

**ASTHMA CONTROL QUESTIONNAIRE IN CHILDREN
VALIDATION, MEASUREMENT PROPERTIES, INTERPRETATION**

Elizabeth F Juniper¹, Kevin Gruffydd-Jones², Sabbi Ward³, Klas Svensson⁴.

1. Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Canada.
2. Box Surgery Wiltshire, UK, University of Bath, UK, University of Aberdeen UK
3. Box Surgery Wiltshire, UK,
4. HEOR Consulting, Linerovagen 15, S-22475 Lund, Sweden.

Financial Support: Astra Zeneca

Corresponding Author and requests for reprints:

Professor Elizabeth Juniper MCSP, MSc,
20 Marcuse Fields, Bosham,
West Sussex, PO18 8NA, England
Phone: +44 (0) 1243 572124
Fax: +44 (0) 1243 573680
E-mail: juniper@qoltech.co.uk

March 23, 2010

ABSTRACT

Background: The Asthma Control Questionnaire (ACQ) has been validated in adults to measure the primary goal of management (minimisation of symptoms, activity limitations, short-acting β_2 -agonist use and airway narrowing).

Aim: This study evaluated the validity, measurement properties and interpretability of the ACQ in children 6-16 yrs.

Methods: 35 children attended clinic on 3 occasions (0,1& 4 wks) and completed the ACQ, Mini Paediatric Asthma Quality of Life Questionnaire and Royal College of Physicians Questionnaire. Parents completed the Paediatric Asthma Caregivers Quality of Life Questionnaire. Between visits children completed the Asthma Control Diary and measured PEF. At weeks 1& 4, clinicians and parents completed global rating of change questionnaires.

Results: All patients completed the study. 19 children were stable between two assessments and provided evidence of good test-retest reliability (Intraclass Correlation Coefficient=0.79). The ACQ was responsive to change in asthma control ($p=0.026$) and the Minimal Important Difference was 0.52 ± 0.45 . Both cross-sectional and longitudinal correlations between the ACQ and the other outcomes were close to predicted and provided evidence that the ACQ measures asthma control in children.

Conclusion: The ACQ has strong measurement properties and is valid for use in children 6-16 yrs. In children 6-10 yrs, it must be administered by a trained interviewer.

Abbreviations

ACD	Asthma Control Diary
ACQ	Asthma Control Questionnaire
FEV ₁	Forced Expiratory Volume in 1 Second
ICC	Intraclass Correlation Coefficient
MID	Minimal Important Difference
MiniPAQLQ	Mini Paediatric Asthma Quality of Life Questionnaire
PACQLQ	Paediatric Asthma Caregiver's Quality of Life Questionnaire
PAQLQ	Paediatric Asthma Quality of Life Questionnaire
PEF	Peak Expiratory Flow
RCP	Royal College of Physicians' 'Three Questions'

INTRODUCTION

The Asthma Control Questionnaire (ACQ) (1) was developed to measure asthma control as defined by international guidelines, namely, that the goal of management should be to minimise asthma symptoms, activity limitations, airway narrowing and rescue bronchodilator use and thus reduce the risk of exacerbations. Ninety-one clinicians, who were members of international asthma guideline committees (2-5) and who represented clinicians looking after both adults and children, identified the symptoms that are most important for assessing control. The 5 top scoring symptoms, which were the same for both adults and children, were included in the ACQ. The sixth question asks about the number of puffs of rescue short-acting β_2 -agonist used each day. The clinicians indicated that the measurement of airway calibre should be the FEV₁% predicted pre-bronchodilator and this is the seventh question. Patients recall their experiences during the previous week and to respond to the first 6 questions (night-time waking, symptoms on waking, activity limitation, shortness of breath, wheeze and rescue short-acting β_2 -agonist use) on a 7-point scale (0 = no impairment; 6 = maximum impairment). Clinic staff score FEV₁% predicted pre-bronchodilator on a similar 7-point scale. The items are equally weighted and the ACQ score is the mean of the 7 items and therefore between 0 (well controlled) and 6 (extremely poorly controlled).

