Asthma Control Test[™]: A User's Guide



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Preface

The Asthma Control Test™ is a 5-item, patient-based, clinically validated assessment of asthma control. The Asthma Control Test:

- is fast to complete and score;
- is precise, reliable, and valid;
- reflects the multidimensional nature of asthma control;
- can be used to measure change over time; and
- is easy for clinicians and patients to interpret.

This user's guide describes how to use, score and interpret the Asthma Control Test and discusses its applications. The guide is divided into six sections:

Section 1 provides an introduction to the Asthma Control Test

Section 2 describes how to administer the Asthma Control Test

Section 3 describes how to score the Asthma Control Test

Section 4 provides preliminary interpretation guidelines for the Asthma Control Test score

Section 5 provides answers to common questions about the Asthma Control Test

Section 6 provides a summary of current and potential applications of the Asthma Control Test

The appendix provides a copy of the English version of the Asthma Control Test. Additional language translations are currently available, including French, Japanese, Korean and US Spanish.

Refer to the Copyright page for information on Asthma Control Test Licensing & User Registration.

Refer to the References section for sources of additional information regarding the development of the Asthma Control Test.

We acknowledge Robin Scheer for her assistance in preparing this user's guide.

Section 1. Introduction

What is the Asthma Control Test

The Asthma Control Test TM (hereafter referred to as the "ACT") is a brief, 5-item patient-based assessment designed to measure dimensions of asthma control outlined in the current asthma management guidelines as defined by the National Heart, Lung, and Blood Institute (NHLBI): asthma symptoms, utilization of rescue medications, and the impact of asthma on everyday functioning. It is suitable for use with or without lung-function testing.

Development of the ACT

During the last decade, an improved understanding of the pathophysiology underlying asthma and the emergence of medications to more effectively prevent acute exacerbations have led clinicians to shift their focus from managing acute attacks to achieving asthma control. Current asthma treatment guidelines highlight this change in focus and underscore the multidimensional nature of asthma control. There is a need for a simple method to quantify asthma control, as patients and clinicians often overestimate control. Existing measures of asthma control have not been validated in relation to control criteria (e.g., FEV_1 levels), and have not been readily integrated into clinical practice settings because they involve complicated scoring and interpretation guidelines.

The ACT was designed to produce a valid measure reflecting the multi-dimensional nature of asthma control that is easy for clinicians to use, and for clinicians and patients to interpret. Leading asthma specialists and primary care physicians participated in the development of the ACT by guiding the selection of specific survey items, using a criterion measure of asthma control. The criterion measure was based on clinical interviews and lung function tests and was implemented in two studies: one a developmental study and the other a longitudinal validation study. The survey items were evaluated for use with individuals 12 to 84 years of age. During the initial developmental study a survey with 22 questions (items) was administered to 471 patients with asthma in offices of asthma specialists. Specialists collected spirometry data for each patient and provided a global rating of the patient's asthma control. The specialist's global rating of control was based on how well the National Asthma Education and Prevention Program-defined goals of asthma were being met as determined by information from the patient's history, physical examination, and FEV₁ values.

Stepwise logistic regression methods were used to select the five ACT items from the 22-item survey completed by patients. The five ACT items showed the greatest ability to discriminate between patients that differed in the specialist's global assessment of asthma control. The internal consistency reliability (coefficient alpha) of ACT was 0.84. Scale construct validity was demonstrated using the method of *known group's validity*. in which the ACT was shown to significantly discriminate between groups of patients that differed in the specialists' global rating of asthma control, FEV₁ levels, and change in therapy in the hypothesized direction using analysis of variance methods. Finally, receiver operating characteristic (ROC) analysis was conducted to compute *sensitivity* and *specificity* statistics for each score level of the ACT for purposes of screening subjects with poorly controlled asthma.

During the longitudinal validation study, the ACT was further evaluated for its reliability and validity in a sample of patients new to an asthma specialist and its responsiveness to change in asthma control over time. The survey was administered to 313 patients new to asthma specialists during two different office visits separated by 4 to 12 weeks. Spirometry data was collected and asthma specialists, blinded to the ACT responses, rated asthma control. The reliabilities of the ACT scores in this study were 0.85 for internal consistency reliability and 0.78 for test-retest reliability. Results of correlation analyses and know-groups validity analyses showed that the ACT was responsive to changes in asthma control over time as defined by changes in FEV₁ values, changes in specialist's rating of asthma control, and changes in an independent patient-based assessment of asthma control (Juniper, O'Byrne, Guyatt, Ferrie, and King, 1999)

Additional information regarding the development of the ACT may be found in Nathan et al. (2004) and Schatz et al. (in submission).

