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Assessing Paediatric Asthma Occurrence through Dispensed Prescription Data and Questionnaires

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Background: The prevalence of asthma, a common disorder in childhood, is often estimated by cross-sectional studies based on questionnaires, with the drawback that estimates are limited to certain age groups and areas. The use of electronic health data is increasingly allowing researchers to overcome these limitations. This study is aimed at assessing asthma occurrence of a school-aged population in Northeast Italy using two different data sources. **Methods:** In 2004, a population-based survey using a standardized questionnaire was conducted to estimate asthma occurrence among a resident population of children aged 6–7 years and adolescents aged 13 years. A selection of dispensed asthma medications was extracted from electronic databases for a 4-year period prior to questionnaire completion (2000–03). Asthma prevalence was estimated by commonly used questionnaire classifications and compared with use of inhaled bronchodilators (alone or in combination) in various time periods. Correlations between the two approaches were calculated. **Results:** A total of 10 252 subjects were eligible for analysis (85% of the resident population). A total of 4747 subjects (38% of the resident population) were registered in the drug database during 2000–03. Asthma prevalence was higher in males and in children. Congruence between the two enquiry methods varied according to criteria applied and improved with the protraction of the observation period. **Conclusion:** A longer period for the capture of medication data yielded higher congruence. A degree of mismatch was observed between the two methods most likely related to factors of drug use and questionnaire reliability. Nonetheless, the benefits of using easily accessible population data prevail, and further studies are warranted.

Introduction

Asthma is a common chronic condition in childhood and an enormous burden for families and society. Its assessment is complex due to several existing phenotypes and age-related disease manifestations.[1,2] Several studies aimed at estimating the prevalence and determinants of asthma have been undertaken.[3–5] In the absence of a gold standard for the assessment of asthma in epidemiological studies,[6] screening questionnaires are frequently used to measure asthma prevalence.[5] Even though these studies have used standardized enquiry procedures on representative population samples, they are primarily cross-sectional, covering determined areas and age groups, and are prone to selection and recall bias. On the other hand, the association of asthma with environmental risk factors, such as air pollution, has been mainly investigated by mortality and morbidity data (hospital admission, emergency room).[7,8]

Asthma medications are some of the most frequently prescribed drugs in childhood.[9] Given the availability of computerized databases, these now offer an inexpensive and easily accessible research tool. Electronic drug databases are increasingly suggested for research and have been applied to assess prescription practises and to measure asthma prevalence in Italy[9–12] and elsewhere.[13–18] The use of drug data is thus an efficient means of identifying asthma, a chronic condition, which can require frequent pharmacological treatment. Drug data have recently been linked to environmental hazards, such as air pollution, of both antropic[19–22] and natural orgin.[23]

Pharmaceutical data do not normally include diagnosis; therefore, disease status needs to be inferred from the number and type of prescribed or dispensed drugs. Different algorithms have been applied to identify asthma.[9–18] Hospital discharge and emergency room data do not effectively depict asthma occurrence as only in cases of severe asthma exacerbation episodes was hospitalization sought. In the period and area of the study, there were no electronic databases of general practitioner records. Thus, the only way was to reference dispensed drug databases with an asthma questionnaire.

The main objective of this study is to investigate the association between drug consumption data with estimates from a questionnaire survey as a possible method of measuring asthma prevalence in a school population.

The results are expected to inform whether asthma-related drug consumption might be used to implement a surveillance system to investigate trends in asthma exacerbation associated to environmental hazards. Our study is intended as a first step towards validating drug consumption data as a marker in monitoring asthma.

In Italy, dispensed prescriptions are routinely recorded and might well reflect the need for pharmacological aid in response to environmental pressure.

Methods

The study comprised the provinces of Rovigo and Ferrara, located in the Po Valley (Northeast Italy) with approximately 595 395 residents. The Italian Ministry of the Environment identified 15 areas throughout the country as being at 'high risk from environmental crisis'; among them in 1996 the provinces of Rovigo and Ferrara were included. The local environments in question are characterized by several pressure factors, including heavy industry and road traffic. The district comprises the urbanized areas of the two provincial capitals, one with an industrial site featuring a large thermal power plant and a rural area mainly in the south-east.[24]

This area was not included in Italian Studies on Respiratory Disorders in Children and the Environment (SIDRIA),[3] the Italian equivalent of the International Study of Asthma and Allergies in Childhood (ISAAC).[5] In

compliance with ISAAC/SIDRIA criteria, the entire population aged 6–7 (8215) and 13 years (4321) was studied.[3–5]

