

# Validation and psychometric properties of the Asthma Control Questionnaire among children

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**Background:** The Asthma Control Questionnaire (ACQ) is a patient-centered tool for evaluating asthma control. It has been validated in adults, but not well-validated among children.

**Objective:** We evaluated the reliability, validity, and responsiveness to change of the ACQ for assessing asthma control in children ages 6 to 17 years. A threshold value for poor disease control and a minimally important difference were also determined.

**Methods:** Data from 305 asthmatic children enrolled in a clinical trial were examined. The ACQ was administered at 8 visits. We analyzed results for the combined age group and for the 6- to 11-year-old and 12- to 17-year-old age groups separately.

**Results:** Overall, the Cronbach  $\alpha$  value (internal consistency) for the ACQ was 0.74 at baseline, and the intraclass correlation coefficient (test-retest reliability) for repeated questionnaires among stable patients was 0.53. The Pearson correlations between the ACQ and other asthma questionnaires were moderate to strong ( $-0.64$  to  $-0.73$ ). Mean ACQ scores were higher (worse) in patients whose peak flow decreased, who used more rescue medications, or who sought medical care for asthma than in patients who were stable ( $P < .0001$  for all measures). Changes in ACQ scores were significantly different among patients with deteriorating, improving, or stable asthma symptoms ( $P \leq .01$ ). The optimal threshold indicating poor asthma control was 1.25 or greater. The minimally important difference was established to be 0.40. Results for the separate age groups were similar.

**Conclusion:** The ACQ is a moderately reliable, valid, and responsive tool with adequate psychometric properties for assessing recent asthma control among children. (*J Allergy Clin Immunol* 2013;■■■■:■■■-■■■.)

**Key words:** Asthma, asthma control, Asthma Control Questionnaire, validity, minimally important difference

Establishing asthma control is a cornerstone of asthma therapy. Asthma control is defined by several factors, including pulmonary function, symptoms, and activity limitation. Several measurement tools have been validated for use in assessing asthma control among adults, including the Asthma Control Test (ACT) and the Asthma Control Questionnaire (ACQ).<sup>1,2</sup> At present, the childhood Asthma Control Test (cACT) is the only questionnaire recommended for assessing asthma control in children less than 12 years of age.<sup>3</sup>

The ACQ is an attractive alternative to the cACT because it would be useful to have a single instrument that could be used in both adults and children. The ACQ scale is the same in adults and children, and scoring is the same, whereas the cACT and ACT have different scales for adults and children, making it difficult to combine the scores in studies that include both adults and children. Validation of the ACQ among children is limited. A study by Juniper et al<sup>4</sup> with 35 pediatric patients from a single center demonstrated the ACQ to be valid and reliable in assessing asthma control among children.<sup>4</sup> However, this study used a United Kingdom version of the questionnaire that offered alternative wording to younger children and was administered by trained interviewers.

In this study, we evaluated the reliability, validity, and responsiveness of the ACQ among pediatric patients with poorly controlled asthma enrolled in a multicenter clinical trial. We examined threshold values to distinguish controlled versus uncontrolled asthma. Moreover, we estimated the minimally important difference (MID), which is defined as the smallest difference in the mean score associated with a clinically significant change in asthma control level as assessed by daily diary records of  $\beta$ -agonist use, urgent asthma care, prednisone use, nocturnal awakenings, and the peak expiratory flow rate (PEFR).

## METHODS

### ACQ

The ACQ consists of 6 questions about key symptoms (dyspnea and wheezing), daytime and nighttime symptoms, activity limitation, and rescue bronchodilator use in the past 7 days. One response is determined by the FEV<sub>1</sub> percent predicted.<sup>2</sup> Each item is scored on a 7-point scale ranging from 0 to 6. The final score is generated by averaging the total scores for the 7 items. Higher scores indicate worse asthma control. In this study, children ages 11 to 17 years self-completed the questionnaire. Children ages 6 to 10 years

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**Abbreviations used**

|        |                                                |
|--------|------------------------------------------------|
| ACQ:   | Asthma Control Questionnaire                   |
| ACT:   | Asthma Control Test                            |
| ASUI:  | Asthma Symptom Utility Index                   |
| cACT:  | Childhood Asthma Control Test                  |
| EPAC:  | Episode of poor asthma control                 |
| ICC:   | Intraclass correlation coefficient             |
| MID:   | Minimally important difference                 |
| pAQLQ: | Pediatric Asthma Quality of Life Questionnaire |
| PEFR:  | Peak expiratory flow rate                      |
| ROC:   | Receiver operating characteristic              |

completed the questionnaire with the assistance of an accompanying adult, either a parent or guardian.<sup>5</sup>

**Data collection**

**Patients.** Data were collected from patients enrolled in a clinical trial: the Study of Acid Reflux in Children with Asthma.<sup>6</sup> Three hundred five patients ages 6 to 17 years with inadequately controlled asthma despite treatment with inhaled corticosteroids were enrolled. Poor asthma control was defined as 1 or more of the following: use of short-acting bronchodilators 2 or more times weekly, nocturnal asthma awakenings more than once weekly during the prior month, 2 or more asthma exacerbations requiring urgent medical care in the prior year, or a score of 1.25 or higher on the ACQ at the screening visit. One patient who turned 18 during the study was excluded from the analysis. The study was approved by institutional review boards of all participating centers and registered at [clinicaltrials.gov](http://clinicaltrials.gov) (NCT00442013). Parents of participants provided written informed consent for enrollment in the clinical trial. We received permission from all questionnaire copyright holders to administer their respective questionnaires to participants enrolled in the trial. Elizabeth Juniper approved the use and format of the ACQ for this trial and provided instructions for its administration.

