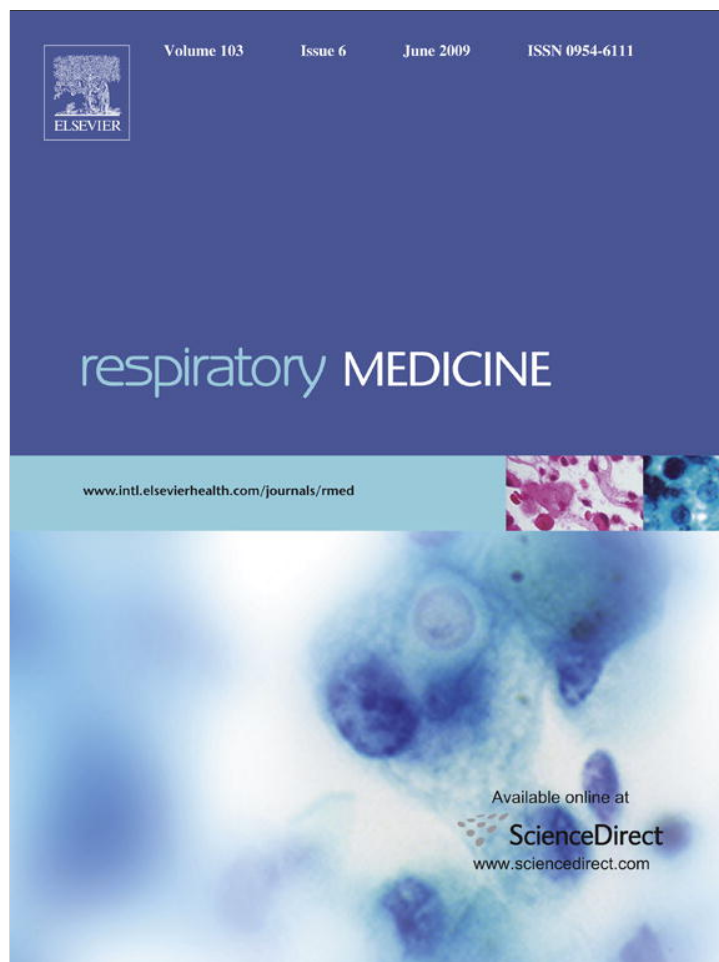


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## COPD case finding by spirometry in high-risk customers of urban community pharmacies: A pilot study

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### KEYWORDS

COPD;  
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### Summary

**Background:** COPD case finding is currently recommended at primary and tertiary care levels only.

**Aim:** To evaluate the feasibility of a community pharmacy program for COPD case finding in high-risk customers by means of spirometry.

**Methods:** Pilot cross-sectional descriptive study in 13 urban community pharmacies in Barcelona, Spain, from April to May 2007. Customers >40 years old with respiratory symptoms and/or a history of smoking were invited to participate in the study during pharmacists' routine work shifts. High-risk customers were identified by means of a 5-item COPD screening questionnaire based on criteria of the Global Initiative for Chronic Obstructive Lung Disease, and were invited to perform spirometry accordingly. Those with an FEV<sub>1</sub>/FVC ratio less than 0.70 were referred to the hospital for a repeat spirometry.

**Results:** Of the 161 pharmacy customers studied, 100 (62%) scored 3 or more items in the COPD screening questionnaire, and after spirometry, 21 (24%) had an FEV<sub>1</sub>/FVC ratio < 0.7. When these subjects with airflow limitation were offered referral to a hospital respiratory function laboratory for further assessments, 11 (52%) attended the appointment. Over 70% of spirometries were rated as being of acceptable quality. No significant differences were observed in lung function parameters between the pharmacy and hospital measurements.

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*Conclusions:* COPD case finding by spirometry in high-risk customers of urban community pharmacies is feasible. Similarly to primary care practitioners, pharmacists have access to high-risk, middle-aged subjects who have never been tested for COPD. Pharmacists can help with early detection of COPD if they are correctly trained.

