

The minimally important difference of the Asthma Control Test

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Background: The Asthma Control Test (ACT) has been well validated, but a minimally important difference (MID) has not been established.

Objective: We sought to identify an MID for the ACT.

Methods: Data come from 4 independent samples of adult asthmatic patients. Distributional methods for determining the MID included 0.5 SD, 1 SEM, and 2 SEM. Anchor-based methods assessed the relationship of differences in ACT scores to (1) self-reported asthma severity, (2) asthma episode frequency in the past 4 weeks, (3) physician ratings of asthma control, (4) physician recommendation of a change in therapy, (5) FEV₁, (6) the risk over the next 12 months of excess short-acting β -agonist use and exacerbations, and (7) patient-defined changes in asthma course over 3 months.

Results: Four thousand one hundred eighteen patients completed the ACT. The 0.5 SD criterion for MID ranged from 2.03 to 2.45 points (mean, 2.2 points). The 1 SEM criterion ranged from 1.77 to 2.05 points (mean, 1.88 points), and the 2 SEM criterion ranged from 3.55 to 4.10 points (mean, 3.75 points). Differences in mean ACT scores across patient groups differing on criterion measures ranged from 1.06 to 5.28 points (mean, 3.1 points). Predictive analyses showed that a difference of 3 points on the ACT was associated with a subsequent 76% increased risk (95% CI, 73% to 79%) of excess short-acting β -agonist use and a 33% increased risk (95% CI, 31% to 35%) of exacerbations.

Conclusion: The data support an MID for the ACT of 3 points. (J Allergy Clin Immunol 2009;■■■:719-723)

Key words: Asthma, asthma control, Asthma Control Test, minimally important difference, distribution-based method, anchor-based method

Asthma is a very common chronic medical condition associated with substantial morbidity.^{1,2} The goal of asthma therapy is disease control, which has been emphasized and specifically defined in recent national and international guidelines.^{2,3} Several validated questionnaires have been developed to facilitate assessment of asthma control.⁴⁻⁶ One of these, the Asthma Control Test (ACT),

Abbreviations used

ACQ: Asthma Control Questionnaire
ACT: Asthma Control Test
MID: Minimally important difference
SABA: Short-acting β -agonist

has been validated in the office setting,⁷ by mail,⁸ and by telephone.⁹ The ACT is a self-report questionnaire that includes 5 items assessing each of the following for the previous 4 weeks: the frequency of shortness of breath and general asthma symptoms, use of rescue medications, the effect of asthma on daily functioning, and overall self-assessment of asthma control (see Fig E1 in this article's Online Repository at www.jacionline.org). Each item includes 5 response options with values that range from 1 to 5. In scoring, the ACT 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), with higher scores reflecting greater asthma control. An ACT score of greater than 20 indicates well-controlled asthma.^{4,7}

Responsiveness of the ACT to a change in clinical status has also been demonstrated.⁷ However, when comparing scores of validated questionnaires in different populations and in individuals over time, an important property to define is the minimally important difference (MID), which is defined as the smallest difference in score on the instrument that represents a clinically significant change. In 2 populations this would be the minimal difference in means that suggests clinically meaningful differences in control levels between the 2 groups. In individuals this would be the minimal change in score over time that suggests clinically important improvement or worsening of asthma control has occurred. An MID for the ACT for either populations or individuals has not been defined.

Two general approaches to estimating the MID of an instrument have been established: the distribution-based approach and the anchor-based approach.¹⁰⁻¹⁴ The hallmark of the distribution-based approach is to examine the properties of the scale itself based on the distribution of scores within a sample. The anchor-based approach uses clinical reference points as the basis for determining the MID of a measure. The purpose of this study is to apply both of these approaches to establish the MID of the ACT for both differences between populations and for changes in individuals over time.

