbations, 20% had only 1 non–hospital-related exacerbation, 22.2% had ≥2 non–hospital-related exacerbations, and 2.5% had ≥1 hospitalization for asthma exacerbations. Based on the ACT + exacerbations standard, 32% were categorized as well-controlled, 22.5% as not well-controlled, and 45.5% as very poorly controlled.

Logistic regression analyses and model selection

The 15 candidate items for the logistic regression analyses were based on patient recall and addressed symptoms, social and physical activities, exacerbations and related health care resource utilization, perception of control of asthma, medication use, and spirometry testing (Table II). The final models containing 6 of the original 10 questions and 4 of the additional questions best fulfilled item selection criteria and were used for the final 10-item AIRQ (Figure E1, available in this article's Online Repository at www.jaci-inpractice.org). Items that were significant in both models were past 2-week social activity limitation, daily rescue inhaler use, and prior-year oral/injected corticosteroids for exacerbations. Items that were significant only in the well-controlled versus not well-/very poorly controlled model were daily activity limitation, daytime symptoms, and limitations in ability to exercise over the prior 2 weeks. Items that were significant only in the well-/not well-controlled versus very poorly controlled model were sleep disruption, difficulty controlling asthma in the prior 2 weeks, and previous-year emergency department or unplanned health care provider visits for exacerbations. Hospitalization due to asthma in the past year was not significant in either model but was retained as the 10th item due to its clinical relevance. Thus, final item selection was determined by the composite ability of the selected AIRQ questions to capture impairment and risk relevant to both well-controlled and very poorly controlled patients (Table II, and Tables E2 and E3, available in this article's Online Repository at www.jaci-inpractice.org).

Both dependent-variable models performed well, exceeding model-fit criteria with ROC curves of 0.94 for the individual item model (and 0.93 for the 0-10 summed score model) to identify well-controlled versus not well-/very poorly controlled and 0.93 for the individual item model (and 0.90 for the 0-10 summed score model) to identify well-/not well-controlled versus very poorly controlled asthma, as reflected by the ACT + exacerbations standard (Figure 2). To select cut points to identify level of control using the AIRQ 0-10 summed score of yes responses, the sensitivity and specificity of each model were considered. The well-controlled versus not well-/very poorly

TABLE II. AIRQ questions evaluated for inclusion

Item	Model 1 Dependent variable group: well-controlled vs not well-controlled/very poorly controlled	Model 2 Dependent variable group: well-controlled/not well-controlled vs very poorly controlled
1. Are you currently prescribed any of the inhalers below? (GINA 4/5 ICS/LABA fixed-dose combinations)	–	–
In the past 2 weeks has coughing, wheezing, shortness of breath, or chest tightness:		
2. Caused you to use your rescue inhaler or nebulizer more than 4 times?	–	–
3. Limited the activities you want to do every day?	X*	–
4. Bothered you during the day on more than 4 days?	X†	–
5. Woke you up from sleep more than 1 time?	–	X*
In the past 12 months has coughing, wheezing, shortness of breath, or chest tightness:		
6. Caused you to take steroid pills or shots, such as prednisone or Medrol?	X†	X†
7. Caused you to go to the emergency department or have unplanned visits to a health care provider?	–	X†
8. Caused you to stay in the hospital overnight?	–	–
Has coughing, wheezing, chest tightness, or shortness of breath:		
9. Ever caused you to be in an intensive care unit, have a breathing tube put down your throat, or made you think your life was in danger?	–	–
Spirometry is a breathing test where you are coached to blow all your air out as hard and as fast as you can ("blow, blow, blow") until there is no more air to blow out:		
10. Has it been more than a year since you had this test?	–	–
In the past 2 weeks:		
11. Did you have to limit your social activities (such as visiting with friends/relatives or playing with pets/children) because of your asthma?	X†	X†
12. Do you feel that it is difficult to control your asthma?	–	X†
13. Has wheezing, coughing, shortness of breath, or chest tightness caused you to use your rescue inhaler or nebulizer every day?	X†	X†
14. Has wheezing, coughing, shortness of breath, or chest tightness limited your ability to exercise?	X*	–
15. Has wheezing, coughing, shortness of breath, or chest tightness bothered you during the day every day?	–	–

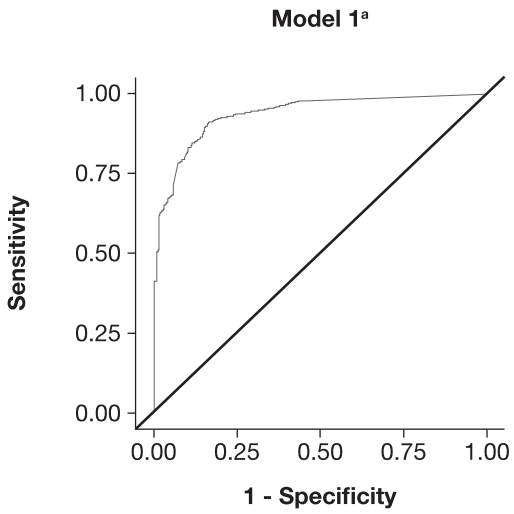
1-10 were the initial questions previously evaluated in the patient cognitive interviewing study. 11-15 were the additional questions selected by literature review and expert opinion. Italicized text indicates retained AIRQ items. "–" indicates items that were nonsignificant in the model. X indicates significant items in a specific model.
AIRQ, Asthma Impairment and Risk Questionnaire; *GINA*, Global Initiative for Asthma; *ICS*, inhaled corticosteroid; *LABA*, long-acting β-agonist.
*$P < .05$.
†$P < .001$.

