

Diagnostic Labeling of COPD in Five Latin American Cities*

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Background: COPD is a major worldwide problem with a rising prevalence. Despite its importance, there is a lack of information regarding underdiagnosis and misdiagnosis of COPD in different countries. As part of the Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar study, we examined the relationship between prior diagnostic label and airway obstruction in the metropolitan areas of five Latin American cities (São Paulo, Santiago, Mexico City, Montevideo, and Caracas).

Methods: A two-stage sampling strategy was used in each of the five areas to obtain probability samples of adults aged ≥ 40 years. Participants completed a questionnaire that included questions on prior diagnoses, and prebronchodilator and postbronchodilator spirometry. A study diagnosis of COPD was based on airway obstruction, defined as a postbronchodilator $FEV_1/FVC < 0.70$.

Results: Valid spirometry and prior diagnosis information was obtained for 5,303 participants; 758 subjects had a study diagnosis of COPD, of which 672 cases (88.7%) had not been previously diagnosed. The prevalence of undiagnosed COPD was 12.7%, ranging from 6.9% in Mexico City to 18.2% in Montevideo. Among 237 subjects with a prior COPD diagnosis, only 86 subjects (36.3%) had postbronchodilator $FEV_1/FVC < 0.7$, while 151 subjects (63.7%) had normal spirometric values. In the same group of 237 subjects, only 34% reported ever undergoing spirometry prior to our study.

Conclusions: Inaccurate diagnostic labeling of COPD represents an important health problem in Latin America. One possible explanation is the low rate of spirometry for COPD diagnosis.

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Key words: COPD; diagnostic errors; prevalence; spirometry

Abbreviations: GOLD = Global Initiative for Chronic Obstructive Lung Disease; IBERPOC = Estudio Ibérico de Prevalencia de EPOC; PLATINO = Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar

COPD is a major health problem, and the worldwide number of patients with the disease continues to rise.^{1–9} According to the Global Burden of Disease Study,^{1,2} COPD will be the fifth-leading cause of disability and the third-leading cause of death in the world in the first half of the 21st century. For developing countries, COPD is expected to be the fourth cause of disability for men and the third cause of disability for women by 2020.^{1–2}

In addition to measuring the prevalence and risk factors for a disease, it is important to determine whether the health-care system correctly identifies

diseased persons, and whether the number of identified patients corresponds to the true prevalence of the disease in the community. Lack of awareness in diagnosing a disease may be reflected by the degree of underdiagnosis; however, it is also important to know the number of subjects with an incorrect diagnosis of the disease (misdiagnosis). This is especially important for COPD because patients at an early stage of the disease may be unaware of their condition or reluctant to consult their physician for respiratory symptoms. Consequently, most patients with mild disease do not receive active counseling against tobacco smoking or appropriate pharmaco-

logic treatment. Moreover, some treatments administered to patients with COPD are not appropriate for their degree of disease severity and do not always follow current guidelines.^{9–12} Accurate information about underdiagnosis and misdiagnosis may help health authorities, physicians, and other health decision makers to improve the system in order to correctly find and help subjects with COPD at any severity level.

Despite the importance of COPD, population-based studies that include spirometric determinations are scarce outside Europe and North America. Furthermore, there is a lack of information on differences in underdiagnosis and misdiagnosis among different countries. The aim of this study was to measure the rate of inaccurate diagnostic labeling of COPD in five Latin American cities. We also explored possible factors explaining inaccurate diagnostic labeling.

METHODS AND MATERIALS

The Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar (PLATINO) study³ was a population-based epidemiologic study conducted in five major Latin American cities: São Paulo (Brazil), Santiago (Chile), Mexico City (Mexico), Montevideo (Uruguay), and Caracas (Venezuela). Complete details of the PLATINO methodology have been published.¹³

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Briefly, a two-stage cluster sampling method was used at each site in order to obtain a random sample of households. All adults ≥ 40 years old living in selected households were invited to participate. The study exclusion criteria were mental illness and institutionalization. The local ethical committee of each institution involved in the study approved the protocol, and all subjects gave their written informed consent.

