



Key points

- › Asthma patients want help to improve their ability to function in their daily lives (physical, social, occupational and emotional).
- › Awareness of patients' problems and a willingness to treat them may improve both asthma control and quality of life.
- › The clinician and the patient should negotiate a treatment plan that addresses both asthma control and the patient's needs, and that the patient is willing to follow.
- › Valid, easy-to-use, self-administered asthma quality-of-life questionnaires can be used in the clinic to identify quickly the patient's specific problems and treatment goals.

Assessing asthma quality of life: its role in clinical practice

E.F. Juniper

Educational aims

- ▶ To define HRQL and emphasise its importance in patients with asthma.
- ▶ To describe the HRQL impairments experienced by adults and children with asthma.
- ▶ To discuss the role of HRQL in clinical practice and the concept of shared decision making.
- ▶ To provide information on the selection, methods of administration, analysis, interpretation and cultural adaptation of HRQL questionnaires

Summary

An important contributor to poor patient compliance with treatment instructions may be a discrepancy between the goals of the clinician and those of the patient. Improved clinician awareness of patients' asthma-related quality-of-life goals and a readiness to address them may enhance patients' willingness to take medications and, thus, improve both their asthma control and their quality of life. The aim of this article is to explain how quick, valid, easy-to-use, self-administered and clinic-friendly HRQL can be used to identify patients' greatest needs, ascertain how troublesome they are and ensure that they are included in the treatment plan. HRQL questionnaires can also be used to monitor patient progress over time.

With a wide range of efficacious asthma medications and clear guidelines for their use now available [1–4], it is often low rates of patient compliance that pose the major challenge to effective asthma management [5–9]. An important contributor to poor patient compliance may be a discrepancy between the goals of the clinician and those of the patient [10]. Clinicians tend to focus on preventing mortality and reducing morbidity by good asthma control, whereas patients are usually more concerned with their ability to function normally in their day-to-day lives. Improved clinician awareness of patients' asthma-related quality-

of-life goals and a willingness to address them may enhance patients' willingness to take medications and, thus, improve both their asthma control and their quality of life. Hence, there is a need for quick, valid, easy-to-use, self-administered and clinic-friendly health-related quality-of-life (HRQL) questionnaires. The responses to these questionnaires can be used during a consultation to identify the patient's greatest needs, ascertain how troublesome they are and ensure that they are addressed in the treatment plan. Questionnaires with strong measurement properties can also be used to monitor patient progress over time.

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HRQL

The quality of a person's life may be considered in terms of its richness, completeness and contentedness. A number of factors contribute to this sense of well-being, and these include good health, a secure social and occupational environment, financial security, spirituality, self-confidence, and strong, supportive relationships. Each factor may be a determinant of a person's quality of life and may be closely interrelated with each of the others. For instance, a patient will often be able to deal with an illness better if they have good family support, a strong faith and the financial ability to acquire nourishing food, shelter and treatment.

HRQL can be considered as the part of a person's overall quality of life that is determined primarily by the person's health status and which can be influenced by clinical interventions. The definition provided by Schipper *et al.* [11] is both simple and focused: "the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient". The final phrase is important because it emphasises that these are

the impairments that patients themselves consider important. Schipper *et al.* [11] go on to say that quality of life has four basic components: physical and occupational function, psychological state (emotional function), social interaction, and somatic sensation (the problems associated with symptoms).

This definition is used by many clinicians and academics, and it has guided the development and validation of many disease-specific quality-of-life questionnaires [12]. However, it is worth being aware that not everyone uses this definition, and the term has been discontinued in some areas. In the USA, and particularly within the US pharmaceutical industry, "quality of life" has been replaced by "patient-reported outcomes". This has caused some confusion because clinicians tend to think that "patient-reported outcomes" are the ones, both subjective (*e.g.* symptoms) and objective (*e.g.* peak expiratory flow (PEF)), recorded by patients. Elsewhere, "quality of life" is referred to as "health status", but, once again, "health status" is often considered by clinicians to be any objective or subjective measure of patient health. In recent years, there has been a growing public

Table 1 Factor analysis showing that HRQL is a distinct component of asthma health status (varimax rotated factor pattern)

