Published in final edited form as:
J Allergy Clin Immunol. 2012 March ; 129(3 0): S24–S33. doi:10.1016/j.jaci.2011.12.980.

Asthma Outcomes: Composite Scores of Asthma Control

Michelle M. Cloutier, MD [(co-primary author)],
University of Connecticut

Michael Schatz, MD [(co-primary author)],
Kaiser Permanente

Mario Castro, MD,
Washington University in St Louis

Noreen Clark, PhD,
University of Michigan

H.W. Kelly, PharmD,
University of New Mexico

Rita Mangione-Smith, MD,
University of Washington

James Sheller, MD,
Vanderbilt University

Christine Sorkness, PharmD,
University of Wisconsin

Stuart Stoloff, MD, and
Independent Family Practice

Peter Gergen, MD
National Institute of Allergy and Infectious Diseases

Abstract

Background—Current asthma guidelines recommend assessing the level of a patient's asthma control. Consequently, there is increasing use of asthma control as an outcome measure in clinical research studies. Several composite assessment instruments have been developed to measure asthma control.

Corresponding author: Peter Gergen, MD, Division of Allergy, Immunology, and Transplantation (DAIT); National Institute of Allergy and Infectious Diseases (NIAID); National Institutes of Health (NIH), 6610 Rockledge Drive, Bethesda, Md 20892, Telephone: 301-496-8973, pgergen@niaid.nih.gov.

Objective—National Institutes of Health (NIH) institutes and federal agencies convened an expert group to propose the most appropriate standardized composite score of asthma control instruments to be used in future asthma studies.

Methods—We conducted a comprehensive search of PubMed, using both the National Library of Medicine's Medical Subject Headings (MeSH) and key terms to identify studies that attempted to develop and/or test composite score instruments for asthma control. We classified instruments as core (required in future studies), supplemental (used according to study aims and standardized), or emerging (requiring validation and standardization). This work was discussed at an NIH-organized workshop convened in March 2010 and finalized in September 2011.

Results—We identified 17 composite score instruments with published validation information; all had comparable content. Eight instruments demonstrated responsiveness over time; 3 demonstrated responsiveness to treatment. A minimal clinically important difference has been established for 3 instruments. The instruments have demographic limitations; some are proprietary, and their use could be limited by cost.

Conclusion—Two asthma composite score instruments are sufficiently validated for use in adult populations, but additional research is necessary to validate their use in nonwhite populations. Gaps also exist in validating instruments for pediatric populations.

Keywords

Asthma Control Questionnaire; Asthma Control Test; Asthma Therapy Assessment Questionnaire; childhood Asthma Control Test

INTRODUCTION

Asthma clinical research lacks adequate outcomes standardization. As a result, our ability to examine and compare outcomes across clinical trials and clinical studies, interpret evaluations of new and available therapeutic modalities for this disease at a scale larger than single trial, and pool data for observational studies (eg, genetics, genomics, pharmacoeconomics) is impaired.[1] Several National Institutes of Health (NIH) institutes that support asthma research (National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases, National Institute of Environmental Health Sciences, and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development), as well as the Agency for Healthcare Research and Quality, have agreed to an effort for outcomes standardization. This effort aims at (1) establishing standard definitions and data collection methodologies for validated outcome measures in asthma clinical research with the goal of enabling comparisons across asthma research studies and clinical trials and (2) identifying promising outcome measures for asthma clinical research that require further development. In the context of this effort, 7 expert subcommittees were established to propose and define outcomes under 3 categories—core, supplemental, and emerging:

- *Core outcomes* are identified as a selective set of asthma outcomes to be considered by participating NIH institutes and other federal agencies as requirements for institute/agency-initiated funding of clinical trials and large observational studies in asthma.

- *Supplemental outcomes* are asthma outcomes for which standard definitions can or have been developed, methods for measurement can be specified, and validity has been proven, but whose inclusion in funded clinical asthma research will be optional.
- *Emerging outcomes* are asthma outcomes that have the potential to (1) expand and/or improve current aspects of disease monitoring and (2) improve translation of basic and animal model-based asthma research into clinical research. Emerging outcomes may be new or may have been previously used in asthma clinical research, but they are not yet standardized and require further development and validation.

Each subcommittee used the recently published *American Thoracic Society (ATS)/European Respiratory Society (ERS) Statement: Asthma Control and Exacerbations—Standardizing Endpoints for Clinical Asthma Trials and Clinical Practice*[2] (hereafter referred to as the *ATS/ERS Statement*) as a starting point and updated, expanded, or modified its recommendations as the subcommittee deemed appropriate. Each subcommittee produced a report that was discussed, modified, and adopted by the Asthma Outcomes Workshop that took place in Bethesda, Md, on March 15 and 16, 2010. The reports were revised accordingly and finalized in September 2011. The workshop's recommendations in regard to asthma control composite scores are presented in this article.