Information was collected on several factors potentially associated with COPD, including age, sex, ethnicity (self-reported), smoking habits, years of formal education, employment, respiratory symptoms, and prior spirometric testing. Copies of the questionnaires used at each site are available at the PLATINO Web site (<http://www.platino-alat.org>). A portable, battery-operated, ultrasound transit-time–based spirometer (Easy-One; NDD Medical Technologies; Chelmsford, MA) was used to perform pulmonary function testing among eligible subjects. Each day, the calibration was checked with a 3-L syringe. Subjects performed up to 15 forced expiratory maneuvers (average, 5 to 6 maneuvers) to obtain three acceptable maneuvers according to the American Thoracic Society,¹⁴ with FVC and FEV₁ reproducible within 150 mL. Salbutamol, 200 μ g, was then administered by inhalation using a 500-mL spacer, and the test was repeated 15 min later (average, four to five maneuvers). The spirometric tests were done with the subject seated, using a nose clip and a disposable mouthpiece. The exclusion criteria for spirometry were recent thoracic or abdominal surgery, myocardial infarction, eye surgery or retinal detachment, hospitalization for any cardiac condition, tuberculosis, pregnancy, or a pulse rate > 120 beats/min.

The definition of COPD proposed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD)¹⁵—a ratio of the postbronchodilator FEV₁ over FVC < 0.70 —was used in the present study. The same definition was proposed by the new European Respiratory Society/American Thoracic Society document.¹⁶ Prior diagnostic label was determined using a self-reported prior diagnosis of emphysema, chronic bronchitis, or COPD. Prior diagnosis of asthma was determined in the same manner.

In addition to population prevalence rates of underdiagnosis, we performed descriptive comparative analyses of persons with a prior diagnosis consistent with COPD and persons with a study diagnosis of COPD. Multivariate logistic regression was aimed at identifying variables associated with the lack of a prior COPD diagnosis in persons with spirometric evidence of airway obstruction. All analyses were performed with the using statistical software (STATA version 9.0; STATA Corporation; College Station, TX).

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RESULTS

Detailed descriptions of participation rates and the sample characteristics in the study, both total and for individual countries, have been published previously.³ In summary, from a total of 6,711 eligible individuals, complete interviews were achieved in 5,571 subjects and spirometry was performed in 5,315 subjects. Both valid spirometry results and prior diagnosis information were available for 5,303 subjects.

There were 758 subjects with postbronchodilator FEV₁/FVC < 0.7 . The prior diagnostic labeling of

obstructive respiratory disease in these subjects is provided in Table 1. There was a high proportion of subjects with no prior COPD diagnosis (672 of 758 subjects, 88.7%), which was similar among the five countries. In other words, only 86 of the 758 obstructed subjects (11.3%) had a prior correct COPD diagnosis. The population prevalence of airway obstruction without a prior COPD diagnosis was lowest in Mexico City and highest in Montevideo, as presented in Table 2.

The relationships between prior diagnosis and study diagnosis are illustrated in Figure 1. There were 237 subjects with a prior medical diagnosis of emphysema, chronic bronchitis, or COPD. Among these 237 subjects, only 86 subjects (36.3%) had postbronchodilator FEV₁/FVC < 0.7, while 151 subjects (63.7%) had postbronchodilator FEV₁/FVC > 0.7. Among the 151 subjects with a prior diagnosis of COPD and no obstruction, 27 subjects (17.9%) showed a restrictive pattern (FEV₁/FVC ≥ 0.70; FVC < 80% predicted) and 72 subjects (47.7%) qualified as GOLD stage 0. In the entire group of 237 subjects with a prior COPD diagnosis, only 34% reported ever undergoing spirometry prior to our study. However, 683 subjects reported a prior medical diagnosis of asthma. Among these, only 173 subjects had postbronchodilator FEV₁/FVC < 0.7. From this group, 55 subjects had a prior medical diagnosis of asthma and any concurrent diagnostic label consistent with COPD.