	Factor 1	Factor 2	Factor 3	Factor 4
AQLQ				
Overall	93#	8	-24	-24
Activities	89#	11	-12	-17
Environment	83#	7	-3	-7
Symptoms	78#	6	-37	-30
Emotions	74#	5	-21	-24
FEV ₁	0	92#	-8	-4
PEF pm	23	84#	-3	18
PEF am	15	83#	0	-11
FVC	15	80#	-2	8
FEF	-19	69#	-12	-16
Night-time waking	-24	-6	84#	15
Night-time rescue β_2 -agonist	-10	-6	75#	18
Night-time symptoms	-25	-4	50#	47#
Nights without β_2 -agonist %	13	6	-77#	-8
Nights without waking %	22	3	-84#	-7
Short of breath daytime	-30	-7	5	65#
Activity limitation	-37	-2	14	63#
Δ PEF pm-am	17	5	-5	59#
Chest tightness daytime	-30	0	0	57#
Wheeze daytime	-23	6	16	50#
Rescue β_2 -agonist daytime	-4	-10	18	46#
Days without β_2 -agonist %	4	0	-11	-44#

#: statistically significant loading on factor. For clarity of reading, all values have been multiplied by 100. AQLQ: Asthma Quality of Life Questionnaire. Data taken from [14].



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awareness of the concept of “quality of life”, and so it seems sensible that the component of it that is associated with health should be called “health-related quality of life”. For those of you who prefer “patient-reported outcomes” and “health status” when referring to the functional impairments that patients consider important, please forgive me for continuing to use “quality of life”.

The importance of HRQL in asthma

There are three reasons for treating patients: to prevent mortality, to reduce the probability of future morbidity, and to improve patient well-being [13]. Most conventional clinical measures of asthma control and asthma severity assess the status of the airways, and are primarily used to gauge whether the first two goals are being achieved. In the past, it was frequently assumed that these measures also provided insight into patients’ well-being. Certainly, patients with very severe asthma tend to have a worse quality of life than patients with milder disease; however, a recent factor analysis has revealed that not only does quality of life not correlate closely with clinical status, but it is also a very distinct component of overall asthma health status and, therefore, the impact that asthma has on a patient’s quality of life cannot be inferred from the clinical indices, it must be measured directly (table 1) [14].

Why is the relationship between clinical measures and quality of life so weak? At the moment, there is no evidence to establish whether the cause is purely extrinsic or a combination of intrinsic and extrinsic. An intrinsic component is suggested by the results of a pharmaceutical clinical trial which showed clinically important improvements in HRQL, but no evidence of change in clinical asthma status in an intervention group when compared with control [15]. The reason for this discrepancy has not yet been explained. However, extrinsic causes for the weak

correlation between quality of life and clinical asthma are quite easy to understand. Let us take, as an example, two hypothetical patients with identical clinical asthma. Both females are 35 years of age with a moderate degree of bronchoconstriction (forced expiratory volume in one second (FEV₁) 65% predicted) and moderate airway hyperresponsiveness to methacholine (PC₂₀; 1 mg·mL⁻¹). The first patient has very poor perception of airway narrowing, she works at home and can regulate her lifestyle according to how she feels. She lives a very sedentary life and is generally a very relaxed person. The second patient is very different. She has very good perception of airway narrowing, she works in a high pressure job and has to attend meetings where people smoke. She is an athlete and is a very uptight person. In the past, she has had a life-threatening asthma episode. Although both these patients present with similar degrees of airway narrowing and hyperresponsiveness, the second patient is likely to have much greater impairment of quality of life than the former as a result of her asthma. Similar scenarios can easily be imagined for children with asthma where additional factors, such as family support and desire to keep up with peers, will also affect the child’s quality of life.