Current asthma guidelines emphasize that asthma control is a key therapeutic goal and recommend assessments of asthma control to guide step therapy. As such, composite measures of asthma control would be essential outcome measures for clinical trials assessing the efficacy of therapeutic interventions. However, asthma control appears to be a multidimensional construct, and there has been no universally recognized gold standard. In recent years, several questionnaire instruments have been developed and validated as measures of the construct of asthma control. These instruments include dimensions beyond symptoms and rescue therapy frequency. The task for the Composite Scores of Asthma Control subcommittee was to review instruments that attempt to capture the multiple dimensions of asthma control in a composite score.

A comprehensive search of the literature, combined with expert input, identified a total of 17 instruments to capture asthma control. We identified and reviewed studies that validated the different instruments, as well as publications of epidemiologic studies and clinical trials that used them. We then summarized characteristics of instruments with at least 1 published validation study and drew conclusions, based on this literature review, regarding the use of these instruments as outcome measures. The results are summarized in Tables VI and VII, and the recommendations are summarized in Tables I through III.

REVIEW OF ASTHMA CONTROL COMPOSITE SCORE INSTRUMENTS

Definitions and Methodology for Measurement

The *ATS/ERS Statement* divided its "Composite Measures of Asthma Control" section into composite measures expressed as (1) categorical variables in which a descriptive category of asthma control is measured (such as asthma control days/asthma-free days/episode-free

days, “well-controlled” asthma weeks/“total control” weeks, or guideline-based categories including “well controlled,” “not well controlled,” or “poorly controlled” asthma), and (2) numeric variables in which several independent variables are scored numerically and a composite score of asthma control is derived. The *ATS/ERS Statement* indicates that limitations of the measures expressed as categorical variables include “empiric derivation, lack of standardization, and the limited information they provide on control in individual patients.” A recent study[3] found that a composite measure expressed as a numeric variable (Asthma Control Questionnaire [ACQ]) “is more responsive to change in a clinical trial setting than a categorical scale.” We did not pursue composite measures expressed as categorical variables in the current review; instead we focused only on measures expressed as numeric variables, which we call asthma control composite score instruments.

We defined asthma control on the basis of the *Guidelines for the Diagnosis and Management of Asthma* (EPR-3) definition of patient-reported elements of *impairment* (symptom frequency, use of short-acting β-agonist [SABA] medication for quick relief, or “rescue,” sleep interference, and activity limitation) and *risk (*history of exacerbations in the prior 12 months), as well as objective measures of lung function in the impairment domain.[4]

The subcommittee defined asthma control composite score instruments as single questionnaires (with or without physiologic measures) designed to (1) measure the multidimensional construct of asthma control (which comprises more than just asthma symptoms and frequency of SABA use), and (2) produce a numeric score. Instruments could target adults, children, or both.

The *ATS/ERS Statement* reviewed 4 asthma control composite score instruments for adults: the Asthma Control Questionnaire (ACQ), the Asthma Control Test (ACT), the Asthma Therapy Assessment Questionnaire (ATAQ), and the Asthma Control Scoring System (ACSS).[5–8] We reviewed newer studies using those instruments, as well as studies involving the use of 13 additional instruments for which at least 1 validation study was published in a peer-reviewed journal (Table VI). One instrument (Perceived Control of Asthma Questionnaire) had a validation study published but then retracted; we did not consider this instrument further. We regarded another instrument, the Asthma Control Diary (Juniper), as a daily version of the ACQ, rather than as an independent instrument.

All 17 asthma control composite score instruments have comparable content (Table VI). All instruments assess nocturnal symptoms or interference with sleep. All but 1 instrument capture symptom frequency, either of any asthma symptom or of specific symptoms (cough, wheeze, dyspnea), and most instruments also assess SABA use.

All but 1 instrument reflect some form of activity limitation, including interference with daily activities, exercise, and school or work attendance. Only 2 instruments (ACQ and ACSS) include pulmonary function parameters, and 1 instrument (ACSS) includes sputum eosinophilia.

Slightly more than half of the instruments assess exacerbations, but only the Test for Respiratory and Asthma Control in Kids (TRACK) assesses the “risk of exacerbations” domain, as recommended in the EPR-3 guidelines (number of exacerbations requiring oral

corticosteroids in the prior 12 months). The most common recall windows for the instruments are 1 and 4 weeks, although windows as long as 2 years are included in some instruments. Several instruments have different windows for different questions. The instruments have not been validated to assess exacerbations, and they can only be considered to reflect status within their specific recall windows.

The above information leads to the following caveats when using the asthma control composite score instruments to assess asthma control on the basis of current guidelines.

1. Asthma control score instruments are meant to reflect chronic disease activity, usually over a 1- to 4-week period, and have not been validated for use during an asthma exacerbation.
2. Except for TRACK, currently available instruments assess only the impairment domain of asthma control and must be used in conjunction with assessments of asthma exacerbations requiring oral corticosteroids in the prior 12 months to be able to evaluate the EPR-3-defined risk domain of asthma control.
3. Except for the ACQ and ACSS, these instruments should be used in conjunction with pulmonary function tests to more fully assess the impairment domain of asthma control.

