

Original article

The control of asthma in Italy. A multicentre descriptive study on young adults with doctor diagnosed current asthma

Background: Few data are available on the management of asthma in the general population. The aim of this study was to evaluate the level of asthma control in Italian patients, a decade after the publication of the international guidelines.

Materials and methods: Within the framework of a multicentre, population-based study on people aged 20–44 years, 18 873 subjects replied to a postal screening questionnaire (response rate = 72.7%) on the presence of asthma symptoms and exacerbations, and their impact on daily life. All subjects reporting having ever had a doctor diagnosis of asthma and either taking medicine for asthma when interviewed or having had an asthma attack in the last 12 months, were considered current asthmatics.

Results: Of the screened subjects, 649 (3.4%) were current asthmatics. Of these, only 14% did not report exacerbations or had been symptom-free in the last 12 months. More than 20% of current asthmatics had their daily life activities seriously impaired and 54 patients (8%) had at least one hospital/emergency department admission as a result of asthma exacerbation in the last 12 months. The life impairment and the rates of hospitalization significantly increased as the control of the symptoms worsened. The use of asthma drugs was quite common in current asthmatics: 586 (90.2%) reported having been under pharmacological treatment in the last 12 months. Only 63 patients (10%) had the disease under control (neither symptoms nor life impairment): they had a significantly higher percentage of drug use (100% *vs* 89%) and of daily use prescriptions (50% *vs* 36%) than non/moderately controlled asthmatics. Poorly controlled asthmatics had a significantly higher percentage of women (63% *vs* 44%), of patients with the coexistence of chronic cough and phlegm (47% *vs* 30%) than moderately/well-controlled asthmatics. The comparison between our data and similar data collected in 1991 in Italy showed that the use of asthma drugs increased by about 12%, while the control of symptoms did not improve in the last decade.

Conclusion: Despite the high percentage of drug users, the control of symptoms and exacerbations was overall poor in Italy and resulted in a heavy individual and social burden, pointing out that the guideline goals have far from been reached in Italy.

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Key words: asthma control; asthma treatment; clinical epidemiology; health care; life impairment.

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Asthma is a chronic illness that affects a substantial proportion of the population both in children and adults

(1, 2). The prevalence of asthma has increased in western countries and the economic cost of asthma is substantial, amounting to 12.7 billion dollars in the USA (3).

* See Appendix 2

Although asthma is a condition subject to exacerbation, it can be controlled with appropriate therapy. Many clinical trials have shown that good care and optimum drug treatment can convert asthma from a major handicap to a minor inconvenience (4, 5). During the early 1990s, the National Heart, Lung and Blood Institute and the World Health Organization set up a task force to develop a global strategy for asthma management and prevention, whose work was summarized in the international guidelines on asthma management and prevention Global Initiative for Asthma (GINA) (6). The GINA guidelines have been disseminated to improve the quality of life of asthmatics and to reduce the socio-economic burden of asthma. Among the goals of an adequate long-term management of the disease, GINA include: minimal chronic symptoms, minimal exacerbation, no emergency visits and no limitation of daily activities.

However, there is little data available on the effectiveness of the management of asthma in the general population.

The aim of this study was to evaluate the current level of asthma control in young Italian adult patients, a decade after the publication of the international guidelines. For this purpose the data from the Italian Study on Asthma in Young Adults (ISAYA), which encompass asthmatics with a wide spectrum of severity and a variety of disease management, were used.

Materials and methods

Study design

The ISAYA is a multicentre cross-sectional survey on the young adult general population, specifically aimed to assess: (i) the variations of asthma, asthma-like symptoms and chronic bronchitis prevalence, and (ii) the current management of asthmatics and the socio-economic costs of asthma in Italy.

