Assessing the validity of the RAND Negative Impact of Asthma on Quality of Life Short Forms

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Background: In response to recommendations from the 2010 National Institutes of Health Asthma Outcomes Workshop, we developed a system for measuring the negative impact of asthma on quality of life (QoL), which was referred to as the RAND Negative Impact of Asthma on Quality of Life (RAND-IAQL) item bank. The bank contains 65 items that focus on the patient's perception of the impact or bother of asthma on his or her life.

Objective: Evidence for the validity of 2 short forms, the RAND-IAQL 4-item and 12-item Short Forms, from the bank is presented.

Methods: Using a sample of 2032 adults with asthma, we validated our short forms against the Asthma Quality of Life Questionnaire–Marks (AQLQ-M), the Asthma Control Test, and generic measures of QoL developed by the Patient-reported Outcomes Measurement Information System (PROMIS). Discriminant validity was examined by comparing scores of respondents who differed according to multiple health indicators.

Results: Our sample ranged in age from 18 to 99 years (mean, 43 years), with 14% Hispanic, 11% Asian, 19% African American, and 56% non-Hispanic white race/ethnicity. Men had a significantly worse impact of asthma on QoL than women. The impact of asthma on QoL was greatest in African American and Hispanic subjects compared with that seen in non-Hispanic white subjects. Our measures correlated highly with the AQLQ-M and more strongly with the PROMIS global physical than mental scales. They differentiated between adults with asthma according to their perceived severity, level of control, presence or absence of exacerbations, and physical comorbidity.

Conclusion: The RAND-IAQL item bank, measuring the impact of asthma on QoL, will complement other patient-reported outcomes, such as measures of asthma symptoms, functioning, and control. (J Allergy Clin Immunol 2014;■■■:■■■-■■■.)

Key words: *Validity, asthma, quality of life, short forms*

The 2010 National Institutes of Health Asthma Outcomes Workshop recommended that a new generation of quality-of-life (QoL) instruments was needed. These instruments should focus specifically on the patient's perception of the impact of asthma on QoL separate from measures of asthma symptoms, functioning, or control.[1] This recommendation is consistent with the recent emphasis in patient-centered outcomes research on patients' perceptions and outcomes that persons care about, including their health-related QoL.[2] In this era of increasing health care costs, there is a need for standard outcomes that allow for comparisons across clinical trials and other research studies to inform what works in patient care from the patient's point of view and allow for patient-informed choices in health care. Although historically clinicians have been concerned with physiologic and clinical symptom control measures, these outcomes have not been shown to be strongly related to how patients with asthma feel about the burden associated with their asthma on aspects of their everyday life.[3,4] QoL concerns might be one reason why patients choose one type of treatment over another. In addition, administration of the treatment might affect QoL independent of its effect on disease control. Asthma-specific QoL measures have the potential to offer detailed information on the impacts of asthma that is complementary to information obtained from measures of asthma control and lung functioning and that is more sensitive than generic measures of QoL to smaller differences and smaller change over time.[5] Although there are a number of established tools that have been used to measure QoL in asthmatic patients, most contain items that reflect symptoms and level of functioning, as well as perceived effect.[6-17] Thus the QoL subcommittee recommended development of new measures focused primarily on the perceived impact of asthma on QoL to disentangle these concepts.

In response to this recommendation, we developed the RAND Negative Impact of Asthma on Quality of Life (RAND-IAQL) item bank of 65 asthma-specific QoL items.[18,19] New items developed from patient focus groups, existing QoL items from a literature review of outcome measures for asthma, and recommendations from experts on asthma were assessed with state-of-the-art psychometric methods, including item response theory. Analyses supported the unidimensionality of the 65 items, suggesting that all items in the bank measure the same underlying construct. An item bank containing a large set of items, such as the RAND-IAQL bank, has many advantages over traditional scales. For example, not all the items in the bank need to be administered to produce a reliable score. Items can be administered adaptively (ie, with computer adaptive testing), or reliable subsets of items can be drawn from the bank manually to produce traditional, brief fixed-length instruments (ie, short forms) that retain the psychometric advantages of the larger item bank.