METHODS

Patients

Analyses to determine the MID for the ACT were conducted by using data from each of 4 independent study samples. The patient characteristics, the conditions under which data were collected, and the types of data measured varied across the 4 samples. Details on the study design and each of the 4 samples have been previously published elsewhere. Briefly, sample 1 consisted of 1090 prescreened asthmatic patients (mean age, 47.8 $\pm$ 14.0 years; 61% female) from a large nationally representative sample recruited through the

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TABLE I. Summary of “anchor” measures used within each sample

Measure	Sample			
	1	2	3	4
Patient self-report of asthma severity	X			
Patient self-report of no. of asthma episodes	X			
Spirometry (PPFEV ₁)		X	X	
Specialist global assessment		X	X	
Specialist recommended change in therapy		X	X	
Patient self-report of change in asthma				X
SABA dispensing >6 canisters*				X
Asthma exacerbation (asthma hospitalization, ED visit, or oral corticosteroid dispensing)*				X

PPFEV₁, Percent predicted FEV₁; ED, emergency department.

*Administrative data accumulated for 12 months after ACT survey completion.

internet who participated in a mode of survey administration cross-over comparison study using the ACT.¹⁵ The ACT was completed by means of telephone interview, paper-and-pencil administration or both, on two occasions with a 2-week period in between. Sample 2 consisted of 471 patients (mean age, 45.1 ± 18.6 years; sex distribution not reported) receiving care from one of 6 asthma specialty groups located in western, central, eastern, and southern regions of the United States. The ACT was self-administered by patients during a routine care visit to their doctor.⁴ Patients in this study had been under the routine care of an asthma specialist for a minimum of 6 months. Sample 3 consisted of 313 patients (mean age, 35.3 ± 15.4 years; sex distribution not reported) who were recruited through local media advertising or by virtue of their consulting one of the above participating asthma specialty practices for the first time.⁷ These patients were never under the routine care of an asthma specialist and were seeing a specialist for the first time. The ACT was self-administered during the initial visit to the specialist and again at a follow-up session 4 to 12 weeks later. Patients in sample 4 consisted of 2244 members (mean age, 42.1 ± 10.7 years; 76% female) of the San Diego Kaiser Permanente asthma database as of August 2004, as previously described.⁹ The ACT was administered to this sample by telephone by using an interactive voice-response system. There was no overlap among patients in the 4 samples.

Data analysis

Distribution-based analyses. These analyses were conducted by using baseline data in each of the 4 study samples. The first distribution-based analysis was based on the SD of ACT scores in each study sample, and the second distribution-based analysis was based on the SEM computed in each study sample. The SEM of a measure is defined as follows:

$$\text{SEM} = \text{SD}_{\text{ACT}} * \text{SQRT} (1 - \text{Reliability}_{\text{ACT}}).$$

In the current analyses the reliability of the ACT was estimated for each sample by using the Cronbach α value for internal consistency.

After recommendations from the literature, the distribution-based MID was defined by using as criteria both 0.5 SD¹⁶ and 1 SEM,¹⁷ each of these being consistent with Cohen's¹⁸ generally accepted rule of thumb for determining a medium-sized difference. In addition, a criterion of 2 SEMs was used, which approximates a 95% CI and thus the Jacobson-Truax Reliable Change Index.¹⁹ A magnitude of 2 SEMs indicates that differences in scores are reliable and not caused by measurement error. The 2 SEM criterion has been used in several studies as a measure of meaningful intraindividual change over time.²⁰

Anchor-based analyses. Table I lists the criterion measures in each sample that were used as “anchors” to study the meaningfulness of differences in ACT scale scores. The anchor-based analyses were carried out in 2 steps. First, ANOVA was conducted to evaluate the magnitude and

TABLE II. Summary of the distribution-based approach to determining the MID for the ACT

	Reliability*	Criterion		
		0.5 SD	1 SEM†	2 SEM
Sample 1	0.85	2.45	1.89	3.79
Sample 2	0.84	2.22	1.78	3.55
Sample 3	0.82	2.09	1.77	3.55
Sample 4	0.77	2.10	2.05	4.10
Mean		2.21	1.88	3.75
95% CI		2.06–2.38	1.74–2.00	3.49–4.01
Weighted mean		2.21	1.96	3.91

*Cronbach α .