The survey was carried out between 1998 and 2000 in nine Italian centres: six in Northern Italy (Ferrara, Pavia, Sassuolo, Turin, Udine, and Verona), one in Central Italy (Pisa) and two in Southern Italy (Sassari, on the Island of Sardinia, and Siracusa, on the Island of Sicily). Each centre selected an up-to-date sampling frame of the residents of the target area, from which a random sample of approximately 3000 people aged 20–44 years (men/women ratio = 1) was chosen, using the same design utilized in the European Community Respiratory Health Survey (ECRHS) – stage 1 (7, 8). A two-page screening questionnaire was sent by post to each subject up to three times in the case of nonresponse; the questionnaire was finally administered by phone to the remaining nonresponders.

Questionnaire

The questionnaire used has been published elsewhere and tested in an Italian pilot study (9). The first page contains validated questions on the presence of asthma and asthma-like symptoms, the frequency of asthma attacks, age at onset and remission of asthma, doctor diagnosis of asthma, the presence of chronic cough and phlegm, and smoking habits. The second page collects information related to the last 12 months about: indirect costs (number of working days lost and number of impaired general activity days resulting from asthma); type and frequency of doctor visits and

laboratory tests performed because of asthma; frequency of hospital admissions and emergency department (ED) visits resulting from asthma; treatment, type of prescription (when needed or for daily use) and reported compliance.

Data management and statistical analysis

This analysis is limited to the doctor diagnosed current asthmatics screened within the framework of the ISAYA. A subject was eligible for the study if he/she positively answered to the question on having ever had asthma confirmed by a doctor and a positive answer to either the question on currently taking medicine for asthma or having had an attack of asthma in the last 12 months.

For each patient a Current Symptom Severity Score was devised as a linear combination of five asthma-like symptoms (wheeze, wheeze with breathlessness, wheeze apart from cold, waking with tightness in the chest and waking with shortness of breath) and the number of asthma attacks (0; 1–3; 4–10; >10) reported in the last 12 months. As all the previous variables were categorical, the optimal linear combination was found using the first factor extracted throughout Multiple Correspondence Analysis (10) (see Appendix). Based on the distribution of the individual score on the first factor, the asthmatics were classified into four groups of increasing current severity, according to the quartiles.

The disease duration was computed as the time (in years) between the first asthma attack and the age at the interview. The reported compliance to treatment was defined as: good, if subjects reported taking all of the prescribed medicines; moderate/poor, if subjects reported taking some or none of the prescribed medicines (11).

Subjects were classified as: nonsmokers, if they had not smoked as long as a year at least one cigarette per day or one cigar a week; past smokers, if they had smoked for at least 1 year but not during the last month; current smokers, if they had smoked for at least 1 year and also during the last month. Allergic rhinitis (12) and chronic cough and phlegm were considered present if a subject answered affirmatively to the following questions: 'Do you have any nasal allergies including hay fever?' and 'Have you had cough and phlegm on most days for a minimum of 3 months a year and for at least two successive years?'

Current asthmatics were defined *well controlled* if they were in the first quartile of the Current Symptom Severity Score and if they neither had exacerbations, nor hospital/ED admissions, nor impaired life activities. On the contrary, they were defined *poorly controlled* if they were in the fourth quartile of the Current Symptom Severity Score and/or if they had visited an ED or were hospitalized and/or if they had lost at least one working day and/or if they had at least 1 day a month of heavy limitation to the daily activities in the last 12 months because of asthma. The remaining subjects were considered *moderately controlled* asthmatics.

Summary statistics are reported as mean values for continuous variables and percentages for categorical variables. Comparison of variables across strata were performed using the chi-square statistics for categorical variables and the Kruskal–Wallis test distribution for continuous variables (due to their skewed distributions).

The statistical analysis was performed using STATA software, release 7.0 (StataCorp., College Station, TX, USA).

Results

Out of 25 969 eligible subjects in nine centres, 18 873 (72.7%) filled in the questionnaire. The age–sex distribution of responders was similar to that of nonresponders.