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## Introduction

Early diagnosis of COPD is important because smokers with demonstrated airway obstruction are more likely to quit smoking.<sup>1</sup> Recently, the U.S. Preventive Services Task Force (USPSTF) recommended against screening the general population for chronic obstructive pulmonary disease (COPD) using spirometry (grade D recommendation).<sup>2</sup> However, the same document recognised that individuals presenting respiratory symptoms (chronic cough, increased sputum production, wheezing, or dyspnea) should be tested. This position is consistent with the recommendations of other relevant groups: the American Thoracic Society (ATS) and the European Respiratory Society (ERS) advise performing spirometry on all persons with smoking exposure, a family history of chronic respiratory illness, or respiratory symptoms,<sup>3</sup> and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommends that clinicians consider a diagnosis of COPD 'in any patient who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease' and that the 'diagnosis should be confirmed by spirometry'.<sup>4</sup>

At present, detection of COPD is limited to case finding at the primary or tertiary care levels, a strategy that has proven largely inadequate. One large population-based survey showed that a high percentage (63%) of subjects with airflow limitation had never received a diagnosis of obstructive lung disease.<sup>5</sup> In Spain, underdiagnosis has been estimated to be around 80%.<sup>6</sup>

Pharmaceutical care, which has been useful in the management of ambulatory patients with chronic diseases such as asthma,<sup>7</sup> might offer a new approach to COPD case finding. Community pharmacists trained to perform spirometry have been successful in improving access to lung function measurement in rural communities,<sup>8</sup> and we hypothesized that they might also be able to help in an urban general population. For such an approach to work, the pharmacist would need to be able to select high-risk individuals in whom spirometry should be performed. The aim of this pilot study was to assess the feasibility of a program of case finding of COPD by spirometry in community pharmacies.

## Methods

### Pharmacist selection and training

To recruit pharmacist participants, we contacted community pharmacies in a smoking prevention group formed through the professional association for this sector (Official College of Pharmacists, COFB) in Barcelona, Spain. The study had been approved by the ethics committee of

Hospital Clinic i Provincial, Barcelona. Thirteen of the 19 members of the smoking prevention group accepted, agreeing that a staff pharmacist would attend a four-day spirometry training course in February and March 2007. Training was based on the guidelines of the National Institute for Occupational Safety and Health (NIOSH),<sup>9</sup> the ERS/ATS,<sup>10</sup> and the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).<sup>11</sup> The volunteer pharmacists recruited subjects from among customers arriving during their regular work shifts of about 8 h per day and they conducted interviews and tests between attending customers. The daily routine of the pharmacy was not modified so that our results would not overestimate the number of new cases of COPD that can be found by this route in real conditions.

### Spirometer and assessment procedures

The portable spirometer (Easy-One Spirometer, ndd Medical Technologies, Zürich, Switzerland) was chosen because it is easy to handle and has been used in other population screening studies.<sup>12</sup> Calibration was checked at the beginning of the study and did not have to be re-checked daily. The device has built-in software that ranks spirometry quality (grades A–F) in accordance with standard European classifications.<sup>10</sup> An A or B rating indicated acceptable quality, because both levels supposed three good manoeuvres with at least two readings of forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV<sub>1</sub>) differing by <150–200 ml. In addition, an expert in lung function (F.B.) reviewed and rated all spirometry curves according to the same criteria.

Lung function measurements included FEV<sub>1</sub>, FVC and the FEV<sub>1</sub>/FVC ratio. FEV<sub>1</sub> and FVC were expressed in liters and as the percentage of reference values for the Spanish population.<sup>13</sup> According to the Spanish COPD guidelines,<sup>14</sup> and as recently proposed elsewhere for mass screening programs,<sup>15</sup> we used pre-bronchodilator lung function to classify airflow limitation, defined by an FEV<sub>1</sub>/FVC ratio < 0.70.

### Subject selection and evaluation

During April and May 2007, customers who entered the participating community pharmacies and who seemed to be in the targeted age range (>40 years) were approached with opening questions about respiratory symptoms or smoking. If a candidate expressed interest in the topic, the pharmacist explained the objectives of the research and the voluntary nature of participation. Participants signed a consent form if interested, and the pharmacist then asked about previous diagnoses of lung disease or use of inhaled medication and sociodemographic data as stipulated by

a written questionnaire. Individuals aged < 40 years or who had a history of lung disease or use of inhalers were excluded at this time. To assess the risk of COPD, we used the GOLD screening questionnaire, as recommended in the 2006 guidelines.<sup>4</sup> This questionnaire consisted of questions on five items referring to more breathlessness than people of the same age, chronic cough, chronic sputum, age > 40 years, and smoking. Subjects with  $\geq 3$  affirmative answers were offered spirometry. Those in whom the FEV<sub>1</sub>/FVC ratio was < 0.70 were referred to a lung function unit in a university hospital (Hospital de la Santa Creu i Sant Pau or Hospital Clinic I Provincial, both in Barcelona). Within 24–48 h spirometry was repeated by an expert nurse using the same brand of spirometer. Refusal to continue participating in the study was recorded with the specified reason. Smokers were also encouraged to quit smoking through a cessation program, as giving this advice was part of the normal routine for these volunteer community pharmacists.