Italy operates a national health-care programme, and all citizens enjoy free access to a family doctor or paediatrician. Thus, individuals could be traced by public health-service databases. Since the mid-1990s, administrative databases have been available in the study area, collecting dispensed prescriptions of reimbursable drugs.[25]

Questionnaire

In February 2004, the parents of children attending the first two grades of primary school (aged 6–7 years) and the third year of middle school (aged 13 years) were asked to complete a standardized questionnaire by responding to questions on respiratory and allergic diseases, familiarity with these diseases and lifestyle factors. Before the questionnaire was conducted, headmasters, teachers, paediatricians and family physicians were duly informed about the study. Parents were informed by letter.

Cases of asthma were identified by questionnaire items according to the following criteria:[3–5]

(i) Lifetime asthma: doctor-diagnosed asthma and
(ii) Current asthma: wheezing symptoms in past year (shortness of breath with wheezing, nocturnal dry cough, speech-limiting breath) and reporting of lifetime asthma.

Dispensed prescription

To identify asthmatic subjects, therapeutic groups were used to 'label' children as asthmatic.[16] According to the Anatomic Therapeutic Chemical classification (ATC),[26] selective β-2-adrenergic agonists (ATC: R03AC) and adrenergics in fixed combination (ATC: R03AK) were chosen, as they represent asthma-specific drugs commonly prescribed for the selected age groups.[13,16] These drug categories comprise long-acting β-agonists (LABAs), controller medication for regular therapy of severe asthma and short-acting β-agonists (SABAs), quick relief drugs for acute attack control.[1] Although the R03 classification comprises drugs for asthma treatment, their use is not restricted to asthma and may overlap with other respiratory disorders.[10]

It must be underlined that inhaled corticosteroids (ICS), recommended by international guidelines as first-line daily controller therapy for children,[1] were not included. The use of ICS was suggested as inappropriate in studying the paediatric population, due to the widespread overuse of ICS for non-asthmatic conditions in Italy.[27] In this study, we aimed at evaluating the management of asthma attacks, in which the conventionally prescribed drugs are β2-agonists, while ICS are the most commonly prescribed type of long-term asthma medication.[28]

Throughout the study period, the selected therapeutic groups were traceable by prescriptions and reimbursed within the public health-care service.[29]

To relate questionnaire-reported symptoms to prescription patterns, the selected drug categories were extracted for a period preceding questionnaire completion (in 2004). Overall, 4 years of dispensed prescriptions were extracted for the same age groups of the survey study, i.e. subjects born in 1990 (aged 13 years) and 1996–97 (aged 6–7 years). Medication use was classified for three different time periods. First, dispensed medication in a single year was considered, i.e. drugs dispensed in 2003, the year prior to questionnaire completion, reflecting the reported current symptoms. Furthermore, two other observation periods were created: a 2-year (2002–03) and a 4-year period (2000–03) to allow for intermediate medication use, as in the case of mild asthma with low refill frequency.

To discriminate between asthmatics and non-asthmatics, subjects of any of the three observation periods were identified as asthmatic according to a quantitative threshold defined as having filled more than one prescription during the specific time period. We assumed that occurrence of current medication reflects the prevalence of questionnaire-reported current asthma, whereas the broader observation window of 4 years would better approximate lifetime asthma.

Analysis

Questionnaire-based asthma prevalence was calculated as the proportion of children identified as asthmatics in relation to the eligible subjects. The prevalence of asthmatics determined by dispensed medication was correlated with the resident child population ($n = 12\,536$).

The response rate to the questionnaire was calculated in relation to the school population (12 073), which is slightly lower than the resident child population, given that some students attend schools outside the province. Records of the questionnaire and medicine consumption database were merged by demographic variables. To assess the accuracy of the medicine-based estimate in relation to the questionnaire-based one, sensitivity, specificity and the corresponding 95% confidence intervals (95% CIs) were calculated.[30] We also calculated positive agreement, a useful measure in cases where crosstables reveal a marked imbalance (i.e. with a large number of true negatives).[31]

Results

A total of 11 063 questionnaires were completed (among the school population of 12 073), corresponding to a response rate of 92%. In all, 811 questionnaires were excluded mainly due to non-accordance with the age criterion, and 1% due to residence outside the study area, which resulted in 10 252 eligible subjects (response rate of 85%).

