Quality of routine spirometry tests in Dutch general practices

Tjard RJ Schermer, Alan J Crockett, Patrick JP Poels, Jacob J van Dijke, Reinier P Akkermans, Hans F Vlek and Willem R Pieters

ABSTRACT

Background
Spirometry is an indispensable tool for diagnosis and monitoring of chronic airways disease in primary care.

Aim
To establish the quality of routine spirometry tests in general practice, and explore associations between test quality and patient characteristics.

Design of study
Analysis of routine spirometry test records.

Setting
Fifteen general practices which had a working agreement with a local hospital pulmonary function laboratory for spirometry assessment regarding test quality and interpretation.

Method
Spirometry tests were judged by a pulmonary function technician and a chest physician. Proportions of test adequacy were analysed using markers for manoeuvre acceptability and test reproducibility derived from the 1994 American Thoracic Society spirometry guideline. Associations between quality markers and age, sex, and severity of obstruction were examined using logistic regression.

Results
Practices performed a mean of four (standard deviation = 2) spirometry tests per week; 1271 tests from 1091 adult patients were analysed; 96.4% (95% confidence interval [CI] = 95.6 to 97.2) of all tests consisted of ≥3 blows. With 60.6% of tests, forced expiratory time was the marker with the lowest acceptability rate. An overall 38.8% (95% CI = 36.0 to 41.6) of the tests met the acceptability as well as reproducibility criteria. Age, sex, and severity of obstruction were associated with test quality markers.

Conclusion
The quality of routine spirometry tests was better than in previous reports from primary care research settings, but there is still substantial room for improvement. Sufficient duration of forced expiratory time is the quality marker with the highest rate of inadequacy. Primary care professionals should be aware of patient characteristics that may diminish the quality of their spirometry tests. Further research is needed to establish to what extent spirometry tests that are inadequate, according to stringent international expert criteria, result in incorrect clinical interpretations in general practice.

Keywords
diagnosis; family practice; lung diseases, obstructive; quality of health care; spirometry.

INTRODUCTION

Spirometry is currently being promoted as an indispensable tool for primary care doctors and nurses to diagnose and monitor chronic airways disease.[1,2] Several previous studies indicate that primary care spirometry increases rates of diagnosis for chronic respiratory disease and may also lead to improvements in its treatment.[3–5] However, good-quality spirometry requires comprehensive training of staff, reliable equipment, and well-standardised measurement procedures.[6] This may be difficult to achieve in primary care practice, especially when tests are rather infrequently administered, which appears to be the case in most practices.[7]

In a previous study by the current authors it was observed that the most relevant spirometric indices,

***TRJ Schermer**, MSc, PhD, senior researcher, Department of Primary and Community Care, Asthma and COPD Research Unit, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands, and Primary Care Respiratory Research Unit, Discipline of General Practice, School of Population Health and Clinical Practice, University of Adelaide, Australia. **AJ Crockett**, PhD, associate professor, Primary Care Respiratory Research Unit, Discipline of General Practice, School of Population Health and Clinical Practice, University of Adelaide, Australia. **PJP Poels**, MD, PhD, GP; **RP Akkermans**, MSc, statistician, Department of Primary and Community Care, Asthma and COPD Research Unit, Radboud University Nijmegen Medical Centre, Nijmegen and General Practice Bles and Poels, Huissen, The Netherlands. **JJ van Dijke**, MD, GP, General Practice Van Dijke, Westervoort, The Netherlands. **HF Vlek**, MD, PhD, Quartz Transmural Centre, Helmond, The Netherlands. **WR Pieters**, MD, chest physician, Department of Pulmonary Medicine, Elkerliek Hospital, Helmond, The Netherlands.*

Address for correspondence
Tjard RJ Schermer, Radboud University Nijmegen Medical Centre, Department of Primary and Community Care (117-ELG), PO Box 9101, 6500 HB Nijmegen, The Netherlands.
E-mail: t.schermer@elg.umcn.nl

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as measured by trained general practice staff, were comparable to those measured in pulmonary function laboratories.[8] In an earlier study, investigators from New Zealand demonstrated a significant effect of spirometry workshops on test quality, but concluded that the spirometry performed in primary care practices did not generally satisfy the full criteria for acceptability and reproducibility.[9] One feature that these two studies have in common is that they were both conducted as research exercises. Because of this, the findings may not provide a reflection of the actual quality of spirometry as performed in usual primary care practice.