Overall, 1397 (7.4%) subjects reported having ever had asthma confirmed by a doctor, 649 (3.4%) of these were current asthmatics. Of the current asthmatics, 37.3% developed asthma early in childhood (<10 years) while 33.9% in adulthood (Table 1). The average duration of the disease was at least 17.0 years. Women had a statistically significant later onset and a higher prevalence of chronic cough and phlegm than men. Asthma coex-

Table 1. Main characteristics of doctor diagnosed current asthmatics, according to sex

	Men (n = 313)	Women (n = 336)	Total	P-value
Mean age (years) (SD)	31.4 (7.1)	32.9 (7.1)	32.2 (7.1)	0.0064
Age at onset (years) (%)				0.0004
<10	44.6	30.6	37.3	
10–20	27.9	29.7	28.8	
≥20	27.5	39.7	33.9	
Mean asthma duration (years) (SD)	18.2 (10.4)	15.9 (10.6)	17.0 (10.6)	0.2772*
Allergic rhinitis (%)	71.2	69.9	70.5	0.7350
Chronic cough and phlegm (%)	28.0	38.7	33.5	0.0041
Smoking habits (%)				0.7879
Nonsmokers	49.8	52.6	51.3	
Past smokers	17.6	16.5	17.0	
Current smokers	32.6	30.9	31.7	

* P-value was obtained adjusting for the effect of age at onset.

Table 2. The control of asthma, according to sex

	Men (n = 313)	Women (n = 336)	Total	P-value
Number of asthma attacks in the last 12 months (%)				0.2670
0	14.1	11.3	12.7	
1–3*	56.9	62.4	59.7	
4–10	22.3	17.9	20.0	
>10	6.7	8.4	7.6	
Prevalence of asthma-like symptoms in the last 12 months (%)				
No symptoms	14.4	13.3	13.8	0.6791
Diurnal symptoms†	80.4	81.2	80.8	0.8098
Nocturnal symptoms‡	51.9	64.7	58.5	0.0010
At least one working day lost (%)	11.8	19.3	15.6	0.0150
Mean number of days lost§	14.0	14.5	14.3	0.8808
At least 1 day impaired (%)	14.9	24.8	20.0	0.0020
Mean number of days impaired per month§	4.4	5.5	5.1	0.1910
ED visits (%)	6.4	9.7	8.1	0.1272
Mean number of ED visits §	2.2	1.2	1.6	0.0349
Hospital admissions (%)	1.6	3.7	2.7	0.1087
Mean number of hospital admissions§	1.0	1.1	1.1	0.5896

ED: Emergency Department.

* Forty-two subjects reporting at least one asthma attack in the last year, without specifying the number, were allocated to the 1–3 asthma attack class.

† Diurnal: wheeze and/or wheeze with breathlessness and/or wheeze without cold.

‡ Nocturnal: waking with tightness in the chest and/or waking with shortness of breath.

§ Mean values refer to subjects who experienced at least one event.

isted with allergic rhinitis in 70.5% of patients. A high proportion of patients (31.7%) were current smokers.

The control of symptoms was generally poor (Table 2): less than 14% were symptom-free and/or did not have exacerbation in the last 12 months. Of the patients, 15.6% reported to have lost on average 14.3 days per year and 20% to have had on average 5.1 days per month impaired because of asthma; 8.1% visited an ED at least once and 2.7% had at least one hospitalization because of asthma. In general, women reported a poorer symptom control and a greater life impairment than men. The percentage of asthmatics with impaired daily life activities and/or admission to hospital/ED increased significantly when the control of symptoms was poorest (when the Current Symptom Severity Score increased) (Fig. 1). Subjects in the upper two quartiles of the Current Symptom Severity Score accounted for about 85% of total hospitalization/ED admissions (Fig. 2) and 60% of the total days with impaired daily life activities. According to our definition,