The resident population in the study area was assumed as being stable during the 4-year study period, as 86.5% of the eligible subjects declared that they had been living in their place of residence since 2000 (start of the study) or before, and 6.5% did not reply to this question. The remaining respondents (7%) changed their place of residence during the study period; however, it is not known if they moved from outside the local health authority catchment area.

During the 4-year study period, 4747 subjects (38% of the resident child population) had at least one prescription for anti-asthmatics. Among them, 84% (3074) of the subjects with anti-asthmatic prescriptions also filled in the questionnaire. The excluded subjects did not differ significantly from the included ones (data not shown). Overall, the majority of subjects received SABA only or in combination with other drug categories. Approximately, 10% were registered for more than one therapeutic group.

Figure 1 outlines the study design and population characteristics. No male/female and age differences were observed for those who filled in the questionnaire, whereas prescription data indicate more male and on average younger medication users (figure 1 and supplementary table S1). Distribution figures for both questionnaires and prescriptions were similar in the provinces of Rovigo and Ferrara; thus, the analyses are pooled. Table 1 illustrates questionnaire-reported asthma features stratified by age and gender. The results were similar across the age groups, even though lifetime asthma is higher in 13-year olds, and current wheezing is higher in the younger subjects. Overall, parents reported 583 cases with doctor-diagnosed asthma and 317 with current asthma (symptoms and diagnosis), which corresponds to a prevalence of 5.7 and 3.1, respectively. Questionnaire responses reveal that the majority of asthma cases affected boys.

Table 2 illustrates the distribution of prescription patterns throughout the three observation periods. The overall prevalence of medication use varied from 9.5% to 10.5% according to the time window applied. The number of prescriptions is markedly higher in subjects attending primary school (6–7 years), with prevalence up to twice that of 13-year-old subjects. To differentiate between asthmatic and non-asthmatic subjects, asthma status was classified according to the quantitative threshold of more than one prescription in any of the observation periods. The overall questionnaire-based prevalence of current asthma was 3.1 and thus lower than the frequency of >1 prescription in one year (2.7), and higher regarding the 2-year (3.7) and 4-year (4.4) observation period (tables 1 and 2).

Congruence between questionnaire-reported asthma and that based on dispensed prescriptions is given in table 3. Results are only stratified by age groups, as gender stratification does not improve congruence. As expected, specificity was always higher than sensitivity, due to

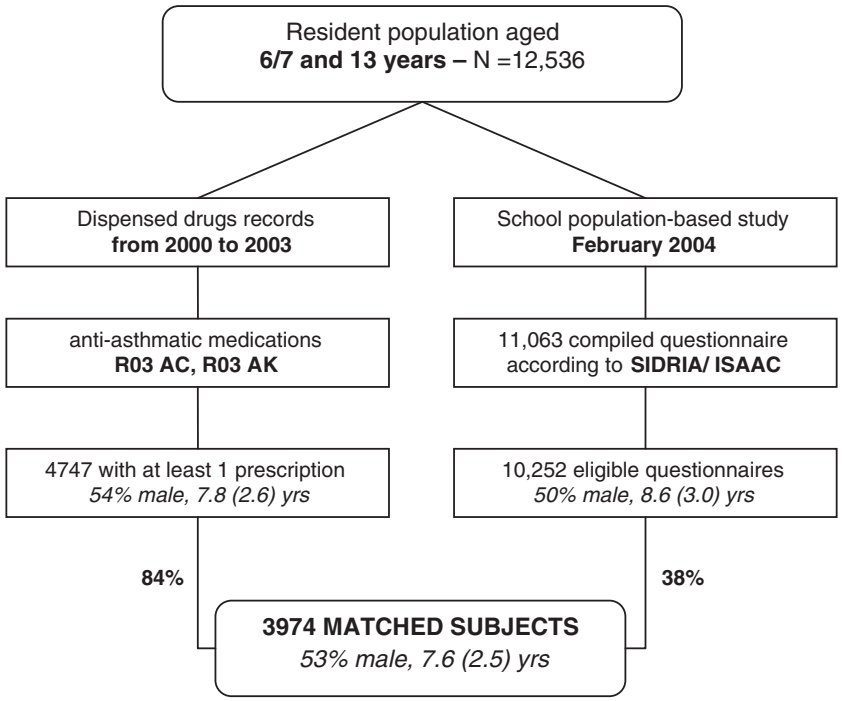

Figure 1 Flow chart of study design and population characteristics: gender and mean age (SD) in years

Table 1 Prevalence of asthma classifications derived from questionnaire per age-group

