

# Assessing health-related quality of life in asthma

Elizabeth F Juniper MCSP MSc

Department of Clinical Epidemiology and Biostatistics, Faculty of Health Sciences, McMaster University  
Hamilton, Ontario

**EF Juniper.** Assessing health-related quality of life in asthma. *Can Respir J* 1997;4(3):145-151. Many clinicians now recognize the importance of incorporating an assessment of health-related quality of life (HRQL) into their clinical studies and practices. Conventional clinical measures provide valuable information about the status of the affected organ system but rarely capture the functional impairments (physical, emotional and social) that are important to patients in their everyday lives. To obtain a complete picture of a patient's health status, both the conventional clinical indices and the patient's HRQL must be measured. Both adults and children with asthma are distressed by symptoms, such as shortness of breath, cough and chest tightness, and they are limited in their day-to-day activities, such as sports, employment or school work and participation in activities with friends. In addition, both adults and children with asthma are concerned about having asthma, fearful of not having their medications when they need them and frightened of having an asthma attack. They become very frustrated, and children in particular often feel different and isolated from their friends. Disease-specific HRQL questionnaires have been developed and validated for both adults and children with asthma. This paper provides a review of these questionnaires and identifies their strengths and weaknesses. The questionnaires chosen for review have good measurement properties and validity and can be used in both clinical trials and clinical practice to assess the impact of asthma on a patient's life. Because one of the aims of treatment is to ensure that patients benefit from treatment, an essential component of clinical assessment should be evaluation of HRQL.

**Key Words:** *Asthma, Adults, Pediatrics, Quality of life, Questionnaires*

## Évaluation de la qualité de vie liée à la santé dans l'asthme

**RÉSUMÉ :** Nombreux sont les cliniciens qui reconnaissent maintenant l'importance d'incorporer une évaluation de la qualité de vie liée à la santé dans leurs études et dans leurs pratiques cliniques. Les mesures cliniques conventionnelles fournissent des informations utiles sur l'état des organes touchés par la maladie mais saisissent rarement les déficiences fonctionnelles (physiques, émotionnelles et sociales) qui jouent un rôle important dans la vie quotidienne des patients. Pour avoir un tableau complet de l'état de santé d'un patient, on doit à la fois mesurer les indices cliniques classiques et la qualité de vie liée à la santé du patient. Les symptômes tels que l'essoufflement, la toux et l'oppression dans la poitrine sont pénibles pour les adultes et les enfants asthmatiques. Par ailleurs, ces patients sont aussi limités dans leurs activités de la vie quotidienne telles que la pratique d'un sport, la vie professionnelle ou le travail scolaire et dans leur participation à des activités avec des amis. De plus, les adultes et les enfants asthmatiques s'inquiètent de leur asthme et de ne pouvoir disposer de leurs médicaments en cas de besoin, et redoutent aussi de subir une crise d'asthme. Ils ont un sentiment de frustration et les enfants, en particulier, se sentent différents de leurs amis et s'isolent. Des questionnaires sur la qualité de vie liée à la santé et spécifiques d'une maladie ont été développés et validés, à la fois pour les adultes et les enfants asthmatiques. Le présent article passe en revue ces questionnaires et identifie leurs forces et leurs faiblesses. Les questionnaires qui ont été sélectionnés pour être revus démontrent de bonnes propriétés de mesure et de validité, et ils peuvent être utilisés à la fois en pratique clinique et au cours d'essais cliniques pour étudier l'impact de l'asthme sur la vie d'un patient. Parce que l'un des objectifs du traitement est de garantir que les patients retirent des avantages du traitement, l'évaluation de la qualité de vie liée à la santé devrait être une composante essentielle de l'évaluation clinique.

Over the past 10 years, there has been an increasing awareness of the importance of including health-related quality of life (HRQL) in asthma clinical assessments. For many clinicians HRQL is a new term but certainly not a new

concept. Quality of life questionnaires ask patients the questions that clinicians have been asking for many generations. How are you feeling? Does your asthma limit you in your daily activities? Does this bother you? Did the new medica-

Correspondence and reprints: Prof Elizabeth Juniper, Department of Clinical Epidemiology and Biostatistics, McMaster University Medical Centre, Room 2C11, 1200 Main Street West, Hamilton, Ontario L8N 3Z5. Telephone 905-525-9140, ext 22153, fax 905-577-0017, e-mail Juniper@fhs.mcmaster.ca

tion help? The questionnaires provide a standardized, quantified and recorded summary of the problems patients themselves consider important, identify quickly any specific impairments that are troublesome and record, more accurately than recall, changes over time.