### Statistical methods

Descriptive data of participants and subgroups are presented as mean and standard deviation unless otherwise stated. We compared participants with a low and high COPD risk, and spirometry data in the normal and abnormal groups, using *t*-tests for normally distributed parametric data and the Kolmogorov–Smirnov test for non-parametric data (quality spirometry, gender, tobacco exposure and GOLD screening score). Using the Wilcoxon rank sum test we compared each subject's expiratory flow rates measured at the pharmacy and the hospital. A Bland–Altman graph was also created to show individual differences between pharmacy and hospital FEV<sub>1</sub> values. Statistical significance was set at  $P \leq 0.05$  for comparisons between groups. All analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows, version 15.0 (SPSS Inc., Chicago, Illinois, USA).

### Results

A total of 254 customers approached by the pharmacists expressed interest in the study; 188 (74%) agreed to participate by signing the consent form after the nature of the study was explained. Reasons given by the 66 subjects who declined to participate included no time to wait ( $n = 28$ , 42%), no interest ( $n = 12$ , 18%), already diagnosed with a respiratory condition ( $n = 14$ , 21%) and others ( $n = 12$ , 18%). Twenty-seven of these 188 initial participants were excluded by the pharmacists when criteria were reviewed; reasons for exclusion at this time were age < 40 years or previous lung disease (Fig. 1).

The 161 remaining volunteers agreed to fill in the GOLD screening questionnaire for COPD. The average age of these participants was  $55 \pm 11$  years, 94 (58%) were women, and 124 (77%) were smokers or ex-smokers. The mean GOLD screening score was  $3.0 \pm 1.2$ . Sixty-one of the 161 respondents (38%) had a score < 3 and 100 (62%) a score of  $\geq 3$ , indicating they were at high risk for COPD (Table 1). The age and proportion of women in the two groups were similar. More high-risk customers were smokers or ex-smokers, and they also had a higher mean GOLD

screening score than those at low risk. Those in the high-risk group were offered spirometry; only three refused and one was excluded because she was ill with a respiratory infection at that time. Customers who attended spirometry had at least one symptom. Chronic cough was the most common (66%) but each symptom was present in about half the subjects (chronic sputum 54%, breathlessness 63%). Low-risk subjects were more frequently asymptomatic (chronic cough 6%, chronic sputum 5%, breathlessness 3%).

Thus, 96 high-risk subjects performed spirometry in the pharmacy. Sixty-five (68%) had an FEV<sub>1</sub>/FVC% ratio  $\geq 0.70$  and 21 (22%) had an FEV<sub>1</sub>/FVC% ratio < 0.70, indicating airflow limitation. The distribution of airflow limitation by age is shown in Fig. 2. Ten were unable to perform the manoeuvres correctly. Personal characteristics and spirometry results for those who performed a correct spirometry are shown in Table 2. According to our pre-bronchodilator data, airflow limitation was mild in 13 (62%) of the subjects in whom it was detected, moderate in 7 (33%) and severe in 1 (5%).

Out of the 86 patients who underwent spirometry, airflow limitation (FEV<sub>1</sub>/FVC ratio < 0.70) was detected in 21 (24%), and they were invited for referral to a hospital pulmonary function laboratory for further assessment. Only 11 (52%) subjects both accepted referral and actually went to the laboratory. In all cases, the airway obstruction was confirmed. Moreover, the lung function values recorded in the community pharmacy and in the hospital pulmonary function laboratory were similar in both settings (FEV<sub>1</sub>,  $P = 0.5$ ; FVC,  $P = 0.89$ ; and FEV<sub>1</sub>/FVC ratio,  $P = 0.14$ ) (Fig. 3). Of note, among those referred to the hospital, two presented a pre-bronchodilator FEV<sub>1</sub> < 60%.