**Procedures.** Participants were evaluated at 8 visits separated by approximately 4 weeks. Patients or parents of patients ages 6 to 10 years kept daily asthma diaries that included morning PEFR, asthma symptom scores,  $\beta$ -agonist use, nocturnal asthma awakenings, asthma treatments, and health care use. At each visit, questionnaires were completed by the patient (age  $\geq 11$  years) or with the assistance of a parent/guardian (ages 6–10 years), including the following: the ACQ, cACT (ages 6–11 years), ACT (ages 12–17 years), Asthma Symptom Utility Index (ASUI), and Pediatric Asthma Quality of Life Questionnaire (pAQLQ). The cACT is a 7-question instrument for use among children ages 4 to 11 years, with 4 questions answered by the child and 3 questions answered by the caretaker.<sup>7</sup> The ACT is a 5-question, well-validated tool for assessing asthma control among subjects ages 12 years and greater.<sup>1</sup> The ASUI is a 10-item instrument designed to assess the frequency and severity of 4 asthma symptoms (cough, wheeze, dyspnea, and awakening at night) and side effects weighted by patient preferences.<sup>8</sup> The pAQLQ is a 23-item survey in 3 domains (symptoms, activity limitation, and emotional function) that measures functional impairments in children ages 7 to 17 years.<sup>9</sup>

During the course of the study, patients were monitored for episodes of poor asthma control (EPACs), which were defined as the occurrence of 1 or more of the following clinical events: decrease of 30% or greater in morning PEFR (from personal best during the 2-week run-in period) for 2 consecutive days, addition of oral corticosteroids to treat asthma symptoms, urgent care for asthma, or increased use of rescue medication from baseline (ie, either  $\geq 4$  additional puffs of bronchodilator or  $\geq 2$  additional nebulizer treatments in 1 day).<sup>6</sup> The EPAC was determined from the daily asthma diaries over a 4-week period between visits.

**Assessments**

**Statistical analysis.** All analyses were stratified by age (6–11 vs 12–17 years) and then for the entire sample. We analyzed these 2 groups

separately because they correspond to the age ranges used for the cACT and ACT, respectively. We used diary card data to evaluate a patient's asthma control for the period between visits with either the ACQ score at the end of the period or the change in ACQ scores between visits as the dependent variable. Analyses that included multiple measurements from patients used generalized estimating equations to account for the correlation between repeated measures from the same patient.<sup>10</sup>

**Reliability.** Internal consistency and test-retest statistical methods were used to evaluate the reliability of the ACQ. For internal consistency, the Cronbach  $\alpha$  value was calculated based on ACQ scores in patients at the baseline visit. Test-retest reliability was assessed with the intraclass correlation coefficient (ICC) based on ACQ scores in stable patients who maintained good asthma control between 2 consecutive follow-up visits without an EPAC.

**Construct validity.** Construct validity was evaluated by determining the Pearson correlation coefficient between the ACQ scores at the baseline visit with cACT or ACT, ASUI, and pAQLQ scores.

The ability of the ACQ to discriminate between patient groups with different levels of asthma control was assessed by comparing mean ACQ scores across groups who had the presence or absence of clinical events that constitute an EPAC during the prior period. Mean ACQ scores were compared between the patient groups who did or did not have the specific clinical event by using ANOVA adjusted for repeated measures.

**Responsiveness.** Four levels of asthma control were defined based on the patient's record of EPACs during follow-up: *good control*, no events between visits; *worsening control*, good control followed by an event before the next visit; *improved control*, an event in the prior period but no event in the subsequent period; and *continuing poor control*, an event in the prior period and in the subsequent period. Responsiveness of the ACQ was assessed by evaluating the change in ACQ scores from the beginning to the end of a period. The mean changes in ACQ scores were compared across the 4 control levels by using ANOVA with adjustment for repeated measures.

**Diagnostic assessment.** Mean ACQ scores were compared by means of ANOVA between patient groups who did or did not have an EPAC. ACQ threshold values for determining uncontrolled asthma were evaluated with receiver operating characteristic (ROC) analyses. Occurrence of an EPAC in the prior period was used as the gold standard for determining uncontrolled asthma. We analyzed multiple threshold values of ACQ scores from 0.25 to 2.00 to calculate the sensitivity, specificity, positive and negative predictive values, percentage correctly classified, and area under the ROC curve.

**MID.** Distribution- and anchor-based approaches were used to determine the MID, which was defined as the smallest mean change in the ACQ score considered clinically meaningful. The distribution-based approach analyzes the properties of the scale by using the statistical properties of the scale, whereas the anchor-based approach uses clinical reference points to determine the MID.<sup>11–15</sup> These methods have been used for estimation of the MID for quality of life, health status, and other patient-reported outcomes.<sup>13</sup> For the distribution-based analysis, baseline data were used to determine the SD and SEM of the ACQ. The SEM was calculated according to the following formula:

$$SEM = SD_{ACQ} * \left[ \text{Square root} \left( 1 - \text{Reliability}_{ACQ} \right) \right],$$

where reliability corresponded to the Cronbach  $\alpha$  value. The MID was defined by both  $0.5 * SD^{16}$  and  $1 * SEM^{17}$ . For the anchor-based approach, the mean ACQ scores between patient groups who differed on the presence or absence of 4 clinical components that constitute an EPAC during the prior period were used to estimate the magnitude and significance of differences in mean ACQ scores between these groups, which corresponded to the MID.