HRQL impairments in asthma

Adults

Extensive research has highlighted the functional impairments that are most troublesome to adults with asthma (table 2) [16–20]. They are certainly bothered by the symptoms themselves. The most troublesome are usually 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 occupational, recreational and social activities. Environmental stimuli, such as cigarette smoke,

Table 2 Functional impairments most important to adults with asthma

Symptoms	Emotions	Activities	Environment
Short of breath	Afraid of not having	Exercise/sports	Cigarettes
Chest tightness	medications available	Hurrying	Dust
Wheeze	Afraid of getting out of breath	Social activities	Air pollution
Cough	Concerned about the need to	Pets	Cold air
Tired	use medications	Work/housework	Pollen
	Frustrated		

strong smells and troublesome weather conditions, may interfere with family and social activities. Asthma patients are bothered by not being able to get a good night's sleep and often feel tired. In addition, they experience fears and concerns about having asthma and the need to take medications. They become frustrated by their limitations. The functional impairments (physical, social, emotional and occupational) that are important to patients are remarkably consistent in both sexes, and across a wide range of ages, cultures and severity of asthma [16, 21]. However, females tend to experience greater impairment than males [16, 22], inner city African Americans have poorer scores than other Americans [23], patients with low socio-economic status are worse than higher groups [24], and patients with occupational asthma are worse than patients whose asthma is not of occupational origin [25]. All of these observations have been made after correcting for clinical asthma severity.

Children

The burden of illness and functional impairments experienced by children with asthma are similar to those experienced by adults (table 3) [26–29]. In addition, children are troubled because they cannot integrate fully with their peers, they feel isolated and left out, and this often causes them to feel frustrated, irritable and angry. There is growing evidence that parents often have a poor perception of the problems and emotions that are troubling the child, and so it is essential to obtain quality-of-life information directly from the child [30–32]. Children as young as 6 years have little difficulty understanding HRQL questionnaires, and they are able to provide reliable and valid responses [33–34].

HRQL in clinical practice

As already mentioned, patients are treated for three reasons: to prevent mortality, to reduce the probability of future morbidity and to improve

patient well-being (quality of life) [13]. Clinicians tend to focus on the first two goals, prevention of mortality and reduction of morbidity. In asthma, these two goals can be achieved by improving and maintaining asthma control. All international guidelines for the management of asthma indicate that good control can be achieved by minimising day- and night-time symptoms, activity limitation, airway narrowing and rescue bronchodilator use, and, thus, reduce the risk of life-threatening exacerbations and long-term airway morbidity.

However, patients' own goals may be very different from those of clinicians and, although some patients may be concerned about dying, their primary goals are usually about their quality of life [10]. Most patients seek help from their clinicians in order to feel and function better in their everyday activities. They want to be able to enjoy sports, function well at work, participate in social activities with their friends and family, and cope easily with day-to-day activities of living. In addition, they want to have their fears and concerns addressed. These fears and concerns often include anxiety about the use of medications.

Shared decision making

Shared decision making [35] is an approach to patient management in which the clinician and the patient decide together on the patient's management plan (table 4). In asthma, the clinician brings to the encounter expertise in diagnosis, the goals of clinical asthma control and asthma treatment options. The patient brings to the encounter his/her own goals for improving asthma-related quality of life, concerns about medications and likes/dislikes of various forms of treatment regimens. Together, the clinician and patient negotiate an asthma management plan that works towards both their goals and which, most importantly, the patient is willing to follow.

Inadequate asthma control frequently occurs when patients take the decision-making role away from clinicians and make their own choices about their management (usually a conscious or subconscious decision not to take their

Table 3 Functional impairments most important to children with asthma

Symptoms	Emotions	Activities
Short of breath	Feel different and left out	Sports and games
Chest tightness	Frustrated	Activities with friends
Cough	Angry	Playing with pets
Wheeze	Sad	School activities
Tired	Frightened/anxious	Sleeping

medication as prescribed). Most patients do not have an adequate understanding of asthma and the mechanisms of action of the interventions to make such decisions, and usually fail to meet both their own goals and those of the clinician. Although patients usually do not want to be the prime decision maker [36, 37], they take over that role when they are unhappy with a treatment regimen paternalistically prescribed for them by their clinician. With the Internet and other modern technologies providing patients with a plethora of information, often inaccurate or misleading, they need a supportive environment in which they can discuss treatment options.