In an attempt to arrange good-quality primary care spirometry, 15 general practices in the region surrounding the Elkerliek general hospital in the city of Helmond, the Netherlands have established a working agreement with the hospital regarding the support of spirometry training, interpretation, and performance. Practices can request on-site technical support and supervision by a technician from the hospital's pulmonary laboratory service. The current study aimed to establish the quality of routine general practice spirometry tests within this 'real-life' setting. In addition, it explored whether in this particular setting the quality of spirometry tests is associated with patients' sex and age, and the presence of obstruction.

How this fits in

Spirometry is an indispensable tool for primary care doctors and nurses to diagnose and monitor chronic airways disease. Good-quality spirometry requires comprehensive training of staff, reliable equipment, and well-standardised measurement procedures, which may be difficult to achieve in a general practice. In this study, the quality of routine spirometry tests was better than in previous reports from primary care research settings, but there is still substantial room for improvement. Sufficient duration of forced expiratory time is the quality marker with the highest rate of inadequacy. Primary care professionals should be aware of patient characteristics that may diminish the quality of their spirometry tests.

METHOD

Setting and spirometry tests

Using a central database, analysis was carried out of all routine care spirometry tests (either a prebronchodilator test alone or a full reversibility test consisting of a prebronchodilator and a postbronchodilator test) that had been submitted by GPs from March 2003 to August 2005. Each of the 15 general practices involved owns a PC-based spirometer and software (SpiroPerfect™, Welch Allyn, Delft, the Netherlands). The hospital's pulmonary laboratory service has direct access to the tests submitted by GPs. Spirometry training and support has been offered to GPs (with a focus on test interpretation), practice nurses, and practice assistants (with a focus on performing tests) once or twice a year since the late 1990s.

After online submission of results to the central database, the quality of spirometry tests is first judged by a pulmonary function technician. Based on the 1994 American Thoracic Society spirometry guideline,[6] several spirometry quality markers were derived for every test submitted by the general practices. (It was decided not to use the more recent 2005 guideline[10] because it had not yet been published at the time when the spirometry tests were performed.) Box 1 shows the test quality markers as extracted from the 1994 American Thoracic Society

Box 1. Markers of spirometry test quality as derived from the 1994 American Thoracic Society spirometry guideline.[6]

	Criteria to differentiate test quality	Included in current study
▶ Markers for acceptability of separate blows		
Flow–volume curve shows steep initial incline	Acceptable versus unacceptable	Yes
Flow–volume curve shows sharp peak	Acceptable versus unacceptable	Yes
Flow–volume curve shows uninterrupted forced expiration	Acceptable versus unacceptable	Yes
Forced expiration of reasonable duration[a]	Acceptable versus unacceptable	Yes
Forced expiratory time	<6 seconds versus ≥6 seconds	Yes
Back-extrapolated volume	<5% of FVC or 0.15 litre, whichever is greater	No
Volume–time curve shows an obvious plateau[b]	Acceptable versus unacceptable	No
▶ Markers for reproducibility of test		
Number of acceptable forced manoeuvres	≥3 manoeuvres versus <3 manoeuvres	Yes
Reproducibility[c] of FEV_1	<0.2 litre versus ≥0.2 litre	Yes
Reproducibility[c] of FVC	<0.2 litre versus ≥0.2 litre	Yes

FVC = forced vital capacity. FEV_1 = forced expiratory volume in 1 second. [a]For patients with airways obstruction or older patients, exhalation times longer than 6 seconds are frequently needed to reach a plateau. [b]No change in volume for at least 1 second after an exhalation time of at least 6 seconds. [c]Difference between highest and second highest values of the two manoeuvres with the highest sum of FEV_1 and FVC.

