

SPIROMETRY VARIABILITY CRITERIA—ASSOCIATION WITH RESPIRATORY MORBIDITY AND MORTALITY IN A COHORT OF COAL MINERS

SHIRLEY E. KELLIE,¹ MICHAEL D. ATTFIELD,² JOHN L. HANKINSON,² AND ROBERT M. CASTELLAN²

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To clarify the association between spirometry variability and respiratory morbidity and mortality, the authors analyzed data for miners examined in the first round of the National Coal Study, 1969–1971, and they compared groups of miners who failed with those who met each of two spirometry variability criteria: a 5% criterion recommended by the American Thoracic Society, and a 200 ml criterion used in prior research studies. Compared with miners who met the 5% criterion (the best two forced vital capacities must be within 5% or 100 ml of one another), the group that failed had a lower mean for forced expiratory volume in one second (FEV₁), and odds ratios for cough, phlegm, wheeze, shortness of breath, and death of 1.75, 1.67, 1.76, 2.71, and 1.30, respectively. The findings for the 200 ml criterion (the best two FEV₁s must be within 200 ml of one another) were somewhat different. The group that failed versus the group that met this criterion had a higher mean for FEV₁, and odds ratios for cough, phlegm, wheeze, shortness of breath, and death of 1.13, 1.07, 1.15, 1.43, and 0.94, respectively. Although the findings differ for the two criteria, the findings demonstrate that increased spirometry variability is associated with poorer health.

pneumoconiosis; respiratory function tests; spirometry

Epidemiologic studies of respiratory disease usually include measures of lung function. The most commonly used are those obtained in spirometry testing in which a series of maximal forced expiratory time-volume curves, or spirograms, are recorded for each study subject. Two volumes calculated from the spirometry curves are the total volume of air forcibly exhaled following a full inspiration, or the forced vital capacity (FVC), and the volume of air forcibly exhaled during the first second following a full inspiration, or forced expiratory

volume in one second (FEV₁). If test subjects do not produce maximal effort, the volumes recorded are underestimates of their true lung volumes. Such submaximal efforts are recognized by the increased variability which occurs in the subject's series of spirograms. In 1979, the American Thoracic Society published a set of standards to control this, as well as other sources of error in spirometry measurements in epidemiologic studies. These standards include a variability criterion recommending that the best two of the study subject's

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Abbreviations: FEV₁, forced expiratory volume in one second; FVC, forced vital capacity.

¹Department of Preventive Medicine and Community Health, University of Illinois College of Med-

icine at Chicago, Health Sciences Center, P.O. Box 6998, Chicago, IL 60680. (Reprint requests to Dr. Shirley E. Kellie.)

²Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Morgantown, WV.

series of forced expiratory volumes, either FEV₁s or FVCs, fall within a 5 per cent or 100 ml range of one another (1).

Following the publication of the American Thoracic Society spirometry standards in 1979, it has become standard practice to exclude data for study subjects who produce forced expiratory volumes which exceed the range of variability established in the published criterion. However, as noted in several published studies by Eisen et al. (2-4), it appears that spirometry variability is not solely a result of measurement error, but is also related to the study subject's level of lung function. In a prospective study of Vermont granite workers, Eisen et al. found that workers whose FEV₁s were not within 200 ml of one another at each survey on at least two of six successive annual surveys experienced a mean annual decline in FEV₁ of 81.1 ml, as compared with a mean decline of 45.9 ml for those whose FEV₁s were within 200 ml of one another on each of the six annual surveys (2). In addition, in a study of textile workers, in which linear regression was used to estimate the dose-response relation between years of cotton dust exposure and level of FEV₁, the regression coefficient was -3.47 for all males in the study and -1.56 when males whose FEV₁s were not within 5 per cent or 100 ml of one another were excluded from the regression model (4). These findings clearly demonstrate that use of a spirometry variability criterion in epidemiologic studies can lead to selection bias. In both studies, exclusion of data for subjects with excessive spirometry variability led to an underestimate of the effect of dust exposure on decline in lung function.

This study was done to further explore the association between spirometry variability and health status. We used respiratory morbidity and mortality data for 8,475 coal miners who participated in the first round of the National Coal Study. To assess spirometry variability we used the 1979 American Thoracic Society variability criterion and a 200 ml variability criterion used by Eisen et al. (2, 3). According to the

American Thoracic Society criterion, the two best FVCs or FEV₁s must be within 5 per cent or a 100 ml range of one another. This range is proportional to size of the FVCs or FEV₁s down to a minimal range of 100 ml (5 per cent of a 2-liter FVC or FEV₁). In our study we applied the 5 per cent or 100 ml criterion to the FVCs and refer to this criterion as the 5 per cent criterion. A second criterion, the 200 ml criterion was used by Ferris et al. (5) prior to the 1979 publication of the American Thoracic Society variability criterion, and by Eisen et al. (2, 3) following the publication of the American Thoracic Society variability criterion. Eisen et al. applied the criterion to the FEV₁s of Vermont granite workers' spirometry data collected between 1970 to 1975. The 200 ml criterion requires that the two best forced expiratory volumes be within 200 ml of one another. This range is independent of the size of the forced expiratory volumes and is proportionately larger for smaller lung volumes. In this study we applied the 200 ml criterion to the FEV₁s, and refer to the criterion as the 200 ml criterion. We studied both criteria to assess potential differences in the selection bias caused by the use of absolute and proportional variability criteria.