A descriptive comparison of subjects by prior diagnostic status is presented in Table 3. There were no significant differences in age, gender, ethnicity, years of education, or tobacco consumption between subjects with a correct prior diagnosis of COPD and those with no prior diagnosed disease. Compared to correctly diagnosed subjects, persons with an incorrect prior diagnosis (*ie*, a diagnostic label consistent with COPD in the absence of airway obstruction) were significantly more likely to be younger, female, employed, and have lower smoking exposure.

Respiratory symptoms (cough, phlegm, wheezing, and dyspnea) were more frequent in subjects with

correctly diagnosed COPD compared with those who had obstruction but no previous COPD diagnosis (Fig 2). Cough, phlegm, and wheezing were more frequent among persons with a correct prior COPD diagnosis than among those with an incorrect prior diagnosis; however, shortness of breath was similar between these two groups. Subjects with a correct prior diagnosis of COPD were much more likely to have undergone spirometry than those without a correct prior diagnosis (Fig 3).

Table 4 presents results from a regression model examining factors associated with underdiagnosed COPD in persons with airway obstruction. The odds of underdiagnosis were significantly higher among persons with lower age, lower severity of airway obstruction (GOLD severity), fewer respiratory symptoms (cough, phlegm, wheezing, and shortness of breath), and no prior diagnosis of asthma. Analysis of variance inflation factors indicated the covariates did not exhibit significant multicollinearity (maximum variance inflation factor of 1.50).

DISCUSSION

The aim of the PLATINO study was to measure COPD prevalence in five Latin American cities. However, the study also offers an excellent opportunity to examine diagnostic patterns using a population-based sample. We observed a high prevalence of airway obstruction without a prior diagnostic label consistent with COPD: 12.7% of all subjects examined fell into this category. Among subjects with a study diagnosis of COPD, 88.7% of cases had not been previously diagnosed. However, a prior diagnosis of COPD in the absence of airway obstruction was also a frequent problem. Among 237 subjects with a prior diagnosis consistent with COPD, well over one half did not meet criteria for obstruction.

The prevalence of undiagnosed airflow obstruction has been described in several countries,⁴⁻⁹ and estimates have varied widely, ranging from 3.2 to 12%. Isoaho and coworkers⁶ reported an overall

Table 1—Prior Diagnosis of Obstructive Lung Disease in Subjects With Airway Obstruction (Postbronchodilator FEV₁/FVC < 0.70)*

Cities	Emphysema	Chronic Bronchitis	COPD	Any Prior COPD Diagnosis	No Prior COPD Diagnosis	Prior Asthma Diagnosis	Total Obstructed
São Paulo	3 (2.0)	16 (10.5)	3 (2.0)	19 (12.5)	133 (87.5)	28 (18.4)	152 (100)
Santiago	10 (5.1)	17 (8.6)	6 (3.0)	25 (12.6)	173 (87.4)	55 (27.8)	198 (100)
Mexico City	3 (3.9)	6 (7.8)	4 (5.2)	8 (10.4)	69 (89.6)	8 (10.4)	77 (100)
Montevideo	5 (2.9)	8 (4.6)	3 (1.7)	13 (7.5)	161 (92.5)	49 (28.2)	174 (100)
Caracas	10 (6.4)	12 (7.6)	3 (1.9)	21 (13.4)	136 (86.6)	33 (21.0)	157 (100)
Total	31 (4.1)	59 (7.8)	19 (2.5)	86 (11.3)	672 (88.7)	173 (22.8)	758 (100)

*Data are presented as No. (%).