Applications

The ACT is a simple measure for assessing asthma control, with or without lung function testing, that is suitable for application in a variety of settings ranging from clinical practice to population screening, disease management, and clinical trials. Section 6 of this user's guide provides specific information regarding application of the tool. Preliminary evidence from the longitudinal study also supports its use as an outcomes tool. Several manuscripts from the longitudinal study are currently in review.

Section 2. Administering the ACT

The format of the ACT makes it easy and fast to use. With just five items on a one-page form, the ACT can be integrated easily into many settings, including routine clinical practice, disease management programs, public awareness campaigns, clinical trials, and quality improvement initiatives. The questionnaire is self-administered and can be completed in a clinical practice setting, at home, or in any other location. It can be administered as a mail-back form, during telephone or face-to-face interviews, or by almost any electronic application (IVR, PDA, desk-top software, EMR).

Using the Standard Survey Form

The standard ACT form presented in the appendix of this user's guide should be used because any change to the format or wording could affect the way patients respond to the items. This helps ensure standardization in administration and accuracy in the interpretation of ACT results.

Who Should Complete the ACT

The ACT is intended for use with adolescents or adults with asthma as the survey was developed using data from asthma patients 12 to 84 years of age. Preliminary interpretation guidelines presented in Section 4 of this guide are based on those same data. Thus, results obtained from the administration of the ACT to younger patients may not be reliable or valid.

Who Can Administer the ACT

Anyone can administer the ACT. No special training is required. As with the completion of any health survey, it is preferable that the person who administers the ACT introduces the survey by briefly explaining what the survey measures and why the patient is being asked to complete it. In the case of a population screening effort, materials accompanying the survey should introduce the survey with a similar approach. When possible, after respondents have completed the ACT, the administrator should confirm that all five items have been answered. If answers are missing, the administrator should encourage (but not force) the patient to complete these items.

Timing of Administration during Health Care Visits, Interactions or Public Awareness Campaigns

The ACT can be administered any time during a health care visit or contact with the asthma patient. It is preferred, but not required, that the survey be completed when the patient checks in for an appointment, before other procedures occur or materials are shared that might influence responses. Administration of the ACT before the patient has consulted with a health care staff or provider is ideal because that timing will ensure that the respondent's answers to the ACT items are not influenced by interactions with health care providers or discussions about health care issues. However, the ACT may also be administered as part of the discussion between patient and health care provider about the patient's medical history or reasons the patient is seeking care.

Table 2.1 DO's and DON'Ts of ACT Administration

DO	DON'T
DO introduce the ACT and explain reasons for completing, importance and advantages for patients.	DO NOT minimize the importance of the ACT.
DO have patients fill out the ACT by themselves.	DO NOT allow spouses, family members, or friends to help patients complete the ACT.
DO tell patients to answer items based on what they think the item means.	DO NOT interpret or explain any items for patients.
DO read and repeat an item verbatim for patients if asked.	DO NOT change wording in items or interpret their meaning for patients.
DO encourage patients to complete all of the items.	DO NOT accept an incomplete ACT without first asking the patient to complete unanswered items.

How Often to Administer the ACT

The ACT can be administered as often as needed; however, since all five items ask about events that have occurred in the past four weeks, the test is not recommended for administration more than once every four weeks.

Section 3. Scoring the ACT

The ACT is scored so that a higher score indicates better asthma control. Scoring each form is accomplished in two easy steps:

- 1. Assign a point value to each response choice
- 2. Sum the point values across the five items

Scoring the ACT

Each ACT item response is scaled from a 1 to 5. The scoring method consists of summing response values across items to produce a scale score that can range from 5 (poorly controlled asthma) to 25 (well-controlled asthma).

Step 1: Assign a point value to each response choice

Tables 3.1 through 3.5 provide the information on the appropriate point values assigned to the response choices for each ACT item. The tables present the verbatim content of each item, response choices, and the value assigned to each response choice. Item numbers in Tables 3.1 through 3.5 correspond to the order of the items as they appear on the ACT survey form.

Table 3.1 Asthma Control Test Question 1: Verbatim Item and Scoring

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

Response Choices	Point Value Assigned
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

Table 3.2	Asthma Control Test
	Question 2: Verbatim Item and Scoring

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

Response Choices	Point Value Assigned
More than once a day	1
Once a day	2
3 to 6 times a week	3
Once or twice a week	4
Not at all	5

Table 3.3 Asthma Control Test Question 3: Verbatim Item and Scoring

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

Response Choices	Point Value Assigned
4 or more nights a week	1
2 to 3 nights a week	2
Once a week	3
Once or twice	4
Not at all	5

Table 3.4 Asthma Control Test Question 4: Verbatim Item and Scoring

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

Response Choices	Point Value Assigned
3 or more times per day	1
1 or 2 times per day	2
2 or 3 times per week	3
Once a week or less	4
Not at all	5

Table 3.5 Asthma Control Test Question 5: Verbatim Item and Scoring

5. How would you rate your <u>asthma</u> control during the <u>past 4 weeks?</u>

Response Choices	Point Value Assigned
Not controlled at all	1
Poorly controlled	2
Somewhat controlled	3
Well controlled	4
Completely controlled	5

Step 2: Sum the point values across the five items

The ACT is scored by summing the point values assigned to each of the five items. All ACT items must be answered to calculate a score. Methods to score the ACT with incomplete responses are being evaluated for future use.

