

## Asthma Control Test: Reliability, validity, and responsiveness in patients not previously followed by asthma specialists

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**Background:** The development of the Asthma Control Test (ACT), a short, simple, patient-based tool for identifying patients with poorly controlled asthma, was recently described in patients under the routine care of an asthma specialist.

**Objectives:** We sought to evaluate the reliability and validity of the ACT in a longitudinal study of asthmatic patients new to the care of an asthma specialist.

**Methods:** Patients (n = 313) completed the ACT and the Asthma Control Questionnaire (ACQ) at 2 physician visits (4-12 weeks apart). Pulmonary function was measured, and asthma specialists rated asthma control.

**Results:** Internal consistency reliability of the ACT was 0.85 (baseline) and 0.79 (follow-up). Test-retest reliability was 0.77. Criterion validity was demonstrated by significant correlations between baseline ACT scores and baseline specialists' ratings of asthma control ( $r = 0.52, P < .001$ ) and ACQ scores ( $r = -0.89, P < .001$ ). Discriminant validity was demonstrated, with significant ( $P < .001$ ) differences in mean ACT scores across patients differing in asthma control, pulmonary function, and treatment recommendation. Responsiveness of the ACT to changes in asthma control and lung function was demonstrated with significant correlations between changes in ACT scores and changes in specialists' ratings ( $r = 0.44, P < .001$ ), ACQ scores ( $r = -0.69, P < .001$ ), and percent predicted FEV<sub>1</sub> values ( $r = 0.29, P < .001$ ). An ACT score of 19 or less provided optimum balance of sensitivity (71%) and specificity (71%) for detecting uncontrolled asthma.

**Conclusions:** The ACT is reliable, valid, and responsive to changes in asthma control over time in patients new to the care of asthma specialists. A cutoff score of 19 or less identifies patients with poorly controlled asthma.

**Clinical implications:** In a clinical setting the ACT should be a useful tool to help physicians identify patients with uncontrolled asthma and facilitate their ability to follow patients' progress with treatment. (J Allergy Clin Immunol 2006;117:549-56.)

**Key words:** Asthma control assessment, Asthma Control Test

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Approximately 20 million individuals in the United States, 7.5% of the population, have asthma, and nearly 5000 Americans die from it each year.<sup>1,2</sup> The prevalence of asthma and its personal and societal tolls continue to increase despite advances in knowledge about the pathophysiology of asthma and the availability of effective therapy.<sup>1-4</sup> The National Asthma Education and Prevention Program's (NAEPP's) 1997 "Expert panel report: guidelines for the diagnosis and management of asthma" and the update in 2002 were intended to help improve the quality of care of asthma and to reduce asthma-associated disability, lost productivity, emergency health care use, and

*Abbreviations used*

ACQ: Asthma Control Questionnaire

ACT: Asthma Control Test

NAEPP: National Asthma Education and Prevention Program

ROC: Receiver operating characteristic

death.<sup>5,6</sup> These guidelines are broadly endorsed and were widely disseminated among health care providers. However, studies show that although several years have passed since the guidelines were issued, they have not been effectively implemented in many health care settings.<sup>7-11</sup> Furthermore, the NAEPP-defined goals of asthma care (ie, prevention of symptoms and exacerbations; maintenance of normal pulmonary function and activity levels; provision of well-tolerated, effective pharmacotherapy; minimization of the need for emergency department visits or hospitalizations; and achieving patients' expectations of asthma care) have not been met for a substantial proportion of patients with asthma.<sup>12-14</sup> Two nationally representative US surveys conducted after publication of the guidelines suggest that poor asthma control remains pervasive.<sup>2,13</sup> In a recent survey based on the 2002 Behavioral Risk Factor Surveillance System, more than 30% of patients reported an urgent visit to their physician for asthma in the prior year, more than 30% reported activity limitation caused by asthma in the prior year, and more than 50% reported sleep disturbance caused by asthma in the prior month.<sup>2</sup>

Asthma control is important to assess in clinical practice, although it is multidimensional in nature, characterized by symptoms, changes in pulmonary function, and effects on quality of life and functional ability.<sup>14</sup> Measures of pulmonary function, symptoms, and quality of life often correlate poorly with one another and appear to provide independent information about clinical status, with lung function providing a point-in-time assessment and with questionnaires assessing status over a given time period.<sup>15-18</sup> Assessing any one of these aspects alone does not accurately gauge asthma control, but routine assessment of all of these aspects individually is usually not feasible given constraints on time and resources in the clinical setting. In particular, spirometry is often not available in the primary care setting.

