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► **To cite this version:**

Falk Hoffmann, Gerd Glaeske. Prescriptions as a proxy for asthma in children: a good choice?. European Journal of Clinical Pharmacology, 2009, 66 (3), pp.307-313. 10.1007/s00228-009-0755-z . hal-00536834

**HAL Id: hal-00536834**

**<https://hal.science/hal-00536834>**

Submitted on 17 Nov 2010

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# Prescriptions as a proxy for asthma in children: a good choice?

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Received: 16 July 2009 / Accepted: 27 October 2009 / Published online: 17 November 2009  
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## Abstract

**Purpose** Stock et al. (Eur Respir J 25:47–53, 2005) recently estimated asthma prevalence in Germany using claims data on prescriptions and hospital diagnoses and found high prevalence peaks in infants. Our objective was to critically assess and discuss various aspects of identifying children with asthma using prescription data.

**Methods** We replicated the selection procedure of Stock et al. using data on 290,919 children aged 0–17 years insured in the Gmünder ErsatzKasse (GEK) in 2005. Asthma prevalence was also estimated in a sample of 17,641 children aged 0–17 years participating in the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) from 2003 to 2006.

**Results** In children aged 0–4 years insured in the GEK, prevalences were found to range from 11.7 to 17.7% for boys and from 7.2 to 11.1% for girls when the criteria of Stock et al. were applied. A steady decline in prevalences was observed in older age groups. Asthma prevalence estimated in the KiGGS data showed a quite different distribution. In the age group 0–4 years, prevalences were found to range from 0 to 2.6% in boys and from 0 to 1.0% in girls; in children >4 years, prevalences were found to increase with increasing age.

**Conclusions** When additional validation studies were taken into account, asthma medications were found to be prescribed not only for asthma but also for other respiratory diseases. In addition, not all children with current asthma had prescriptions. We therefore conclude that asthma medications are therefore not a good proxy for the disease.

**Keywords** Asthma · Children · Claims data · Cross-sectional study · Prevalence

## Introduction

Asthma is one of the most common chronic diseases in children [1–3]. Consequently, estimations of prevalence and costs that also pertain to younger age groups are of major public-health impact. Stock et al. recently published such a study in the *European Respiratory Journal* [4]. Using claims data of six health insurance companies covering a 1-year period, the aim of the authors was to estimate the prevalence of asthma in Germany. To this end, Stock et al. [4] used prescriptions for inhaled selective beta-2 agonists and inhaled corticosteroids and hospitalizations as a proxy for this disease. They excluded persons with a hospital diagnosis of chronic obstructive pulmonary disease (COPD). The authors found high peaks in asthma prevalence among infants that were as high as 25 and 17% in male and female infants, respectively. Asthma prevalence steadily declined after an age of 4 years in both sexes, ranging from 3 to 7% in persons aged 16–62 years [4]. These patterns—especially the high peaks in infants—were somewhat unexpected when compared to those found in other studies measuring asthma prevalence that were based on other methods [5–7].

The objective of this study was to critically assess and discuss the identification of children with asthma using data

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on prescriptions and hospital diagnoses as a proxy for the disease. Our aim was to replicate the prevalence estimation of Stock et al. [4] and compare the results with other identification criteria using data from both claims submitted to a nation-wide health insurance company and a nation-wide health survey on children.

## Methods

### Health survey data

Data obtained in the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) were used [8]. The KiGGS survey, which was conducted from May 2003 to May 2006 by the Robert Koch Institute (RKI) in Berlin, gathered information on health status in a nationally representative sample of children and adolescents aged 0–17 years. A two-stage sampling design was used. First, a systematic sample of 167 primary sample units (PSUs) was drawn from an inventory of German communities, with a disproportionate number of PSUs in the former East Germany. Second, 8 weeks prior to the start of the health examinations, an equal number of addresses ( $n=24$ ) per birth cohort were selected from local population registries within selected PSUs using a simple random sampling procedure. A final simple random sample of eight, nine, or ten children and adolescents per birth cohort was compiled at the RKI, resulting in a target population of 144, 162, or 180 persons per PSU. The total KiGGS sample included 28,299 children and adolescents of whom 17,641 participated (8985 boys, 8656 girls) in the survey. The overall response was 66.6% with no discernible differences by sex and age, but with a lower response (51%) among non-German families. Due to the sampling strategy, sample sizes of between 411 and 547 persons are available per birth cohort and sex stratum. To enable representative data to be estimated, survey weights with respect to age, sex, region of residence, and nationality were applied in all statistical analyses.