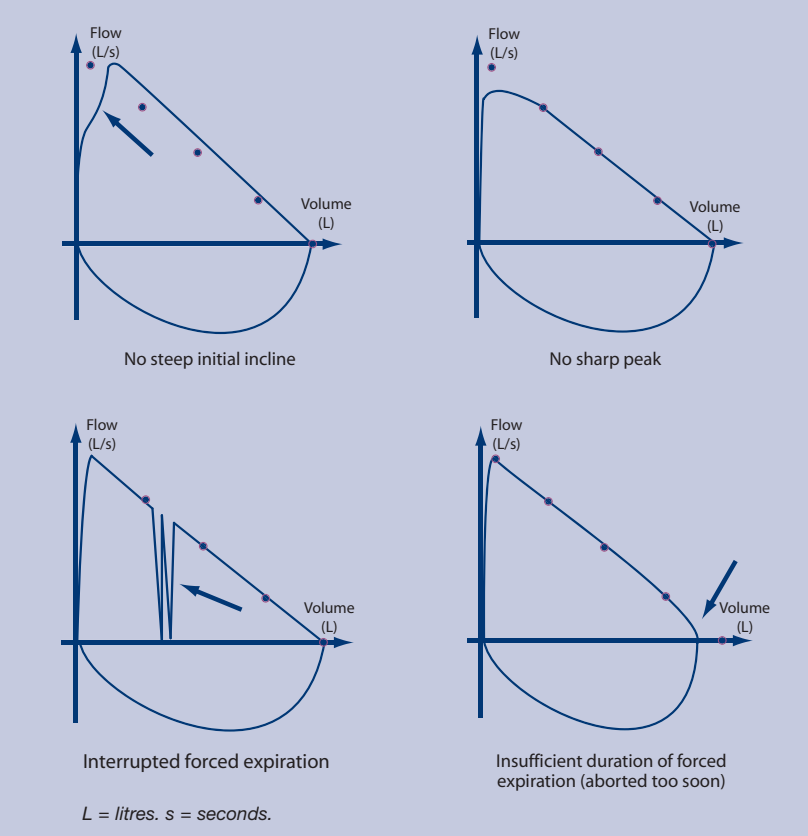

Figure 1. Examples of unacceptable spirometry test quality markers as read from the flow–volume curve.

spirometry guideline, and for each marker whether or not it could be included in the study analysis of general practice spirometry test quality. Figure 1 shows examples of unacceptable blows for markers that can be judged from the flow–volume curve. After the pulmonary function technician's quality assessment, each test is diagnostically assessed by one of the hospital's chest physicians, who records the presence and/or severity of airflow obstruction, reversibility after bronchodilation, and a possible restrictive pattern. The combined results of the quality assessment and the diagnostic assessment of each test are reported back to the general practice.

Table 1. Characteristics of the study population (*n* = 1091) and the subgroup identified with airflow obstruction as judged by a chest physician (*n* = 675).[a]

		Presence of obstruction according to chest physician (*n* = 675)				
	Total	No	Mild	Moderate	Severe[c]	*P*-value[b]
n	1091	357	136	112	70	
Sex, % male	49.0	42.3	49.3	60.7	71.4	<0.001
Age, years	53.4 (16.9)	47.5 (16.2)	50.2 (16.4)	60.9 (13.8)	65.8 (11.0)	<0.001
FEV_1,[d] litres	2.52 (0.93)	3.07 (0.74)	2.60 (0.79)	1.96 (0.61)	1.33 (0.52)	<0.001
FEV_1 % predicted[d]	82.5 (21.0)	98.1 (14.3)	83.1 (13.0)	66.9 (11.5)	48.1 (17.4)	<0.001
FVC,[d] litres	3.35 (1.10)	3.74 (0.93)	3.68 (1.15)	3.12 (0.93)	2.59 (0.92)	<0.001
FEV_1/FVC,[d] %	75.2 (12.6)	82.5 (6.8)	71.2 (8.9)	63.6 (8.8)	52.1 (11.8)	<0.001

[a]Figures are means (SD) unless stated otherwise. [b]Test for differences between subgroups based on severity of airflow obstruction. [c]Including very severe obstruction. [d]Based on first postbronchodilator measurement available in the database for each patient. FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity.

