

# Research Review

## EDUCATIONAL SERIES

### The Asthma Control Test



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#### **The burden of asthma in New Zealand**

Around 1 in 6 New Zealanders has asthma. The prevalence of asthma, along with other allergic disorders such as eczema, allergic rhinitis and peanut allergy is increasing and New Zealand has the joint highest levels of these allergic disorders in the world. This rise in prevalence that has been seen in Westernised countries may well be explained by the hygiene hypothesis (which states that as we have a much reduced exposure to micro-organisms, our immune systems react instead to everyday harmless items in our environment such as pollens) although other theories also have their supporters.

Thankfully, since the end of the epidemic of deaths that peaked in the late 1970s that was attributed to the beta-agonist fenoterol, mortality from asthma is low. Now, around 1 in 200 deaths are due to asthma and most of these occur in elderly people with multiple co-morbidities.

Although deaths from asthma are now less common, asthma is still a very important disease as it is both common and chronic. The economic burden has been estimated to be over \$1 billion a year in New Zealand, the vast majority of this being indirect costs such as those associated with time off school and work due to exacerbations. Around half of costs are incurred by the 10% of patients with the most uncontrolled asthma, and the cost of care for a person with asthma has been estimated to be 100 times greater if a patient's asthma is uncontrolled rather than controlled. In terms of years lost to disability (YLD), asthma ranks first in males, third in females and third overall.

#### **The disconnect between asthma control and its perception**

Two large studies have estimated the level of asthma control in New Zealand patients and these studies also provide a fascinating insight into the disconnect that occurs between asthma control and how this level of control is perceived.

The Patient Outcomes Management Survey (POMS) found that the vast majority of New Zealand patients did not have well-controlled asthma (see box). However, a surprise finding was that 80% of patients were satisfied with their level of asthma control and 76% thought that their asthma was well-controlled.

Similarly, the 2007 NZ mini-INSPIRE study found that although 76% of patients were using their reliever on most days and 34% were taking 3 or more puffs of reliever on most days, 81% thought that their asthma was well-controlled and 77% were satisfied with their level of control.

How can it be that so many patients have poor asthma control, but think that they are actually well-controlled and are happy with the level of control? And how can understanding this disconnect help clinical practice? The answer to the first question is that patients have a natural tendency to tell their doctor what they think they want to hear. But more importantly, it is likely that patients with asthma have never experienced a time with no or very few symptoms and so they do not know what good asthma control feels like – they have nothing to compare their current symptom level with. Asthma researchers and clinicians are well aware of this fact if they have added a LABA to a patient's treatment as part of a clinical study – many patients report that they never knew what it was like to experience no or few symptoms. The GOAL study demonstrated that excellent control can be achieved in the vast majority of patients.

As for the second question, how can understanding this disconnect help clinical practice . . . one lesson we can learn is that the way that we are assessing asthma control now is often not detecting these high levels of poor control, and so we need other, better ways to assess asthma control.

#### **The need for a simple asthma monitoring tool**

What is asthma control? The answer is that it depends who you talk to as patients, parents, doctors and regulatory authorities have very different ideas (see box). In order to assess control a wide variety of questions are asked, such as the presence of night-time cough, and several techniques used, such as measuring peak flow. Not surprisingly, these varied approaches to assessing asthma control mean that poor control is often not detected, even by respiratory specialists. And if control is not accurately assessed, how can we effectively alter a patient's management, the primary aim of which must be to obtain the best level of asthma control possible?

Asthma is almost unique when compared to other long-term chronic conditions in that there is not a single, simple, objective measure of the disease manifestation, which can be monitored over time and with treatment changes. For hypertension we measure blood pressure, for hypercholesterolaemia we measure blood lipids and for our patients with diabetes we measure HbA<sub>1c</sub> levels. No such measure is commonly used for asthma. Such a measure would enable health care professionals to identify poor asthma control in their patients and treatments could be altered accordingly.