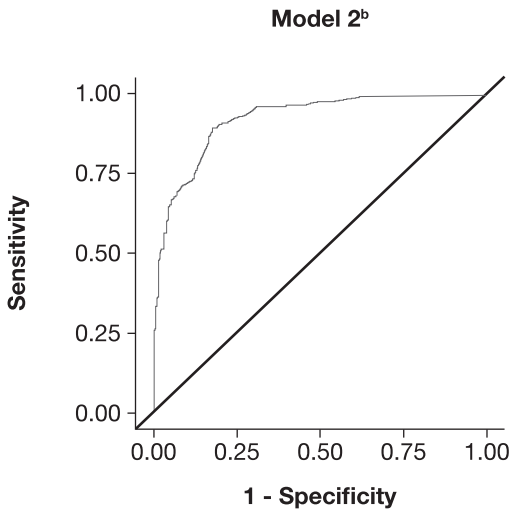
controlled model was designed with a focus on higher sensitivity; the well-/not well-controlled versus very poorly controlled model was designed with higher specificity. In this manner, control cut points would maximize identification of patients who were categorized as well-controlled and likely not in need of further assessment and minimize overidentification of patients classified as very poorly controlled and requiring intensive evaluations. An AIRQ score cut point of ≥ 2 for separating well-controlled versus all others yielded a sensitivity of 0.90, a specificity of 0.79, and positive and negative predicted values of 0.90 and 0.79, respectively. A cut point of ≥ 5 showed a specificity of 0.95, a sensitivity of 0.59, and positive and negative predictive values of 0.92 and 0.74, respectively, for separating very poorly controlled from all others (Figure 2).

A multinomial logistic regression was fitted to evaluate the association between each summed AIRQ score and the 3 levels of control as determined by the ACT + exacerbations standard. The model fit well with a concordance index of 0.89. The odds and probabilities of being in each ACT + exacerbations control category by AIRQ summed score are predicted from this model and shown in Figure 3. For example, an AIRQ score of 5 (lowest cut point for very poorly controlled asthma) reflects an 81% probability of very poorly controlled, an 18% probability of not well-controlled, and a 0% probability of well-controlled asthma based on the ACT + exacerbations standard. An AIRQ cut point of 1 (highest cut point for well-controlled) reflects a 66% probability of well-controlled, a 25% probability of not well-controlled, and a 9% probability of very poorly controlled asthma.

Validity

As a validity check, the frequency of yes responses to each final AIRQ item by the AIRQ control group is presented in Table III. The numbers and percentages of patients answering yes to each item increased significantly with worsening AIRQ control category ($P < .001$ for each). Moreover, impairment domains not generally captured in standard guidelines-based surveys markedly contributed to patients' burden of disease. AIRQ validity was also demonstrated by significant correlations between AIRQ and ACT scores ($r = -0.84$) and AIRQ and patient and provider assessment of asthma control ($r = 0.71$ and 0.58, respectively; $P < .001$ for each).





AIRQ score cut-off	LR+	LR-	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Area under ROC
≥1	2.18	0.04	0.98	0.55	0.82	0.93	0.765
≥2	4.29	0.13	0.90	0.79	0.90	0.79	0.845
≥3	10.57	0.28	0.74	0.93	0.96	0.62	0.832
≥4	58.00	0.42	0.58	0.99	0.99	0.52	0.781
≥5	43.00	0.58	0.43	0.99	0.99	0.45	0.710

AIRQ score cut-off	LR+	LR-	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Area under ROC
≥1	1.50	0.03	0.99	0.34	0.56	0.99	0.670
≥2	2.13	0.07	0.96	0.55	0.64	0.94	0.756
≥3	3.27	0.20	0.85	0.74	0.73	0.85	0.796
≥4	6.73	0.29	0.74	0.89	0.85	0.80	0.815
≥5	14.75	0.43	0.59	0.96	0.92	0.74	0.775
≥6	46.00	0.55	0.46	0.99	0.97	0.69	0.723
≥7		0.69	0.31	1.00	0.98	0.63	0.651

FIGURE 2. ROC curves for models 1 and 2. *AIRQ*, Asthma Impairment and Risk Questionnaire; *LR*, likelihood ratio; *ROC*, receiver operating characteristic. [a]Area under the curve (AUC) = 0.93 for 0-10 summed score (0.94 for individual items) for model 1, which distinguishes well-controlled from not well-controlled/very poorly controlled asthma. [b]AUC = 0.90 for the 0-10 summed score (0.93 for individual items) for model 2, which distinguishes well-controlled/not well-controlled from very poorly controlled asthma.