Shared decision making requires clinicians to move out of their conventional role as the sole decision maker, and engage with the patient in a discussion of the clinical goals, the patient's personal goals and the management options. Already there is evidence that willingness of physicians to discuss management is strongly related to asthma outcomes and patient satisfaction [38]. Initial studies have suggested that HRQL questionnaires may have an important role in facilitating the identification of patients' goals and concerns. After the patient has completed the questionnaire in the waiting room, a quick scan of the responses allows the clinician to focus on the problems that are most troublesome, and this quickly leads to the identification of the patient's treatment goals. Initial studies in primary care have suggested that prescribing practices are altered when clinicians are provided with Mini Asthma Quality of Life Questionnaire [39] data during a consultation [40, 41], and similar experiences have been reported in children. Feedback

from patients has been positive: they have reported that they like the questionnaires because their own concerns are being addressed, and they have identified that the questionnaires give them permission to discuss asthma-related concerns, other than symptoms, with their clinician. However, the real test of whether there is a place for HRQL questionnaires in this model of clinical practice will be whether both asthma control and quality of life are enhanced by the use of the questionnaires. There are currently international studies, both in primary and secondary care, addressing this question.

HRQL in clinical trials

The recognition of the importance of quality of life, the poor correlation between the conventional clinical indices of airway impairment and quality of life, and the advent of HRQL instruments with strong measurement properties has ensured that most asthma clinical trials now include quality of life as one of the primary endpoints [42]. Since these instruments are short, easily understood and usually in self-administered format, completion is very little burden, either to the investigator or the patient. In fact, it has been 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 taken into consideration. In addition, national pharmaceutical regulatory agencies often require quality-of-life data for new product submissions.



Table 4 The shared decision-making model in asthma

	Clinician alone	Clinician + patient	Patient alone
<i>Model</i>	<i>Paternalistic</i>	<i>Shared decision making</i>	<i>Informed decision making</i>
<i>Primary goals</i>	<i>Asthma control</i>	<i>Asthma control Asthma-related quality of life Acceptable treatment regimen</i>	<i>Asthma-related quality of life Acceptable treatment regimen</i>
<i>Information</i>	<i>Clinician knows about diagnosis, guidelines for asthma control and treatment options</i>	<i>Exchange of facts and treatment preferences</i>	<i>The patient is provided with all the facts in order to make the decision</i>
<i>Reality</i>	<i>Majority of treatment strategies are decided by clinicians on their own</i>	<i>Clinician's and patient's goals achieved</i>	<i>Patients, without the facts, reject the clinician's directions and decide for themselves how to take their medication Non-compliance</i>

Examples of questions from the AQLQ(s)

Please complete all questions by circling the number that best describes how you have been during the last 2 weeks as a result of your asthma.

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID YOU:

- 1= All of the Time
 2= Most of the Time
 3= A Good Bit of the Time
 4= Some of the Time
 5= A Little of the Time
 6= Hardly Any of the Time
 7= None of the Time

Feel SHORT OF BREATH as a result of your asthma?

- 1 2 3 4
 5 6 7

Feel bothered by or have to avoid DUST in the environment?

- 1 2 3 4
 5 6 7

Feel FRUSTRATED as a result of your asthma?

- 1 2 3 4
 5 6 7

Feel bothered by COUGHING?

- 1 2 3 4
 5 6 7

Have DIFFICULTY GETTING A GOOD NIGHT'S SLEEP as a result of your asthma?

- 1 2 3 4
 5 6 7

Selecting the right questionnaire

Questionnaires

1. Generic health profiles

Generic health profiles are designed to be applicable to patients with all medical conditions [43–46]. In adults, the most commonly used and the best validated is the Medical Outcomes Survey Short Form 36 (SF-36) [43]. For children, probably the most widely used is the Child Health Questionnaire [47]. These questionnaires measure impairment over a broad spectrum of functions and their great advantage 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 asthma, chronic obstructive pulmonary disease, rhinitis, inflammatory bowel disease, rheumatoid arthritis, *etc.* [48, 49]. However, because they are required to be broad in their comprehensiveness, they have very little depth and, therefore, impairments that are important to patients with a specific condition may not be included. Consequently, in many conditions, including asthma, generic instruments are not only unable to identify specific problems in individual patients, but are also unresponsive to small but important changes in quality of life [50, 51]. Therefore, the use of generic instruments in both clinical practice and clinical trials is limited.