Medical and Scientific Value

Asthma control is a major goal of asthma therapy. Asthma control is now defined in terms of 2 domains—impairment and risk. Although nonstandardized/nonvalidated questions can be used to define asthma impairment and risk, questionnaire instruments with defined psychometric properties should provide more valid and reliable information. In addition, accurate and reliable assessment of asthma control in clinical trials requires the use of measures shown to be both responsive to change and stable when no clinically meaningful change has occurred.

Range of Values

Individual instruments contain 3 to 10 questions, and scoring varies by instrument. The ACQ score ranges from 1 to 7 and the ACT from 5 to 25. Most instruments provide discrete quantitative data, although they are often analyzed as continuous variables.

Four instruments have established cutoff values for uncontrolled versus controlled asthma: ACQ ≥1.5,[9] ACT ≤19,[6] ATAQ ≥1,[10] and Childhood Asthma Control Test [cACT] ≤19 (US study).[11] Two instruments also have defined cutoffs for the EPR-3 category of “very poorly controlled” asthma: ACT ≤15[12] and ATAQ ≥3.[10] These cutoffs have been defined in populations, generally on the basis of optimizing the balance between sensitivity and specificity, but may not always be accurate for individual patients. Distributions of scores for the various instruments vary by study population.

Repeatability

Test-test reliability, the consistency of the instrument results measured on 2 occasions with no change in asthma control in between, has been shown for 5 instruments in at least 1

sample (Table VII). Factors known to affect repeatability have not been identified for any of the instruments.

Responsiveness

Responsiveness over time (with no specifically prescribed therapeutic intervention) has been demonstrated for 8 instruments in at least 1 sample (Table VII), and responsiveness to specific therapy has been demonstrated for 3 instruments (Table VII). Minimal clinically important differences (MCIDs) have been defined for the ACQ (0.5 point),[13] the ACT (3 points),[14] and the Lara Asthma Symptom Scale (LASS) in adults (7 points).[15]

Asthma control score instruments that are clinically useful in individual patients may not be effective for measuring differences between populations in clinical trials, and vice versa. The ACQ has proven capable of distinguishing between treatment groups in clinical trials, even though its MCID has been derived from individual patients over time. Although the ACT has been used less than the ACQ in clinical trials to date, the MCID for the ACT has been defined both for individuals over time and for differences between populations.

Validity

Overall validity has been demonstrated in more independent study population samples for the ACT than for the other instruments (Table VII).

Content validity[16] is the extent to which an instrument measures the concept of interest—in this case, asthma control. Content validity to demonstrate study participant understanding of the instruments has not been rigorously demonstrated for most asthma control composite score instruments. However, concordance of the content of these instruments (Table VI) with the EPR-3 guideline definition of *control*, described above (especially regarding impairment), supports the content validity of these instruments from the clinician perspective.

Criterion validity,[16] the correlation of the instrument with some other measure of the specific construct of asthma control, such as another validated asthma control instrument or another “gold standard” for asthma control (eg, physician assessment), has been demonstrated in at least 1 study sample for 13 instruments, most often using physician assessments of asthma control or other validated instruments (Table VII).

Construct validity,[16] relationships of the instrument to other variables and measures that are not identical to the construct of asthma control but to which the construct of asthma control should be related (includes relationships to various asthma patient characteristics, measures, and outcomes), has been demonstrated for 16 instruments in at least 1 study sample (Table VII). Constructs shown to be related to asthma control instruments include pulmonary function, asthma-specific and generic quality of life, exacerbations, and missed school or work. Construct validity may be labeled as *convergent* validity, *discriminant* validity, or *known-groups* validity in some publications.

Predictive validity,[16] a measure of whether an instrument accurately predicts future outcomes of interest (using other measures), has been shown for 6 instruments for future

exacerbations, future healthcare utilization, or future quality of life. Internal consistency reliability (as indicated by a Cronbach's $\alpha > 0.7$) has been demonstrated for 13 instruments.

Associations

Associations with other outcome measures have been identified, as described above for construct validity. However, no specific predictive properties (sensitivity, specificity, positive predictive values) of the asthma control instruments for these outcomes have been defined. Poorer asthma control, as measured by these instruments, has been shown to be associated with risk factors such as older age (adults), lower socioeconomic status, smoking, obesity, gastroesophageal reflux disease, anxiety and/or depression, and lack of asthma specialist care.

Practicality and Risk

All asthma control composite score instruments are based on questionnaires that comprise 3 to 10 questions and that may entail some inconvenience but no risk. Two instruments (ACQ and ACSS) include forced expiratory volume in 1 second (FEV_1), although exclusion of FEV_1 did not change the measurement properties of the ACQ in 1 study.[13] One instrument (ACSS) includes sputum eosinophilia, which requires specialized equipment and training to use and may entail some patient discomfort and risk of bronchospasm.

The asthma control score instruments recommended as core or supplemental outcomes are all copyrighted. Using these instruments in clinical research entails obtaining permission from the copyright holder and may involve some expense. The amount may depend on the specific type of study and the type of user institution; in some cases, the expense may preclude the use of the instrument.