Finally, spirometric curves in the pharmacy were of acceptable quality overall, with 70% rated as A or B quality by the spirometer software and 73% were considered of acceptable quality by the lung function expert. The quality rating tended to be even better in subjects with airflow limitation, 76% of whom were considered to have A or B quality curves, but the difference was not significant ( $P = 0.71$ ).

### Discussion

Individuals at high risk for COPD can be detected by spirometry screening undertaken by adequately trained pharmacists in urban community pharmacies. Our data show that pharmacists were able to identify customers with respiratory symptoms and/or smokers in a population in which the majority were middle-aged subjects who had never been tested for COPD. Furthermore, the pharmacists were able to supervise high quality spirometry manoeuvres in 70% of subjects, finding one case of airflow limitation for every five individuals tested, a rate that was similar to that reported for the UK primary care setting.<sup>16</sup>

Spirometry in the primary care setting has been shown to be useful in screening for COPD and it continues to be promoted as the means for diminishing the population underdiagnosis of this disease.<sup>17</sup> Additionally, the usefulness of reporting individual lung age to smokers has been elegantly confirmed recently.<sup>19</sup> However, lack of technical or human resources in primary care is a limiting

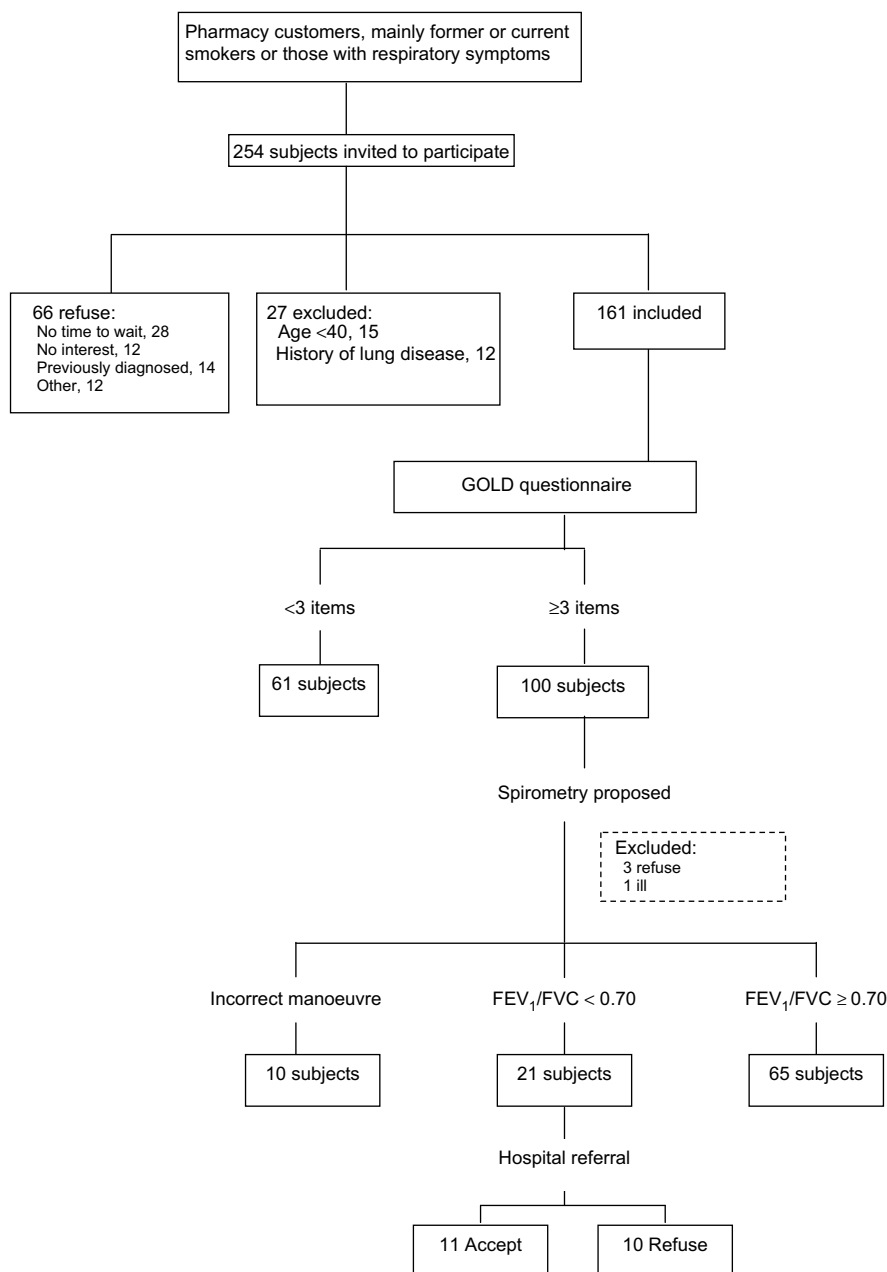


Figure 1 Flow chart showing subject processing from pharmacy to hospital referral.