The ACQ has been validated for use in adults and has strong measurement properties for use in both clinical practice and clinical trials (1). Ideally, all 7 questions in the ACQ should be used. However, measurement of airway calibre and rescue bronchodilator use are sometimes not available and three shortened versions of the questionnaire have been validated (symptoms alone, symptoms plus FEV₁, symptoms plus bronchodilator) (6). The aim of this study was to assess the

measurement properties and validity of the ACQ in children 6-16 years and to determine what change in score can be considered clinically important. We used the complete 7-question ACQ but have analysed the data using both the complete questionnaire and the three shortened versions.

In an initial cognitive debriefing study, children 6-16 years were asked to complete the self-administered version of the ACQ. Those who were able to do this task were asked to explain the meaning of each question and the concept of the 7-point scale. We found that the self-administered version is easily and accurately understood by children 11 years and older. We worked with younger children to identify difficult concepts and to find alternative wording and instructions (Table 1). The resultant interviewer-administered version of the ACQ was tested in a separate group of children 6-10 years of age and fine-tuned to ensure ease and accuracy of understanding (7). Children themselves always respond to the questions and help from a parent/caregiver is only sought as a last resort (usually about rescue bronchodilator use). Included in the interviewer-administered version are instructions to the interviewer on how to ensure that each child understands the 7-point scale and the concept of 'during the last week' (Table 2).

The questions posed in this study were:

1. In children 6-17 years with stable asthma, what is the test-retest reliability of the ACQ?
2. In children whose asthma control changes between clinic visits, is the ACQ able to detect these changes (responsiveness)?
3. Does the ACQ measure asthma control in children 6-17 years (content and construct validity)?

4. What change in ACQ score is the smallest that can be considered clinically important (Minimal Important Difference - MID)?

METHODS

Subjects

Thirty-five children (6-16 years) with well established and physician-diagnosed asthma and who had current symptoms of asthma (ACQ score > 0.5) were enrolled from 5 primary care practices across the South of England and one hospital clinic. They represented a wide range of asthma severity, age and gender (Table 3). They were not permitted to require daily oral steroids, have life-threatening asthma or have any other current illness with symptoms similar to those of asthma. Both the children and their primary caregiver were informed about the study and both signed consents that had been approved by South West of England Multi-Centre Research Ethics Committee.

Study Design

In this four-week observational study, children and their primary caregiver (usually a parent) attended the clinic on 3 occasions (baseline and after 1 and 4 weeks). At each visit the child completed the ACQ followed by spirometry and the Mini Paediatric Asthma Quality of Life Questionnaire (MiniPAQLQ) (8,9). The parent completed the Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) (10). After which, the clinician discussed the child's clinical status with the child and the caregiver, evaluated adequacy of asthma control using the criteria in the GINA guidelines (not using ACQ scores) and completed the Royal College of Physicians "Three questions"(10) At the first visit, the child and parent were shown how to measure Peak Expiratory Flow (PEF) and complete the Asthma Control Diary (ACD) each morning and evening (12). If the clinician considered that the inadequacy of the child's asthma control required an immediate increase in medication, this was done according to the child's own treatment plan. All other

children continued on their current medication until the next visit (1 week) with the instruction to increase medication if their asthma deteriorated further.

At the second visit, all children with inadequately controlled asthma had their medication increased. At the end of each follow-up visit, clinicians and caregivers each completed a global rating of change questionnaire.

Outcome Measures

Asthma Control Questionnaire (ACQ) (see above)

Mini Paediatric Asthma Quality of Life Questionnaire (MiniPAQLQ) (8,9)

This validated shortened version of the original Paediatric Asthma Quality of Life Questionnaire (8) has 13 questions and measures the physical, emotional and social problems that are experienced by children with asthma. Children are asked to recall their experiences during the previous week and respond to each question on a 7-point scale (7= no impairment, 1 = severe impairment). The overall score is the mean of the 13 responses.

