Published in final edited form as:
J Allergy Clin Immunol. 2012 March ; 129(3 0): S88–123. doi:10.1016/j.jaci.2011.12.988.

Asthma Outcomes: Quality of Life

Sandra R. Wilson, PhD,
Palo Alto Medical Foundation Research Institute

Cynthia S. Rand, PhD,
Johns Hopkins University

Michael D. Cabana, MD, MPH,
University of California, San Francisco

Michael B. Foggs, MD,
Advocate Medical Group of Advocate Health Care

Jill S. Halterman, MD, MPH,
University of Rochester

Lynn Olson, PhD,
American Academy of Pediatrics

William M. Vollmer, PhD,
Kaiser Permanente

Rosalind J. Wright, MD, MPH, and
Harvard Medical School

Virginia Taggart, MPH
National Heart, Lung, and Blood Institute

Abstract

Background—"Asthma-related quality of life" refers to the perceived impact that asthma has on the patient's quality of life.

Objective—National Institutes of Health (NIH) institutes and other federal agencies convened an expert group to recommend standardized measures of the impact of asthma on quality of life for use in future asthma clinical research.

Methods—We reviewed published documentation regarding the development and psychometric evaluation; clinical research use since 2000; and extent to which the content of each existing quality of life instrument provides a unique, reliable, and valid assessment of the intended

Corresponding author: Virginia Taggart, MPH, Division of Lung Diseases (DLD); National Heart, Lung, and Blood Institute (NHLBI);, National Institutes of Health (NIH), 6701 Rockledge Drive, Bethesda Md 20892, Telephone: 301-435-0202, taggartv@nih.gov.
Sandra R. Wilson(co-primary author), Cynthia S. Rand(co-primary author).

construct. We classified instruments as core (required in future studies), supplemental (used according to the study's 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—Eleven instruments for adults and 6 for children were identified for review. None qualified as core instruments because they predominantly measured indicators of asthma control (symptoms and/or functional status); failed to provide a distinct, reliable score measuring all key dimensions of the intended construct; and/or lacked adequate psychometric data.

Conclusions—In the absence of existing instruments that meet the stated criteria, currently available instruments are classified as either supplemental or emerging. Research is strongly recommended to develop and evaluate instruments that provide a distinct, reliable measure of the patient's perception of the impact of asthma on all of the key dimensions of quality of life, an important outcome that is not captured in other outcome measures.

Keywords

Asthma burden; asthma-related well-being; health perceptions; health status; patient-reported outcomes

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 (the National Heart, Lung, and Blood Institute [NHLBI]; 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-related quality of life are presented in this article. Asthma-related quality of life (QOL) as an outcome measure refers to the perceived impact that asthma has on the patient's QOL. Historically, QOL instruments were key to measuring the burden of a disease as perceived by the patient. Many currently available asthma-related QOL instruments were developed prior to formulation of the construct of asthma control. Hence, these so-called asthma-related QOL instruments often included (or totally consisted of) items that focused on quantifying the individual's functional status (ability to perform daily functions; limitations on daily or desired activities) or health status (frequency and intensity of asthma symptoms, need to use short-acting β-agonist [SABA], need for urgent medical care), and/or social or emotional functioning. Few items were included that directly assessed how and how much the patient's health or functional status affected his or her QOL. In the meantime, growing emphasis has been placed on patient-reported outcomes for clinical research, and the lines between patient-reported outcomes in general and measures of perceived impact of a disease on QOL have become blurred or overlapping. Separate measures of the domains of functional status and health status, as reported by the patient, have now been developed, with greater attention to objectivity, to unique measurement challenges of each domain, and to potential data sources (see Asthma Symptoms and Composite Scores of Asthma Control articles). Because the burden of disease, as measured by symptom or activity levels, does not give a complete picture, an assessment of the patient's perception of the impact of these impairments on his or her QOL remains essential. A new generation of QOL instruments is needed to focus more specifically on the patient's perception of the impact of asthma on QOL, so that there is less conceptual overlap in measures.

There is a need to question the assumption that the degree of asthma control (as manifest in symptom frequency and intensity, lung function, or impairment in physical activities) correlates perfectly with the way the patient perceives the impact of asthma on QOL. Considerable clinical experience and research evidence suggest that patient perceptions of the impact of asthma vary to an extent that is not explained by differences in asthma control

or the various components of control. In fact, clinicians may gain important information when separate measures of these constructs do not co-vary and by trying to understand the reason for such discrepancies. If multiple domains are incorporated in future QOL instruments, the various constructs should not be mixed in a single score. The ability of an asthma QOL instrument to distinctly and reliably measure the perceived impact of asthma on QOL gives that instrument a unique value in the "toolbox" of asthma assessments and outcome measures, over and above the value provided by symptom scores or composite measures of asthma control.

This article includes a table describing the key characteristics and measurement properties of currently available instruments (9 adult instruments and 6 pediatric instruments): a narrative summary evaluation of each instrument's ability to measure the construct of the perceived impact of asthma on QOL, the instrument's practicality and demographic generalizability, and finally, a general recommendation regarding the use of each instrument.

To develop this article, each Quality of Life Subcommittee member was assigned to review several instruments and report back to the full subcommittee. The review included obtaining the published documentation of the original instrument and its development and validation studies, as well as a search of the recent literature (since 2000) regarding its use in clinical research. See Table III for descriptive information about each instrument. Evaluative summaries also were reported to the subcommittee for review and as a basis for development of recommendations and key points regarding the measurement of asthma QOL. Further, an independent literature search and review of the instruments was conducted to validate the subcommittee findings and to ensure that all relevant instruments and published asthma clinical research studies in which the instruments were used were identified. The subcommittee met through regularly scheduled telephone conference calls. Recommendations and key points required approval by all members.

This review of QOL instruments builds on the 2009 *ATS/ERS Statement* by providing more detail on each instrument, which may assist researchers in selecting the most appropriate instrument for their studies, and by providing a more detailed assessment of the content domains of the instruments. Key objectives of the review were to consider evidence and to:

- Determine what, specifically, is being measured and not measured by existing instruments intended to assess QOL
- Identify the extent to which each instrument includes items measuring patient perception of the impact of asthma on his or her QOL
- Identify conceptual confusions and critical distinctions between different types of instrument content
- Provide information that would allow a comparison of the content and other properties, as well as what is known and not known about the various instruments

In addition, we saw a need to carefully evaluate the psychometric properties of instrument scores (reliability, cross-sectional, or predictive associations with other measures; responsiveness to changes or differences in asthma status; subscale score uniqueness; and minimal clinically important score differences), and the way these properties were

determined in relation to the established standards for psychological measurement tools as set forth by the relevant professional associations.

The *ATS/ERS Statement* includes comments on generic health-related QOL questionnaires. The statement notes that generic instruments were generally designed for use by individuals with no functional limitations or symptoms, or with only the most common ones (eg, mobility limitations, pain). The utility of these instruments is questionable in the context of asthma, and they should be complemented by use of a more specific tool. Consequently, the Quality of Life Subcommittee chose to focus entirely on reviewing asthma-related QOL instruments.

ASTHMA-RELATED QUALITY OF LIFE AS AN OUTCOME MEASURE

Definition

Asthma-related QOL, as an outcome measure, refers to the perceived impact of asthma on a patient's (ie, respondent's) QOL. As noted, several constructs have historically been included in QOL measures: health status (eg, symptom levels), functional status (eg, activity capabilities or impairments), and the patient's perception of the impact of these impairments on his or her QOL. Other functional domains and symptomatology, such as emotional well-being, depression or anxiety, and social function, also have been included in some instruments, with or without specific inquiry as to whether the patient's asthma (as opposed to other factors) affects his or her status in these respects or his or her QOL. Acknowledging that there are overlaps among these domains, as well as correlations among items measuring different domains, researchers still must consider the extent to which the scores on available instruments reliably assess the unique construct of interest—the patient's perspective on the effects of asthma on QOL. These effects could potentially arise from many different sources, including symptom intensity and frequency, activity limitations and/or impairments, environmental restrictions and the need to avoid precipitants, the cost of medications and asthma medical care, disruptions in plans, limitations or disruptions of employment and career choices, and adverse effects on personal relationships.

One might expect that greater frequency and intensity of symptoms would be associated with greater impairment in physical, social, and/or emotional function—and, in turn, with more negative consequences for the patient's QOL—leading to the assumption that it would only be necessary to assess these domains to determine the impact of asthma on an individual's QOL. However, the degree to which the patient's QOL is compromised by any particular level of symptoms and/or functional limitations is a different construct, and the way this is evaluated by the patient may vary as a function of the patient's own priorities, expectations, and lifestyle, and not solely as a function of objective functional status or symptoms. For example, a woman who prefers a sedentary lifestyle and has no reason to climb stairs at work or home may not be as bothered by the inability to climb a flight of stairs without becoming short of breath as would someone whose lifestyle requires that he or she be able to do this. On the other hand, this patient may have chosen a sedentary lifestyle because she could not be active without experiencing asthma symptoms (ie, she has adapted her lifestyle to accommodate her disease) and has accepted this without further thought. Given options or a need to be more active or reasons to view a sedentary lifestyle as

problematic, she might view this functional limitation differently. Only by measuring both functional status and the patient's perspective on this status, and its impact on his or her well-being, can a complete picture emerge.

Historically, the term "quality of life" has generally encompassed multiple and potentially overlapping domains intended to characterize the burden of disease as perceived by the patient—in other words, a range of different types of patient-reported outcomes. As instruments have been refined and constructs and methods for monitoring asthma outcomes have evolved, more specificity is possible and desirable. In this article, "functional status" and "health status" refer to degree of impairment. The impact of asthma on a respondent's QOL refers to how much that degree of impairment, as well as the asthma symptoms and the treatment of the condition, matters to the patient and adversely affects his or her QOL.

Methodology for Measurement

Subcommittee members identified and evaluated the psychometric properties of the different QOL instruments. The review considered instruments' content validity, internal consistency, and other forms of reliability; concurrent and predictive validity; responsiveness; the discriminant validity of the overall instrument score relative to other asthma assessment instruments; and if the instrument included subscale scores, the discriminant validity of these subscores. An overview of measurement psychometric properties, based on standards issued jointly by the American Educational Research Association, American Psychological Association, and National Council on Measurement in Education,[3] is presented below as the context for the QOL subcommittee's review of QOL instruments. Particular considerations regarding the psychometric properties of QOL instruments also are discussed.

Administration of currently available paper-and-pencil asthma QOL instruments is either through patient self-administration or through interviews with patients or caregivers. An emerging method uses computer-assisted questionnaire administration, and 1 case used a computer-tailored assessment.

Content validity of a measurement instrument—regardless of whether it is measuring physical, biological, or psychological phenomena—refers to the extent to which the instrument measures what it is intended to measure, which is integral to whether the results of the measurement serve the purpose(s) for which they are intended. A prerequisite for valid use of an instrument for a particular purpose, even before consideration of the instrument's reliability or criterion validity, is its *content validity*. This is usually considered to have 2 aspects. *Face validity* is the apparent relevance of the content of the measure as judged by potential users, subject matter experts, or experts in the development of psychometric instruments. *Construct validity* refers to the adequacy of the empirical evidence and/or the theoretical rationale behind the choice of content in constructing the measurement instrument, and also may be supported by information on the pattern of the associations and nonassociations between the instrument score and any subscale scores and other measures, either concurrently or predictively. For example, a stadiometer for determining height would have little plausible validity as an instrument to measure lung function, despite its reliability or the association between its measurements and lung function. Similarly, asthma symptom frequency and intensity may be an important

patientreported outcome and could be measured reliably, and the measurements could correlate well with other asthma outcomes. Nevertheless, a patient's report of his or her symptoms is not a direct assessment of the patient's perception of the impact asthma has on his or her QOL.

The issue of content validity is emphasized in this article because prior evaluations of instruments intended to measure asthma-related QOL have failed to address this issue adequately. In our review, we noted that many published reports on the development of such instruments have failed to provide an explicit rationale for the instrument's content. Those that have done so have often adopted the view that such instruments should measure dimensions that are important to asthma patients in general—that is, what bothers or concerns them. What has been lacking are careful distinctions, in the construction of items, between measurement of symptom frequency and intensity, measurement of functional impairments or limitations imposed by asthma, and measurement of other concerns (eg, dying as a result of asthma) versus measurement of the impact of these and other factors on the quality of the patient's life, as perceived by the patient.

Moreover, in recent years, other measures of asthma symptoms have been developed, both separately and as 1 aspect of composite measures of asthma control. The inclusion of items concerning symptoms and functional status and, in some cases, items assessing other aspects of asthma (such as the need to avoid environmental triggers) in measures of QOL may be outdated or conceptually confused, and may result in instruments that are redundant with other, more recent, measures of asthma control. This has many implications for the creation of an efficient yet comprehensive "toolbox" of asthma outcome measures for research and clinical purposes. In some QOL instruments, items that assess asthma symptoms constitute a substantial proportion of the instrument and may be very highly correlated with the remaining items, the majority of which measure functional status. In such cases, and especially when evidence regarding the discriminant validity of the various subscales or components of the instrument is not available, it is not clear that the total score, or any of its subscores, provides unique information that would not otherwise be captured—perhaps more effectively—by separate measures of symptoms or functional status, or even by a composite measure of asthma control. Hence, the subcommittee emphasizes the need to carefully consider the content of any QOL instrument when selecting outcome measures for a research project.

Reliability refers to the consistency or reproducibility of a measurement, and adequate reliability is essential to the validity of any measurement tool. Greater reliability is achieved when a measurement tool has a lesser amount of random measurement error. To the extent that a measurement is less than perfectly reliable, this imposes an upper bound on the validity of the instrument.

Two kinds of reliability are generally considered relevant: internal consistency and testretest reliability. *Internal consistency reliability* refers to the extent to which all of the items in a psychometric instrument measure the same construct. Since psychological constructs are often multifaceted, and because no 1 item is likely to yield a perfectly reliable assessment of the construct, reliable measurement typically requires multiple items, each of which

measures some aspect of the construct of interest (eg, QOL). This consistency is reflected in the correlations among responses to different items within the instrument and in the associations between individual items and total scores based on all items purporting to measure the same construct.

Internal consistency is most often described using Cronbach's α statistic, a type of correlation coefficient. The level of internal consistency reliability that is necessary for a psychometric instrument depends to some extent on the purpose of the measure and the nature of the decisions to which it will contribute. For purposes of group comparisons, an α of 0.70 or above is typically considered acceptable; for purposes of evaluating change at the individual level, an α value of near 0.90 is requisite. An α value above 0.90 indicates that the items are very homogeneous and suggests they are measuring a single underlying construct. For some purposes, such unidimensionality is appropriate. However, if the intended construct is multidimensional, extremely high internal consistency may mean that the measure is not sampling all the key aspects of the construct or is only measuring them in a very narrow manner. As a consequence, the validity and usefulness of the measure may be compromised.

Reliability was considered by the subcommittee with particular attention to the implications of both low and very high α values, at the level of subscale scores as well as for the instrument as a whole.

Test-retest reliability refers to the consistency, repeatability, or stability of a measurement, and is typically assessed over periods during which the underlying construct can be assumed to have remained stable, which tends to mean over relatively brief time periods but periods that are sufficiently long as to reduce recall and learning effects. Test-retest reliability is usually expressed as a correlation between 2 measurements made on the same instrument at different time points. There is no universally agreed-upon threshold for acceptable test-retest reliability. Under ideal conditions (ie, no carryover of the previous measurement—which would inflate the apparent test-retest reliability and no underlying change in the patient's status—which would deflate the apparent reliability), a perfectly reliable instrument would result in a perfect correlation between the 2 consecutive measurements on the same patient. However, psychometric instruments are not perfectly reliable, and the preconditions of no measurement reactivity and patient stability typically do not exist. Hence, test-retest reliability values of 0.70 and above, under appropriate conditions, are typically considered minimally acceptable.

Criterion validity has been the focus of most developmental studies of QOL tools to date. However, much of the literature concerning QOL measures has assumed that the higher the correlation between a QOL measure and other asthma outcome measures (forced expiratory volume in 1 second, or FEV_1; asthma symptoms; functional status; etc), the more valid the QOL measure. Similarly, an imperfect association has been assumed to demonstrate that the QOL measure is providing unique information. Both assumptions are open to question on a number of grounds. A very high correlation would call into question the need for the QOL measure—that is, whether it yields any unique information not provided by the other measures and whether it is a measure of QOL at all or simply a duplication of what is being

measured by the outcome with which it is correlated (eg, symptoms, functional status, healthcare utilization). A modest correlation may reflect the imperfect reliability of 1 or both measures being correlated, and is not necessarily evidence that the QOL instrument provides unique information. More fundamentally, from a clinical and research standpoint, the important question with regard to QOL measures concerns the extent to which the patients' asthma (whether referring to lung function, symptom status, asthma control, costs of medications and care, need to avoid asthma triggers, or other features of their asthma) is detracting from their QOL, and whether various medical or other interventions lessen this burden. In that sense, the magnitude of the correlation between a QOL measure and some measure of health status or functional status is not direct evidence either for or against the validity of the QOL instrument. The correlations may reflect the extent to which patients' QOL is, on average across patients, determined by what is being measured by the variables with which the QOL instrument is being correlated versus the extent to which it is determined by the values, lifestyle, and other characteristics of the individual patient. The individual's perspective on the impact of his or her asthma—rather than the individual's status on dimensions that are important or bothersome to the typical person with asthma—is what QOL instruments could uniquely provide. Thus, a QOL instrument's validity is best judged in terms of (1) its content (ie, whether the items require the respondent to indicate the extent to which his or her QOL is being compromised by asthma on all the dimensions on which individuals evaluate their QOL, or at least on all those dimensions that might possibly be affected by asthma), and (2) whether the assessment it provides is reliable.