Further details regarding design, sampling strategy, modular structure, and non-response of the KiGGS are described elsewhere [9, 10].

The KiGGS survey consisted of questionnaires to be filled in by parents and parallel questionnaires to be completed by the participating children and adolescents aged  $\geq 11$  year, physical examinations and tests, and a computer-assisted personal interview (CAPI) performed by a physician. Using the CAPI, the physician determined the asthma status of the child by asking parents whether a physician had ever diagnosed asthma in their child and if this condition had been present in the past 12 months. This last question was a measure of current asthma status and was used in subsequent analyses.

### Health insurance claims data

We analyzed the claims data of the statutory health insurance company Gmünder ErsatzKasse (GEK), which has clients throughout Germany. In order to define a time period comparable with that of the KiGGS, we selected data for 2005. As suggested by Grobe et al. [11], we included only persons insured at least 1 day in all four quarters of 2005. This selection resulted in a population of 290,919 children aged 0–17 years (148,915 boys, 142,004 girls). The vast majority (96.8%) of these children were continuously insured throughout 2005. Due to this inclusion criterion, a considerable number of the 2827 infants born in the first quarter of 2005 could also be included. Sample sizes of between 1398 and 11,031 persons are available per year of birth and sex stratum.

In line with the definition applied by Stock et al. [4], we used data on prescriptions and hospitalizations. We included persons with at least one prescription for inhaled selective beta-2 agonists (Anatomical Therapeutic Chemical Classification (ATC) System: R03AC) or inhaled corticosteroids (ATC-Code: R03BA) or who had been hospitalized at least once due to asthma (ICD-10: J45) in 2005. Children with a main hospital diagnosis of COPD (ICD-10: J44) were excluded. In another paper by Stock et al. [12], however, another approach was described: selection based on a prescription for all drugs for obstructive lung disease (ATC-Code: R03) instead of only prescriptions for selective beta-2 agonists or inhaled corticosteroids. Although this latter selection approach may have been a typing error, we also included this criterion since it is often used in studies based on prescription data [e.g., 13, 14]. Both criteria (ATC-Codes: R03AC or R03BA and R03) were applied using at least one versus at least two prescriptions. In agreement with Zuidgeest et al. [15], medications prescribed on the same day were considered to represent one prescription.

### Further analysis

We compared 12-month asthma prevalence (current asthma) based on the KiGGS survey and on GEK claims data using the definition of Stock et al. [4]. We also included the definition of Stock et al. [12] using all drugs with ATC-Code R03. Both criteria were applied with at least one and at least two prescriptions, respectively. Details on the methods used are summarized in Table 1. To take into account different age distributions, we standardized data of the GEK according to the age distribution of KiGGS. Analyses are presented descriptively. No confidence intervals or statistical testing were applied.

All statistical analyses were performed with SAS for Windows ver. 9.2 (SAS Institute, Cary, NC).

**Table 1** Comparison of different methods used

Identification	Year	Claims data on medications <sup>a</sup>	Number of prescriptions	Claims data on hospitalizations	Physician-diagnosed asthma (CAPI)
Stock et al. (2005) [4]	1999	ATC-Codes: R03AC, R03BA <sup>b</sup>	At least 1	Inclusion of asthma (ICD-9: 493), exclusion of COPD (ICD-9 not stated by authors)	-
Definition of Stock et al. (2005) [4]	2005	ATC-Codes: R03AC, R03BA	At least 1	Inclusion of asthma (ICD-10: J45), exclusion of COPD (ICD-10: J44)	-
Definition of Stock et al. (2005) [4] with at least 2 prescriptions	2005	ATC-Codes: R03AC, R03BA	At least 2	Inclusion of asthma (ICD-10: J45), exclusion of COPD (ICD-10: J44)	-
Definition of Stock et al. (2008) [12] including all R03	2005	ATC-Codes: R03	At least 1	Inclusion of asthma (ICD-10: J45), exclusion of COPD (ICD-10: J44)	-
Definition of Stock et al. (2008) [12] including all R03 with at least two prescriptions	2005	ATC-Codes: R03	At least 2	Inclusion of asthma (ICD-10: J45), exclusion of COPD (ICD-10: J44)	-
KiGGS	05/2003–05/2006	-	-	-	Assessed by asking parents