The relationship between the AIRQ control categories and indices of clinical and physiologic morbidity and biomarkers of inflammation are shown in Table IV. As AIRQ control categories worsened, so did lung function (pre-bronchodilator FEV_1% predicted: 87.6%, 86.6%, and 81.3% for well-, not well-, and very poorly controlled groups: well- and not well-controlled versus very poorly controlled; $P < .03$ for each pairwise comparison). Similar findings were shown for post-bronchodilator FEV_1% predicted. Bronchodilator responsivity did not differ between AIRQ control categories. The percentages of patients experiencing any medical record—documented exacerbation event (oral corticosteroids only, emergency department or unplanned visits, or hospitalizations) increased progressively with worsening AIRQ control group ($P < .05$, all pairwise comparisons except hospitalizations between well- and not well-controlled groups). There were no significant relationships observed between serum eosinophil count or FeNO and AIRQ control groups. Serum IgE and the proportion of patients showing allergen sensitization differed significantly between AIRQ control categories, with the lowest IgE values found in the very poorly controlled cohort and the greatest proportion of patients with allergic sensitization in the well-controlled AIRQ cohort.

Mean AIRQ scores differed with physician and patient global control ratings (Table V). For both groups' global assessments of control, the mean AIRQ score increased with worsening AIRQ control category ($P < .001$ for all pairwise comparisons). The concordant relationship between physician and patient categorical ratings of global control and the AIRQ levels of asthma control is further illustrated by the progressive increase in the frequency of poorly/not-controlled global ratings and the decrease in the frequency of completely/well-controlled assessments with worsening AIRQ level. However, among the 228 patients rated by physicians as well- or totally controlled, 31.5% experienced exacerbations in the prior year. Similarly, 35% of 259 patients who reported they were completely or well-controlled also experienced prior-year exacerbations.

DISCUSSION

AIRQ final version

The 10 questions identified for inclusion in the AIRQ combined 7 impairment and 3 risk items addressing symptoms, social and physical activities, exacerbations, related health care resource utilization, perception of control of asthma, and rescue medication use. The AIRQ performed exceptionally well with respect to the ACT + exacerbations standard in identifying well-controlled versus not well-/very poorly controlled and well-/not well-controlled versus very poorly controlled asthma, with ROC curves of 0.94 and 0.93, respectively. The combination of

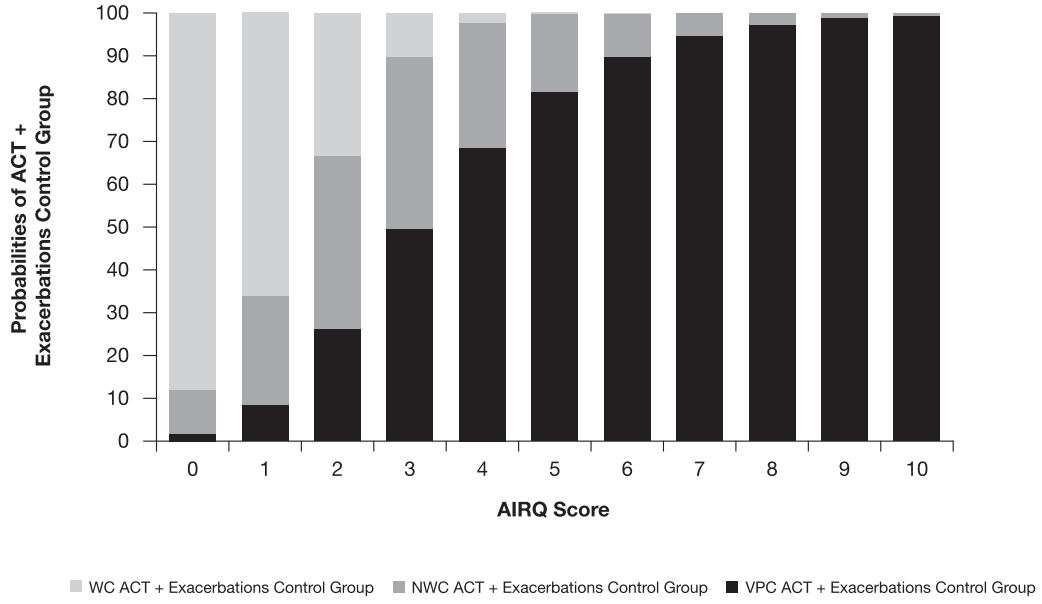


FIGURE 3. Probabilities of the ACT + exacerbations control group by the AIRQ total score. Probabilities predicted from a multinomial model with AIRQ score included as a continuous variable. The probabilities are relative to the ACT + exacerbations standard control groups. *ACT*, Asthma Control Test; *AIRQ*, Asthma Impairment and Risk Questionnaire; *NWC*, not well-controlled; *VPC*, very poorly controlled; *WC*, well-controlled.

TABLE III. Final AIRQ item response* by AIRQ control categories

N = 439 responding to each question	Patients responding yes (%)	Well-controlled (0-1)†	Not well-controlled (2-4)†	Very poorly controlled (5-10)†	*P* value‡
"Yes" to AIRQ item, n (%)					
1. Bothered you during the day on more than 4 days?	186 (42.4%)	7 (3.8%)	73 (39.2%)	106 (57.0%)	<.001
2. Woke you up from sleep more than 1 time?	146 (33.3%)	8 (5.5%)	45 (30.8%)	93 (63.7%)	<.001
3. Limited the activities you want to do every day?	141 (32.1%)	1 (0.7%)	40 (28.4%)	100 (70.9%)	<.001
4. Caused you to use your rescue inhaler or nebulizer every day?	104 (23.7%)	4 (3.8%)	29 (27.9%)	71 (68.3%)	<.001
5. Limited your social activities?	99 (22.6%)	1 (1.0%)	23 (23.2%)	75 (75.8%)	<.001
6. Limited your ability to exercise?	252 (57.4%)	24 (9.5%)	108 (42.9%)	120 (47.6%)	<.001
7. Feel that it is difficult to control your asthma?	116 (26.2%)	0 (0%)	30 (25.9%)	86 (74.1%)	<.001
8. Caused you to take steroid pills or shots, such as prednisone or Medrol?	184 (41.9%)	8 (4.4%)	83 (45.1%)	93 (50.5%)	<.001
9. Caused you to go to the emergency department or have unplanned visits to a health care provider?	139 (31.7%)	4 (2.9%)	59 (42.4%)	76 (54.7%)	<.001
10. Caused you to stay in the hospital overnight?	13 (2.9%)	0 (0%)	2 (15.4%)	11 (84.6%)	<.001

