



# Asthma control in patients treated with inhaled corticosteroids and long-acting beta agonists: A population-based analysis in Germany



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## ABSTRACT

**Background:** The prevalence and the characteristics of poor asthma control among adults treated with combinations of inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA) are not completely understood.

**Methods:** Data from adult patients in Germany with self-reported asthma treated with an ICS-LABA combination in the National Health and Wellness Survey (NHWS) were analysed. Patients with well-controlled and not well-controlled asthma according to the Asthma Control Test (ACT) score were compared, with respect to socio-demographic characteristics, attitudes, adherence and outcomes.

**Results:** Among the German patients with self-reported asthma (5.2% of the respondents), 16.2% (382 patients) were treated with an ICS-LABA combination and did not report concomitant chronic obstructive pulmonary disease, chronic bronchitis or emphysema. In this subgroup, 55.8% had not well-controlled asthma (ACT < 20). ICS-LABA treated patients with not well-controlled asthma were more likely to report emergency visits (16.4% vs. 8.9%), missed more time from work (absenteeism: 12.9% vs. 4.3%), were more impaired while at work (presenteeism: 29.0% vs. 14.9%) and were more likely to be women (69.0% vs. 57.4%), compared with well-controlled patients. There were no significant differences in age, body mass index, smoking, income, education or self-reported adherence between the two groups, but different attitudes regarding the patient-physician relationship.

**Conclusions:** A substantial proportion of patients treated with ICS and LABA had not well-controlled asthma. These patients did not differ from well-controlled patients in terms of education or self-reported adherence, but in terms of their attitudes regarding the patient-physician relationship.

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## 1. Introduction

Asthma ranks among the most common chronic diseases globally and affects an estimated 300 million people worldwide [1]. Previous classifications of asthma severity based on lung function impairment have been replaced by classifications based on asthma control. This concept has been adopted in the recommendations of the global initiative for asthma (GINA) ([www.ginasthma.org](http://www.ginasthma.org)) and in several national asthma guidelines. Accordingly, controlled asthma is defined by minimal or no daytime and night-time symptoms,

maintenance of normal activity and little or no need for reliever medication. Asthma control can be measured using questionnaires such as the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT) [2]. Large surveys showed that approximately 50% of all patients with asthma are not well controlled [3–7]. Poor asthma control is associated with increased risk of exacerbations, impaired quality of life, absences from school or work and increased health-care resource utilisation [8,9].

A minority of patients with asthma remain symptomatic despite treatment with an inhaled corticosteroid (ICS) and a long-acting beta-agonist (LABA). Although this subpopulation accounts for the majority of medical resource use [10], there is little information on the prevalence and the characteristics of poor asthma control in patients treated with ICS-LABA combinations. It was the aim of this analysis, therefore, to investigate this issue using a population-based

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## Abbreviations

ICS	Inhaled corticosteroid
LABA	Long-acting beta-agonist
ACQ	Asthma Control Questionnaire
ACT	Asthma Control Test
NHWS	National Health and Wellness Survey
BMI	Body mass index
MMAS-4	4-item Morisky Medication Adherence Scale
MMAS-8	8-item Morisky Medication Adherence Scale
GINA	Global Initiative for Asthma
SF-12	12-item Short Form Survey
SF-36	36-item Short Form Survey
MCS	Mental Component Summary
PCS	Physical Component Summary
WPAI	Work Productivity and Activity Impairment
COPD	Chronic Obstructive Pulmonary Disease
EHWS	European National Health and Wellness Survey
INSPIRE	Investigating New Standards for Prophylaxis in Reducing Exacerbations
LIAISON	International cross-sectional and longitudinal assessment on asthma control

approach in Germany. In contrast to previous analyses describing the whole population of patients with asthma [3–5], we focused our analysis on the sub-population of patients treated with ICS-LABA combinations to explore patient characteristics associated with poor asthma control in subjects treated with ICS-LABA combinations.