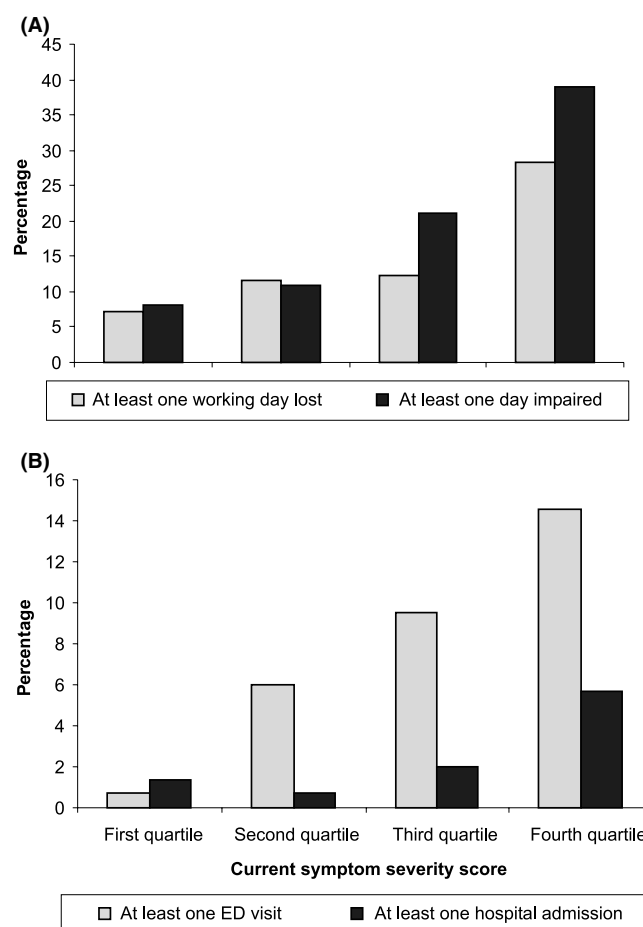


Figure 1. Percentage of doctor diagnosed current asthmatics with at least one working day lost, or 1 day with impaired daily life activities (A), and one ED visit and/or one hospital admission (B) because of asthma in the last 12 months, according to the Current Symptom Severity Score.

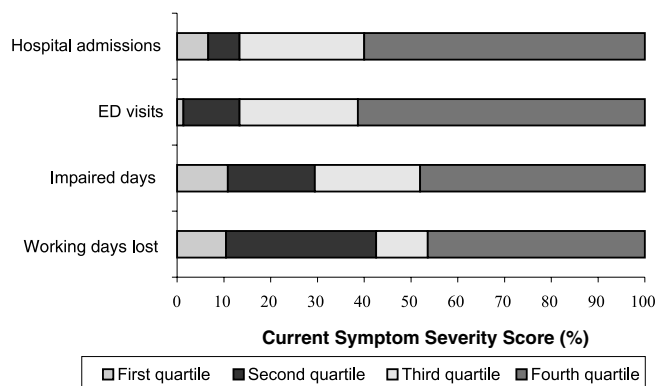


Figure 2. Distribution of Current Symptom Severity Score (in quartiles) for the total number of hospital admissions, ED visits, impaired days and working days lost.

10.3% of current asthmatics were well controlled, 48.4% moderately controlled and 41.3% poorly controlled. Poorly controlled asthmatics were mainly women (Table 3), had a later onset of asthma, a shorter duration of the disease and a higher prevalence of chronic cough and phlegm, than well-controlled asthmatics; however, well-controlled asthmatics had a higher prevalence of cough and phlegm than moderately controlled subjects. The use of asthma drugs was quite common in current asthmatics (90.2%) (Table 4). Well-controlled asthmatics had a better reported compliance and significantly more daily use prescription drugs than noncontrolled asthmatics, while they visited a doctor less frequently. Only 26.2% of asthmatics reported a lung function measurement in the last year.

The prevalence of symptoms and current treatment was compared in two random samples of asthmatics answering the same questions, administered with the same method, in 1991 (7) and in 2000, in three Italian centres

(Pavia, Turin and Verona) (Table 5). Despite a 12% increase in treatment, the control of symptoms did not improve, but even worsened in the last decade.