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Abbreviations used

ACT: Asthma Control Test
AQLQ-M: Asthma Quality of Life Questionnaire–Marks
COPD: Chronic obstructive pulmonary disease
PROMIS: Patient-reported Outcomes Measurement Information System
QoL: Quality of life
RAND-IAQL-4: RAND Negative Impact of Asthma on Quality of Life 4-item Short Form
RAND-IAQL-12: RAND Negative Impact of Asthma on Quality of Life 12-item Short Form

Two short forms were developed from the RAND-IAQL 65-item bank.[19] The first is based on the determination that the impact of asthma on the global aspects of QoL could be reliably assessed with as few as 4 carefully selected items (ie, the RAND Negative Impact of Asthma on Quality of Life 4-item Short Form [RAND-IAQL-4]; marginal reliability, 0.86). For the second, we broadened the content coverage and increased precision by adding 8 additional items (RAND Negative Impact of Asthma on Quality of Life 12-item Short Form [RAND-IAQL-12]; marginal reliability, 0.93). These short forms are highly intercorrelated ($r = 0.96$) and correlate highly with the RAND-IAQL item bank scores ($r = 0.93$ and 0.97, respectively), indicating that both short forms adequately represent the underlying latent dimension of asthma.

This article reports information on the construct and discriminant validity of the short-form instruments and provides descriptive information about the ways in which QoL scores vary by demographic and health characteristics of the sample.

METHODS

Subjects

Data come from a national sample registry of English-speaking adults (age ≥18 years) with asthma who were recruited by Harris Interactive (www.harrisinteractive.com), a global interactive media and services company that administered the items through Internet assessment. Recent research suggests that Internet-based sampling is feasible and that samples gathered in this manner and their findings do not differ significantly from samples and findings drawn with traditional methods.[20] Eligible subjects included those in the registry who self-reported asthma and confirmed that they had been told by a doctor or other health care professional that they had asthma and reported that they still have asthma. To ensure variability across a range of asthma severities, we required that 90% of the sample had experienced an episode of asthma or an attack in the prior 12 months.[21] African American, Asian, and Hispanic subjects were oversampled to obtain at least 200 interviews from each for psychometric analyses reported earlier.[19] Similarly, targets were set within each of 4 age groups (18-34, 35-49, 50-64, and ≥65 years) to enable sufficient power for subgroup analyses. The sample was also recruited to reflect the sex distribution of asthma in the general US adult population (40% men and 60% women).[22] All participants received points through Harris's online loyalty program, which could be redeemed for gifts, such as an Amazon gift card.

The study was approved by RAND's Institutional Review Board.

Measures

RAND-IAQL-4 and RAND-IAQL-12. We developed 2 short-form representations of the item bank consisting of 4 and 12 items judged as psychometrically strong and widely relevant across the latent QoL continuum.[19] The contents of the items are provided in Table I. The measures' standardized scores are derived from an item response theory model, which has been translated along a T-score metric with a mean of 50 for the field test population and an SD of 10.*,[23-26] Higher scores indicate a more perceived negative impact of asthma on QoL. For example, a score of 60 is 1 SD greater than the mean and suggests a greater impact of asthma on QoL. There were very few missing data for the QoL items in our sample. Only 34 (1.7%) of 2032 were missing 1 or more of the items in the RAND-IAQL-4 and therefore received a missing scale score. Only 5 (<1%) were missing more than 6 items in the RAND-IAQL-12. As per the Patient-reported Outcomes Measurement Information System (PROMIS) scoring rules, subjects who had 6 or fewer responses missing in the RAND-IAQL-12 received the mean score of the nonmissing items (n = 86 [4%]). Scoring algorithms are provided on the RAND Web site (http://www.rand.org/health/surveys_tools/iaql.html).

Asthma Quality of Life Questionnaire–Marks. We validated our short-form measures against the Asthma Quality of Life Questionnaire–Marks (AQLQ-M), which includes 20 questions yielding a total QoL score and 4 subscales: breathlessness, concern, mood, and social.[15] This measure has been shown to have good cross-sectional construct validity and reproducibility[16,27] and to predict asthma severity and work days missed and be responsive to changes in pulmonary function.[8]

Asthma Control Test. The Asthma Control Test (ACT)[28] was used to measure asthma control, a multidimensional construct that encompasses both symptoms and use of rescue medications and the impact of asthma on daily functioning. The ACT consists of 5 items and has strong psychometric properties, including good internal consistency, test-retest reliability, validity, and responsiveness.[17,29,30] Scores on this 5-item measure range from 5 to 25, with cutoffs of 5 to 15 (poorly controlled), 16 to 19 (somewhat controlled), and 20 to 25 (well controlled).