## 2. Methods

### 2.1. Data source

Data were extracted from the 2010, 2011 and 2013 German National Health and Wellness Survey (NHWS; not conducted in Europe in 2012) and deduplicated, i.e., only answers from the respective first year were included for any respondent participating several times in the survey. The NHWS was a self-administered, Internet-based questionnaire from a nationwide sample of adults that was stratified by gender and age to represent the demographic composition of the German adult population. Potential respondents to the NHWS were recruited primarily through an existing web-based consumer panel (Lightspeed LLC®, Washington, USA). Online recruitment was supplemented by telephone recruitment to allow better representation of older adults (65 years of age or older), who were less likely to be a member of the consumer panel. Since the survey did not allow skipping of questions reported here, there were no missing data.

In the NHWS, each respondent had to complete all relevant items in the questionnaire to be included in the final data, with some items such as height, weight, and income providing an option to decline to answer. Potential respondents to the NHWS were recruited through an existing, general-purpose (i.e. not health care-specific) web-based consumer panel. The consumer panel recruited its panel members through opt-in e-mails, co-registration with panel partners, e-newsletter campaigns, banner placements and affiliate networks. All panellists explicitly agreed to be a panel member, registered with the panel through a unique e-mail address and completed an in-depth demographic registration profile. A stratified random sampling procedure, with strata by age and gender, was implemented to ensure that the demographic

composition of the NHWS sample is representative of each country's adult population. The NHWS was reviewed and approved by Essex Institutional Review Board (Lebanon, NJ, USA).

### 2.2. Patient characteristics

The following socio-demographic and health characteristic variables were included for description of the study population: self-reported physician-diagnosed asthma, age, gender, marital status, education, income, employment type, health insurance, body mass index (BMI), smoking behaviour and self-reported asthma characteristics such as duration of the disease, frequency of asthma symptoms and severity with and without prescribed asthma medication. According to the guidelines of the World Health Organization (WHO), the following BMI categories were used: underweight to normal weight (<18.5 to <25 kg/m<sup>2</sup>), overweight (25 to <30 kg/m<sup>2</sup>) and obesity (≥30 kg/m<sup>2</sup>).

### 2.3. Asthma control

The Asthma Control Test (ACT) [11] is a patient self-administered tool for the assessment of asthma control, composed of 5 items, with a 4-week recall on symptoms and daily functioning. The scores range from 5 (poor control of asthma) to 25 (complete control of asthma). An ACT score ≥20 indicates well-controlled asthma, a score of less than 20 indicates not well-controlled asthma.

### 2.4. Healthcare resource use

Healthcare resource use was assessed by the self-reported number of physician visits, emergency visits and hospitalisations during the past six months. Total numbers were considered (not limited to asthma symptoms).

### 2.5. Health-related quality of life

Short form health surveys were used to assess generic Health-related Quality of Life (HR-QoL). The 2011 respondents completed the revised SF-12, and 2013 respondents completed the longer revised SF-36 scale. From these data, Physical and Mental Component Summaries (PCS and MCS) and health utility scores were derived. Physical Component Summary (PCS), an index of overall physical health status (population standard mean = 50), Mental Component Summary (MCS), an index of overall mental and emotional health status, and the Short Form 6D health state (SF-6D) health utility score, a preference-based index describing overall health on a scale from 0 (equivalent to death) to 1 (equivalent to perfect health) were used.

### 2.6. Adherence

The 4-item Morisky Medication Adherence Scale (MMAS-4) is a generic self-reported behaviour scale on medication adherence. It consists of four items with dichotomised scoring ("Yes" = 1 and "No" = 0) [12–14]. The items are summed to give a range of 0–4, corresponding with high (0) to medium (1–2) to low adherence (3–4). The MMAS-8 is the more recent and expanded version of MMAS-4. It consists of eight items, with yes/no-responses for the first seven and a 5-point Likert response for the last item. The items are summed and scores range from 0 to 8, indicating high (0) to medium (1–2) to low adherence (3–8). The MMAS-4 was included in the 2011 and 2012 surveys, while the MMAS-8 was included in 2013. To allow comparison, the MMAS-8 in this study was scored to proxy the 4-item measure. This scoring provides values similar to those of the MMAS-4.

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