Tools that reflect the multidimensional nature of asthma control and that are easily and quickly administered and interpreted are needed to facilitate the assessment of asthma control in a busy clinical practice. The Asthma Control Test (ACT), a 5-item, patient-administered survey for assessing asthma control (Fig 1), was developed to meet this need. In a previous study the development of the ACT was documented in a sample of asthmatic patients under the routine care of an asthma specialist.<sup>19</sup> Results indicated that the ACT is a clinically valid measure that can be useful to clinicians and should be evaluated in assessing asthma control in different patient

populations. The study reported herein was conducted to evaluate the reliability and validity of the ACT survey and to assess its responsiveness to changes in asthma control over time in a sample of patients new to the care of an asthma specialist. It was thought that this sample of patients might be more likely than those being followed by specialists to have poorly controlled asthma and to be more representative of the patient population in which the ACT survey might be most useful; that is, among those for whom little or no historical data are available to assist the physician in assessing the current level of asthma control.

## METHODS

### ACT survey

The ACT survey is a patient-completed questionnaire with 5 items assessing asthma symptoms (daytime and nocturnal), use of rescue medications, and the effect of asthma on daily functioning (Fig 1). Each item includes 5 response options corresponding to a 5-point Likert-type rating scale. In scoring the ACT survey, responses for each of the 5 items are summed to yield a score ranging from 5 (poor control of asthma) to 25 (complete control of asthma). Details of the development of the ACT are reported elsewhere.<sup>19</sup>

### Data collection

*Patients.* Patients were recruited through local media advertising of the study or by virtue of their consulting one of the participating asthma specialty practices for the first time. Patients 12 years of age or older were eligible if they had not consulted an asthma specialist within 5 years before the study, had a physician diagnosis of asthma without respiratory comorbidities, were literate in English, and were not participating in other clinical studies at the time of enrollment. All patients, their parents or guardians, or both provided written informed consent.

*Procedures.* The protocol for this study was approved by institutional review boards for each of the 6 participating asthma specialist practices. At 2 scheduled physician office visits separated by 4 to 12 weeks (the baseline visit and the follow-up visit), patients completed (1) the ACT survey; (2) the Asthma Control Questionnaire (ACQ),<sup>20</sup> a previously validated tool for measurement of asthma control (6-item version without pulmonary function); and (3) prebronchodilator measurements of FEV<sub>1</sub>. Asthma specialists blinded to ACT and ACQ survey responses rated asthma control on a 5-point scale ranging from "not controlled at all" to "completely controlled." The specialists were instructed to base their ratings on how well the NAEPP-defined goals of asthma were being met, as determined on the basis of information from the patient history, physical examination, and FEV<sub>1</sub> measurement.

### Assessments

*Reliability.* The reliability of ACT scores was assessed by using internal consistency and test-retest methods. For internal consistency reliability, the Cronbach  $\alpha$  value was estimated from ACT item responses at baseline and follow-up visits. Test-retest reliability was assessed by computing the intraclass correlation between ACT scores at the baseline and follow-up visits. The test-retest reliability analysis was limited to a subset of patients whose asthma control was stable, as determined by the same specialist ratings of asthma control at both baseline and follow-up visits.

*Criterion validity.* Criterion validity of the ACT survey was evaluated by computing correlations between ACT scores at the baseline visit and (1) the specialist assessment of asthma control and

### Asthma Control Test™

1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
0	0	0	0	0
1	2	3	4	5

2. During the past 4 weeks, how often have you had shortness of breath?

More than Once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all
0	0	0	0	0
1	2	3	4	5

3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?