The survey user should contact QualityMetric Incorporated if the ACT scoring process is too difficult or time-consuming in his or her setting.

Section 4. Interpreting ACT Scores

Studies of validity are about the meaning of scores and whether or not they have their intended interpretations. Traditional analyses of validity include empirical tests of whether and how valid a measure is, and results are most often expressed in terms of correlation coefficients. In contrast to such correlational data, the data presented here were designed to yield interpretation guidelines for differences in ACT scores. Three kinds of results are presented. The first includes statistics on the accuracy of ACT scores in screening for patients with asthma control problems. The second includes mean scores and frequency distributions of ACT scores in two distinct asthma populations: (1) asthma patients under the routine care of asthma specialists, and (2) asthma patients new to the care of an asthma specialist. These data will provide benchmark (or normative) values useful for interpreting scores for an individual patient or the average for a group of patients. Furthermore, these scores are presented separately for patients determined to have well-controlled asthma and poorly-controlled asthma. Lastly, interpretation guidelines for ACT scores are presented on the basis of results of analyses linking differences in ACT scores to "external" criteria, such as clinician's rating of asthma control, lung function (FEV₁), use of rescue medication use, activity limitation, and presence of asthma symptoms.

Screening

Because ACT was constructed with guidance from asthma specialists and in accordance with NHLBI guidelines, users may interpret ACT scores in terms of how closely they replicate what a clinician's assessment would be concerning the patient's level of asthma control. Accordingly, ACT cut-point scores can be used to distinguish patients whose asthma is well-controlled from those whose asthma is not well-controlled. Based on empirical evidence from two studies involving patients who were under the routine care of asthma specialists and patients new to care of an asthma specialist, an ACT cut-point score of 19 (scores 19 and below) was determined to be optimal for screening patients with asthma control problems. However, recognizing that ACT may be used for many different purposes, the optimal cut-point score for screening for asthma control problems may vary according to the specific purpose and use of the ACT. Therefore, users of the ACT are encouraged to select the cut-point score that makes sense for their particular application of ACT as a screening tool.

Choosing the appropriate cut-point score for screening can be guided by the *sensitivity* and *specificity* statistics presented for specific cut-point scores. Information about the *sensitivity* and *specificity* of a test like the ACT helps users understand the accuracy of the test in screening for patients with asthma control problems. A test is *sensitive* to a condition if it is positive for most individuals who have the condition. *Sensitivity* is also known as the "true positive" rate (see Table 4.1). This "true positive" rate may be calculated and reflected as a percentage. Sensitivity is estimated by the following formula: 100[d/(c+d)].

Table 4.1 Defining Sensitivity and Specificity			
	Asthma Control Test Result		
Condition Category	Well-Controlled Asthma	Poorly Controlled Asthma	
	(negative)	(positive)	
Well-Controlled Asthma (absent)	a (true negative)	b (false positive)	
Poorly Controlled Asthma (present)	c (false negative)	d (true positive)	

A test is *specific* if it is positive for only a small percentage of those without the condition. *Specificity* of a test is the percentage of those without the disease who is classified as not having the disease, and is also known as the "true negative" rate (see Table 4.1). Specificity is estimated by the following formula: 100[a/(a+b)].

Using receiver operating characteristic (ROC) curve analysis, the sensitivity and specificity of the ACT, as well as the ROC curve, which combines both sensitivity and specificity, was evaluated across the full range of ACT scores. The criterion measure of asthma control used in this analysis was the specialist's global rating of asthma control. The specialist's rating was blinded to the patient's responses to the ACT items and was in accordance with how well the National Asthma Education and Prevention-defined goals of asthma were being met as determined by information from the patient's history, physical examination, and FEV₁ value. Patients with a specialist global rating of asthma control of "poorly controlled," "not controlled," and "somewhat controlled" were considered to have asthma control problems in the analysis.