Asthma features by questionnaire	All ($n = 10\ 252$)		13 years ($n = 3232$)		6–7 years ($n = 7014$)	
	N	Prevalence[a] (95% CI)	*N*	Prevalence[a] (95% CI)	*N*	Prevalence[a] (95% CI)
Lifetime asthma all	583	5.7 (5.3–6.1)	230	7.1 (6.2–8.0)	353	5.0 (4.5–5.5)
Lifetime asthma—boys[b]	361	7.0 (6.3–7.7)	133	8.6 (7.2–10.0)	228	6.3 (5.5–7.1)
Lifetime asthma—girls[c]	222	4.4 (3.8–4.9)	97	3.0 (2.2–3.8)	125	3.7 (3.0–4.3)
Current asthma	317	3.1 (2.8–3.4)	101	3.1 (2.5–3.7)	216	3.1 (2.7–3.5)
Current asthma—boys[b]	199	3.9 (3.4–4.4)	59	3.8 (2.8–4.8)	140	3.9 (3.2–4.5)
Current asthma—girls[c]	118	2.3 (1.9–2.7)	42	1.3 (0.8–1.8)	76	2.2 (1.7–2.7)
Current wheezing	729	7.1 (6.6–7.6)	192	5.9 (5.1–6.7)	537	7.7 (7.1–8.1)
Current wheezing—boys[b]	432	8.4 (7.6–9.2)	107	6.9 (5.6–8.2)	325	9.0 (8.1–9.9)
Current wheezing—girls[c]	297	5.8 (5.2–6.5)	85	2.6 (1.9–3.4)	212	6.2 (5.4–7.0)
Regular respiratory drug use (questionnaire)	175	1.7 (1.4–2.0)	53	1.6 (1.2–2.0)	122	1.7 (1.4–2.0)
Regular drug use—boys[b]	106	2.1 (1.7–2.5)	35	2.3 (1.6–3.0)	71	2.0 (1.5–2.4)
Regular drug use—girls[c]	69	1.4 (1.0–1.7)	18	0.6 (0.2–0.9)	51	1.5 (1.1–1.9)
Doctor visit for asthma (last 12 months)	369	3.6 (3.2–4.0)	121	3.7 (3.1–4.4)	248	3.5 (3.1–3.9)
Doctor visit—boys[b]	244	4.7 (4.1–5.3)	72	4.6 (3.6–4.6)	172	4.8 (4.1–5.5)
Doctor visit—girls[c]	125	2.5 (2.0–2.9)	49	1.5 (0.9–2.1)	76	2.2 (1.7–2.7)

a: Proportion of children identified as asthmatics in relation to the eligible subjects
b: Male population: $n = 5165$ (13 years = 1552; 6–7 years = 3613)
c: Female population: $n = 5081$ (13 years = 1680; 6–7 years = 3401)

the restricted drug selection. However, as the observation period extended, sensitivity went up from 32% to 70%, indicating the ability of this method in identifying asthma cases. In contrast, specificity decreased only slightly from 98% to 83%, with a constantly low number of false positives. The best compromise between sensitivity and specificity was found for the 4-year period, especially when considering questionnaire-reported current asthma (overall and by age groups). Positive agreement did not improve its performance and remained low; it was highest when estimating lifetime asthma, particularly for teenagers (44%).

Discussion

Record linkage is increasingly used to correlate patient and disease data in health research. Such data sources have the advantage of being easily accessible, cost-effective and not subject to recall bias. In Italy, annual drug prescription analysis is a useful tool used in epidemiology for identifying consumption patterns; it clearly illustrates that respiratory drugs (R03) are one of the most prescribed in childhood for asthma-related symptoms.[29]

Our study explores the performance of medication data for asthma identification in a paediatric population. The obtained results indicate that prevalence of current asthma appeared equal (i.e. 3.1) across the age groups. It was lower overall compared with the results of the SIDRIA-II study, which, unlike our findings, reported higher prevalence for adolescents (4.5) than for children (4.1).[32] Migliore *et al.*[33] applied the SIDRIA protocol in an urban area and reported a current asthma prevalence of 5.3.