Generic health status/QoL. We used generic (ie, not disease-specific) multi-item short-form measures of QoL and health status developed by PROMIS and available through their assessment center (http://www.assessmentcenter.net/) to assess global physical and mental health, anxiety, sleep disturbance, and ability to participate in social roles and activities with 4 items in each domain.[31,32]

Asthma severity was assessed by using a single-item 5-point rating of the subject-perceived severity of asthma in the past month in terms of "very mild" to "very severe."

Demographics and health and service use. Subject-reported information was collected on the participant's sex, race, ethnicity, age, and education level. We asked subjects about the number of asthma-specific overnight stays in a hospital and emergency department or urgent care center visits in the last year and whether a doctor or other health care professional had ever told them that they had sinusitis, diabetes or high blood sugar, heart disease, chronic obstructive pulmonary disease (COPD), or migraine or other chronic severe headaches. The frequency of rescue inhaler use for quick relief from asthma symptoms during the past 4 weeks was assessed on a 5-point scale from "never" to "several times a day on most days." Use of controller medication was assessed by asking whether in the past 4 weeks the subject had taken a controller medication daily to protect their lungs and prevent asthma symptoms (attacks). Among those who answered yes, we asked, on average, how many times a day they took their controller medication. Work/activity loss days were determined by asking how many days subjects were unable to work or carry out their usual activities because of their asthma during the past 12 months.

Statistical analysis

Descriptive analyses were conducted to examine asthma-specific QoL as measured by the RAND-IAQL-4 and RAND-IAQL-12 for the entire sample,

*Standardized item response theory–based T-scores were generated from summed scores by using procedures described by Thissen et al[23] and later by Thissen and Wainer.[24] For the RAND-IAQL-4, T-scores were fixed at "missing" for participants with 1 or more missing item responses to the 4 items. For participants with 6 or fewer missing responses to the 12-item RAND-IAQL-12, the mean on the completed item responses was imputed for missing values before obtaining the standardized T-score. For more examples of this scoring methodology, see a number of articles describing PROMIS item banking procedures.[25,26]

TABLE I. Content of the RAND-IAQL-4 and RAND-IAQL-12 Short Forms

The following statements are about how asthma affects the quality of your life. For each statement, please give the 1 answer that comes closest to the way asthma has affected your life.
In the past 4 weeks, I worried about the long-term effects of asthma on my health.
In the past 4 weeks, I had to worry about asthma triggers.*
In the past 4 weeks, my asthma was on my mind.
In the past 4 weeks, it was hard to get a good night's sleep because of my asthma.
In the past 4 weeks, I felt like I couldn't enjoy life because of my asthma.*
In the past 4 weeks, I felt that asthma was controlling my life.
In the past 4 weeks, I felt frustrated that I couldn't make plans in advance because of my asthma.
In the past 4 weeks, because of my asthma, everyday activities were a struggle.
In the past 4 weeks, asthma placed stress on my relationships with family, friends, significant others, or coworkers.
In the past 4 weeks, because of my asthma, I felt frustrated that I have to do things differently than people who don't have asthma.*
In the past 4 weeks, I felt like I missed out on doing things with others because of my asthma.*
In the past 4 weeks, because of my asthma, I had to do a lot of planning to make sure I always had an inhaler ready.

Response choices: 0, not at all; 1, a little bit; 2, somewhat; 3, quite a bit; and 4, very much.
*Questions included in the RAND-IAQL-4.

as well as by demographic subgroups. We expected that asthma-specific QoL would be lower in persons with less than a high school education and lower in Hispanic and African American subjects than non-Hispanic white subjects.[33-35]

Construct validity was examined by looking at associations (Pearson correlation coefficients and Spearman rho $[r_s]$ for single-item variables) with related measures. We hypothesized that the RAND-IAQL-4 and RAND-IAQL-12 would correlate strongly with subject-reported single-item ratings of asthma severity and the extent to which asthma interferes with normal activities. We hypothesized that our measures would correlate highly with the AQLQ-M total score and the 4 construct-specific subscales but that the correlations would be stronger with the concerns, social, and mood subscales than with the breathlessness subscale, which contains symptom items. We expected strong correlations with the generic PROMIS QoL short forms. Given that the impact of asthma has been shown to be greater on the physical functioning component of QoL than on mental functioning,[36-38] we expected higher correlations with the PROMIS global physical health measure than with the PROMIS global mental health measure.

