

The status of asthma control in the U.S. adult population

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ABSTRACT

Treatment guidelines recognize the importance of achieving and maintaining asthma control. This study was designed to assess the prevalence of asthma control in a representative U.S. population. A survey regarding asthma and associated symptoms was sent to a representative national sample of 134,401 households managed by the National Family Opinion WorldGroup from May to July 2007. Subjects ≥ 18 years with current asthma were identified and completed the Asthma Control Test (ACT), a brief validated self-administered survey that assesses asthma control. Subjects with an ACT score of >19 have been defined as having well-controlled asthma (WCA) and those with a score of ≤ 19 were defined as having not well-controlled asthma (NWCA). The prevalence of WCA was identified for the total population as well as subjects who currently were only using albuterol to control asthma symptoms. In addition, the frequency of past asthma exacerbations was studied and correlated with ACT. Surveys were returned by 81,505 households (61% return rate). A total of 10,139 adults self-reported having asthma and completed the ACT. Forty-one percent of these had NWCA and 39% of the subjects using albuterol as the only asthma medication had NWCA. Fifty-eight percent of subjects with NWCA in the total population had an asthma-related exacerbation (asthma-related oral corticosteroid use, emergency department, or hospitalization) in the previous year compared with 24% of subjects with WCA. This large representative national asthma sample using a validated asthma control instrument identified $>40\%$ of subjects with NWCA. In addition, subjects using albuterol monotherapy, who would be expected to have mild asthma and thus be well controlled, had a similar high prevalence of NWCA.

(Allergy Asthma Proc 30:529–533, 2009; doi: 10.2500/aap.2009.30.3276)

Key words: ACT, asthma, control, epidemiology, population, survey, U.S.

Achieving and maintaining asthma control is the goal of current national and international treatment guidelines.^{1,2} The assessment of asthma severity is highlighted in the initial evaluation of patients and before beginning controller therapy in the Expert Panel Report 3.¹ However, once controller therapy has been started, the focus for routine assessment and monitoring of therapy is the measurement of asthma control. According to the National Asthma Education and Prevention Program (NAEPP), asthma control is achieved by reducing both current impairment and future risk.¹ Current impairment stresses the importance of preventing or limiting daytime symptoms, nighttime awakenings, need for short-acting β -agonists, and work/school days missed, while maintaining normal or near normal lung function and normal activity lev-

els. Future risk can be minimized by preventing exacerbations and progressive loss of lung function or risk of adverse effects from medication.

Recent asthma surveillance studies from the Centers for Disease Control and Prevention suggest that the burden of asthma remains high with a high cost burden.^{3,4} In 2004, asthma was responsible for 1.8 million emergency department visits and 497,000 hospitalizations. Although these data are useful measures of serious asthma morbidity related to asthma exacerbations, these studies were not designed to specifically evaluate the more common occurrence of uncontrolled asthma control caused by impairment. One of the first studies to investigate the symptom burden of asthma in a large, unselected population was conducted in 1998⁵ and it indicated that the majority of persons with asthma experience moderate to severe symptom burden, and two-thirds of persons reported substantial functional limitations.

The present survey was conducted to characterize the current level of asthma control in a representative sample of the U.S. adult population and to assess the changes in asthma control since the previous report. Since the earlier survey of asthma in 1998 validated asthma control questionnaires such as the Asthma Control Test (ACT) have been developed to assess asthma control. ACT is a brief, clinically validated, patient-based questionnaire that is one of three such

From GlaxoSmithKline, Research Triangle Park, North Carolina
Presented in part at the annual meeting of the American Thoracic Society, Toronto, Canada, May 16–21, 2008

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control questionnaires that the 2007 National Heart, Lung, and Blood Institute asthma guidelines have recommended for use to assess asthma control.⁶

METHODS

Taylor Nelson Sofres identified a cohort of patients with asthma by screening a panel of households that is representative of general U.S. households. A panel of households was recruited through a variety of sources, including direct mail and referral. Those interested in participating in the panel completed a recruitment survey to provide demographic information on family members. At the time of the present survey, the mean panelist tenure was ~9 years. Respondents were not compensated for their participation. Information about the gender, household income size, race, education, and age of all members of the household was obtained to extrapolate the results to the general age and gender population strata of the United States.