### WHAT IS HRQL?

'Quality of life' is a rather nebulous expression, often meaning different things to different people, and this has made defining it very difficult. However, most agree that many factors, such as finances, spirituality and health, contribute to quality of life and also affect each other. HRQL is the component of overall quality of life that is determined primarily by the person's health and can be influenced by clinical interventions. For simplicity and focus, the definition by Schipper and colleagues (1), "the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient" is good. The final phrase is important because it emphasizes that these are the impairments that the patients themselves consider important.

### WHY IS HRQL IMPORTANT IN ASTHMA?

It has been proposed that there are three reasons for treating patients: to prevent mortality, to reduce the probability of future morbidity and to improve patient well-being (2). Most conventional clinical measures of asthma assess the status of the airways (spirometry, symptoms, airway hyperresponsiveness, medication use) to achieve the first two goals. In the past, it was frequently assumed that these measures also provided insight into the patient's well-being. Certainly, patients with very impaired airways tend to have worse HRQL than patients with milder disease, but there a growing body of evidence shows that correlations between clinical measures of asthma severity and HRQL are only weak to moderate (Table 1) (3,4). Thus, to obtain a complete picture of a patient's health status, HRQL needs to be measured along with conventional indices.

Why should the relationship between clinical measures and HRQL be so weak? Take for example, two hypothetical patients with identical clinical asthma. Both women are age 35 years with a moderate degree of bronchoconstriction (65% predicted forced expiratory volume in 1 s [FEV<sub>1</sub>]) and moderate airway hyperresponsiveness to methacholine

(PC<sub>20</sub>: 1 mg/mL). The first patient has very poor perception of airway narrowing, works at home and can regulate her life style according to how she feels. She lives a very sedentary life and is generally a very laid back person. The second patient is very different. She has acute perception of airway narrowing, works in a high pressure job and has to attend meetings where people smoke. She is an athlete and is generally a very uptight person. She had a life-threatening asthma episode in the past. Although both patients present with similar degrees of airway narrowing and hyperresponsiveness, the second patient is likely to have much greater impairment of HRQL than the former as a result of her asthma. Now assume that both patients are given an inhaled steroid and both patients airway calibre increases to a FEV<sub>1</sub> of 95% predicted and PC<sub>20</sub> increases to 8 mg/mL. It is likely that, although clinical improvement is similar in both patients, the improvement in HRQL is likely to be much greater in the second patient than in the first.

### FUNCTIONAL IMPAIRMENTS THAT ARE MOST IMPORTANT TO PATIENTS WITH ASTHMA

Extensive HRQL research has highlighted the functional impairments that are most troublesome to adults with asthma (5-8). Adults with asthma are certainly bothered by the symptoms, the most troublesome being shortness of breath, chest tightness, wheeze and cough. Many patients have problems with physical activities such as sports, hurrying, going upstairs and shopping. Allergens may cause difficulties with daily activities such as vacuuming and other household chores, gardening and hobbies. Environmental stimuli, such as cigarette smoke, strong smells and troublesome weather conditions, may limit family activities and social visits. Asthma patients are bothered by poor sleep and often feel tired. In addition, they experience fears and concerns about having asthma and become frustrated by not being able to do the things they want to do. Occupational asthma causes its own special problems, with HRQL being poorer in these patients than in clinically matched patients whose asthma is not of occupational origin (9).

The burden of illness and functional impairments for children with asthma are similar to those experienced by adults. In addition, children are troubled because they cannot integrate fully with their peers. They feel isolated and left out,

**TABLE 1**

**Longitudinal correlations between quality of life and clinical outcomes in adults with asthma (3)**

Change in clinical outcomes	Overall HRQL	Change in Asthma Quality Of Life Questionnaire scores			
		Symptoms	Emotions	Activities	Environment
PEFR: morning	0.58	0.60	0.56	0.43	0.42
PEFR: Evening	0.48	0.50	0.43	0.36	0.40
Morning symptoms	0.47	0.49	0.45	0.38	0.28
Disturbance-free nights	0.28	0.30	0.26	0.20	0.17
Daytime symptoms	0.54	0.52	0.54	0.45	0.44
Forced expiratory volume in 1 s	0.38	0.36	0.37	0.33	0.28
Salbutamol use	0.43	0.41	0.46	0.35	0.29

HRQL Health-related quality of life; PEFR Peak expiratory flow rate

**TABLE 2**  
**Reliability of the Paediatric Asthma Quality of Life Questionnaire in children with stable asthma (14)**

Age Groups (years)	Reliability (intraclass correlation coefficient)			
	Overall HRQL	Symptoms	Activites	Emotions
All subjects	0.95	0.93	0.84	0.89
7 to 10	0.89	0.87	0.83	0.68
11 to 14	0.96	0.95	0.86	0.92
15 to 17	0.87	0.89	0.67	0.80

HRQL Health-related quality of life

which often causes them to feel frustrated, sad and angry (10-14). There is growing evidence that parents of children with asthma often have a poor perception of the problems and emotions that are troubling their child, and so it is essential to obtain the information directly from the child (15,16). Children as young as age seven years have little difficulty understanding the Paediatric Asthma Quality of Life Questionnaire and providing reliable and valid responses (Table 2).