Discriminant validity was examined by comparing the RAND-IAQL-4 and RAND-IAQL-12 scores for respondents who differed according to indicators of asthma severity (number of asthma attacks), asthma control as measured by the ACT, presence or absence of comorbid medical conditions, number of work/activity loss days, and measures of health care use. We expected the impact of asthma on QoL would be greater in persons with indicators of more uncontrolled asthma and more work days missed[8] and in persons with greater health care use (more emergency department visits and hospitalizations for asthma during the past year and more frequent use of controller medications).

Tests of significance were calculated by using *t* tests for dichotomous variables or ANOVAs with Wald F tests for differences among 3 or more groups. *Post hoc* mean comparisons (Tukey) were calculated to test the significance of differences among pairs of groups, and effect sizes were estimated by using the Cohen *d* statistic.[39] For the Cohen *d* statistic, an effect size of 0.2 to 0.3 is often considered a small effect, and an effect size of approximately 0.5 is considered a medium effect, and an effect size of 0.8 or greater is considered a large effect.

TABLE II. Demographic characteristics of the asthma sample (n = 2032)

Median age (interquartile %)	42 (24)
Sex	
Female	1219 (60)
Ethnicity/race	
Hispanic	282 (14)
Asian	221 (11)
African American	381 (19)
Non-Hispanic white	1148 (56)
Region of United States	
East	478 (24)
Midwest	432 (21)
South	578 (28)
West	544 (27)
Education	
High school or less	353 (17)
Some college	743 (36)
College graduate	490 (24)
Some graduate school or graduate degree	446 (22)
Medical comorbidities	
Sinusitis	1284 (63)
Diabetes	505 (25)
Heart disease	194 (9)
COPD	287 (14)
Migraine headaches	660 (32)
Hospital stay in past year	385 (19)
Emergency visits for asthma in past year	
0	1248 (61)
1	282 (14)
2	204 (10)
≥3	297 (15)
Self-rating of asthma severity	
Very mild	383 (19)
Mild	580 (28)
Moderate	824 (41)
Severe	207 (10)
Very severe	36 (2)
Frequency of rescue inhaler use in past 4 wk	
Never	495 (24)
1/wk	510 (25)
≥2/wk but not daily	600 (29)
Daily	279 (14)
Several times a day on most days	143 (7)
Used controller medication daily in past 4 wk	1163 (57)
ACT level (score)	
Controlled (≥20)	770 (38)
Somewhat controlled (16-19)	446 (22)
Poorly controlled (5-15)	796 (39)

Values are presented as medians or numbers (percentages).

RESULTS

Our sample included a diverse group of 2032 asthmatic people (Table II). The mean age was 43 years (range, 18-99 years); 14% were Hispanic, 11% were Asian, 19% were African American, and 56% were non-Hispanic white. Of those who identified as Hispanic, 46% were of Mexican origin, 20% were of Puerto Rican origin, 11% were of Cuban origin, and 23% were of other Hispanic origin. Subjects were distributed throughout the United States (about a quarter each in the East, Midwest, South and West). The sample was fairly highly educated, with only 17% having less than or only a high school education. The sample included a range of asthma control levels, with 38% with controlled asthma, 22% with somewhat controlled asthma, and 39% with poorly