Responsiveness refers to the ability of a measure to detect changes in the underlying construct over a time period in which change is expected to have occurred or in which some relevant intervention was delivered, and the measure's ability to detect individual differences in asthma-related QOL, such as between individuals with comparable asthma status but who have very different life circumstances, goals, or values. In QOL research, responsiveness is most frequently evaluated by examining change in scores on the measure in response to asthma treatment or changes in other measures of health status (eg, lung function). Evidence that scores on a QOL measure differ in relation to disease activity or among groups with known differences in asthma severity, for example, has been considered to provide evidence of the measure's responsiveness. The converse is not the case, however. The failure of a QOL measure to detect group differences or to detect within-group changes over time is not, *per se*, evidence that the measure is unresponsive. It simply may be that the expected differences or changes did not occur, were too limited to have an impact on the patient's QOL in the context of other factors that might influence his or her QOL, or were offset by negative QOL effects of side effects of the treatment.

Medical and Scientific Value

It is increasingly recognized that the evaluation of therapeutic interventions should include assessment of outcomes that matter to patients. Measures of patient perspective on the impact of asthma are not fully reflected in measures of clinical signs and symptoms, lung function, or the underlying pathology on which most clinical trials focus. QOL measures can provide unique information as a component of the toolbox of asthma outcome measurements

and can thus provide a more complete characterization of the study population's asthma and of the benefits or drawbacks of particular interventions.

Priority for NIH-Initiated Clinical Research

The subcommittee considers measures of functional status to be essential for characterizing patient populations because this information is critical for understanding the type of patients included in the study. Currently available QOL instruments may be helpful in this regard, but other instruments may capture this domain more efficiently. The subcommittee recommends that QOL measures be classified as a supplementary outcome measure in prospective clinical trials and observational studies for 2 reasons. First, currently available instruments do not meet the subcommittee's expectations for performance in distinctly and robustly capturing the construct of the patient's perspective on the impact of asthma on his or her QOL. Second, the desirability of measuring this construct is highly likely to depend on the aims of a particular research project. However, the subcommittee strongly encourages researchers to consider including measures of asthma-related QOL as an outcome because, even if imperfectly measured, many currently available asthma QOL instruments can capture unique characteristics of study populations and the benefits or harms of asthma interventions that may not be otherwise assessed.

Future Directions for Asthma-Related Quality of Life as an Outcome

If a methodological goal for asthma clinical research is to construct a toolkit of outcome measures, it would be most efficient to have each outcome measurement make a unique contribution to the whole and not duplicate what other measures accomplish. The patient's perception of asthma's impact on his or her QOL is a unique construct and must be measured separately from other domains, such as functional status or clinical signs and symptoms. The recent development of instruments to measure functional status and health status through a composite asthma control score offers the opportunity to encourage future generations of QOL measures to focus more specifically on the patient's perception of the impact of asthma. This would avoid overlap with other measures and make a unique contribution to the ideal toolbox of asthma outcome measures.

REVIEW OF ASTHMA-RELATED QUALITY OF LIFE INSTRUMENTS

Descriptive summaries of 9 asthma-related QOL instruments for adult study populations and 4 instruments for pediatric study populations follow. The subcommittee does not recommend any instrument as a core instrument, because findings from the subcommittee's review of asthma QOL instruments revealed the following limitations: Most instruments include measures of functional and health status or consist entirely of these measures; none of the instruments measures the full range of dimensions that affect QOL, and few of the instruments provide a distinct score that yields a robust and individually reliable measure of the patients' perspective on their QOL as affected by their asthma. Thus, the available instruments are listed as "supplementary."

The subcommittee has not prioritized the list for research use. At this point in time, the extent to which the content of existing instruments was uniquely directed at measurement of

asthma's impact on a patient's QOL was not found to be positively associated with the extent of the instrument's prior use or the availability of data on its psychometric properties. It would be inappropriate to promote widespread use of an inadequate measure simply because of its history of use, and equally inappropriate to promote the use of a promising measure that lacks adequate psychometric data. Because there are no existing instruments that uniquely measure the impact of asthma on patient QOL and have adequate psychometric data, the subcommittee elected to provide descriptions in the tables and following narrative summary, pointing out the strengths and weaknesses of the available instruments. These are provided in the hope of guiding investigators to the most appropriate instrument or instruments for the requirements of their research aims and study populations.

Each summary highlights the subcommittee's evaluation of the key features of the content domains measured by that instrument and its key strengths and weaknesses, and concludes with a recommendation regarding the use of the instrument in clinical research. Tables III and IV provide detailed information for adult and pediatric QOL instruments, respectively, about the content domains assessed by each instrument, its target populations, demographic considerations, and methodological considerations (range of values, repeatability, responsiveness, validity, practicality, or risk); information about how widely the instrument has been used in published clinical studies and other research; and key references.

ASTHMA-RELATED QUALITY OF LIFE INSTRUMENTS FOR ADULT STUDY POPULATIONS

Asthma Bother Profile (Developed by M.E. Hyland)

Summary—The Asthma Bother Profile (ABP) is a 22-item instrument requiring 10 minutes to complete that was developed for the primary purpose of clinical management of patients and not necessarily for use as an outcome measure in clinical studies. The ABP is designed to assess adult patient perception of the asthma experience and distress in different situations and areas of life, as well as patients' perception of their asthma management. This asthma QOL instrument is unique among currently available instruments in its emphasis on the psychosocial impact of asthma, including items measuring perceived bother, mood, fear, social relations, and financial impact. The initial ABP questionnaire was constructed on the basis of earlier asthma QOL research and modified by patients' discussion, in focus groups, of the way their lives were affected by asthma. The instrument includes a 15-item scale measuring asthma bother. All 15 items measure the impact of asthma on the respondent. For example, item 4 of this scale asks, "Overall, how much does your asthma bother your personal life (such as love life, personal relationships, family life)?" No items in this bother scale measure health status or symptoms, and so the ABP comes somewhat closer than other instruments to measuring the construct of QOL as defined by the subcommittee. However, there is arguably a significant difference between asking how much an individual is "bothered" and asking about the extent and direction of the effect of asthma on the person's QOL. The instrument's 15 items are scored on a 6-point scale; at 1 end of the scale is "no bother at all" for 10 items or "I never have a worry" for 5 items; all 15 items then share the remaining scale ranging from "minor irritation," "slight bother," "moderate bother," "a lot of bother," to "makes my life a misery." The overall bother scale score is the sum of the 15

item scores. The ABP also includes a single item asking which months of the year the person is bothered by his or her asthma and a 7-item asthma management scale, which is scored separately. This 7-item scale is not intended to measure asthma QOL, but instead measures psychological mediators of asthma self-management, including beliefs about self-efficacy and confidence.

Strengths and Weaknesses—Strengths of the ABP include high internal consistency of the 15-item bother scale, substantial correlation of the 15-item bother scale with other QOL instruments, and good test-retest reliability. The 15 bother items exclusively focus on the perceived impact of asthma on the patient's psychological state. The total score is not directly influenced by items assessing symptom frequency or severity, or functional ability. Thus, this instrument is highly specific for measuring the patient's perspective on how much he or she is bothered by asthma and its impact on his or her life. Weaknesses of the instrument include very limited data on its use in clinical or research settings and lack of validated translations. The only translations studied are in Norwegian and Japanese.[4, 5] No information is provided on the minimal clinically important difference (MCID) on this instrument. Only 4 published studies have cited it. The 7-item self-management scale has a weak association with the asthma bother scale, and it is unclear how its inclusion adds to the overall measure. The instrument has been shown to be sensitive to asthma self-management education; however, no published clinical trials have used this QOL measure as an outcome.

Recommendation—The subcommittee recommends classifying the ABP as a supplemental instrument for clinical research. Although the ABP has had limited utilization and was developed for clinical use, the instrument's unique focus on the psychosocial impact of asthma and mediators of asthma self-management makes it potentially useful as a supplemental outcome measure in interventional studies (including behavioral) that might alter the psychosocial impact of asthma.

Asthma Impact Survey (AIS-6) (Developed by Kaiser Permanente Care Management Institute and Quality Metrics)

Summary—The Asthma Impact Survey (AIS-6) is a brief (3-minute) 6-item asthma-specific QOL instrument intended for use by clinicians to measure the impact asthma has on their patients' lives. The AIS-6 was originally developed from a bank of 52 questions that assessed the impact of disease on physical functioning, social and role participation, emotional distress or well-being, and energy or fatigue. The authors' hypothesis for the development of the asthma impact item bank was that "the 52 items would assess one single dimension of asthma impact and that assessment of asthma impact could be based on a single score." These authors used data from a general population survey of persons with asthma and calibrated and scaled the respondents' answers, using the generalized partial credit (GPC) item response theory (IRT) model. The authors also used the item discrimination and category parameters drawn from the GPC IRT model to estimate information functions for each item. From this procedure, 6 items were selected that spanned a wide range of asthma impact and represented the main content areas defined by all items in the item bank (physical functioning, social and role participation, emotional distress or well-being, and energy or fatigue). The development of the AIS-6 was guided by a

conceptual model that makes important distinctions between domains of health and their operational definitions. This 6-item instrument measures how much and how often asthma limits participation in normal daily activities, and also measures feelings of frustration because of asthma—specifically, the social, functional, and emotional impact of asthma and its symptoms. An example of the items: "In the past 4 weeks, how much did your asthma limit your usual activities or enjoyment of everyday life?" The 5 response categories range from "not at all" to "extremely." Two items of this 6-item scale assess how often in the past 4 weeks asthma has left the participant frustrated or tired. Three items assess the functional impact of asthma by asking how often in the past 4 weeks asthma has limited activities, socialization, or work. No items directly assess symptoms.

Strengths and Weaknesses—Strengths of the AIS-6 include its rigorous methodological development, high internal consistency reliability, modest to substantial correlations with other asthma outcome measures, and its brevity and ease of use clinically. Limitations include the relative lack of use of this instrument in clinical research, the fact that it assesses only a limited range of ways in which asthma can affect a patient's QOL, and the fee due to Quality Metrics to use the instrument. Only a total score is calculated on this short instrument.

Recommendation—The subcommittee recommends classifying the AIS-6 as a supplemental instrument for clinical research in which the brevity of the instrument is a primary consideration, but the usefulness of the instrument is limited by cost considerations and the sparse evidence of its utility for measurement of change and group differences.

Asthma Quality of Life Questionnaire-Standardized (Developed by E.F. Juniper)

Summary—The Asthma Quality of Life Questionnaire-Standardized (AQLQ-S) is a 32-item instrument that targets adults and requires approximately 4–15 minutes to administer. It has been translated into more than 20 languages and used in international settings with ethnically diverse populations and among low socioeconomic status (SES) and ethnic minority adults with asthma in the United States. However, the psychometric properties of the instrument in various populations have not been reported, especially in low-education populations that may have difficulty understanding the items or instructions.

The AQLQ-S was based on the Asthma Quality of Life Questionnaire (AQLQ) developed previously by the same author, E.F. Juniper. The AQLQ-S differs from the original AQLQ in that it provides standardized activities that may be limited by asthma, rather than having patients generate activities, to reduce time burden and increase consistently. Other than that, its content is identical to that of the original AQLQ, and the items in both instruments concern topics derived from Kinsman's study[6] of asthma patients and their concerns, general health-related QOL measures, discussions with physicians, and interviews with patients. The topics include circumstances such as chest tightness, inability to carry out physical activities, experiencing symptoms resulting from cigarette smoke exposure, fear of not having medication available, and failure to get a good night's sleep due to asthma.

From among a large initial set of statements, a sample of asthma patients identified those circumstances or occurrences that had been troublesome to them in the previous year and

how important each was to them. The 32 items selected for the AQLQ-S were those that had the highest product of the proportion of individuals for whom the item was troublesome multiplied by its average importance across individuals. These items were grouped, on logical grounds, into 4 subscore domains: symptoms (12 items), activity limitations (11 items), emotional function (5 items), and exposure to environmental stimuli (4 items). No factor/cluster analysis procedure was used to ensure that the score domains were reasonably statistically independent. The composition of the initial pool of candidate items was not reported; nor was it reported whether the process of item selection eliminated items that might have tapped the impact of asthma on a wider range of dimensions of QOL (eg, social relations, financial well-being, and employment opportunities) that might be important to significant subsets of patients. The final selection, however, resulted in total scores on the AQLQ and AQLQ-S that were primarily a composite of 2 dimensions now considered to be indicators of asthma control—symptom frequency and activity limitations—plus a limited number of items that reflected the degree of negative emotions associated with asthma (concern or frustration about asthma and asthma medications, and fear of shortness of breath) and how frequently the respondent encountered or had to avoid agents in the physical environment that triggered symptoms. The number of items devoted to each domain was not planned to achieve adequate reliability in the resultant subscores, but simply reflected the distribution of items that survived the selection process; hence, the resultant reliability of the smaller subscales is low. No evidence of an analysis of discriminant validity of the subscale scores has been found, and so it is not known how much unique information they provide; such information would be essential to justifying their reporting and use.

The items in the AQLQ and AQLQ-S are in the form of questions: “How often did you experience [or did you feel, or were you bothered/limited by] X?” “How much Y did you feel?” or “How much were you limited in doing Z?” Four different 7-point Likert-type response scales are used: a frequency scale (23 items), an amount of discomfort/distress scale (2 items), and 2 different scales assessing degree of impairment (6 items and 1 item, respectively). Each of the scale points on each Likert scale is anchored by a word or phrase, rather than being anchored only on the extremes and midpoint, which is a common and well-justified practice. The use of so many descriptors is problematic. The 4 sets of scale descriptors are: (1) “totally,” “extremely,” “very,” “moderate,” “some,” “a little,” and “not at all limited”; (2) “severely,” “very,” “moderately,” “slightly,” “very slightly,” “hardly at all,” and “not limited at all”; (3) “a very great deal,” “great deal,” “good deal,” “moderate amount,” “some,” “very little,” and “no discomfort”; and (4) “all,” “most,” “a good bit,” “some,” “little,” “hardly any,” and “none of the time.” Some of these scales may be confusing to respondents because they mix adjectives with other grammatical elements, and some descriptive terms are relatively uncommon in American usage (“a good bit,” “a good deal”) and rarely used in psychometric scales. There is no published evidence that the anchor words or phrases can be consistently ordered by respondents independent of their numerical positioning on the response scales or that the relative positions of different phrases represent approximately equal psychometric intervals. It is also unclear that 4 different sets of responses are actually necessary.

The statistical and psychometric methodology used to obtain an estimate of the MCID on the AQLQ/AQLQ-S and other instruments has been seriously criticized.[7–9] Without recognition of the methodological problems, the estimated MCID of 0.5 units on the AQLQ-S score scale has been widely adopted as a criterion for a clinically meaningful group mean difference and, more recently, as a criterion for the minimum clinically meaningful change at the individual level, resulting in group comparisons in terms of the proportions achieving a difference of this magnitude or greater. The AQLQ-S has been administered along with other measures of clinical improvement in many studies with repeated measures, which would permit use of the commonly recommended approach to determination of the MCID. However, the MCID for the AQLQ-S has not been reexamined in light of data from these studies, and it remains unclear whether the commonly accepted value of 0.5 units is the minimal difference that has clinical importance.

Strengths and Weaknesses—Strengths of the AQLQ-S include the reliability of its total score, its responsiveness, and its widespread use and availability in many languages. It is free for use in some noncommercial clinical practice settings, but some research and strict copyright restrictions apply. The AQLQ-S provides separate and reliable measures of asthma symptoms and of asthma-related functional status (measured as activity limitations in this instrument)—currently viewed as elements of asthma control, a construct for which other instruments have become available since the AQLQ and AQLQ-S were originally developed. Weaknesses include its substantial overlap with domains assessed by newer measures of asthma control, the over-representation of these items in the total score, and hence the inability to distinctly measure the patient's perspective of the impact of asthma on his or her QOL, the lack of evidence of discriminant validity of its subscales and poor reliability of the smaller subscales, and the lack of research to validate (or modify) the conventionally accepted MCID value as a criterion for assessing improvement at either the individual or group level.

Recommendation—The subcommittee recommends classifying the AQLQ-S as a supplementary instrument for situations and purposes that can be justified in light of the limitations noted above.