**RESULTS****Study population**

Three hundred five children participated in the study. Completed diaries and corresponding ACQ scores were obtained on

**TABLE I.** Sample characteristics

|                                                       |              |
|-------------------------------------------------------|--------------|
| Age (y), no. (%)                                      |              |
| All                                                   | 305 (100)    |
| 6-11                                                  | 164 (54)     |
| 12-17                                                 | 141 (46)     |
| Age at randomization (y), mean (SD)                   | 11 (3)       |
| Sex, no. (%)                                          |              |
| Female                                                | 118 (39)     |
| Male                                                  | 187 (61)     |
| Race, no. (%)                                         |              |
| White                                                 | 102 (34)     |
| Black                                                 | 154 (50)     |
| Hispanic                                              | 34 (11)      |
| Other                                                 | 15 (5)       |
| Asthma characteristics                                |              |
| Age at asthma onset (y), mean (SD)                    | 3 (3)        |
| Urgent care for asthma in past year, no. (%)          | 224 (73)     |
| Oral corticosteroids for asthma in past year, no. (%) | 206 (67)     |
| Use of rescue inhaler 2 or more times/wk.* no. (%)    | 227 (74)     |
| Daily use of ICS/LABA in past 6 mo, no. (%)           | 177 (58)     |
| Daily use of leukotriene-modifying agent, no. (%)     | 167 (55)     |
| Self-reported atopic conditions, no. (%)              |              |
| Rhinitis                                              | 181 (59)     |
| Eczema                                                | 133 (43)     |
| Food allergies                                        | 81 (26)      |
| Allergies worsen asthma                               | 245 (80)     |
| Asthma Questionnaires, mean (SD)                      |              |
| ACQ at randomization†                                 | 1.2 (0.8)    |
| cACT (ages 6-11 y)‡                                   | 19 (4)       |
| ACT (ages 12-17 y)§                                   | 20 (4)       |
| ASUI                                                  | 0.82 (0.15)  |
| Lung function, mean (SD)                              |              |
| Prebronchodilator FEV <sub>1</sub> (% predicted)      | 91.9 (15.9)  |
| Postbronchodilator FEV <sub>1</sub> (% predicted)     | 99.7 (14.8)  |
| Prebronchodilator FVC (% predicted)                   | 100.8 (14.2) |
| Postbronchodilator FVC (% predicted)                  | 103.0 (14.2) |
| Change in FEV <sub>1</sub> after bronchodilator       | 9.7 (11.1)   |
| Change in FVC after bronchodilator                    | 2.8 (6.2)    |

FVC, Forced vital capacity; ICS, inhaled corticosteroid; LABA, long-acting  $\beta$ -agonist.

\*Use of a rescue inhaler is based on self-report of average use in the month before the screening visit.

†The range of ACQ scores is 0 to 6, with lower scores indicating better asthma control.

‡The range of cACT scores is 0 to 27, with higher scores indicating better asthma control.

§The range of ACT scores is 5 to 25, with higher scores indicating better asthma control.

||The range of ASUI scores is 0 to 1, with higher scores indicating better asthma control.

96% of participants and were available for 1555 (85%) of 1836 possible visits. Participants' characteristics are shown in Table I.

## Reliability

The Cronbach  $\alpha$  value of the ACQ was 0.74 for the entire sample ( $n = 305$ ), 0.75 for the 6- to 11-year-old group ( $n = 164$ ), and 0.72 for the 12- to 17-year-old group ( $n = 141$ ) at the baseline visit. A value of greater than 0.70 is considered sufficiently internally consistent to compare different study groups, whereas a value of greater than 0.90 is considered necessary to apply the metric to a subject. The ICC for ACQ scores between 2 consecutive visits among stable subjects who reported no EPACs for that period ranged between 0.42 and 0.82 for the overall group (Table II), between 0.34 and 0.95 for the 6- to 11-year-old age

**TABLE II.** ICCs for ACQ scores between consecutive visits for stable patients

|                                | No. | ICC  |
|--------------------------------|-----|------|
| Overall visit                  |     |      |
| V <sub>2</sub> -V <sub>4</sub> | 60  | 0.60 |
| V <sub>4</sub> -V <sub>5</sub> | 60  | 0.50 |
| V <sub>5</sub> -V <sub>6</sub> | 54  | 0.70 |
| V <sub>6</sub> -V <sub>7</sub> | 53  | 0.42 |
| V <sub>7</sub> -V <sub>8</sub> | 49  | 0.55 |
| V <sub>8</sub> -V <sub>9</sub> | 49  | 0.82 |

group (see Table E1 in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org)), and between 0.22 and 0.74 for the 12- to 17-year-old age group (see Table E1). Taking into account all stable visit pairs, the ICC from a random-effects model is 0.53, including 911 of 1566 visits from 258 participants with 1 or more stable intervals. The ICC is 0.62 for children ages 6 to 11 years of age and 0.45 for children 12 years of age and greater. Therefore, the reliability of the instrument is moderate for the overall group but only fair in older children.

## Construct validity

Statistically significant correlations were present between the ACQ versus the cACT/ACT for the entire sample for 6- to 11-year-old subjects (Fig 1, A) and for ages 12- to 17-year-old subjects (Fig 1, B) at the baseline visit ( $P < .0001$  for all groups). Similar findings were seen for the ACQ versus the pAQLQ and for the ACQ versus the ASUI (Table III and see Table E2 in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org)).

Mean ACQ scores were different between patients who had experienced an EPAC in the prior period versus those who did not (Table IV and see Table E3 in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org)). The mean ACQ scores were significantly higher, indicating worse control among patients who had experienced an EPAC, compared with those who did not, for the overall group and each age subgroup. Depending on the type of event indicating poor control, the group difference ranged from 0.34 to 0.59.