### SELECTING A QUALITY OF LIFE QUESTIONNAIRE FOR ASTHMA

If a clinician is going to include a measure of HRQL in a clinical assessment, it is important to select the instrument that is most appropriate for the task. There is no 'best' instrument because they all have strengths and weaknesses. The clinician should decide which properties and measurement characteristics are going to be essential for the particular task. **Measurement properties:** When selecting an instrument, it is important to ensure that it has both face and content validity, that is, the instrument appears to measure what it purports to measure (face validity), and the items in the questionnaire have been selected using recognized procedures that ensure that all areas of function considered important by patients are captured (content validity). Questionnaires in which items have been selected by clinicians rarely meet this criterion because some impairments that patients consider important may have been omitted.

**Discriminative properties:** Instruments used to distinguish among individuals or groups of patients require good discriminative properties (reliability and cross-sectional construct validity) (17). For example, when screening, or in a cross-sectional survey, one might want to distinguish between individuals who do or do not have asthma or, among asthma patients who have mild, moderate or severe impairment.

**Evaluative properties:** Instruments used in clinical trials and for following individual patients in the clinic are required to measure change in HRQL over time, and for this they must have good evaluative properties (responsiveness and longitudinal construct validity) (17).

**Interpretability:** Repeated experience with a wide variety of physiological measures allows clinicians to make meaningful interpretations of results. For instance, the experienced asthma clinician will have little difficulty interpreting a 0.5 L

increase in FEV<sub>1</sub>. In contrast, the meaning of a change in score of 0.5 on a HRQL instrument is less intuitively obvious, not only because there are no units but also because, as yet, health professionals seldom use HRQL measures in clinical practice. The approach that is used for interpreting quality of life data is referred to as 'anchor-based' (18), where the changes in HRQL measures are compared, or anchored, with other clinically meaningful outcomes. A minimal important difference (MID) is defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and would mandate, in the absence of troublesome side-effects and excessive cost, a change in the patient's management" (19).

### HRQL INSTRUMENTS FOR ASTHMA

**Generic versus specific:** There are two types of HRQL questionnaires, generic and specific. Generic instruments are designed to apply to patients in all health states. The most commonly used and the best validated are the Sickness Impact Profile (SIP) (20), the Medical Outcomes Survey Short Form 36 (SF-36) (21), the Nottingham Health Profile (22) and the McMaster Health Index (23). Although each profile attempts to measure all important aspects of health-related function, they achieve this in different ways. For instance, the SF-36 contains nine domains, which can be combined into two primary functions, mental and physical. In contrast, the SIP has two major domains, physical and psychosocial, which combine to give one overall score.

The great advantage of generic instruments is that burden of illness can be compared across different medical conditions. For instance, one can compare the burden of illness experienced by patients with rhinitis and asthma (24,25). However, because generic questionnaires are required to be broad in their comprehensiveness to cover all medical conditions, they have very little depth, and, as a result, impairments that are important to patients with a specific condition may not be included. Consequently, in many conditions, including adult and pediatric asthma, generic instruments tend to be unresponsive to small changes (that are important to patients) in HRQL (4,26). Therefore, the use of generic instruments in clinical trials and practice, where one wants to examine the effect of treatment within individuals or groups of patients, is limited.

This lack of depth of focus in generic instruments has led to development of disease-specific instruments for patients with asthma. Disease-specific instruments are developed by asking patients about the impairments that are most important to them, and, therefore, these instruments really focus on the problems for which patients seek help. Disease-specific instruments are much more responsive to clinically important changes in HRQL.