ATC, Anatomical Therapeutic Chemical Classification System; COPD, chronic obstructive pulmonary disease; CAPI, computer-assisted personal interview; KiGGS, German Health Interview and Examination Survey for Children and Adolescents

<sup>a</sup> R03AC, Inhaled selective beta-2 agonists; R03BA, inhaled corticosteroids; R03, all drugs for obstructive lung disease

<sup>b</sup> Selection via all drugs with ATC code R03 was described in another paper [12]

## Results

A total of 22,305 children aged 0–17 years insured with the GEK had at least one prescription of inhaled selective beta-2 agonist or inhaled corticosteroid in 2005. Interestingly, 57.2% received these medications on only one occasion within this year. A further 129 persons without prescriptions were hospitalized due to asthma, and a total of 93 were excluded from inclusion in the analysis due to a hospital diagnosis of COPD. This resulted in a study population of 22,341 according to the definition of Stock et al. [4].

In Fig. 1 this prevalence is illustrated according to sex and age. The highest peak, 17.7%, was found for male infants aged 1 year. In comparison, the highest prevalence peak in girls, 11.1%, occurred in young girls aged 4 years. In infants and preschool children aged 0–4 years, prevalences were observed to range between 11.7 and 17.7% for boys and between 7.2 and 11.1% for girls. A steady decline occurred with age in children of both sexes aged >4 years.

The 12-month asthma prevalence estimated using the KiGGS data shows a quite different distribution from that based the definition of Stock et al. [4] using data of the GEK, as illustrated in Fig. 1. In the former, prevalences are slightly increasing with age in both sexes. However, the difference is particularly striking for children aged 0–4 years, for whom prevalences based on the KiGGS data are much lower (boys, 0–2.6%, girls, 0–1.0%) than those based the definition of Stock et al. [4].

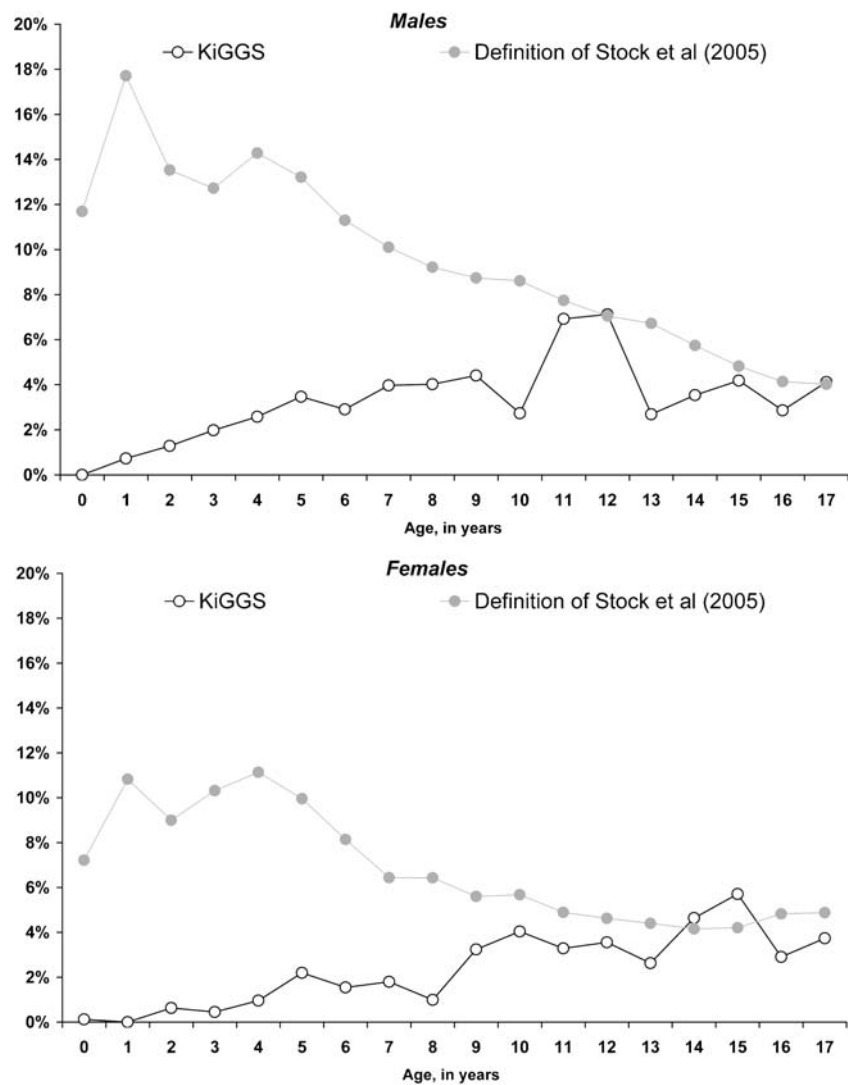
Figure 2 shows the results of using the different identification criteria. Overall, the prevalences estimated