A brief, four-page survey regarding asthma and associated symptoms was administered from May to July 2007 (spring/summer) to a representative national sample of 134,401 U.S. households *via* the mail. Surveys were sent directly to one household member who provided responses for up to a total of five household members. Screening survey items addressed sociodemographics (age, gender, educational level, income, and race); diagnosis of comorbid respiratory conditions; current asthma symptoms and seasonality of disease; asthma medication use, disease burden, and health resource use; and smoking history. Subjects aged ≥ 18 years old were classified as having current asthma if they answered yes to two questions regarding physician-diagnosed asthma: (1) ever been diagnosed with asthma by a doctor or health care professional and (2) having asthma symptoms such as coughing, wheezing, or shortness of breath in the past year. These two questions are similar to those used by the National Health and Nutrition Examination Survey, which is used to determine asthma prevalence in the United States.

Subjects who answered yes to the aforementioned two questions regarding asthma were then asked to complete the five-item ACT. The ACT inquires about asthma impairment over the past 4 weeks: (1) impact of asthma on work, home, or school; (2) frequency of shortness of breath; (3) frequency of nighttime awakenings due to asthma symptoms; (4) frequency of rescue medication use; and (5) self-graded level of asthma control. An ACT score of ≤ 19 is validated as the cutoff point identifying persons with not well-controlled asthma (NWCA) while those with ACT scores of >19 are considered to have well-controlled asthma (WCA).

Categorical variables were compared across groups using a crosstab procedure, and continuous variables

were examined using mean comparisons. No inferential statistical testing was conducted because of the demographic nature of this survey. All statistical analyses were conducted using SPSS Version 15.0 (SPSS for Windows, Chicago, IL).

RESULTS

Baseline Demographics

Completed surveys were returned by 81,505 households (61% return rate), yielding data for 162,269 individual adults aged ≥ 18 years old. A total of 13,048 (8%) adults met the criteria for current asthma and 10,139 persons completed all five items of the ACT. The demographic characteristics of the asthma population are shown in Table 1. The mean age of the total population was 46.6 years and approximately two-thirds were women. Differences in household income and educational level were observed across racial/ethnic groups. Slightly more than one-half of the patients (5505) reported use of asthma controller medications in the past 4 weeks and 26% (2678) reported using only albuterol monotherapy. Among the subjects using albuterol monotherapy, 20% (546) used it daily.

Asthma Control

NWCA was identified in 41% of all subjects, and 39% of subjects using albuterol monotherapy met criteria for NWCA. Demographics of patients with NWCA were typical of previously reported patterns. NWCA was more frequently reported in African Americans (50%) compared with Hispanics (42%) and white populations (39%; Fig. 1). NWCA was most common in those with an annual income of $< \$30,000$ (59%) and lowest in those with an income $> \$75,000$ (30%). In addition, having only attended high school was associated with the highest rate of NWCA (68%) and this rate declined as educational level increased to graduate degrees where NWCA was 29%.

One of the five items in the ACT includes the global assessment of asthma. This global assessment of control was evaluated separately and then compared with the overall ACT scores to determine how subjects perceive their asthma control. Eighty-five percent of the asthma participants perceived their asthma to be either "well/completely controlled" or "somewhat controlled," whereas the total ACT score indicated that only 59% of the total population had WCA. Only 15% of subjects with NWCA rated their level of asthma control as "poor/not controlled." In addition, for subjects with NWCA, ~33% rated their level of asthma control as "well/completely controlled" and 50% rated their asthma control as "somewhat controlled."

Table 1 Demographic characteristics of asthma population

	Total (n = 10,139)	White Population (n = 8053)	Black/African American (n = 1101)	Hispanic (n = 385)	Other (n = 600)
Mean age, yr (SD)	46.6 (15.8)	46.8 (15.7)	48.9 (16.7)	42.2 (15.1)	43.6 (15.4)
Female (%)	66.8%	66.0%	73.1%	68.6%	64.5%
Household income (%)					
<\$30,000	29.1%	26.3%	43.2%	35.6%	36.2%
\$30,00–49,999	18.4%	17.4%	24.4%	23.9%	16.8%
\$50,000–74,999	17.9%	18.1%	17.3%	16.6%	18.0%
≥\$75,000	34.6%	38.2%	15.1%	23.9%	29.0%
Educational level (%)					
Less than high school graduate	3.0%	2.5%	6.1%	4.9%	1.8%
High school graduate	15.9%	16.0%	16.3%	14.3%	16.2%
Some college	38.7%	37.3%	45.8%	44.2%	41.2%
Bachelors degree	23.2%	24.0%	19.2%	21.7%	20.5%
Postgraduate	18.3%	19.4%	11.1%	14.0%	19.3%
No answer	0.9%	0.8%	1.6%	0.8%	1.0%
Baseline asthma treatment					
Albuterol monotherapy	26.4%	26.2%	26.2%	28.6%	28.3%
Controller therapy*	54.3%	54.6%	55.5%	51.2%	50.7%

*Controller = inhaled corticosteroid, leukotriene modifier and cromolyn sodium, fluticasone propionate and salmeterol combination, and xanthines and long-acting β -agonists.