As summarized in Table 4.2, the most favorable all-round cut-off score for the ACT is at a score of 19 and below, which achieves an area under the ROC curve of 0.73 and a sensitivity and specificity of 72.0% and 74.1%, respectively. For purposes of screening applications requiring larger or smaller rates of false positives or false negatives, other ACT score cut-offs can be used, as documented in Table 4.2. For example, higher cut-point score (meaning better control) is more inclusive (has greater sensitivity), but also identifies more "false positives" (100 minus specificity). This may be useful in a population management activity when screening for the greatest number of individuals with asthma control problems is desired. A lower cut-point score (meaning worse control) has greater specificity (fewer false positives); however, by selecting a lower cut point, a user may run the risk of missing true cases (false negative, 100 minus sensitivity). This may be useful when screening large numbers of individuals for study inclusion, but only those individuals with the greatest likelihood of problems are desired.

Table 4.2 Summary of the Performance of the ACT at Various Cut-point Scores in Screening for Asthma Control Problems ¹					ores in
ACT			(+)	(-)	Area
Cut Point	Sensitivity (%)	Specificity (%)	Predictive	Predictive	Under
Scores			Value	Value	ROC
≤ 10	13.7	98.7	86.9	63.7	0.56
≤ 11	18.8	98.0	85.9	65.0	0.58
≤ 12	23.5	97.3	85.2	66.2	0.60
≤ 13	29.0	95.3	80.2	67.4	0.62
≤ 14	35.5	93.6	78.2	69.1	0.64
≤ 15	43.0	91.6	76.8	71.2	0.67
≤ 16	50.2	88.5	73.9	73.2	0.69
≤ 17	57.7	82.9	68.7	75.1	0.70
≤ 18	62.8	78.3	65.3	76.4	0.71
≤ 19	72.0	74.1	63.7	79.2	0.73
≤ 20	78.5	63.4	58.2	81.9	0.71
≤ 21	86.3	78.8	52.3	84.6	0.67
≤ 22	87.9	37.3	38.1	87.6	0.63
≤ 23	94.0	25.4	35.6	90.6	0.60
≤ 24	94.7	15.1	33.0	87.0	0.55

¹Asthma control problems: Patients with an asthma specialist global rating of control of "poorly controlled," "not controlled," or "somewhat controlled."

Norm-based Interpretations

Normative data makes it possible to interpret ACT scores for an individual respondent or the average for a group of respondents by comparing them with the distribution of scores for other individuals. Typically, the generation of normative data requires an adequate sampling frame to ensure representativeness of the population of interest. Neither of the ACT studies, developmental or longitudinal, were designed to meet this criteria for producing normative data. Despite this limitation, there is still value in producing benchmark scores from the two distinct populations sampled for both developmental and longitudinal studies. These benchmarks will be useful in determining whether the control scores of patients in future applications of the ACT are on average close to what would be expected for patients of similar clinical backgrounds (i.e., new to care with asthma specialists or under routine care of asthma specialist). In this study, benchmark scores for the ACT were produced separately for patients under the routine care of asthma specialist (developmental study patients) and patients new to care with an asthma specialist (longitudinal study). Benchmark scores were also produced by categories of control as derived from the physician global assessment of asthma control. For these analyses, the samples from both development and longitudinal studies were aggregated.

Table 4.3 presents descriptive statistics for ACT scores for the combined sample of patients under the routine care of asthma specialist (developmental study) and patients new to the care of an asthma specialist (longitudinal study), and separately for both samples. Descriptive statistics include the mean, median (50th percentile), 25th and 75th percentiles, standard deviation, and the observed range of scores. The mean and standard deviation are 18.96 and 4.68, respectively, for ACT scores in the total combined sample. The median ACT score is somewhat higher (20.0) than the mean, reflecting some skewness of the score

distribution in the total combined sample, with more patients scoring above the mean. As expected, the mean ACT score of the sample of patients new to the care of asthma specialists was lower (mean = 18.08), by one and one-half points (or roughly 3/10th's of a standard deviation lower, which is a small effect size), than the sample of patients under the routine care of an asthma specialist (mean = 19.59). The data presented in Table 4.3 are useful in determining whether a score for asthma patients in subsequent studies is below or above these preliminary normative scores for patients under the routine care of an asthma specialist and patients new to the care of an asthma specialist.

Table 4.3 Normative Scores for the ACT among Patients New to Care of Asthma Specialist, Patients under the Routine Care of Asthma Specialist, and Combined Patient Samples

		Asthma Patient Groups	
	Total Combined Sample ¹	New to Specialist ²	Under Care of Specialist ³
Mean	18.96	18.08	19.59
25th Percentile	16.00	15.00	17.00
50th Percentile	20.00	19.00	21.00
75th Percentile	22.50	22.00	23.00
Standard Deviation	4.68	4.87	4.44
Range	5 – 25	5 – 25	6 - 25
Sample (N)	752	312	440

¹Combined samples from developmental and longitudinal validation studies.