Table 2—Population Prevalence of Airway Obstruction Without Prior COPD Diagnosis

Cities	Airway Obstruction Without Prior COPD Diagnosis, No.	Study Population, No.	Prevalence, %	95% Confidence Interval
São Paulo	133	961	13.8	11.7–16.0
Santiago	173	1,172	14.8	12.8–16.7
Mexico City	69	995	6.9	5.1–8.8
Montevideo	161	883	18.2	15.8–20.7
Caracas	136	1,292	10.5	8.8–12.3
Total	672	5,303	12.7	11.7–13.7

prevalence of undiagnosed airflow obstruction (defined as $FEV_1/FVC \leq 65\%$) of 3.2% in a population-based sample of 1,196 elderly Finns. In the Estudio Ibérico de Prevalencia de EPOC (IBERPOC),⁵ a multicenter survey of 4,035 Spanish subjects aged 40 to 69 years, there was no previous COPD diagnosis in 78.2% of cases identified using the spirometric definition of the European Respiratory Society, representing a prevalence of 7.0%. A study from Northern Sweden⁹ reported that only 18% of persons > 45 years old with COPD according to GOLD criteria had a prior diagnosis of chronic bronchitis, emphysema, or COPD. This represents a population prevalence of undiagnosed COPD of approximately 12%. The third National Health and Nutrition Examination Survey in the United States found that 6.8% of adults aged ≥ 17 years had “low lung function

($FEV_1/FVC < 0.70$ and $FEV_1 < 80\%$ predicted), and 63.3% of these subjects (population prevalence, 4.1%) had no current diagnosis of any obstructive lung disease.⁴ The Nippon COPD epidemiology study⁸ found that only 9.4% of cases with airflow limitation reported a previous COPD diagnosis. Based on their reported prevalence of airflow limitation of 10.9%, this yields an estimated 9.9% population prevalence of undiagnosed COPD. Our results are consistent with a high level of COPD undiagnosis; however, the magnitude of the problem appears to be especially great in some of the Latin American cities included in the PLATINO study—São Paulo, Santiago, and Montevideo all had population rates of undiagnosed COPD well > 12%.

The wide variation in the prevalence of undiagnosed COPD among the regions studied is noteworthy.