## What is asthma control?

**Patient** - no symptoms which interfere with normal lifestyle, no exacerbations, normal quality of life, particularly, no cough

**Carers (parents)** - able to get to school, no night cough

**GP** - no unscheduled visits, few exacerbations, no admissions, maintenance of PEF

**Respiratory physician** - no night symptoms, maintenance of lung function (FEV<sub>1</sub>), few exacerbations, no admissions

**Regulatory authorities** - improvement in morning PEF & FEV<sub>1</sub>, improvement in symptom scores and quality of life, enhanced cost-effectiveness analyses

## The Asthma Control Test

A simple 5-question test for asthma has been developed and validated in several studies (some of these key studies are summarised below). The score was developed in a study which looked at 22 of the most common questions that doctors ask when talking to patients about asthma control, with 5 questions standing out as being the most accurate predictors. The questions take less than a minute to answer and can be asked by the health care professional or the patient can complete the test themselves. There is a score of 1–5 for each question, and an overall score in the range of 5–25, with low scores corresponding to a high level of symptoms and therefore poor asthma control.

Studies have shown that the ACT score effectively discriminates between patients who differ in asthma control, is responsive to changes in control and it can discriminate between groups of patients in different lung function ranges. The ACT score has been shown to be highly effective as a screen for uncontrolled asthma and can correctly predict GINA-defined partly controlled or uncontrolled asthma in 94% of cases.

A score of 20–25 means that a patient's asthma is controlled, and a score of 19 or less means that it may well be possible to increase the level of asthma control and a full review of the treatment plan, including education on inhaler technique and the importance of compliance with treatment, is warranted. In addition, a score of 14 or less indicates that asthma is poorly or not controlled and that a review of and changes to the patient's management are highly likely to be needed.

- Q1** In the **past four weeks**, how often did your asthma prevent you from getting as much done at work, school or home? **SCORE**
- All of the time 1 Most of the time 2 Some of the time 3 A little of the time 4 Not at all 5
- Q2** During the **past four weeks**, how often have you had shortness of breath?
- More than once a day 1 Once a day 2 3 to 6 times a week 3 Once or twice a week 4 Not at all 5
- Q3** During the **past four weeks**, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?
- 4 or more times a week 1 2 to 3 nights a week 2 1 night a week 3 Less than 1 night a week 4 Not at all 5
- Q4** During the **past four weeks**, how often have you used your reliever medication (such as your blue inhaler or rescue inhaler)?
- 3 or more times a day 1 1 or 2 times a day 2 2 or 3 times a week 3 Once a week or less 4 Not at all 5
- Q5** How would you rate your asthma control during the **past four weeks**?
- Not controlled 1 Poorly controlled 2 Somewhat controlled 3 Well controlled 4 Completely controlled 5

## Development of the Asthma Control Test: a survey for assessing asthma control<sup>3</sup>

**Authors:** Nathan RA et al

**Summary:** This article describes the development of a brief patient-based assessment tool to assess asthma control with or without the use of lung function testing. In developing the Asthma Control Test (ACT), the investigators sought to (1) produce a questionnaire that reflected the multidimensional nature of asthma control and (2) demonstrate its performance against criterion measures of asthma control.

**Method:** 471 patients with asthma completed a survey comprising 22 questions during a routine, previously scheduled physician office visit. These questions recorded the frequency and intensity of asthma symptoms, use of asthma medications, and the effect of asthma on daily activities, during the 4 weeks prior to the visit. Regression analyses were used to select a subset of 5 items showing the greatest discriminant validity against the specialist's rating of asthma control. ACT scale scores were then validated by comparison with the specialist's rating of asthma control, the patient's lung function, and the influence on the specialist's decision to change therapy.