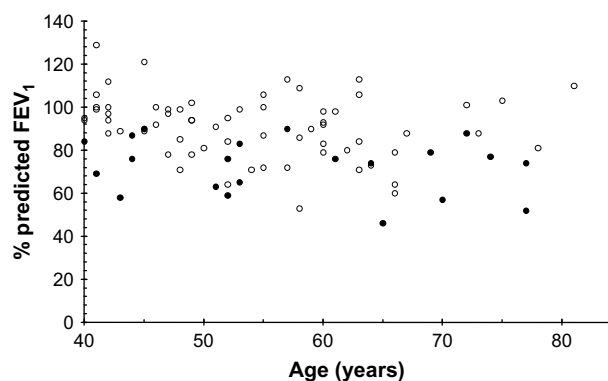
factor,<sup>18</sup> compounded by primary care physicians' low rate of request for spirometry.<sup>20</sup> Therefore, underdiagnosis in the primary care setting continues to be inordinately common.<sup>21</sup> In this pilot study, our finding

that the community pharmacy can provide a complementary setting for COPD case finding in the general population offers hope of improving the health care system's screening potential.

Table 1 Characteristics of the participating pharmacy customers.

	All customers (n = 161)	Low risk (n = 61)	High risk (n = 100)
Age, mean ± SD	55 ± 11	56 ± 11	55 ± 11
Women, n (%)	94 (58)	38 (62)	56 (56)
Smoking history, n (%)	124 (77)	36 (59)	88 (88) <sup>a</sup>
GOLD score, mean ± SD	3.0 ± 1.2	1.7 ± 0.4	3.8 ± 0.8 <sup>a</sup>

<sup>a</sup> Significant differences were found between low-risk and high-risk groups for smoking history (smokers or ex-smokers) (P = 0.01) and GOLD score (P = 0.01). GOLD = Global Initiative for Chronic Obstructive Lung Disease.



**Figure 2** Distribution of percent predicted FEV<sub>1</sub> by age for all participants (subjects with airflow limitation are represented by filled circles).

Widespread use of spirometry in screening for COPD has been questioned.<sup>2</sup> The current recommendations are to study subjects at high risk.<sup>2-4</sup> All subjects offered spirometry in our study were in fact symptomatic as detected by the questionnaire, suggesting that inappropriate resource consumption can be kept under control by applying a GOLD-criteria-based screening questionnaire. Our use of the GOLD screening questionnaire to assess the risk of COPD followed recommendations in the 2006 guidelines,<sup>4</sup> although recently validated questionnaires with the same goal are available elsewhere.<sup>22</sup>

Our study also shows that pharmacists can obtain valid spirometries if they are well-trained and highly motivated. Seventy percent of the spirometry curves were judged to be of A- or B-level quality after review by an expert in lung function testing; that success rate was higher than the reported 63% in a previous pharmacy study.<sup>8</sup> Only 10% of the subjects who were invited to perform spirometry in the community were unable to produce correct manoeuvres under the pharmacists' supervision, a situation quite similar to that reported for the primary care level.<sup>23</sup> The quality of spirometry was also reflected in the lack of differences in results in pharmacy and hospital measurements for the same subjects.