Mini-Asthma Quality of Life Questionnaire (Developed by E.F. Juniper)

Summary—The Mini-Asthma Quality of Life Questionnaire (Mini-AQLQ) is a 15-item, asthma-specific instrument requiring 3–4 minutes to complete that measures health-related QOL in adults. It yields an overall score, as well as 4 subscale scores (symptoms, activities, emotions, and environment). All 15 questions are scored on 4 7-point Likert scales, and the overall score and subscale scores are simple averages of the responses to their component questions. The 5-item symptom scale is a measure of symptom frequency, and the 4-item activity scale is a measure of the extent to which an individual's asthma limits his or her ability to engage in various types of activities. The 3-item emotional scale reflects the extent to which the individual's asthma triggers feelings of frustration, fear, or concern, and finally, the 3-item environmental scale reflects the extent to which individuals are bothered by, or have to avoid, certain airborne environmental stimuli (dust, cigarette smoke, and air pollution). The Mini-AQLQ was developed as an alternative to the original AQLQ and

AQLQ-S, to meet the needs of large clinical trials and long-term monitoring, where efficiency (ie, 15 items compared with 32 on the AQLQ-S) may take precedent over precision of measurement. A composite approach was used to arrive at the Mini-AQLQ from the original instruments, with the goal of including the physical and emotional impairments that adults with asthma consider most important, while maintaining as much as possible the measurement properties of the original AQLQ and each of its 4 domains. First, items with high item-item correlations were evaluated by a clinician panel to see whether they were similar enough in concept to combine. Second, items in the activity domain were standardized using 4 of the 5 generic activities from the AQLQ-S. Finally, those items from the original AQLQ having the lowest impact scores in the original developmental work were removed until the prespecified number of items desired in each domain was reached. The Mini-AQLQ takes 3–4 minutes to administer and is free for use in some noncommercial clinical practice and research settings, with copyright restrictions as described for the AQLQ-S. The questionnaire may be self-administered or interviewer-administered, although no approved online version exists. It has good reliability and responsiveness, and is correlated with other measures of asthma status, but its psychometric properties are not as strong as those of the AQLQ and AQLQ-S. The Mini-AQLQ total score is still predominantly influenced by the symptom and activity domains, which collectively account for 9 of the 15 questions, although this is less an issue here than it is with the AQLQ and AQLQ-S. The Mini-AQLQ has been widely used in diverse samples, including in 21 countries outside the United States, but its psychometric properties have not been determined or reported in these latter samples.

Strengths and Weaknesses—The main advantages of the Mini-AQLQ over the larger AQLQ-S are its shorter length and its more balanced representation of the subscales in the overall score. Its weaknesses are similar to those of the parent instrument, and it has lower reliability than the parent instrument.

Recommendation—The subcommittee recommends classifying the Mini-AQLQ as a supplementary instrument for use in asthma research in which efficiency is prioritized over precision of measurement.

Living With Asthma Questionnaire (Developed by M.E. Hyland et al)

Summary—The Living With Asthma Questionnaire (LWAQ) is a 68-item self-reported, self- or interviewer-administered, multidomain scale designed to measure asthma-specific QOL in adults; it takes 15–20 minutes to complete. The instrument was developed to provide an outcome measure for use in clinical trials, as well as to assist individual patient management. The original item set was generated through focus groups consisting of adults who had asthma, who were asked about everyday experiences of living with asthma. These were refined through standard psychometric techniques (eg, a principal components factor analysis), using data gathered from a total of 783 patients recruited from multiple clinical sites. The scale consists of 25 positively worded items and 43 negatively worded items. Responses are on a 3-point scale (“untrue of me,” “slightly true of me,” “very true of me”) or “not applicable.” The LWAQ covers 11 domains of asthma experience: social or leisure, sport, holidays, sleep, work and other activities, colds, mobility, effect on others, medication

usage, sex, and dysphoric states and attitudes. Scale scores are calculated as average scores on all applicable items, after reversing the value of each negative item. In addition to providing subscores for each of the 11 domains, the LWAQ also can be divided into 2 construct subscales encompassing the patient's perception of functional limitations (also termed the "problems construct"—49 items) and the patient's perception of the emotional impact of limitations related to asthma (also termed the "evaluation construct"—19 items).

Strengths and Weaknesses—While the LWAQ includes questions related to asthma symptoms and functional status, it also contains a substantial number of items (more than 50% of the total number) focused more specifically on the emotional and social impact of having asthma. The LWAQ is unique in that it can be analyzed in 3 different ways in a clinical trial—on the basis of an overall score, in terms of 11 domains, and from the perspective of 2 construct subscales. There is some evidence that the construct subscales differentially predict outcomes in clinical trials and are differentially sensitive to change (eg, the problems construct maybe more sensitive to change over time compared with the evaluation construct; lung function and change in lung function may be more sensitive to cognitive factors than to emotional ones). There is little evidence that the individual domains differentially predict outcomes. The LWAQ has excellent internal consistency for the total scale and constructs, due in part to the large number of items in this instrument. Reliability is more variable across the domain scores. This questionnaire also has good test-retest reliability and good concurrent validity. Translations of the LWAQ exist in Danish, Dutch, Finnish, French, German, Italian, Japanese, Norwegian, and Swedish, although a description of the linguistic validation process used for these translations is not readily available.

Weaknesses include the following: At 68 items, this is the longest of the asthma-specific QOL measures, which reduces its feasibility for widespread use. While the LWAQ captures a number of domains, there are some potentially important domains missing (eg, financial problems associated with asthma). Also, there is little evidence of discriminant validity for the individual domain scores or that they differentially predict outcomes, and discriminant validity is unlikely to meet conventional criteria, since a single factor appears to characterize the instrument as a whole. Evidence for responsiveness of the instrument is lacking in US samples. The instrument has been used in only 1 study of lower income subjects in the United Kingdom and has not been used in ethnically and/or socioeconomically diverse US populations.

Recommendation—The subcommittee recommends classifying the LWAQ as a supplemental instrument for clinical trials in which (1) an instrument of this length is feasible, (2) its content is appropriate for the purpose of the trial, and (3) there is a recognition of the potential overlap with more recently developed measures of asthma control that include assessment of symptoms and functional status. The LWAQ provides a reliable measure of functional limitations due to asthma and of the patient's perception of the emotional impact of those limitations.

Modified Asthma Quality of Life-Marks (Developed by G.B. Marks)

Summary—The Modified Asthma Quality of Life (M-AQLQ-Marks) is an asthma-specific, self- or interviewer-administered 22-item instrument requiring less than 5 minutes to complete and designed to measure perceived QOL associated with asthma in adults. The recall period is 4 weeks. It differs from the original AQLQ-Marks in that 2 items were split into separate items and a 7-point Likert-type scale was used instead of a 5-point Likert scale. The increase in response options was designed to increase this instrument's reliability and responsiveness to change. It assesses 4 domains: (1) breathlessness (physical restrictions), (2) mood disturbance, (3) social dysfunction, and (4) concern for health. Like the original Marks instrument, it yields a total score and 4 subscale scores. Ten items appear to measure QOL; 7 measure physical symptoms and health status; and 5 measure emotional states. Unlike the original AQLQ-Marks, items on the M-AQLQ-Marks are not transformed, so that higher scores on the M-AQLQ-Marks indicate less impairment. Both the original and M-AQLQ-Marks can be administered by telephone. Both instruments attempt to ascertain how asthma affects a patient's life with regard to his or her social situation, psychological well-being, expectations, values, and perceived impact of having to avoid places or activities that could trigger increased asthma symptoms. The final items included in the original AQLQ and M-AQLQ-Marks were empirically determined. Initial identification of items for the questionnaire was derived from patients with asthma who participated in a focus group, from interviews with asthma nurse educators, and from the clinical experience of the investigators. Subsequent drafts of the instrument were subjected to validation studies with asthma patients. A factor analysis performed on the initial item pool confirmed that the components were broadly similar to those domains that formed the initial framework, and that analysis also identified a smaller set of items that best measured 4 key domains, which now constitute subscales and make up a total score. The instrument's concurrent validity is supported by the finding that the total score and all 4 subscale scores were significantly correlated with symptoms, medication use, FEV_1, global health rating, and all SF-36® Health Survey subscales. The total score also was associated with clinical asthma severity according to the severity criteria in the National Asthma Education and Prevention Program (NAEPP) guidelines.

Strengths and Weaknesses—The M-AQLQ-Marks was developed to measure the impact of asthma on QOL. Ten of 22 questions within the 4 domains appear to assess the perceived impact of asthma on QOL, and 5 questions relate to emotional states; these 15 questions specifically deal with topics that are relevant to concerns of asthma patients. The M-AQLQ-Marks is user friendly and can be completed in about 5 minutes. Internal consistency and test-retest reliability are higher for the M-AQLQ-Marks than for the original instrument, although the very high internal consistency of the total score raises questions about the discriminative validity of the subscales. The instrument is responsive in that it is able to detect within-subject changes in total score over time and is associated with changes in total score and changes in symptoms, FEV_1, self-rated severity, and medication use. The minimal floor and ceiling effects of M-AQLQ-Marks demonstrate its potential usefulness as a clinical assessment tool. The M-AQLQ-Marks has been validated in a socioeconomically diverse Australian sample. Weaknesses include the consideration that its MCID of 0.5 was calculated using the same methodology used in Juniper's AQLQ for determining the MCID,

which has been questioned, and only limited data exist regarding the MCID for either the original AQLQ-Marks or the modified instrument. Few clinical studies have used the M-AQLQ-Marks. Further, neither the original AQLQ-Marks or the M-AQLQ-Marks has been validated in US study populations or used extensively in populations outside Australia.

Recommendation—The subcommittee recommends classifying the M-AQLQ-Marks instrument as a supplementary instrument for clinical trials in which a short questionnaire is desired; 10 of the 22 items measure patient perception of the impact of asthma on QOL, although data on its use in clinical trials are limited.

Asthma Short Form (Developed by Integrated Therapeutics Group and QualityMetrics, Inc)

Summary—The Asthma Short Form (ASF) is a 15-item, self-administered instrument requiring an estimated 3–4 minutes to complete. It is based on the original 20-item AQLQ-Marks instrument and items from the Integrated Therapeutics Group (ITG) physical and psychosocial symptom/side effects batteries. Its purpose is to assess symptoms, functional status, and other constructs considered relevant to QOL in adolescents (aged 14 years and above) and adults. Like the AQLQ-Marks, it has a 4-week recall period and a reading grade level of 4.8 but requires only 3–4 minutes to administer. The ASF was created to improve on lengthy instruments (ie, LWAQ, St George's Respiratory Questionnaire) and the original, nonstandardized AQLQ developed by Juniper, and to eliminate item overlap between 2 subscales in the AQLQ-Marks, while retaining or improving its reliability and validity relative to that instrument.

The ASF has 5 domains: the symptom-free index (5 items), functioning with asthma (5 items), psychosocial impact (3 items), confidence in one's health/well-being (1 item), and energy (1 item). The psychometric methodology used to develop this instrument was very thorough, involving administration of items or draft forms to 3 patient samples from a clinical trial, an observational study, and a study that provided only cross-sectional data. The initial pool of 26 items was subjected to similar analyses in all 3 samples: (1) factor analysis to assign items to scales; (2) elimination of items with floor or ceiling problems and deletion of items so as to retain those that best predicted patient ratings of asthma severity, NHLBI severity classification, and lost work days; (3) evaluation of the predictive ability of the shorter relative to the longer version; and (4) specification and evaluation of the short form scale scores. Means and SDs have been reported for the ASF total, and all 5 subscale scores in each of the 3 samples. Only 1 sample had any substantial representation of racial/ethnic minorities (black or Hispanic) or persons with limited education.

Strengths and Weaknesses—Strengths of the ASF include its careful psychometric development, acceptable reliability, and superiority to the (longer) AQLQ-Marks in sensitivity to group differences and associations with other important asthma outcomes. Weaknesses include its relatively limited use, uncertain availability, the substantial role played by its symptom-free index in its predictive power, and the modest improvement it provides over the predictive power of a generic health QOL instrument, the physical summary and role-physical scores of the SF-36®. This instrument provides separate reliable measures of (freedom from) asthma symptoms and of asthma-related functional status, but

the remaining 5 items, comprising 3 scales, 2 with a single item each, do not provide a reliable measure of patients' perception of their asthma's impact on their lives.

Recommendation—The use of the ASF, even as a supplementary instrument, cannot be recommended due to its uncertain availability and its very limited assessment of patients' perceptions of the impact of asthma on their QOL.

St George's Respiratory Questionnaire (Developed by P.W. Jones)

Summary—The St George's Respiratory Questionnaire (SGRQ) was designed to measure health impairment and perceived well-being (QOL) associated with airways disease, although not specifically asthma, and was seen as a potentially more responsive alternative to generic instruments such as the Sickness Impact Profile and Quality of Well-Being Scale. The SGRQ yields a total score based on all 50 items and scores for 3 subscales (symptoms, activity, and impact) whose structure was supported by the results of a principal components analysis. The 8 questions that make up the symptoms subscale encompass the frequency, intensity, and duration of breathing symptoms. The 16-item activity subscale consists of 7 yes/no questions that reflect whether certain activities (eg, getting dressed or washed, walking outside on level ground) make the respondent feel breathless and 9 yes/no questions about whether certain activities are affected by the respondent's breathing (eg, "I take a long time to get dressed or washed"; "I walk slower than other people"; or "I stop for rests"). Finally, the 26-item impact subscale assesses the impact of the respondent's breathing problems on a wide variety of domains: 2 items on how great a problem the person's chest condition is; 2 items on breathlessness when talking or bending over; 4 items on sleep disturbance, tiredness, and pain associated with the person's condition; 8 items on emotions, nuisance, or uncontrollability associated with breathing problems; 4 items on how much medication affects QOL; and 6 items on whether the individual cannot engage in certain activities due to breathing problems. The majority (at least 19) of the items in the impact subscale appear to directly measure the perceived impact of the respondent's breathing on QOL. These items do not assess economic impacts, however.

Altogether, the 50 items that constitute the SGRQ reflect a mix of yes/no questions and ordinal response option questions. The responses to these questions are individually weighted, with a total of 76 non-zero-weighted response options. The weights reflect the relative level of distress associated with each response and were computed by having 124 asthma patients drawn from 4 countries rate the degree of distress they would experience for the situation described by each individual response for each item. Ratings were made on a 10 cm (centimeter) visual analog scale ranging from "no distress" to "maximum imaginable distress," and the final weights were calculated by expressing the mean ratings as a percentage of the maximum possible rating of 10 cm. The weights are reported to be relatively unaffected by age, sex, and nationality, and not to differ between patients with asthma and patients with chronic obstructive pulmonary disease (COPD). Due to the nature of these weights, even questions that do not directly assess the impact of the individual's asthma on QOL, such as those in the symptom subscale, may indirectly serve as a measure of the distress that is caused by these symptoms and, in that sense, may constitute a measure of the impact of asthma on the patient's QOL.

Strengths and Weaknesses—Strengths include the fact that the SGRQ is free for use in noncommercial clinical practice and research. Although the SGRQ is designed for self-administration, someone should be available to answer questions, if required. Telephone administration of the SGRQ also has been validated, as has computer-based presentation, but postal administration has not. Further, the scoring of the instrument is complex and should be done using a computer. The SGRQ is reliable and responsive to changes in COPD status, although less information is available on its performance in samples of individuals with asthma. The SGRQ is available in numerous languages, and evaluations of the psychometric properties of many of the translated versions have been published. Its weaknesses are the length and time to completion: at 50 items and taking 8–15 minutes to complete, it is 1 of the longest QOL instruments for patients with asthma. In addition, because of the way in which the response weights were constructed, the SGRQ may tap patients' perceptions of the direction and degree of impact that breathing problems have on certain dimensions of their lives, although only indirectly, but does not assess certain dimensions (such as financial status and employment). Finally, despite its worldwide use, the psychometric properties of the SGRQ have not been assessed in a diverse sample of people who have asthma in the United States.

Recommendation—The subcommittee recommends classifying the SGRQ as a supplementary instrument for use in asthma research because of the limitations imposed by the length of the instrument.

Airways Questionnaire-20 (Developed by E.A. Barley, F.H. Quirk, and P.W. Jones)

Summary—The Airways Questionnaire-20 (AQ-20) is a short version (20 items) of the SGRQ. The AQ-20 is a unidimensional scale; no domain subscores are suggested. Of the 20 items, at least 6 appear to measure symptoms (eg, breathlessness, coughing attacks), 5 appear to measure health status (eg, difficulty engaging in activities because of symptoms), 5 to assess emotions related to symptoms (eg, worry, restlessness), and 4 QOL, more narrowly defined (eg, bother, cannot enjoy a full life). The instrument employs yes/no responses rather than a Likert scale, making it very simple and quick to administer (2–3 minutes). There is no cost for using this instrument, but permission must be obtained from the authors.

With respect to rationale and construct validity, the authors sought to develop a brief instrument with low respondent burden that could be used in clinical practice with patients with either asthma or COPD and that was minimally influenced by demographic variables such as age, sex, and disease duration. They employed a criterion-based process of item selection and reduction that utilized both patient perceptions and factor analysis. There is evidence for the instrument's concurrent validity: The AQ-20 total score correlated significantly with generic QOL instruments (SF-8®), perceived stress, and asthma severity, as well as depression and anxiety; with 7 of 8 SF-36® scales; LWAQ and AQLQ scales; and with SGRQ. Sample demographics are not available in all published studies, but a recent US study sample using the AQ-20 was predominantly white and relatively well educated; a recent UK study sample was 50% South Asian; and the instrument has recently been used in Japan and Finland. With respect to responsiveness, there is evidence that the AQ-20 is able

to detect within-subject changes over time. Change in AQ-20 was correlated with change in total and all subscale scores for SGRQ and the AQLQ developed by Juniper. An MCID has not been established for the instrument.

Strengths and Weaknesses—The advantage to the AQ-20 is that it is a significantly shorter version of the well-established SGRQ; however, the AQ-20 has less published evidence of use in clinical research than the SGRQ. Limitations include the lack of subscores to distinguish patient perception of the impact of asthma on QOL from the large proportion (11/20) of questions that relate to health status or functional status.

Recommendation—The subcommittee recommends classifying the AQ-20 as a supplementary instrument for asthma clinical research in which the breadth of domains used in the SGRQ is desired but brevity is required, recognizing that the number of items measuring patient perception of the impact of asthma on QOL is limited.