It also should be noted that when these validated asthma control instruments are used in clinical research, they should not be changed from their original validated form in any way. Modified instruments cannot be assumed to be valid without additional validation data.

Demographic Considerations

The demographic issues of most interest are gender, age, and race/ethnicity. All the above-mentioned instruments have been studied with both females and males. In some studies, the instruments have shown reduced asthma control in females compared with males.

Some instruments have been developed for patients of all ages (LASS, Royal College of Physicians "3 Questions" [RCP]), but others have been developed and validated specifically for patients aged 0 to 4 years (TRACK), older children (Asthma Quiz, ATAQ for Children and Adolescents, Breathmobile Assessment of Asthma Control, Asthma Control in Children [CAN], Functional Severity of Asthma Scale [FSAS], cACT, Pediatric Asthma Control Tool [PACT]), patients aged 12 years and older (ACQ, ACT), or those aged 18 years and older (Asthma Control and Communication Instrument [ACCI], ACSS, ATAQ, Seattle Asthma Severity and Control Questionnaire [SASCQ], 30-Second Asthma Test).

Validation study samples in the United States have generally included mostly white patients, but also some black and Hispanic patients. The ACCI primary validation study was

conducted in a racially diverse sample. Robust generalizability across racial/ethnic groups has not been demonstrated for any of the instruments, although several studies demonstrate poorer asthma control among nonwhite than among white participants. Several instruments have been translated into Spanish, but only 2 instruments (ACQ and ACT) have been validated in Spanish-speaking groups.

Priority for NIH-Initiated Clinical Research

Two asthma control composite score instruments (ACQ and ACT) have been designated as core measures for NIH-initiated clinical research in adults because of (1) the importance of asthma control as a goal of therapy; (2) extensive validation data for these instruments, using the widest range of criterion and construct measures and including demonstration of responsiveness to therapy and an MCID; and (3) low patient burden and risk. The ACQ has been used in the majority of clinical trials to date, and the ACT has the most published validation data to date. Both instruments have been validated for use as self-administered instruments in person, at home, or by telephone. Studies that have compared the ACQ and the ACT have found them to correlate strongly ($r = -0.82$ to -0.89) and perform similarly.[12, 17–19] While numeric scores from the ACQ and the ACT cannot be used interchangeably or combined across studies, cross-study comparisons could be made using the proportion of study participants designated as “controlled” versus “uncontrolled” or the proportion who achieved a change greater than the MCID for each instrument (Table IV).

Particular study designs may deem either the ACQ or the ACT preferable on the basis of the recall windows of the instruments (1 week for ACQ, 4 weeks for ACT). The availability of spirometry also could influence the decision, since the ACQ requires spirometry whereas the ACT does not.

The cACT has more validation data than other instruments for children aged 4 to 11 years and can be considered to have met the minimum standard as a core measure for participant characterization and observational studies. However, the cACT must be considered only supplemental for clinical trials until more responsiveness data and an MCID are presented. All other instruments reviewed here are considered emerging at this time, pending better data on their psychometric properties and more use in clinical studies.

When the ACQ or the ACT are used for the characterization of the study population, it would be desirable to use these instruments as close as possible to the time when phenotype/genotype information is collected.

Acknowledgments

Funding:

The Asthma Outcomes workshop was funded by contributions from the National Institute of Allergy and Infectious Diseases, the National Heart, Lung, and Blood Institute, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the National Institute of Environmental Health Sciences, and the Merck Childhood Asthma Network, as well as by a grant from the Robert Wood Johnson Foundation. Contributions from the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the National Institute of Environmental Health Sciences, and the US Environmental Protection Agency funded the publication of this article and for all other articles in this supplement.

Abbreviations

30-Second	30-Second Asthma Test
κ	Kappa coefficient
ACCI	Asthma Control and Communication Instrument
ACQ	Asthma Control Questionnaire
ACSS	Asthma Control Scoring System
ACT	Asthma Control Test
ATAQ	Asthma Therapy Assessment Questionnaire
ATS	American Thoracic Society
Breathmobile	Breathmobile Assessment of Asthma Control
cACT	Childhood Asthma Control Test
CAN	Asthma Control in Children
cATAQ	ATAQ for Children and Adolescents
Co	Content validity
Cr	Criterion validity
CT	Clinical trial
EPR-3	Guidelines for the Diagnosis and Management of Asthma
ERS	European Respiratory Society
FEV_1	Forced expiratory volume in 1 second
FSAS	Functional Severity of Asthma Scale
HPP	At-home paper and pencil
IC	Internal consistency reliability
ICC	Intraclass Correlation Coefficients
IP	Interviewer in person
LASS	Lara Asthma Symptom Scale
MCID	Minimal clinically important difference
NIH	National Institutes of Health
Ob	Observational
P	Predictive validity
PACT	Pediatric Asthma Control Tool
PEF	Peak expiratory flow
PPP	In-person, self-administered, paper and pencil