Asthma Control Diary (ACD)(12)

The wording of the 7 questions and response options in the ACD is almost identical to that used in the ACQ. The only major difference is that PEF is recorded instead of FEV₁. Before taking any medication in the morning, children made three measurements of PEF and recorded the best value (later converted to % predicted in the clinic). At the same time, they scored the questions about nocturnal waking and morning symptoms. At bedtime, they scored the amount of activity limitation, shortness of breath and wheeze experienced during the day and recorded β_2 -agonist use during the previous 24 hours. The diary is scored by adding the responses for each of the 7 questions for each of the 7 days and dividing the total score by 49 (ie. the resultant score is between 0=well controlled and 6=extremely poorly controlled).

Spirometry

Pre-bronchodilator FEV₁ was measured at each clinic visit and expressed as a % predicted normal. Short-acting β_2 -agonists were not taken for at least 4 hours before each clinic visit.

Royal College of Physicians (RCP)(10)

The Royal College of Physicians has identified 3 asthma symptom questions (difficulty sleeping due to asthma, daytime asthma symptoms, activity limitation) with dichotomous responses ('yes' or 'no') that should be used by UK clinicians in the routine management of asthma patients. Patients responding positively to one or more questions provide evidence of poor asthma control.

Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ)(11)

This 13-item questionnaire measures the impact that the child's asthma has on the primary caregiver's day-to-day experiences (usually a parent). Parents respond to each question on a 7-point scale (7= no impairment, 1= severe impairment). The overall score is the mean of the 13 responses. There are two domains, emotional function and activity limitation. The same parent or primary caregiver completed this questionnaire at every visit.

Parent's Global Rating of Change Questionnaire(13)

The parent was asked whether there had been any change in their child's asthma control since the previous visit (+7 = a very great deal better, 0 = no change, -7 = a very great deal worse).

Clinician's Global Rating of Change (13)

The clinician was also asked whether there had been any change in the child's asthma control since the previous visit. They used current RCP scores, ACD data, spirometry and his/her clinical consultation with the child and the caregiver, but not ACQ data, to respond to this question. The clinician also identified whether the change was of clinical importance (i.e. justified a change in treatment).

ANALYSIS

Content Validity

The items in the ACQ were selected by paediatric asthma clinicians as being the most important for determining asthma control using the 'importance method' for item selection (1). Therefore the content validity of the ACQ in children has already been established.

Testing the Measurement Properties

General Approach

Construct Validation

Since there is no gold standard for measuring asthma control in children, evidence that the ACQ truly measures asthma control has been established through 'construct validation'. This is achieved by showing that it shows appropriate correlations with established health status measures (14).

Measurement Properties

A health status instrument that is required to measure change over time (eg. clinical trials and clinical practice) must have good evaluative properties which are responsiveness (the ability to detect important within-patient changes, even if they are small) and longitudinal construct validity (appropriate correlations between changes in the new instrument and changes in established health status measures). An instrument that is required to distinguish between people at a single point in time (eg. surveys and impairment assessment) must have good discriminative properties which are reliability (high ratio of variance between-patients to variance within-patients) and cross-sectional construct validity (appropriate correlations between established measures and the new instrument). We tested the ACQ for both evaluative and discriminative properties.

Statistical Analysis

Categorising Patients

Conceptually, testing the ACQ's measurement properties required defining a group of children who remained clinically stable between consecutive clinic visits (weeks 0-1 and 1-4) and another group who experienced change their asthma control. For each time period, we categorised each patient using the clinician's global rating of change score: stable group = scores of -1, 0 or +1; unstable group = scores -7 to -2 and +2 to +7.