AIRQ, Asthma Impairment and Risk Questionnaire.
*Impairment measures (questions 1-7) are over a prior 2-week period. Risk measures (questions 8-10) are over the prior 12 months.
†The denominator for each column is based on the number of patients responding yes to the question with N per row noted in the first column.
‡Categorical data in 3 control groups evaluated by χ^2 with *P* value reported.

selected AIRQ items and cut points of control demonstrated high sensitivity and specificity in the identification of patients who were on either end of the asthma control spectrum and will be further evaluated in the full 1100-patient cohort with a 12-month follow-up period. In the longitudinal analysis, patient-reported exacerbation will be used as the dependent variable.

The AIRQ development process included rigorous testing and refinement of items and demonstrates its face, convergent, and discriminant validity. The instrument's simple dichotomous response format allows for a broader array of items that can more fully represent the burden of disease without increasing respondent burden. The modeling approach undertaken allowed for selection of questions that were relevant to both well-controlled and very poorly controlled patients, providing further face validity.

Importantly, AIRQ included exacerbation items that represent a significant component of asthma morbidity and are not captured in existing, clinically used, numerical control questionnaires for adults and adolescents. GINA suggests that ≥1

TABLE IV. AIRQ scores by clinical benchmarks and biomarkers

	AIRQ Well-controlled (0-1) (N = 138)	AIRQ Not well-controlled (2-4) (N = 167)	AIRQ Very poorly controlled (5-10) (N = 126)	Overall *F* (*P* values) or χ^2 *P* values*	Pairwise comparisons† (*P* values)
FEV_1% predicted (pre-bronchodilator), mean (SD)	87.6 (13.65)	86.6 (17.72)	81.3 (18.11)	5.32 (.005)	a: .88 b: .01 c: .03
FEV_1% predicted (post-bronchodilator), mean (SD)	90.6 (13.89)	90.0 (17.73)	84.9 (19.01)	4.35 (.01)	a: .95 b: .03 c: .05
FEV_1/FVC (pre-bronchodilator), mean (SD)	0.8 (0.08)	0.8 (0.08)	0.8 (0.08)	0.41 (.67)	
FEV_1% change (pre- to post-bronchodilator responsivity)‡, mean (SD)	6.5 (28.49)	4.6 (10.09)	4.9 (9.98)	0.43 (.65)	
Baseline eosinophil count, n (%)					
<150	50 (36.2%)	66 (39.5%)	67 (53.2%)	.95	
150-299	42 (30.4%)	53 (31.7%)	32 (25.4%)		
≥300	34 (24.6%)	37 (22.2%)	21 (16.7%)		
Missing	12 (8.7%)	11 (6.6%)	6 (4.8%)		
Eosinophil count§, mean (SD)	223.0 (167.7)	225.9 (203.6)	192.9 (186.1)	1.21 (.30)	
IgE‖,¶ (IU/mL), mean (SD)	225.3 (348.8)	332.8 (842.6)	164.3 (260.6)	3.08 (.05)	a: .2841 b: .7009 c: .0551
Baseline FeNO ppb, mean (SD)	23.9 (21.2)	23.5 (21.1)	21.4 (20.1)	0.56 (.57)	NS
Baseline FeNO ≥25 ppb#, n (%)	45 (32.6%)	46 (27.5%)	33 (26.2%)	.47	
Atopy**, n (%)	97 (70.3%)	96 (57.5%)	72 (57.1%)	.04	
No. of OCS courses, mean (SD)	0.1 (0.46)	0.4 (0.83)	0.8 (1.12)	18.75 (<.001)	a: .005 b: <.001 c: .006
0	126 (91.3%)	118 (70.7%)	73 (57.9%)	<.001	
1	9 (6.5%)	33 (19.8%)	28 (22.2%)		
≥2	3 (2.2%)	16 (9.6%)	25 (19.8%)		
No. of ED/unplanned visits, mean (SD)	0.1 (0.46)	0.9 (1.52)	1.8 (2.36)	33.32 (<.001)	a: <.001 b: <.001 c: <.001
0	124 (89.9%)	99 (59.3%)	50 (39.7%)	<.001	
1	10 (7.2%)	32 (19.2%)	27 (21.4%)		
≥2	4 (2.9%)	36 (21.6%)	49 (38.9%)		
No. of hospitalizations, mean (SD)	0.0 (0.17)	0.0 (0.08)	0.1 (0.26)	5.52 (.004)	a: .92 b: .03 c: .008
0	137 (99.3%)	166 (99.4%)	117 (92.9%)	<.001	
1	0 (0%)	1 (0.6%)	9 (7.1%)		
2	1 (0.7%)	0 (0%)	0 (0%)		

AIRQ, Asthma Impairment and Risk Questionnaire; *ED*, emergency department; *FeNO*, fraction of expired nitric oxide; *FEV_1*, forced expiratory volume in the first second of expiration; *FVC*, expiratory forced vital capacity; *NS*, not significant; *OCS*, oral corticosteroid; *SD*, standard deviation.