RCP	Royal College of Physicians “3 Questions”
SABA	Short-acting β-agonist
SASCQ	Seattle Asthma Severity and Control Questionnaire
TR	Test-retest reliability
TRACK	Test for Respiratory and Asthma Control in Kids
TrCT	Treatment in clinical trial
TrNCT	Treatment in nonclinical trial setting

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Future Directions or Research Questions

1. Identify core and supplemental asthma control score outcome measures for children younger than age 5.
2. Conduct studies to define the optimal way to incorporate the risk domain of asthma control within the asthma control score instruments.
3. Validate the instruments in population subgroups defined by age (eg, adolescents, older adults), race/ethnicity, socioeconomic status, health literacy, specific comorbidities (if any), asthma severity or phenotype, or treatment.
4. Obtain additional validation data for supplemental, emerging, and potential new instruments. Such studies should include the reasons for instrument development, qualitative assessments using cognitive interviewing to demonstrate patient understanding of the instruments, assessment of instrument utility in different populations, and head-to-head comparisons with other validated asthma control score instruments.
5. Conduct studies to define the value of including physiologic measures along with the questionnaires in asthma control score instruments, and determine the best physiologic measures to include.
6. Confirm or define 2 types of MCIDs for all instruments: First, MCID to document change in an individual over time, which could be used for clinical care or to identify a responder in a clinical trial; and second, MCID for differences between populations, which could be used to compare asthma control in 2 groups for research or quality improvement purposes.
7. Further demonstrate, for all instruments, their responsiveness over time and to therapy.
8. Determine the predictive properties (sensitivity, specificity, positive predictive value) of the instruments for other asthma outcomes, especially for future outcomes.
9. Quantitatively validate more instruments in more languages.
10. If the proprietary nature of currently recommended instruments prevents their widespread use in clinical research, develop and validate an asthma control score instrument that will reside in the public domain.

TABLE I

Recommendations for classifying asthma control composite score outcome measures for NIH-initiated clinical research: adult and adolescent populations (≥12 years of age)

	Characterization of study population for prospective clinical trials (ie, baseline information)	**Prospective clinical trial efficacy/effectiveness outcomes**	**Observational study outcomes***
Core outcomes	Either ACQ or ACT	Either ACQ or ACT	Either ACQ or ACT
Supplemental outcomes	ATAQ in studies of healthcare utilization	None	ATAQ in studies of healthcare utilization
Emerging outcomes	Other adult instruments (Tables VI & VII)	Other adult instruments (Tables VI & VII)	Other adult instruments (Tables VI & VII)
Call for new instruments	Development of an instrument in the public domain		

ACQ, Asthma Control Questionnaire; *ACT*, Asthma Control Test; *ATAQ*, Asthma Therapy Assessment Questionnaire; *NIH*, National Institutes of Health.

* Observational study designs include cohort, case control, cross sectional, retrospective reviews, and genome-wide association studies (GWAS), and secondary analysis of existing data. Some measures may not be available in studies using previously collected data.

TABLE II

Recommendations for classifying asthma control composite score outcome measures for NIH-initiated clinical research: pediatric populations (5–11 years of age)

	Characterization of study population for prospective clinical trials (ie, baseline information)	**Prospective clinical trial efficacy/effectiveness outcomes**	**Observational study outcomes***
Core outcomes	cACT	None	cACT
Supplemental outcomes	None	cACT	None
Emerging outcomes	Other childhood instruments (Tables VI & VII)	Other childhood instruments (Tables VI & VII)	Other childhood instruments (Tables VI & VII)
Call for new instruments	Development of an instrument in the public domain		

cACT, Childhood Asthma Control Test; *NIH*, National Institutes of Health.

* Observational study designs include cohort, case control, cross sectional, retrospective reviews, and genome-wide association studies (GWAS), and secondary analysis of existing data. Some measures may not be available in studies using previously collected data.

TABLE III

Recommendations for classifying asthma control composite score outcome measures for NIH-initiated clinical research: pediatric populations (≤4 years of age)

	Characterization of study population for prospective clinical trials (ie, baseline information)	Prospective clinical trial efficacy/effectiveness outcomes	Observational study outcomes*
Core outcomes	None	None	None
Supplemental outcomes	None	None	None
Emerging outcomes	TRACK	TRACK	TRACK
Call for new instruments	Development of an instrument in the public domain		

NIH, National Institutes of Health; *TRACK*, Test for Respiratory and Asthma Control in Kids.

* Observational study designs include cohort, case control, cross sectional, retrospective reviews, and genome-wide association studies (GWAS), and secondary analysis of existing data. Some measures may not be available in studies using previously collected data.