4 or more nights a week	2 to 3 nights a week	Once a week	Once or twice	Not at all
0	0	0	0	0
1	2	3	4	5

4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all
0	0	0	0	0
1	2	3	4	5

5. How would you rate your asthma control during the past 4 weeks?

Not Controlled at All	Poorly Controlled	Somewhat Controlled	Well Controlled	Completely Controlled
0	0	0	0	0
1	2	3	4	5

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FIG 1. Asthma Control Test.

(2) scores on the ACQ.<sup>20</sup> Correlations were also computed between baseline ACT scores and percent predicted FEV<sub>1</sub> values.

**Discriminant validity.** The discriminant validity of the ACT was also evaluated in clinical tests by using the methods of known-groups validity<sup>21</sup> and data from the baseline visit. The method of known-groups validity compares mean ACT scores across groups of patients known to differ on a relevant clinical measure. In this study 3 such measures were used. The first was the asthma specialist's rating of asthma control, which consisted of 5 categories: (1) not controlled at all; (2) poorly controlled; (3) somewhat controlled; (4) well controlled; and (5) completely controlled. The second measure consisted of percent predicted FEV<sub>1</sub> values. Patients were categorized into 4 groups on the basis of their percent predicted FEV<sub>1</sub> values: (1) less than 60%; (2) 60% to 79%; (3) 80% to 100%; and (4) greater than 100%. This stratification of percent predicted FEV<sub>1</sub> values was roughly based on the NAEPP breakdown of asthma severity (mild intermittent and mild, moderate, and severe persistent asthma).<sup>5,6</sup> The third measure consisted of the asthma specialist's treatment recommendation, which was used to categorize patients into 3 groups: (1) step up in therapy; (2) no change in therapy; and (3) step down in therapy. For each of the above measures, mean ACT scores were computed and compared across patient groups. One-way ANOVA methods were used to test the significance of differences in mean

ACT scores across groups of patients who differed in specialist ratings of asthma control, percent predicted FEV<sub>1</sub> values, and treatment recommendation. It was hypothesized that ACT scores would be higher (indicating better control) among groups of patients with better asthma control reflected in specialist ratings and percent predicted FEV<sub>1</sub> values compared with scores in patients with poorer control. Similarly, ACT scores were expected to be higher among the group of patients in whom a step down in therapy was recommended compared with the group of patients for whom a step up in therapy was recommended.

**Screening accuracy.** The accuracy of the ACT as a tool for screening patients with asthma control problems was assessed with logistic regression methods and receiver operating characteristic (ROC) curve analyses by using baseline data. The criterion measure for these analyses was the specialist's rating of asthma control. In the primary evaluation patients were categorized as having uncontrolled asthma if the specialist rating was "somewhat controlled," "poorly controlled," or "not controlled at all." Patients were categorized as having controlled asthma if the specialist rating was "well controlled" or "completely controlled." A separate analysis was conducted for every possible cut-point score from 10 to 24 on the ACT. Results were summarized in terms of sensitivity, specificity, percentage of patients correctly classified, positive and negative

**TABLE I.** Sample characteristics

	Baseline visit (n = 313)*	Follow-up visit (n = 250)*
Mean age, y (SD)	35.3 (15.3)	35.8 (15.0)
Specialist control rating, n (%)		
Not controlled at all	12 (3.9)	0 (0.0)
Poorly controlled	60 (19.4)	13 (5.2)
Somewhat controlled	88 (28.5)	65 (26.1)
Well controlled	121 (39.2)	133 (53.4)
Completely controlled	28 (9.0)	38 (15.3)
Mean % predicted FEV <sub>1</sub> (SD)	89.0 (20.7)	91.2 (15.7)
% Predicted FEV <sub>1</sub> categories, n (%)		
<60%	22 (7.1)	9 (3.6)
60% to 79%	64 (20.7)	47 (18.9)
80% to 100%	140 (45.3)	127 (51.0)
>100%	83 (26.9)	66 (26.5)

\*The frequencies might not add up to the total sample size because of missing data.

predictive values, and area under the ROC curve. In a secondary evaluation to determine the lower cutoff point for somewhat controlled asthma, the above methods were used, but patients with somewhat controlled asthma were considered to be controlled, and patients with well-controlled or completely controlled asthma were excluded.