*Interval data evaluated using general linear models with overall *F* reported; categorical data evaluated using χ^2 tests with *P* value reported.

†Pairwise comparisons as follows: (a) well-controlled vs not well-controlled; (b) well-controlled vs very poorly controlled; (c) not well-controlled vs very poorly controlled.

‡n = 2 patients in the well-controlled cohort had missing values for the percent change in the FEV_1 component.

§n = 12, n = 11, and n = 6 patients in the well-controlled, not well-controlled, and very poorly controlled cohorts, respectively, had missing values for the mean eosinophil count component.

‖At baseline or within the prior 12 months if assessed before enrollment.

¶n = 12, n = 9, and n = 6 patients in the well-controlled, not well-controlled, and very poorly controlled cohorts, respectively, had missing values for the mean IgE concentration component.

#n = 1 patient in the very poorly controlled cohort had missing values for the baseline FeNO >25 ppb component.

**Determined by either a positive skin or serum specific IgE test before enrollment.

severe exacerbation is a major risk factor for future adverse asthma outcomes. There is evidence in the asthma population overall and in patients with severe or difficult-to-treat asthma that a history of severe exacerbations, as defined in the current study per the ATS/ERS definitions, places patients at substantial risk for future exacerbations.[5,23-25]

TABLE V. Relationship between AIRQ score and control category versus physician and patient global assessments

AIRQ	Physician global assessment of patient control*				
	Completely controlled and well-controlled (n = 228)	Somewhat-controlled (n = 152)	Poorly controlled and not controlled (n = 52)	Overall *F* *P* value χ^2†	Pairwise comparisons‡ (*P* values)
AIRQ score, mean (SD)	1.8 (1.87)	4.2 (2.45)	5.8 (2.28)	102.41 <.001	a: <.001 b: <.001 c: <.001
Well-controlled, N (%)	113 (49.6%)	23 (15.1%)	2 (3.8%)	<.001	
Not well-controlled, N (%)	93 (40.8%)	64 (42.1%)	12 (23.1%)		
Very poorly controlled, N (%)	22 (9.6%)	65 (42.8%)	38 (73.1%)		
	Patient global assessment of control§				
	Completely controlled and well-controlled (n = 265)	Somewhat controlled (n = 146)	Poorly controlled and not controlled (n = 27)	Overall *F* *P* value χ^2†	Pairwise comparisons‡ (*P* values)
AIRQ score, mean (SD)	1.8 (1.85)	4.9 (2.12)	6.8 (1.76)	173.6 (<.001)	a: <.001 b: <.001 c: <.001
Well-controlled, N (%)	135 (50.9%)	6 (4.1%)	0 (0%)	<.001	
Not well-controlled, N (%)	106 (40.0%)	62 (42.5%)	3 (11.1%)		
Very poorly controlled, N (%)	24 (9.1%)	78 (53.4%)	24 (88.9%)		

AIRQ, Asthma Impairment and Risk Questionnaire; *SD*, standard deviation.
*Physician global assessment of patient control, N = 432.
†Interval data evaluated using general linear models with overall *F* reported; categorical data evaluated by χ^2 with *P* value reported.
‡Control categories evaluated by respective pairwise comparisons: (a) completely/well-controlled vs somewhat controlled; (b) completely/well-controlled vs poorly/not controlled; (c) somewhat-controlled versus poorly/not controlled.
§Patient global assessment of control, N = 438.

Comparison with existing measures of asthma control

There are several widely used, validated measures of asthma control already in existence (Table E1, available in this article's Online Repository at www.jaci-inpractice.org). As with the AIRQ, ACT and ACQ are validated for patients aged ≥12 years with asthma and are numerical questionnaires providing total scores and cut points for varying levels of asthma control.[9,11] Numerical assessments may be advantageous compared with categorical measures because they are more sensitive to changes in control status and can provide cut points of control. However, ACT and ACQ are limited by assessing only the impairment domain of control.[9,11] For example, in the current study, 31% of patients classified as well-controlled by ACT (scores ≥20) suffered ≥1 exacerbation in the previous year, suggesting limitations of using ACT as a sole measure of asthma control. Studies have also shown that to appreciate the full burden of uncontrolled disease, a wide array of items should be assessed.[8] The current study confirms this observation because exercise limitations and exacerbations characterized by oral corticosteroids or emergency department/unplanned visits affected at least as many patients as did the standard guidelines measures of daytime symptoms and nighttime awakenings.