**Results:** The 5 items on the ACT questionnaire, as determined by regression analyses, include an assessment of dyspnoea frequency, self-assessment of asthma control, rescue medication requirement, the number of work days lost or school days missed, and nocturnal awakenings. The internal consistency reliability of the 5-item ACT survey was 0.84. Table 1 shows the results of empirical validation testing of ACT in discriminating among groups known to differ in asthma control and change in therapy. ACT scores for both scoring options differed significantly across the groups of patients who differed in level of asthma control defined by the specialist's rating of control, by the need for change in patient's therapy, and by FEV<sub>1</sub> values. As a screening tool, the overall agreement between ACT and the specialist's rating ranged from 71.3% to 78.2% at cut points between 10 and 19, and the area under the ROC curve was 0.77.

	Specialist rating of control					F
	Not controlled (n=2)	Poorly controlled (n=28)	Somewhat controlled (n=103)	Well controlled (n=224)	Completely controlled (n=79)	
ACT sum scoring	7.5	15.5	16.9	20.8	21.5	34.5*
ACT sum of counts	0	1.8	2.6	3.9	4.2	33.7*
	Change patient's therapy					F
	Stepped down (n=52)	No change (n=269)	Stepped up (n=115)			
ACT sum scoring	20.6	20.8	16.6	–	–	40.4*
ACT sum of counts	3.9	3.9	2.4	–	–	38.9*
	% Predicted FEV <sub>1</sub> values				F	
	30%–59% (n=48)	60%–79% (n=113)	80%–100% (n=192)	101%–140% (n=87)		
ACT sum scoring	18.3	19.0	19.9	20.9	–	4.3
ACT sum of counts	3.1	3.3	3.5	4.0	–	3.8

ACT = Asthma Control Test. \* p<0.001; \*\* p<0.01.

**Table 1. Comparison of mean ACT scores across groups differing in asthma control**

## Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists<sup>11</sup>

**Authors:** Schatz M et al

**Summary:** The Asthma Control Test (ACT) proved to be reliable, valid, and responsive to changes in asthma control over time in a sample of patients who were new to the care of an asthma specialist. A cut-off score of  $\leq 19$  identified patients with poorly controlled asthma.

**Method:** 313 asthmatic patients aged  $\geq 12$  years who had not consulted an asthma specialist within 5 years and had a previous diagnosis of asthma completed the ACT and the Asthma Control Questionnaire (ACQ) at 2 physician visits (4–12 weeks apart). Pulmonary function was measured, and asthma specialists rated asthma control.

**Results:** At baseline, specialists rated asthma control as well controlled or completely controlled (48%), somewhat controlled (29%), and not controlled (23%). Internal consistency reliability of the ACT was 0.85 at baseline ( $n=313$ ) and 0.79 for the follow-up visit ( $n=248$ ). Among 86 patients with the same specialist rating for asthma, the test-retest assessment was 0.77. The criterion validity was demonstrated by statistically significant correlations between ACT scores at the baseline visit and the specialists' assessment ( $r=0.52$ ;  $p<0.001$ ) and ACQ scores ( $r=-0.89$ ;  $p<0.001$ ). Baseline ACT scores also correlated significantly with baseline percent predicted FEV<sub>1</sub> values ( $r=0.31$ ;  $p<0.001$ ). Discriminant validity was demonstrated, with significant ( $p<0.001$ ) differences in mean ACT scores across patients differing in asthma control, pulmonary function, and treatment recommendation. Responsiveness of the ACT to changes in scores between the baseline and follow-up visits was demonstrated by a highly consistent correlation with changes in ACQ scores ( $r=-0.81$ ;  $p<0.001$ ), a moderate correlation with specialist control ratings ( $r=0.44$ ;  $p<0.001$ ), and minimal correlation with changes in FEV<sub>1</sub> ( $r=0.29$ ;  $p<0.001$ ). An ACT score of  $\leq 19$  detected uncontrolled asthma (71% sensitivity; 71% specificity).