**Responsiveness.** The responsiveness of ACT scores was evaluated with correlations and ANOVA methods. First, changes in ACT scores from baseline to the follow-up visit were correlated with changes in the specialist's rating of asthma control, changes in lung function as measured by the change in FEV<sub>1</sub> values, and changes in ACQ scores. Second, ANOVA was used to compare mean changes in ACT scores across groups of patients who differed in the level of change in the specialist's rating of asthma control, change in percent predicted FEV<sub>1</sub> values, and change in ACQ scores. The patient groups for each of these criterion measures were derived as follows:

1. **Specialist control rating:** Change in specialist control rating was derived by simply subtracting the baseline rating from the follow-up rating. Because few patients got worse on the specialist control rating over time, it was necessary to collapse the categories of change indicative of worsening into one category. Patients were grouped into 4 categories of change in control ratings: (1) worse rating by 1 or more levels; (2) same rating; (3) improved rating by 1 level; and (4) improved rating by 2 levels.
2. **Percent predicted FEV<sub>1</sub> values:** Change in percent predicted FEV<sub>1</sub> values was derived by subtracting the baseline percent predicted FEV<sub>1</sub> values from the follow-up percent predicted FEV<sub>1</sub> values and dividing by the baseline percent predicted FEV<sub>1</sub> value to produce an indicator of the percentage of improvement in percent predicted FEV<sub>1</sub> values. Patients were categorized into 2 groups according to the working group's recommended threshold for clinical meaningful improvement in percent predicted FEV<sub>1</sub> values. The first group consisted of patients who improved by 10% or more from baseline. The second group consisted of patients who did not improve by 10% or more from baseline.
3. **ACQ scores:** Change scores were computed by subtracting the baseline ACQ score from the follow-up ACQ score. Patients were categorized into 3 groups according to the magnitude of their ACQ score change. By using the minimal important difference established for the ACQ,<sup>22</sup> patients were categorized as better if their improvement in ACQ score was equal to or better than

**TABLE II.** Discriminant validity tests on mean ACT scores at baseline (n = 301)

	Mean (SD) ACT score	F statistic
Specialist assessment		
Not controlled at all (n = 11)	13.3 (4.7)	27.5*
Poorly controlled (n = 59)	14.5 (4.8)	
Somewhat controlled (n = 87)	17.4 (4.7)	
Well controlled (n = 166)	20.3 (3.4)	
Completely controlled (n = 28)	21.5 (3.9)	
Percent predicted FEV <sub>1</sub>		
<60% (n = 23)	14.4 (4.7)	16.1*
60% to 79% (n = 62)	15.7 (4.8)	
80% to 100% (n = 133)	19.2 (4.6)	
>100% (n = 83)	19.5 (4.1)	
Therapy recommendation		
Stepped down (n = 13)	17.9 (5.6)	32.9*
No change (n = 141)	20.4 (3.6)	
Stepped up (n = 147)	16.1 (5.0)	

\* $P < .001$ .

0.5. Patients were categorized as worse if the decrease in ACQ score was equal to or worse than 0.5. Lastly, patients were categorized as the same if the change in ACQ score was between  $-0.5$  and  $+0.5$ .

It was hypothesized that ACT scores would improve on average among patient groups whose asthma control improved, as defined by changes in the specialists' ratings of control, percent predicted FEV<sub>1</sub> values, and ACQ scores.

## RESULTS

### Sample

The number of patients participating in the study was 313. The mean age of the patients was 35 years (SD, 15.3), with a range of 12 to 84 years. At the baseline visit, specialists rated asthma control as well controlled or completely controlled in 48% of the 301 patients for whom data were available, somewhat controlled in 29% of the patients, and poorly controlled or not controlled at all in 23% of patients. The mean percent predicted FEV<sub>1</sub> value at the baseline visit for the 301 patients for whom data were available was less than 60% for 7.6% of patients, 60% to 79% for 20.6% of patients, 80% to 100% for 44.2% of patients, and more than 100% for 27.5% of patients (Table I).

### Reliability

The internal consistency reliability of the ACT survey was 0.85 at the baseline visit (n = 313) and 0.79 at the follow-up visit (n = 248). The test-retest reliability among the 86 patients with the same specialist rating of asthma control at the baseline and follow-up visits was 0.77.