Evaluative Properties

Responsiveness of the ACQ was examined in three ways. First, for patients in the unstable group, we determined whether the ACQ could detect within-patient change using a paired t-test. Second, we assessed whether the ACQ could detect differences between stable and unstable patients using an unpaired t-test. Third, we calculated the responsiveness index (Δ/Δ_{sd}) where Δ is the change in score between visits. To ensure that the contribution of two observations by some patients did not result in an overestimate of the precision of responsiveness, we inflated the variance by the quantity $1+(n-1)\rho$ where ρ is the Intraclass Correlation Coefficient (ICC) of the change scores and $n=2$ (# of observations per subject). For longitudinal validity, we made *a priori* predications about the amount of correlation we should expect to observe if the ACQ truly measures change in asthma control. The predictions were based on results from previous studies in children and adults (1,6, 8,15,16) and clinical experience.

The Minimal Important Difference (MID) was calculated in two ways. First, it was calculated as the mean change in score between clinic visits in children who scored +3, +2, -2 and -3 on the clinician's global rating of change questionnaire (13). Symmetry of positive and negative responses allowed the data to be combined for analysis by changing the sign of the negative responses. Second, the change in

ACQ scores that was equivalent to a change in MiniPAQLQ score of 0.5 was calculated by regressing the change in ACQ scores on change in MiniPAQLQ scores, using a geometric mean regression model (6,17). This method allows for measurement errors in the independent (PAQLQ) variable as well as the dependent (ACQ) variable.

Discriminative Properties

Reliability of the ACQ was determined from patients in the stable group. If a patient was stable between both weeks 0-1 and weeks 1-4, a single observation was selected using a random number generator. Reliability was estimated as the within-subject standard deviation and related to the total standard deviation as an ICC. For cross-sectional validity, we used data from the second clinic visit (week 1) and once again made *a priori* predications about the level of correlation we should expect to observe if the ACQ truly measures asthma control.

RESULTS

All 35 children completed the first and second visits but two failed to attend for the third visit. Their demographic and baseline asthma data are shown in Table 3. Although concordance between the ACQ and the three shortened versions was high (ICC>0.93), the symptoms alone and the symptoms plus FEV₁ versions gave significantly higher scores ($p<0.01$) (Table 4). In addition, change scores between baseline and 4 weeks was significantly greater in these two versions than the complete ACQ ($p<0.006$).

Nineteen children remained stable between two consecutive clinic visits and provided evidence of good test-retest reliability with the following ICCs: ACQ = 0.79, symptoms alone = 0.67, symptoms+FEV₁ = 0.79, symptoms+ β_2 agonist = 0.68. Evidence of good cross-sectional construct validity is shown in Table 5 with

correlations close to predicted (week 2 was used so that ACD data could be included).

The ACQ and all three shortened versions showed good responsiveness (Table 6). In children whose asthma control changed between clinic visits, the questionnaire was able to detect change ($p < 0.026$) and it was able to distinguish between those who remained stable and those who changed. By the global rating of change method ($n=11$), the smallest change in ACQ score that can be considered clinically important, the MID, was 0.52 ± 0.45 (symptoms alone = 0.65, symptoms+FEV₁ = 0.52, symptoms+ β_2 agonist = 0.63). Longitudinal correlations with other clinical outcomes provided further evidence that the ACQ really does measure asthma control (Table 7). The geometric mean regression method ($n=31$) gave a similar result (MID=0.50:sem=0.05).

DISCUSSION

This study has provided evidence that the Asthma Control Questionnaire is a valid instrument for measuring asthma control in children 6-16 years. It can be used with confidence to determine the level of control, changes in control and whether changes in control can be considered of clinical importance. Previous work (7) has shown that the questionnaire must be administered to children 6-10 years by a trained interviewer who initially ensures that the child understands the concept of the 7-point scale and the time specification of 'during the last week'.

Although only 35 children were enrolled in this study (the same number as were enrolled in the original validation study of the Asthma Quality of Life Questionnaire (18)), they were sufficient to provide strong evidence of the validity of the instrument (e.g. there was sufficient power for expected differences to reach statistical significance). In addition, the measurement properties of the ACQ in children (reliability, responsiveness, construct validity and interpretability) found in this study are all very similar to those observed adults (1,6). The MID was estimated using two different but established methods (6,13,17). The consistency of the estimates (global rating: 0.52 geometric mean regression: 0.50) provides further evidence that the sample size was adequate. To ensure generalisability, children were enrolled to represent a wide range of asthma severity, the full range of age, both genders and they came from primary care clinics and a hospital situated in areas of differing socioeconomic status (Table 3). Children requiring regular oral steroids or life-threatening asthma were excluded and therefore we cannot be certain about validity in this small group of children.