TABLE III. RAND-IAQL-4 and RAND-IAQL-12 scores by demographic group

			Differences between races			
			F = 46.1 (*P* < .001) for RAND-IAQL-4 F = 60.4 (*P* < .001) for RAND-IAQL-12			
Race/ethnicity		**Mean (SD)**	**Hispanic (*P* value)**	**African American (*P* value)**	**Asian (*P* value)**	**Non-Hispanic white (*P* value)**
Hispanic	RAND-IAQL-4	53.5 (9.2)	—	.17	.003	<.001
	RAND-IAQL-12	54.2 (9.6)		.08	<.001	<.001
African American	RAND-IAQL-4	52.1 (8.9)		—	.26	<.001
	RAND-IAQL-12	52.4 (9.2)			.18	<.001
Asian	RAND-IAQL-4	50.7 (9.7)			—	<.001
	RAND-IAQL-12	50.8 (9.9)				<.001
Non-Hispanic white	RAND-IAQL-4	47.6 (9.0)				—
	RAND-IAQL-12	47.2 (9.3)				
			Differences between educational levels			
			F = 16.6 (*P* < .001) for RAND-IAQL-4 F = 18.9 (*P* < .001) for RAND-IAQL-12			
Education		**Mean (SD)**	**Less than high school (*P* value)**	**Some college (*P* value)**	**College graduate (*P* value)**	**Some graduate school or graduate degree (*P* value)**
Less than high school	RAND-IAQL-4	51.5 (9.6)	—	.34	<.001	<.001
	RAND-IAQL-12	51.6 (10.1)		.43	<.001	<.001
Some college	RAND-IAQL-4	50.5 (9.0)		—	<.001	<.001
	RAND-IAQL-12	50.6 (9.2)			.002	<.001
College graduate	RAND-IAQL-4	48.5 (9.6)			—	.50
	RAND-IAQL-12	48.6 (10.1)				.11
Some graduate school or graduate degree	RAND-IAQL-4	47.6 (9.1)				—
	RAND-IAQL-12	47.2 (9.6)				
			Differences between age groups			
			F = 24.3 (*P* < .001) for RAND-IAQL-4 F = 23.7 (*P* < .001) for RAND-IAQL-12			
Age group		**Mean (SD)**	**18-34 y (*P* value)**	**35-49 y (*P* value)**	**50-64 y (*P* value)**	**≥65 y (*P* value)**
18-34 y	RAND-IAQL-4	51.8 (9.3)	—	<.001	.001	<.001
	RAND-IAQL-12	51.8 (9.9)		<.001	<.001	<.001
35-49 y	RAND-IAQL-4	49.2 (9.7)		—	.46	<.001
	RAND-IAQL-12	49.1 (10.2)			.46	.002
50-64 y	RAND-IAQL-4	48.4 (8.7)			—	.03
	RAND-IAQL-12	48.3 (8.8)				.05
≥65 y	RAND-IAQL-4	46.1 (8.6)				—
	RAND-IAQL-12	46.0 (8.9)				

Significance values are based on the Tukey-Kramer correction for multiple comparisons.

controlled asthma according to the ACT. Approximately 57% used a controller medication daily during the past 4 weeks to protect their lungs and prevent asthma symptoms, and only 24% reported never using a rescue inhaler in the past 4 weeks.

Description of RAND-IAQL-4 and RAND-IAQL-12

Men reported a significantly greater impact of asthma on their QoL than women (mean of 50.3 vs 49.1 [t = 2.9, $P = .004$] for the RAND-IAQL-4 and 50.6 vs 48.8 [t = 4.0, $P < .001$] for the RAND-IAQL-12), although the effect size was small (0.13 for the RAND-IAQL-4 and 0.18 for the RAND-IAQL-12). As expected (Table III), the negative impact of asthma on QoL was less for non-Hispanic white subjects and worst for Hispanic subjects (effect size 0.66 for the RAND-IAQL-4 and 0.75 for the RAND-IAQL-12) and other minorities (effect size = 0.50 and 0.57 between white and African American subjects and 0.34 and 0.39 between white and Asian subjects for the RAND-IAQL-4 and RAND-IAQL-12, respectively). There was a less negative impact of asthma on QoL as age increased (range of effects comparing age groups was 0.08-0.63 for the RAND-IAQL-4 and 0.09-0.60 for the RAND-IAQL-12, with the largest differences between those aged 18-34 and ≥65 years). In addition, more years of education was associated with a lesser effect of asthma on QoL (range of effects comparing education groups was 0.09-0.42 for the RAND-IAQL-4 and 0.10-0.45 for the RAND-IAQL-12, with the largest differences between those with a high school education or less and those with some graduate schooling).