Table 4.4 presents descriptive statistics for ACT scores for the groups of patients that differed according the physician's rating of asthma control. As expected, the mean ACT score was lowest among patients rated as not in control (mean = 14.54) and the highest mean ACT score was observed for patients rated as in control (mean = 20.81). The mean ACT score among patients rated as somewhat controlled was 17.12, which is between the uncontrolled and controlled groups. The data presented in Table 4.4 are useful in determining whether a score for asthma patients in subsequent studies is below or above these preliminary normative scores observed for patients with controlled asthma, somewhat controlled asthma, and uncontrolled asthma.

Table 4.4 Combined Sample Normative Scores for the ACT among Patients Differing in the Level of Physician Ratings of Asthma Control from 2 Studies

	Asthma Control Groups		
_	Uncontrolled ¹	Somewhat Controlled	Controlled ²
Mean	14.54	17.12	20.81
25th Percentile	11.00	14.00	19.00
50th Percentile	14.50	18.00	21.00
75th Percentile	17.00	21.00	23.00
Standard Deviation	4.75	4.66	3.52
Range	5 – 25	5 – 25	7 – 25
Sample (N)	102	191	451

¹Combined physician ratings of "poorly controlled" and "not controlled at all."

²Longitudinal validation study population.

³Developmental study population.

²Combined physician ratings of "well-controlled" and "completely controlled."

Table 4.5 presents the frequency distribution for ACT scores separately by patients new to an asthma specialist, patients under the routine care of asthma specialist, and for the combined sample. Table 4.6 presents frequency distributions of ACT scores separately by asthma control groups. The frequency distributions in Tables 4.5 and 4.6 can be used to determine more precisely where in the distribution an ACT score falls. For example, assume that a patient scores 15 on the ACT. From Table 4.5 a score of 15 is at the 22nd percentile in the "normative" population of asthma patients (total combined sample), which is a low score indicating control problems. Since the frequency distributions are presented separately for patients under the routine care of a specialist and patients new to the care of a specialist, more precise interpretations of ACT scores can be made for patients with similar care profiles. For example, using the example from above, if the patient with the ACT score of 15 is under the routine care of a specialist then that patient's score is at the 19th percentile of the "normative" population, which is much lower than if the frequency distribution for patients new to care of a specialist was used, where a score of 15 is at the 27th percentile.

The data presented in Tables 4.5 and 4.6 can also be used to interpret changes in scores for an individual patient or a group of patients. For example, let's say that the patient who scores 15 on ACT improved to a score of 20 after some period of time on treatment. We could interpret the significance of that score change as a move from the 22nd percentile of the total "normative" population to the 53rd percentile of the total normative population (Table 4.5, Total Combined Sample data).

Table 4.5 Frequency Distribution of ACT Scores among Patients New to Care of Asthma Specialist, Patients under the Routine Care of Asthma Specialist, and Combined Patient Samples

	T-4-1	. Ca	d Cl	Patients Under Routine Care of Specialist			Patients New to Care of Specialist		
A CT			ned Samples						
ACT	Freq.	%	Cumulative %	Freq.	%	Cumulative	Freq.	%	Cumulative
Scores	_					%	_		%
5	2	0.27	0.27	0	0.00	0.00	2	0.64	0.64
6	5	0.66	0.93	1	0.23	0.23	4	1.28	1.92
7	11	1.46	2.39	5	1.14	1.36	6	1.92	3.85
8	7	0.93	3.32	5	1.14	2.50	2	0.64	4.49
9	13	1.73	5.05	3	0.68	3.18	10	3.21	7.69
10	10	1.33	6.38	2	0.45	3.64	8	2.56	10.26
11	18	2.39	8.78	10	2.27	5.91	8	2.56	12.82
12	17	2.26	11.04	12	2.73	8.64	5	1.60	14.42
13	26	3.46	14.49	16	3.64	12.27	10	3.21	17.63
14	28	3.72	18.22	16	3.64	15.91	12	3.85	21.47
15	31	4.12	22.34	14	3.18	19.09	17	5.45	26.92
16	35	4.65	26.99	19	4.32	23.41	16	5.13	32.05
17	48	6.38	33.38	22	5.00	28.41	26	8.33	40.38
18	36	4.79	38.16	20	4.55	32.95	16	5.13	45.51
19	41	5.45	43.62	21	4.77	37.73	20	6.41	51.92
20	74	9.84	53.46	39	8.86	46.59	35	11.22	63.14
21	90	11.97	65.43	57	12.95	59.55	33	10.58	73.72
22	72	9.57	75.00	49	11.14	70.68	23	7.37	81.09
23	69	9.18	84.18	44	10.00	80.68	25	8.01	89.10
24	44	5.85	90.03	31	7.05	87.73	13	4.17	93.27
25	75	9.97	100.00	54	12.27	100.00	21	6.73	100.00
Total	752	100.0		440	100.0		312	100.0	