The complete ACQ and the three shortened versions each attained measurement properties that are acceptable for strong evidence of validity. The

measurement properties of the three shortened versions tended not to be quite so strong as the complete ACQ. Therefore, it is best if the shortened versions are used only when either FEV₁ or rescue bronchodilator use are not available. In the absence of either FEV₁ or rescue bronchodilator use either of the three shortened versions may be used. However, although concordance between each of the shortened versions and the complete ACQ was high (ICC>0.93), there were statistically significant differences in score suggesting that although each instrument is valid in its own right, there is a bias between them and therefore the different versions should not be used interchangeably. In addition, the MID was higher when rescue bronchodilator use was omitted.

A limitation of this study is that the clinician could not be completely blinded to the current ACQ data. To minimise the risk of this influencing the clinician's global estimate of change at the end of each clinic visit, the clinician did not have access to ACQ data from previous visits and therefore had no reference point. In addition, the ACQ was always completed at the beginning of the visit and the clinician completed the global rating of change at the end of the visit (after the MiniPAQLQ, spirometry, review of diary data and PEF technique, clinical discussion with the child and parent on the child's asthma status, RCP and treatment plan).

The ACQ was only tested in children 6 years and older because we wanted the children to respond to the questions. This is because parents often are not able to give an accurate estimate of their child's health status, as shown by their only modest accurate estimate of change in their child's asthma control between visits (Table 7) and previous studies on the accuracy of parental reporting (19). This inaccuracy can occur because the parent is not with the child 24 hours per day (e.g. nighttime and school), children sometimes hide from their parent how their asthma

really is (e.g. to prevent missing playing with their friends/sports), and parents sometimes score how they personally would feel if they had similar asthma (e.g. activity limitation). Children under 6 years have difficulty understanding the concept of 'during the last week', they know how they are today but for longer recall they become inaccurate. Since a single snapshot of how the child is today is not an accurate reflection of the child's asthma control, the ACQ should not be used in children under 6 years.

International guidelines advocate the use of the ACQ in the clinical management of adults with asthma (20) because there is evidence that a valid instrument for assessing control (both current status and change over time) is more accurate than conventional clinical assessments (21,22). The construct validation in this study has provided evidence that the ACQ really does measure asthma control in children over 6 years. However, it also provides evidence, through the modest correlation between ACQ and clinician's global rating of change score, that clinicians' accuracy in estimating adequacy of asthma control in children is similar to that observed in adults. .

Although the primary goal of clinical asthma management must be to achieve optimum control, it is also important to ensure that the goals that are important to the children themselves (asthma-specific quality of life) are also included in the treatment plan. In this study, the correlation between the ACQ and the MiniPAQLQ was quite high suggesting that the two questionnaires might be measuring a similar concept. However, these results are similar to previous observations and factor analysis has shown that asthma control and quality of life are two distinct components of clinical asthma (23). Therefore, both outcomes have to be assessed in order to set the treatment goals and follow the effectiveness of treatment. This is

already occurring in the management of adults with asthma and the validation of the ACQ means that, in conjunction with either the PAQLQ(S) or MiniPAQLQ, a similar approach to management is possible in children.

The recent American Thoracic Society/European Respiratory Society statement on asthma control and exacerbations (24) states that “acceptance of its (ACQ’s) use needs to be determined in primary care”. This validation of the ACQ was conducted mainly in primary care and, following the latest GINA guidelines (19), clinicians around the world have started to use the ACQ in primary care. This has come about through individual national asthma guidelines and pharmaceutical companies promoting the GINA guidelines. The statement (24) also suggests that the 7-point response scale is too “complex and laborious”. However, it is the 7-point scale that gives the instrument its high degree of responsiveness allowing it to detect accurately small but clinically important changes in asthma control (0.5 change on the 7-point scale is clinically important). Children as young as 6 years have not had any problems understanding or using a 7-point scale (15).