MATERIALS AND METHODS

Data collection

The National Institute for Occupational Safety and Health field teams visited 31 coal mine sites in the United States to collect data for the first round of the National Coal Study held from 1969 to 1971. The study protocol called for each miner, after appropriate instructions and coaching, to make two practice tries, and then three technically satisfactory spirometers. Technically satisfactory spirometers showed unhesitating starts, and apparent maximal smooth and continuous expirations. Those judged unsatisfactory by the technicians were not used in this study. The total number done by each miner was not recorded. No variability criterion was

in use. A modification of the Medical Research Council's questionnaire was administered for demographic, smoking, job history, and respiratory symptom data. Posterior and lateral radiographs were taken. "B" readers classified the radiographs for pneumoconiosis according to the International Labor Office classification system (11). To standardize the reading of chest radiographs for pneumoconiosis, The National Institute for Occupational Safety and Health certifies physicians who successfully pass a certifying exam as "B" readers.

Mortality follow-up study

Miners were classified as dead if our search of Social Security Administration or United Mine Workers Welfare and Retirement Fund files indicated that they were no longer paying into these retirement funds, or if we found their death certificates in our search of the State Vital Statistics files. Miners whose addresses were current with the Postmaster, or who were still paying into a retirement fund were considered to be alive. If we did not determine vital status with these procedures, miners were followed-up on an individual basis.

Data analysis

The analysis was limited to 7,790 miners who produced three technically satisfactory spirograms. Prevalence rates and odds ratios were calculated to compare the frequency and risk of coal workers' pneumoconiosis, four respiratory symptoms (cough, phlegm, wheeze, and severe shortness of breath), and death in those who failed versus those who met each of the two variability criteria. To assess the statistical significance of the odds ratios, 95 per cent confidence intervals were calculated with the test-based approach proposed by Miettinen (6). To further examine the associations observed between spirometry variability and the outcome variables, we used the Statistical Analysis System multiple logistic regression program (7) to adjust the odds ratios for three extraneous and poten-

tially confounding variables. A separate model was developed for each of six outcome variables, coal workers' pneumoconiosis, cough, phlegm, wheeze, severe shortness of breath, and death for each of the two variability criteria. An indicator variable for meeting, or failing to meet, each of the two criteria was used in each model. Three extraneous variables, age, pack-years of smoking, and years of coal mine dust exposure were included in each model. The beta coefficients derived for the indicator variables in each of the models were converted to the odds ratios for the specified conditions in those failing versus those meeting each of the two criteria. The standard error term for the beta coefficient of the indicator variable was used to calculate 95 per cent confidence intervals for the adjusted odds ratios. We calculated group means for FEV₁ to compare lung function in the groups of miners who met each of the two criteria with those who failed the criteria. FEV₁ is positively correlated with height, and declines with age in nonsmokers at about 25–30 ml per year, and at faster rates in smokers (8). We used the Statistical Analysis System linear regression program (9) to adjust the group means of FEV₁ for height, age, pack-years of smoking, as well as for years of coal mine dust exposure.

RESULTS

Eleven per cent of miners did not reproduce their two best FVCs within 5 per cent or 100 ml of one another, and failed the 5 per cent variability criterion. In regard to the 200 ml criterion, 10 per cent of miners did not reproduce their two best FEV₁s within 200 ml of one another, and failed this criterion (table 1). Miners who failed the 5 per cent criterion were older, and had more pack-years of smoking and more years of coal mine dust exposure than did those who met this criterion. Failure to meet the 200 ml criterion had a different effect. These miners were younger, had fewer pack-years of smoking, and similar years of coal mine dust exposure.

While failure to meet the 5 per cent criterion was associated with a lower group mean for FEV₁, failing the 200 ml criterion was associated with a higher group mean for FEV₁ (table 2). The statistically significant differences in lung function between the groups of miners meeting and failing each of the two criteria remained after adjustment for age, height, pack-years of smoking, and years of coal mine dust exposure.