†SEM = SD_{ACT} * SQRT (1 – Reliability_{ACT}).

significance of differences in mean ACT scores between patient groups differing on each of the following criterion measures:

- patient self-report of asthma severity—“How would you rate the severity of your asthma? (not noticeable, mild, moderate, severe, very severe)”;
- patient self-report of the number of asthma episodes—“In the past 4 weeks, how often did you have an asthma episode or attack that required use of an oral corticosteroid or inhaler? (not at all, less than once a week, once a week, 2 or 3 times a week, 4 or more times a week)”;
- physician's global rating, which included the categories not controlled at all, poorly controlled, somewhat controlled, well controlled, and completely controlled;
- clinician's recommendation for change in therapy, which included the categories step-down therapy, no change in therapy, and step-up therapy;
- spirometry, for which patients were categorized as having normal versus reduced values based on a cutoff score of 80% predicted FEV₁. In addition, changes in ACT scores were compared between groups of patients whose percent predicted FEV₁ improved by 10% or more versus patients whose percent predicted FEV₁ did not improve by 10% or more; and
- patient self-report of their recent course of asthma compared with the previous time point in the study, including the categories much better, a little better, stayed the same, a little worse, and much worse.

In the second step, to determine the MID from these analyses, we computed the differences in mean ACT scores between categories of each criterion measure. In addition, effect sizes were computed from the differences in mean ACT scores observed between categories to identify the size at which meaningful differences in ACT scores emerged. Effect sizes were computed by using Hedges g -statistic,²¹ which modifies the Cohen d by taking into account group sample size. Hedges' g -statistics were used instead of Cohen d -statistics because of the unequal Ns in many of the comparisons; guidelines for interpretation of effect size magnitude is the same as those for Cohen d -statistics (0.2 = small effect, 0.5 = medium effect, and 0.8 = large effect).¹⁸

A second approach taken in sample 4 to evaluate the meaningfulness of differences in ACT scores was to link ACT scores at a point in time (ie, baseline) to an outcome/event that occurred at some point later in time (predictive validity). Using logistic regression analyses, we investigated the odds of future asthma exacerbations and future high short-acting β -agonist (SABA) canister dispensings as a function of differences in baseline ACT scale scores from a score of 20 (the previously defined threshold for controlled asthma).^{4,7} Results of the logistic regression models were interpreted only if they were statistically significant (based on χ^2 goodness-of-fit tests), with significant coefficient terms (Wald $P < .05$) for ACT scores. The dependent variables used for the logistic regression analyses included the following:

- Asthma exacerbations occurring over the 12 months after the completion of the ACT—Exacerbations were defined as asthma hospitalizations, emergency department visits, or oral corticosteroid dispensing. A dichotomous variable was derived from the number of asthma exacerbations (1 or more exacerbations vs no exacerbations).

TABLE III. Summary of differences in ACT scores between criterion groups

	Absolute difference	ES (Hedges $\hat{g}$ -statistic)*
Sample 1 asthma severity, baseline		
None vs mild	3.41	1.44
Mild vs moderate	4.37	1.56
Moderate vs severe	5.28	1.65
Sample 1 asthma severity, follow-up		
None vs mild	3.38	1.46
Mild vs moderate	4.58	1.66
Moderate vs severe	4.29	1.36
Sample 1 asthma episodes, baseline		
None vs <1 a week	1.77	0.52
<1 a week vs once a week	2.25	0.7
Once a week vs ≥ 2 a week	2.85	0.7
Sample 1 asthma episodes, follow-up		
None vs <1 a week	2.2	0.67
<1 a week vs once a week	2.14	0.64
Once a week vs ≥ 2 a week	2.59	0.67
Sample 2 physician control rating		
Poorly/not well controlled vs somewhat	1.98	0.42
Somewhat vs well controlled/complete control	4.04	1.05
Sample 3 physician control rating		
Poorly/not well controlled vs somewhat	3.04	0.64
Somewhat vs well controlled/complete control	3.17	0.79
Sample 2 therapy change recommendation		
No change/step down vs step up	3.99	0.97
Sample 3 therapy change recommendation		
No change/step down vs step up	4.24	0.97
Sample 2 PPFEV ₁		
<80% vs $\geq 80\%$	1.22	0.28
Sample 3 PPFEV ₁		
<80% vs $\geq 80\%$	4.03	0.89
PPFEV ₁ improved $\geq 10\%$ vs PPFEV ₁ <10% change	3.15	1.06
Sample 4 self-reported change in asthma		
Much vs little worse	2.99	0.82
Little worse vs same	3.83	0.96
Same vs little better	1.63	0.4
Little vs much better	1.06	0.31
Sample 4 self-reported change in asthma (uncontrolled cases, ACT <20)		
Little worse vs same	3	0.91
Little better vs same	3	0.75
Mean (95% CI)	3.09 (2.68–3.50)	0.90 (0.75–1.05)
Weighted mean	3.20	1.00
Median	3.04	0.79