2. Disease-specific questionnaires

The inadequate depth of focus of generic health profiles has led to the development of disease-specific questionnaires. These instruments include all the functional impairments (physical, emotional, social and occupational) that are most important to patients with a specific disease and are, therefore, ideal for identifying specific problems that are bothering individual patients [17–20, 52]. In addition, a number of studies have shown that disease-specific questionnaires are very much more sensitive to changes in patients' HRQL than generic health profiles [33, 50–52]. These questionnaires are not only used extensively in clinical trials, but clinicians are also now using them in clinical practice to help identify patients' asthma goals and to evaluate the effect of interventions.

Measurement properties

1. Face and content validity

When selecting an instrument, one first needs to ensure that it has face and content validity; that

is so say, the instrument appears to measure what it purports to measure (face validity) and that the items in the questionnaire have been selected using recognised procedures which ensure that they capture all the areas of function that are considered important by patients (content validity) [12, 53, 54]. Questionnaires in which items have been selected by clinicians rarely have content validity because there is no evidence that the impairments they have selected are important to patients, neither is there evidence that the questionnaires include all the problems that patients consider most troublesome.

2. Evaluative versus discriminative properties

Instruments which are to be used in cross-sectional studies (*e.g.* clinical screening and surveys) must have good discriminative properties [55], because they are required to discriminate between patients and groups of patients of different levels of impairment. Instruments which are to be used in longitudinal studies (clinical trials and clinical practice) need to have good evaluative properties [55], because they are required to evaluate change in impairment over time.

Discriminative properties. An instrument that is used to distinguish between individuals or groups of patients at a single point in time, for example, between individuals who do or do not have impaired HRQL, or, within asthma patients, between those who have mild, moderate or severe impairment, requires reliability and cross sectional validity [55].

Reliability is the ability of the instrument to measure differences between patients at a single point in time (signal = between-subject variance, noise = within-subject variance). The test statistic usually used to express reliability is the intraclass correlation coefficient (ICC), which relates the between-subject variance to the total variance. (Cronbach's alpha, which measures the internal consistency, *i.e.* similarity of the questions, does not give an indication of this property. The Pearson correlation coefficient evaluates the closeness of association between consecutive assessments, but does not capture bias.)

Occasionally it is possible to evaluate whether a questionnaire is measuring what it purports to measure (validity) by comparing it with a gold standard (criterion validity). This may occur when a shorter or simpler version of a well-established and validated questionnaire has been developed to measure the same construct (concept) as the original. For instance, the Standardised and Mini versions of the Asthma Quality of Life

Questionnaire [39, 56] were validated against the original version [52]. When there is no gold standard, the developer can put forward hypotheses or constructs, which, if they are met, provide evidence that the instrument is valid (construct validity). The approach frequently used is to demonstrate that the various domains of a new HRQL instrument correlate, in a predicted manner, with other indices of asthma severity and with other HRQL instruments [21, 22, 26, 34, 50, 52, 57].

Evaluative properties. An instrument that is used to measure longitudinal change within an individual or group of patients must have good responsiveness and longitudinal validity [55].

Responsiveness is the ability of the instrument to respond to small but clinically important changes that occur either spontaneously or as the result of an intervention. The signal is the true within-subject change over time and the noise is the within-subject variance unrelated to the true within-subject change; the relationship between the two is known as the responsiveness index [58]. The most common method for assessing responsiveness is to evaluate the sensitivity of the instrument to changes following treatment of known therapeutic benefit. If a formal estimate of the responsiveness index is not available, an instrument that has already performed well in a clinical trial will probably have acceptable responsiveness.

Evaluative instruments also require longitudinal validity. Longitudinal validity is usually demonstrated by showing that changes in the various domains of the new quality-of-life instrument correlate in a predicted manner with changes in other outcome measures, such as clinical asthma severity and generic quality of life.

Most developers publish reliability and cross-sectional validity data and, good as these may be, they are no guarantee that the instrument will be capable of performing well in a clinical trial. There are now a number of clinical trials in which patients experienced clinically important changes in quality of life that instruments with good reliability and cross-sectional validity failed to detect.

Interpretation of HRQL data

For many disease-specific HRQL questionnaires, we now have estimates of what difference or change in score can be considered clinically meaningful. This value is usually referred to as the minimal important difference (MID). It has been defined as "the smallest difference in score 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" [59].