**Utilities:** Utility instruments measure the value that either the patient or society places on various health states. They are very popular with health economists, not only because they provide a single number, representing HRQL from 0 (death) to 1 (perfect health), but also because the majority of instruments meet the assumptions for utility theory. For measuring

**TABLE 3**  
**Health related quality of life questionnaires for adult asthma\***

Instrument	Type	Patients	Number of questions
Asthma Quality of Life Questionnaire (Juniper) (31)	Disease-specific	Asthma	32
Asthma Quality of Life Questionnaire (Marks) (33)	Disease-specific	Asthma	20
Living with Asthma Questionnaire (34)	Disease-specific	Asthma	68
St George's Respiratory Questionnaire (35)	Disease-specific	COPD and asthma	76
Respiratory Illness Quality of Life Questionnaire (38)	Disease-specific	COPD and asthma	55
Life Activities Questionnaire for Asthma (8)	Disease-specific	Asthma	71
Asthma Bother Profile (39)	Disease-specific	Asthma	22
Sickness Impact Profile (4,20)	Generic		137
Medical Outcomes Survey Short Form 36 (21,25)	Generic		36

\*Health related quality of life questionnaires for which there are published validation studies in adults with asthma. COPD Chronic obstructive pulmonary disease. All of these questionnaires are copyrighted and should not be altered or translated without the author's permission

the value that patients themselves place on their own health state, the most common instruments are the Standard Gamble (27), the Time Trade Off (27) and the Feeling Thermometer (27). For measuring the value that society places on various health states, there are the Quality of Well-being Scale (28), the Multiattribute Health Utilities Index (29) and the Euro-Qol (30). For a long time, these instruments were only used in generic form (ie, to apply to all medical conditions), and in this form they have the same weakness as the generic health profiles – they are unresponsive to small but important changes (4). Recently, the Standard Gamble and the Feeling Thermometer have been modified for use as disease-specific instruments in children with asthma and appear to have much improved measurement properties (26).

### DISEASE-SPECIFIC QUESTIONNAIRES FOR ADULTS WITH ASTHMA

A number of instruments claim to measure HRQL in asthma but focus exclusively on symptoms and physical activity limitations that clinicians consider important and do not incorporate all the functional impairments that are important to patients. The present review is restricted to those instruments that measure functions that patients with asthma have identified as important and for which there are at least initial reports of development methods and measurement properties (Table 3). To ensure that all potentially eligible instruments were considered, searches were done using MEDLINE, Citation Index and Current Contents, and information was sought from other investigators working in asthma HRQL.

**The Asthma Quality Of Life Questionnaire (Juniper) (AQLQ):** The AQLQ is a 32-item questionnaire in which items were selected entirely according to their importance to patients (5,31). Patients were asked to identify items, from a pool of 150 potentially important items, that they had experienced in the last year, and score the importance of each positively identified item on a five-point scale. Items identified most frequently, and scoring the highest, were those included in the AQLQ. The items are in four domains (symptoms, emotions, exposure to environmental stimuli and activity limitation). Patients respond to each item on a seven-point scale, and the results are reported as the mean score of all

items (1, extremely impaired, to 7, no impairment). The instrument is in both interview and self-administered formats and takes approximately 10 mins to complete at the first visit and 5 mins at follow-up. A unique feature of the AQLQ is that five of the 11 items in the activity limitation domain are 'individualized'. Each patient identifies five important activities that are done regularly, and at each clinic visit the patient is asked about limitations experienced during these activities. For long term studies, where individualized activities are impractical, a standardized version of the questionnaire is available. In addition, a shortened version of the AQLQ, the Mini AQLQ, which has 15 items, has been validated.

Three independent studies have evaluated the measurement properties of the AQLQ (4,31,32). Each has shown that the instrument has excellent reliability and responsiveness, and strong validity. For interpretability of the seven-point scale, a change in mean score of 0.5, both for overall quality of life and for each of the individual domains, represents a MID. **The Asthma Quality of life Questionnaire (Marks):** The Asthma Quality of Life Questionnaire (6,33) is a self-administered questionnaire containing 20 items in four domains (breathlessness and physical restrictions, mood disturbance, social disruption and concerns for health) (6,33). Patients rate each item on a five-point scale. The investigators selected items using both importance, as rated by patients, and psychometric techniques. The questionnaire takes approximately 5 mins to complete. The instrument has been thoroughly tested and has good discriminative and evaluative properties (6,33), but interpretability has not yet been addressed.

**The Living With Asthma Questionnaire:** The Living with Asthma Questionnaire (7,34) is a 68-item instrument with 11 domains (social/leisure, sport, holidays, sleep, work, colds, morbidity, effects on others, medication use, sex, and dysphoric states and attitudes). Items identified from patient focus group discussions were selected for the questionnaire using psychometric techniques and factor analysis. Unlike the instruments of Juniper et al (31) and Marks et al (33), impairments experienced as a direct result of asthma symptoms are not included. Responses are given using a three-



point scale. The instrument has good discriminative properties but its evaluative properties are not as good as those of the Juniper AQLQ (4). Interpretability has not yet been addressed.

