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### **REVIEW**



# Primary care spirometry\*

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ABSTRACT: Primary care spirometry is a uniquely valuable tool in the evaluation of patients with respiratory symptoms, allowing the general practitioner to diagnose or exclude chronic obstructive pulmonary disease (COPD), sometimes to confirm asthma, to determine the efficacy of asthma treatment and to correctly stage patients with COPD. The use of spirometry for case finding in asymptomatic COPD patients might become an option, once early intervention studies have shown it to be beneficial in these patients.

The diagnosis of airway obstruction requires accurate and reproducible spirometric measurements, which should comply with the American Thoracic Society (ATS)/European Respiratory Society (ERS) guidelines. Low acceptability of spirometric manoeuvres has been reported in primary care practices. This may hamper the validity of the results and affect clinical decision making. Training and refresher courses may produce and maintain good-quality testing, promote the use of spirometric results in clinical practice and enhance the quality of interpretation.

Softening the stringent ATS/ERS criteria could enhance the acceptability rates of spirometry when used in a general practice. However, the implications of potential simplifications on the quality of the data and clinical decision making remain to be investigated.

Hand-held office spirometers have been developed in recent years, with a global quality and user-friendliness that makes them acceptable for use in general practices. The precision of the forced vital capacity measurements could be improved in some of the available models.

KEYWORDS: Airways obstruction, American Thoracic Society/European Respiratory Society criteria, chronic obstructive pulmonary disease, flow-volume loop, forced expiratory volume in one second, pulmonary function

n increasing number of peer-reviewed papers tend to support the role of spirometry as a diagnostic and therapeutic tool in primary care [1, 2]. Moreover, access of general practitioners (GPs) and their practice staff to hand-held office spirometers has been proposed as an important instrument in the early diagnosis of asymptomatic patients with chronic obstructive pulmonary disease (COPD) [3]. The place of spirometry in general practice should be seen in the light of the epidemiology of chronic health problems in the community. Nowadays, COPD is Europe's fourth largest killer and, as the number of patients is strongly on the rise, COPD mortality will reach third place in the coming decades [4]. Despite this increase, recognition and diagnosis of the disease and, consequently, proper therapy are still relatively poor. It is estimated that up to 75% of COPD patients in Europe remain under-diagnosed [5]. Spirometry remains largely underused in primary care, despite the availability of specially designed hand-held spirometers at affordable prices [6–8]. The present study, which reviews the challenges in pursuing quality of spirometry in the primary care setting, is the result of a Round Table Conference organised to honour the memory of Prof. Romain Pauwels.

## OBJECTIVES OF PRIMARY CARE SPIROMETRY

The cost-effectiveness of the use of spirometry in primary care for case finding and early detection of COPD remains a matter of debate. At present, the only therapy for asymptomatic COPD patients consists of smoking cessation [9], advice which

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should be delivered to all smokers, independently of their spirometric status. Although a review recently commissioned by the Agency of Health Research and Quality (Rockville, MD, USA) concluded that little benefit may be expected from spirometric status as a motivational tool in giving up smoking or predicting cessation rates [10-17], an observational study performed in Polish smokers [18] suggested that spirometry, followed by immediate feedback, slightly improved smoking cessation in subjects with airways obstruction after 1 yr. However, from a public health perspective, effective smoking cessation is imperative even in subjects with normal pulmonary function and, for that reason, spirometry is not recommended in the promotion of smoking cessation. Screening of the whole population or populations at risk for COPD due to smoking remains a matter of discussion [16], since there is virtually no support to initiate drug treatment in asymptomatic COPD patients. Indeed, early intervention studies are still ongoing and the disease-modifying, life-prolonging effects of long-term treatment with inhaled bronchodilator or anti-inflammatory therapy have not been established so far [19].

There is definitely a very important role for office spirometry in patients (smokers, ex-smokers or nonsmokers) with respiratory symptoms, since spirometry facilitates the diagnosis of asthma or COPD [2]. In this manner, spirometry becomes an integral part of the diagnostic approach in primary care, where GPs pursue undifferentiated symptoms. Their diagnosis is often an early diagnosis and, occasionally, a tentative interpretation of the patient's health status, requiring further corroboration. In this diagnostic process, procedures are triggered by symptoms that patients present, but also by their risk profile or health problems encountered earlier in their medical history. The distinction between screening, case finding and early diagnosis is often arbitrary. In engaging respiratory morbidity, spirometry can be issued after the presentation of suspicious symptoms, but also on the basis of smoking status, family history of allergy or guided by earlier upper and lower respiratory tract episodes.