1. Clinical trials

Using the MID to interpret clinical trial data is not as simple as it might first appear. Just comparing the mean differences between treatment groups with the MID is very inadequate, may lead to erroneous conclusions and a lot of valuable information is lost. Patients are very heterogeneous in their responses to interventions and by only looking at the mean one ignores the distribution about the mean. One method has been developed, using the proportions of patients who improve and deteriorate by the MID on the trial interventions, to calculate the number-needed-to-treat (NNT) [60]. This is the number of patients who need to be treated with the new intervention in order for one patient to have a clinically important improvement in their quality of life over and above that which they would have had on the control treatment. For years, statisticians have been warning about the limitations of only looking at mean data and ignoring distributions, but terms like confidence intervals and standard deviations usually draw a veiled glaze over the eyes of non-statisticians. We believe that this method of presenting quality-of-life results not only addresses the concerns of statisticians, but also provides clinicians with a conceptually easy and clinically meaningful way of understanding the results of clinical studies.

2. Clinical practice

The MID may be determined by examining change in the questionnaire score relative to patients' perception of change (global rating of change) [59] or linking the change scores to other clinical indices whose MID is well established [61]. Whichever method is used, clinicians should recognise that, although MID may be accurate for group data, there may be quite large differences between individual patients. Therefore, the MID should only be used as a rough guide and discussions with patients about whether the changes they have experienced are important should also be included in any decision-making process. However, it is also important to remember that there is now evidence that both patients and clinicians may be very inaccurate in their ability to estimate change in status over time [62, 63]! For estimating whether changes in quality-of-life scores are clinically important, it is probably wisest to use all sources of information, and to recognise their strengths and weaknesses.

Examples of questions from the AQLQ(s)

HOW LIMITED HAVE YOU BEEN DURING THE LAST 2 WEEKS DOING THESE ACTIVITIES AS A RESULT OF YOUR ASTHMA?

- 1= Totally Limited
- 2= Extremely Limited
- 3= Very Limited
- 4= Moderate Limitation
- 5= Some Limitation
- 6= A Little Limitation
- 7= Not at all Limited

STRENUOUS ACTIVITIES (such as hurrying, exercising, running up stairs, sports)

- 1 2 3 4
 5 6 7

MODERATE ACTIVITIES (such as walking, housework, gardening, shopping, climbing stairs)

- 1 2 3 4
 5 6 7

SOCIAL ACTIVITIES (such as talking, playing with pets/children, visiting friends/relatives)

- 1 2 3 4
 5 6 7

Practical considerations

Methods of administration

1. Self-reported *versus* interviewer-administered

Paper versions of questionnaires completed by patients themselves in the clinic remain the most popular method for collecting quality-of-life data. The strengths and weaknesses of the various methods are shown in table 5. Although there are many studies showing very little difference in overall scores when questionnaires are completed by patients and when administered by a trained

interviewer, it is usually considered wise to stick to one method when the patient is being followed over time. In clinical trials, a minority of patients may not have adequate reading or numeracy skills. There is a minimal risk of bias if these patients consistently have the questionnaire administered by an interviewer while the rest of the patients complete it on their own.

2. Telephone *versus* clinic

Studies comparing telephone *versus* clinic interviews are far less consistent, and so it is sensible to check whether the questionnaire that you are using has been evaluated for telephone administration. Some questionnaires score consistently higher by telephone, while others score lower [64,