Discussion

The main aim of this paper was to assess the current level of asthma control, in order to evaluate the extent to which guideline goals have been reached in Italy. For this purpose, a large sample of young adult asthmatics, from the general population in different Italian areas, encompassing a wide spectrum of disease management, has been used.

Our analysis focused on those asthmatics who had been diagnosed by a doctor and hence were in a position to have optimal treatment. Among these, we selected the subjects who used asthma medication or who reported at least one asthma attack in the last year. In this group, the observed prevalence of symptoms/exacerbation and life impairment is a function of the effectiveness of asthma management: in theory, we could have observed a prevalence ranging from 0% (all asthmatics are treated and controlled) to 100% (all asthmatics are out of control, even if treated).

Most of the patients who met the eligibility criteria were chronic asthmatics (one third had developed asthma early in childhood), with a mean duration of the disease of at least 17 years. Therefore, they represent the most relevant and suitable target for the evaluation of whether the guideline goals have been reached in young adults, and only a few current asthmatics should have escaped our definition.

If the GINA goals are the reference to evaluate how asthma is controlled in a country, our results show that the control of asthma is poor in Italy: only about one of 10 patients did not report exacerbation or life impairment in the last 12 months.

Table 3. Distribution of sex, age, age at onset, duration of the disease, allergic rhinitis, chronic cough and phlegm and smoking habits according to asthma control

	Poorly controlled (n = 252)	Moderately controlled (n = 295)	Well controlled (n = 63)	P-value
Women (%)	60.3	45.1	41.3	0.0005
Age at onset (years) (%)				0.0112
<10	37.2	34.0	57.6	
10–20	28.4	30.6	25.4	
≥20	34.4	35.4	17.0	
Mean asthma duration (years)	16.7	16.5	22.1	<0.0001*
Allergic rhinitis (%)	66.9	73.2	73.0	0.2491
Chronic cough and phlegm (%)	46.6	20.6	33.9	<0.0001
Smoking habits (%)				0.4250
Nonsmokers	51.2	53.1	41.3	
Past smokers	18.8	15.3	20.6	
Current smokers	30.0	31.6	38.1	

* P-value was obtained adjusting for the effect of age at onset.

Table 4. Use of drugs, type of prescription, reported compliance, doctor visits and lung function tests performed in current asthmatics in the last 12 months, according to asthma control

	Poorly controlled (n = 252)	Moderately controlled (n = 295)	Well controlled (n = 63)	Total	P-value
Asthma drug users (%)	95.6	83.2	100.0	90.2	<0.0001
Type of prescription (among users) (%)					0.0040
Daily use	42.7	30.4	50.0	38.0	
When needed	57.3	69.6	50.0	62.0	
Reported compliance (%)					0.2144
Good	58.6	55.2	67.2	57.8	
Moderate/poor	41.4	44.8	32.8	42.2	
Seen by a doctor (%)	77.5	45.3	33.3	57.4	<0.0001
Only by a general practitioner	27.3	19.5	7.9	21.5	<0.0001
Specialist	50.2	25.8	25.4	35.9	
Mean number of doctor visits	5.3	2.4	2.3	4.1	<0.0001
Spirometry tests (%)	36.1	18.6	22.2	26.2	<0.0001

Table 5. Prevalence of current treatment for asthma (at the time of the interview), diurnal and nocturnal symptoms in random samples of asthmatics * answering a postal screening questionnaire. Variations from ECRHS (1991–1993, screening questionnaire) to ISAYA (2000) in three Italian centres in Northern Italy

	ECRHS – 1991 (n = 255)	ISAYA – 2000 (n = 301)	P-value
Current treatment (%)	48.0	59.7	0.0061
Diurnal symptoms † (%)	56.9	73.4	<0.0001
Nocturnal symptoms ‡ (%)	49.8	58.8	0.0224

ECRHS: European Community Respiratory Health Survey; ISAYA: Italian Study on Asthma in Young Adults.

* Asthmatics: having had at least one attack of asthma in the last year and/or being in treatment at the moment of the survey.

† Diurnal symptoms: wheeze and/or wheeze with breathlessness and/or wheeze without cold.