### Criterion validity

Statistically significant correlations were observed between ACT scores at the baseline visit and baseline values for the specialist rating of asthma control ( $r = 0.52$ ,

**TABLE III.** Performance of the ACT survey at various cut points in screening for uncontrolled asthma\*

Cut-point score	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Percent correctly classified	Area under ROC curve
≤10	17.5	98.6	93.3	52.4	56.4	0.581
≤11	22.5	98.6	94.7	53.9	58.9	0.606
≤12	25.6	97.9	93.2	54.8	60.3	0.618
≤13	28.8	95.9	88.5	55.3	60.9	0.623
≤14	35.0	93.9	86.2	57.0	63.2	0.644
≤15	41.9	90.5	82.7	58.9	65.2	0.662
≤16	50.0	87.1	80.8	61.5	67.8	0.685
≤17	58.8	80.9	77.1	64.3	69.4	0.698
≤18	62.5	74.8	73.0	64.7	68.4	0.687
≤19	71.3	70.8	72.6	69.3	71.0	0.710
≤20	78.8	57.1	66.7	71.2	68.4	0.679
≤21	88.1	45.6	63.8	77.9	67.8	0.669
≤22	92.5	32.0	59.7	79.7	63.5	0.622
≤23	96.3	19.1	56.4	82.3	59.3	0.577
≤24	98.8	12.9	55.2	90.5	57.7	0.558

\*Categorized by asthma specialist as somewhat controlled, poorly controlled, or not controlled at all.

$P < .001$ ) and ACQ scores ( $r = -0.89, P < .001$ ). Baseline ACT scores also correlated significantly with baseline percent predicted FEV<sub>1</sub> values ( $r = 0.31, P < .001$ ).

### Discriminant validity

Significant differences in mean scores across groups of patients who differed on each clinical measure related to asthma control according to hypotheses lend support to the discriminant validity of ACT scores (Table II). Mean ACT scores were significantly lower among patients with poorer control as judged by the specialist than among patients with more favorable control ratings ( $F = 27.5, P < .001$ ). Likewise, patients with poorer lung function (percent predicted FEV<sub>1</sub>) scored significantly lower on the ACT than patients with better lung function ( $F = 16.1, P < .001$ ). Finally, patients whose therapy was stepped up as a result of the visit with the specialist scored significantly lower than patients with no change in therapy or with stepped-down therapy ( $F = 32.9, P < .001$ ).

### Accuracy in screening for poorly controlled asthma

Table III summarizes the performance of the ACT in screening for asthma control problems across various cut-point scores. Classification statistics are presented for each cut-point score on the ACT, beginning with a score of 10. Score levels of less than 10 are not presented because of poor classification statistics. As shown in Table III, lower cut-point scores on the ACT yielded lower sensitivity and higher specificity statistics and high positive predictive values (fewer false-positive results). Higher cut-point scores on the ACT yielded higher sensitivity and lower specificity statistics and relatively lower positive predictive values (higher false-positive rate). The highest area under the ROC curve was observed for a cut-point score of 19, at which the sensitivity and specificity of the ACT was 71.3% and 70.8% and the positive and negative predictive values were 72.6% and 69.3%,

respectively, and the percentage of patients correctly classified was 71%. By using this cut point, of patients with controlled asthma on the basis of ACT score ( $>19$ ), only 8% were deemed by the specialist to have their symptoms not controlled or poorly controlled. In contrast, of patients with uncontrolled asthma on the basis of ACT score ( $\leq 19$ ), 27% were rated by the specialist as having their symptoms well controlled or completely controlled.

Table IV shows the evaluation of a cutoff for somewhat controlled asthma versus asthma that is poorly controlled or not controlled at all. The table shows that a cut point of  $\leq 15$  yields the highest percentage of patients correctly classified and the highest area under the ROC curve.

### Responsiveness

Evidence of the responsiveness of ACT scores to changes in asthma control was demonstrated in correlations between changes in ACT scores and changes in specialist control ratings, percent predicted FEV<sub>1</sub> values, and ACQ scores. As shown, changes in ACT scores were moderately correlated with changes in specialist control ratings ( $r = 0.44, P < .001$ ) and highly correlated with changes in ACQ scores ( $r = -0.81, P < .001$ ). The correlation between changes in ACT scores and percent predicted FEV<sub>1</sub> values was considerably lower ( $r = 0.29, P < .001$ ).