This study has provided evidence that the Asthma Control Questionnaire, if completed by the children themselves, is a valid instrument for measuring asthma control in children 6-16 years. The measurement properties in this age group are strong and very similar to those observed when the questionnaire is used in adults. In children under 10 years, the questionnaire should be administered to the child by a trained health professional.

REFERENCES

1. Juniper EF, O'Byrne PM, Guyatt GH, Ferrie PJ, King DR. Development and validation of a questionnaire to measure asthma control. *Eur Respir J* 1999; 14: 902-7.
2. US Department of Health Services. International Consensus Report on Diagnosis and Treatment of Asthma. Bethesda: National Heart, Lung, and Blood Institute, 1992.
3. British Thoracic Society, Research Unit of the Royal College of Physicians of London, King's Fund Centre, National Asthma Campaign. Guidelines for management of asthma in adults: I chronic persistent asthma. *Br Med J* 1990; 301: 651-3.
4. Thoracic Society of Australia and New Zealand. Woolcock A, Rubinfeld AR, Seale JP, Landau LL, Antic R, Mitchell C, Rea HH, Zimmerman P. Asthma management plan 1989. *Med J Aust* 1989; 151: 650-3.
5. Ernst P, Fitzgerald JM, Spier S. Canadian asthma consensus conference: summary of recommendations. *Can Respir J* 1996; 3: 89-100.
6. Juniper EF, Svensson K, Mörk AC, Ståhl E. Measurement properties and interpretation of three shortened versions of the asthma control questionnaire. *Respir Med* 2005; 99: 553-8.
7. Juniper EF, Gruffydd-Jones K, Thomas M, Ward S. Developing an interviewer-administered version of the Asthma Control Questionnaire for children 10 years. *Eur Respir J* 2007; (Abstract)
8. 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.

9. Juniper EF, Wing A, Weller P, Walker S, Upton J, Fletcher M. Development and validation of the Standardised and Mini versions of the Paediatric Asthma Quality of Life Questionnaire. *Eur Resp J* 2009; (Abstract)
10. 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.
11. Pearson MG, Bucknall CE. Measuring clinical outcomes in asthma - A patient focussed approach. Clinical Effectiveness and Evaluation Unit, Royal College of Physicians, London 1999.
12. Juniper EF, O'Byrne PM, Ferrie PJ, King DR, Roberts JN. Measuring asthma control: clinic questionnaire or daily diary? *Am J Respir Crit Care Med* 2000; 162: 1330-1334.
13. Juniper EF, Guyatt GH, Willan A, Griffith LE. Determining a minimal important change in a disease-specific quality of life instrument. *J Clin Epidemiol* 1994; 47: 81-87.
14. Guyatt GH, Kirshner B, Jaeschke R. Measuring health status: what are the necessary measurement properties? *J Clin Epidemiol* 1992; 45: 1341-1345.
15. 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* 1997; 10: 2285-2294.
16. Juniper EF, Wisniewski ME, Cox FM, Emmett AH, Nielsen KE, O'Byrne PM. Relationship between quality of life and measures of clinical status in asthma: a factor analysis. *Eur Respir J* 2004; 23: 287-291.
17. Ricker, W.E. Linear regression in fishery research. *J.Fish.Res.Board Can* 1973; 30; 409-434.
18. Juniper EF, Guyatt GH, Ferrie PJ, Griffith LE. Measuring quality of life in asthma. *Am Rev Respir Dis* 1993; 147: 832-838.