ASTHMA-RELATED QUALITY OF LIFE INSTRUMENTS FOR PEDIATRIC STUDY POPULATIONS

QOL instruments developed for adults are not appropriate for use with children. There are several special considerations in developing pediatric instruments that have been described as the “4 Ds of childhood”: developmental change, dependence on adults, different disease epidemiology from adults, and demographic characteristics unique to childhood.[10] Because of these challenges, pediatric QOL instruments are relatively less developed than adult instruments, but a growing number of pediatric instruments are available.[11]

Researchers should consider 2 interrelated, key questions. First, will data be obtained from the child directly or from a proxy respondent (typically a parent)? For children who are too young or too ill to respond, parents are often the only logical informants. However, parents and children may have different views on the impact of disease, and some attributes of health, such as emotional distress, are difficult for parents to observe. Parental assessments also may be incomplete because most school-aged and older children are away from their parents for many hours each day. Thus, there is consensus that, as appropriate, children should report on their own health[12] and that, whenever possible, information about QOL should be obtained from both the parent and the child.[11] The second question for researchers to consider is whether the instrument been developed and tested for the child age group in their study. Pediatric instruments should be tested with large and diverse enough samples to assess performance by age categories. Children’s developmental capabilities shape their understanding of health. The dimensions of QOL may be less differentiated for the younger child. In very young children, the measurement of QOL may be limited to whether the child is temporally upset, frustrated, angry, frightened, and/or hurting as the result of asthma. Asking children younger than 10 years of age to make complex, qualitative judgments about their QOL may well be beyond their developmental capabilities. Thus, pediatric questionnaires for young children and those that span a large age range must be interpreted with caution. As they grow older, children are more likely to comprehend more abstract concepts related to QOL. A related consideration is mode of administration and available study resources; collecting data from children generally takes more time, and collecting data

from younger children may require interviewer administration. Researchers should obtain QOL data in pediatric studies, but they need child-friendly and child-appropriate study design and instruments appropriate for administration to children or their parents.

Summary reviews of 4 pediatric asthma QOL instruments follow. Not included in this review are the Childhood Asthma Questionnaires, which were originally developed in 3 different forms for children of different age ranges (form A for children aged 4–7 years, form B for those aged 8–11 years, form C for those aged 12–16 years). These instruments are not currently available for general use.

Child Health Survey for Asthma (Developed by the American Academy of Pediatrics)

Summary

The Child Health Survey for Asthma (CHSA) is a paper-and-pencil instrument completed by parents of children aged 5–12 years with chronic asthma. It takes 20 minutes to complete. The CHSA was designed to enable children with asthma and their parents to provide input on how the children view their QOL. The instrument includes a broad spectrum of 48 childand family-focused items divided into 5 subscales (physical health, 15 items; activity [child], 5 items; activity [family], 6 items; emotional health [child], 5 items; and emotional health [family], 17 items). For each of the 5 scales, computed scores are transformed, giving each scale a minimum score of 0 and a maximum score of 100. For all CHSA scales, higher scores indicate more positive outcomes or better health status. There are specific questions that refer to the way a child's degree of impairment affects either the child or the family. For example, questions about family activity include "We changed family plans or trips because we were not sure when an attack could occur"; "We canceled social plans because our child had a problem with asthma"; and "We avoided activities or places that might trigger an attack (such as visits to the zoo or a farm, camping, or going outside in the cold)." The responses are "all of the time," "most of the time," "some of the time," "little of the time," and "none of the time." The questions about the emotional health of the child and the emotional health of the family also can refer to how much the degree of impairment due to asthma matters to the child and family. The CHSA yields 5 subscale scores (physical health, child activity, family activity, child emotional health, and family emotional health), with limited data on the MCID for just 1 subscale.

In developing the instrument, the researchers based initial items on comments from an American Academy of Pediatrics workgroup, parent focus groups, and parent cognitive interviews. The initial version of the CHSA had 71 questions, which were reduced to 48 items on the basis of several studies and specific elimination criteria (eg, low expert review rating, high ceiling effect, correlation and covariance with other items). In addition, content validity, internal consistency, and test-retest reliability have been assessed through a series of studies.

Strengths and Weaknesses

The strengths of the CHSA are that the instrument is freely available and has well-defined psychometric properties. Perceived impact of asthma on QOL might be inferred from the family activity subscale (changes in family activities because of the child's asthma), the child emotional health subscale (child's frustration and upset related to asthma and asthma treatments), and the family emotional health subscale (bother associated with asthma management, frustrations, concerns and worries, and stress for the family because of the child's asthma). The instrument has been used in socioeconomically and ethnically diverse populations within the United States, and a version for Spanish-speaking US residents has been developed. In addition, there is an accompanying version of the CHSA that can be completed by the child (CHSA-C). Weaknesses include limited published data on population norms.

Recommendation

The subcommittee recommends classifying the CHSA as a supplementary instrument, recognizing that much of the content (20 of the 48 items) includes functional status and health status and may overlap with that of measures of asthma control.

Child Health Survey for Asthma-Child Version (Developed by the American Academy of Pediatrics)

Summary—The Child Health Survey for Asthma-Child Version (CHSA-C) is an asthma-specific QOL instrument administered to children, requiring an average of 10 minutes to complete, depending on the child's age; it is based on the CHSA, which is administered to caregivers. The CHSA and CHSA-C may be used as stand-alone or companion instruments. The 25 items include 3 scales: physical health (7 items), child activities (6 items), and emotional health (12 items). The 7 items on physical health focus on asthma symptoms. The 6 items on child activities address asthma-related limitations in school, play, and sports. The items about emotional health include 8 questions focused on feelings about asthma and 4 items about stress, frustration, anger, and knowledge about asthma medications. For example, items include "My asthma causes stress in my family"; "I am frustrated that other people don't understand what it is like to have asthma"; and "Sometimes I get angry and ask 'why is this happening to me?'" Responses are "strongly disagree," "disagree," "not sure," "agree," and "strongly agree." The items that focus on emotional health, stress, frustration, and anger may reflect the degree to which impairment from asthma matters to the child, as well as the child's perception of the effect on the family. For each scale, scores are transformed to a scale of 0 to 100, with 100 being most positive.

Items for the CHSA-C were developed based on intensive individual interviews with children, as well as expert review. The authors have published a description of the "psychometric properties of the CHSA-C, descriptive statistics, reliability (internal consistency and test-retest reliability), validity, and differences in performance characteristics by selected covariates (eg, child sex, race/ethnicity, and household income)."

Strengths and Weaknesses—Strengths include appropriateness for use by children aged 7–16 years. Weaknesses of the CHSA-C include limited published psychometric

properties, lack of population norms, overlap in content with measures of asthma control regarding the assessment of symptoms and functional status, and relative lack of use in the published literature. However, this is a relatively new instrument (2008).

Recommendation—The subcommittee recommends classifying the CHSA-C as an emerging instrument that requires further investigation and evaluation.

Pediatric Asthma Quality of Life Questionnaire (Developed by E.F. Juniper)

Summary—The Pediatric Asthma Quality of Life Questionnaire (PAQLQ), developed in the mid-1990s by Juniper and colleagues, is a 23-item, child-reported instrument of the problems (physical, emotional, and social) most troublesome to children with asthma. It requires 10–15 minutes to complete. The instrument in use today also may be found under the name Standardized Pediatric Asthma Quality of Life Questionnaire (PAQLQ(S)). There is no cost for using the PAQLQ in noncommercial research or practice; there is, however, a fee for commercial use. Copyright restrictions apply to all uses.

To develop the original content, a list of 77 candidate items was generated from a variety of sources, including interviews with health professionals, a review of the literature, and interviews with children and parents, who were encouraged to suggest aspects of their asthma that imposed a burden on them, including emotional and physical effects. One hundred Canadian pediatric asthma patients were then interviewed to rate the frequency and importance of the 77 candidate items. The resulting instrument includes symptoms (eg, feel out of breath, trouble sleeping). About half the symptom items might be considered to assess QOL because they assess the extent to which the symptoms bother the child. Also measured are activity limitations and emotional impact (eg, feeling left out because of asthma, feeling frustrated because of asthma). An overall PAQLQ score is calculated, as are 3 domain subscales: symptoms (10 items), activity limitations (5 items), and emotional function (8 items). All items use a 7-point Likert response scale (eg, 1 = extremely bothered; 7 = not bothered) with a 1-week recall period. The overall PAQLQ score is the mean of all 23 items, and the individual domain scores are the means of the items in each domain.

Strengths and Weaknesses—The PAQLQ is a relatively short instrument designed for children (aged 7–17 years) to report on their own experiences. The instrument includes symptoms of asthma, as well the child's emotional reactions to the symptoms and limitations caused by asthma. The developers advise using the interviewer-administered version of the PAQLQ for all children younger than 11 years. The PAQLQ demonstrates good measurement properties; eg, internal consistency and test-retest reliability, plausible cross-sectional associations with other measures, and responsiveness to change and group differences. Weaknesses include the fact that age-specific psychometric information about the PAQLQ is limited, and this wide age range crosses several important developmental stages. Further, information on the discriminative validity of its subscales is unavailable. The social and economic diversity of the original sample is unknown, although the instrument has subsequently been used in many pediatric asthma studies of diverse populations in many countries and is available in multiple languages. Furthermore, the PAQLQ reading level is not documented.

Recommendation—The subcommittee recommends classifying the PAQLQ as a supplemental instrument for pediatric studies, recognizing the limitations noted above, particularly the predominance of items related to health status and functional status and potentially limited ability to yield a distinct measure of the perceived impact on QOL, as well as the wide age range the instrument expects to cover.

Pediatric Asthma Caregiver Quality of Life Questionnaire (Developed by E.F. Juniper)

Summary—The Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ), published in the mid-1990s by Juniper and colleagues, was designed to measure the impact of the child's asthma on the QOL of the caregivers (typically, parents). It takes 3–5 minutes to complete. There is no cost for using the PACQLQ in noncommercial research or practice; there is, however, a fee for commercial use. Copyright restrictions apply to all uses. In instrument development, items were generated through literature review, discussion with health professionals, and unstructured interviews with parents of children with asthma. One hundred primary caregivers were then asked to rank the resulting 69 candidate items in terms of frequency and burden. The final instrument contains 13 items divided between activity limitations (eg, interference with work or sleep) and emotional function (eg, upset due to child's symptoms, worry over medication side effects). Respondents were asked to assess how, during the past week, their children's asthma had interfered with their normal daily activities and how this had made the caregivers feel. An overall PACQLQ score was calculated, as well as 2 domain subscales: activity limitations (4 items) and emotional function (9 items). All items use a 7-point Likert response scale (eg, 1 = "very worried"; 7 = "not worried") with a 1-week recall period. The overall PACQLQ score is the mean of all 13 items, and the individual domain scores are the means of the items in each domain subscale.

Strengths and Weaknesses—The strengths of the PACQLQ: It is a short, readily administered instrument for assessing the impact of asthma on caregivers', not children's, QOL. In addition, the PACQLQ was originally tested on a small (n = 52) Canadian sample of parents and was able to detect changes in both the activity and emotional domains among parents who reported that their child's asthma status had changed. The social and economic diversity of the original sample is unknown, although the instrument has subsequently been used in many pediatric asthma studies of diverse populations and is available in multiple languages. Its limitations include potential overlap with measures of asthma control and the small sample size of the parent group on which the instrument was tested.

Recommendation—The subcommittee recommends classifying the PACQLQ as a supplemental instrument for pediatric studies when understanding the effect of a child's asthma on caregivers is of importance. However, researchers should consider the potential overlap between instrument content and measures of asthma control, and also that the instrument only assesses the impact of the child's asthma on the caregiver in terms of the emotional and activity domains (ie, not economic, social, or other domains).

Pictorial Quality of Life Measure for Young Children With Asthma (Developed by R.S. Everhart and B.H. Fiese)

Summary—The Pictorial Quality of Life Measure for Young Children With Asthma (Pictorial PAQLQ) is a new asthma-specific QOL instrument for children, adapted from the PAQLQ that was developed by Juniper. Information on time required to complete this instrument was not reported. It includes 2 subscales: symptoms (10 items) and emotions (5 items). The items in the symptoms subscale focus on how frequently symptoms such as cough and wheeze and difficulty sleeping bother the child. The emotional scale inquires about feelings of worry, anger, and crankiness because of asthma. The activities subscale that is part of the original PAQLQ is not included in this version.

This instrument was designed for pencil-and-paper administration for children with asthma aged 5–7 years. It is administered by an interviewer, with pictorial representations to allow for developmentally appropriate reporting directly from young children. The pictorial response format allows the child to anchor his or her response decisions among 3 thermometers, which are empty, half-filled, and filled, to represent “none,” “some,” or “all of the time.” Children are asked to rate their response to each item anywhere on a line below the 3 thermometers, and a scoring template is used to score responses on the line. The range of values is 1 (empty thermometer) to 7 (full thermometer). Subscale scores are calculated from the mean of responses for each subscale, and total QOL is calculated from the mean of all responses.

Initial testing included a confirmatory factor analysis and validity testing with a diverse sample of 101 children with asthma. Convergent validity was assessed by correlating scores with children’s FEV_1 and caregiver scores on the PACQLQ. Discriminant validity of the total score was assessed by comparing scores with measures of children’s verbal ability. Predictive validity was assessed by comparing scores on the instrument with later scores on the PAQLQ for a subset of children at 8 years of age (n = 48 for the longitudinal assessment).

Strengths and Weaknesses—The Pictorial PAQLQ holds promise as a new instrument for direct reporting of QOL from young children. This is particularly important because young children can provide information that is distinct from that obtained from their caregivers, and few instruments currently are available for this age group. Initial testing of this instrument suggests adequate psychometric properties and provides preliminary evidence of convergent, discriminant, and predictive validity for the overall score. The instrument was developed with specific attention to the cognitive abilities and developmental status of young children. Its limitations: No discriminant validity information is available for the subscores. In addition, further testing to confirm the proposed factor structure and provide further validation is needed.

Recommendation—The subcommittee recommends classifying this instrument an emerging instrument for use in clinical research.

Pediatric Quality of Life Inventory 3.0 Asthma Module (of the Pediatric Quality of Life Inventory) (Developed by J.W. Varni)

Summary—The Pediatric Quality of Life Inventory 3.0 Asthma Module (PedsQL 3.0 Asthma Module) is 1 of many disease-specific modules that are part of the Pediatric Quality of Life Inventory (PedsQL). The PedsQL Measurement Model uses a modular approach, with generic and disease-specific scales. It is noteworthy that the generic QOL Module, not the Asthma Module, contains the QOL questions. The PedsQL 3.0 Asthma Module is combined with this generic QOL instrument. The Asthma Module collects additional information regarding social relations, worry, and specific asthma treatment issues; however, it does not measure the child's or caregiver's perception of the impact of asthma on the child's QOL. Information on the time required to complete this instrument was not reported.

The asthma module is designed for children and adolescents aged 2–18 years. There are a version for parent report on toddlers (aged 2–4 years) and versions for parent report and child report for young children (5–7 years), children (8–12 years), and teens (13–18 years). In the disease-specific Asthma Module, there are 4 scales (asthma symptoms, 11 items; treatment problems, 11 items; worry, 3 items; and communication, 3 items). The treatment-problem questions are difficult to categorize in Table IV. These range from "Do your medicines make you feel sick?" to "Do you have trouble using your inhaler?" to questions about adherence, such as, "Do you refuse to take your medicines?" to questions about being scared, such as "Do you get scared when you have to go to the doctor?" As a result, the PedsQL 3.0 Asthma Module focuses more on assessment of asthma symptoms and problems than on general QOL. The questions were based on previous experience with the generic PedsQL, focus groups, cognitive interviews, pretesting, and field testing. A 5-point scale is used. Items are reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0); higher scores indicate better QOL. For self-report by a young child, a simplified 3-point scale is used (0 = "not at all a problem," 2 = "sometimes a problem," and 4 = "a lot of a problem"). Reliability and validity have been assessed in several different studies.

A modified version of the PedsQL 3.0 Asthma Module, called the PedsQL 3.0 SF22 Asthma Module, includes questions about asthma symptoms (eg, problems with asthma symptoms, 11 items) and treatment problems (eg, problems with medicines or inhalers, 11 items). These 2 components were considered to be most relevant and were retained in the PedsQL 3.0 SF22 Asthma Module. These scales have demonstrated reliability (Cronbach's $\alpha \geq .70$) and validity in previous analyses.[13]

Strengths and Weaknesses—Although the PedsQL core instrument is well defined and versions for 3 different age groups were developed, the psychometric properties of the asthma module instrument are still emerging. Weaknesses include the fact that the instrument's questions are dominated by questions of asthma management—that the asthma module does not directly assess the child's perspective on how his or her life is affected by asthma, or how much asthma bothers him or her. There are limited published data on

population norms, respondent burden, and the minimally important difference. Except for cases of unfunded academic research, there is a fee for using this instrument.

Recommendation—The subcommittee recommends classifying the PedsQL 3.0 Asthma Module as a supplementary instrument for use in clinical research.