by the definition of Stock et al. [4] are about 2.7-fold higher than those using the KiGGS data (boys, 9.1 vs. 3.4%; girls, 6.6 vs. 2.5%, respectively). When all drugs coded by ATC as R03 were used as the selection criterium, these differences became even more accentuated. Again, over half of these children received only one prescription (54.6%). The selection of children with at least two prescriptions for R03 drugs instead of at least one was found to lead to a much lower prevalence (boys, 8.1 vs. 16.8%; girls 5.5 vs. 13.2%, respectively).

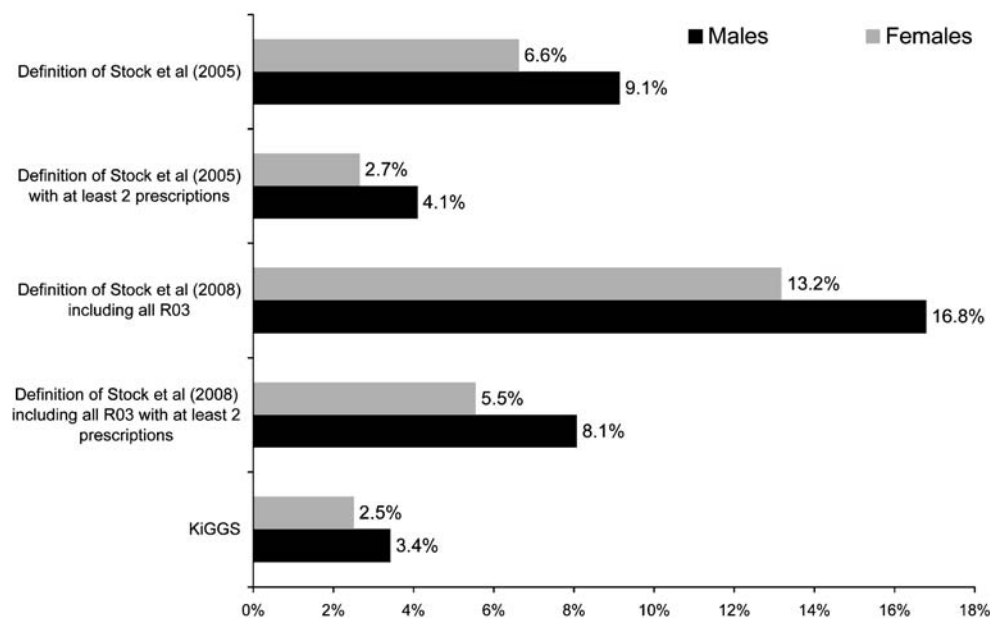
## Discussion

In this study we compared the 12-month prevalence of asthma in German children aged 0–17 years based upon a nation-wide survey with that based upon the approach of Stock et al. [4] using claims data. This comparison revealed large differences in age-specific prevalences, especially in infants and preschool children. Based on the survey data, the asthma prevalence increased with age, with very few children (up to 2.6%) aged 0–4 years having asthma. In contrast, asthma prevalence based on the definition of Stock et al. [4] had much higher peaks in children <5 years (up to 17.7%), with declining prevalences thereafter. The additional use of hospital diagnoses did not alter these latter results as >99% of the included children had already been identified via prescriptions. The trends obtained by Stock et al. [4] with respect to age are very similar to those of other studies using prescriptions as a proxy for asthma [13, 15–