Chronic obstructive lung diseases (asthma, COPD) feature prominently in the practice population of the GP (table 1) [23, 24]. In the Netherlands, an average GP will encounter annually only eight new cases of asthma and seven of COPD, while

managing 50 patients with asthma and 60 with COPD [20]. Approximately 20% are under the treatment of a pulmonary specialist, emphasising the central role of primary care in diagnosis and management. The pre-test probability of airflow obstruction is increased in patients with respiratory signs and symptoms [9, 25], so spirometry is usually indicated to detect airflow obstruction in these patients. This is the primary care setting in which spirometry has to support clinical decision making, as it is the only way to document airflow obstruction. The need for spirometry may be further emphasised by the finding that not all symptomatic cases of asthma or COPD in the community are diagnosed ("under-diagnosis") [26], which makes primary care spirometry indispensable in the quest for early diagnosis and case finding [27].

The diagnostic process in primary care starts usually from undefined symptoms and spirometry has to be part of a symptoms-delineated diagnostic procedure, as indicated by the International Primary Care Airways Group [28]. The location of spirometry testing may be: 1) in the primary care setting; 2) in a traditional hospital-based pulmonary function laboratory; or 3) if convenient, in community-based service settings, run by experienced technicians or nurses using diagnostic-quality spirometers [29, 30]. Spirometry in the primary care office enables unrestricted access to patients visiting the practice, which is usually the case in the evaluation of signs and symptoms.

The annual presentation of shortness of breath or dyspnoea as a new respiratory symptom to GPs in the Netherlands is frequent, averaging 23 per 1,000 patients [21, 22]. An average GP may thus encounter 50–70 patients with dyspnoea yearly, depending upon the practice population. In particular, young children and elderly patients present with this symptom. Table 1 illustrates the diagnostic context of spirometry in general practices for a limited number of diseases, while ignoring the contribution of additional information, such as concomitant symptoms, comorbidities and physical examination.

GPs will always consider dyspnoea as a potential alarm symptom for severe chronic morbidity and start diagnostic reasoning from the presenting symptom. In general practice, only 1–10% of the patients with minor conditions, such as

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Incidence and prevalence of a selected number of respiratory and cardiac diseases in general practice, frequency of shortness of breath as the presenting symptom for the different diseases, and likelihood of diagnosis following presentation of shortness of breath

Disease	Incidence#	Prevalence#	Shortness of breath		
			Frequency as presenting symptom %	Likelihood of diagnosis following presentation %	
Asthma	3	21	29	10	
COPD	2.5	25	38	3	
Acute upper respiratory tract infection	193		1	7	
Acute bronchitis	22		10	28	
Heart failure	2	12	35	9	

Based on data from [20-22]. COPD: chronic obstructive pulmonary disease. #: data presented as number of cases per 1,000 patients.

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upper respiratory tract infections, present with dyspnoea, whereas dyspnoea is reported by 29–39% of patients with asthma, heart failure and COPD [20–22]. Given the much higher incidence of upper respiratory tract infections compared with asthma, heart failure and COPD, the likelihood of diagnosing an acute upper respiratory tract infection in patients presenting with dyspnoea in that setting is in the same order as that of asthma and heart failure, but somewhat higher than that in COPD (table 1). Spirometry will be directed, in this context, at excluding the presence of airflow obstruction, as much as at confirming it. This approach works for COPD, but not for all cases of asthma, a condition characterised by variable airways obstruction [31].

Spirometry could also assist the GP in optimising the pharmacological treatment of patients with asthma, in correctly staging the COPD patient, and in detecting those patients who should be referred for detailed diagnostic work-up due to insufficient response [2]. This approach necessitates that a reversibility test is performed in every new patient presenting with airflow obstruction.