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, the Agency for Healthcare Research and Quality, 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

6MWD	6-minute walking distance
ABP	Asthma Bother Profile
ACQ	Asthma Control Questionnaire
AIS-6	Asthma Impact Survey
AOMS	Asthma Outcomes Monitoring System
AQ-20	Airways Questionnaire-20
AQLQ	Asthma Quality of Life Questionnaire
AQLQ-S	Asthma Quality of Life Questionnaire-Standardized
ASF	Asthma Short Form
ATAQ	Asthma Therapy Assessment Questionnaire
ATS	American Thoracic Society
BMI	Body mass index
CHSA	Child Health Survey for Asthma
CHSA-C	Child Health Survey for Asthma-Child Version
cm	Centimeter(s)
COPD	Chronic obstructive pulmonary disease
ED	Emergency department
ERS	European Respiratory Society
FEV_1	Forced expiratory volume in 1 second
FQHC	Federally qualified health center

FWA	Functioning with asthma
GPC	Generalized partial credit
HAD	Hospital Anxiety and Depression Self-Assessment Score
HRQL	Health-related quality of life
ICC	Intraclass correlation coefficient
IRT	Item response theory
ITG	Integrated Therapeutics Group
IVR	Interactive voice response
LASS	Lara Asthma Symptom Scale
LWAQ	Living With Asthma Questionnaire
M-AQLQ-Marks	Modified Asthma Quality of Life
MCID	Minimal clinically important difference
Mini-AQLQ	Mini-Asthma Quality of Life Questionnaire
MRC	Medical Research Council
NAEPP	National Asthma Education and Prevention Program
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
PACQLQ	Pediatric Asthma Caregiver Quality of Life Questionnaire
PAQLQ(S)	Standardized Pediatric Asthma Quality of Life Questionnaire
PAQLQ	Pediatric Asthma Quality of Life Questionnaire
PDA	Personal digital assistant
PedsQL 3.0 Asthma Module	Pediatric Quality of Life Inventory 3.0 Asthma Module
PedsQL	Pediatric Quality of Life Inventory
PEF	Peak expiratory flow
PIA	Psychosocial impact of asthma
Pictorial PAQLQL	Pictorial Quality of Life Measure for Young Children With Asthma
QOL	Quality of life
RV%	Relative validity percentage
SABA	Short-acting β-agonist
SCHIP	State Children's Health Insurance Program
SEM	Standard error of measurement

SES	Socioeconomic status
SFI	Symptom-free index
SGRQ	St George's Respiratory Questionnaire
SIP	Sickness Impact Profile
VLA	Valued life activity
WISC	Wechsler Intelligence Scale for Children
WPPSI	Wechsler Preschool and Primary Scale of Intelligence

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TABLE I

Recommendations for classifying asthma-related quality of life measurement instruments for NIH-initiated clinical research

	Characterization of study population for prospective clinical trials (ie, baseline information)	**Prospective clinical trial efficacy/ effectiveness outcomes**	**Observational study outcomes***
Core outcome instrument	None	None	None
Supplemental instrument	Same as for "Prospective clinical trial efficacy/ effectiveness outcomes"	ADULT **1** ABP **2** AIS-6 **3** AQLQ-S **4** Mini-AQLQ **5** LWAQ **6** Modified AQLQ-Marks **7** SGRQ **8** AQ-20 CHILDREN **1** CHSA **2** PAQLQ **3** Pediatric Caregiver AQLQ **4** PedsQL 3.0 Asthma Module	Same as for "Prospective clinical trial efficacy/ effectiveness outcomes"
Emerging instrument		**1** CHSA-C **2** Pictorial PAQLQ	
Call for new instruments		Develop and evaluate instruments appropriate for different age groups that provide a separate measure of the patient's perception of the impact of asthma on QOL (distinct from symptoms and functional limitations).	
See Table III for methods for measuring and reporting QOL measures.			

ABP, Asthma Bother Profile; *AIS-6,* Asthma Impact Survey; *AQ-20,* Airways Questionnaire-20; *AQLQ,* Asthma Quality of Life Questionnaire; *AQLQ-S,* Asthma Quality of Life Questionnaire-Standardized; *CHSA,* Child Health Survey for Asthma; *CHSA-C,* Child Health Survey for Asthma-Child Version; *LWAQ,* Living With Asthma Questionnaire; *NIH,* National Institutes of Health; *PAQLQ,* Pediatric Asthma Quality of Life Questionnaire; *PedsQL,* Pediatric Quality of Life Inventory; *Pictorial PAQLQL,* Pictorial Quality of Life Measure for Young Children With Asthma; *QOL,* quality of life; *SGRQ,* St George's Respiratory Questionnaire.

*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

Key points and recommendations

1	QOL is an important dimension of asthma outcomes, distinct from other outcome measures of clinical signs and symptoms.
2	Currently available QOL instruments vary in the domains they measure. By definition, asthma QOL instruments should measure patients' personal perceptions of the impact of asthma on the quality of their lives. Many current QOL instruments measure a different domain—namely, impairment, which may include the patient's symptoms or functional status (ie, the ability to perform daily activities or some set of minimum physical activities). Some instruments measure asthma's impact on social, psychological, and emotional well-being, as well as financial status. Although, in general, we would expect higher symptom levels and poorer functional status to be associated with reduced QOL, a patient's perspective on disease impact can vary greatly as a function of the patient's own priorities, expectations, and lifestyle. Thus, a key defining characteristic of any measurement of QOL is that it should assess the degree to which impairment matters to the patient.
3	It is important to identify exactly what an instrument measures and what domain(s) generate the scores derived from the questionnaire.
4	Although internal consistency, reliability, and concurrent/predictive associations with other outcomes has been established for a number of instruments, many suffer from 1 or more of the following limitations: • Lack of information about key development or validation processes. • A mixture of domains within the same instrument and summary scores that are based on items from multiple domains. For example, many instruments comprise mainly symptom or functional status items, which are included in a total score, with few items assessing patients' perspectives on how they are affected by these conditions. • Subscores being reported and recommended despite limited evidence regarding subscore discriminant validity (ie, that each subscore provides unique information). Evidence of an acceptable level of discriminant validity is essential to justify reporting and use of instrument subscores. • Lack of information about core psychometric properties. • Either complete lack of information on an MCID or else use of questionable methodology to establish a value for MCID. This is important, because achieving differences between groups or changes in the same individuals over time that meet or exceed the MCID plays a critical role in evaluating the benefit of a medical or other treatment. • Limited validity data on populations that are disproportionately affected by asthma—ie, low-income or minority populations—or for low-literacy populations.
5	No particular QOL instrument is recommended as a "standard." Selecting from the currently available instruments (see Tables III and IV) will depend on the domains of interest and the characteristics (eg, demographics, practicality) most relevant to a particular clinical research project.
6	Many instruments have been translated into languages other than English; several used rigorous translation and back-translation methods. Such rigor is encouraged to address the cultural context of questions.
7	QOL instruments also need to be age-appropriate. Caution should be used with instruments that cover a wide age range because these may not adequately account for different age-related developmental capabilities. Further, there are limited data on the use of QOL instruments for the elderly, among whom there may be confounding issues of comorbidities.
8	There is benefit in using even imperfect QOL instruments if their domain coverage includes content that taps dimensions of QOL and there is an accurate understanding of any limitations. QOL is an important construct for characterizing patient populations and evaluating therapeutic interventions, and this construct is not captured in other biological or clinical asthma outcome measures or even measures of functional status or other patient-reported outcomes. Functional status and symptoms are increasingly viewed as domains of asthma control, and measures of these constructs have been recommended in this article.
9	Research is strongly recommended to develop instruments that provide a separate measure of the patient's perception of the impact of asthma on QOL and that tap all the key dimensions of QOL. Instruments that focus on the patient's perspective on asthma's impact on his or her QOL could add unique value to the "toolbox" of asthma assessments and outcome measures.

MCID, minimal clinically important difference; *QOL*, quality of life.

TABLE III

Summary of adult quality of life instruments

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
Author/developer											
	Hyland (mhyland@plymouth.ac.uk)	Kaiser Permanente and Quality Metrics, Inc (www.qualitymetric.com)	Juniper (www.qoltech.co.uk)	Juniper (www.qoltech.co.uk)	Juniper (www.qoltech.co.uk)	Hyland, Dann, & Finnis	Marks	Marks	Integrated Therapeutics Group & Quality Metrics, Inc	P.W. Jones (www.healthstatus.sgul.ac.uk)	Barley, Quirk, & Jones (www.healthstatus.sgul.ac.uk)
Domains covered											
Symptom frequency			12 items	12 items	5 items	2 items			5 items	8 items (symptom subscale)—re: frequency, intensity, and duration	7 items
Perceived functional limitations									5 items	26 items (impact subscale)	1 item
Participation in normal activities	3 items	4 items	11 items (5 based on self-identified activities)	11 items (5 based on standardized activities)	4 items (based on standardized activities)	Measured across many domains: sport, 3 items; holidays, 3 items; sleep, 4 items; work, 6 items; mobility, 6 items; and colds, 5 items	9 items	11 items		16 items (activity subscale)—how problems affect, or are affected by, activities	4 items
Tolerance of physical environment			4 items	4 items	3 items	1 item	1 item	1 item			
Social relations	2 items	1 item				6 items	4 items	4 items		Included in Impact subscale	3 items
Mood and emotional well-being	4 items	1 item	5 items	5 items	3 items	22 items	5 items	5 items	3 items	Included in Impact subscale	3 items
Perceived risk/fear	2 items					4 items	6 items	6 items		Included in Impact subscale.	

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
Health and longevity	3 items					9 items	2 items	2 items	2 items	Included in Impact subscale	1 item
Financial well-being	1 item									Included in Impact subscale	
Bother	15 items (all of the above)					Included across several domains				Included in Impact subscale	1 item
Total no. of items	22 items (15 bother, 7 management)	6 items	32 items	32 items	15 items	68 items*	20 items*	22 items*	15 items	50 items	20 items
Instrument characteristics											
Response format	Two 6-point Likert scales	Two 5-point Likert scales	Four 7-point Likert scales	7-point Likert scale	7-point Likert scale	4-point Likert scale	5-point Likert scale	7-point Likert scale	5-point Likert scale	Yes/no and ordinal response options	Dichotomous: yes/no
Intended use	Clinical research	Clinical research	Clinical research, patient monitoring	Clinical research, patient monitoring	Clinical research, patient monitoring	Clinical trials	Clinical research, patient monitoring	Clinical research, patient monitoring	Clinical research, patient monitoring	Clinical research	Clinical research
Target population	Adults	Adults	Adults	Adults	Adults	Adults	Adults	Adults	≥14 years	Adults	Adults
Time to complete	10 min	3 min	5–15 min	5–15 min (4–5 min according to Qoltech Web site)	3–4 min	15–20 min	<5 min	NA; probably <5 min	NA; probably 3–4 min	8–15 min	2–3 min
Patient report	Patient	Patient	Patient	Patient	Patient	Patient	Patient	Patient	Patient	Patient	Patient
How is it administered?	Self	Self, interviewer, paper and pencil, fax, phone, PDA, IVR	Self, interviewer, online, electronic devices	Self, interviewer, online, electronic devices	Self, interviewer	Self	Self, phone interview	Self	Self	Self, phone interview, online, computer-based	Self
Recall period	None	4 weeks	2 weeks	2 weeks	2 weeks	None	4 weeks	4 weeks	4 weeks	Varies: 4 weeks, 3 months, or 1 year	None
Reading level	NA	NA	NA	NA	NA	NA	>Grade 5	>Grade 5	Grade 4.8	NA	NA

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
Languages in addition to English	Japanese, Norwegian	Spanish	>20	>20	>20	Danish, Dutch, Finnish, French, German, Italian, Japanese, Korean, Norwegian, Spanish, Swedish, possibly Croatian	Spanish, Norwegian, Portuguese, French, Punjabi	NA	Spanish, Chinese-American	>20	Chinese, Dutch, Portuguese for Brazil, Swedish, Japanese, Russian, Spanish, Finnish
Cost to use	Free. Contact M.E. Hyland for permission to use.	Fee, but amount unknown.	Free for noncommercial clinical practice and research. Contact E. Juniper for permission to use. Otherwise, there is a 1-time fee.	Free for noncommercial clinical practice and research. Contact E. Juniper for permission to use. Otherwise, there is a 1-time fee.	Free for noncommercial clinical practice and research. Contact E. Juniper for permission to use. Otherwise, there is a 1-time fee.	Unknown. Appears to be free.	NA	NA	NA	Free for noncommercial clinical practice and research. Otherwise, there is a license fee.	No cost, but permission must be obtained from the authors.
Scoring method	Paper and pencil; total score and scores for 2 domains: distress, asthma management.	Self- or computer-scored. No domain subscores are suggested.	7-point scale for each domain. Overall score is mean of all 32 items (range 1–7). Domain scores are mean of specific domain items (range 1–7). 4 domains: symptoms, activity limitation, emotional function, and environmental exposures.	7-point scale for each domain. Overall score is mean of all 32 items (range 1–7). Domain scores are mean of specific domain items (range 1–7). 4 domains: symptoms, activity limitation, emotional function, and environmental exposures.	7-point scale for each domain. Overall score is mean of all 32 items (range 1–7). Domain scores are mean of specific domain items (range 1–7) 4 domains: symptoms, activities, emotions and environmental exposures.	Scored as overall score; construct scores for problems and evaluation; construct scores for activities, avoidance, distress, and preoccupations; or 11 domain scores.	Items scored from 0 to 4. Subscale scores = mean of subscale items × 2.5 (resultant scores range from 0 to 10, with higher scores indicating poorer QOL). Subscales are breathlessness, mood, social, and concerns. Total score = mean of 4 subscale scores.	Unlike the original AQLQ-Marks, items are not transformed , so higher scores indicate less impairment. Yields total score and subscale scores for breathlessness, mood, social, and concerns. Subscale scores = mean of all the items in that domain. Total score = mean of all items.	Likert method of summated ratings. Yields a total score and 5 subscale scores: SFI (5 items), FWA (5 items), PIA (3 items), asthma energy (1 item), and asthma-confidence in health (1 item).	Computer scored; scoring algorithm available online. 3 subscales: symptoms, activity, and impact.	Items are marked as “yes,” “no,” or “not applicable.” Positive responses only are summed to provide a total score out of 20. Unidimensional; no domain subscores are suggested.
Psychometric testing											
Reliability	In Norwegian sample, internal	Cronbach’s $\alpha = 0.95$.[14]	Internal consistency : NA in recent	Internal consistency: Cronbach’s $\alpha = 0.96$ for	Internal consistency: Cronbach’s $\alpha = 0.80$–	Internal consistency: Cronbach’s α for total	Internal consistency: Cronbach’s α for total	Internal consistency: Cronbach’s α for total	Internal consistency: Cronbach’s $\alpha = 0.88$–	Internal consistency: NA in asthma	Internal consistency: Cronbach’s $\alpha = 0.81$–

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
	consistency: Cronbach's α = 0.92–0.93; test-retest: r = 0.76–0.88.[4]		North American studies. In Spanish sample, Cronbach's α for overall score = 0.96, symptoms = 0.95, activity = 0.83, emotions = 0.84, environment = 0.78.[15,16] High concordance between electronic and paper versions, overall score ICC = 0.99, ICCs for 4 domains 0.97–0.99.[17] Test-retest: ICC = 0.95 in Canadian sample.[18] In Spanish sample, ICC for overall score = 0.90, symptoms = 0.82, activity = 0.92, emotions = 0.86, environment = 0.86.[15,16]	overall score in US sample.[19] In English-speaking Singapore sample, α = 0.97 for overall score, 0.95 for symptoms, 0.80 environment, 0.88 emotions, 0.89 activities.[20] In Swedish sample, overall α = 0.93, domains 0.75–0.94.[21] (Consistency between paper and electronic administrations, ICC = 0.90–0.95 for domains, 0.96 overall.[19]) Test-retest: ICC = 0.96.[22] For electronic version, 1-week ICC = 0.88 for overall score, 0.90 for activity limitation, 0.87 for symptoms, 0.81 emotional function, 0.85 environmental stimuli.[19] In English-speaking Singapore sample, ICC = 0.97 for overall score, 0.95 for symptoms, 0.88 environment	0.89 across scales.[23] In Swedish sample, overall Cronbach's α = 0.93, α for domains ranged from 0.68 to 0.87.[21] Test-retest: ICC = 0.79–0.83 for overall index and 3 of 4 subscales, activity subscale ICC = 0.72.[23] Swedish overall test-rest reliability was 0.86, with reliability for domains 0.78–0.83. (High concordance between mail-in and supervised completion, ICC = 0.96.[24])	score is very high in US and Norwegian samples: = 0.97.[4,25], Cronbach's α high for problems = 0.94; evaluations α = 0.90; and for dysphoric states and attitudes domain = 0.93. Most other domains α > 0.70, except social (α = 0.63) and medication usage (α = 0.57–0.67).[4,25] Test-retest: High in US/UK (r = 0.90–0.95) and Norwegian samples (r = 0.95).[4,26] Good in Japanese sample (r = 0.81).[27]	score = 0.92–0.95. Subscales: breathlessness = 0.86–0.89, mood = 0.82–0.85, social = 0.88–0.91, concerns = 0.84–0.89.[28,29] Test-retest: ICC for total score = 0.80. Subscales: breathlessness = 0.61, mood = 0.78, social = 0.78, concerns = 0.80.[29]	score = 0.97. Subscales: breathlessness = 0.95, mood = 0.90, social = 0.96, concerns = 0.92.[30] Test-retest: ICC for total score = 0.93. Subscales: breathlessness = 0.91, mood = 0.88, social = 0.93, concerns = 0.91.[30]	0.93 for total score. Subscales: SFI α = 0.78–0.84, FWA α = 0.85–0.90, PIA α = 0.79–0.90.[31] Total and 3 subscale α values exceed minimum 0.70 level for group comparison, and are at or near the 0.90 minimum recommended for instruments used to evaluate clinical change in individuals. Test-retest: ICC = 0.89 for total score, 0.72–0.90 for subscales.[32]	studies since 2000 in English-speaking samples. In Spanish sample, Cronbach's α for overall score = 0.86, symptoms = 0.70, activity = 0.88, impacts = 0.82.[16] In Taiwan, α = 0.93, 0.82, 0.88, and 0.87, respective domains noted above.[33] Test-retest: Spearman's rho = 0.90 for total, 0.85 for symptoms, 0.83 for activity, and 0.88 for impacts subscales, over 2 weeks.[34] In Spanish sample, 2-week ICC for overall score = 0.94, symptoms = 0.82, activity = 0.91, impacts = 0.91.[16] Reliability data are also available for Morrocan sample of asthma and COPD patients.[35] (Results provided are for asthma patients only; there	0.92. Test-retest: 2 weeks apart, r = 0.93,[36] 6 months apart, r = 0.72.[37]