Use of AIRQ in clinical practice

Previous studies have shown that health care providers and patients tend to overestimate asthma control.[7,26] Similar findings were seen in the current study and underscore the importance of validating the AIRQ against a validated measure of impairment and an objective determination of risk. A composite control measure such as AIRQ that more accurately identifies uncontrolled asthma than the current impairment questionnaires or patient and physician impression could be a first step in addressing the current and projected morbidity from uncontrolled disease.[1]

However, to affect asthma morbidity, an intervention must be adopted by patients and providers. In formative patient experience testing, the initial 10-item, fifth-grade reading level AIRQ was easy to understand and complete in electronic, paper-and-pencil, and interview-administrated formats.[27] Notably, the AIRQ development process was informed by a large and diverse group of scientists, clinicians, and educators with expertise and hands-on experience in asthma management and who represent the ultimate end-users of the tool. Unlike existing control questionnaires, AIRQ was formulated through a grass-roots needs-assessment and development process that concluded that a novel, composite questionnaire that more effectively identifies uncontrolled asthma is required by US clinicians to mitigate their patients' burden of disease.

Limitations and areas for further study

A limitation of any cross-sectional validation is that only the current level of control is being evaluated using exacerbation data from retrospective chart review and current ACT score; thus, the probability of future adverse events or responsiveness to change cannot be assessed. The ongoing year-long longitudinal analysis will evaluate the predictive ability, clinical usefulness, responsiveness, and reproducibility of the AIRQ using prospectively collected monthly exacerbations as an outcome. In this manner, critical information will be gained on the properties of the AIRQ score and individual questions in predicting future exacerbations. Although a longitudinal evaluation of the ACT was only weakly predictive of exacerbations,[28] the AIRQ longitudinal study design employs monthly patient exacerbation and symptom

assessments, as well as biannual health-related quality of life measures. This should provide a robust dataset to fully evaluate the questionnaire and determine the overall clinical usefulness of the tool.

From a measurement perspective, the dichotomous response format may lack the sensitivity of a Likert-type or numeric rating scale. However, this simpler approach can enhance ease of use and comprehension while affording the opportunity to explore more content without increasing respondent burden. In addition, although asthma severity based on GINA step-therapy did not prove to be a significant covariant in the current validation analyses, the population studied was followed within subspecialty care; thus, the performance of AIRQ may differ for patients treated in primary care. In addition to the longitudinal study, further deployment of the AIRQ with primary care patients, cohorts with more or less severe asthma, specific ethnic groups, and populations in countries outside of the United States is planned to determine reliability and discriminant validity in subpopulations of interest, as has been done for the ACT in patients with asthma who smoke.[29]

In addition, the longitudinal analysis will provide clarity with respect to mixed data on the relationships between control tools and severity assessments with biomarkers and atopy.[30-37] AIRQ score and control categories will be assessed longitudinally along with biomarkers and atopy measures as prospective predictors of severe exacerbations and health-related quality of life, considering factors such as treatment adherence, recent systemic corticosteroids use or biologics, and ICS therapy levels. Of note, the Severe Asthma Research Program's phenotypic clusters did show differences between groups in atopy and IgE; however, no relationships were found for serum eosinophils and FeNO.[30] In another study, asthma control was shown to be related to circulating eosinophils and eosinophil-related biomarkers; however, patients were newly diagnosed and not treated with anti-inflammatory therapies.[31] Additional studies in patients with asthma who were either treated[32,33] or not treated with ICS[34,35] found no relationship between asthma control and atopy or FeNO.

CONCLUSIONS

Use of AIRQ in clinical practice could serve to heighten awareness of the need for clinical interventions among all health care providers, accelerate identification of patients in primary care who might benefit from specialty referral, and reveal to specialists those patients within their practices with unrecognized morbidity.

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ONLINE REPOSITORY

PRECISION

Asthma Impairment and Risk Questionnaire (AIRQ™)

For use in patients 12 years and older who have been diagnosed with asthma

Please answer all of the questions below.

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

1. Bothered you during the day on **more than 4 days**? Yes No
2. Woke you up from sleep **more than 1 time**? Yes No
3. Limited the activities you want to do **every day**? Yes No
4. Caused you to use your rescue inhaler or nebulizer **every day**? Yes No


Primatene® MIST (Amphastar Pharmaceuticals) or Epinephrine


ProAir® HFA (Teva Respiratory, LLC) or Albuterol sulfate


ProAir RespiClick® (Teva Respiratory, LLC) or Albuterol sulfate


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


Ventolin® HFA (GlaxoSmithKline) or Albuterol sulfate


Xopenex HFA® (Sunovion Pharmaceuticals Inc.) or Levalbuterol tartrate


Albuterol sulfate or Xopenex® (Sunovion Pharmaceuticals Inc.) or Levalbuterol HCl

In the past 2 weeks:

5. Did you have to limit your social activities (such as visiting with friends/relatives or playing with pets/children) because of your asthma? Yes No
6. Did coughing, wheezing, shortness of breath, or chest tightness limit your ability to exercise? Yes No
7. Did you feel that it was difficult to control your asthma? Yes No

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

8. Caused you to take steroid pills or shots, such as prednisone or Medrol®*? Yes No
9. Caused you to go to the emergency room or have unplanned visits to a health care provider? Yes No
10. Caused you to stay in the hospital overnight? Yes No

Total YES Answers ☐

*Medrol® (Pfizer, Inc.) or methylprednisolone

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FIGURE E1. The final 10-item Asthma Impairment and Risk Questionnaire (AIRQ), a novel composite asthma control tool designed to measure impairment and risk. © 2020 AstraZeneca. All rights reserved. AIRQ is a trademark of AstraZeneca. The AIRQ is reproduced with permission from AstraZeneca. AstraZeneca is the copyright owner of the AIRQ; however, third parties will be allowed to use the AIRQ free of charge. The AIRQ must always be used in its entirety. Except for limited reformatting, the AIRQ may not be modified or combined with other instruments without prior written approval. The 10 questions of the 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 AIRQ and on all copies. The layout of the final authorized AIRQ may differ slightly, but the item wording will not change. The AIRQ score is calculated as the sum of the yes responses.