**The St George's Respiratory Questionnaire:** The St George's Respiratory Questionnaire (35) is self-administered and is applicable to patients with both reversible and fixed airway obstruction. It contains 76 items in three domains (symptoms, activity and impacts on daily life). The methods used for its development have not yet been published, and so the criteria for item selection are unclear. The instrument has excellent reliability and very acceptable cross-sectional validity. It has been used in a number of clinical trials (36); however, its responsiveness does not seem to be as good as that of the other asthma-specific instruments. On a scale of zero to 100, a change in score of 4.0 represents the MID (37).

**Respiratory Illness Quality of Life Questionnaire:** Like the St George's Respiratory Questionnaire, the items in the Respiratory Illness Quality of Life Questionnaire (38) were selected to be apply to both chronic pulmonary obstructive disease (CPOD) and asthma patients. Initially, a pool of 221 potentially important items was generated from a literature review, existing measures and consultation with health professionals. Two hundred and four patients identified the amount of bother experienced with each item during the previous year. Items were included if they were applicable to at least 70% of respondents and loaded highly on the first two or three factors in the factor analysis. There are 55 items in seven domains: breathing problems; physical problems; emotions; situations triggering or enhancing breathing problems; daily and domestic activities; social activities, relationships and sexuality; and general activities. Cross-sectional correlations between the domains and clinical indexes of disease severity suggest that the instrument may have good discriminative properties. However, reliability, in terms of the intraclass correlation coefficient (ICC), has not yet been reported and neither have the measurement properties necessary for use in clinical trials.

**Life Activities Questionnaire for Adult Asthma:** The Life Activities Questionnaire for Adult Asthma instrument (8) has 70 items in seven domains: physical activities; work activities; outdoor activities; emotions and emotional behaviour; home care; eating and drinking activities; and miscellaneous. Items were selected based on frequency of experience by patients. Responses are given on a five-point scale, and the questionnaire is self-administered. The instrument shows high internal consistency, but other measurement properties necessary for confident use as either a discriminative or evaluative instrument have not been published. The questionnaire reports only activity limitations and does not include other aspects of HRQL that other investigators have shown are important to patients with asthma (eg, emotional function, concerns about health, symptoms, etc).

**Asthma Bother Profile:** The 22 items in the self-administered Asthma Bother Profile (39) were selected from five earlier asthma and COPD quality of life questionnaires (31,33-35,40) to measure the psychological impact of asthma. There are two domains, which measure the distress

that asthma occasions in a variety of contexts (15 items) and asthma management, which itself has three subdomains: asthma knowledge, quality of care and confidence in self-management (seven items). Focus group discussions with 32 asthma patients helped to refine the items and determined that the content was relevant. The management domain, but not the distress domain, was able to detect differences between patients who attended a self-management asthma clinic and those who did not. The reliability for the full instrument and the measurement properties necessary for clinical trials have not yet been reported.

**Summary of adult asthma-specific quality of life instruments:** Data available suggest that the first five adult instruments discussed (AQLQ, the Asthma Quality of Life Questionnaire, the Living with Asthma Questionnaire, the St George's Respiratory Questionnaire and the Respiratory Illness Quality Of Life Questionnaire) (31,33-35,38) have measurement properties that enable them to be used satisfactorily for discriminative purposes, but only the first two by Juniper et al (31) and Marks et al (33) have shown good responsiveness and longitudinal construct validity, properties that are essential for use in clinical trials and clinical practice. Five of the instruments are specific for asthma (AQLQ, the Asthma Quality of Life Questionnaire, the Living With Asthma Questionnaire, a Life Activities Questionnaire for Adult Asthma and the Asthma Bother Profile) (8,31,33,34,39), whereas the St George's Respiratory Questionnaire (35) and the Respiratory Illness Questionnaire (38) are for both asthma and COPD patients. The MID has been determined for only the Juniper AQLQ (31) and the St George's Respiratory Questionnaire (35).

#### DISEASE-SPECIFIC QUESTIONNAIRES FOR CHILDREN WITH ASTHMA

Several questionnaires assess impairments in children with asthma but only three (14,41,42) meet the two criteria specified for inclusion in the adult instrument review (Table 4). The method of development ensured that items important to children with asthma were included, and there is evidence of the development methods and measurement properties. Usherwood et al (13) developed an instrument for assessing symptoms and disability in children, but the items were selected by general practitioners and mothers of children with asthma and do not cover emotional or social function. In addition, the questionnaire is completed by the mother, and there is now evidence that parents may have a poor perception of their child's asthma-related quality of life (15,16).