A subgroup of children had measures of airway inflammation measured. We found no significant baseline correlation of exhaled nitric oxide levels ( $n = 146$ ) or expired breath condensate pH ( $n = 239$ ) with ACQ scores.

## Responsiveness

Responsiveness of the ACQ to changes in asthma control was demonstrated by evaluating the change in ACQ scores between visits. Mean changes in scores in patients who did not experience a clinical event during the period or continued to have poor asthma control were close to zero (Table V). In contrast, the change in scores for patients with either improved or deteriorating control during the period either decreased (better control) or increased (worsening control), respectively (Table V and see Table E4 in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org)). Mean changes in ACQ scores differed significantly across groups of patients based on their state for the overall group ( $P < .0001$ ), the 6- to 11-year-old age group ( $P < .001$ ), and the 12- to 17-year-old age group ( $P = .01$ ).

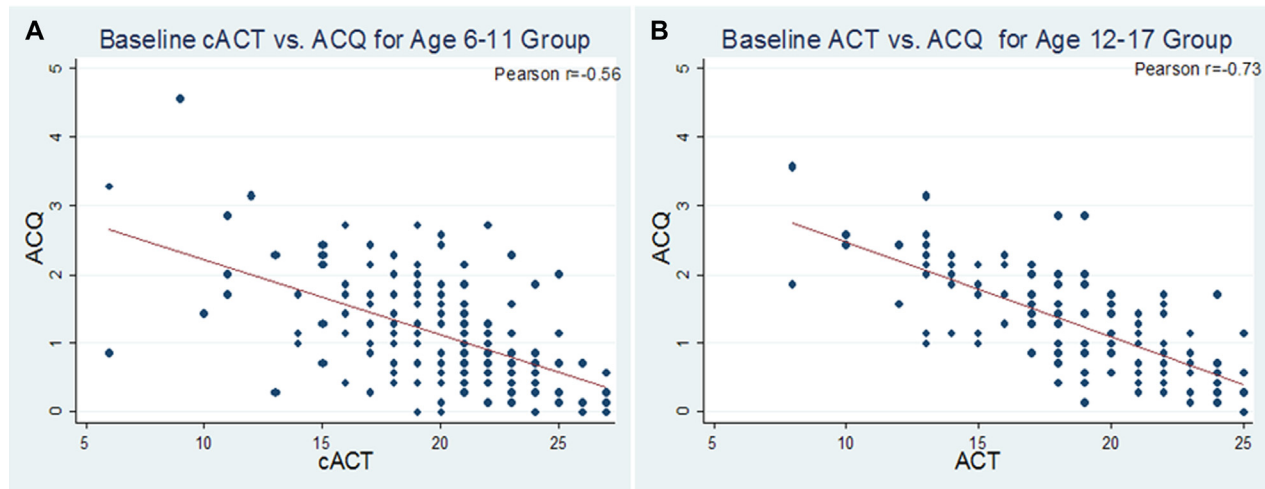


**FIG 1.** Scatter plots, regression lines, and Pearson correlation coefficients for the ACQ and cACT (ages 6-11 years) or ACT (ages 12-17 years). **A**, Equation:  $y(\text{ACQ}) = 3.31 - 0.11x(\text{cACT})$ . **B**, Equation:  $y(\text{ACQ}) = 3.82 - 0.14x(\text{ACT})$ .

**TABLE III.** Correlation of the ACQ to other asthma questionnaires for the entire sample

| Questionnaire | Pearson correlation coefficient ( <i>r</i> ) | 95% CI         |
|---------------|----------------------------------------------|----------------|
| cACT/ACT      | −0.64                                        | −0.57 to −0.70 |
| pAQLQ         | −0.68                                        | −0.62 to −0.74 |
| ASUI          | −0.73                                        | −0.68 to −0.78 |

All groups were statistically significant at a *P* value of less than .0001.

### Diagnostic assessment for detecting poorly controlled asthma

The mean ACQ scores presented in Table IV were used to generate the range of ACQ scores applied as threshold values for distinguishing controlled from uncontrolled asthma. Table VI lists the diagnostic test accuracy of various ACQ score thresholds for detecting poorly controlled asthma with their respective sensitivity, specificity, positive and negative predictive values, percentage correctly classified, and area under the ROC curve for the overall group by using events from the asthma diary as the reference standard. ACQ scores of less than 0.4 had good sensitivity (>90%) but poor specificity, whereas ACQ scores of greater than 2.0 had good specificity (>90%) but poor sensitivity. The ACQ score associated with the highest area under the ROC curve was 1.25, with a sensitivity of 53%, a specificity of 67%, and positive and negative predictive values of 58% and 62%, respectively. The threshold value corresponding to an EPAC was less (0.25) in the 6- to 11-year-olds than in the 12 to 17-year-olds (0.4; see Table E5 in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org)).