	Advantages	Disadvantages
<i>Self-completed in clinic (paper)</i>	<ul style="list-style-type: none"> Most popular, because accurate, easy and cheap Honest responses (no embarrassment or wanting to please interviewer) Clinic staff available to help No missing responses (if permitted by ethics) Time to think 	<ul style="list-style-type: none"> Need some literacy and numeracy skills Must attend the clinic
<i>Self-completed in clinic (computer)</i>	<ul style="list-style-type: none"> Honest responses No missing responses Time to think about responses No transcription errors 	<ul style="list-style-type: none"> Very difficult to program High mistake rate (none are idiot proof) Need computer Train clinic staff in computer use Need for basic computer skills Expensive
<i>Interviewer-administered in clinic</i>	<ul style="list-style-type: none"> No missing responses Can correct misunderstood questions or response options Need minimal numeracy skills (ideal for young children and adults with low literacy skills) 	<ul style="list-style-type: none"> Employ and train interviewers Risk of interpretation and/or response guidance by interviewer Embarrassment or desire to please may affect responses Poor-interviewing can cause errors
<i>Telephone</i>	<ul style="list-style-type: none"> No missing responses Do not have to attend clinic More honest responses than postal (minimal family impact) 	<ul style="list-style-type: none"> Need for telephone Employ and train interviewers Provide response options before call Cannot ensure the respondent is the patient
<i>Post</i>	<ul style="list-style-type: none"> Do not have to attend clinic Time to think about responses 	<ul style="list-style-type: none"> Missing data and questionnaires not returned Need literacy and numeracy skills Nobody to help Family may influence responses Questionnaires lost in post
<i>Surrogate</i>	<ul style="list-style-type: none"> Better than nothing 	<ul style="list-style-type: none"> Inaccurate, response may not reflect patient's experiences (especially emotional)

65]. It is important not to mix telephone interviews with clinic ones in a clinical trial or when following individual patients. If response options are more than dichotomous (*e.g.* 7-point scale), it is wise to provide the patient with the response options ahead of the phone call (we also give them a magnet to put them on the refrigerator).

3. Electronic versus paper

Scores from electronic and paper versions are usually very similar [66]. However, although programmers have been trying for over a decade, there are still very few successful systems for electronic data collection. Programming can be quite complicated in order to overcome both practical and ethical problems. On the practical side, it is important for patients to be able to check and change responses they have already given. Programming flexible movement around questionnaires and providing change options can be quite difficult. In addition, the screen on handheld devices is often not large enough to include a complete question plus response options.

On the ethical side, many countries now require patients to be able to skip questions they don't want to answer. Questionnaires that have been successfully programmed then tend to run into practical problems because they cannot be made totally "idiot proof". Apart from problems caused by people who are not computer literate, some patients and clinic staff love to "find out how it works", manage to get into incredibly secure software and then the whole system crashes. It then requires a programmer to get it back into action.

4. Postal versus clinic

It is always best if patients are on their own when they complete questionnaires, and there is only one way to ensure that this happens and that is in the clinic (telephone is almost as good). There is a risk when questionnaires are completed outside the clinic that you get a family consensus. In addition, some patients don't want their families to know what they are really experiencing, whereas others seek their family's guidance on both the interpretation of questions and the choice of responses. Although postal completion runs the risk of missing data, a recent study comparing postal and clinic completion suggested that failure to attend the clinic may be comparable to the missing postal data [67].

Children

A large number of studies in a wide range of

childhood illnesses have shown that parents have a very poor perception of the problems that bother the child [30–32]. There have been a number of hypotheses as to why this happens, such as the parent imagining how they would feel if they had the illness, not knowing about the child's experiences at school and at night, the child not wanting the parent to know about their true experiences because of over/underprotection, *etc.* Whatever the reason, the message is the same: ask the child. There is strong evidence that children as young as 6 years can respond to HRQL questionnaires accurately and reliably [33, 34]. The problem with going any younger is that the concept of time doesn't develop until about 6 years of age and, if you ask children how they have been "over the last week", for example, they cannot understand. They know how they are now, but, with functional impairments varying during the day and from day to day, it is necessary to include several days in an assessment of HRQL to get an average and not accidentally catch a peak or trough. Children over ~11 years can usually self-complete questionnaires with no help. The limiting factor in going any lower does not appear to be reading skills, but a willingness to concentrate. Little boys tend to scatter responses like confetti so that they can get on with more interesting activities!

Cultural adaptation/linguistic validation

Adapting HRQL questionnaires for another language and culture is a great deal more complicated than doing a simple translation [68]. Although the problems that are important to asthma patients are fairly consistent across continents and cultures, there are occasionally minor differences that need to be taken into consideration. For instance, although "feeling frustrated" is important to patients in most countries, Portuguese patients say they do not experience this emotion, they accept asthma and its effects on their day-to-day lives as something with which they have to live. Parents in North America feel "anger" that their child has asthma, whereas, in the rest of the world, "sadness" is a more commonly identified emotion [69]. Part of the adaptation process must ensure that the problems that are important to local patients are included in the new language (content validity).