19. Guyatt GH, Juniper EF, Feeny DH, Griffith LE. Children and adult perceptions of childhood asthma. *Pediatrics* 1997; 99: 165-168.
20. Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2006. Available from: <http://www.ginasthma.org>.
21. Boulet L-P, Phillips R, O'Byrne P, Becker A. Evaluation of asthma control by physicians and patients: comparison with current guidelines. *Can Respir J* 2002; 9: 417-423.
22. Juniper EF, Chauhan A, Neville E, Chatterjee A, Svensson K, Mörk A-C, Ståhl E. Clinicians tend to overestimate improvements in asthma control: an unexpected observation. *Primary Care Respir J* 2004; 13: 181-184
23. Juniper EF, Wisniewski ME, Cox FM, Emmett AH, Nielsen KE, O'Byrne PM. Relationship between quality of life and measures of clinical status in asthma: a factor analysis. *Eur Respir J* 2004; 23: 287-291.
24. Reddel HK, Taylor R, Bateman ED, Boulet L-P, Boushey HA, Busse WW, Casale TB, Chanez P, Enright PL, Gibson PG, de Jongste JC, Kerstjens HAM, Lazarus SC, Levy ML, O'Byrne PO, Partridge MR, Pavord ID, Sears MR, Sterk PJ, Stoloff SW, Sullivan SD, Szefer SJ, Thomas MD, Wenzel SE. on behalf of the American Thoracic Society/European Respiratory Society Task Force on Asthma Control and Exacerbations. An Official American Thoracic Society/European Respiratory Society Statement: Asthma Control and Exacerbations. Standardising Endpoints for Clinical Asthma Trials and Clinical Practice. *Am J Resp Crit. Care Med* 2009; 180: 59-99

Table 1. Example of a question from the ACQ[®] that required a supplementary for children in the UK

First, read each question to the child using the primary wording. If the child does not fully understand the question, read it again using the secondary wording shown in brackets.

- 3 During the past week, how **limited were you in your activities** because of your asthma?
- 3a (During the past week, how **bothered were you in the things you do every day** because of your asthma?)

© Reprinted with the permission of QOL Technologies Ltd.

N.B. The supplementary wording applies only to the UK English version. Questions that require a supplementary vary between languages and countries.

Table 2 UK English ACQ - Instructions for Interviewers

ASTHMA CONTROL QUESTIONNAIRE (for children 6-10 years)[©]

Please read these instructions carefully before administering the questionnaire

Parents may be present during the interview but you should encourage the child to respond and only ask the parent to help if the child is having difficulties.

Some younger children may have difficulty understanding the meaning of some questions. First, you should read each question to the child exactly as written in the text. If the child doesn't understand, read the question again using the secondary wording included in the brackets. Try not to place your own interpretation on the question.

The questionnaire will ask how the child's asthma has been during the last week (7 days). Check that the child understands this time frame. If in doubt, ask the parent to identify an event that occurred a week previously (e.g. a football match) and then ask the child to tell you how she/he has been since that event

Show the child the response card and explain the options. Explain the concept of the 7 responses. Explain that 0 = means that they have not had any asthma symptoms at all and that 6 means that their symptoms have been really, really bad. Explain that the other numbers (1-5) represent levels in between. For children who can read, we suggest that you ask them to read aloud each of the responses. For younger children, start by reading to them just the 7 responses to question one (both number and words) and check that they understand the concept (then repeat at the beginning of each question).

Reassure the child that there are no right or wrong answers.

© Extract from the Asthma Control Questionnaire (for children 6-10 years old).
Reproduced with the permission of QOL Technologies Ltd.