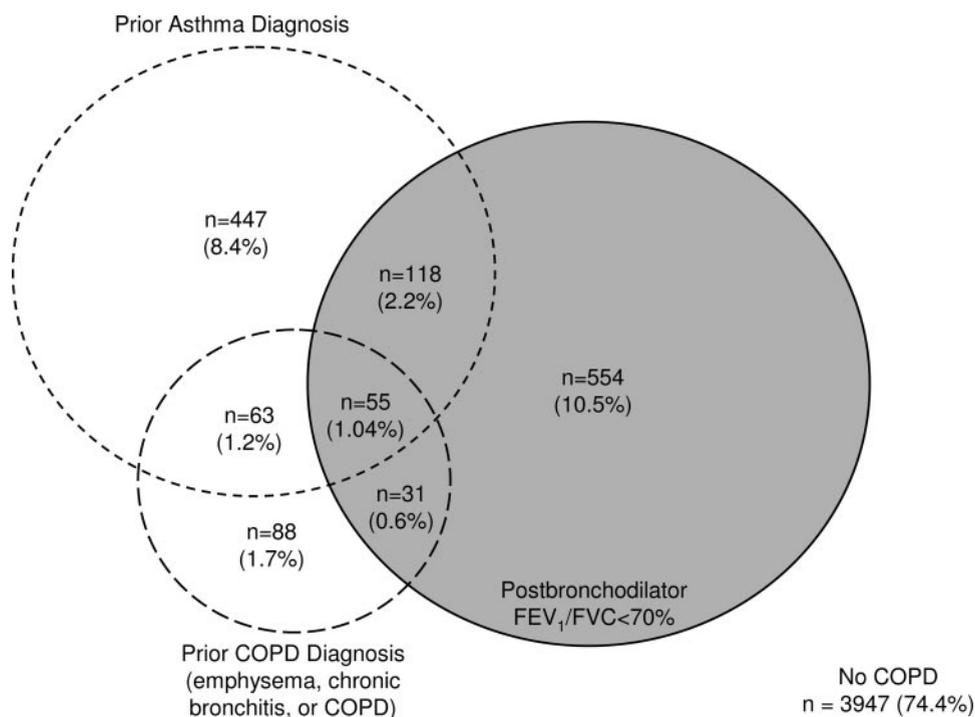


FIGURE 1. Venn diagram showing relationships between prior diagnosis (chronic bronchitis, emphysema, COPD, or asthma) and study diagnosis ($FEV_1/FVC < 70\%$) in the PLATINO study.

Table 3—Description of the Study Population by Prior Diagnosis of COPD (Emphysema, Chronic Bronchitis, or COPD)*

Variables	Correct Prior Diagnosis of COPD	Incorrect Prior Diagnosis of COPD	No Prior Diagnosis of COPD (Underdiagnosed)
Subjects, No.	86	151	672
GOLD severity			
Stage 0		72 (47.7)	
Stage I	26 (30.2)		424 (63.1)
Stage II	37 (43.0)		219 (32.6)
Stage III	16 (18.6)		25 (3.7)
Stage IV	7 (8.1)		4 (0.6)
Restrictive pattern (FEV ₁ /FVC ≥ 0.70, FVC < 80% predicted)		27 (17.9)	
Age, yr	66.4 ± 12.5	55.6 ± 11.0†	63.8 ± 12.2
Age group, yr			
40–49	11 (12.8)	56 (37.1)‡	98 (14.6)
50–59	14 (16.3)	49 (32.5)	165 (24.6)
> 60	61 (70.9)	46 (30.5)	409 (60.9)
Gender			
Male	41 (47.7)	34 (22.5)‡	355 (52.8)
Female	45 (52.3)	117 (77.5)	317 (47.2)
Ethnicity			
White	54 (62.8)	74 (49.7)	435 (64.7)
Black	7 (8.1)	7 (4.7)	32 (4.8)
Asian	1 (1.2)	1 (0.7)	8 (1.2)
Mulatto	21 (24.4)	59 (39.6)	166 (24.7)
Indian	3 (3.5)	8 (5.4)	31 (4.6)
Education, yr	6.83 ± 4.58	7.63 ± 4.91	6.69 ± 4.61
Employment			
Yes	28 (32.6)	83 (55.0)‡	288 (42.9)
No	58 (67.4)	68 (45.0)	384 (57.1)
Smoking, pack-yr	25.9 ± 38.1	12.4 ± 17.9§	18.9 ± 26.0
Smoking, pack-year categories			
< 10	43 (50.6)	96 (63.6)	342 (50.9)
10 to < 20	10 (11.8)	14 (9.3)	95 (14.1)
≥ 20	32 (37.6)	41 (27.2)	235 (35.0)
Prior diagnosis of asthma	55 (64.0)	63 (41.7)	118 (17.6)
FVC, L	2.87 ± 0.99	3.04 ± 0.82	3.47 ± 0.72†
FEV ₁ , L	1.56 ± 0.65	2.42 ± 0.69†	2.19 ± 0.72†
FEV ₁ /FVC	0.54 ± 0.12	0.80 ± 0.05†	0.63 ± 0.07†

*Data are presented as No. (%) or mean ± SD unless otherwise indicated.

†p < 0.0001 vs correct prior diagnosis of COPD.

‡p < 0.001 vs correct prior diagnosis of COPD.

§p < 0.05 vs correct prior diagnosis of COPD.

thy. We observed a range from 6.9% in Mexico City to 18.2% in Montevideo. It is important to mention that the percentage of COPD underdiagnosis was similar among the sites (Table 1), suggesting that the underlying prevalence of airflow obstruction is the principal driver of the prevalence of undiagnosed disease. Thus, the low prevalence of airway obstruction without prior COPD diagnosis in Mexico City is better explained by the lower prevalence of the disease in this site than by a higher rate of correct diagnosis. As mentioned in the previous report, one of the strengths of the present study is the consistency of methods in all countries.³ Therefore, the differences among sites are not probably related to

methodologic issues. If this is correct, our results imply that underdiagnosis is a consistent, regional issue rather than an isolated problem in some countries.