Statistical analysis

For repeated measurements, the same patient could contribute multiple spirometry tests. For the analysis of spirometry test quality, only the prebronchodilator tests of patients aged ≥12 years were used. After analysis of the test quality markers for the total study population, 675 patients (62%) could be stratified according to the severity of their airflow obstruction as judged by a chest physician. When the chest physician had judged that obstruction was present but had not indicated the severity (12% of all patients with obstruction), the cut-off values from the Global Initiative for Chronic Obstructive Lung Disease guideline[11] were used to categorise severity: forced expiratory volume in 1 second (FEV_1) % predicted >80% for mild; 50–80% for moderate; and <50% for severe and very severe obstruction. European Coal and Steel Community reference equations were used to calculate FEV_1 predicted values.[12] Patient characteristics were compared between severity subgroups using χ^2 tests and analysis of variance. Multivariable logistic regression analysis was used to explore associations between spirometry test quality markers and sex, age, and severity of obstruction. The odds ratio (OR) estimates from the logistic regression models express the (adjusted) risk for an inadequate test quality marker to be present. Statistical tests were two-sided, and $P<0.05$ was considered statistically significant.

RESULTS

General practices

Spirometry tests had been submitted by all 15 general practices comprising 49 GPs (mean number of GPs per practice = 3.3, range = 1–5). Two practices (13%) had implemented spirometry <1 year ago, three practices for 1–2 years ago, and the remaining practices ≥2 years ago. A mean of four spirometry tests (standard deviation [SD] = 2) were performed per week. Spirometry was administered by a practice assistant in 12 practices, by a practice nurse in six practices, and by a GP in two practices (in some practices, more than one type of healthcare professional administered spirometry).

Patients

Mean age of the study population (*n* = 1091) was 53.4 (SD 16.9) years (Table 1), and mean FEV_1 %

predicted was 82.5% (SD 21.0%); 143 patients (13.1%) contributed two spirometry tests to the database on two different dates, 18 patients (1.7%) contributed three or more tests. Bronchodilator reversibility testing was performed in 92.5% of all the patients involved.

Indications for spirometry as reported by the GPs were: (re)assessment of previous diagnosis of chronic airways disease, including tests to assess possible exacerbations (42%); diagnostic assessment without prior diagnosis of chronic airways disease (35%); periodic monitoring of lung function (13%); evaluation of diagnostic prednisolone test (6%); and screening of smokers (4%).

Acceptability and reproducibility of spirometry tests

A total of 1271 prebronchodilator tests comprising 3968 forced expiratory manoeuvres (blows) were available for analysis. Mean number of blows per test was 3.1 (range = 1–9) and 97.8% (95% confidence interval [CI] = 97.0 to 98.6) of all tests consisted of three or more blows; 38.8% (95% CI = 36.0 to 41.6) of the tests met the acceptability as well as the reproducibility criteria (Table 2). The proportion of tests that met all five assessed acceptability markers was 43.3% (95% CI = 40.2 to 45.8; Table 3).

In 37.6% of all tests, one marker was judged by the pulmonary function technician to be unacceptable, two markers in 11.4%, three markers in 5.2%, and four or five markers in 2.5%. With 60.6%, forced expiratory time was the marker with the lowest rate of acceptability. The average forced expiratory time was 7.6 seconds (SD 3.9 seconds). Adequacy of the other acceptability markers ranged from 80.5% for duration of the forced expiration to 92.7% for steep initial incline of the flow–volume curve (Table 3).

Associations between acceptability markers and patient characteristics

Age, sex, and severity of obstruction were associated with one or more of the acceptability markers (Table 4). Compared with males, females had a higher 'risk' of unacceptable blows for two markers, that is, duration of forced expiration (OR = 1.57, 95% CI = 1.15 to 2.14) and initial incline to peak flow (OR = 3.00, 95% CI = 1.50 to 6.00). In one or more of the older age groups, the risk of an unacceptable marker increased for initial incline to peak flow, sharpness of peak, and course of forced expiration. The presence of obstruction showed an inverse relationship with the initial incline to peak flow, sharpness of peak, course of forced expiration, and duration of the forced expiration (Table 4). When the fully acceptable tests were offset against the tests with one or more markers that indicated unacceptability, females showed a higher risk of test unacceptability (OR = 1.67, 95% CI = 1.23 to 2.35; not shown in Table 4).