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
				, 0.94 emotions, 0.94 activities.[20] In Swedish sample, overall score = 0.95, domains 0.81–0.90.[21]						are many more COPD studies.)	
Validity	In Norwegian sample, ABP highly correlated with LWAQ (r = 0.89), moderately correlated with state and trait anxiety, 6MWD.[4] In Japanese sample, ABP total scores correlated with depression and anxiety, all SF-36® subscales, and all LWAQ and AQLQ subscales.[5] Content and construct validity: scale formed using previous scales and focus group feedback.	The AIS-6 is strongly correlated with the total Mini-AQLQ (r = 0.84) score, as well as the activity (r = 0.82) and symptoms (r = 0.78) subscales (all p < 0.0001). Also, AIS-6 total score was correlated with Mini-AQLQ emotions (r = 0.70) and environment (r = 0.54) subscales. Convergent validity: AIS-6 scores were significantly related to smoking, BMI, history of COPD, systemic corticosteroid use, and asthma hospitalization in past year (p < 0.001). The AIS-6 total score was moderately to strongly correlated with general health rating (r =	Spearman's r = 0.64 vs ACQ, r = 0.20 vs PEF, r = 0.18 vs % predicted FEV_1, r = 0.03 vs SABA use.[18] Total AQLQ also significantly correlated with LASS symptom score (r = −0.68), SABA medication and albuterol use (r = 0.33, 0.37), SF-36® physical (r = 0.53–0.69 across 2 studies), SF-36® mental (r = 0.48–0.49 across studies), and the other SF-36® domains (r = 0.45–0.65); and all AQLQ subscales significantly correlated with all SF-36® subscales (r = 0.36–0.68).[18, 38–41]	Correlations with overall score r = 0.62–0.74 (across studies) vs ACQ, r = 0.19–0.40 (across studies) vs PEF, r = 0.21–0.38 (across studies) vs % predicted FEV_1, r = 0.05 vs SABA use, r = –0.30 for no. of admissions, r = −0.26 for no. of asthma medications , r = −0.43 with depression scores (HAD).[22, 50, 51] Subscale correlations for each domain are comparable to those for overall score (see Tan et al, 2004,[20] Singapore study). There is also strong evidence for concurrent validity in international samples in	Cross-sectionally, the Mini-AQLQ has similar validity to AQLQ. Longitudinally, the Mini-AQLQ is not as good as the AQLQ at measuring change in QOL. Correlations between Mini-AQLQ and full AQLQ ranged from 0.81 to 0.90 overall and for 3 of 4 subscales, but was only 0.63 for activity subscale.[23] Item functioning is similar for English and Spanish versions, and in Latino and black samples, although measure may have 3-factor structure in these minority samples.[53] A factor analysis of several asthma	In US sample, total LWAQ significantly associated with subjective illness severity (r = 0.48), objective illness severity (r = 0.33), anxiety (r = 0.50), and depression (r = 0.31).[55] In UK samples, total LWAQ score has good convergent validity (r = 0.66 with SIP) and predictive validity (r = 0.35 with corticosteroid prescribing, r = 0.44 with PEF).[26] Worse LWAQ scores in patients with poor compliance.[56] In Norwegian sample, LWAQ total score was significantly correlated with ABP score, state and trait	AQLQ-Marks total score correlated with asthma medication use, unemployment due to asthma, asthma symptom level, depressive symptoms, BMI, general physical function, and VLA function. Correlations with other markers of severity, such as FEV_1, were in the expected direction but not significant.[29, 63–68] Regarding subscales, total score and all 4 subscale scores were associated with workplace exacerbation of asthma, smoking status, and asthma medication use. Breathlessness, concerns,	Total score and all 4 subscale scores significantly correlated with symptoms, medication use, FEV_1, global health rating, and all SF-36® subscales. Total score also was associated with clinical asthma status by NAEPP severity criteria. Regarding predictive validity, total score and all 4 subscale scores predicted hospital admission and ED visits for asthma over the 12-month study period.[30, 69, 70]	Concurrent: All ASF scales were predictive of global patien-trated severity, NAEPP severity classification, and no. of missed work days, with the ASF total score having greater validity than the AQLQ-Marks regarding the breathlessness scale and for the total score predicting the NAEPP severity classification and missed work days, and for predicting patient-rated severity.[31] The ASF SFI was the strongest predictor of NAEPP asthma severity and workdays missed. The other scales showed	Significant correlation between total score and presence of cough, sputum, and wheeze; health status; asthma severity; symptom frequency; FEV_1; dyspnea; and physician contact. Total scores also correlated with other asthma QOL scales: AQLQ-Juniper, AQ-20, LWAQ; as well as the SF-36®. Regarding subscales, significant correlation between other measures of disease activity (lung function - FEV_1, FVC, PEF, oxygen saturation at rest; 6MWD;	Significantly correlated with other QOL measures: all AQLQ-Juniper (r = −0.40–0.80) and SGRQ (r = 0.46–0.86) scales, and total AQLQ-Marks (r = 0.85).[65, 83] Significantly correlated with clinical indicators such as PEF (in some but not all studies), asthma severity, asthma impact, sleep disturbance, and bronchodilator use.[37,83] AQ-20 prospectively predicted asthma exacerbations during 6-month follow-up.[37] In Japanese samples, AQ-20 total significantly correlated with generic QOL (SF-

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
		0.52), ATAQ (r = 0.67), AOMS (r = 0.57), and self-severity rating (r = 0.69). Regarding construct validity, the item pool was developed according to a conceptual model for constructing health-related QOL measures for clinical outcomes. Research items were chosen using IRT analyses. All validity data are from Schatz et al (2007).[14]	Significant correlations of overall AQLQ score with other measures by asthma severity. For example: FEV_1, r = 0.18 for mild asthma although not significant for moderate-severe asthma; AM PEF, r = 0.18 for mild asthma and 0.13 for moderate-severe; PM PEF, r = 0.20 for mild, and 0.13 for moderate-severe; rescue puffs of SABA, r = −0.49 and not significant; shortness of breath, r = −0.56 for mild and −0.25 for moderate-severe; wheeze, r = −0.50 for mild and −0.21 for moderate; cough, r = −0.34 for mild and −0.27 for moderate.[40] Evidence for concurrent validity in international samples in Spain, Japan, and	Denmark and Sweden.[21, 52] See AQLQ column for rationale.	QOL measures identified that the 2 most prominent factors, asthma symptom frequency and asthma symptom bother, were captured by the Mini-AQLQ.[54] In a Swedish sample, correlations between Mini-AQLQ and AQLQ-S were strong (r = 0.80), except for the environmental domain (r = 0.73).[21]	anxiety, and 6MWD.[4] In Japanese sample, LWAQ total score and activities, avoidance, distress, and preoccupation scales were all significantly associated with ABP and AQ-20 scores. LWAQ total score also was associated with global QOL and well-being measures, FEV_1, anxiety, and depression. Pattern of correlations for all 4 subscales were similar.[5,57] In Korean sample, total LWAQ score associated with duration of asthma, hospital admissions, PEF, and recent symptoms.[58] There also was evidence for convergent validity with various asthma symptoms in Chilean sample,[59] and associations between	and social scales correlated with corticosteroid use (ie, not mood subscale), but hospitalization correlated with concerns subscale only.		significant but slightly lower predictive power.[31] Better baseline total scores were associated with lower risk of an asthma-related ED visit or hospitalization and decreased asthma-related costs during 1-year follow-up. Better FWA subscale scores were associated with a decreased risk of asthma-related ED visit/ hospitalization during follow-up, but there was no predictive relation between other subscale scores and asthma-related utilization.[32]	MRC dyspnea grade; anxiety score, depression score, SIP total score, SIP physical domain, SIP psychosocial domain, smoking, ED visits, hospital admissions) and SGRQ symptom, activity, and impact domains. Evidence of validity from studies in the US, UK, Australia, Finland, Hungary, Japan, Morocco, Spain, and Taiwan.[5, 15, 16, 33, 35, 43, 44, 47, 71–81] It is unclear whether there is a theoretical rationale behind the measure, but the 3-subscale structure is supported by the results of principal components analysis.[82]	8®), perceived stress, and asthma severity,[84] as well as depression and anxiety, 7/8 SF-36® scales, and all LWAQ and AQLQ scales.[5] In a Finnish sample, AQ-20 was strongly correlated with SGRQ total (r = 0.86).75 With respect to rationale and construct validity, the authors used a criterion-based process of item selection and reduction that utilized both patient perceptions and factor analysis.[36] An 18-item version is unidimensional, but 20-item version may be measuring >1 dimension.[34]

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
			Portugal.[5, 15, 16, 42–47] Regarding rationale and construct validity, items were generated through literature review, discussion with chest physicians, and patient interviews, and chosen by having patients rate which were most troublesome.[48] Factor analysis including items from AQLQ and measures of asthma clinical status identified asthma-specific QOL, as measured by the AQLQ, as a separate factor.[49]			LWAQ and depression and anxiety symptoms in German sample.[60] Rationale and construct validity: Item content was derived from focus groups of asthma patients, items selected based on their psychometric properties. Initial factor analysis indicated a unidimensional scale,[26] but later factor analyses supported the existence of 2–4 constructs.[61, 62]					
Responsiveness (sensitivity to change). Referred to as "Respons. index"	Evidence that ABP scores change over time in UK and Norwegian samples.[4]	Within-subject changes over time have not been assessed. 1 study examined between-group changes in intervention vs control groups and found no group difference.[85] However, the groups did not differ on most other measures;	Able to detect within-subject changes over time and between-subject differences. Respons. index = 1.35.[18, 86]	Able to detect within-subject changes over time and between-subject differences. Respons. index = 1.34.[22]	Able to detect within-subject changes. Respons. index = 0.97. Intervention studies using the Mini-AQLQ are able to detect changes in QOL over time.[87] In Swedish sample, Mini-AQLQ's responsiveness to change is similar to	In Japanese samples, changes in the mobility, medication usage, holidays, sport, work and other activities, and dysphoric states and attitudes subscales were observed as a result of treatment. However, the LWAQ	Able to detect within-subject changes in total score and all 4 subscale scores in response to treatment.[91] There were within-subject changes in total score in response to changes in general physical function, VLA function, symptom	Able to detect within-subject changes in total score over time, and associations between changes in total score and changes in symptoms, FEV_1, self-rated severity, and medication use.	Over 8 weeks: RV%= 110% for change in % predicted FEV_1; RV% = 93% for 1-year change in NAEPP severity category; RV% = 84% for 1-year change in global, patient-rated asthma severity; and RV% = 89% for 1-year	Able to detect within-subject changes in total score over time, and associations between changes in total score and changes in other measures (eg, dyspnea, AQLQ scores).	Able to detect within-subject changes over time. Change in AQ-20 was correlated with change in total and all subscale scores for SGRQ and AQLQ-Juniper.[83] In a Japanese sample, AQ-20 was highly responsive after 6-month follow-up,

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
		so results may reflect the intervention more than the measure.			AQLQ-S.	was less responsive than both the AQLQ and the AQ-20.[45] A study in Malta provided evidence for change in total LWAQ score as a result of treatment.[88] Also, there was evidence for change over time Swedish and German samples.[89,90] Recent studies in US samples have not provided evidence for the measure's responsiveness.	scores, and bronchial responsiveness.[65,66] Total score and mood and social subscales were able to differentiate between improved and stable subjects; breathlessness and concerns subscales were not.[92]		change in work days missed in the past 4 weeks. In addition to total score, SFI and FWA scores were responsive to changes in these criteria.[31] Over 1 year, ASF scores were responsive to changes in asthma severity, especially the SFI (improved patients had 0.60 SD change). The other subscales did not show statistically significant changes in response to changing severity.[93] Note: RV is referenced to scales of all 20 AQLQ-Marks plus 6 ITG physical and psychosocial symptom/ side effect items.		but there was a ceiling effect. Change in AQ-20 was correlated with change in FEV_1 and total AQLQ and LWAQ.[45] Also able to detect change over time in a Finnish sample.
MCID	NA	NA	0.50 point,[94] but this is debated in the literature.[7] Critiques recommend a Number-Needed-to-Treat analysis, using the	0.50 point, but this is debated in the literature.[7] Critiques recommend a Number-Needed-to-Treat analysis, using the 0.50-point	0.50 point was established for the AQLQ and AQLQ-S, and has been adopted for the Mini-AQLQ as well. However,	NA	Katz et al 2004)[65] applied 2 methods of computing an MCID to the AQLQ-Marks, SEM and Norman et al (2003)[96] method of	0.50 point, established using Juniper methodology.[70]	NA	4 points for overall scale, and activity and impact subscales; no known MCID for symptoms subscale.[97]	NA

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	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
			0.50-point increase criterion. For determining MCID, the use of the proportions of individual patients achieving a 0.50 improvement, rather than group mean improvement of 0.50, also has been suggested.[95]	increase criterion. For determining MCID, the use of the proportions of individual patients achieving a 0.50 improvement, rather than group mean improvement of 0.50, also has been suggested.[95]	the original methodology used to establish this value has been questioned.[7] Critiques recommend a Number-Needed-to-Treat analysis, using the 0.50-point increase criterion. For determining MCID, the use of the proportions of individual patients achieving a 0.50 improvement, rather than group mean improvement of 0.50, also has been suggested.[95]		using 0.5 SD difference as threshold. Using SEM method, MCID = 3.3. Found that 1 VLA affected was associated with 1.9 difference in AQLQ; so 2 VLAs affected would be an MCID. Using Norman's 0.5 SD method, MCID = 7.3; so 4 VLAs affected would result in MCID.				
Sample size(s) tested	n = 40–327.	n = 554 in validation study[14]; n = 6948 for intervention study.[85]	n = 30 in original study. Other studies' sample sizes range from 30 to 3000+, in recent studies n range = 40–763.	n = 40 in original study. Other studies' sample sizes range from 30 to 3000+, in recent studies n range = 55–3297.	n = 40 in development study. In other studies, n = 96–35450.	n = 783 in original study. In recent studies, n = 44–879.	n = 283 in development study. In recent studies, n = 78–743.	n = 293.	n = 142–269 in original study. Other studies' sample sizes range from 119 to 3482.	This instrument has been tested in numerous populations. In recent asthma studies, n ranged from 31 to 396.	n = 90 in validation study. In recent studies, n ranged from 135 to 695.
Sample characteristics: income/SES, race/ethnicity, country	NA	Patients in validation sample were older than 35 years (23% ≥65) and more likely to be white (91%), well educated (40% college grads), and nonpoor (48% had income ≥$50K).	Instrument has been used in international settings representing ethnically diverse populations, and among low-SES and ethnic-minority adults with asthma in US. Sample info is available from published studies.	Instrument has been used in international settings representing ethnically diverse populations, and among low-SES adults with asthma. Sample info is available from published studies.	Instrument has been used in international settings representing ethnically diverse populations, and among low-SES and minority adults with asthma. Has been used in samples with diverse	Available from published studies about country, age range, and sex. Has been used in diverse international settings, including Germany, Norway, Japan, Korea,	Very little info is available. Many populations using this instrument have been quite homogeneous. Predominantly used in higher income and education samples. Most samples >	Instrument was validated in a socioeconomically diverse Australian sample.	Available from published studies about race/ethnicity, age, sex, and SES. Has been used in 6 published studies in both predominantly white and in broadly representative	Instrument has been used in a variety of settings presumably representing a broad range of populations, including studies around the world (US, UK, Australia, Finland, Hungary, Italy, Japan,	Info NA in most published studies. A recent US study using the AQ-20 was predominantly white and well educated; in a recent UK study sample was 50% South Asian. Has also been

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
		Patients in intervention sample were middle-aged (M = 51.8, range 18–99), 65% female, predominantly white (92%).			ages (eg, Feifer et al, 2004[87] includes 27% younger than 18 years, 22% 65+), but has not been validated for different age groups. Sample info is available from published studies.	Malta, and Croatia, and in a low-income UK sample. However, it has not been used in ethnically/ socioeconomically diverse US samples (predominantly upper middle-class, white).	70% white, but 1 Canadian sample was > 50% East Indian and 1 US sample 41% minority. Used in Australia and France, in addition to Canada and the US.		populations, but not in predominantly minority or low-income populations. Most studies have been conducted in the US.	Malaysia, Morocco, Netherlands, Norway, Spain, and Taiwan). However, most studies did not provide demographic info on income/ SES or race/ ethnicity.	recently used in Japan and Finland.
Diversity of psychometric evaluations (different populations, methods of administration, age groups, etc)	Norwegian and Japanese validation studies.	NA	Yes. Available directly from published studies in diverse US and international samples.	Yes. Available directly from published studies.	Swedish validation study.[21] Psychometrics available for black and Latino US samples.[53] Juniper's Web site indicates that Mini-AQLQ has been translated and culturally adapted for 21 countries in 12 languages, but psychometric data are not available for all samples. It does not indicate which samples psychometric info is available for.	Yes. Psychometric info is available from published studies based on US, UK, Norwegian, Japanese, and Korean samples. However, recent US studies have not used diverse samples more than 90% white).	Psychometric info is available from published studies based on Australian and US samples.	No. All psychometric data are from an Australian sample.	Psychometric info is needed from more diverse samples. A pediatric version has been developed that is completed by parents.	Unclear whether validated (for asthma rather than COPD) in diverse US samples, but has been validated in different languages in samples around the world (see above).	Unclear, as validation studies present little demographic info. Validated in Japanese and Finnish samples.
Instrument summary											
Additional info needed.	Need info on psychometric properties in US sample; info on sample	Substantial proportion (22%) of patients with self-reported coexisting	Need reliability and validity info for non-English translations and other	Need reliability and validity info for non-English translations and other	Need reliability and validity info for non-English translations and other	Needs validation in more socioeconomically and ethnically diverse US	Need more studies to be done regarding AQLQ-Marks' utility as a	Measure needs to be validated in diverse US samples.	Separate validation data for non-English-language versions of	Measure needs to be validated for people with asthma in diverse US	Needs more studies on psychometric properties in diverse US samples.