Another potential role of office spirometry could be to avoid incorrect labelling of patients exhibiting respiratory symptoms suggestive of COPD. Indeed, spirometric signs of airway obstruction may be absent in 10–30% of patients labelled with a clinical diagnosis of COPD [3, 32–34]. A GP confronted with normal spirometry in a patient with persistent respiratory symptoms should thus consider an alternative diagnosis: asthma, congestive heart failure, interstitial lung disease, respiratory muscle weakness, obesity or pulmonary vascular disease. Further research on the negative predictive value of spirometry and the outcome or management of symptomatic patients with normal spirometry in general practice is needed.

#### APPLICABILITY OF AMERICAN THORACIC SOCIETY/ EUROPEAN RESPIRATORY SOCIETY CRITERIA IN PRIMARY CARE SPIROMETRY

Only accurate and reproducible spirometric measurements allow a diagnosis of airway obstruction, assessment of reversibility of airway obstruction and evaluation of response to therapeutic interventions. Submaximal manoeuvres or manoeuvres with artefacts may lead to an underestimation of vital capacity, occasionally to an underestimation of forced expiratory volume in one second (FEV1), but rarely to an overestimation of FEV1, the latter being caused by a decrease in dynamic compression of the airways [35]. Any underestimation of the forced vital capacity (FVC), or overestimation of the FEV1, may result in an overestimation of the FEV1/FVC ratio (potentially labelling an obstructive patient as normal); while any underestimation of FEV1 may yield an underestimation of the FEV1/FVC ratio (potentially labelling a normal subject as obstructive). As a consequence, the main problem to be expected from technically inappropriate spirometry is a false-positive test result. Inappropriate diagnosis and treatment that may follow from this can be harmful in terms of unnecessary stress and worry for the patient, sideeffects from inappropriate treatment and the withholding of effective treatments. Replication of spirometry to verify the status of patients with an initially positive test result is advised to reduce the impact of false-positive findings. No empirical data on the impact of inaccurate spirometric measurements in general practice have been published thus far.

In an attempt over the past few decades to improve the accuracy and reduce the variability of spirometric measurements, both the European Respiratory Society (ERS) and the American Thoracic Society (ATS) have issued guidelines on standardisation, which have recently been harmonised [36]. An acceptable FVC manoeuvre requires a rapid start of exhalation (low back-extrapolated volume), a prolonged exhalation time (near-zero end-expiratory flow) and a flow-volume loop without any significant artefact. Reproducibility should be within 5% or 150 mL for both the FEV1 and FVC, for at least two of the three manoeuvres [37].

It has been claimed that the ATS/ERS criteria are too stringent to be applied in office spirometry [3], since they might be exhausting for older patients or patients with severe respiratory impairment. Failures in general practice are predominantly end-of-test related [29] and, as FVC is an important spirometric index (especially its ratio with FEV1), this may hamper the validity of spirometry in general practice. As the end-of-test criterion is often a reason to fail to obtain three acceptable measures [29, 38], the National Heart, Lung and Blood Institute advised substituting the traditional FVC by forced expiratory volume in six seconds (FEV6) [3]. Several investigators supported this recommendation [39, 40], underlining the high specificity and sensitivity of the FEV1/FEV6 ratio for detection of airway obstruction. However, a recent analysis of a large database of spirometric tests has pointed out that discordances may exist between the new FEV1/FEV6 ratio and the traditional FEV1/FVC ratio. Using the 95 and 99% confidence limits as cut-off values to distinguish normality from abnormality, the newly proposed FEV1/FEV6 ratio resulted in 4.1% false negatives and reduced to 70% the sensitivity of spirometry to diagnose airflow obstruction, compared with the traditional FEV1/FVC ratio [41]. This occurred especially in older individuals and those with lesser obstruction, particularly smokers. Therefore, it seems that the FEV1/FEV6 ratio might not be the most appropriate test for early detection of airways obstruction, often encountered in a general practice. Tests of suboptimal quality or borderline abnormal results may further increase the degree of uncertainty in clinical decision making.