An interesting finding was the predominance of women among the pharmacy customers. Given that the prevalence of COPD in Spain has been found to be 14.3% in men and 3.9% in women in a population-based study,<sup>6</sup> we expected males to predominate among the tested subjects. However, women accounted for 58% of the subjects and 57% of the positive spirometries. The pharmacy seems to be a particularly good setting, therefore, to find cases in women, among whom the prevalence of COPD seems to be rising.<sup>24</sup>

A limitation of this study was the absence of a bronchodilator test. Although most guidelines recommend the use of post-bronchodilator spirometry to diagnose and stage COPD, other authors call for simplicity, especially for large-scale screening.<sup>15,25,26</sup> We ruled out the use of post-bronchodilator tests in pharmacies because of evident concerns about practicality, safety, and efficiency. Should this approach be implemented, we continue to consider that bronchodilator tests should be performed in the hospital laboratory after referral. Another limitation and the main logistical problem of this study is related to referral of subjects with possible COPD from the community pharmacy to the hospital. In our study, nearly half of those with spirometry results indicating airflow limitation declined a hospital appointment. No time or lack of interest were the reasons most often stated. We suspect that declining referral may reflect either a lack of interest in quitting smoking or milder disease. The general population has little knowledge about COPD,<sup>27</sup> in comparison with other conditions such as cardiovascular disease, and they, therefore, do not consider respiratory disease to be a serious personal threat.

To conclude, in this pilot study, we have shown that COPD case finding by spirometry in urban community pharmacies is feasible. Pharmacists have access to high-risk, middle-aged subjects who have never been tested for COPD, and if the pharmacists are correctly trained, they can detect airflow limitation by spirometry with results that are similar to those previously reported at primary care level. Pharmacists are health service professionals who are not presently involved in screening for COPD but whose

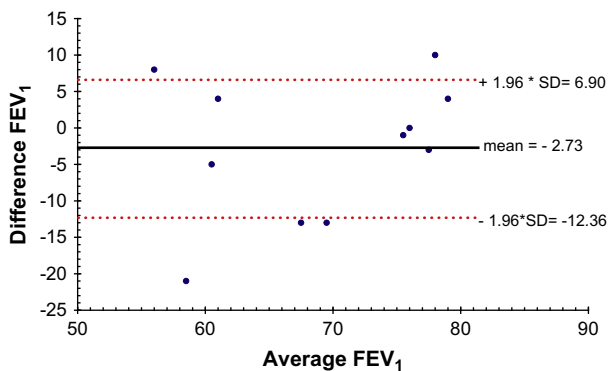
**Table 2** Characteristics and respiratory function data for subjects who performed spirometry correctly and were classified by FEV<sub>1</sub>/FVC ratio as having normal (ratio  $\geq 0.70$ ) or reduced airflow.

	All spirometries (n = 86)	Normal spirometry (n = 65)	Airflow limitation (n = 21)
Women, n (%)	49 (57)	37 (57)	12 (57)
Age (y)	55 $\pm$ 11	54 $\pm$ 10	57 $\pm$ 12
Smoking history, n (%)	74 (86)	56 (86)	18 (86)
GOLD score	3.8 $\pm$ 0.8	3.8 $\pm$ 0.8	3.7 $\pm$ 0.8
BMI	27.1 $\pm$ 5.1	27.8 $\pm$ 4.7	25 $\pm$ 5.7 <sup>a</sup>
FEV <sub>1</sub> (l)	2.5 $\pm$ 0.7	2.7 $\pm$ 0.6	2.1 $\pm$ 0.7 <sup>a</sup>
FEV <sub>1</sub> (% ref. val.)	86 $\pm$ 0.2	91 $\pm$ 0.1	72 $\pm$ 0.1 <sup>a</sup>
FVC (l)	3.4 $\pm$ 0.9	3.4 $\pm$ 0.9	3.24 $\pm$ 1.0
FVC (% ref. val.)	89 (0.2)	90 (0.2)	85 (0.1)
FEV <sub>1</sub> /FVC ratio	0.76 (0.1)	0.79 (0.1)	0.64 (0.1) <sup>a</sup>

Data are expressed as mean  $\pm$  SD unless otherwise noted.

<sup>a</sup> Significant differences in BMI ( $P = 0.03$ ), FEV<sub>1</sub> ( $P = 0.01$ ), FEV<sub>1</sub>% ( $P = 0.01$ ) and FEV<sub>1</sub>/FVC ratio ( $P = 0.01$ ) were found between the normal and abnormal spirometry groups.

FEV<sub>1</sub> = forced expiratory volume in 1 s; FVC = forced vital capacity; and GOLD = Global Initiative for Chronic Obstructive Lung Disease.



**Figure 3** Bland–Altman graph for comparison of the pharmacy- versus hospital-obtained percent predicted FEV<sub>1</sub>.

participation may represent a useful complementary strategy for early case finding.

### Conflict of interest statement

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