Construct validity

As hypothesized, the RAND-IAQL-4 and RAND-IAQL-12 correlated strongly with a single-item self-reported rating of

TABLE IV. Correlations of RAND-IAQL-4 and RAND-IAQL-12 scores with AQLQ-M and PROMIS generic QoL measures

	RAND-IAQL-4 (95% CI)	RAND-IAQL-12 (95% CI)
AQLQ-M		
Total scale	0.88 (0.86 to 0.88)	0.90 (0.89 to 0.91)
Breathlessness subscale	0.80 (0.78 to 0.81)	0.84 (0.82 to 0.85)
Concerns subscale	0.86 (0.85 to 0.87)	0.88 (0.87 to 0.89)
Mood subscale	0.78 (0.76 to 0.80)	0.81 (0.79 to 0.82)
Social subscale	0.87 (0.86 to 0.88)	0.87 (0.86 to 0.88)
PROMIS generic QoL measures		
Global physical health	−0.54 (−0.57 to −0.51)	−0.57 (−0.60 to −0.54)
Global mental health	−0.42 (−0.46 to −0.39)	−0.43 (−0.46 to −0.39)
Ability to participate in social roles/activities	−0.69 (−0.71 to −0.66)	−0.70 (−0.72 to −0.68)
Anxiety	0.61 (0.58 to 0.64)	0.63 (0.60 to 0.65)
Sleep disturbance	0.39 (0.36 to 0.43)	0.42 (0.38 to 0.45)

Note: Higher scores on the PROMIS global physical and mental health short forms and the ability to participate in social roles/activities short form indicate better QoL.

severity of asthma (Spearman rho $[r_s] = 0.59$ and 0.63 with the RAND-IAQL-4 and RAND-IAQL-12, respectively) and a single-item subject-reported rating of how much asthma interferes with normal activities (Spearman rho $[r_s] = 0.72$ and 0.75, respectively). Correlations were high with the AQLQ-M total score (Pearson $r = 0.88$ and 0.9, Table IV). Slightly lower correlations were seen with the breathlessness and mood subscales than the concerns and social subscales. The RAND-IAQL-4 and RAND-IAQL-12 correlated less strongly with PROMIS generic measures of QoL than with the AQLQ-M measure. Correlations with the PROMIS generic QoL measures ranged from 0.39 to 0.70. Weakest correlations were with PROMIS sleep disturbance, and strongest correlations were with the PROMIS measure of one's ability to participate in social roles and activities. As expected, the asthma-specific QoL short forms were more strongly correlated with the PROMIS physical measure than the general mental health measure.

Discriminant validity

Table V shows the relationship between RAND-IAQL short-form scores and measures of health and asthma-related health care use. Mean asthma impact scores discriminated significantly between different levels of asthma-related health care use, presence versus absence of comorbid COPD, and levels of asthma control. Those who had an asthma attack in the past year had a significantly greater impact of asthma on QoL than those who had not had an attack in the past year (effect sizes for RAND-IAQL-4 and RAND-IAQL-12 = 1.06 and 1.13, respectively); a similar result was found comparing those who had been hospitalized for asthma in the past year with those without a hospitalization (effect sizes = 1.28 and 1.38), comparing those who used controller medications daily with those who did not use controller medications (0.62 and 0.71), and comparing those with comorbid COPD with those without COPD (0.62 and 0.68). Effect sizes ranged from 0.39 to 1.70 when comparing different numbers of attacks in past 4 weeks, 0.66 to 1.57 when comparing the number of times hospitalized in the past year, 0.38 to 1.85 when comparing the number of emergency department visits, 0.26 to 1.85 when comparing the number of times a day controller medications are used, and 0.65 to 1.73 when comparing the number of work days lost because of asthma in the past year. As presented previously, not only do impact scores decrease with increasing asthma control, as defined by the ACT, but mean RAND-IAQL scores for those in the somewhat controlled ACT category are very close to 50, indicating that the mean RAND-IAQL score is comparable with the somewhat controlled ACT category. Furthermore, the RAND-IAQL mean scores for the poorly controlled and well-controlled ACT groups were symmetrically distributed around the mean of the somewhat controlled category (ie, mean = 50; the difference in scores is approximately ±7 points or 0.7 SDs), suggesting a linear relationship between the RAND-IAQL and ACT.[19]

DISCUSSION

QoL is a key index of asthma's effect on subjects, and improved QoL is a key goal of treatment. Although a number of asthma-specific QoL instruments have been developed and used widely, available instruments often confound QoL with asthma symptom control and functional impairment.[1] To address this, we developed a more precise measurement of asthma QoL, the RAND-IAQL item bank and 4- and 12-item short forms, excluding symptoms and level of functional impairment and focusing explicitly on patients' perceptions of how much they are affected or bothered by their asthma. Previous reports supported the content validity of the item bank, which was generated from statements made by adults with asthma supplemented by items from a review of the literature and from expert recommendations.[18]

However, before one can be confident that a measure should be used to assess asthma-specific QoL, evidence of its validity is required. This study provided initial information about how this new measure varies by demographic characteristics and provided preliminary evidence to support the construct and discriminant validity of the 2 short-form measures, including information on how well asthma-specific QoL scores distinguish between different levels of asthma control. Because the short forms are comprised of items from the RAND-IAQL bank, any validity information obtained can be generalized to the full bank, as well as any other assessments generated from the bank (eg, computer adaptive tests and tailored short forms).