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	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
	characteristics and characteristics and population norms is not available.	COPD, but we have no reason to believe that would influence the study results. Need evidence for test-retest reliability. Validity has not been tested in people younger than 35 years. Future studies should validate in younger samples. Also needs validation in more diverse samples (validation and intervention study samples were more than 90% white).	versions. Need to validate in older adults (>65 years). Recent US studies have not provided reliability data.	versions. Need to validate in older adults (>65 years). Need more research on ethnically and socioeconomically diverse US samples.	versions. Need to validate in older adults (>65 years).	samples. Needs more info on responsiveness in US samples.	discriminative measure (with regard to other clinical indices and asthma severity), and further research is needed on between-subject and within-subject variability. Its predictive capabilities also need to be assessed. Needs validation in more diverse samples.		the ITG-ASF have not been published; nor were studies found that used the instrument in low-income, multiethnic settings. Also needs info on test-retest reliability.	samples.	
Strengths and weaknesses	*Strengths:* Captures psychosocial areas of burden and distress not measured in most QOL instruments. Exclusively measures perception of asthma's impact on QOL. *Weaknesses:* Not validated in a US sample. Relatively new instrument;	*Strengths:* Short, simple measure for clinical populations. Rigorous development. *Weaknesses:* Has not been widely used, particularly in diverse samples. Cannot derive a separate score for patient perception of asthma impact on QOL.	*Strengths:* Widely used and validated (in both long and short forms) for use in multiple countries. Adapted to create versions for use in pediatric asthma and rhinitis. *Weaknesses:* Substantial overlap with domains in newer measures of asthma	*Strengths:* Widely used and validated for use in multiple countries. Has also been adapted to create versions for use in pediatric asthma and rhinitis. Quicker and easier to use than original AQLQ. *Weaknesses:* MCID has been questioned	*Strengths:* The Mini-AQLQ has good reliability, cross-sectional validity, responsiveness, and longitudinal validity (per Web site) and behaves similarly to the full version AQLQ-S. *Weaknesses:* Psychometric properties are not as strong as the full	*Strengths:* Captures many domains. 50% of items across 11 domains focus on emotional and social impact of asthma. Good psychometric properties overall. *Weaknesses:* At 68 items/15–20 min, it is the lengthiest of the QOL measures,	*Strengths:* The scale appears to be relatively independent of subject characteristics. It has some cross-sectional relations to other measures. Its validity has been established against some markers of asthma severity. *Weaknesses:* Less reliable and responsive	*Strengths:* The measure has greater reliability and responsiveness than the original AQLQ-Marks. 10/22 items appear to assess perceived impact of asthma on QOL. *Weaknesses:* Limited data on MCID. Has not been validated in	*Strengths:* The scale is short and was carefully developed. Subscale scores have been shown to have discriminant validity, and both concurrent and predictive validation is strong. *Weaknesses:* It is unclear whether the ASF is available, and it may	*Strengths:* The SGRQ has been widely used, and evaluations of the psychometric properties of many of the translated versions have been published. Psychometric testing has demonstrated its repeatability, reliability, and validity. Sensitivity has been demonstrated in clinical trials.	*Strengths:* Very simple and brief (2–3 min) to administer, well-validated, and responsive. *Weaknesses:* Unclear how applicable it is to diverse US samples. MCID has not been established. Does not yield any specific subscale scores to distinguish

	ABP	AIS-6	AQLQ	AQLQ-S	Mini-AQLQ	LWAQ	AQLQ-Marks	M-AQLQ-Marks	ASF	SGRQ	AQ-20
	Limited data on use in research.		control. Poor reliability of its smaller subscales. MCID has been questioned in the literature. Original AQLQ is more time-consuming and complex to administer than the standardized version.	in the literature. Over-representation of symptoms and functional status in total score; inability to distinctly measure patient perception of impact of asthma on QOL.	version. Some researchers have questioned the methodology used to define the MCID. Total score is somewhat over-represented by symptom and activity domains.	which reduces its feasibility. No evidence that the 11 domains differentially predict outcomes. Lacking evidence for responsiveness in US samples.	to change, as compared with M-AQLQ-Marks. It is more suitable for use in clinical trials than for use in clinical practice. Relative to AQLQ-Juniper, its use in clinical research settings is limited.	US samples or other samples outside Australia. Modified version has not been widely used.	have been replaced by the AIS-6. info is not available on stability over time or psychometrics in more diverse samples or specific subgroups. Cannot derive a reliable measure of patients' perception of asthma impact on QOL.	*Weaknesses:* At 50 items, it is one of the longest asthma QOL measures. Scoring is complex: Provides indirect measure of impact of asthma on QOL.	patients' perception of impact of asthma on QOL.
No. of published English-language studies using tool since 2000 (ie, original empirical studies that actually used tool in a sample of asthma patients)	3 studies (reported in 4 different articles, plus 3–4 reviews)	2 studies (1 validation study, 1 intervention study)	29 studies (reported in 31 articles)	15 studies	8 studies	17 studies (reported in 21 articles)	10 studies	1 study (reported in 3 articles)	4 studies	32 studies (reported in 35 articles)	10 studies
Applicability to different populations	Translated for use in Norway and Japan; developed in UK; unclear whether applicable to US.	NA	Has been successfully linguistically and culturally translated for use in other countries.	Has been successfully linguistically and culturally translated for use in other countries.	Has been successfully linguistically and culturally translated for use in other countries.	May lack lifestyle-specific items for specific populations. Has been translated for use in other countries.	Has been translated for use in other countries.	NA	Has been translated into Spanish and Chinese for US samples.	Has been successfully linguistically and culturally translated for use in other countries.	Unclear. At least 1 item (re: maintaining the garden) is less applicable to urban and low-SES populations. Has been translated for use in other countries.

6MWD, 6-minute walking distance; *ABP,* Asthma Bother Profile; *ACQ,* Asthma Control Questionnaire; *AIS-6,* Asthma Impact Survey; *AOMS,* Asthma Outcomes Monitoring System; *AQ-20,* Airways Questionnaire-20; *AQLQ-S,* Asthma Quality of Life Questionnaire-Standardized; *ASF,* Asthma Short Form; *ATAQ,* Asthma Therapy Assessment Questionnaire; *BMI,* body mass index; *COPD,* chronic obstructive pulmonary disease; *ED,* emergency department; *FEV1,* forced expiratory volume in 1 second; *FWA,* functioning with asthma; *HAD,* Hospital Anxiety and Depression Self-Assessment Score; *ICC,* intraclass correlation coefficient; *IRT,* item response theory; *ITG,* Integrated Therapeutics Group; *ITG-ASF,* Integrated Therapeutics Group–Asthma Short Form; *IVR,* interactive voice response; *LASS,* Lara Asthma Symptom Scale; *LWAQ,* Living With Asthma Questionnaire; *M-AQLQ-Marks,* Modified Asthma Quality of Life; *MCID,* minimal clinically important difference; *min,* minute(s); *Mini-AQLQ,* Mini-Asthma Quality of Life Questionnaire; *MRC,* Medical Research Council; *NA,*

not available; *NAEPP,* National Asthma Education and Prevention Program; *PDA,* personal digital assistant; *PEF,* peak expiratory flow; *PIA,* psychosocial impact of asthma; *QOL,* quality of life; *RV%,* relative validity percentage; *SABA,* short-acting β-agonist; *SEM,* standard error of measurement; *SES,* socioeconomic status; *SFI,* symptom-free index; *SGRQ,* St George's Respiratory Questionnaire; *SIP,* Sickness Impact Profile; *VLA,* valued life activity.

*Total number of items does not equal items enumerated above because some items cover more than 1 domain.

TABLE IV

Summary of pediatric quality of life instruments

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
Author/developer						
	American Academy of Pediatrics	American Academy of Pediatrics	E.F. Juniper	E.F. Juniper	R.S. Everhart and B.H. Fiese	
Domains covered						
Symptom frequency	7 items		10 items		10 items	11 items
Perceived functional limitations						
Participation in normal activities	6 items	5 items	5 items	4 items		
Tolerance of physical environment						
Social relations		6 items				3 items on communication problems
Mood and emotional well-being	12 items (feelings about asthma)	22 items	8 items	9 items	5 items	
Perceived risk/fear						3 items on worry
Health and longevity		15 items				
Financial well-being						
Bother						11 items on treatment problems (trouble using inhaler, forgetting, medications “make me feel sick”)
Total no. of items	25 items	48 items	23 items	13 items	15 items	28 items
Instrument characteristics						
Response format	Text answers are accompanied by visual cues in the form of graduated circles. For each question, the child looks at the card and	5-point Likert scale, with higher scores indicating better QOL	7-point Likert-type scale (1 = “severe impairment” to 7 = “no impairment”)	7-point Likert scale (1 = “severe impairment” to 7 = “no impairment”)	Pictorial response format—allows the child to anchor his/her response decisions among 3 thermometers, which are empty, half-filled,	Ages 8–18: 5-point Likert scale; ages 5–7: 3-point scale

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	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
	responds by verbalizing his/her answer or pointing to corresponding circle.				and filled, to represent “none,” “some,” or “all of the time.”	
Intended use	Clinical research and practice	Clinical research and practice	Measurement of the functional problems (physical, emotional, and social) that are most troublesome to children with asthma	Measurement of the problems that are most troublesome to the parents (primary caregivers) of children with asthma	Measurement of asthma-specific QOL directly from young children.	Not reported
Target population	Children aged 7–16 years	Children aged 5–12 years (but used in ages 2–17)	Children aged 7–17 years	Parents of children aged 7–17 years	Children aged 5–7 years	Children with asthma aged 2–18 years
Time to complete	Average 9–10 min. Average completion time varies with age: 13 min at age 7; 7 min at age 13; children <10 require greater response time.	20 min for phone administration (less for self-administration)	10–15 min	3–5 min		Not reported. Note that this is 1 of many disease-specific modules that is part of the PedsQL general instrument.
Patient vs proxy report	Patient (child) report	Parent	Patient (child) report	Proxy	Patient (child) report	Parent proxy (for children aged 2–4, 5–7, 8–12, and 13–18 years) and children (aged 5–7, 8–12, and 13–18 years)
Method of administration	Interviewer-administered	Self-administered using paper and pencil	Interviewer-administered version recommended for use with children <11 years. Otherwise, can be self-completed.	Self-administered, paper and pencil or electronic version	Interviewer-administered; the child is asked to indicate his/her response anywhere on the line below the 3 thermometers.	Self-administered (for children aged 2–4 years, parents complete)
Recall period	2 weeks	2-, 4-, and 8-week versions	1 week	1 week	1 week	1 month
Reading level	Grade 3	Grade 6	NA	NA	NA	Not reported
Languages in addition to English	None	Spanish (for US)	>20	>20	None	Not reported
Cost to use	Free for use in noncommercial research or clinical practice applications.	Free for use in noncommercial research or clinical practice applications.	Free for use in noncommercial research or clinical practice applications. Contact E. Juniper for	Free for use in noncommercial research or clinical practice applications. Contact E. Juniper for	Still under development.	The license fee for using the PedsQL scales, modules, and translations varies according to the study type and

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
			permission to use. Otherwise, there is a 1-time fee.	permission to use. Otherwise, there is a 1-time fee.		financing. See http://www.pedsql.org/conditions.html
Scoring method	Scores 0–100; higher scores = better outcomes. Does not mention if additional software is needed or if the instrument needs to be scored centrally. 3 subscales: physical health, activities, and emotional health.	All scale items require subjects to respond on 5-point scale. 5 subscales: physical health, activity (child), activity (family), emotional health (child), and emotional health (family).	Overall score is the mean of all 13 responses (scores range from 1 to 7). Individual domain scores (emotional function, activity limitations) are the means of the items in those domains.	Overall score is the mean of all 13 responses (scores range from 1 to 7). Individual domain scores (emotional function, activity limitations) are the means of the items in those domains.	Children are asked to rate their response to each item anywhere on a line below the 3 thermometers, and a scoring template is used to score responses on the line. The range of values is 1 (empty thermometer) to 7 (full thermometer). Subscale scores are calculated from the mean of responses for each subscale, and total QOL is calculated from the mean of all responses.	Items are reverse scored and transformed to a 0–100 scale, with higher scores indicating better QOL.
Psychometric testing						
Reliability	Internal consistency: Across different ages, the majority of reliability estimates for CHSA-C scales were ≥0.70. Range was 0.61 (for 8-year-olds completing physical health subscale) to 0.93 (14-year-olds, emotional health). Internal consistency tended to increase with child's age. Internal consistency ≥0.70 for all sex, race/ethnicity, and income groups.[98, 99] Test-retest reliability: Correlation between forms ranged from 0.83 (physical health, child activities) to 0.89	Internal consistency: In addition to high-item-total correlations for the majority of items, Cronbach's α is very high for the total score (0.94) and moderately high for the various subscales: child physical health α = 0.89–0.92, child emotional health α = 0.87–0.91, child activity α = 0.81–0.89, family emotional health α = 0.65–0.90, family activity α = 0.79–0.85.[100] The subscales of the CHSA are moderately correlated with one	Internal consistency: Cronbach's α = 0.92,[102] 0.86 for a pictorial version.103 Paper and electronic forms are consistent with each other.[19] In Thailand sample, Cronbach's α = 0.83–0.97 across domains and assessments.[104] In Spanish sample, α also high: overall = 0.95, symptoms = 0.91, activities = 0.86, emotions = 0.89.[105] In Swedish sample, overall α = 0.92, symptoms = 0.86, activities = 0.79, emotions = 0.84.[106] Test-retest reliability: Test-retest	Internal consistency: Cronbach's α for overall score = 0.92 in US sample.[19] In Swedish sample, α = 0.89 for the overall score, 0.90 for activities, and 0.87 for emotions.[108] Also, electronic versions have been developed.[109] Test-retest reliability: ICC = 0.84 among the parents who said their child's asthma was stable.[110] Stability was acceptable for electronic version: overall ICC = 0.85, activity limitation = 0.78, emotional function = 0.85.[19]	Internal consistency: Factor 1, Cronbach's α = 0.83, Factor 2, Cronbach's α = 0.71. Total QOL score, Cronbach's α = 0.86.[103]	In an American sample of children aged 8–12 years,[111] internal consistency reliability coefficients for each scale ranged from 0.58 (child self-report, treatment problems) to 0.91 (parent proxy report, asthma symptoms). In a sample of 252 "vulnerable children" in FQHCs,[112] asthma symptoms α was 0.78 for child self-report and 0.81 for parent proxy report. In a US sample of 70 black children with persistent asthma, α = 0.90.[113]

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
	(emotional health); ICC = 0.88. (physical health) - 0.91 (child activities). Stratified by age, younger children were generally less reliable; lowest = 0.57, although most ages' reliability estimates were above 0.75. Reliability was strong for all sex, race/ethnicity, and income groups.[98, 99]	another (r = 0.23–0.66).[101] Test-retest reliability: Correlation among forms was very high (0.81–0.86) for all subscales except child emotional health (0.62).[100]	conducted among patients with stable asthma (n = 37, stability measured using 3 methods); within-subject SD of change was 0.17 for the overall QOL score. Related to total variance, ICC = 0.95. Similar findings reported for the 3 domain scores.[107] Stability was acceptable for electronic version: overall ICC = 0.78, activity limitation = 0.66, symptoms = 0.76, emotional function = 0.80.[19] In Thailand sample, there was also good stability (ICC = 0.78–0.84 across domains).			
Validity	Validity: Lower CHSA-C scores (indicating worse asthma QOL) on all 3 subscales were observed among children with more symptom days. Lower scores on all subscales also were observed among children whose parents reported higher medication use (SABA and nebulizer treatment). Higher CHSA-C scores on all subscales were observed among children whose parents described their health as very good-excellent. However, there was	Lower total CHSA scores were associated with more healthcare utilization, asthma symptom days, school absences, and caregiver distress.[114] Children with airway obstruction, measured by FEV_1 ratio, had lower total CHSA scores in 1 study,[115] but another study found that FEV_1 is not consistently correlated with CHSA.[114] With respect to subscales, physical health, family activity, child emotional health,	Longitudinal validity was assessed against several measures: clinical change in asthma (lung function tests, SABA use), feeling thermometer, patients' global ratings of change, caregivers' perception. Cross-sectional concurrent validity measured against clinical change in asthma and feeling thermometer. Moderate associations for most, some mixed results, no correlation with FEV_1 % predicted Overall, PAQLQ had	Validity was assessed against a separate generic caregiver burden of illness scale and several measures of child's asthma severity. Moderate to strong correlations were found between the PACQLQ and caregiver burden of illness.[110] Total score, emotional function, and activity limitation subscales all correlated with various measures of child's asthma severity (symptom-free days, etc). Total scores and emotion function scores also were associated with	*Convergent validity*: Symptom subscale scores significantly correlated with total scores on the PACQLQ (M = 5.34, SD = 1.49; r = 0.23, $p < 0.05$). Scores on emotional subscale correlated with total PACQLQ scores (r = 0.23, $p < 0.05$). Scores on symptoms subscale related to FEV_1 scores (M = 1.48, SD = 0.51; r = 0.22, $p < 0.05$). *Discriminant validity*: Verbal ability for the 5-year-olds (based on WPPSI-Revised vocabulary subtest) was not significantly	Construct validity was based on intercorrelations among the PedsQL 3.0 generic core total scale score, as well as a modified multitrait-multimethod matrix. Convergent validity was tested by examining the intercorrelations between the PedsQL 3.0 Asthma Module scales and the PAQLQ.[111] Seid (2010)[112] noted intercorrelation between generic core scales and Asthma Module asthma symptoms scale score. Greenley (2008)[113]