### MID

The MID (ie, smallest difference in the score that represents a clinically meaningful change) was determined through 2 approaches. The distribution-based method produced an MID of 0.375 by using  $0.5 \times \text{SD}$  and 0.382 by using SEM for the overall group, 0.40 by using both  $0.5 \times \text{SD}$  and SEM for the 6- to 11-year-old age group, and 0.35 by using  $0.5 \times \text{SD}$  and 0.37 by using SEM for the 12- to 17-year-old age group. For the anchor-based

approach, the mean ACQ scores among patients who experienced a specified clinical event related to an EPAC between visits were compared with those who did not. The difference between those groups was statistically significant for all of the EPAC components (Table IV and see Table E3). For example, patients reported use of systemic corticosteroids for asthma 153 times during the study; the difference between ACQ scores for those patient visits versus patient visits in which corticosteroid use in the prior interval was not reported was 0.47 (SD, 0.05). Overall, the mean difference in ACQ scores was 0.4 to 0.5 (range, 0.34-0.59 points) for the combined age group, 0.5 to 0.6 (range, 0.39-0.65 points) for the 6- to 11-year-old age group, and 0.3 to 0.4 (range, 0.27-0.54 points) for the 12- to 17-year-old age group. Anchoring the ACQ against the ACT by using 3 points as the MID of the ACT produces an estimated  $\text{MID}_{\text{ACQ}}$  of 0.42 for the 12- to 17-year-old age group as based on the equation generated from the regression line (Fig 1, B). Although no MID has been established for the cACT, a 3-point change in the cACT corresponds to an estimated  $\text{MID}_{\text{ACQ}}$  of 0.33 for children ages 6 to 11 years based on the regression equation (Fig 1, A). Thus by using the triangulation method,<sup>18</sup> the estimated MID is 0.40 for the overall group.

### DISCUSSION

The ACQ is a moderately reliable and responsive tool to assess asthma control in a sample of 6- to 17-year-old children with poor asthma control at baseline enrolled in a clinical trial. We estimated the MID for the ACQ to be 0.40 and the optimal threshold value for distinguishing between well-controlled and poorly controlled pediatric asthma groups to be 1.25, which is similar to values established for adults.<sup>19,20</sup> The results of this study support findings from a previous study of the ACQ in children by using a slightly different questionnaire format.<sup>4</sup> Our study extends these findings in a larger population studied over multiple visits at multiple sites. We did not find any substantial difference between younger and older children for most of the metrics evaluated.

Asthma control questionnaires are commonly used to evaluate individual patient's asthma control and also as outcome

**TABLE IV.** Mean ACQ scores and mean differences in ACQ scores between patients with and without an EPAC in the prior period for the entire sample

| Clinical event                    | Overall all<br>No. of EPACs/% visits | Mean ACQ score (SD) |             | Differences in ACQ score |         |
|-----------------------------------|--------------------------------------|---------------------|-------------|--------------------------|---------|
|                                   |                                      | EPACs               | No EPACs    | Mean (SD)                | P value |
| EPAC                              | 655/42%                              | 1.31 (0.04)         | 0.93 (0.04) | 0.38 (0.01)              | <.0001  |
| EPAC components                   |                                      |                     |             |                          |         |
| Decrease in PEFr                  | 458/29%                              | 1.33 (0.05)         | 0.99 (0.04) | 0.34 (0.02)              | <.0001  |
| Increase in rescue medication use | 309/20%                              | 1.50 (0.06)         | 0.98 (0.03) | 0.52 (0.02)              | <.0001  |
| Urgent care*                      | 87/6%                                | 1.64 (0.10)         | 1.05 (0.04) | 0.59 (0.07)              | <.0001  |
| Systemic corticosteroids          | 153/10%                              | 1.51 (0.09)         | 1.04 (0.04) | 0.47 (0.05)              | <.0001  |

\*Urgent care is defined as an “urgent unscheduled health care contact for asthma” and includes emergency department, hospital, clinic, or doctor’s office visits.

**TABLE V.** Mean change in ACQ scores between consecutive visits by asthma control status for the entire sample

| Status*                 | No. | Visit periods | Mean change in ACQ | 95% CI         |
|-------------------------|-----|---------------|--------------------|----------------|
| Good control            | 196 | 547           | −0.02              | −0.05 to 0.01  |
| Worsening control       | 155 | 177           | 0.26               | 0.11 to 0.41   |
| Improved control        | 165 | 200           | −0.33              | −0.44 to −0.22 |
| Continuing poor control | 148 | 337           | 0.06               | 0.00 to 0.12   |

\*Status: *Good control* = no EPAC for 2 consecutive visits, where an EPAC is defined as a 30% or greater decrease in PEFr on 2 consecutive days or requirement for rescue bronchodilator use, urgent care visit, or systemic corticosteroid therapy; *Worsened control* = no EPAC before the first visit and an EPAC between the first and second visits; *Improved control* = EPAC before the first visit and no EPAC between the first and second visit; and *Continued poor control* = EPAC before and after the first visit in sequence. Differences between categories of control was significant by means of ANOVA ( $P < .0001$ ).

**TABLE VI.** Testing parameters for ACQ threshold values for determining poorly controlled asthma for the entire sample

| Overall ACQ threshold score | Sensitivity (%) | Specificity (%) | Positive predictive value (%) | Negative predictive value (%) | Correctly classified (%) | Area under ROC curve |
|-----------------------------|-----------------|-----------------|-------------------------------|-------------------------------|--------------------------|----------------------|
| ≥0.40                       | 90.2            | 15.9            | 48.4                          | 64.9                          | 50.5                     | 0.530                |
| ≥0.55                       | 86.4            | 23.2            | 49.6                          | 66.0                          | 52.7                     | 0.548                |
| ≥0.70                       | 81.1            | 34.4            | 51.9                          | 67.5                          | 56.2                     | 0.577                |
| ≥0.85                       | 72.7            | 40.4            | 51.6                          | 62.9                          | 55.5                     | 0.566                |
| ≥1.00                       | 65.9            | 51.0            | 54.0                          | 63.1                          | 58.0                     | 0.585                |
| ≥1.10                       | 59.8            | 57.6            | 55.2                          | 62.1                          | 58.7                     | 0.587                |
| ≥1.25                       | 53.0            | 66.9            | 58.3                          | 62.0                          | 60.4                     | 0.600                |
| ≥1.40                       | 47.0            | 71.5            | 59.0                          | 60.7                          | 60.1                     | 0.592                |
| ≥1.55                       | 38.6            | 76.8            | 59.3                          | 58.9                          | 59.0                     | 0.577                |
| ≥1.70                       | 33.3            | 81.5            | 61.1                          | 58.3                          | 59.0                     | 0.574                |
| ≥1.85                       | 25.0            | 87.4            | 63.5                          | 57.1                          | 58.3                     | 0.562                |
| ≥2.00                       | 23.5            | 91.4            | 70.5                          | 57.7                          | 59.7                     | 0.574                |