Table 4.6 Frequency Distribution of ACT Scores across Patients Differing in Physician-Assigned Asthma Control Ratings

	Somewhat Controlled								
<u>-</u>	Unc	ontrolled	d Asthma ¹	Asthma			Controlled Asthma ²		
ACT	Freq.	%	Cumulative	Freq.	%	Cumulative	Freq.	%	Cumulative
Scores			%			%			%
5	1	0.98	0.98	1	0.52	0.52	0	0.00	0.00
6	3	2.94	3.92	2	1.05	1.57	0	0.00	0.00
7	5	4.90	8.82	4	2.09	3.66	2	0.44	0.44
8	3	2.94	11.76	2	1.05	4.71	2	0.44	0.89
9	4	3.92	15.69	6	3.14	7.85	1	0.22	1.11
10	5	4.90	20.59	4	2.09	9.95	1	0.22	1.33
11	8	7.84	28.43	7	3.66	13.61	3	0.67	2.00
12	4	3.92	32.35	10	5.24	18.85	3	0.67	2.66
13	9	8.82	41.18	7	3.66	22.51	9	2.00	4.66
14	9	8.82	50.00	10	5.24	27.75	8	1.77	6.43
15	11	10.78	60.78	11	5.76	33.51	9	2.00	8.43
16	8	7.84	68.63	13	6.81	40.31	14	3.10	11.53
17	7	6.86	75.49	15	7.85	48.17	25	5.54	17.07
18	2	1.96	77.45	13	6.81	54.97	21	4.66	21.73
19	5	4.90	82.35	16	8.38	63.35	19	4.21	25.94
20	4	3.92	86.27	21	10.99	74.35	48	10.64	36.59
21	6	5.88	92.16	17	8.90	83.25	66	14.63	51.22
22	1	0.98	93.14	11	5.76	89.01	60	13.30	64.52
23	4	3.92	97.06	10	5.24	94.24	55	12.20	76.72
24	2	1.96	99.02	3	1.57	95.81	39	8.65	85.37
25	1	0.98	100.00	8	4.19	100.00	66	14.63	100.00
Total	102	100		191	100		451	100	

¹Combined physician ratings of "poorly controlled" and "not controlled at all."

Criterion-based Interpretations

Criterion-based tests of validity are based on analyses of relationships between the measures in question and other variables referred to as "criteria," measured either concurrently or after some period of time. Criteria relied upon in this study were chosen to be conceptually related to the ACT and, in the absence of a "gold standard," to provide the most useful preliminary interpretation guidelines. Given limited data collected with the ACT and other clinically or socially relevant criteria, the criterion-based interpretations pursued in this study used patient responses to specific survey items on use of rescue medication, asthma symptoms, activity limitations, and clinical data on lung function. Specifically, the following were plotted across discrete levels of ACT scores: (1) the percentage of patients reporting rescue medication use, presence of asthma symptoms, and activity limitations; (2) the percentage of patients who were below the clinical criteria of asthma control based on % predicted FEV₁ values below 80%; and (3) the percentage of patients rated by the asthma specialist as "poorly controlled" or "not controlled at all." Note that it was necessary to collapse ACT scores into eight categories in order to have large enough sample sizes at each score level to facilitate interpretations.

²Combined physician ratings of "well-controlled" and "completely controlled."

Table 4.7 presents estimates of the percentage of patients whose asthma was rated as "controlled" by a physician or by a clinical standard of predicted FEV1 value equal to or greater than 80% across eight levels of ACT scores. As shown, there is a perfect ordering (from the bottom to the top ACT score level) in the percentage of patients whose asthma was in control. For example, the percentage of patients rated as in control by a physician increases gradually with each level of ACT scores. At the bottom score level only 13% of patients were rated as in control by a physician. At the top score level, 85% of patients were rated as in control by a physician, which is nearly a sevenfold increase in the percentage of patients rated as in control. The Table 4.7 can be used to help interpret the likelihood of having controlled asthma across the levels of ACT scores between the extremes. For example the difference in an ACT score from 15 to 20 can be interpreted as a 25% difference (from 34.85% to 59.29%) in the likelihood of having controlled asthma as rated by the physician.

Table 4.7 Percentage of Combined Sample of Patients New to Care and Under Routine Care of an Asthma Specialist with Controlled Asthma across Eight Levels of ACT Scores

`	ACT Scores			Criterion Measures of Asthma Control				
Levels	Range	Mean	(N)	Physician Rating ¹	PFEV ₁ ²			
1	5-10	8.12	46	13.04%	41.18%			
2	11-12	11.48	35	17.14%	45.28%			
3	13-14	13.52	52	32.69%	47.83%			
4	15-16	15.53	66	34.85%	63.64%			
5	17-18	17.43	83	55.42%	64.29%			
6	19-20	19.64	113	59.29%	69.57%			
7	21-22	21.44	161	78.26%	74.47%			
8	23-25	24.03	188	85.11%	77.16%			

¹Combined ratings of "well-controlled" and "complete control."