Table 2. Quality assurance data from 1271 prebronchodilator spirometry tests from the 15 general practices involved in the study.

	Number of tests	% (95% CI)
Number of patient tests[a]	1271[a]	100
≥3 blows	1243	97.8 (97.0 to 98.6)
≥3 acceptable blows	550	43.3 (40.2 to 45.8)
≥2 acceptable and reproducible blows	493	38.8 (36.0 to 41.6)

[a]*Comprising 3968 blows.*

DISCUSSION

Summary of main findings

This study aimed to establish the quality of general practice spirometry tests outside a typical research setting, and explored whether spirometry test quality was associated with patients' sex and age, and the presence of obstruction in patients tested in general practice. It was found that 39% of all tests performed in the general practices met the combined set of acceptability and reproducibility markers as derived from the 1994 American Thoracic Society spirometry guideline. Too short forced expiratory time was the marker with the lowest rate of acceptability (60.6%). Several associations were observed between test acceptability markers and sex, age, and presence or severity of airflow obstruction.

Strengths and limitations of the study

Particular strengths of this study are that all the tests in the spirometry database were obtained from 'regular' (that is, non-academic) general practices, and that they were performed as a part of routine testing in daily patient care. Compared to Dutch national figures, the general practices in the present

Table 3. Results of overall assessment of acceptability markers for 1271 general practice spirometry tests comprising 3968 forced expiratory manoeuvres.

	% adequate	95% CI
Flow–volume curve shows steep initial incline[a]	92.7	91.3 to 94.1
Flow–volume curve shows sharp peak[a]	88.1	86.3 to 89.9
Flow–volume curve shows uninterrupted expiration[a]	84.3	82.3 to 86.3
Forced expiration of reasonable duration[a]	80.5	78.3 to 82.7
Forced expiratory time	60.6	58.6 to 62.6
Adequate for all acceptability markers	43.3	40.2 to 45.8

[a]*According to judgement of pulmonary function technician.*

Table 4. Results of multivariable logistic regression analyses for associations between markers of forced expiratory manoeuvre acceptability and sex, age, and degree of airflow obstruction as established by a chest physician.

Acceptability marker	OR (95% CI)	*P*-value
Initial steep incline of flow–volume curve		
Females[a]	3.00 (1.50 to 6.00)	0.002
50–60 years[b]	2.41 (0.92 to 6.30)	0.073
60–70 years[b]	7.03 (2.94 to 16.81)	<0.001
>70 years[b]	5.87 (2.11 to 16.32)	0.001
Mild obstruction[c]	0.28 (0.10 to 0.77)	0.013
Moderate obstruction[c]	0.47 (0.20 to 1.10)	0.080
(Very) severe obstruction[c]	0.09 (0.12 to 0.69)	0.021
Sharp peak of flow–volume curve		
Females[a]	1.46 (0.89 to 2.40)	0.133
50–60 years[b]	1.10 (0.58 to 2.11)	0.764
60–70 years[b]	2.76 (1.51 to 5.04)	0.001
>70 years[b]	1.12 (0.46 to 2.75)	0.799
Mild obstruction[c]	0.20 (0.09 to 0.46)	<0.001
Moderate obstruction[c]	0.29 (0.14 to 0.63)	0.002
(Very) severe obstruction[c]	0.05 (0.01 to 0.38)	0.004
Uninterrupted course of expiratory part of flow–volume curve		
Females[a]	1.06 (0.68 to 1.64)	0.789
50–60 years[b]	1.04 (0.58 to 1.85)	0.894
60–70 years[b]	2.31 (1.33 to 4.03)	0.003
>70 years[b]	1.30 (0.62 to 2.83)	0.485
Mild obstruction[c]	0.17 (0.08 to 0.37)	<0.001
Moderate obstruction[c]	0.20 (0.10 to 0.43)	<0.001
(Very) severe obstruction[c]	0.25 (0.11 to 0.60)	0.002
Duration of forced expiration ≥6 seconds		
Females[a]	1.57 (1.15 to 2.14)	0.005
50–60 years[b]	0.68 (0.45 to 1.03)	0.069
60–70 years[b]	1.14 (0.75 to 1.74)	0.540
>70 years[b]	0.72 (0.44 to 1.19)	0.197
Mild obstruction[c]	0.60 (0.40 to 0.88)	0.010
Moderate obstruction[c]	0.31 (0.19 to 0.49)	<0.001
(Very) severe obstruction[c]	0.50 (0.29 to 0.86)	0.013
Reasonable duration of forced expiration		
Females[a]	0.97 (0.63 to 1.48)	0.876
50–60 years[b]	1.16 (0.66 to 2.03)	0.609
60–70 years[b]	1.32 (0.74 to 2.35)	0.353
>70 years[b]	1.31 (0.69 to 2.49)	0.401
Mild obstruction[c]	0.90 (0.50 to 1.61)	0.719
Moderate obstruction[c]	1.16 (0.65 to 2.06)	0.617
(Very) severe obstruction[c]	2.09 (1.12 to 3.89)	0.020