TABLE E1. A selection of available patient, caregiver, or clinician-reported measures of asthma control

Questionnaire	Items	Control*	Admin†	Literacy demand‡	Recall time	Response options	Scoring system	Avail	Age (y)	Exac
ACCI[E1] Asthma Control and Communication Instrument	12; 5 dom§	Both	Self	5th	Since prior visit‖; control dom: 1 wk (noct awk: 2 wk)	Categories: 0 d-all day every day Sum score: 0-4 (Nos.: 7, 8, 10, 11); 0-3 (No.: 9) Problem index: 0-1 (5-dom, controlled-not controlled)	Categories: 4 levels of severity/control¶ Sum score: 0-19 Better control−worse control Problem index: 0-5 Controlled-not controlled	Yes	≥12	Yes
ACT[E2] Asthma Control Test	5	Imp	Self	NA	4 wk	1-5 Poor-complete control of asthma	Total 5-item score: 5-25 Well-controlled: ≥20 Not well-controlled: 16-19 Very poorly controlled: ≤15	Licensed, see NAEPP	≥12	No
cACT[E3] Childhood Asthma Control Test	7	Imp	Child and caregiver	NA	4 wk	0-3 (Nos.: 1-4); 0-5 (Nos.: 5-7)	Total 7-item score: 0-27 Well-controlled: ≥20 Not well-controlled: 13-19 Very poorly controlled: ≤12	Yes	4-11	No
ACQ[E4,E5] Asthma Control Questionnaire	7#	Imp	Self: ≥11 y Trained interviewer: 6-10 y**	NA	1 wk	0-6 Totally controlled-severely uncontrolled	Mean of 7 items: 0-6 Well-controlled: ≤0.75 Not well-controlled: ≥1.5[E6]	Requires permission	≥6	No
Asthma APGAR[E7]	6; 5 dom††	Imp	Self	NA	2 wk	0-6 Adequate to inadequate control	Total 6-item score: 0-100	Yes	5-45	No
ATAQ[E8] Asthma Therapy Assessment Questionnaire (for adult)	4	Imp	Self	NA	4 wk	0 (no) or 1 (yes) Control problem	Total 5-area score: 0 = no control problems; 4 = 4 control problems Well-controlled: 0 Not well-controlled: 1-2 Very poorly controlled: 3-4[E9]	Yes	≥17	No
ATAQ[E10] Asthma Therapy Assessment Questionnaire (for children/ adolescents)	20‡‡	Imp	Caregiver	NA	4 wk or 12 mo	0 (no) or 1 (yes) Control problem	Total 7-item score for control scale: 0-7	Yes	5-17	No
CASI[E11] Composite Asthma Severity Index	8; 5 dom§§	Both	Clinician	NA	2 wk (exac: 2 mo)	0-3 (Nos.: 1-5) 0-5 (No.: 6) 0, 2, 4, 6 (Nos.: 7-8)	Weighted 5-dom total: 0-20‖‖	Yes	6-17	Yes
LASS[E12] Lara Asthma Symptom Scale	8	Imp	Clinician	NA	4 wk	1-5 Never, a few days, some days, most days, every day	Total 8-item score: 8-40	Yes	3-17; 18-64	No
PACCI[E13] Pediatric Asthma Control and Communication Instrument	12; 5 dom¶¶	Both	Caregiver	5th	Since prior visit¶; control dom: 1 wk (noct awk: 2 wk)	Sum score: 0-4 (Nos.: 7, 8, 10, 11); 0-3 (No.: 9) Problem index: 0-1 (5-dom, yes/no controlled) Categories: assigned based on Nos. 7-11	Sum score: 0-19 Better control−worse control Problem index: 0-5 controlled-not controlled Categories: 4 levels of severity/control¶	Yes	≤21	Yes

RAND-ACM[E14] RAND Asthma Control Measure	5	Imp	Self	NA	4 wk	1-5 (Nos.: 1, 2, 4, 5) 1-4 (No.: 3)	Total 5-item score: 5-24 Well-controlled: 5-7 Not well-controlled: 8-12 Very poorly controlled: 13-24	Yes	≥18	No
RCP[E15] Royal College of Physicians	3	Imp	Self	NA	1 wk or 1 mo	0 (no) or 1 (yes) Control problem	Total 3-item score: 0-3 Good control: 0 Poor control: 2-3	Yes	6-15; 19-71	No
TRACK[E16] Test for Respiratory and Asthma Control in Kids	5	Both	Caregiver	NA	4 wk (rescue med: 3 mo; exac: 12 mo)	0-20 (0, 5, 10, 15, or 20 points) Worse control—better control	Total 5-item score: 0-100	Yes	<5	Yes

Admin, Administration; *avail*, freely available for use; *awk*, awakening; *comb*, combination (physician- and patient-administered); *dom*, domain; *exac*, exacerbation; *imp*, impairment; *med*, medication; *NA*, not available; *NAEPP*, National Asthma Education and Prevention Program; *noct*, nocturnal; *perm*, permission.