TABLE IV

Methods for measuring and reporting core and supplemental outcomes for asthma control composite scores

ACT	Measure by a 5-item self-administered questionnaire Report as • Composite, numerical score (range 5–25) • Change in study population scores (MCID is a change of 3 points) • Percentage of study population with score indicating controlled (>19) or uncontrolled (≤19) asthma; uncontrolled further broken down into not well controlled (16–19) or very poorly controlled (<16)
cACT	Measure by a 7-item self-reported questionnaire: 4 items completed by child and 3 by parent • Composite, numerical score (range 5–25) • No MCID to date Percentage of study population with score indicating controlled (>19) or uncontrolled (≤19) asthma
ACQ	Measure by 7 items: 6 self-reported questionnaire and FEV_1: • Composite, numerical score (range 0–6) • Change in study population scores (MCID change of 0.5 point) • Percentage of study population with score indicating controlled (≤0.75) or uncontrolled (≥1.5) asthma
ATAQ	Measure by 4 self-reported items • Composite, numerical score (range 0–4 control problems) • No MCID established • Percentage of study population with score indicating controlled (0) or uncontrolled (≥1) asthma; uncontrolled further broken down into not well controlled (1–2) or very poorly controlled (3–4)

ACQ, Asthma Control Questionnaire; *ACT*, Asthma Control Test; *ATAQ*, Asthma Therapy Assessment Questionnaire; *cACT*, Childhood Asthma Control Test; *FEV_1*, forced expiratory volume in 1 second; *MCID*, minimal clinically important difference.

TABLE V

Key points and recommendations

1	An asthma control composite score instrument is recommended as a core measure in prospective clinical trials in individuals ≥12 years of age for both characterization of the study population and as an outcome measure, and as a core measure for those observational studies that have direct contact (in person, by mail, or by telephone) with study participants. Either the ACQ or the ACT is recommended as an appropriate asthma control composite score instrument.
2	The cACT is recommended as a core measure for participant characterization and for observational studies in children aged 4–11 years but can be considered only supplemental for clinical trials until more responsiveness data are obtained and an MCID is determined.
3	Only 1 validated instrument was identified for children under age 5. However, more validation data are needed before it can be recommended as a core or supplemental measure.
4	Other instruments identified in this review are considered emerging, pending additional validation data and use in clinical studies.
5	Most of the currently available asthma control composite score instruments assess only the impairment domain of asthma control and must be used in conjunction with assessments of asthma exacerbations requiring oral corticosteroids in the prior 12 months to be able to assess the risk domain of asthma control.
6	Even instruments with substantial validation data have not been specifically validated in high-risk populations, such as racial/ethnic minorities, patients of low socioeconomic status, low-literacy patients, older adults, patients with comorbidities, and those with severe asthma.
7	The recommended asthma control composite score instruments are meant to reflect chronic disease activity over a 1- (ACQ) to 4- (ACT, cACT) week period, and have not been validated to assess exacerbations; nor have they been shown to reflect status over a longer time period.
8	Most available instruments need additional validation information, especially regarding responsiveness and clinically relevant changes.
9	The recommended instruments are proprietary, and require permission and, frequently, expense to administer. If this prevents widespread use as a core outcome in clinical research, consideration should be given to developing an asthma control composite score instrument that will reside in the public domain.

ACQ, Asthma Control Questionnaire; *ACT*, Asthma Control Test; *cACT*, Childhood Asthma Control Test; *MCID*, minimal clinically important difference.

TABLE VI

Summary of the characteristics of asthma control score instruments

Instrument	Number of questions	Recall window	Questionnaire content						Physiologic measures
			Symptom frequency	Rescue therapy use	Sleep interference	Activity limitation	Exacerbations	Other	
ACCI	5	1 week (2 weeks for sleep)	X	X	X	X	X		
ACQ	6	1 week	X	X	X	X			FEV_1
ACSS	8	1 week	X	X	X	X			PEF or FEV_1, sputum eosinophilia
ACT	5	4 weeks	X	X	X	X		Self-rating of control	
ATAQ	4 (control dimension)	4 weeks		X	X	X		Self-rating of control	
Breathmobile	7	4 weeks (3 items); 2 years (2 items); no specific window (2 items)	X	X	X	X	X		
cACT	7	4 weeks	X		X	X		Self-rating of control	
CAN	9	4 weeks	X		X	X	X		
30-Second	5	1 week (3 items); 3 months (2 items)	X	X	X	X			
Asthma Quiz	6	1 week (4 items); 30 days (activity, exacerbations)	X	X	X	X	X		
cATAQ	7 (control dimension)	4 weeks or 12 months	X	X	X	X		Parent rating of child's control	

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Instrument	Number of questions	Recall window	Questionnaire content						Physiologic measures
			Symptom frequency	Rescue therapy use	Sleep interference	Activity limitation	Exacerbations	Other	
FSAS	6	12 months	X		X	X	X		
LASS	8	4 weeks	X		X		X	Parent rating of child's control	
PACT	10	3 months	X	X	X	X	X		
RCP	3	1 week or 1 month	X		X	X			
SASCQ	5	4 weeks	X	X	X	X	X		
TRACK	5	4 weeks (3 items); 3 months (rescue medication); 12 months (exacer-bations)	X	X	X	X	X		