ES, Effect size; PPFEV₁, percent predicted FEV₁.*Effect sizes were computed by using the Hedges $\hat{g}$ -statistic²¹; 0.2 = small effect, 0.5 = medium effect, and 0.8 = large effect.¹⁸

- SABA canister dispensing over the 12 months after the administration and completion of the ACT—A dichotomous variable was derived from the number of SABA canisters dispensed (>6 SABA canisters vs ≤ 6 SABA canisters).

RESULTS

Distribution-based results

Results of the distribution-based analyses are presented in Table II. Examination of results indicates a good deal of

stability in both the reliability and MID estimates of ACT scores across all 4 samples. Both the 0.5 SD and 1 SEM criteria produced similar results, with the former mostly yielding estimates slightly greater than 2 (range, 2.09–2.45; M = 2.21) and the latter mostly yielding estimates slightly less than 2 (range, 1.77–2.05; M = 1.88). Estimates produced by the 2 SEM criteria range from 3.55 to 4.10 (M = 3.75).

Anchor-based results

Differences in mean ACT scores between and across patient groups differing on each of the criterion measures were statistically significant ($P < .01$), with all differences in the hypothesized direction. Table III summarizes group differences in mean ACT scores observed between each of the patient groups across all of the criterion measures. Mean differences in ACT scores ranged from 1.06 to 5.28 points. Differences in mean ACT scores between all patient groups averaged 3.10 points, and the median difference in mean ACT scores between groups was 3.04 points. Effect sizes computed for the mean differences in ACT scores between patient groups ranged from 0.31 to 1.66. The mean effect size computed across all comparisons was 0.91, and the median was 0.79, which are considered large effect sizes.¹⁸

In predictive analyses ACT scores were shown to be significantly ($P < .001$) related to subsequent asthma exacerbations (Fig 1) and greater than 6 SABA dispensings (Fig 2). The model coefficients of the ACT showed that lower ACT scores were associated with an increased probability of 1 or more asthma exacerbations and greater than 6 SABA canisters dispensed over the 12 months after the administration and completion of the ACT (Table IV). The odds ratio for 1 or more asthma exacerbations associated with a 1-point, 2-point, 3-point, 4-point, and 5-point lower ACT score (from 20) was found to be 1.09, 1.21, 1.33, 1.46, and 1.60, respectively (Table IV). Thus scoring 3 points lower than 20 on the ACT means that an asthmatic patient is 33% more likely (95% CI, 31% to 35%) to have an asthma exacerbation in the next 12 months. The odds ratio for greater than 6 SABA canisters dispensed associated with a 1-point, 2-point, 3-point, 4-point, and 5-point lower ACT score (from 20) was found to be 1.21, 1.46, 1.76, 2.13, and 2.57, respectively (Table IV). Thus scoring 3 points lower than 20 on the ACT means that an asthmatic patient is 76% (95% CI, 73% to 79%) more likely to receive greater than 6 SABA canisters in the next 12 months.