‡ Nocturnal symptoms: waking with tightness in the chest and/or waking with shortness of breath.

In agreement with previous findings, we found that the control of asthma is worse in women (13, 14) than in men. Poorly controlled asthma results in a heavy individual and social burden (13, 15–17): 20% of the subjects had their daily life activities impaired for 5.1 days on average each month, 15.6% lost on average 14.3 working days, 8% visited an ED and 2.7% spent at least one night in the hospital because of asthma in the last 12 months.

The evidence that the control of asthma is sub-optimal for many patients is not unique to Italy, as it has also been reported being a common feature of the management of asthmatics in Europe (18) and in the USA (19).

In agreement with other previous studies (20–22), our results suggest that the burden of the disease increased when the control of symptoms was poor. In fact, almost all hospitalizations/ED visits and about 60% of the total working days lost or impaired days were accounted for by asthmatics in the two upper quartiles of the Current Symptom Severity Score (which is mainly a function of the level of the control of symptoms). As treatment has been proved highly effective in the control of moderately

severe asthma (23), adherence to guidelines and care optimization could reduce costs substantially and improve the quality of life for a vast majority of these patients.

The lack of treatment for asthma and a low use of anti-inflammatory drugs have been invoked as one of the main reasons for the poor control of the disease in Italy (24). However, our data show that the vast majority of current asthmatics (90.2%) had treatment. The comparison with previous similar data showed that asthmatics have considerably increased their use of asthma drugs in Italy, as in many countries (25, 26) in the last decade, while the control of symptoms has even worsened.

A drawback of the present study is that we have no direct information on the type of anti-asthmatic drugs used by the subjects. However, preliminary data on the type of drugs used by a sample of Italian current asthmatics showed that the ratio between inhaled anti-inflammatory drugs and bronchodilators increased from 0.36 in 1991 to 1.03 in 2000 (27).

This means that, at least in Italy, the failure of the GINA goals comes within the framework of a relative increase in drug use, particularly inhaled anti-inflammatory medications. Perhaps this increase is not enough to control the disease, but it is likely that other dimensions, such as an insufficient patient education or the inadequacy of the treatment to the patient's severity (correct dosage and correct frequency), are the main reasons for the poor control of asthma. Our data seem to support this hypothesis: in fact, all well-controlled asthmatics were under treatment, had a better reported compliance and were more frequently prescribed daily use medication than less-controlled asthmatics. Furthermore, the fact that less than three of 10 asthmatics underwent objective lung function measurements (spirometry) in the last 12 months indicates an inadequate monitoring of the progression and severity of the disease.

Our analysis also suggests that the control of asthma is more difficult in women, in patients with a later onset of the disease and when symptoms of chronic cough and phlegm are present.

While the gender effect on asthma control is well known, our results partially disagree with previous studies reporting that later onset asthma is associated with a lower degree of severity (28–31), and hence could be more easily controlled. It is likely that the association between late onset and poor control of asthma reflects a greater difficulty in managing symptoms and exacerbations: in fact it is more difficult to evaluate, classify and consequently, adequately, treat symptoms that occur later in life (17, 32). Furthermore, as the duration of the disease increases, the patients could be more familiar with the symptoms and acquire more experience in self-treatment and control of the disease (33).

The presence of chronic cough and phlegm, independent of smoking exposure, was strongly associated with the poor control of the disease. This symptom, which is now considered the stage 0 of chronic obstructive pulmonary disease (COPD) (34), is frequently associated with irreversible impaired lung functions (35–38), and it is likely to be an indicator of the most difficult patients to treat, in whom asthma and COPD coexist. However, the prevalence of chronic cough and phlegm was not linearly related to the control of the disease: in fact, well-controlled asthmatics had a higher prevalence than moderately controlled asthmatics (34% vs 21%). This could be due to the fact that the current level of control depends either on the severity of the disease or on the efficacy of the treatment: so, well-controlled asthmatics could be a more severe group than moderately controlled asthmatics, but with a better use of medication (as shown by the higher percentage of drug users in the well-controlled group than in the moderately controlled group).