30-Second, 30-Second Asthma Test; *ACCI*, Asthma Control and Communication Instrument; *ACQ*, Asthma Control Questionnaire; *ACSS*, Asthma Control Scoring System; *ACT*, Asthma Control Test; *ATAQ*, Asthma Therapy Assessment Questionnaire; *Breathmobile*, Breathmobile Assessment of Asthma Control; *cACT*, Childhood Asthma Control Test; *CAN*, Asthma Control in Children; *cATAQ*, ATAQ for Children and Adolescents; FEV_1, forced expiratory volume in 1 second; *FSAS*, Functional Severity of Asthma Scale; *LASS*, Lara Asthma Symptom Scale; *PACT*, Pediatric Asthma Control Tool; *PEF*, peak expiratory flow; *RCP*, Royal College of Physicians "3 Questions"; *SASCQ*, Seattle Asthma Severity and Control Questionnaire; *TRACK*, Test for Respiratory and Asthma Control in Kids.

TABLE VII

Characteristics of specific asthma control score instruments

Instrument	Age (years)	Validity samples*	Reliability samples†	Responsiveness samples‡ MCID samples§	Modes evaluated**	Inclusion of diverse populations in validation studies	Use in studies††	Comments
30-Second	≥19	Cr: 1 Co: 1 P: 0	TR: 0 IC: 1	None	PPP		CT: 0 Ob: 0	Compared to ACT, full ACQ, and non-FEV_1 ACQ: higher sensitivity, lower specificity, lower percentage correctly classified
ACCI	≥17	Cr: 1 Co: 1 P: 0	TR: 0 IC: 1	None	PPP	55% black in validation study	Ob: 1	Validation for control domain
ACQ	≥12	Cr: 10 Co: 10 P: 1	TR: 5 IC: 7	Time: 8 TrCT: 18 TrNCT: 4 MCID: 2 (0.5 point)	PPP, HPP, phone	Not validated for inner-city residents or Hispanics; 1 study with blacks	CT: 43 Ob: 14	ACQ without FEV_1 correlates with full ACQ (extent of validation of non-FEV_1 ACQ limited)
ACSS	≥18	Cr: 1 Co: 1 P: 0	Tr: 1 IC: 1	Time: 1 Tr: 0 MCID: 0	IP		CT: 0 Ob: 0	Validation only in 1 site, small sample
ACT	≥12	Cr: 12 Co: 29 P: 2	TR: 6 IC: 11	Time: 4 TrCT: 3 TrNCT: 3 MCID: 4 (3 points)	PPP, HPP, phone, Internet	Some validation studies included blacks (3–70%), Asians (2–4%), and Hispanics (1– 17%); 1 study in pregnant women	CT: 3 Ob: 34	
Asthma Quiz	1–17	Cr: 1 Co: 1 P: 0	TR: 1 IC: 1	Time: 1 Tr: 0 MCID: 0	Caregiver (aged 1–17 years), patient (aged 9–17 years), PPP	Black: 9% Other: 15%	CT: 0 Ob: 0	
ATAQ	≥18 (≥12 in 1 study)	Cr: 0 Co: 5 P: 1	TR: 0 IC: 0	None	PPP, HPP		CT: 0 Ob: 8	4 questions in control domain; construct

Instrument	Age (years)	Validity samples*	Reliability samples†	Responsiveness samples‡ MCID samples§	Modes evaluated**	Inclusion of diverse populations in validation studies	Use in studies††	Comments
								validity prim validity prim validity prim validity prim validity prim
Breath-mobile	2–14	Cr: 1 Co: 0 P: 0	TR: 0 IC: 0	None	Caregiver, PPP	Black: 7% Hispanic: 85% Other: 6%	CT: 0 Ob: 0	
cACT	4–11	Cr: 3 Co: 4 P: 1	TR: 1 IC: 2	Time: 2 TrCT: 2	Patient and caregiver, PPP	Black: 11% Hispanic: 6% Asian and Native American: 15% in US study; 100% Chinese in 2 studies	CT: 2 Ob: 6	Optimal cutoff for uncontrolled asthma varied
CAN	2–14	Cr: 1 Co: 1 P: 0	TR: 0 IC: 1	Time: 1 Tr: 0 MCID: 1	Caregiver (aged 2–14 years), patient (aged 9–14 years), PPP	100% Spanish population (study done in Spain)	CT: 0 Ob: 0	
cATAQ	5–17	Cr: 0 Co: 1 P: 1	TR: 0 IC: 1	None	Caregiver, HPP	Black: 29% Other: 10%	CT: 0 Ob: 0	
FSAS	3–17	Cr: 0 Co: 1 P: 0	Tr: 0 IC: 1	None	Caregiver, HPP	Australian: 22% “Disadvantaged”	CT: 0 Ob: 1	
LASS	3–17 (child) 18–64 (adult)	Cr: 0 Co:1 child, 1 adult P: 1 (adult)	TR: 0 IC: 1 child, 1 adult	Time: 1 child, 1 adult Tr: 0 MCID: 1 (adult) (7 points)	Caregiver (child), IP	English and Spanish versions, but insufficient number of Spanish-only to validate for them specifically; Adult: 20% Black: 45% Hispanic: 49% uninsured or disadvantaged	CT: 0 Ob: 0	
PACT	1–18	Cr: 1 Co:1 P: 0	TR: 0 IC: 1	None	Caregiver (with input from child), PPP	Black: 32% Hispanic: 2%	CT: 0 Ob: 0	