DISCUSSION

Asthma control is the goal of asthma therapy,^{2,3} and the ACT has been validated in several settings and with multiple criterion measures to reflect asthma control.^{4,7-9} However, the MID for the instrument must be defined to optimally use the ACT in intervention studies or to follow individual patients over time. The current study used both distributional and anchor-based methods in multiple populations to identify the MID of the ACT. Almost all (35/39) of the individual results (Tables II and III) were between 2 and 4 when rounded to the closest whole number. Based on all of these data, we would propose an MID of 3 for the ACT because a difference of 3 was the mean and median of the criterion-based measures (Table III) and a difference of 3 was associated with clinically significant increased risks of subsequent exacerbations and excess rescue therapy use (Table IV).

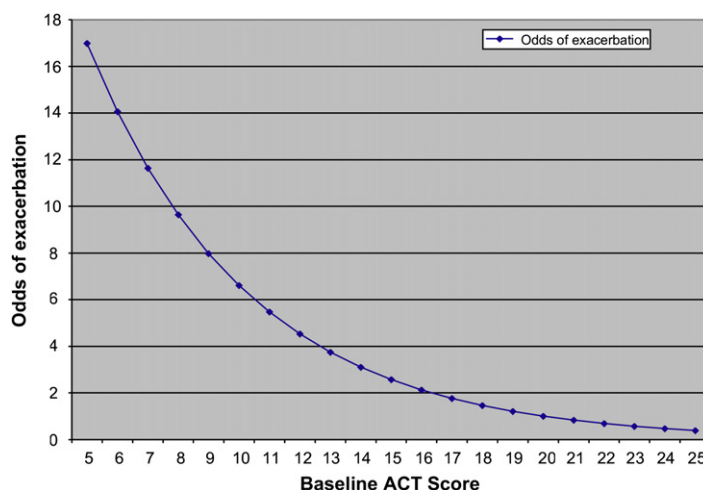


FIG 1. The relationship of baseline ACT scores to subsequent odds of exacerbations (asthma hospitalization, emergency department visit, or oral corticosteroid dispensing) in the subsequent 12 months in 2244 patients.⁹

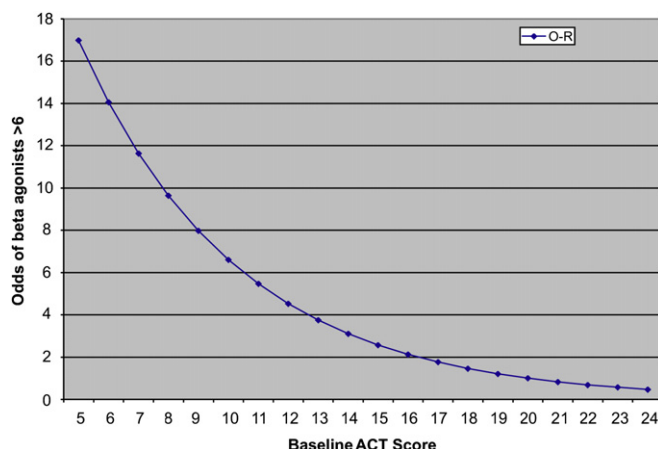


FIG 2. The relationship of baseline ACT scores to subsequent odds of excess β -agonist canister dispensings (>6) in the subsequent 12 months in 2244 patients.⁹

TABLE IV. ACT score at baseline used to predict asthma exacerbations and greater than 6 β -agonist canisters used over 6 months after completion of the ACT

	Asthma exacerbations		>6 β -Agonist canister use	
	OR	95% CI	OR	95% CI
ACT (continuous score)	0.910*	0.889–0.932	0.828*	0.804–0.852
Point difference from 20				
ACT (1 point)†	1.09	1.07–1.11	1.21	1.18–1.24
ACT (2 points)†	1.21	1.19–1.23	1.46	1.43–1.49
ACT (3 points)†	1.33	1.31–1.35	1.76	1.73–1.79
ACT (4 points)†	1.46	1.44–1.48	2.13	2.10–2.16
ACT (5 points)†	1.60	1.58–1.62	2.57	2.54–2.60

OR, Odds ratio.

* $P < .001$.

†Odds ratios for 1- to 5-point differences in ACT scores from a score of 20 were calculated based on the regression coefficients. For exacerbations, the intercept was 0.3205, and the β coefficient was -0.0938 . For β -agonists, the intercept was 1.4381, and the β coefficient was -0.1888 .