The 1994 ATS guidelines [42] and the most recent 2005 ATS/ ERS guidelines [37] remain somewhat vague in defining criteria for "significant artefact" and "start of test" of a forced expiratory manoeuvre, stating only that manoeuvres characterised by submaximal effort or manifest hesitation should be definitely rejected. Indeed, poor effort has been associated with an overestimation of FEV1 by >50 mL in 26% and by >150 mL in 7% of the manoeuvres [35]. It remains unclear what should be done with manoeuvres which show a slightly hesitant start, at least as long as the extrapolated volume does not exceed 150 mL or 5% of FVC. The potential impact of accepting manoeuvres that do not completely comply with ERS/ATS rules on clinical decision making is unknown. However, as long as the application of less stringent criteria has not been validated, the requirements issued by the ATS/ERS should be applied in all spirometric manoeuvres, both in institutional pulmonary function laboratories and primary care offices.



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### **QUALITY ASSESSMENT OF OFFICE SPIROMETERS**

GPs should be encouraged to perform high-quality spirometry, for which a good spirometer is at least as important as good training. Previous studies have been conducted to assess the quality of some hand-held office spirometers. In these studies [43, 44], the performance of a portable office spirometer was compared with conventional hospital-based equipment, which was then considered as the reference. Significant differences between the office spirometers and the reference were reported [43, 44]. Since the technology used in office spirometers is in constant evolution, it is difficult to assess the quality of the models currently present on the market, without testing them at regular time intervals. Moreover, circumstantial evidence is present that some office spirometers are of poor quality, which may render their use in daily practice difficult. This issue was recently addressed in a study [45], in which the technical properties of 10 spirometers designed for use in general practice (Spirobank®, Simplicity®, OneFlow®, Datospir 70®, Datospir 120®, SpiroPro®, EasyOne®, MicroLoop®, Spirostar® and Pneumotrac®) were evaluated. The 10 devices were first tested independently in three different pulmonary function laboratories for accuracy and precision. Thereafter, FVC and FEV1 were measured in 399 subjects with the office spirometers and with laboratory-based spirometers, which were used as reference. Three GPs also assessed the devices' userfriendliness, using a newly developed questionnaire.

The overall precision of office and reference spirometers for FEV1 measurements was comparable, except for one device, in which the limits of precision exceeded 200 mL. Three office spirometers showed precision limits exceeding 200 mL for FVC. Assessing the bias and limits of agreement between standard and office spirometers indicated that one spirometer presented a significant bias for FEV1, four spirometers for FVC and five for the FEV1/FVC ratio. However, these biases did not exceed 100 mL. Limits of agreement for FVC were sometimes very broad, falling between -1.00 and 1.07 L for one spirometer. Similarly, limits of agreement between -0.55 and 0.55 L were observed for FEV1 in one device. Only three devices had acceptable limits of agreement for FVC and four devices for FEV1. Some office spirometers presented a proportional difference on the FEV1 in comparison with hospital-based spirometers. For example, one of these spirometers underestimated lower volumes and overestimated larger volumes. The limits of agreement for the FEV1/FVC ratio between the reference and some office spirometers exceeded 10%.

The overall user-friendliness was estimated to be good, as was the information provided by the devices. However, most devices were unable to display the flow-volume loop or the time-volume curve during the manoeuvre, which is essential to assess the cooperation of the patient and, hence, the reliability of the measurement. Furthermore, most manufacturers claim that their portable devices do not have to be calibrated before the measurements. Although this is a potential advantage in primary care, it is reasonable to state that regular calibration of hand-held spirometers is vitally important as long as the stability over time of volume and flow measurements of hand-held spirometers has not been systematically addressed.

From these observations, it could be concluded that the global quality and user-friendliness of several office spirometers make them acceptable instruments for the detection of COPD, although the lack of agreement between the laboratory-based and office spirometers rules out interchangeability of spirometric values [45]. Manufacturers should focus especially on the improvement of the precision of FVC measurements, calibration issues and the ability to display the flow–volume and time–volume curves, in order to evaluate the quality of the measurements after the manoeuvre.

The software of most hand-held spirometers allows the expression of measured flow and volumes as a percentage of predicted values. However, it is essential that the user has the ability to use reference values that correspond with the characteristics of the patient population. Thus, the software should not only contain the National Health and Nutrition Examination Survey III and ERS reference values, but it should also allow the download of additional reference values.