The responsiveness of the ACT was also demonstrated by evaluating mean changes in ACT scores across groups of patients differing in the level of change in the specialist's rating of asthma control, change in percent predicted FEV<sub>1</sub> values, and minimally important changes in ACQ scores (Table V). Mean score changes on the ACT differed significantly across the groups of patients differing in the level of change on the specialist control rating ( $F = 24.2, P < .001$ ), percent predicted FEV<sub>1</sub> value ( $F = 32.9, P < .001$ ), and ACQ score ( $F = 71.0, P < .001$ ). As hypothesized, ACT scores improved among patient groups whose asthma control improved, as defined by changes

**TABLE IV.** Summary of the performance of the ACT at various cut points in screening for uncontrolled asthma\* versus somewhat controlled asthma

Cut-point score	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Percent correctly classified	Area under ROC curve
≤10	23.6	87.5	60.7	58.3	58.8	0.5556
≤11	30.6	84.1	61.1	59.7	60.0	0.5732
≤12	36.1	82.9	63.4	61.3	61.9	0.5953
≤13	43.1	82.9	67.4	64.0	65.0	0.6301
≤14	50.0	77.3	64.3	65.4	65.0	0.6364
≤15	61.1	73.9	65.7	70.0	68.2	0.6768
≤16	69.4	65.9	62.5	72.5	67.5	0.6749
≤17	77.8	56.8	59.6	75.8	66.3	0.6730
≤18	79.2	51.1	57.0	75.0	63.8	0.6515
≤19	83.3	38.6	52.6	73.9	58.8	0.6098
≤20	87.5	28.4	50.0	73.5	55.0	0.5795
≤21	—	—	—	—	—	—
≤22	—	—	—	—	—	—
≤23	—	—	—	—	—	—
≤24	—	—	—	—	—	—
Continuous score	50.0	77.3	64.3	65.4	65.0	0.6892

\*Uncontrolled asthma defined by physician global assessment (not controlled plus poorly controlled, n = 72) versus somewhat controlled (n = 88).

**TABLE V.** Mean changes in ACT scores as a function of changes in specialists' ratings of asthma control and changes in FEV<sub>1</sub> values and ACQ scores

	Mean (SD) change in ACT score	F statistic
Specialist assessment		
Worse (n = 44)	-0.02 (1.7)	24.2*
Same (n = 85)	0.73 (2.2)	
Better by 1 rating level (n = 80)	1.88 (3.1)	
Better by 2 rating levels (n = 37)	4.8 (3.9)	
FEV <sub>1</sub>		
<10% improvement (n = 212)	1.17 (2.8)	32.9*
≥10% improvement (n = 34)	4.32 (4.0)	
ACQ score		
Better (n = 93)	3.94 (3.4)	71.0*
Same (n = 129)	0.39 (1.6)	
Worse (n = 24)	-1.08 (2.2)	

\**P* < .001.

in the specialists' ratings of control, percent predicted FEV<sub>1</sub> values, and ACQ scores.

## DISCUSSION

A cornerstone of the NAEPP guidelines for managing asthma is the ongoing assessment of asthma control, which is crucial for optimizing care and reducing the humanistic, economic, and societal burdens of the disease. Data suggest that patients with asthma and their physicians often overestimate the degree to which asthma is controlled.<sup>12</sup> Overestimation of asthma control can result in failure to use needed interventions or to make necessary adjustments to medication regimens; the lack of intercession in turn can result in worsening asthma-associated

disability that in some cases can culminate in death. Improving the ability to assess asthma control is imperative but has proved difficult. The results of this study demonstrate that the ACT, developed to facilitate rapid and accurate assessment of asthma control, is reliable, valid, and responsive to changes in asthma control over time in a sample of patients new to the care of an asthma specialist.