SD = standard deviation.

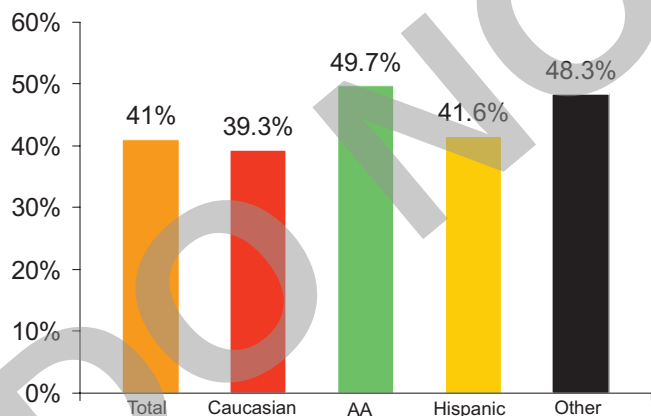


Figure 1. Proportion with uncontrolled asthma by race. ED/UC = emergency department/urgent care; IP = inpatient.

Asthma-Related Exacerbations

Subjects with NWCA reported more asthma-related exacerbations in the previous year compared with the WCA population (Fig. 2). Overall, 58% of the group with NWCA reported an asthma-related exacerbation in the previous year. Comparatively, almost 25% of subjects with WCA (ACT scores of >19) reported having at least one exacerbation in the previous year. Among subjects currently taking albuterol only to treat their asthma, 31% reported having an asthma-related exacerbation in the previous year regardless of control status. In addition, the

proportion of patients with asthma exacerbations was 49% for daily users of albuterol and 23% for nondaily users of albuterol (Fig. 3).

DISCUSSION

The importance of achieving and maintaining asthma control is recognized by national and international guidelines.^{1,2} However, the results of the present national survey reveal a high level of uncontrolled asthma in a general population of subjects with self-reported asthma. Overall, 41% of subjects with a history of health care provider–diagnosed asthma and current active disease met ACT criteria for NWCA. In addition, the prevalence of NWCA was similar in patients that reported using albuterol as their only asthma medication. These results are particularly noteworthy given that the survey was conducted during the spring/summer months (May through July) when patients generally experience better asthma control compared with other seasons.^{7,8} Additionally, ACT was measured in the household where one might expect to find a higher level of asthma control than in a physician's office or pharmacy where patients are presenting for treatment of acute symptoms.^{9,10}

Not surprisingly, the proportion of patients reporting an asthma exacerbation in the prior year was twofold greater for patients with NWCA, compared

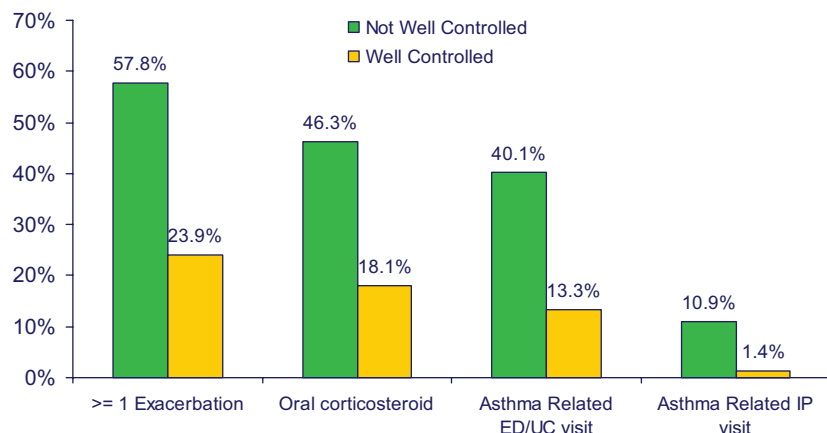


Figure 2. Asthma-related exacerbations in the previous year by asthma control status. ED/UC = emergency department/urgent care; IP = inpatient.