The RAND-IAQL-4 and RAND-IAQL-12 had high correlations with the AQLQ-M, especially with the 2 subscales having content more likely to reflect the negative impact of asthma on QoL (the concerns and social subscales as opposed to the breathlessness and mood subscales) supporting the validity of our scale. The social/concerns subscales were shown to reflect a single factor in the modified version of the AQLQ-M questionnaire.[6] High correlations were expected, especially because one particular item included in the RAND-IAQL-12 was identical to an AQLQ-M item (item 6 in Table I). Correlations were lower with generic (PROMIS) measures of QoL, as expected.

TABLE V. RAND-IAQL-4 and RAND-IAQL-12 scores by health characteristics and service use

Health characteristics	RAND-IAQL-4 (high score = greater effect) Mean (SD)	RAND-IAQL-12 (high score = greater effect) Mean (SD)	F or *t* test (RAND-IAQL-4/ RAND-IAQL-12 [*P* value])
Had asthma attack in past year			t = 14.1 (<.001) t = 15.1 (<.001)
Yes	50.5 (9.2)	50.6 (9.5)	
No	41.0 (6.2)	40.1 (6.8)	
No. of attacks in past 4 wk*			F = 251.2 (<.001) F = 301.0 (<.001)
0	44.1 (7.4)	43.5 (7.8)	
1	48.7 (9.0)	48.4 (8.8)	
2-4	51.9 (8.0)	52.3 (8.2)	
≥5	56.4 (8.5)	57.0 (8.3)	
Hospitalized for asthma in past year			t = 22.2 (<.001) t = 24.3 (<.001)
Yes	58.2 (7.4)	59.1 (7.8)	
No	47.5 (8.6)	47.2 (8.8)	
No. of times hospitalized in past year*			F = 263.1 (<.001) F = 305.2 (<.001)
0	47.5 (8.6)	47.2 (8.8)	
1	54.7 (8.9)	55.6 (9.6)	
≥2	59.6 (6.2)	60.5 (6.5)	
No. of emergency department visits in past year*			F = 279.5 (<.001) F = 352.6 (<.001)
0	45.8 (7.7)	45.2 (7.9)	
1	52.5 (8.7)	52.8 (8.6)	
2	55.7 (8.2)	56.5 (7.9)	
≥3	58.7 (7.3)	59.7 (7.4)	
Used controller medications daily past 4 wk			t = 13.6 (<.001) t = 15.7 (<.001)
Yes	51.9 (9.3)	52.3 (9.5)	
No	46.4 (8.5)	45.8 (8.9)	
Controller medication use (times/day)*			F = 69.3 (<.001) F = 81.0 (<.001)
0	46.4 (8.5)	45.8 (8.9)	
1	48.6 (8.2)	48.9 (8.2)	
2	52.1 (9.2)	52.3 (9.1)	
≥3	58.7 (8.2)	59.8 (8.6)	
Has COPD			t = 9.7 (<.001) t = 10.6 (<.001)
Yes	54.5 (9.0)	55.1 (9.0)	
No	48.8 (9.2)	48.6 (9.6)	
No. of days unable to work in past year because of asthma*			F = 429.2 (<.001) F = 502.7 (<.001)
0	42.9 (6.5)	42.2 (6.8)	
1-5	49.4 (8.7)	49.3 (9.0)	
≥6	54.9 (8.2)	55.4 (8.2)	
ACT*			F = 707.3 (<.001) F = 1007.2 (<.001)
Poorly controlled	56.4 (8.0)	57.3 (7.5)	
Somewhat controlled	49.4 (7.2)	49.5 (6.7)	
Well controlled	42.7 (6.2)	41.6 (6.4)	

**Post hoc* comparisons indicate that all control categories are significantly different from each other.

The highest correlations were with the generic measure of ability to participate in social roles and activities, highlighting the importance of this concept to perceived overall QoL in persons with asthma. Interestingly, the weakest correlations were with the sleep disturbance short form, which is one of the core indicators considered when determining asthma control. This might be due to the fact that the PROMIS sleep disturbance measure was defined in terms of sleep quality (eg, sleep was refreshing or sleep quality was poor) rather than in terms of awakening because of asthma symptoms. This suggests that nonspecific sleep disturbance is not a very good indicator of the impact of asthma on QoL.