Medication use was more frequent in male subjects and the younger age groups, which is in accordance with the current literature.[10,17] Vegni *et al.*[9] estimated asthma prevalence by drug use in an Italian paediatric population by different algorithms, varying from 26.6 for all

Table 2 Prevalence of dispensed prescriptions in the three observation periods per age group

Prescription patterns	1-year observation		2-year observation		4-year observation	
	N	Prevalence[a] (95% CI)	*N*	Prevalence[a] (95% CI)	*N*	Prevalence[a] (95% CI)
All						
Any prescription	1381	11.0 (10.5–11.6)	2712	10.8 (10.3–11.4)	4747	9.5 (9.0–10.0)
1 prescription	1042	8.3 (7.8–8.8)	1781	7.1 (6.7–7.6)	2540	5.1 (4.7–5.5)
>1 prescription	339	2.7 (2.4–3.0)	931	3.7 (3.4–4.0)	2207	4.4 (4.0–4.8)
13 years						
Any prescription	313	7.2 (6.5–8.0)	553	6.4 (5.7–7.1)	937	5.4 (4.7–6.1)
1 prescription	230	5.3 (4.7–6.0)	362	4.2 (3.6–4.8)	556	3.2 (2.7–3.7)
>1 prescription	83	1.9 (1.5–2.3)	191	2.2 (1.8–2.6)	381	2.2 (1.8–2.6)
6–7 years						
Any prescription	1068	13.0 (12.3–13.7)	2159	13.1 (12.4–13.9)	3810	11.6 (10.9–12.3)
1 prescription	812	9.9 (9.2–10.5)	1419	8.6 (8.0–9.2)	1984	6.0 (5.5–6.6)
>1 prescription	256	3.1 (2.7–3.5)	740	4.5 (4.1–5.0)	1826	5.6 (5.1–6.1)

a: Population denominator: $n = 12\,536$ (13 years: 4321; 6–7 years: 8215)

Table 3 Congruence between asthma estimated by questionnaire and by anti-asthmatic prescriptions (>1 prescription) in the three observation periods by age group

Congruence indicators by prescription period	Current asthma by questionnaire[a]		
	All ($n = 10\,252$)	13 years ($n = 3232$)	6–7 years ($n = 7014$)
Prescriptions in 1 year			
Sensitivity (95% CI)	32 (31–33)	28 (26–29)	34 (32–35)
Specificity (95% CI)	98 (98–98)	99 (98–99)	98 (97–98)
Positive agreement (95% CI)	33 (32–34)	34 (32–36)	33 (32–34)
Prescriptions in 2 years			
Sensitivity (95% CI)	56 (54–56)	44 (42–45)	61 (60–62)
Specificity (95% CI)	94 (93–94)	97 (96–97)	92 (92–93)
Positive agreement (95% CI)	32 (31–33)	36 (34–38)	31 (29–32)
Prescriptions in 4 years			
Sensitivity (95% CI)	70 (69–71)	57 (56–59)	76 (75–77)
Specificity (95% CI)	83 (83–84)	93 (92–94)	79 (78–80)
Positive agreement (95% CI)	20 (19–21)	30 (29–32)	18 (17–19)
Prescriptions in 4 years		Lifetime asthma	
Sensitivity (95% CI)	61 (60–62)	50 (48–51)	68 (67–69)
Specificity (95% CI)	84 (84–85)	94 (94–95)	80 (79–81)
Positive agreement (95% CI)	29 (28–30)	44 (43–46)	25 (24–26)

a: If not otherwise stated

anti-asthmatic drugs to 8.2 for specific drug categories and 2.6 for frequent users. A Norwegian study on subjects aged 0–19 years reported a prevalence of 9.1 for all R03 prescriptions and 5.4 for specific anti-asthmatics.[17] However, comparison with other studies is difficult owing to different drug classifications and age groups.

A particular strength of our study is that it investigates a relatively long period in an apparently stable population, while many studies on prescribed/dispensed asthma medication restrict the observation time to 1 year.[10,16–18] We would have liked to include pharmacy data for 2004 (year of survey), but given that the data collection system changed in 2004, this was not possible. After questionnaire data had been correlated with dispensed prescriptions, the observed number of mismatches varied according to the classification criteria. Specificity was always high, varying from 83% to 98% according to the capture period, indicating that a high proportion of non-asthmatic subjects were identified by both data sources, and that our drug selection and case definition was specific for asthma. Only 32% of the asthmatics from the questionnaire were also defined as asthmatic by the drug data in the 1-year period. Performance improved in terms of sensitivity with the 4-year period, indicating that 70% of cases were correctly identified. Overall, the best performance emerged from the 4-year study period. The positive agreement provides its best performance in teenagers when the 4-year period is considered, where a clearer clinical picture emerges. However, the medication-based definitions require further consideration.