Pena and coworkers⁵ evaluated the factors associated with having a previous COPD diagnosis in the IBERPOC study. They found that the probability of undiagnosed COPD was significantly associated with increased age, male gender, tobacco consumption, higher levels of education, urban residence, and the existence of chronic bronchitis and other thoracic diseases. Their results suggest that the following may facilitate the diagnosis of COPD: respiratory symptoms associated with smoking, a greater awareness of

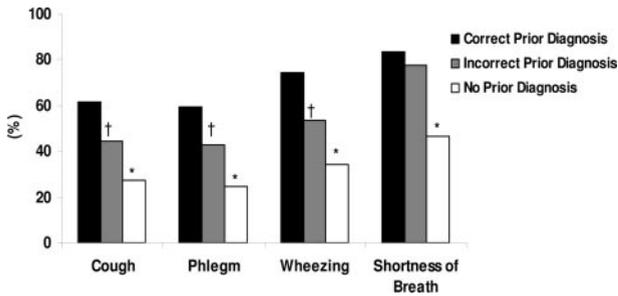


FIGURE 2. Proportion of respondents with respiratory symptoms, by diagnostic status. * $p < 0.0001$ vs correct prior diagnosis. † $p < 0.05$ vs correct prior diagnosis.

the disease and an easier access to medical care for those living in urban areas. Our multivariate analysis showed that lower age, lower GOLD severity, the absence of respiratory symptoms (cough, phlegm, wheezing, and shortness of breath), and no prior diagnosis of asthma were associated with an increased likelihood of having undiagnosed COPD. These results are in agreement with another report¹⁷ from the IBERPOC study suggesting that younger patients with fewer respiratory symptoms are less likely to receive a diagnosis.

The other important result of the present study is the marked prevalence of an apparently incorrect prior diagnosis of COPD. This finding must be viewed with caution, as persons may have anatomic evidence of emphysema or symptoms consistent with chronic bronchitis in the absence of airway obstruction. It is interesting to note that, among persons with a prior diagnostic label of COPD, the presence of symptoms suggesting COPD (phlegm, cough, wheezing, and shortness of breath) were common. In particular, dyspnea was equally reported by subjects with and without airway obstruction (not all dyspnea is COPD). This suggests that dyspnea is synonymous with having COPD for many clinicians. These findings indicate that clinical assessment based on symp-

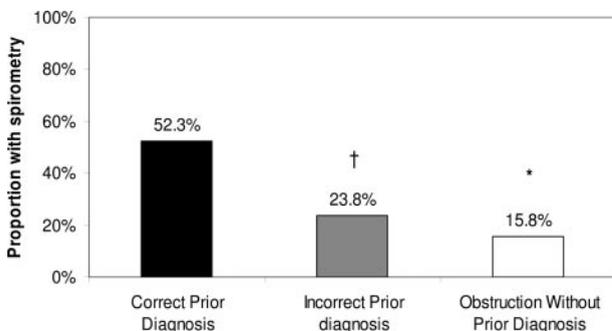


FIGURE 3. Proportion of respondents undergoing spirometry prior to the PLATINO study, by diagnostic status. * $p < 0.0001$ vs correct prior diagnosis. † $p < 0.001$ vs correct prior diagnosis.