*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).

§Domains include acute care/risk, bother, direction of symptoms, control, adherence plus 1 item to enhance physician-patient communication.

‖Or over the past 2 months if it is the patient's first visit.

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

#The ACQ can also be administered in 3 shortened formats: symptom only (ACQ-5), symptoms plus β_2-agonist use (ACQ-6), and symptoms plus β_2-agonist use and forced expiratory volume in the first second of expiration (FEV_1; ACQ-7).[E17]

**Questions 1-6 are self-administered by patients aged ≥11 years or administered by a trained interviewer for patients aged 6-10 years. Question 7 (FEV_1 range) is completed by the clinician.

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

‡‡Questionnaire consists of a 7-item control scale.

§§Domains include daytime symptoms, nighttime symptoms, lung function, treatment, 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), exacerbations (30% of the total).

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

TABLE E2. Baseline AIRQ final model: log odds of asthma control (ACT + exacerbations: well-/not well-controlled vs very poorly controlled)*

					95% CI for OR	
AIRQ 10 items	**B (SE)**	***P* value**	**Wald χ^2**	**OR**	**Lower**	**Upper**
Item 3: limited activities	0.69 (0.38)	.0721	3.23	1.99	0.94	4.22
Item 4: bothered you	0.28 (0.35)	.4208	0.65	1.32	0.67	2.60
Item 5: sleep interruption	0.85 (0.33)	.0108	6.49	2.35	1.22	4.53
Item 6: steroids in past 12 months	1.97 (0.36)	<.0001	29.64	7.18	3.53	14.60
Item 7: ER or office visit	1.13 (0.38)	.0026	9.06	3.10	1.48	6.48
Item 8: hospital stay	1.75 (1.66)	.2905	1.12	5.77	0.22	148.7
Item 11: limit social activities	1.46 (0.42)	.0004	12.38	4.31	1.91	9.74
Item 12: difficult to control asthma	1.27 (0.38)	.0009	11.11	3.55	1.68	7.47
Item 13: rescue inhaler or nebulizer every day	1.57 (0.39)	<.0001	16.18	4.80	2.24	10.31
Item 14: limited ability to exercise	0.29 (0.33)	.3675	0.81	1.34	0.71	2.55
Model fit						
AIC	294.89					
−2Log likelihood	272.89					
R^2, Cox-Snell, Max-rescaled	0.4865, 0.6677					
Score, χ^2 (DF, *P* value)	223.41 (10, <.0001)					
Wald, χ^2 (DF, *P* value)	114.43 (10, <.0001)					
Hosmer-Lemeshow, χ^2 (DF, *P* value)	11.41 (7, 0.1218)					
C-index (AUC)	0.9253					

AIC, Akaike information criterion; *AIRQ*, Asthma Impairment and Risk Questionnaire; *AUC*, area under the curve; *B*, unstandardized beta; *CI*, confidence interval; *DF*, degrees of freedom; *ER*, emergency room; *OR*, odds ratio; *SE*, standard error.
*Total: N = 428; well-/not well-controlled (n = 234) vs very poorly controlled (n = 194).

TABLE E3. Baseline AIRQ final model: log odds of asthma control (ACT + exacerbations: well-controlled vs not well-/very poorly controlled)*

					95% CI for OR	
AIRQ 10 items	**B (SE)**	***P* value**	**Wald χ^2**	**OR**	**Lower**	**Upper**
Item 3: limited activities	1.09 (0.54)	.0430	4.09	2.98	1.03	8.60
Item 4: bothered you	1.84 (0.40)	<.0001	21.02	6.31	2.87	13.88
Item 5: sleep interruption	0.79 (0.42)	.0637	3.44	2.19	0.96	5.03
Item 6: steroids in past 12 mo	2.49 (0.45)	<.0001	30.33	12.06	4.97	29.25
Item 7: ER or office visit	1.01 (0.52)	.0504	3.83	2.74	1.00	7.52
Item 8: hospital stay	−0.13 (1.79)	.9399	0.01	0.87	0.03	29.13
Item 11: limit social activities	2.02 (0.66)	.0023	9.27	7.54	2.05	27.68
Item 12: difficult to control asthma	0.61 (0.55)	.2716	1.21	1.84	0.62	5.46
Item 13: rescue inhaler or nebulizer every day	1.48 (0.55)	.0067	7.35	4.38	1.51	12.76
Item 14: limited ability to exercise	0.75 (0.34)	.0285	4.80	2.11	1.08	4.12
Model fit						
AIC	257.38					
−2Log likelihood	235.38					
R^2, Cox-Snell, Max-rescaled	0.4712, 0.6781					
Score, χ^2 (DF, *P* value)	190.72 (10, <.0001)					
Wald, χ^2 (DF, *P* value)	106.39 (10, <.0001)					
Hosmer-Lemeshow, χ^2 (DF, *P* value)	4.99 (7, 0.6612)					
C-index (AUC)	0.9378					

AIC, Akaike information criterion; *AIRQ*, Asthma Impairment and Risk Questionnaire; *AUC*, area under the curve; *B*, unstandardized beta; *CI*, confidence interval; *DF*, degrees of freedom; *ER*, emergency room; *OR*, odds ratio; *SE*, standard error.
*Total: N = 428; well-controlled (n = 138) vs not well-/very poorly controlled (n = 290).

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