The results of this study corroborate those of the developmental study of the ACT survey in which the ACT scores were shown to be reliable and valid in assessing asthma control in patients under the care of asthma specialists.<sup>19</sup> The current study represents an independent cross-validation of the results observed in the developmental study of the ACT in a sample of patients with asthma who had not consulted an asthma specialist for at least 5 years before enrollment in the study. This population might be more representative of patients seen in the primary care setting than the sample of patients who participated in the development study of the ACT. In addition, the current study extends previous findings by providing evidence of the responsiveness of ACT scores to changes in asthma control over time.

The ACT survey performed well compared with 2 criterion measures, specialists' ratings of asthma control and ACQ scores, in defining the level of asthma control and the need for adjustment of therapy and in detecting changes in asthma control over time. Because the specialists' ratings of asthma control were based on comparison of the patients' status with NAEPP-defined goals of asthma care,<sup>5,6</sup> these findings suggest that the ACT survey can help to gauge the degree to which NAEPP goals are being met. There is no gold standard for asthma control measurement. In lieu of a universal gold standard, we believed that the best approach was to use as our gold standard the summary judgment of experienced specialists

who were aware of both the National Heart, Lung, and Blood Institute goals of therapy, as well as all relevant aspects of their patient's clinical status.

The correlations between ACT scores and FEV<sub>1</sub> values were substantially lower than the correlations between ACT scores and the above criterion measures. This observation is consistent with the findings from other studies that suggest that asthma control cannot be inferred from single measures of lung function.<sup>16,20</sup> The prior observation<sup>19</sup> that ACT scores correlate better with specialist global assessments of asthma control than do FEV<sub>1</sub> measurements confirms that specialists' assessments of asthma control are based on more than just lung function measurements.

Assessments of the ACT's screening accuracy for poorly controlled asthma suggest that patients with an ACT score of 19 or less might be experiencing control problems. This score provided the optimum balance of sensitivity (71%) and specificity (71%) for detecting patients with uncontrolled asthma (Table II). A cut-point score of 19 also yielded the largest area under the ROC curve, which replicates the findings from the developmental study.<sup>19</sup> A score of 19 or less on the ACT might signal the need for further evaluation of the patient to determine whether adjustments to asthma treatment regimens or other measures are required to improve asthma control. Depending on the specific objectives of the user, other cut points could be considered for screening poorly controlled asthma. In general, the higher the ACT scores on the range of 5 to 25, the better the control. For example, if it is important to maximize specificity (fewer false-positive results), then cut-point scores of less than 19 might be appropriate. However, if the intent is to improve asthma symptoms, maintain asthma symptoms, or both at a minimum well-controlled level and with the goal of achieving complete asthma control, then cut-point scores of 20 or more are appropriate with the goal of reaching an ideal score of 25. Our data also suggest that scores of 15 or less are particularly of concern because they predict asthma that is poorly controlled or not controlled at all.

Increasingly, physicians are seeing a higher volume of patients within the same limited time. Given the limited physician-patient interaction time, an accurate, reliable, and easy-to-use control tool might be essential in the management of asthmatic patients. The ACT was specifically designed for use in physician practices. Therefore it provides a more simplified assessment of control by not requiring FEV<sub>1</sub> values, which might not always be available, and by providing a meaningful and easy-to-use scoring method, which is simpler than the ACQ and yet more comprehensive than the Asthma Therapy Assessment Questionnaire for evaluating the range of asthma control. Besides being useful as a screener for uncontrolled asthma, the ACT survey is suitable for periodic monitoring of patients with asthma, as demonstrated by the finding that ACT scores were responsive to changes in asthma control over time. In this study ACT scores were responsive to changes in asthma control, as determined by changes in specialist ratings, lung function, and ACQ

scores. Repeatedly administered to the individual patient over time, the ACT survey might be useful in gauging the success of therapeutic interventions and in identifying deterioration in asthma control and therefore could be considered a useful tool in clinical research, as well as in clinical practice.

In conclusion, the results of this longitudinal validation study show that the ACT is reliable, valid, and responsive to changes in asthma control over time in patients naive to asthma specialty care. The ACT is an easily administered and scored survey that measures asthma control accurately compared with specialist ratings on the basis of history, physical examination, and lung function tests and with the previously validated ACQ. The ACT survey should facilitate efforts to improve assessment of asthma control in the busy clinical practice setting.

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