Of the group of miners who failed the 5 per cent criterion, a subgroup of 626 met the 200 ml criterion and a subgroup of 254 failed the 200 ml criterion (table 3). The subgroup that met the 200 ml criterion had a lower mean for FEV₁ than the subgroup that failed the 200 ml criterion. The subgroup of miners who failed the 200 ml criterion but met the 5 per cent criterion had the highest mean for FEV₁.

Unlike the higher prevalence of coal workers' pneumoconiosis in miners who failed the 5 per cent criterion, the prevalence was lower in those who failed the 200 ml criterion (table 4). Comparison of the adjusted and unadjusted odds ratios for coal workers' pneumoconiosis in the 5 per cent and 200 ml criterion groups indicates that the higher risk in those failing the 5 per cent criterion, or the lower risk in those failing the 200 ml criterion, was due to one or a combination of the confounding variables age, pack years of smoking, or years of coal mine dust exposure.

Prevalence rates for cough, phlegm, wheezing, and severe shortness of breath were higher in those miners who failed the 5 per cent criterion as well as for those who failed the 200 ml criterion (table 5). While the adjusted and unadjusted symptom odds ratios were elevated for miners who failed

TABLE 1

Age, smoking status, pack-years of smoking, and years of coal mine dust exposure by compliance with the 5% and 200 ml variability criteria for miners in the first round of the National Coal Study, 1969-1971

	5% criterion*			200 ml criterion*		
	FVCs not within 5% or 100 ml (n = 880)	FVCs within 5% or 100 ml (n = 6,910)	p	FEV _{1.8} not within 200 ml (n = 748)	FEV _{1.8} within 200 ml (n = 7,042)	p
Mean age (years)	47	43	<0.01	43	44	<0.05
Smoking status (%)						
Never smoked	24	20		23	20	
Ex-smokers	22	26		26	25	
Current smokers	54	54		51	54	
Mean pack-years†	24	22	<0.01	20	22	<0.05
Mean years of coal mine dust exposure	20	16	<0.01	16	16	>0.05

* The 5% and 200 ml variability criteria were separately applied to divide the group of 7,790 miners into those whose spirometry did and did not meet each criterion.

† Mean pack-years for ex-smokers and current smokers.

TABLE 2

Comparison of unadjusted and adjusted FEV₁ means by compliance with the 5% and 200 ml variability criteria for miners in the first round of the National Coal Study, 1969-1971

Mean FEV ₁ (liters)	5% criterion			200 ml criterion		
	FVCs not within 5% or 100 ml (n = 880)	FVCs within 5% or 100 ml (n = 6,910)	p	FEV _{1.8} not within 200 ml (n = 748)	FEV _{1.8} within 200 ml (n = 7,042)	p
Unadjusted	3.18	3.61	<0.01	3.68	3.56	<0.05
Adjusted*	3.34	3.59	<0.01	3.60	3.56	<0.05

* The FEV₁ means were adjusted for age, height, pack-years of smoking, and years of coal mine dust exposure.

TABLE 3

Comparison of mean ages and FEV₁ means by compliance with the 5% and 200 ml variability criteria for miners in the first round of the National Coal Study, 1969-1971

	Failed 200 ml criterion	Met 200 ml criterion	Total
Failed 5% criterion	(n = 254)	(n = 626)	(n = 880)
Mean age (years)	45	48	47
Mean FEV ₁ (liters)	3.44	3.08	3.18
Met 5% criterion	(n = 494)	(n = 6,416)	(n = 6,910)
Mean age (years)	42	43	43
Mean FEV ₁ (liters)	3.82	3.60	3.61
Total	(n = 748)	(n = 7,042)	(n = 7,790)
Mean age (years)	43	44	
Mean FEV ₁ (liters)	3.68	3.56	

TABLE 4

Prevalence rates and unadjusted and adjusted odds ratios for coal workers' pneumoconiosis* by compliance with the 5% and 200 ml variability criteria for miners in the first round of the National Coal Study, 1969-1971

	5% criterion		200 ml criterion	
	FVCs not within 5% or 100 ml (n = 880)	FVCs within 5% or 100 ml (n = 6,910)	FEV _{1s} not within 200 ml (n = 748)	FEV _{1s} within 200 ml (n = 7,042)
% with coal workers' pneumoconiosis	10.4	7.8	5.1	8.4
Odds ratios				
Crude	1.37 (1.09-1.73)‡		0.58 (0.75-1.33)	
Adjusted†	1.00 (0.78-1.29)		1.80 (1.26-2.56)	

* Radiographic coal workers' pneumoconiosis category 2 or greater, including progressive massive fibrosis.

† The odds ratios are adjusted for age, pack-years of smoking, and years of coal mine dust exposure.

‡ Miettinen (6) test-based 95% confidence intervals in parentheses.