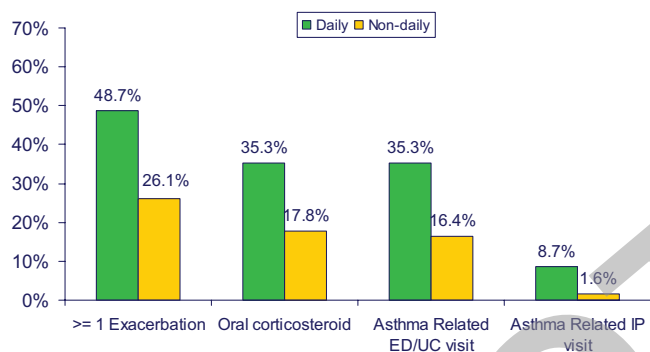


Figure 3. Asthma-related exacerbations in the previous year by albuterol use, daily vs. non-daily users. ED/UC = emergency department/urgent care; IP = inpatient.

with those with WCA; however, equally important was the finding that approximately one in four patients with current WCA experienced an exacerbation in the prior year. In addition, patients who used daily albuterol as the only asthma medication were twice as likely to have an asthma exacerbation in the prior year as those using albuterol monotherapy on a less frequent basis. Because albuterol monotherapy should only be prescribed for patients with intermittent asthma, nearly all of these patients using albuterol monotherapy should be well controlled; however, 39% of these subjects had uncontrolled asthma and 31% had an exacerbation in the prior 12 months. This level of poorly controlled asthma was also seen in the patients with more severe asthma who were using controller medications.

The NAEPP guidelines state that daily albuterol use is a marker for poorly controlled asthma. Among the albuterol monotherapy patients, 20% required albuterol daily and nearly one-half of these subjects reported an asthma exacerbation in the previous year. These findings illustrate the need to continually assess the level of asthma control, even among patients previously thought to have mild, well-controlled asthma on albuterol monotherapy. These

findings also emphasize the importance of monitoring albuterol rescue therapy as a valuable component in the assessment of asthma impairment.

One of the first studies to assess the symptom burden in the U.S. population was conducted in 1998 and it indicated that many people with asthma frequently fail to achieve the goals of asthma care as established by national asthma guidelines.⁵ That study also documented inadequate use of asthma controller medications with only 20% of participants reporting the use of inhaled corticosteroids.¹¹ Although the use of asthma controllers appears to be higher in the present study (54.3%), 4 of 10 patients treated with albuterol monotherapy had NWCA.

The perception of asthma control and the objective measure of control continue to be discordant. Overall, 85% of all survey participants perceived their asthma to be either "well/completely controlled" or "somewhat controlled" when asked a single global asthma control question. However, 41% of the subjects met criteria for NWCA when the level of asthma impairment was measured by the total ACT score. These results highlight the need for comprehensive strategies to improve recognition of NWCA for all patients with asthma using validated instruments such as ACT and the use of objective measures such as spirometry.

The high rate of NWCA observed in this study may underestimate the level of impairment throughout the year, because this study was conducted in the spring and summer. Seasonal peaks of asthma-related office visits, emergency department visits, hospitalizations, and outpatient exacerbations are observed in the fall and winter in both children and adults. Thus, one might expect to see an even greater percent of patients with NWCA in the fall and winter than what was observed in this survey.¹²⁻¹⁴

An important strength of our study was the use of the ACT, a standardized asthma control assessment, to accurately measure the rate of uncontrolled asthma in a large population of people with asthma. The ACT was vali-

dated in a longitudinal study of patients followed by asthma specialists.¹⁵ A subsequent study showed the validity of the ACT in the home setting and supports its use as a tool for assessing asthma control in a general population when administered by mail.¹⁶ In addition, more widespread use of the ACT, and other validated control questionnaires in clinical practice, is endorsed by treatment guidelines and are useful for monitoring asthma control and assessing whether intervention is required.

There are a number of limitations to the present study design and survey methodology. The responder population was not rebalanced, which may have led to an asthma sample that may not be representative of the U.S. population. However, this method allows for comparisons within that overall paneled sample. Responders compared with nonresponders may differ with respect to disease severity and comorbidities and could have biased the overall prevalence of uncontrolled asthma. In addition, because the head of household is responsible for filling out the survey, this possibly led to incomplete or incorrect answers and more female responders. However, the ACT surveys were supposed to be filled out by the individual in the household who had asthma if that was different from the head of household. Although standard epidemiological questions were used to determine eligibility (asthma diagnosis), no attempts were made to confirm this diagnosis clinically. In addition, the current study used a panel of individuals to develop the sample, whereas the study by Adams *et al.*¹¹ used random digit dialing to construct its asthma sample. With the increasing use of cell phones and call screening devices on telephones, response rates have declined over the last 10 years, making random digit dialing less appropriate.^{17,18} The use of patient panels, however, provides a high response rate, usually >60%, and facilitates completion of surveys in a timely fashion.