The responsiveness of the ACT was also demonstrated by mean score changes on the ACT differing significantly across groups of patients differing in the level of change in specialists' ratings of asthma control, changes in FEV<sub>1</sub> values, and ACQ scores (Table 2).

	Mean change in ACT score	F statistic
Specialist assessment		
Worse ( $n=44$ )	-0.02	24.2*
Same ( $n=85$ )	0.73	
Better by 1 rating level ( $n=80$ )	1.88	
Better by 2 rating levels ( $n=37$ )	4.8	
FEV <sub>1</sub>		
<10% improvement ( $n=212$ )	1.17	32.9*
$\geq 10\%$ improvement ( $n=34$ )	4.32	
ACQ score		
Better ( $n=93$ )	3.94	71.0*
Same ( $n=129$ )	0.39	
Worse ( $n=24$ )	-1.08	

ACT = Asthma Control Test; ACQ = Asthma Control Questionnaire.  
\*  $p<0.001$ .

**Table 2. Mean changes in ACT scores as a function of changes in specialists' ratings of asthma control and changes in FEV<sub>1</sub> values and ACQ scores**

## The Asthma Control Test™ (ACT) as a predictor of GINA guideline-defined asthma control: analysis of a multinational cross-sectional survey<sup>12</sup>

**Authors:** Thomas M et al

**Summary:** In this real world study, reflective of real world hurdles that clinicians face in interpreting GINA guidelines, the ACT was easily and rapidly completed by patients and proved that it can serve as a useful tool in the clinic to assess asthma control, ideally in conjunction with a complete medical history and lung function testing. The findings showed that an ACT score  $\leq 19$  is useful to identify patients with poorly controlled asthma for whom a full clinical review is needed.

**Method:** Data are reported from the multinational cross-sectional Respiratory Disease Specific Programme VI, conducted in the first quarter of 2007 and involving 2949 patients with asthma attending primary care physicians and specialists in France, Germany, Italy, Spain, the UK, and the USA. ACT scores were compared with GINA classifications of asthma control.

**Results:** The area under the ROC curve for the ACT score predicting the GINA control classification was 0.84. An ACT score of  $\leq 19$  correctly predicted GINA 'partly controlled' or 'uncontrolled' asthma 94% of the time overall and  $\geq 93\%$  of the time in each country. An ACT score  $\geq 20$  predicted GINA-defined controlled asthma 51% of the time, and the kappa statistic (0.42) suggested a moderate agreement using the cut-off point of  $\geq 20$  for 'well controlled' asthma. Table 3 summarises the positive and negative predictive values, as well as sensitivity and specificity, of the ACT score cut-off point of  $\geq 20$  for all patients and by country.

	Sensitivity	Specificity	Correctly classified	Positive predictive value	Negative predictive value
Global ( $n=2949$ )	60	92	70	94	51
France ( $n=697$ )	58	93	72	93	58
Germany ( $n=495$ )	59	93	73	93	60
Italy ( $n=495$ )	56	85	63	93	38
Spain ( $n=395$ )	55	97	65	98	41
UK ( $n=154$ )	73	88	77	94	56
US ( $n=713$ )	64	91	72	94	51

All data are percentages.

**Table 3. Specificity, sensitivity, positive and negative predictive values for ACT score cut-off point of  $\geq 20$  for well-controlled asthma and GINA binary split of controlled vs partly controlled/uncontrolled asthma, globally and by country**

### Patient Outcomes Management Survey results

- 7% - well controlled
- 93% - asthma not controlled as well as it could be
- 72% - asthma not well controlled
- 19% - asthma markedly out of control