## EFFECTS OF TRAINING ON THE QUALITY OF SPIROMETRY

Since portable spirometers became available, some concern about the quality of office spirometry has been expressed. Several authors emphasised the importance of intensive training of technicians, GPs or practice nurses, whoever is involved with the performance and interpretation of spirometry [46–48]. Conversely, the consensus statement from the National Lung Health Education Program in the USA about office spirometry [3] stated that "office spirometers must be sold with easy-to-understand educational materials", as "it is unlikely that many primary care physicians will spend the time and money necessary to send their technician or nurse to a 2-day spirometry training course." The same document urged further research regarding the levels of training required to obtain results of acceptable quality.

Aspects of training and learning curves of each individual patient undergoing spirometric evaluation fall beyond the scope of the present review. It is likely that acceptable and reproducible tests will be more difficult to obtain in a naïve population, *e.g.* in screening or case-finding settings, than in a group of asthma and COPD patients who are used to performing spirometry tests.

Adequate training of GPs and/or their staff reduces underutilisation of spirometry in patients with obstructive airway disease [49]. Data on the effects of training on the quality of spirometric manoeuvres have also been reported. Bellia et al. [50] trained 48 staff members in spirometry over 3.5 days. The teaching programme consisted of 15 h of lectures and workshops. It covered various aspects of pulmonary disease, the rationale and practice of spirometry, and the ATS standardised procedure. It included individual and group sessions about calibration, use and maintenance of the instrument. Trainees also received information about problems peculiar to geriatric patients, the target group in their study [50]. All trainees underwent a written and a practical examination. After 1 yr, all trainees attended a 1-day meeting in which the performance of each centre was reviewed and compared with the overall achievement of the project. Two remarkable evolutions were observed. There was a significant trend towards improvement in the reproducibility of the spirometric tests, whereas there was no change for acceptability. There was a clear linear

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correlation between the percentage of acceptable tests of individual centres and the number of tests performed.

The study by EATON et al. [38] is one of the few prospective, controlled studies in this field. The spirometry training given to the primary care nurses and doctors was of rather short duration. Over 2 h, theoretical and practical aspects of spirometry performance were covered, with particular attention paid to acceptability and reproducibility criteria and the importance of quality assurance. After 12 weeks, a 90-min "maintenance of standards" workshop was held. This was followed by an individual discussion with each practitioner about the results of the written and practical assessments, and feedback about the spirometry they had performed. Both the knowledge and the performance of the practitioners improved significantly after the initial training, decreased as a function of time, and improved again after the reminder workshop. The spirometry quality assurance data were significantly better for the trained practitioners, compared with a control group. Despite this training, the authors concluded that the spirometry performed in primary care did not generally satisfy ATS criteria for acceptability and reproducibility.

In a more recent study, SCHERMER et al. [30] found that the validity and quality of spirometric tests in general practice was satisfactory in comparison with the same procedure performed by the same group of COPD patients in a pulmonary function laboratory. The costs of enhancing the expertise of GPs and their staff were low, but the organisation of spirometry facilities in the practice must be addressed, since poorly performed spirometry could lead to an increased and inappropriate referral to chest physicians. This again stresses the importance of adequate training and quality for successful spirometry in primary care. The training of the GPs and practice assistants in the Dutch group consisted of two 2.5-h sessions separated by an interval of 1 month. In table 2, the content of this course is compared with the course carried out in New Zealand [38]. The Dutch course [30] emphasised those elements of the test performance that are known often to be insufficient in general practice.

EATON et al. [38] stated that "longer, more intensive workshops may have produced better results. However, if spirometry is to be widely available in primary care, the sheer logistics of training and maintaining standards among large numbers of GPs dictates a condensed and pragmatic training programme." The logistic implications for healthcare systems cannot be overemphasised: GPs are the single largest group of medical practitioners in most countries, but as they are in regular contact with the majority of patients in their communities [51], investment in primary care spirometry may also yield benefits for public health.

As has been stated earlier, different opinions exist about the role and function of office spirometry. If this technique is only dedicated to screening or case finding, it is probably useless to provide GPs with exhaustive knowledge and skills in this domain. If diagnostic decisions [52] and follow-up measurements are within the scope of office spirometry, a broad spectrum of competences should be included in a GPs training programme, whereas training for practice nurses or technicians can be more concise and focus merely on techniques and criteria for acceptability and reproducibility.