In summary, the results of our cross-sectional national survey document that 41% of subjects with self-reported asthma are not well controlled. Fifty-eight percent of patients with NWCA reported an exacerbation of asthma in the prior 12 months. In addition, many subjects using albuterol as monotherapy in the treatment of their disease also reported NWCA. Twenty-five percent of patients with WCA reported an exacerbation in the previous year, highlighting the variability of this disease and the importance of frequent monitoring of asthma control. These results indicate that uncontrolled asthma and inadequate use of asthma controller medicines is a continuing problem in a general population sample of patients with asthma. The updated asthma guidelines highlight the importance of routine longitudinal assessment of asthma control in the management of patients with asthma. Implementation of validated control surveys into routine practice may significantly increase the recognition of NWCA and improve the burden of asthma across the country.

REFERENCES

1. National Heart, Lung, and Blood Institute. Expert panel report 3: Guidelines for the diagnosis and management of asthma. Full report 2007. National Heart, Lung, and Blood Institute, National Institutes of Health, National Heart, Lung, and Blood Institute. Available online at www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm; last accessed January 16, 2008.
2. National Heart, Lung, and Blood Institute. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2007. Available online at www.ginasthma.org; last accessed January 16, 2008.
3. Moorman JE, Rudd RA, Johnson CA, et al. National surveillance for asthma—United States, 1980–2004. *MMWR Surveill Summ* 56:1–54, 2007.
4. Cheng JW, and Arnold RJ. Pharmacoeconomic review of medical management of persistent asthma. *Allergy Asthma Proc* 29:109–122, 2008.
5. Fuhlbrigge AL, Adams RJ, Guilbert TW, et al. The burden of asthma in the United States. Level and distribution are dependent on interpretation of the National Asthma Education and Prevention Program Guidelines. *Am J Respir Crit Care Med* 166:1044–1049, 2002.
6. Nathan RA, Sorkness CA, Kosinski M, et al. Development of the Asthma Control Test: A survey for assessing asthma control. *J Allergy Clin Immunol* 113:59–65, 2004.
7. Gergen PJ, Mitchell H, and Lynn H. Understanding the seasonal pattern of childhood asthma: Results from the National Cooperative Inner-City Asthma Study (NCICAS). *J Pediatr* 141:631–636, 2002.
8. Jones C, Clement L, Morpew T, et al. Achieving and maintaining asthma control in an urban pediatric disease management program: The Breathmobile Program. *J Allergy Clin Immunol* 119:1445–1453, 2007.
9. Carlton BG, Lucas DO, Ellis EF, et al. The status of asthma control and asthma prescribing practices in the United States: Results of a large prospective asthma control survey of primary care practices. *J Asthma* 42:529–535, 2005.
10. Lenoir M, Williamson A, Stanford RH, and Stempel DA. Assessment of asthma control in a general population of asthmatics. *Curr Med Res Opin* 22:17–22, 2006.
11. Adams RJ, Fuhlbrigge A, Guilbert T, et al. Inadequate use of asthma medication in the United States: Results of the Asthma in America national population survey. *J Allergy Clin Immunol* 110:58–64, 2002.
12. Johnston NW, Johnston SL, Duncan JM, et al. The September epidemic of asthma exacerbations in children: A search for etiology. *J Allergy Clin Immunol* 115:132–138, 2005.
13. Johnston NW, Johnston SL, Norman GR, et al. The September epidemic of asthma hospitalization: School children as disease vectors. *J Allergy Clin Immunol* 117:557–562, 2006.
14. Pendergraft TB, Stanford RH, Beasley R, et al. Seasonal variation in asthma-related hospital and intensive care unit admissions. *J Asthma* 42:265–271, 2005.
15. Schatz M, Sorkness CA, Li JT, et al. Asthma Control Test: Reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol* 117:549–556, 2006.
16. Schatz M, Mosen DM, Kosinski M, et al. Validity of the Asthma Control Test completed at home. *Am J Manag Care* 13:661–667, 2007.
17. Curtin R, Presser S, and Singer E. Changes in telephone survey nonresponse over the past quarter century. *Public Opin Q* 69: 87–98, 2005.
18. Tourangeau R. Survey research and societal change. *Annu Rev Psychol* 55:775–801, 2004. □

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