Odds ratio (OR) expresses the risk of an inadequate test quality marker compared to the reference category. Statistically significant associations (P<0.05) are printed bold. [a]Males as reference category. [b]Age <50 years as reference category. [c]No obstruction as reference category.

study were mostly group practices with three or more GPs (56% versus 13% nationally), had slightly less experience with spirometry (6 versus 7 years), and performed a similar number of spirometry tests per month (16 versus 17 tests/month).[13,14] A weakness of the study may be that all practices involved in the evaluation participated in the working agreement with the local hospital, which may limit the external validity of the findings; it is not possible to tell from this study how practices that have no expert support for their spirometry would perform.

Despite these shortcomings, the present findings contribute to the current knowledge regarding spirometry test quality in primary care, and identify points of impact for quality improvement.

Comparison with existing literature

Too short forced expiratory times and early termination of expiratory manoeuvres have previously been recognised as one of the main deficiencies of spirometry in general,[15,16] and of primary care spirometry in particular.[9,17] In this study, associations were observed between several spirometry acceptability markers and both presence of airflow obstruction and older age. An association between older age and worse spirometry test performance has been reported previously, and is likely to be explained by cognitive impairment in older people.[9,18–20] Contrary to previous reports in which male sex was associated with poorer reproducibility of FEV_1,[19] the present study showed an association of female sex with test inadequacy for two acceptability markers: forced expiratory time and initial incline to peak flow. The explanation may be that females feel more embarrassed than males while performing forced expiratory manoeuvres because of the possibility of leaking urine.[13]

Differences between previous studies and the present observations may be caused by several factors. Different levels of spirometry training among the primary care professionals who administer the tests is certainly one of these factors.[7] The achievements of the general practices in the current study contrast with those previously reported from a New Zealand study, which showed far more dramatic results: 3–13% percent of all tests were acceptable and reproducible, with almost the same set of criteria as used in the present study.[9]

A comparison with the studies reported from pulmonary function laboratories shows that in research as well as in routine care the proportion of reproducible tests is generally at least 90% (Appendix 1). It is doubtful whether primary care professionals will ever be able to approach this performance level. Apart from limited training and quality assurance activities, lack of experience and routine are likely to be important factors in the high rate of low-quality spirometry tests observed in general practice.[7,21] On the other hand, it is currently unclear what the actual impact of inadequate spirometry tests on diagnosis and patient management is. The current authors have previously demonstrated that, compared with measurements from pulmonary function laboratories in the same patients, FEV_1 and forced vital capacity as measured by trained general practice staff do not necessarily result in differences that are relevant in general practice.[22] This suggests

that an important proportion of spirometry tests that are technically 'imperfect' according to the stringent international test criteria[6,10] may still provide the GP with useful results on which to base diagnosis and patient management. In the authors' view, obtaining sufficiently reliable and clinically meaningful spirometry tests — not necessarily perfect tests — is what primary care should be striving for.