**The Paediatric Asthma Quality of Life Questionnaire:** The Paediatric Asthma Quality of Life Questionnaire has been designed for children with asthma, age seven to 17 years (14). It has 23 items in three domains (symptoms, activity limitation and emotional function); three of the activity items are 'individualized'. Items were selected on their importance to the children. It is in both interviewer and self-administered versions, has seven-point response options and takes approximately 10 mins to complete. Patients experience no difficulty understanding the questions or the response options. In a

**TABLE 4**  
**Health related quality of life questionnaires for pediatric asthma\***

Instrument	Type	Patient groups	Number of questions
Paediatric Asthma Quality of Life Questionnaire (14)	Disease-specific	Seven to 17 years	23
Life Activities Questionnaire for Childhood Asthma (41)	Disease-specific	Five to 17 years	71
Childhood Asthma Questionnaires (CAQ) (42)	Disease-specific		
CAQA		Four to seven years	18
CAQB		Eight to 11 years	34
CAQC		12 to 16 years	–
Paediatric Asthma Caregivers' Quality of Life Questionnaire (43)	Disease-specific	Parents of children with asthma	36

\*Health related quality of life questionnaires for which there are published validation studies in children with asthma. All of these questionnaires are copyrighted and should not be used or translated without the author's permission

52-patient validation study, the questionnaire has shown good measurement properties as both an evaluative and discriminative instrument (14). In patients who are stable, it has very acceptable reliability with an ICC of 0.84. It has also shown good responsiveness in its ability to detect changes in patients whose health state changed ( $P < 0.001$ ) and differentiate between patients in stable and unstable clinical states ( $P < 0.0001$ ). Correlations between the instrument and among conventional clinical asthma measures and generic HRQL, were close to those predicted for both longitudinal and cross-sectional validation. The clinical interpretation of changes in score is very similar to that found for the AQLQ (31), namely, a change in score of approximately 0.5 on the seven-point scale represents a MID.

**A Life Activities Questionnaire for Childhood Asthma:** In an open-ended questionnaire (41), 92 children (five to 17 years of age) with asthma were asked to identify activities in which they were limited by their asthma. Of the 246 activities identified, 71 were reported by two or more children and included in the questionnaire. Activities are in seven domains: physical; work; outdoor; emotions and emotional behaviour (eg, laughing); home care; eating and drinking; and miscellaneous. Children are asked to recall limitations during the past week and to score these on a five-point scale (no restriction to total restriction). Test-retest yielded a Pearson  $r$  of 0.76, and there was internal consistency with Cronbach's alpha of 0.97. Other measurement properties have not yet been reported.

**Childhood asthma questionnaires (CAQs):** Three separate instruments have been developed for children age four to seven years (CAQA), eight to 11 years (CAQB) and 12 to 16 years (CAQC) (11,42). The questionnaires were developed from discussions with children but the actual method of item selection is unclear. The CAQA is in two domains: quality of living (applicable to asthmatic and nonasthmatic children, 14 items) and distress (asthma only, four items). Response options are four 'smiley' faces, and the questionnaire is completed with the help of the parent. The CAQB has four domains: active quality of living and passive quality of living (22 items), distress (six items) and severity (six items). Response options are five faces. The CAQC has five domains: active and teenage quality of living, distress, severity and reactivity. The instruments were tested in 535 children, 281

(age four to 16 years) with a history of asthma and 256 (age four to 11 years) with no history of asthma. Although reliability is acceptable in all three instruments, no differences were observed between asthmatics and nonasthmatics. This suggests that the questionnaires lack cross-sectional validity and thus have limited discriminative properties. There are no data on responsiveness or longitudinal construct validity.

**Summary of pediatric asthma-specific quality of life instruments:** The Paediatric Asthma Quality of Life Questionnaire (14) has demonstrated good properties as both an evaluative and discriminative instrument. The question of interpretation of data has been addressed, and it can therefore be used with confidence in both clinical trials and surveys. The Life Activities Questionnaire for Childhood Asthma (41) measures activity limitations but not other quality of life impairments that are important to children with asthma. Neither discriminative nor evaluative properties have yet been reported. Although the Childhood Asthma Questionnaires (42) show moderate to good reliability, discriminative ability may be poor, and no evidence is available on whether the instruments are sufficiently responsive for use in clinical trials.