Table 4.8 presents estimates of the percentage of patients new to the care of an asthma specialist with activity limitations, morning symptoms, rescue medication use, nighttime symptoms, and wheezing or shortness of breath across eight levels of ACT scores. Across these 5 criterion measures there was a perfect ordering (from the top to the bottom ACT score level) in the percentage of patients experiencing activity limitations, morning symptoms, rescue medication use, nighttime symptoms, and wheezing or shortness of breath. For example, there was nearly a tenfold difference in the percentage of patients with activity limitations from the top score level (8.47% limited) to the bottom score level (85.38% limited). The data presented in Table 4.8 are useful in interpreting the meaningfulness of differences and/or changes in ACT scores. For example, a difference in ACT scores from 15 to 20 can be interpreted as a 46% (66.67% to 20%) difference in the likelihood of activity limitation; a 29% (63.64% to 34.55%) difference in the likelihood of having asthma symptoms upon waking up in the morning; a 35% (78.57% to 43.64%) difference in the likelihood of having nighttime symptoms; or a 20% (92.86% to 72.73%) difference in the likelihood of having nighttime symptoms; or a 20% (92.86% to 72.73%) difference in the likelihood of having wheezing or shortness of breath.

²Defined as % predicted FEV₁ values greater than 80%.

Table 4.8 Percentage of Patients New to Care of Asthma Specialist, with Activity
Limitations, Morning Symptoms, Rescue Medication Use, Night Symptoms
and Wheezing/Shortness of Breath across Eight Levels of ACT Scores

ACT Scores				Criterion Measures					
Levels Range Mean (N			(N)	Activity Limitation ¹	Morning Symptoms ²	Rescue Med. Use ³	Nighttime Symptoms ⁴	Wheeze/ Short of Breath ⁵	
1	5-10	8.12	32	84.38	100.0	90.62	93.75	100.00	
2	11-12	11. 4 8	13	72.73	93.75	90.91	90.91	100.00	
3	13-14	13.52	22	53.85	90.91	84.62	76.92	100.00	
4	15-16	15.53	33	66.67	63.64	78.57	60.61	92.86	
5	17-18	17. 4 3	42	47.62	57.14	58.06	59.52	90.91	
6	19-20	19.6 4	55	20.00	34.55	43.64	32.73	72.73	
7	21-22	21.44	56	16.07	30.36	33.93	16.07	67.86	
8	23-25	24.03	59	8.47	8.62	18.64	6.78	30.51	

¹During the past 4 weeks did your asthma keep you from getting as much done at work or at home?

Closing Remarks

The data presented in this section are meant to help interpret differences and/or changes in scores on the ACT. The normative data presented here are limited somewhat in that the samples of asthma patients are not truly representative of the general population of asthma patients. However, in the absence of a truly representative patient population, these data serve as adequate benchmarks for the interpretation of ACT scores for individual patients or groups of patients. The criterion-based interpretation analyses are helpful in translating differences and/or changes in ACT scores into clinically and socially relevant terms. Future studies should be conducted to evaluate the ability of the ACT scores to predict certain clinically meaningful consequences (i.e., predicting the future risk of using health care services), which could be used for interpreting health risk.

²During the past 4 weeks did you awaken at your usual time in the morning with asthma symptoms once a week or more?

³During the past 4 weeks did you have to use your quick relief inhaler or Albuterol more than two times a week?

⁴During the past 4 weeks did you wake up at night or earlier than usual in the morning with asthma symptoms once a week or more?

⁵During the past 4 weeks did you ever experience wheezing or shortness of breath more than two times a week?

Section 5. Common Questions

This section reviews answers to frequently asked questions about the administration of the ACT.

What should I do if the respondent refuses to complete the ACT?

If the respondent is able to self-administer the ACT but refuses to participate, tell the respondent that completion of the survey is voluntary, but encourage the respondent by emphasizing that the ACT will provide information that may help his or her physician better understand the impact of asthma on the respondent's life. Emphasize that this information can be very important in obtaining a more complete picture of the respondent's health. Emphasize that the survey is simple to complete.

What if a respondent does not complete the ACT?

If the survey is not completed because the respondent has difficulty understanding particular items, reread the item verbatim for the respondent but do not rephrase the item. If the respondent is still unable to complete the survey, accept the survey as incomplete.

What should I do if the respondent requests clarification of an item?