Multiple methods can be used to identify an MID.^{10–14} The current study results were based on the concurrence of several established approaches, including both distributional and anchor-based methods. Another aspect of this study that enhances the generalizability of the results is the use of several populations and several modes of administration. Anchor-based approaches are particularly important to confirm the clinical meaning of an MID, and thus the determination of a general MID for the ACT of 3 was based heavily on these results. The distributional data would suggest that even a difference of 2 might be meaningful for comparisons between populations based on the 0.5 SD and 1 SEM criteria (Table II). It is expected that the MID as used for individual patients over time would be larger than the MID used to compare mean scores in 2 populations because of the effect of measurement error, scoring differences purely caused by chance. Measurement error in studies of populations is randomly distributed and tends to cancel itself out, but in a single individual, this error does not cancel itself out. An even more conservative MID of 4, suggested by the criterion measure of 2 SEM, could be used for

changes in 1 individual over time. This more conservative approach sets a CI of 95% around the MID, meaning that the odds of reflecting measurement error is only 5%.¹⁹ However, a 3-point difference or change in ACT score was shown to be clinically meaningful across several criterion measures, including the patient's self assessment of change in asthma status, and was observed to be a large effect size difference or change in score. Given these observations, we propose that a 3-point MID for the ACT is sufficient for individual patient evaluations.

Current national asthma guidelines define 2 domains of asthma control: impairment and risk.² Impairment includes symptoms, rescue therapy use, and functional limitations, and this domain of long-term asthma control has been shown to be reflected in administrative data by the number of canisters of SABAs dispensed over a 12-month period.²² Risk is defined by the number of exacerbations requiring oral corticosteroids in a 12-month period,² which is similar to the definition of exacerbations in the current study. Thus the 2 administrative data anchors used in this study, SABA canisters and exacerbations, reflect both domains of

guideline-defined asthma control. The clinical importance of the population MID of the ACT (a difference of ≥ 3) defined in this study is supported by its association with at least a 76% increase in impairment (>6 SABA canisters dispensed) and at least a 33% increase in risk (exacerbations) over the subsequent 12 months (Table IV), as well as by meaningful differences (large effect sizes) observed between patient groups differing in asthma severity, number of recent asthma episodes, physician-rated control, change in therapy recommendation, and lung function values.

No prior study has defined an MID for the ACT. The Asthma Control Questionnaire (ACQ) is another asthma control tool with scores ranging from 0 to 6 and higher scores indicating worse control.⁶ The ACQ is the only control questionnaire for which an MID has been formally determined (MID = 0.5) by using anchor-based approaches in patients studied over time.²³ However, it has not been established that this MID for the ACQ performs equally well as a meaningful difference between populations.

In summary, this study suggests that a difference of 3 points between mean ACT scores in 2 or more patient groups is a clinically meaningful MID. Conversely, the data suggest that a difference of mean scores between 2 samples of less than 2 would not be clinically significant, even if statistically significant. This information would be particularly important for interpreting intervention studies that use the ACT as an outcome variable. This study also has shown that a change of 3 points is likely to indicate a clinically meaningful change in asthma control in an individual patient over time, and a change of 4 or more further reduces the chance that the change is due to measurement error. Further studies using these MID results will be necessary to confirm their utility in the assessment of asthma control and effective interventions in individual patients and populations.

Clinical implications: Differences of 3 points in mean ACT scores between 2 groups or over time in an individual patient are clinically significant.

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

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

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

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

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?

Not at all	Once or Twice	Once a week	2 to 3 nights a week	4 or more nights a week
▼	▼	▼	▼	▼
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as Albuterol, Ventolin®, Proventil®, Maxair® or Primatene Mist®)?

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

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

Completely Controlled	Well Controlled	Somewhat Controlled	Poorly Controlled	Not Controlled at all
▼	▼	▼	▼	▼
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

To score the ACT: Each response to the 5 ACT questions has a point value from a 1 to 5 as shown on the form. To score the ACT, add up the point values for each response to all five questions.

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FIG E1. Asthma Control Test™ (ACT).