Table 3 Demographic and Baseline Data

Number of patients	35
Age (mean ± sd)	10.4 (2.6)
Gender (male/female)	21M/14F
Medications*	
SABA alone	3
SABA + IS	13
SABA + IS + LABA	16
SABA + LABA + Leuk + SC	1
SABA + IS + LABA + Leuk	2
ACQ (mean ± sd)	1.76 (0.71)
FEV ₁ % pred. (mean ± sd)	89.4 (14.3)
RCP (mean ± sd)	1.85 (0.74)
MiniPAQLQ (mean ± sd)	5.09 (1.13)
PACQLQ (mean ± sd)	5.23 (1.14)
PEF % pred. (mean ± sd)	83.1 (14.7)
ACD (mean ± sd)	1.30 (0.86)

* Medication abbreviations
SABA Short-acting β_2 agonist
IS Inhaled corticosteroid
LABA Long-acting β_2 agonist
Leuk Leukotriene modifier
SC Sodium Cromoglycate

Outcomes **Scores**
ACQ 0 = well controlled 6 = extremely poorly controlledRCP
 0 = well controlled 1, 2, 3 = not controlled
MiniPAQLQ 7 = no impairment 1 = severe impairment
PACQLQ 7 = no impairment 1 = severe impairment
ACD 0 = well controlled 6 = extremely poorly controlled

Table 4 Shortened Versions compared with the original ACQ
(0 = well controlled, 6 = extremely poorly controlled)

Questionnaire	Score at baseline (mean \pm sd)	Change score between baseline and 4 weeks (mean \pm sd)	Concordance between ACQ and short versions at baseline ICC	Difference between ACQ and short versions (mean \pm sd) p value	Difference between change in ACQ and change in short versions between baseline and 4 weeks (mean \pm sd) p value
ACQ (all questions)	1.76 (0.71)	-0.53 (1.17)			
Symptoms alone	1.88 (0.81)	-0.70 (1.29)	0.93	0.12 (0.26) 0.010	0.17 (0.34) 0.006
Symptoms plus FEV ₁ % pred	1.83 (0.74)	-0.65 (1.20)	0.98	0.07 (0.11) <0.001	0.11 (0.17) <0.001
Symptoms plus short acting β_2 agonist use	1.79 (0.77)	-0.56 (1.25)	0.96	0.03 (0.21) 0.38	0.03 (0.23) 0.49

Table 5. Cross-sectional Construct Validity (Pearson Correlation Coefficients) – Visit 2

Questionnaire	MiniPAQLQ	RCP	ACD	PACQLQ
ACQ (All questions)	-0.83	0.52	0.77	-0.63
Symptoms alone	-0.84	0.57	0.71	-0.56
Symptoms plus FEV ₁ % pred.	-0.83	0.52	0.72	-0.61
Symptoms plus short acting β_2 agonist use	-0.83	0.56	0.77	-0.58

Table 6 Responsiveness

Questionnaire	Change in score between clinic visits Stable patients (mean \pm sd) p value (A)	Change in score between clinic visits Unstable patients (mean \pm sd) p value (B)	A versus B (mean \pm sd) p value	Responsiveness Index
ACQ (All questions)	-0.20 (0.76) p= 0.29	-0.93 (1.45) p=0.026	0.74 (1.13) p=0.072	0.455
Symptoms alone	-0.26 (0.90) p=0.24	-1.24 (1.51) p=0.007	0.98 (1.21) p=0.027	0.544
Symptoms plus FEV ₁ % pred.	-0.28 (0.80) p=0.16	-1.09 (1.45) p=0.011	0.81 (1.14) p=0.051	0.540
Symptoms plus short acting β_2 agonist use	-0.17 (0.85) p=0.42	-1.03 (1.50) p=0.018	0.87 (1.18) p=0.045	0.450

Table 7 Longitudinal Construct Validity (Pearson Correlation Coefficients) - 1-4 Weeks

Questionnaire	Δ MiniPAQL Q	Δ RCP	Δ ACD	Δ PACQLQ	Global Rating Clinician	Global Rating Caregiver
Δ ACQ (All questions)	-0.89	0.81	0.83	-0.79	-0.72	-0.66
Δ Symptoms alone	-0.93	0.81	0.79	-0.84	-0.75	-0.69
Δ Symptoms plus FEV ₁ % pred.	-0.91	0.81	0.82	-0.80	-0.75	-0.68
Δ Symptoms plus short acting β_2 agonist use	-0.91	0.81	0.81	-0.83	-0.71	-0.66