The RAND-IAQL-4 and RAND-IAQL-12 showed clear evidence of discriminant validity. Both short forms were able to differentiate between adults with asthma according to their self-perceived severity, level of asthma control, presence or

absence of exacerbations (eg, number of asthma attacks, hospitalizations, and emergency department visits), and physical comorbidity. These results help to interpret the meaning of scores. On the basis of separate regression analyses, only 35% to 40% of the variance in the RAND-IAQL-4 and RAND-IAQL-12 was explained by a single-item rating of self-perceived severity of asthma, supporting the idea that these 2 concepts (self-perceived asthma severity and self-perceived burden of asthma on aspects of their everyday life) are not synonymous.

A limitation of the study is that it was conducted through an online Internet sample who might differ from patients with asthma seen in clinical settings. However, the sample was comprised of subjects from diverse demographic backgrounds representative of areas across the United States and varied across a range of self-reported asthma control. Diagnosis of asthma and select other medical conditions was self-reported and not confirmed independently by a clinician's report. Thus we cannot be sure that there was not some misdiagnosis of asthma. Although each QoL item asked whether the burden was due to asthma, future research should evaluate the measures in well-defined clinical populations. To ensure variability across a range of asthma severity, we required that 90% of the sample had experienced an episode of asthma or an attack in the prior 12 months. Thus our sample might reflect a more severe and poorly managed group than those in the general asthma population. However, self-ratings of asthma severity were low. It is possible that this discrepancy could have biased results through underestimation of known group differences, such as differences in asthma-specific QoL between those whose symptoms were poorly, somewhat, or well controlled. Although effect sizes might be slightly underestimated, the statistical inferences do not seem to have been affected by the low self-ratings of severity in our sample. We suspect that the low self-ratings might be due to the fact that some persons had adapted to their asthma and habituated to a lower QoL. How we might adapt QoL measurement to address adaptation to asthma is an important direction for future research.

We included subjects with comorbidity in our sample to develop a generalizable tool that could be used in clinical applications and effectiveness studies, which include more heterogeneous samples than those typically seen in efficacy studies of specific treatments. Specifically, comorbid COPD is often excluded in asthma clinical trials. To explore the extent to which our analyses might have been influenced by comorbid COPD, we repeated the analyses but excluding the small subgroup of asthmatic individuals who also reported having COPD. Correlations and score levels were similar, and differences among groups remained significant, even with the exclusion of this group. Further study is needed to examine whether our measures apply equally well to patients with COPD alone.

Our analyses represent the first step in showing the validity of the RAND-IAQL toolkit. Next steps include evaluating our measures in well-defined clinical populations and estimating minimally important differences and responsiveness to change in clinical outcomes. To aid in interpretation, we also recommend linking scores (eg, to use scores on one measure to describe scores on another measure) from the RAND-IAQL to other commonly used asthma-specific QoL measures.[40] The RAND-IAQL toolkit also needs to be adapted and evaluated for use in non–English-speaking populations.

Evidence from this study suggests that the RAND-IAQL item bank and its short forms show promise as a new tool designed to reduce respondent burden yet provide precise estimates of the impact of asthma on a person's QoL. The strong psychometric properties reported in Stucky et al[19] and the encouraging validity evidence reported in this article support the more widespread use of this measure.

We thank our expert panel, which includes Eric Kleerup, MD (Clinical Professor, David Geffen School of Medicine, Division of Pulmonary and Critical Care Medicine); Steve Erickson, PhD (Associate Professor at the University of Michigan College of Pharmacy); Cynthia Rand, PhD (Professor of Medicine at the Johns Hopkins School of Medicine); Felita Jones (Asthma and Allergy Foundation of America); and Chris Draft (community activist and founder of the Chris Draft Family Foundation).

Clinical implications: The RAND-IAQL is a valid gauge of a subject's perceptions of the impact or bother of asthma and its treatment on his or her life.

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