assessment tools for comparing treatments. Although several well-validated questionnaires, including the ACQ and ACT, are available for assessing asthma control among adults, there are few well-validated tools for use in children. The recent National Institutes of Health workshop recommended the cACT for use with children ages 5 to 11 years and the ACT for use with children ages 12 to 17 years.<sup>3</sup> The cACT assesses asthma control in the past 4 weeks and thus might be prone to imperfect recall. The ACQ assesses control over the past week and thus might be more appropriate than the cACT when a short-term estimate of asthma control is needed.

In this study, the ACQ demonstrated fair to good internal consistency for the overall group and separate age groups based on Cronbach  $\alpha$  values. Test-retest reliability, as determined by the intraclass correlations, was moderate for the overall group but only fair in children 12 years and older. The construct

validity and responsiveness of the ACQ were also examined in this study. Given that there is no gold standard for assessing asthma control, other asthma questionnaires and the occurrence of clinical events related to asthma control (EPACs) were used to evaluate these properties. Measures of lung function were not used as a reference standard because FEV<sub>1</sub> is a component of the ACQ. The results of this study showed the ACQ to have good construct validity because it correlated well with the ACT and cACT, pediatric AQLQ, and ASUI for the overall and separate age groups. Moreover, the ACQ could distinguish between groups of patients who differed on the presence or absence of clinical events related to asthma control. Similarly, the ACQ demonstrated responsiveness by showing changes in the ACQ score that tracked with changes in asthma control, as assessed by using diaries for the overall and separate age groups.

The diagnostic test characteristics of the ACQ for determining uncontrolled asthma were also examined in this study. The optimal threshold for distinguishing good from poor asthma control was 1.25 for the overall group. However, the diagnostic accuracy for the ACQ was lower than that for the ACT and cACT. Perhaps this was due to the different criteria used in defining asthma control for these questionnaires, namely physician's global assessment,<sup>1,7</sup> rather than the asthma diaries used in our study. In the previous validation study of the ACQ in children, there was a modest correlation between change in ACQ scores and physician's global change scores; the difference in ACQ scores between those who were stable and those who changed status on the physician's global change score was not significant ( $P = .07$ ).<sup>4</sup>

The MID that would indicate a clinically meaningful change for the ACQ among children was also assessed. There was consistency among the values obtained by using distributive and anchor-based approaches of 0.40, although the 6- to 11-year-old age group showed slightly higher MID values compared with the 12- to 17-year-old age group. This is similar but not identical to the previous MID estimates of 0.50 for adults and children.<sup>4,21</sup> Moreover, results for the overall and separate age groups were similar in all measures evaluated, although the MID showed slightly higher values for the 6- to 11-year-old age group and slightly lower values for the 12- to 17-year-old age group.

This study has several strengths. It involved a large sample from multiple sites and a diverse population with a substantial number of minorities. Moreover, this study used objective measures of asthma control, including symptoms and physiology, which were collected during the look-back period at each visit. Additionally, patients were selected for poor asthma control, and therefore there was considerable variability from visit to visit, which allowed both responsiveness and the MID to be assessed.

This study also had several limitations. There were a small number of stable patients, which limited the ability to assess test-retest reliability. Also, the treatment given in the trial ultimately was determined to be ineffective, and therefore responsiveness to known beneficial treatment could not be assessed; instead, variation of asthma control over time was used. These are similar but not identical phenomena. Moreover, concurrent physician assessment of asthma control was not available in this study, which precluded direct comparison with prior studies. Our subgroups of children in each of the age strata who had serious asthma attacks (see Table E3) were too small to allow us to draw conclusions about the utility of the instrument to predict risk. In the prior validation study in children, the questionnaire that was used incorporated the United Kingdom English version and permitted alternative wording for younger children. In this study, we used the North American English version and permitted an adult to assist the younger children in completing the questions. This might have accounted for the higher reliability of the test among the younger children than among the adolescents.

The results of this study demonstrated the ACQ to be a valid and moderately responsive tool in assessing asthma control among pediatric patients ages 6 to 17 years in a clinical trial. It provides support for an additional tool that can be used in assessing asthma control among children. The ACQ has certain advantages and disadvantages compared with the cACT/ACT; comparison of the psychometric properties of the ACQ based on the results of our study with those of the cACT based on a

previous study<sup>7</sup> is listed (see Table E6 in this article's Online Repository at [www.jacionline.org](http://www.jacionline.org)). The cACT and ACT have an advantage in that they are in the public domain and therefore less costly to use. Moreover, the cACT and ACT do not require measurement of FEV<sub>1</sub>, which might not be available in all settings. However, shorter versions of the ACQ, namely the ACQ5 and ACQ6, which do not use FEV<sub>1</sub>, have been used in adults but require further evaluation in children.<sup>21</sup>

The main advantage of the ACQ is that it has similar psychometric characteristics in adults and children, permitting the use of a single instrument in clinical trials that include both children and adults. In contrast, the cACT and ACT have different ranges, which make it difficult to analyze combined child and adult data. Overall, the ACQ represents a useful and concise tool with symptom and physiologic measures to assess asthma control among adults and children in clinical trials. The ACQ can also be used in a clinical setting, but the moderate reliability and modest diagnostic sensitivity and specificity limit its utility for diagnosing and following individual children.