While completing the survey, some respondents might ask for clarification of specific items in order to answer them. In this case, the administrator can assist the respondent by rereading the item verbatim, but the administrator should not attempt to clarify the item. If the respondent asks what an item means, suggest that the respondent use his or her own interpretation of the item. Sometimes respondents may have trouble with the response choices. They may say "I don't know" or something different than what is stated on the survey. In these circumstances, it is important to guide the respondent to choose the answer that is closest to what he or she is thinking or feeling. If the respondent does not like an item or thinks it is unnecessary or inappropriate, emphasize that all items are included in the survey to help in understanding more about the impact of his or her asthma.

What should I do if a respondent is concerned someone will see his or her answers?

Emphasize that the doctor and other staff members keep all respondents' responses to the ACT, like all other tests, confidential. If an identification number rather than a name is used to identify a respondent, point out that his or her name does not appear anywhere on the questionnaire. If the respondent is enrolled in a clinical study, tell the respondent that answers to the survey will be pooled with other respondents' answers and will be analyzed as a group rather than individually.

What should I do if a respondent asks why he or she may be asked to complete the ACT more than once?

Explain that respondents may fill out the same survey during future visits in order to see if their answers change over time. Taking the survey more than once will provide a more complete picture of changes in the impact that asthma has over the course of time. Compare this practice with common clinical measures such as blood pressure or cholesterol levels that are monitored over time.

Section 6. Applications of the ACT

The ACT is well-suited to measure the degree of asthma control in a variety of settings ranging from clinical practice to disease management and clinical trials. Physicians and other health care providers, payers, clinical researchers, public health analysts, and policy officials each will find uses for the ACT. Brevity and ease of administration are essential for the integration of the ACT into clinical practice and clinical studies.

Clinical Practice

Concise, reliable and inexpensive to administer, the ACT can easily be integrated into ordinary clinical practice in several applications. Point-in-time ACT assessments can help to:

- identify patients whose asthma is poorly controlled, such that they require intervention;
- facilitate communication between patients and health care providers; and
- tailor treatment strategy to the degree or dimension of asthma control.

With repeated use with a given patient or group of patients, the ACT can be used to:

- monitor changes in asthma control over time; and
- determine the effects of a treatment strategy for asthma.

Population Screening and Management

The brevity of the ACT makes it an ideal survey for use in monitoring the health of asthma populations. Managed care organizations or others can use the ACT with supplementary measures (such as biological measures, health care utilization and treatment compliance) to assess and track the burden of asthma and the benefits of treatment.

Managed care organizations may wish to use the ACT to identify those individuals most likely to have asthma control problems, indicating a need for care management intervention. Others may wish to use ACT scores to monitor groups of asthma patients over time to determine the effects of particular treatment interventions or to measure the health risk of the asthma membership. The ACT could play an integral role in a public awareness campaign or any asthma screening effort.

Policymaking

The ACT may also be useful in advancing healthcare policymaking efforts by government or private sector organizations. Incorporation of information about the health effects of asthma into regional and national healthcare databases could guide policymaking decisions. Use of a standardized asthma control survey to assess the burden of disease and compare treatment effectiveness across different types of databases (e.g., clinical database, general population survey data) would enhance the ability to make policy decisions regarding asthma care.

References

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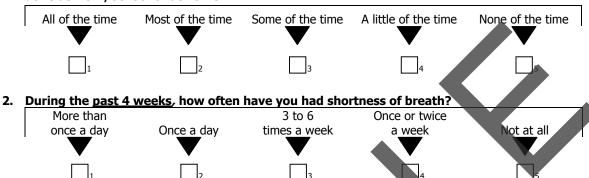
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Appendix A: Asthma Control Test™ - Standard Form

Asthma Control Test™ - Standard Form

This survey was designed to help you describe your asthma and how your asthma affects how you feel and what you are able to do. To complete it, please mark an \square in the one box that best describes your answer.

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?



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?

the morning:				
4 or more nights a week	2 to 3 nights a week	Once a week Once or Twice	Not at all	
riights a week	riigitis a week	Office di Twice	Not at all	ļ
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, Ventolin® Proventil®, Maxair® or Primatene Mist®)?

3 or more	1 or 2	2 or 3	Once a week		
time <u>s per</u> day	times per day	times per week	o <u>r les</u> s	No <u>t at</u> all	
_			_		
1	2	3	4	5	
		*			

mow would you rate y	oui <u>asuilla</u> C	ond of during the pas	or 4 Meevs:	
Not Controlled	Poorly	Somewhat	Well	Completely
at all	Controlled	Controlled	Controlled	Controlled
	2	3	4	5

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 guestions.

If your total point value is 19 or below, your asthma may not be well-controlled. Be sure to talk to your healthcare professional about your asthma score.

Take this survey to your healthcare professional and talk about your asthma treatment plan.