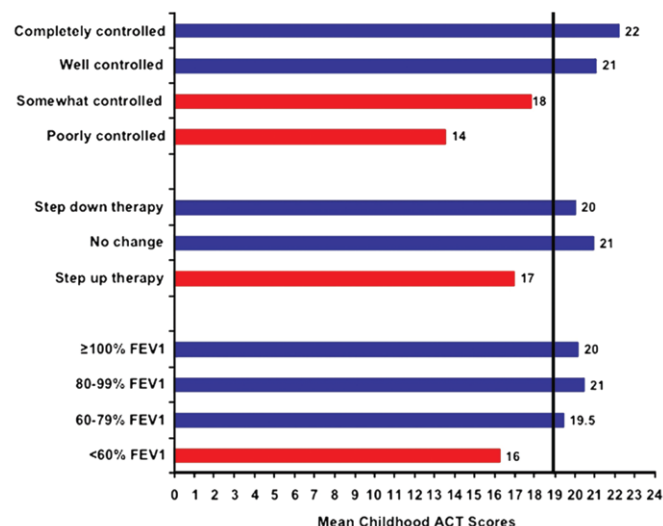
## Development and cross-sectional validation of the Childhood Asthma Control Test<sup>4</sup>

**Authors:** Liu AH et al

**Summary:** This article details the development and validation of the Childhood Asthma Control Test (C-ACT), developed to assess asthma control in children aged 4–11 years with asthma for use in the clinic and at home. A score of  $\leq 19$  indicated inadequately controlled asthma.

**Method:** A 21-item questionnaire was administered to 343 patients with asthma and their caregivers, who were randomly divided into a development and validation sample ( $n=257$ ; 75%) and a confirmatory sample ( $n=86$ ; 25%). Stepwise logistic regression was performed to reduce the 21 items to a set best able to discriminate asthma control.

**Results:** Seven items (4 child-reported and 3 caregiver-reported) were selected from the development sample to comprise the C-ACT, based on their ability to predict asthma control. The items were summed to obtain a total score for the C-ACT, with a potential range in score from 0–27; lower scores indicated poorer control. Summed scores discriminated between groups of patients differing in the specialists' rating of asthma control ( $F=36.89$ ;  $p<0.0001$ ), the need for change in patients' therapy ( $F=20.07$ ;  $p<0.0001$ ), and % predicted FEV<sub>1</sub> ( $F=2.66$ ;  $p<0.05$ ). All results were verified in the confirmatory sample. A score of  $\leq 19$  indicated inadequately controlled asthma (specificity 74%, sensitivity 68%). A clinical validation identified a cut point of  $\leq 19$  in the C-ACT as indicating inadequate asthma control (Figure 1).



**Figure 1. C-ACT cut-point score of 19 compared with clinical measures**

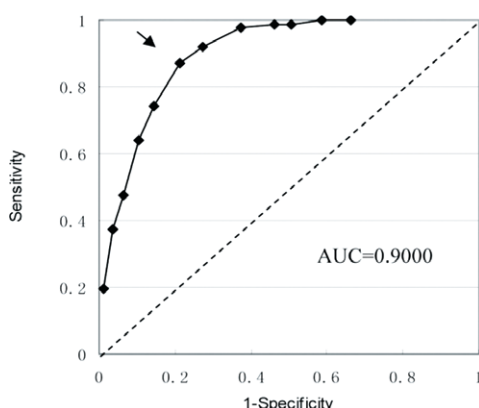
## Validity of Asthma Control Test for asthma control assessment in Chinese primary care settings<sup>13</sup>

**Authors:** Zhou X et al

**Summary:** The Asthma Control Test (ACT) shows reliability, validity, and is practical for asthma control assessment in primary care settings in China and can be routinely used in these settings.

**Method:** This multicentre study involved 403 asthma patients without acute exacerbation treated for asthma in 15 primary care settings in China, who had completed the ACT, Asthma Control Questionnaire (ACQ), and spirometry testing. According to asthma specialists' ratings of asthma control as specified by the Global Initiative for Asthma 2006 guidelines, patients were divided into uncontrolled, partly controlled, and controlled groups to evaluate the reliability, empirical validity, and screening accuracy of the ACT. The screening accuracies of the ACT and ACQ were compared, as were the patients' self-ratings and the specialists' ratings.