Table 4—Regression Model Explaining Undiagnosed COPD Among Subjects With Airway Obstruction ($FEV_1/FVC < 0.70$)

Variables	Odds Ratio	95% Confidence Interval	p Value
GOLD severity			
Stage IV (reference)	1.00		
Stage III	1.94	0.41–9.33	0.406
Stage II	4.55	1.12–18.44	0.034
Stage I	6.50	1.58–26.85	0.01
Age, yr			
> 60 (reference)	1.00		
50–59	2.67	1.29–5.51	0.008
40–49	2.58	1.04–6.39	0.04
Gender			
Male (reference)	1.00		
Female	1.38	0.76–2.52	0.29
Ethnicity			
Nonwhite (reference)	1.00		
White	1.49	0.84–2.64	0.17
Education, yr (continuous)	0.96	0.90–1.02	0.16
Employment			
Yes (reference)	1.00		
No	0.91	0.48–1.75	0.79
Smoking, pack-yr (continuous)			
≥ 20 (reference)	1.00		
10 to < 20	0.98	0.38–2.01	0.75
< 10	0.74	0.39–1.39	0.35
Symptom (cough)			
Yes (reference)	1.00		
No	2.01	1.12–3.63	0.02
Symptom (phlegm)			
Yes (reference)	1.00		
No	2.37	1.31–4.28	0.004
Symptom (wheeze)			
Yes (reference)	1.00		
No	2.11	1.15–3.86	0.016
Symptom (shortness of breath)			
Yes (reference)	1.00		
No	2.38	1.22–4.62	0.011
Prior diagnosis of asthma			
Yes (reference)	1.00		
No	4.46	2.47–8.05	< 0.001

toms alone is insufficient to establish a correct COPD diagnosis and support the recommendation of including spirometry in the evaluation of those patients. Reducing the levels of incorrect COPD diagnosis is likely to be associated with a corresponding reduction in unnecessary medication. Spirometry is not only important for diagnosis but also allows stratifying the severity of the disease that may help to indicate treatment when it is necessary. The lack of previous information about incorrectly diagnosed COPD in other population-based studies makes it difficult to make comparisons with our results.

In our subjects with a correct prior COPD diagnosis, only half reported ever undergoing spirometry prior to this study. This was twice the rate seen in subjects with an incorrect diagnosis, and more than

three times that in subjects with undiagnosed airway obstruction. It is well known that the diagnosis of COPD should be considered in any patient who has cough, sputum production, dyspnea, and a history of exposure to risk factors for the disease. Current diagnostic criteria^{15,16} emphasize that spirometry is the “gold standard” and that objective measurement of airflow limitation is essential in the diagnosis and assessment of COPD. However, several studies^{18–21} undertaken in different countries have suggested a widespread underuse of spirometry by general practitioners to establish COPD diagnosis. Despite incentives to perform spirometry in general practice, the lack of access to spirometers and inadequate training in the use and interpretation of spirometry could result in COPD diagnosis being made on imprecise clinical grounds. The insufficient use of spirometry for the diagnostic assessment of COPD found in the present study suggests the need to implement more specific educational programs targeted to general practitioners. In addition, it is also necessary to increase spirometry availability and examinations in primary health care for improving the likelihood of accurately detecting subjects suffering with COPD.

General limitations of the PLATINO study have been discussed elsewhere.³ Our definition of COPD was based on postbronchodilator FEV₁/FVC below a fixed value at a single examination. Although this fixed ratio can overestimate cases of COPD, especially among the aged, it is currently the most widely accepted definition for COPD. It is important to note that it has been used in this study as an epidemiologic case definition rather than as a clinical COPD diagnosis. It is possible that some subjects labeled as having COPD would have received another diagnosis with a more complete examination, or with a course of corticosteroids. Our determination of prior diagnostic status was based on subjects' report of a prior diagnosis, which is subject to recall bias. Thus, it is likely that our results may tend to underestimate the true rate of physician diagnosis.

In summary, the results of this study indicate that inaccurate diagnostic labeling of COPD represents an important health problem in Latin America. One possible explanation is the low rate of spirometry for COPD diagnosis. The large rate of inaccurate COPD diagnosis found in the present study should be considered by the public health community in order to improve the implementation of current diagnostic criteria and strategies for COPD.

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