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**Clinical implications: In a clinical trial, the ACQ is a valid instrument that can identify patient groups less than 18 years of age with controlled versus uncontrolled asthma and their response to treatment.**

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**TABLE E1.** ICC for ACQ scores between consecutive visits for stable patients

|                                | No. | ICC  |
|--------------------------------|-----|------|
| Visit at ages 6-11 y           |     |      |
| V <sub>2</sub> -V <sub>4</sub> | 26  | 0.46 |
| V <sub>4</sub> -V <sub>5</sub> | 26  | 0.34 |
| V <sub>5</sub> -V <sub>6</sub> | 24  | 0.68 |
| V <sub>6</sub> -V <sub>7</sub> | 24  | 0.66 |
| V <sub>7</sub> -V <sub>8</sub> | 20  | 0.87 |
| V <sub>8</sub> -V <sub>9</sub> | 20  | 0.95 |
| Visit at ages 12-17 y          |     |      |
| V <sub>2</sub> -V <sub>4</sub> | 34  | 0.72 |
| V <sub>4</sub> -V <sub>5</sub> | 34  | 0.63 |
| V <sub>5</sub> -V <sub>6</sub> | 30  | 0.70 |
| V <sub>6</sub> -V <sub>7</sub> | 29  | 0.22 |
| V <sub>7</sub> -V <sub>8</sub> | 29  | 0.35 |
| V <sub>8</sub> -V <sub>9</sub> | 29  | 0.74 |

**TABLE E2.** Correlation of the ACQ to other asthma questionnaires for separate age groups

| Questionnaire | Pearson correlation coefficient ( <i>r</i> ) | 95% CI         |
|---------------|----------------------------------------------|----------------|
| cACT/ACT      |                                              |                |
| 6-11 y        | −0.57                                        | −0.46 to −0.67 |
| 12-17 y       | −0.73                                        | −0.64 to −0.80 |
| pAQLQ         |                                              |                |
| 6-11 y        | −0.71                                        | −0.63 to −0.78 |
| 12-17 y       | −0.66                                        | −0.56 to −0.74 |
| ASUI          |                                              |                |
| 6-11 y        | −0.74                                        | −0.66 to −0.80 |
| 12-17 y       | −0.74                                        | −0.66 to −0.81 |

All groups were statistically significant at a *P* value of less than .0001.

**TABLE E3.** Mean ACQ scores and mean differences in ACQ scores between patients with and without EPACs in the prior period for separate age groups

| Clinical event                    | No. of EPACs/% visits | Mean ACQ score (SD) |             | Difference in ACQ score |         |
|-----------------------------------|-----------------------|---------------------|-------------|-------------------------|---------|
|                                   |                       | EPAC                | No EPAC     | Mean (SD)               | P value |
| Ages 6-11 y                       |                       |                     |             |                         |         |
| EPAC                              | 380/46%               | 1.29 (0.06)         | 0.83 (0.05) | 0.46 (0.01)             | <.0001  |
| EPAC components                   |                       |                     |             |                         |         |
| Decrease in PEFr                  | 281/34%               | 1.30 (0.07)         | 0.91 (0.05) | 0.39 (0.07)             | <.0001  |
| Increase in rescue medication use | 186/22%               | 1.54 (0.08)         | 0.89 (0.05) | 0.65 (0.03)             | <.0001  |
| Urgent care*                      | 58/7%                 | 1.64 (0.12)         | 0.99 (0.05) | 0.65 (0.07)             | <.0001  |
| Systemic corticosteroids          | 88/11%                | 1.55 (0.11)         | 0.98 (0.05) | 0.57 (0.06)             | <.0001  |
| Ages 12-17 y                      |                       |                     |             |                         |         |
| EPAC                              | 275/37%               | 1.33 (0.06)         | 1.03 (0.05) | 0.30 (0.02)             | <.0001  |
| EPAC components                   |                       |                     |             |                         |         |
| Decrease in PEFr                  | 177/24%               | 1.35 (0.08)         | 1.08 (0.05) | 0.27 (0.04)             | <.01    |
| Increase in rescue medication use | 123/17%               | 1.50 (0.08)         | 1.07 (0.05) | 0.43 (0.04)             | <.0001  |
| Urgent care*                      | 29/4%                 | 1.66 (0.18)         | 1.12 (0.05) | 0.54 (0.13)             | .01     |
| Systemic corticosteroids          | 65/9%                 | 1.43 (0.13)         | 1.11 (0.05) | 0.32 (0.08)             | .03     |

\*Urgent care is defined as an "urgent unscheduled health care contact for asthma" and includes emergency department, hospital, clinic, or doctor's office visits.