#### PLACE OF HRQL IN CLINICAL TRIALS AND CLINICAL PRACTICE

Recognition of the importance of HRQL, the poor correlation between conventional asthma measures and HRQL, and the advent of HRQL instruments with strong measurement properties has already ensured that many asthma clinical trials include an assessment of HRQL as a primary end-point. Most instruments are short, easily understood and usually self-administered, making completion very easy for the investigator and patient. In fact, we have found that patients enjoy completing HRQL questionnaires because they can relate to the questions and know that the things that are important to them are being considered. In addition, it is likely that national pharmaceutical regulatory agencies will soon ask for evidence of patient benefit for new product submissions.

The use of HRQL instruments in clinical practice is growing. Disease-specific quality of life questionnaires are a formalized and quantified method for taking a simple patient history. The advantages are that the patient can complete the questionnaire while sitting in the waiting room; a quick scan

of the responses will save consultation time; the interviewer does not have to remember all the important questions; the questionnaire often reveals problems not spontaneously identified by the patient (particularly in children); the clinician can quickly focus on areas of particular importance to the patient; and responses at each clinical visit can be compared to determine whether interventions have been beneficial. As more and more clinicians start using HRQL data in very innovative ways, such as for improving treatment compliance, further uses are likely to emerge.

## REFERENCES

- Schipper H, Clinch J, Powell V. Definitions and conceptual issues. Quality of life assessment in clinical trials. Spilker B, ed. New York: Raven Press Ltd, 1990:11-24.
- Guyatt GH, Naylor D, Juniper EF, Heyland D, Cook D and the Evidence-Based Medicine Working Group. Users' guides to the medical literature IX. How to use an article about health-related quality of life. *JAMA* 1997;277:1232-7.
- Juniper EF, Johnston PR, Borkhoff CM, Guyatt GH, Boulet LP, Haukioja A. Quality of life in asthma clinical trials: comparison of salmeterol and salbutamol. *Am J Respir Crit Care Med* 1995;151:66-70.
- Rutten-van Molken MPMH, Clusters F, Van Doorslaer EKA, et al. Comparison of performance of four instruments in evaluating the effects of salmeterol on asthma quality of life. *Eur Respir J* 1995;8:888-98.
- Juniper EF, Guyatt GH, Epstein RS, Ferrie PJ, Jaeschke R, Hiller TK. Evaluation of impairment of health-related quality of life in asthma: development of a questionnaire for use in clinical trials. *Thorax* 1992;47:76-83.
- Marks GB, Dunn SM, Woolcock AJ. A scale for the measurement of quality of life in adults with asthma. *J Clin Epidemiol* 1992;45:461-72.
- Hyland ME, Finnis S, Irvine SH. A scale for assessing quality of life in adult asthma sufferers. *J Psychosom Res* 1991;35:99-110.
- Creer TL, Wigal JK, Kotses H, McConaughy K, Winder JA. A life activities questionnaire for adult asthma. *J Asthma* 1992;29:393-9.
- Malo JL, Boulet LP, Dewitte JD, et al. Quality of life of subjects with occupational asthma. *J Allergy Clin Immunol* 1993;91:1121-7.
- Townsend M, Feeny DH, Guyatt GH, Seip AE, Dolovich J. Evaluation of the burden of illness for pediatric asthmatic patients and their parents. *Annals Allergy* 1991;67:403-8.
- Christie MJ, French D, Sowden A, West A. Development of child-centred disease-specific questionnaires for living with asthma. *Psychosom Med* 1993;55:541-8.
- Nocon A. Social and emotional impact of childhood asthma. *Arch Dis Child* 1991;66:458-60.
- Usherwood TP, Scrimgeour A, Barber JH. Questionnaire to measure perceived symptoms and disability in asthma. *Arch Dis Child* 1990;65:779-81.
- Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in children with asthma. *Qual Life Res* 1996;5:35-46.
- Guyatt GH, Juniper EF, Feeny DH, Griffith LE. Children and adult perceptions of childhood asthma. *Pediatrics* 1997;99:165-8.
- Wood PR, Hidalgo HA, Prihoda TJ, Kromer ME. Comparison of Hispanic children's and parents' responses to questions about the child's asthma. *Arch Pediatr Adolesc Med* 1994;148:P43.
- Guyatt GH, Kirshner B, Jaeschke R. Measuring health status: what are the necessary measurement properties? *J Clin Epidemiol* 1992;45:1341-5.