This is one of the few population-based studies assessing the extent to which asthma is controlled in the general population. The wide geographical distribution of the patients and the relatively high response rates guarantee that the sample studied represents current asthmatics in Italy, and consequently our results have a broad spectrum of generalization.

Its limitation is mainly due to its cross-sectional nature as it is impossible to assess the temporal direction between severity of the disease, treatment and life impairment. In fact, the current symptom severity is a function of both the severity of the disease and the level of control reached by treatment, and the actual treatment reported by patients could be subsequent to the experience of impairing events like hospitalizations or exacerbations. This could explain why poorly controlled asthmatics had a higher percentage of drug users, of daily use prescription and visited a doctor more frequently than better controlled patients. In any case, our data document an overall

poor control and management of the disease in Italy. In fact, given that current asthmatics had a longer duration of disease (at least 17 years on average), the occurrence of avoidable events (like ED visits or days lost) and the persistence of symptoms and exacerbations reflect an inadequate management of the disease. The possibility that a small number of these asthmatics could not be controlled even with proper medication should not be excluded.

In conclusion, the present scenario of asthma control in young Italian adults shows that the goals of the guidelines have far from been reached in Italy. Asthma is often insufficiently controlled, which results in a poor individual quality of life and in a heavy social burden. Sex, age at onset of asthma and the coexistence with chronic cough and phlegm are the most relevant predictors of the poor control of asthma. Despite a substantial increase in the use of asthma drugs, the control of symptoms did not improve. There are two major reasons why the management of the disease may be unsuccessful: (i) optimal treatment and action plan are not prescribed by the caregiver (39), and (ii) the patient does not actively follow the adequate treatment prescribed (11). Our data do not allow us to understand the extent to which each of these components is involved in the poor control of asthma in Italy. The ongoing follow-up of these patients will give us a deeper insight into the reasons for the failure of the GINA goals in Italy.

Appendix 1

Multiple Correspondence Analysis is a statistical technique of dimensionality reduction, aimed to obtain a representation of the structure of the relationship among p categorical variables in a reduced dimensional space, preserving at its best the total variation (inertia) of the original data (40, 41). When the original variables are highly correlated, one or only few dimensions are enough to explain a large percentage of the total inertia. In this case, the response pattern of each individual to the p variables can be summarized in one or very few new scores, which are linear combinations of the original p variables.

When the reported asthma-like symptoms and asthma attacks were analysed using Multiple Correspondence Analysis, the first dimension accounted for 81.2% of the total inertia, suggesting that only a single dimension underlies the observed pattern of asthma symptoms and asthma attacks. The first dimension, which opposes the absence of both asthma attacks and asthma-like symptoms to the presence of many asthma attacks, nocturnal symptoms and wheezing with breathlessness, can be interpreted as the 'severity dimension'.

The mean number of symptoms and asthma attacks according to Current Symptom Severity Score quartiles showed an increasing trend (Table 1A). In particular,

Table 1A. Mean number (and 95% confidence interval) of asthma-like symptoms and asthma attacks in the last 12 months by Current Symptom Severity Score quartiles

	Current Symptom Severity Score quartiles			
	First quartile	Second quartile	Third quartile	Fourth quartile
Mean number of asthma-like symptoms*	0.9 (0.7–1.0)	1.9 (1.8–2.1)	3.2 (3.1–3.3)	4.7 (4.6–4.7)
Mean number of asthma attacks	1.2 (0.8–1.5)	4.2 (2.2–6.1)	3.6 (2.8–4.5)	9.8 (7.2–12.4)

* Maximum number of simultaneously reported asthma-like symptoms equal to 5.

asthmatics in the fourth quartile showed an eightfold increase in asthma attacks and a fivefold increase in the number of asthma-like symptoms simultaneously present with respect to those in the first quartile.

Appendix 2

List of principal participants in ISAYA:

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