**Fig. 1** Comparison of 12-month asthma prevalence in children using data from the German Health Interview and Examination Survey for Children and Adolescents (*KiGGS*) with that based on the definition of Stock et al. [4] using data of the Gmünder ErsatzKasse (GEK). *Top* males, *bottom* females



**Fig. 2** Comparison of different definitions of asthma in children aged 0–17 years. All other data are standardized to the age distribution of KiGGS



17]. However, field studies measuring asthma or wheezing symptoms in children <5 years of age are very scarce [18]. Studies using diagnoses in claims data or electronic medical records reported much lower prevalences in infants and preschool children [5, 7].

Prescriptions serve as a valid proxy for a disease if every subject with this condition is treated (the indicator is sensitive) and the drug(s) used are not given for any other disease (the indicator is specific) in a defined population. In the case of asthma medications in children, both of these assumptions may not be fulfilled. For example, in agreement with the medical view that asthma is a chronic disease with asymptomatic phases, several studies found that a considerable proportion of asthmatic children did not use anti-asthmatic drugs [6, 7, 15, 19]. For the Medical Expenditure Panel Survey (MEPS), information on 6789 children 0–17 years of age was obtained from family members using CAPI interviews [6]. If possible, pharmacy records were extracted and linked. A definition of asthma was included when the child was bothered by asthma and/or this condition was the reason for a bed day, a school absence, a prescription, or a health care visit during the entire calendar year 1996. Among children with reported asthma, over one third (37.2%) received no asthma medication (including inhaled short-acting beta-2 agonists and inhaled corticosteroids) within this year. These results are consistent with those from surveys conducted in the German cities of Munich and Dresden within the framework of the International Study of Asthma and Allergies in Childhood (ISAAC) [19], which found that, overall, 30.4% of children aged 5–7 and 9–11 years with current asthma had no prescription of anti-asthmatic drugs in the previous 12 months (ATC-Codes: R03, R06, H02).

It must also be considered that these drugs are prescribed for indications other than asthma. This assumption is supported by recently published data of the second Dutch National Survey of General Practice (DNSGP-2). This study analyzed the electronic medical records of 74,580 children aged 0–17 years registered at 95 general practices for 12 months [15]. A total of 7.5% of the study population received asthma medication (including inhaled short-acting beta-2 agonists and inhaled corticosteroids). Similar to our results, the prevalence of receiving prescriptions for asthma medications declined continuously with age—from 11.7% in 0- to 2-year olds to 5.1% in children aged 15–17 years. Only 49% of the 5605 children with prescriptions had a diagnosis of asthma, with other registered diseases being acute upper respiratory tract infection and acute bronchitis/bronchiolitis. The same results were obtained by Joesch et al. when analyzing the MEPS data [6]: about half of the children (52.7%) with asthma medications actually had asthma, and for a total of 85.3%, asthma or plausible alternative medical conditions were reported. These findings