- Lydick E, Epstein RS. Interpretation of quality of life changes. *Qual Life Res* 1993;2:221-6.
- Juniper EF, Guyatt GH, Willan A, Griffith LE. Determining a minimal important change in a disease-specific quality of life questionnaire. *J Clin Epidemiol* 1994;47:81-7.
- Bergner M, Bobbitt RA, Carter WB, Gilson BS. The sickness impact profile; development and final revision of a health status measure. *Med Care* 1981;19:787-805.
- Stewart AL, Hays R, Ware JE. The MOS short-form general health survey. Reliability and validity in a patient population. *Med Care* 1988;26:724-32.
- Hunt SM, McKenna SP, McEwen J, Backett EM, Williams J, Papp E. A quantitative approach to perceived health status; a validation study. *J Epidemiol Community Health* 1980;34:281-6.
- Sackett DL, Chambers LW, MacPherson AS, Goldsmith CH, McAuley RG. The development and application of indices of health; general methods and summary of results. *Am J Public Health* 1977;67:423-8.
- Bousquet J, Bullinger M, Fayol C, Marquis P, Valentin B, Burtin B. Assessment of quality of life in patients with perennial rhinitis with the French version of the SF-36 health status questionnaire. *J Allergy Clin Immunol* 1994;94:182-8.
- Bousquet J, Knani J, Dhivert H, et al. Quality of life in asthma. 1. Internal consistency and validity of the SF-36 questionnaire. *Am J Respir Crit Care Med* 1994;149:371-5.
- Juniper EF, Guyatt GH, Feeny DH, Griffith LE, Ferrie PJ. Minimum skills required by children to complete health-related quality of life instruments: comparison of instruments for measuring asthma-specific quality of life. *Eur Respir J*. (In press)
- Torrance GW. Measurement of health state utilities for economic appraisal. *J Health Econom* 1986;5:1-30.
- Kaplan RM, Anderson JP, Wu AW, Matthews WC, Kozin F, Orenstein D. The Quality of Well-being Scale: application in AIDS, cystic fibrosis and arthritis. *Med Care* 1989;27:S27-43.
- Feeny D, Furlong W, Barr RD, Torrance GW, Rosenbaum P, Weitzman S. A comprehensive multi-attribute system for classifying the health status of survivors of childhood cancer. *J Clin Oncol* 1992;10:923-8.
- The EuroQol Group. A new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199-208.
- Juniper EF, Guyatt GH, Ferrie PJ, Griffith LE. Measuring quality of life in asthma. *Am Rev Respir Dis* 1993;147:832-8.
- Rowe BH, Oxman AD. Performance of an asthma quality of life questionnaire in an outpatient setting. *Am Rev Respir Dis* 1993;148:675-81.
- Marks GB, Dunn SM, Woolcock AJ. An evaluation of an asthma quality of life questionnaire as a measure of change in adults with asthma. *J Clin Epidemiol* 1993;46:1103-11.
- Hyland ME. The living with asthma questionnaire. *Respir Med* 1991;85:13-6.
- Jones PW, Quirk FH, Baveystock CM, Littlejohns P. A self-complete measure of health status for chronic airflow limitation; the St. George's Respiratory Questionnaire. *Am Rev Respir Dis* 1992;145:1321-7.
- Jones PW. Nedocromil sodium quality of life study group. Quality of life, symptoms and pulmonary function in asthma: long-term treatment with nedocromil sodium examined in a controlled multicentre trial. *Eur Respir J* 1994;7:55-62.
- Jones PW, Lasserson D. Relationship between change in St George's Respiratory Questionnaire score and patients' perception of treatment efficacy after one year of therapy with nedocromil sodium. *Am J Respir Crit Care Med* 1994;149:A211.
- Maille AR, Kaptein AA, Koning CJM, Zwinderman AH. Developing a quality of life questionnaire for patients with respiratory illness. *Monaldi Arch Chest Dis* 1994;49:76-8.
- Hyland ME, Ley A, Fisher DW, Woodward V. Measurement of psychological distress in asthma and asthma management programs. *Br J Clin Psychol* 1995;34:601-11.
- Guyatt GH, Berman LB, Townsend M, Pugsley SO, Chambers LW. A measure of quality of life for clinical trials in chronic lung disease. *Thorax* 1987;42:773-8.
- Creer TL, Wigal JK, Kotses H, Hatala JC, McConaughy K, Winder JA. A life activities questionnaire for childhood asthma. *J Asthma* 1993;30:467-73.
- French DJ, Christie MJ, Sowden AJ. The reproducibility of the childhood asthma questionnaires: measures of quality of life for children with asthma aged 4 - 16 years. *Qual Life Res* 1994;3:215-24.
- Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in the parents of children with asthma. *Qual Life Res* 1996;5:27-34.





**Hindawi**  
Submit your manuscripts at  
<http://www.hindawi.com>