Instrument	Age (years)	Validity samples*	Reliability samples†	Responsiveness samples‡ MCID samples§	Modes evaluated**	Inclusion of diverse populations in validation studies	Use in studies††	Comments
RCP	6–15 19–71	Cr: 1 Co:1 P: 0	TR: 0 IC: 0	Time: 1 Tr: 0 MCID: 0	PPP	No information	CT: 0 Ob: 0	Feasibility study n = 15 children; n = 20 adults; cross-sectional validity only in adults; responsive-ness in adults and children
SASCQ	≥12	Cr: 1 Co: 1 P: 0	None	None	HPP	Nonwhite: 7.7%	None	
TRACK	2–4	Cr: 1 Co: 1 P: 0	TR: 0 IC: 1	None	Caregiver, PPP	Black: 11% Hispanic: 9% Other: 8%	CT: 0 Ob: 0	

30-Second, 30-Second Asthma Test; *ACCI*, Asthma Control and Communication Instrument; *ACQ*, Asthma Control Questionnaire; *ACSS*, Asthma Control Scoring System; *ACT*, Asthma Control Test; *ATAQ*, Asthma Therapy Assessment Questionnaire; *Breathmobile*, Breathmobile Assessment of Asthma Control; *cACT*, Childhood Asthma Control Test; *CAN*, Asthma Control in Children; *cATAQ*, ATAQ for Children and Adolescents; *Cr*, criterion validity; *Co*, content validity; *CT*, clinical trial; *FEV_1*, forced expiratory volume in 1 second; *FSAS*, Functional Severity of Asthma Scale; *HPP*, at-home paper and pencil; *IC*, internal consistency reliability; *IP*, interviewer in person; *LASS*, Lara Asthma Symptom Scale; *MCID*, minimal clinically important difference; *Ob*, observational; *P*, predictive validity; *PACT*, Pediatric Asthma Control Tool; *PPP*, in-person, self-administered, paper and pencil; *RCP*, Royal College of Physicians "3 Questions"; *SASCQ*, Seattle Asthma Severity and Control Questionnaire; *TR*, test-retest reliability; *TRACK*, Test for Respiratory and Asthma Control in Kids; *TrCT*, treatment in clinical trial; *TrNCT*, treatment in non-clinical trial setting.

*Number of independent samples in which indicated validity was demonstrated. See the "Validity" section of this article for definitions of criterion validity, construct validity, and predictive validity.

†Number of independent samples in which indicated reliability was demonstrated.

Internal consistency reliability:[16] the degree to which the items of the instrument are related to each other and the total scale score. This is usually expressed as Cronbach's α, which ideally should be between 0.7 and 0.9.[20]

Test-retest reliability:[16] the consistency of the instrument results measured on 2 occasions with no change in asthma control in between. The measures of association between the 2 results are usually expressed as the Intraclass Correlation Coefficients (ICC) for continuous data or the Kappa coefficient (κ) for categorical results. Generally, test-retest reliability ICC or κ values of ≥0.70 are considered acceptable.[20]

‡Number of independent samples in which indicated responsiveness[16] (the ability of the instrument to detect changes in asthma control over time or in response to treatment) was demonstrated.

§Number of independent samples in which an MCID (the smallest difference in score on the instrument that represents a clinically significant change or difference) was defined.

**Patient self-report unless otherwise indicated (eg, caregiver for children).

††The number of studies indicated in this column also were identified by the literature search; these are studies in which the instrument was used as a validated measure of asthma control.

Sources: Listed for instruments and validation references (not including clinical trials and epidemiologic studies without validation data):

Asthma Control and Communication Instrument (ACCI)[21]

Asthma Therapy Assessment Questionnaire (ATAQ)[22–30]

Breathmobile Assessment of Asthma Control (Breathmobile)[31]

Asthma Control in Children (CAN)[32]

Functional Severity of Asthma Scale (FSAS)[33]

Lara Asthma Symptom Scale (LASS)[15, 34]

Pediatric Asthma Control Tool (PACT)[35]

Asthma Quiz[36]

Royal College of Physicians “3 Questions” (RCP)[37]

Seattle Asthma Severity and Control Questionnaire (SASCQ)[38]

Test for Respiratory and Asthma Control in Kids (TRACK)[39]

ATAQ for Children and Adolescents (cATAQ)[7, 40]

Asthma Control Scoring System (ACSS)[8, 41]

Childhood Asthma Control Test (cACT)[11, 42–46]

Asthma Control Questionnaire (ACQ)[5, 9, 13, 17, 18, 21, 47–54]

Asthma Control Test (ACT)[6, 12, 14, 17–19, 27, 37, 45, 55–85]

30-Second Asthma Test (30-Second)[18, 86]