clearly show a discrepancy between asthma medications and asthma diagnosis in children. Such discrepancies may be found more often in infants and preschool children, as shown by Joesch et al. [6] since other respiratory conditions associated with wheezing are very prevalent in this age group. Furthermore, a diagnosis of asthma cannot be made with certainty before an age of 5–6 years [1, 2, 17, 20]. This seems to be supported by the facts that our age-specific distributions (Fig. 1) tend to come closer in children aged  $\geq 10$  years. When the estimates of Stock et al. [4] in adults are examined, the prevalences can be seen to be comparable to the results obtained from the German National Telephone Survey 2003 (GNT-HIS) [21] up to an age of about 60 years. This nationally representative cross-sectional study analyzed lifetime prevalence of physician-diagnosed asthma in a sample of 8318 German adults aged  $\geq 18$  years. However, in individuals aged  $\geq 60$  years, the GNT-HIS found asthma prevalence to be in the range of 4–6%, whereas Stock et al. [4] found that it increased up to 10% in women and 15% in men. Since asthma medications are also recommended for the treatment of COPD and given that the prevalence of COPD increases with age [22], older patients with COPD may be misclassified as asthmatics when asthma medications are used for identification purposes. However, also for younger persons aged 18–49 years, a Dutch study based on the computerized patient records of general practitioners found that 29% of the patients with prescriptions for inhaled short-acting bronchodilators and 21% with prescriptions for inhaled corticosteroids actually had indications other than asthma [14]. Thus, different populations may be identified by these methods even if prevalences are comparable. Based upon these findings, we conclude that asthma medications are not a good proxy for the disease, especially in older patients and children. As a general principle, this conclusion underlines the need for validation studies when identification algorithms or medications are used as a proxy for a disease. This is most important when analyzing claims data which are collected for administrative rather than for research purposes.

In addition to problems associated with the use of prescriptions as a proxy for asthma, there is a continuing debate, especially within the framework of pediatric medicine, on how to define asthma in field studies. The diagnosis of asthma is a clinical one, and a gold standard is lacking. In children, it is based on recognizing specific patterns of episodic symptoms in the absence of alternative explanations [20]. Many surveys, therefore, use questions on wheezing as the most important asthma symptom or physician-diagnosed asthma [18, 23]. Wheezing is common in children [18], but the younger the child, the greater the likelihood that an alternative diagnosis may explain recurrent wheeze [2]. In an English survey on 24,952 people aged  $\geq 11$  years, only 40% of those with wheezing in



the preceding year had ever received a physician's diagnosis of asthma [24]. There is growing evidence that the meaning of the word "wheeze" varies between subjects [18, 25]. On the other hand, reports on physician-diagnosed asthma, as used in the KiGGS survey, require the availability of healthcare services, resulting in lower prevalences when compared to questions regarding wheezing. As noted, a diagnosis of asthma cannot be made with certainty before the child has reached an age of 5–6 years and may therefore not be communicated as asthma in a survey [2, 17]. In the KiGGS survey, asthma was measured by asking parents about physician diagnoses. Although the parents and children responded similarly to questions assessing asthma prevalence in 10- to 11-year-old preadolescents [26], this may not be the case in older children. Parental reports rely on the somewhat unrealistic assumption that the provider-parent communication is sufficient, and a diagnosis of asthma is always communicated. It is, however, of great importance to use just one method for measuring asthma in a study since different definitions will identify different populations. Most of the evidence on prevalence of wheezing or asthma in Germany comes from the ISAAC studies, and these surveys only obtained data on children aged 6–7 years and 13–14 years [18]. However, for a comprehensive overview, knowledge on all age groups is needed.

The main strength of this study was that we were able to use two large datasets. With 17,641 children aged 0–17 years participating in the KiGGS survey and data on 290,919 boys and girls in the GEK database, we had sufficient sample sizes to compare sex- and age-specific distributions between both samples. Using the definition of Stock et al. [4], we found similar trends to those reported in their study. However, our peaks for 2005 are much lower (boys, 18%, girls, 11%) than those observed by Stock et al. [4] for 1999 (boys, 25%, girls, 17%). These different findings may be explained by changing prescription patterns. Since 1999, combinations (ATC: R03AK) have been approved in Germany, and these drugs are increasingly being prescribed for children. Limitations of the KiGGS methodology for measuring asthma have been discussed above.

In conclusion, the determination of asthma prevalence via prescriptions of asthma medications reveals quite different distributions compared to that based on questionnaire surveys in children. Peaks observed in infants may well be explained by respiratory diseases other than asthma or by diagnostic uncertainty. Several studies show, however, that about one third of children with current asthma had no prescriptions. Finally, we agree with Himmel et al. [27] that, in theory, asthma medications may serve as markers or surrogate for the diagnosis but that the reality is much more complex.

**Acknowledgments** This study was not supported by any institution. We thank the Gmünder ErsatzKasse (GEK) for providing the data.

**Conflict of interests** FH and GG received funding to analyze the data of several health insurance companies, including those of the GEK.

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