Our population includes a large number of 6- to 7-year-old children, and a longer observation period overlaps with the time they were at preschool. Diagnosing asthma in preschool children is difficult, as virus-induced wheezing episodes are frequent and often transient.[34] Therefore, we expected lower congruence between questionnaire and medication data in younger age groups over the 4-year period, but we found higher sensitivity compared with the 13-year-old group. Zuidgeest *et al.*[18] observed that congruence between asthma prescriptions and asthma diagnosis from medical records did not increase with age.

It was assumed that asthma medication refill reflects an underlying disease. To minimize the inclusion of non-asthmatic children, we decided to use certain anti-asthmatics. This selection might have been too restrictive, but likely identified the severe cases. However, short-acting bronchodilators are the relief medication of choice for all severity classes, both at the hospital and at home.[1]

Prescription databases in the area were regarded of high quality.[25] Moreover, given that dispensing chemists are reimbursed on the basis of medication records, the data may be considered complete. Asthma medications not recorded in the database, such as over-the-counter drugs (e.g. alternative remedies), were unlikely to have influenced our study.[35]

A further advantage is that our benchmark value was dispensed medication rather than medication prescription, this value being closer to actual use. The high response rate of 92% for the survey makes response bias unlikely. The risk of a selection bias is also limited, as an entire population was included. Furthermore, the population was stable over the 4-year observation, with at least 87% of subjects stating that they had lived during the study. However, for various reasons some subjects with drug prescriptions could not be linked to questionnaire data, some may not have filled in the questionnaire, others might have frequented schools outside the study area. The latter is thought to have negligible impact as <1% of the survey subjects lived outside the study region, while attending schools in the study area. In all events, subjects excluded from the survey did not differ from those included.

Another source of mismatch could be that questionnaire-based classifications might not have yielded reliable responses. Although most studies have used questionnaires to identify asthmatic subjects, this instrument is prone to subjective readings.[36] Underestimation of prevalence by questionnaire has been reported.[2,37] An Italian study highlighted substantial differences between clinical diagnosis and questionnaire definitions, the questionnaire definition "ever asthma" estimated best clinical diagnosis.[37] Our study resulted in better congruence with the current asthma definition rather than with lifetime ("ever") asthma.

Anti-asthmatic medications are often prescribed for non-asthma indications,[10,23] which results in false positives. This issue was highlighted by a Dutch study on paediatric asthma, which indicated that in 34% of frequent medication users, medical records did not reveal a diagnosis of asthma.[18]

It could be argued that the questionnaire's definition of asthma and drug prescription is closely linked in the same way as prescription behaviour reflects symptom awareness and health care use/access. Patient and family characteristics have been suggested as influencing prescription; in particular children of parents from higher socio-economic groups and with a history of asthma were more likely to receive medication.[38] Koster *et al.*[39] concluded that the main factor for drug prescription in infancy was the presence of symptoms.

However, Italy's health system guarantees free asthma medication. In all events, more objective investigations, such as spirometric readings, are not feasible for large-scale studies.

Indeed, and strikingly, an Italian study estimating asthma in a population aged 0–34 years reported that drug data alone identified >90% of cases, whereas hospital discharges indicated <4%.[12]

Conclusion

The 4-year period identified an asthmatic population with a sensitivity of 70% and specificity of 84%. We consider our definition a valid instrument in identifying asthmatic subjects, in particular in its use for epidemiological surveillance. This study investigated the reliability of medication data in the view of monitoring asthmatic attacks, which might be usefully cross-referred with environmental factors. The use of drug data as a marker in such circumstances has been suggested,[19–23] even though a recent review underlined the need for more ecological studies.[20] A surveillance system to track asthma occurrence and determinates would benefit from further health data.[19] The results obtained are promising and offer a platform for future proposals. However, additional studies are required to explore fully the potential offered by drug databases. We are convinced that such information is of vital significance in alerting authorities about the urgency of tackling asthma and determinants from natural and man-made sources. In Italy, there is a great interest in this issue and efforts in setting up surveillance systems related to environmental hazard are in progress. Experiences like this could play a lead role in creating the political will required to stimulate the much-needed investment in surveillance of environmental health hazards.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Conflicts of interest: None declared.

Key points

- As suggested in the literature, existing electronic health data, especially in countries with a national health system, offer inexpensive and practical access to population data, dealing with the shortcomings of questionnaires, such as recall and selection bias.
- Identification of asthmatic individuals through dispensed medication data is proposed.
- A longer observational period of dispensed medication data resulted in better congruence between the data sources.
- The study presents an experience suitable for wider implementation in epidemiological surveillance that targets acute responses to environmental pressures.

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