The spirometry performed in primary care needs continuous quality control, given the fact that many other tasks are to be carried out and a variety of pathologies cared for. Indeed, several studies [30, 38, 50] showed a decline in overall quality of spirometry with the time elapsed after the initial training. EATON *et al.* [38] showed that refresher courses and individual feedback are effective in improving quality. SCHERMER *et al.* [53] concluded that educational outreach visits by pulmonary function technicians, on top of a basic spirometry training programme, have added value in maintaining the validity of spirometric testing in general practice. Educational outreach visits with tailored individual feedback have been shown effective in improving healthcare provision in primary care in other research domains [54].

It is tempting to use the new opportunities that the internet provides in terms of teaching spirometry. Lum and Gross [55] demonstrated that a simple computer-based tutorial on spirometry with a time commitment of  $\sim 30$  min can influence positively the ability to interpret spirograms correctly.

TABLE 2

Comparison of spirometry training in New Zealand (A) [38] with spirometry training for Dutch general practitioners (B) and practice assistants (C) [30]

Items	Α	В	С
Duration of initial training	120 min	150 min	150 min
Duration of reminder workshop	90 min	150 min	150 min
Written assessment	Yes	NA	NA
Practical assessment	Yes	NA	NA
Individual feedback	Yes	NA	NA
Content of first training			
Asthma and COPD (pathophysiology)		Χ	Χ
Indications for spirometry in primary care		Χ	
Definition of the variables	Χ	Χ	
Physiology of flow-volume curve	Χ	Χ	Χ
ATPS-BTPS	Χ		
Normal predicted values	Χ	Χ	
Quality issues	Χ	Χ	Χ
Post-bronchodilator testing (theory)	Χ		
Demonstration of devices	Χ	Χ	Χ
Practical experience	Χ	Χ	Χ
Content of second training			
Summary of the first session		Χ	Χ
Quality assurance (revision)	Χ		
Individual feedback	Χ		
Interpretation of flow-volume curves	Χ	Χ	
Practical experience with individual feedback	Χ		Χ
Review of clinical cases		Χ	
Implementation and organisation of spiro-		Χ	
metry			
Reversibility testing			Χ
Sharing experiences and problems			X

NA: information not available; COPD: chronic obstructive pulmonary disease; ATPS: ambient temperature and pressure saturated with water vapour; BTPS: body temperature, ambient pressure, saturated with water vapour.



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However, it is very likely that web-based training has to be complemented by hands-on sessions.

The internet could also be used in the context of pulmonologist-supervised spirometry. For instance, a pulmonologist could use internet technology to evaluate spirometric results, examine the clinical findings originating from the GP office and provide advice about difficult cases.

#### **CONCLUSIONS**

Spirometry is an important diagnostic tool for general practice and should have a central role in the diagnosis and management of chronic respiratory diseases. Detailed guidelines about how to perform the technique are available, as are reliable hand-held office spirometers. There are various ways in which high-quality spirometry can be made available to primary care. One feasible scenario is equipping, training and supervising GPs and their staff in performing spirometry in their own practice. To ensure quality, the practice nurse has to be trained on how to perform spirometry and GPs on how to evaluate spirograms. Only under these prerequisites, office spirometry can help identify the presence of asthma and COPD.

The exact role of spirometry in the early detection of airway obstruction remains to be assessed. However, spirometry plays a key role in patients presenting symptoms suggestive of a chronic respiratory disease, and the use of these symptoms to guide its application. General practitioners should thus be aware of the primary care principle that an alarming symptom is more often an uncommon presentation of a common illness, such as an upper respiratory tract infection, than the regular manifestation of, at least in general practices, less frequent diseases, such as asthma or chronic obstructive pulmonary disease. For that reason, testing the validity of spirometry in confirming and excluding obstructive airway disease under primary care conditions should be a priority, since the primary aims of office spirometry should be an improved quality of diagnosis and treatment of chronic respiratory disorders. Due to the growing number of patients, the diagnosis of asthma and chronic obstructive pulmonary disease should take place in general practice.

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