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
	no consistent relationship between CHSA-C subscale scores and lung functioning (FEV_1).[98, 100] Validity estimates by child sex, race/ethnicity, and income paralleled the overall sample.	and family emotional health (all but child activity) were associated with symptom severity. Child physical and emotional health were associated with medication use, but the other subscales were not.[100] CHSA physical health, child activity, family activity, and child emotional health were all correlated with number of wheezing episodes (r = −0.16–0.61, depending on the subscale and time point), number of asthma attacks (r = −0.12–0.50), symptom days (r = −0.08–0.45; −0.32–0.45 at strongest follow-up), and night wakings (r = −0.06–0.41; −0.32–0.45 at strongest follow-up). Physical health, child activity, and family activity (not emotional health) were associated with bronchodilator use, r = −0.45, −0.38, and −0.28, respectively, at 1-year follow-up.[114] While the results aren't totally consistent, overall there is little evidence that the different subscales differentially predict various asthma outcomes. Worse CHSA physical health status was associated with	strong longitudinal and cross-sectional correlations with asthma indices and general QOL, across domains and age strata.[107] Total and all subscale scores negatively correlated with disease duration (r = −0.28–0.37), activity scale negatively correlated with asthma symptoms (r = −0.26). There were significant correlations between PAQLQ and various triggers: emotions r = −0.41, animal allergens r = 0.18, pollen allergens r = 0.12, physical activity r = 0.30, air pollution/irritants r = −0.30, infection r = −0.16.[117] Worse emotion domain scores were significantly related to worse asthma control, more days of missed school, and doctor visits for worsening asthma.[118] PAQLQ and PACQLQ were significantly intercorrelated (r = 0.56).[119] Also, evidence for convergent, discriminant, and predictive validity of pictorial version.[103] There is evidence for the PAQLQ's validity in several international samples. In a Dutch sample, all 3	medication use and secondhand smoke exposure—while activity limitation was only associated with symptom variables.[133] Total scores also associated with parent-reported family burden and child-reported QOL.[134] PAQLQ and PACQLQ were significantly correlated (r = 0.56).[119] In a French sample, parent QOL was significantly associated with the child's emotional and academic self-esteem, psychological symptoms, and QOL, but was not associated with child asthma severity.[131] In an Iranian sample, parent QOL was associated with child asthma severity.[132] In an Israeli sample, parent total and domain scores were correlated with child scores, but not child FEV_1 or asthma severity.[109] In a Dutch sample, PACQLQ scores were lower among caregivers of children with asthma vs controls, but children had lower scores than did caregivers in the activity domain.[135] In a Swedish sample, overall and both domain scores	correlated with scores on either subscale. Scores on the emotional subscale were not correlated with verbal ability WISC) for 6- to 7-year-olds, but scores on the symptoms subscale were correlated with verbal ability on the WISC for this age group (r = 0.29, p < 0.05). There is no info on whether each of the subscale scores provide unique info (ie, on what is the discriminant validity of the subscale scores relative to one another). *Predictive validity*: For the children followed longitudinally until 8 years of age (n = 48), scores on the symptoms subscale demonstrated predictive validity with the symptoms subscale of the PAQLQ (M = 5.56, SD = 1.25; r = 0.51, p < 0.01), after controlling for child's age at the initial visit. Scores on the emotional subscale demonstrated predictive validity with the emotions subscale of the PAQLQ (M = 5.65, SD = 1.35; r = 0.41, p < 0.01).	examined intercorrelations of the subscales with one another and with total score to assess convergent validity. The PedsQL 3.0 Asthma Module total score was highly correlated with all subscale scores (r values ranged from 0.72 to 0.89). There was also correlation between the child report and the parent proxy report measure for asthma symptoms (but not for treatment problems, worry, or communication).

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
		socioeconomic factors: lower family income, increasing family size, and living in a single-adult household. Even after adjusting for these factors, black children's CHSA physical health scores were significantly lower than white children's (average of 6 points lower on a 1–100 scale).[116]	PAQLQ domains correlated with SABA use (r = 0.30–0.34); only activity domain correlated with FEV_1 (r = 0.26) and PEF (r = 0.21).[120] For all domains, QOL was lower among children with asthma vs controls, and those with both asthma and excessive body weight.[121] In the Italian sample, PAQLQ significantly correlated with clinical and functional indices, including asthma control and severity.[122] In the Polish sample, PAQLQ total score did not differ among children with different asthma severity levels, but there was a significant correlation between PAQLQ and PEF variability (r = 0.35).[123] In the Israeli sample, total and domain scores were correlated with parent scores, but not FEV_1 or asthma severity.[109] In Spanish samples, significant moderate correlations between the PAQLQ scores and the Asthma Control Score (0.53–0.67), the General Health Perception (0.34–0.55), and the	were all associated with asthma severity from medical records, symptoms rated by caregiver, and child QOL.[108] Rationale and construct validity: Items were generated from interviews of parents of children with asthma, literature review, and discussion with health professionals. Items caregivers rated as most bothersome were included in the measure.[110] It is unclear whether the 2-dimension structure has validity: 1 factor analysis study found a 2-factor solution, but these 2 factors did not map onto Juniper's suggested domains.[134]		

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
			% PEF (0.44–0.55).[105] PAQLQ total score also was associated with asthma severity, immunotherapy, geographical location of residence, and season.[124] In a Thai sample, correlations between PAQLQ domains, asthma diary, PEF, and SABA use were found to be moderate (r = 0.31–0.69); there was no significant correlation with FEV_1% (r = 0.01–0.03).[104] In a German sample, total and subdomain scores all decreased as severity increased.[125] In a Swiss sample, PAQLQ correlated with the German version of Adolescent Asthma Quality of Life Questionnaire (r = 0.86), patient-rated symptom severity (r= 0.76), coughing, wheezing, shortness of breath, and sleep (r = −0.42–0.50).[126] There is also evidence for validity from samples in Sweden, Jordan, Australia, Brazil, Turkey, France, and Iran.[107, 127–132]			
Responsiveness (sensitivity to change)	NA	4 studies found evidence of within-subject changes in the CHSA over	Responsiveness measured among those whose asthma had changed over a 4-week period,	Able to detect within-subject changes in QOL over time and to differentiate between scores	Group differences were found according to race; minority children reported significantly	Seid (2010)[112] noted that within-subject change from baseline to 3-month

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		time.[114, 136–139] All 5 individual subscales have demonstrated some responsiveness. Some individual studies report changes in 1 subscale but not another, but there is no clear pattern of evidence suggesting that some subscales are more responsive overall. Between subjects, there is evidence that as severity increased, QOL measured by the CHSA decreased, and that the CHSA can discriminate between children with and without airway obstruction.	either due to treatment or natural fluctuations (n = 32). Mean change among this group in overall QOL during a 4-week period was 0.98 (SD = 0.88); similar changes were reported for subdomain scores. Thus, the PAQLQ was able to detect changes and to differentiate patients whose health status changed from those who remained stable. Other US samples were similarly able to detect changes over time and in response to treatment.[140,141] There was some evidence of change in PAQLQ over time and/or in response to treatment in Brazilian, Chilean, Italian, Polish, Portuguese, Spanish, Swedish, Thai, Turkish, and multicountry international samples.	(overall, both domains) of stable caregivers and those whose HRQL changed between assessments ($p = 0.0003$).[110] US and international studies were able to detect improvements in PACQLQ in response to treatment.[108, 119, 142, 143] There is also evidence that changes in caretaker's QOL are associated with changes in child's asthma symptoms.[133, 144]	poorer scores on the symptoms subscale and the emotions subscale compared with white children ($p < 0.05$). Group differences also were found by recruitment site, with children recruited from the teaching hospital reporting significantly worse QOL than children recruited from the pulmonary clinic or private pediatric clinics.	follow-up improved for those also classified as clinically improved by asthma symptom frequency. Varni (2004)[111] reported responsiveness analysis, which was limited to 10 children on symptom scale only.
MCID	NA	MCIDs have not been established for 4 of the 5 CHSA scales. However, preliminary studies of physical health scale scores estimate an MCID with a range from 0.83 (SD = 0.39) to 1.24 (SD = 1.32) (L. Asmussen, written communication, Oct 2003, as cited in	MCID was measured by assessing score differences against a global rating of change provided by the child (responses were scored on a 15-point scale; criterion was a 2- to 3-point change. MCID for overall QOL = 0.42;	MCID measured against a global rating of change (15-point, 1-item scale) of the child's asthma provided by the parent. MCID for overall caregiver QOL was 0.50, with similar values for the emotional function domain (0.64) and the activity limitation domain (0.67).	NA	Not reported

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
		Lozano et al, 2004[137]).	symptoms domain = 0.54; activity domain = 0.70; emotional function domain = 0.28. However, the 1 recent study that actually described results in terms of MCID used 0.50.[145]			
Sample size(s) tested	414 parent/child pairs	Originally validated in 3 different studies, involving 276 subjects; later used in samples ranging from 45 to 13878	Originally validated in sample of 52 children (aged 7–17 years)[146]; recent studies with n ranging from 19 to 1758	Originally validated in parents of 52 Canadian children; recent studies with n ranging from 32 to 621	Initial development and testing of this measure with 101 children with mild to severe asthma; 48 children followed longitudinally	Children with asthma aged 5–16.4 years (n = 404) and parents of children aged 2–16.4 years (n = 526), with 529 families overall.[111] Children in FQHCs (n = 252); age range 3–14 years; mean age 7.8 years; varying degrees of asthma severity (27% mild; 41% moderate; 32% severe).[112] US children participating in a randomized controlled trial for black children with persistent asthma (n = 70); age range 9–17 years; mean age 12.2 years.[113] Varni's sample size appears to be a total of 165 participants who completed the Asthma Module, drawn from several sources: a study of families who were newly enrolled in an SCHIP (n = 364), children with asthma who were newly enrolled in a treatment research study at the University of Kansas Medical Center (n = 86), and children

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
						with asthma who attended a summer camp sponsored by the American Lung Association (n = 79).[111]
Sample characteristics—income/SES, race/ethnicity, country	Children and parent pairs from the cities and surrounding suburbs from Chicago, Ill, and Cincinnati, Ohio	See Table 3 of Asmussen (1999) paper.[100] Several studies utilized diverse samples, including predominantly lowincome/ SES individuals and/or predominantly black or Hispanic samples. Some studies using the CHSA had predominantly male samples.	Original validation study: Income/SES and race/ethnicity not reported; country, Canada; age, 7–17 years (mean = 12.0); sex, 22 females and 30 males. Recent studies have included racially and socioeconomically diverse US samples, as well as samples from several other countries.	Original validation study: Income/SES and race/ethnicity not reported; country, Canada; age, 7–12 years (mean = 12.0); sex, 22 females and 30 males. Recent studies have included racially and socioeconomically diverse US samples and samples from several other countries.	More than half the children were boys (64%); 56% were white; 25% were black; 3% Hispanic; 1% Native American; and 15% mixed race.	Tested in a sample of 252 "vulnerable children" in FQHCs; 83% Hispanic.[112] Tested with children participating in a randomized controlled trial for black children with persistent asthma (n = 70), living in inner-city neighborhoods with income below the poverty line. Age range was 9–17 years; mean age 12.2 years.[113]
Diversity in psychometric evaluation (different populations, methods of administration, age groups, etc)	Subjects were 7–16 years old (average = 11.5 years), 59% male, 45% black, 11% Hispanic, and >40% reported annual household income <$30K.	Original validation sample included large numbers of ethnic minorities (black, Hispanic) and low education/low income individuals. More recent validation studies also used ethnically and socioeconomically diverse samples.	Psychometric data are available from diverse US samples and international samples (eg, Spain, Sweden, Thailand), which incorporate various languages and age, socioeconomic, and race/ethnic groups.	Psychometric data are available from diverse US samples and international samples (eg, Sweden).	NA	Tested with 301 boys and 227 girls. Age range was 2–16.4 years; average age 8.8 years. Tested with primarily white non-Hispanic and Hispanic patients.
Instrument summary						
Additional info needed	Need more info about population norms.	Need more info on discriminant validity of subscales.	Need more info on discriminant validity of subscales.	Need more info on discriminant validity of subscales.	This is a new adaptation of the PAQLQ. Need further testing to confirm the proposed factor structure and provide validation.	See above. Varni (2004)[111] noted, "Until further testing is conducted, the child self-report scale that did not achieve the standard 0.70 should be used only for descriptive or exploratory

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
						analyses."
Strengths and weaknesses	*Strengths:* Little burden, evidence of reliability and validity in an ethnically and socioeconomically diverse sample. Validation in children aged 7–16 years. *Weaknesses:* Longer administration time and decreased reliability and validity in children younger than 10 years. Overlap with measures of asthma control. Newer measure (2008); limited data on use.	*Strengths:* Can be reliably used even when reporting on younger children. Evidence of reliability and validity in ethnically and socioeconomically diverse samples. Can be used in combination with child-report version. *Weaknesses:* At 48 items, 20 min, longer than other commonly used asthma QOL measures. Perceived impact of asthma on QOL is inferred from activity and emotional subscales.	*Strengths:* The instrument has been used in a number of pediatric studies in the US and abroad and is available in multiple languages. Published original studies show strong reliability, validity, and responsiveness in diverse US and international samples, although original validation was a small sample. *Weaknesses:* At present, lacks evidence for discriminant validity of subscales. Predominance of items are related to health status and functional status.	*Strengths:* Companion survey for children (PAQLQ) has been fairly widely used in pediatric asthma studies. Measure has good reliability, validity, and responsiveness, and PACQLQ has been used in diverse samples. It is brief (13 items, 3–5 min). *Weaknesses:* At present, lacks evidence for discriminant validity of subscales. Does not measure impact of children's asthma on parents except in terms of the emotional domain.	*Strengths:* The Pictorial PAQLQ holds promise as a new measure for direct reporting of QOL by young children. This is particularly important, since info from young children can provide info that is distinct from info obtained from their caregivers, and few measures currently are available for this age group. Development of the instrument was based on the well-established PAQLQ, with specific attention to the cognitive abilities and developmental status of young children. Initial testing suggests adequate psychometric properties; provides preliminary evidence of validity. *Weaknesses*: This measure is newly developed, and further evaluation is needed. It relies on a pictorial format, and therefore would not be applicable to telephone surveys.	*Strengths:* Although the PedsQL core instrument is well defined, the psychometric properties of the asthma module instrument are emerging. *Weaknesses:* Limited published data on population norms, data regarding burden, and data regarding MCID.
No. of published English-language studies using tool since 2000 (ie, original empirical studies that actually used tool in a sample of asthma	1 study (reported in 2 articles)	12 studies (reported in 14 articles)	44 studies, including 14 clinical trials (reported in 46 articles)	19 studies, including 6 clinical trials (reported in 20 articles)	Not determined	Not determined

	CHSA-C (child)	CHSA (parent)	PAQLQ (child)	PACQLQ (caregiver)	Pictorial PAQLQ (child)	PedsQL 3.0 Asthma Module (child)
patients)						
Applicability to different populations	Applicable to minority and low-income populations in US; not tested in other countries or languages.	Applicable to minority and low-income populations in US, including Spanish-speaking US residents; not tested in other countries.	Applicable to minority and low-income populations in the US; also tested in several other countries; available in many different languages.	Applicable to minority and low-income populations in the US; also tested in several other countries; available in many different languages.		Applicable to wide age range; has been used in different US racial/ethnic groups.

CHSA, Child Health Survey for Asthma; *CHSA-C,* Child Health Survey for Asthma-Child Version; *FEV1*, forced expiratory volume in 1 second; *FQHC,* federally qualified health center; *HRQL,* health-related quality of life; *ICC,* intraclass correlation coefficient; *MCID,* minimal clinically important difference; *min,* minute(s); *NA,* not available; *PACQLQ,* Pediatric Asthma Caregiver Quality of Life Questionnaire; *PAQLQ,* Pediatric Asthma Quality of Life Questionnaire; *PedsQL 3.0 Asthma Module,* Pediatric Quality of Life Inventory 3.0 Asthma Module; *PEF,* peak expiratory flow; Pictorial *PAQLQ,* Pictorial Quality of Life Measure for Young Children With Asthma; *QOL,* quality of life; *SABA,* short-acting β-agonist; *SCHIP,* State Children's Health Insurance Program; *SES,* socioeconomic status; *WISC,* Wechsler Intelligence Scale for Children; *WPPSI,* Wechsler Preschool and Primary Scale of Intelligence.