**Results:** At baseline, specialists' ratings classified asthma control as uncontrolled (50.1%), partly controlled (28.5%), and controlled (21.3%). The internal consistency reliability of the 5-item ACT was 0.861 for the total cohort. The ACT scores were strongly correlated with the specialists' rating ( $r=0.697$ ). The ACT scores showed significant differences between different levels of FEV<sub>1</sub>, % predicted ( $F=37.59$ ;  $p<0.0001$ ) and specialists' ratings of asthma control ( $F=169.53$ ;  $p<0.0001$ ), and also between patients requiring different treatment adjustments ( $F=111.33$ ;  $p<0.0001$ ). The asthma was controlled for an ACT score of  $\geq 20$ , partly controlled for scores of 19 and 18, and uncontrolled for a score of  $\leq 17$ ; an ROC curve revealed an ACT score of 20 to be an optimal cutpoint for screening patients with controlled asthma (Figure 2). The ACT showed similar percentages of correctly classified results with ACQ. The patients' self-rated asthma control level was significantly higher than that rated by the specialists ( $z = 5.93$ ;  $p<0.0001$ ).



**Figure 2. ROC curve of the ACT for assessing controlled asthma. ♦, cutpoints; arrow, cutpoint of 20. AUC = area under the curve**

### Summary

There are high levels of morbidity from asthma in New Zealand, partly as a result of difficulties in identifying patients whose asthma is poorly controlled. There is no simple and objective assessment measure commonly used for asthma, unlike most other chronic conditions. The ACT score provides a very quick and simple assessment of asthma control. The result is objective, easily understood by the

health care professional and patient and changes over time as asthma control changes. By using the ACT score as part of their routine assessment of patients with asthma, busy health care professionals will be able to easily identify patients whose asthma control can be improved, enabling changes to their management to be made and thereby improving outcomes.

### References

- Holt S, Beasley R. The burden of asthma in New Zealand. Published by Asthma and Respiratory Foundation of New Zealand, 2002. ISBN 086471095X
- US Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute. Expert Panel Report Guidelines for the Diagnosis and Management of Asthma (EPR-3 2007). NIH Item No. 08-4051. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>. Accessed March 25, 2010.
- Nathan RA et al. Development of the Asthma Control Test: A survey for assessing asthma control. *J Allergy Clin Immunol*. 2004;113:59-65.
- Liu AH et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *J Allergy Clin Immunol*. 2007;119(4):817-25.
- POMS Steering Committee. Asthma morbidity, control and treatment in New Zealand: results of the Patient Outcomes Management Survey (POMS), 2001. *N Z Med J*. 2003;116(1174):U436.
- Holt S. NZ INSPIRE study. Research Review, 2007. <http://www.researchreview.co.nz/NZ%20Inspire%20Report.pdf>
- Global Burden of Asthma. Global Initiative for Asthma (GINA) 2004 – [www.ginasthma.com](http://www.ginasthma.com)
- Partridge MR et al. Attitudes and actions of asthma patients on regular maintenance therapy: the INSPIRE study. *BMC Pulm Med*. 2006;6:13.
- Bateman ED et al. Can guideline-defined asthma control be achieved? The Gaining Optimal Asthma Control study. *Am J Respir Crit Care Med*. 2004;170(8):836-44.
- Boulet LP et al. Evaluation of asthma control by physicians and patients: Comparison with current guidelines. *Can Respir J*. 2002;9(6):417-23.
- Schatz M et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol*. 2006;117(3):549-56.
- Thomas M et al. The Asthma Control Test™ (ACT) as a predictor of GINA guideline-defined asthma control: analysis of a multinational cross-sectional survey. *Prim Care Respir J*. 2009;18(1):41-9.
- Zhou X et al. Validity of Asthma Control Test for asthma control assessment in Chinese primary care settings. *Chest*. 2009;135(4):904-10.



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