**TABLE E4.** Mean change in ACQ scores between consecutive visits by asthma control status for separate age groups

| Status*                 | No. | Visit periods | Mean change in ACQ score | 95% CI         |
|-------------------------|-----|---------------|--------------------------|----------------|
| Age 6-11 y              |     |               |                          |                |
| Good control            | 97  | 253           | −0.04                    | −0.08 to 0.01  |
| Worsening control       | 86  | 102           | 0.33                     | 0.13 to 0.53   |
| Improved control        | 91  | 113           | −0.36                    | −0.51 to −0.21 |
| Continuing poor control | 87  | 197           | 0.05                     | −0.02 to 0.13  |
| Age 12-17 y             |     |               |                          |                |
| Good control            | 99  | 294           | −0.01                    | −0.05 to 0.04  |
| Worsening control       | 69  | 75            | 0.17                     | 0.04 to 0.39   |
| Improved control        | 74  | 87            | −0.27                    | −0.43 to −0.12 |
| Continuing poor control | 61  | 140           | 0.07                     | −0.04 to 0.18  |

\*Status: *Good control* = no EPAC for 2 consecutive visits, where an EPAC is defined as a 30% or greater decrease in PEFR on 2 consecutive days or requirement for rescue bronchodilator use, urgent care visit, or systemic corticosteroid therapy; *Worsened control* = no EPAC before first visit and EPAC between first and second visit; *Improved control* = EPAC before first visit and no EPAC between first and second visits; and *Continued poor control* = EPAC before and after the first visit in sequence. Differences between categories of control was significant by using ANOVA ( $P < .0001$ ).

**TABLE E5.** Testing parameters for ACO threshold values for determining poorly controlled asthma for separate age groups

| ACO threshold score | Sensitivity (%) | Specificity (%) | Positive predictive value (%) | Negative predictive value (%) | Correctly classified (%) | Area under ROC curve |
|---------------------|-----------------|-----------------|-------------------------------|-------------------------------|--------------------------|----------------------|
| Ages 6-11 y         |                 |                 |                               |                               |                          |                      |
| ≥0.25               | 93.2            | 13.0            | 50.4                          | 66.7                          | 52.0                     | 0.531                |
| ≥0.40               | 89.0            | 19.5            | 51.2                          | 65.2                          | 53.3                     | 0.543                |
| ≥0.55               | 86.3            | 29.9            | 53.8                          | 69.7                          | 57.3                     | 0.581                |
| ≥0.70               | 80.8            | 39.0            | 55.7                          | 68.2                          | 59.3                     | 0.599                |
| ≥0.85               | 69.9            | 46.8            | 55.4                          | 62.1                          | 58.0                     | 0.583                |
| ≥1.00               | 58.9            | 54.5            | 55.1                          | 58.3                          | 56.7                     | 0.567                |
| ≥1.10               | 53.4            | 59.7            | 55.7                          | 57.5                          | 56.7                     | 0.566                |
| ≥1.25               | 43.8            | 68.8            | 57.1                          | 56.4                          | 56.7                     | 0.563                |
| ≥1.40               | 38.4            | 74.0            | 58.3                          | 55.9                          | 56.7                     | 0.562                |
| ≥1.55               | 32.9            | 76.6            | 57.1                          | 54.6                          | 55.3                     | 0.548                |
| ≥1.70               | 26.0            | 80.5            | 55.9                          | 53.4                          | 54.0                     | 0.533                |
| ≥1.85               | 17.8            | 87.0            | 56.5                          | 52.8                          | 53.3                     | 0.524                |
| ≥2.00               | 17.8            | 90.9            | 65.0                          | 53.8                          | 55.3                     | 0.544                |
| Ages 12-17 y        |                 |                 |                               |                               |                          |                      |
| ≥0.40               | 91.5            | 12.2            | 45.4                          | 64.3                          | 47.4                     | 0.518                |
| ≥0.55               | 86.4            | 16.2            | 45.1                          | 60.0                          | 47.4                     | 0.513                |
| ≥0.70               | 81.4            | 29.7            | 48.0                          | 66.7                          | 52.6                     | 0.555                |
| ≥0.85               | 76.3            | 33.8            | 47.9                          | 64.1                          | 52.6                     | 0.550                |
| ≥1.00               | 74.6            | 47.3            | 53.0                          | 70.0                          | 59.4                     | 0.609                |
| ≥1.10               | 67.8            | 55.4            | 54.8                          | 68.3                          | 60.9                     | 0.616                |
| ≥1.25               | 64.4            | 64.9            | 59.4                          | 69.6                          | 64.7                     | 0.646                |
| ≥1.40               | 57.6            | 68.9            | 59.6                          | 67.1                          | 63.9                     | 0.633                |
| ≥1.55               | 45.8            | 77.0            | 61.4                          | 64.0                          | 63.2                     | 0.614                |
| ≥1.70               | 42.4            | 82.4            | 65.8                          | 64.2                          | 64.7                     | 0.624                |
| ≥1.85               | 33.9            | 87.8            | 69.0                          | 62.5                          | 63.9                     | 0.609                |
| ≥2.00               | 30.5            | 91.9            | 75.0                          | 62.4                          | 64.7                     | 0.612                |

**TABLE E6.** Comparison of psychometric properties of the ACQ and cACT

|                              | ACQ (ages 6-11 y) | cACT (ages 4-11 y) <sup>7</sup> |
|------------------------------|-------------------|---------------------------------|
| Cronbach $\alpha$            | 0.75              | 0.79                            |
| ICC                          | 0.34-0.95         | —                               |
| Area under the ROC curve     | 0.599             | 0.713                           |
| MID                          | 0.5               | —                               |
| Optimal diagnostic threshold |                   |                                 |
| Sensitivity                  | 0.81              | 0.63                            |
| Specificity                  | 0.39              | 0.80                            |
| Correlation                  |                   |                                 |
| pAQLQ                        | −0.71             | 0.47                            |
| ASUI                         | −0.74             | —                               |