If spirometry is to be widely available in primary care, the logistics of training and maintaining standards among large numbers of primary care physicians and nurses requires condensed and pragmatic training programmes. However, training alone will not guarantee sufficient test quality in the longer term.[9,19] A recent report from the UK concluded that the quality of primary care spirometry was unsatisfactory, and its authors suggested that remote reporting of tests may be a means of establishing adequate spirometry.[23] Studies conducted in specialised,[16,18,19,24,25] as well as in primary care settings[9,26] suggest that quality-assurance initiatives are able to improve spirometry test quality.

Implications for clinical practice

In this real-life study it was found that quality aspects of spirometry tests in Dutch general practice were better than those previously reported from primary care research settings, but test quality does not approach the levels observed in pulmonary function laboratories. Duration of forced expiration is the quality marker with the highest rate of inadequacy. Primary care professionals who administer spirometry to their patients should be aware of the patient characteristics that may diminish the quality of their spirometry tests. Implementation of contemporary and efficient modes of training and quality assurance feedback may raise and maintain the standards of primary care spirometry.

Funding body

None

Ethics committee

The medical ethics review board of the Elkerliek Hospital approved the study. Because only routine lung function data were used for this retrospective database analysis and the investigators had no access to the patients' medical records or information on patients' identity, no written informed consent was obtained

Competing interests:

The authors have stated that there are none

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[Editor: when creating the AB version, note that these references 27-32 are included only in Appendix 1]

Appendix 1. Proportions of adequate spirometry tests with regard to forced expiratory volume in 1 second (FEV_1) and forced vital capacity (FVC) reproducibility criteria in published primary care studies.

Author, publication year	Country	Setting	Study population	Number of patients	Reproducibility (% adequate)	
					FEV_1, %	FVC, %
Primary care practice						
Schermer *et al*,[I] 2009 (current paper)	The Netherlands	Routine care	Adults and children ≥12 years from 15 primary care practices	1091	43	40
Tuomisto *et al*, 2008[27]	Finland	Routine care	Patients from primary care health centres	489	78 to 80[a,b]	
Walters *et al*, 2008[28]	Australia	Research	Adults from eight primary care practices	618	44 to 76[a,c]	
Eaton *et al*,[II] 1999[9]	New-Zealand	Research	Adults and children from 30 primary care practices	1012	3 to 14[a,c]	
Schermer *et al*,[I] 2003[22]	The Netherlands	Research	Patients with COPD recruited from 61 primary care practices	399	82[d]	–
Zanconato *et al*,[III] 2005[29]	Italy	Research	Children from 10 primary care paediatric practices	109	94[a]	
Pulmonary function laboratory						
Enright *et al*,[IV] 2004[30]	US	Routine care	Adult patients from one outpatient pulmonary function laboratory	18 000	>95	>90
Enright *et al*,[V] 2000[15]	US	Routine care	Public schools students aged 9–18 years from middle-income communities	4000	93	97
Bellia *et al*,[VI] 2000[19]	Italy	Research	Patients ≥65 years attending one of the 24 involved pulmonary or geriatric institutions	1622	>94	>87
Stoller *et al*,[II] 1997[31]	US	Research	Patients with severe α1 antitrypsin deficiency, from 37 hospitals	1090	>95	>91
Enright *et al*,[VII] 1991[16]	US	Research	Cigarette smokers 35 to 60 years of age included in a clinical trial	5887	>99	–

Studies conducted in pulmonary function laboratories are included as points of reference. Studies have used different definitions for reproducibility, which limits direct comparison of results.[32]

Definitions used in the respective studies are: [I]Two highest FEV_1 values <5% and <200 ml; [II]Largest FEV_1 values and largest FVC values ≤200 ml; [III]Two highest FEV_1 values and FVC values ≤5%; [IV]Difference between highest and second-highest FEV_1 <150 mL; [V]FVC and FEV_1 values at least 95% of the largest values; [VI]Difference between highest and second-highest value <200ml for FEV_1 and FVC; [VII]Difference between highest and second-highest FVC <200ml.

[a]Reproducibility results not reported for FEV_1 and FVC separately. [b]For pre- and postbronchodilator tests respectively. [c]For usual and trained practices respectively. [d]Reproducibility calculated without prior selection of acceptable blows according to 1994 American Thoracic Society spirometry guidelines.[6]

COPD = chronic obstructive pulmonary disease.