The process usually involves a team of translators working closely with the developer, because it is important that the team accurately understands the meaning of each question. Members of

Copyright

Most HRQL questionnaires are copyrighted by the developer. This is to ensure that they are not modified, translated or sold (paper and electronic) without the developer's permission. The most important reason for copyrighting is to ensure that nobody changes the questions, response options or time specification, each of which can invalidate the instrument. Rogue versions that get into general circulation can cause enormous problems, because users often don't know that they are not using the original instrument. Entire studies have been lost by investigators not getting an original from the developer. As cultural adaptation/linguistic validation is specialised work, most developers copyright their questionnaires to ensure that translations are done to the highest standard and to ensure that there is only one authorised version available in each language.

the team should not only be medical linguists, but also skilled in clinical measurement and scaling. There are usually two forward translations by independent translators whose primary language is the one into which the questionnaire is being translated. There is then a reconciliation of the two forward translations followed by two backward translations, ideally by people whose primary language is English (or the original language of the questionnaire). Probably the most important part of the whole process is the testing in patients (cognitive debriefing). The purpose of this phase is to ensure that the words chosen by the translators are easily and accurately understood by patients and that all the important problems have been included. It is very important to use the words that patients themselves use to describe their symptoms and limitations, not the terms used by clinicians.

Ideally, every new cultural adaptation should undergo a complete measurement property validation. However, this is expensive and time consuming. There is now good evidence that if the linguistic validation is done to a high standard [68], the resulting questionnaire will have measurement properties very similar to those of the original. When a HRQL questionnaire is used in a

multinational clinical trial [70], data from the various countries can be used to confirm the consistency of the measurement properties (usually responsiveness and construct validity) across languages. Cronbach's alpha will provide evidence of the internal consistency of the items across the different languages, but such analyses make the assumption that similar patients were enrolled in each country and that they have all responded in a similar manner to the intervention.

Conclusion

Apart from achieving good asthma control, an important aim of asthma management should also be to ensure that the patients' own goals are identified and addressed. These goals cannot be inferred from the conventional clinical measures of asthma control, as HRQL correlates poorly with these indices. The inclusion of simple HRQL questionnaires in the routine clinical management of asthma patients may help to identify patients' goals and ensure that they are included in a negotiated treatment plan. Willingness to follow a negotiated plan should lead to both improved HRQL and asthma control.

Educational questions

- The functional problems that are most troublesome to patients with asthma can be accurately assessed using:
 - FEV₁.
 - An asthma-control questionnaire.
 - Neither a) nor b).
 - a) and b) together.
- The clinical goals of asthma management are the same as patients' goals.
 - Correct.
 - Incorrect.
- When a patient with asthma experiences a small but clinically important change in their HRQL, the type of questionnaire most likely to be able to detect this change is:
 - A disease-specific questionnaire.
 - A generic questionnaire.
- A questionnaire with good reliability may have poor responsiveness (sensitivity to change):
 - Incorrect.
 - Correct.
- The problems experienced by children with asthma are the same as those experienced by adults.
 - Incorrect.
 - Correct.
- Parents have an accurate understanding of the problems that their child with asthma is experiencing and should either be present when a questionnaire is completed or they should complete it on behalf of the child.
 - Incorrect.
 - Correct.
- Shared decision-making means that:
 - The clinician identifies the patient's problems and selects the treatment option that should improve asthma control and address the patient's needs.
 - The clinician and patient discuss both the clinical goals of treatment and the needs of the patient and together select a treatment plan that the patient is willing to follow.
 - The clinician explains to the patient the need to achieve good asthma control and the treatment options, and then allows the patient to decide the treatment plan.
- The MID of a HRQL questionnaire is the change or difference in score that is considered important by:
 - The clinician.
 - The patient.

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If readers would like to receive the complete AQLQ or PAQLQ package, either e-mail E. Juniper direct or contact her via her website www.qoltech.co.uk.

Other questionnaires mentioned in the text should be obtained from their developer.

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Suggested answers

1. c
2. b
3. a
4. b
5. a
6. a
7. b
8. b