TABLE 5

Prevalence rates and unadjusted and adjusted odds ratios for four respiratory symptoms* by compliance with the 5% and 200 ml variability criteria for miners in the first round of the National Coal Study, 1969-1971

Symptom	5% criterion		200 ml criterion	
	FVCs not within 5% or 100 ml (n = 880)	FVCs within 5% or 100 ml (n = 6,910)	FEV _{1s} not within 200 ml (n = 748)	FEV _{1s} within 200 ml (n = 7,042)
Cough: %	48.4	34.9	39.3	36.2
Crude odds ratio	1.75 (1.52-2.01)‡		1.13 (0.97-1.32)	
Adjusted odds ratio†	1.51 (1.30-1.75)		1.19 (0.99-1.40)	
Phlegm: %	51.2	38.7	41.5	40.0
Crude odds ratio	1.67 (1.45-1.92)		1.07 (0.92-1.32)	
Adjusted odds ratio†	1.42 (1.23-1.66)		1.11 (0.60-1.40)	
Wheezing: %	44.6	31.4	35.8	32.6
Crude odds ratio	1.76 (1.53-2.02)		1.15 (0.98-1.35)	
Adjusted odds ratio†	1.49 (1.29-1.73)		1.22 (1.04-1.44)	
Severe breathlessness: %	14.1	4.4	9.0	6.4
Crude odds ratio	2.71 (2.20-3.34)		1.43 (1.10-1.88)	
Adjusted odds ratio†	2.24 (1.79-2.79)		1.48 (1.12-1.96)	

* Cough: "Yes" to the question, "Do you cough like this on most days for as much as three months each year?" Phlegm: "Yes" to the question, "Do you bring up phlegm like this on most days for as much as three months each year?" Wheezing: "Yes" to the question, "Do you get this ... wheezing ... most days or nights?" Severe breathlessness: "Yes" to the question, "Do you have to stop for breath when walking at your pace on level ground?"

† The odds ratios are adjusted for age, pack-years of smoking, and years of coal mine dust exposure.

‡ Miettinen (6) test-based 95% confidence intervals in parentheses.

either of the two criteria, the risk of having symptoms was higher for those who failed the 5 per cent criterion.

Vital status was unknown for only 35 (0.5 per cent) miners; two each in those failing the 5 per cent and 200 ml criteria. Failure to meet the 5 per cent criterion was associated with an elevated odds ratio for death (table 6). After adjustment for age, pack-years of smoking, and years of coal mine dust exposure, the odds ratio was 1.03, suggesting that the higher unadjusted odds ratio was due to one or a combination of these three colinear variables. Failure to meet the 200 ml criterion was associated with a slightly decreased risk of death, which was 1.00 after adjustment for age, pack-years of smoking, and years of coal mine dust exposure.

DISCUSSION

Our findings indicate that failure to meet the 5 per cent criterion was associated with poorer health. Compared with the group of miners who met this criterion, the failure group had a lower mean for FEV₁ and were at increased risk of coal workers' pneumoconiosis, cough, phlegm, wheeze, and severe shortness of breath, as well as death. The findings for miners who failed the 200 ml criterion were somewhat different. Compared with the group that met this criterion, the failure group had a higher mean for FEV₁ and lower risk for coal workers' pneumoconiosis and death, and an increased risk of cough, phlegm, wheeze, and severe shortness of breath.

In regard to lung function and the 5 per cent criterion, miners with lower FEV₁s had more difficulty in reproducing their FVCs within the 5 per cent or 100 ml range of variability. After adjustment, the group mean for FEV₁ for miners failing this criterion remained lower than that for miners meeting the criterion. This association between increased spirometry variability and lower levels of FEV₁ suggests that spirometry variability is associated with airways obstruction independent of age, height, cigarette smoke exposure, and coal mine dust exposure. When airflow obstruction occurs, there is usually a component of reversible obstruction. While further study is needed to clarify the association observed between airflow obstruction and spirometry variability, it may be related to reversible obstruction or hyperreactivity of the airways.

Our aggregate lung function findings for the group failing the 200 ml criterion differed from those for the group failing the 5 per cent criterion. The group of miners who failed the 200 ml criterion had a higher group mean for FEV₁. This difference in means of FEV₁ for the groups failing the 200 ml and 5 per cent criteria is explained by noting that the absolute 200 ml criterion imposes a proportionately larger range of variability on smaller forced expiratory volumes, either FEV₁s or FVCs, than does the proportional 5 per cent or 100 ml criterion (figure 1). That is, to meet the absolute 200 ml criterion, a miner with an absolute forced expiratory volume, either FEV₁ or FVC, of 1,500 ml would have to repeat his two best FEV₁s or FVCs within a 200 ml

TABLE 6

Per cent deaths and unadjusted and adjusted odds ratios for deaths by compliance with the 5% and 200 ml variability criteria for miners in the first round of the National Coal Study, 1969-1971

	5% criterion		200 ml criterion	
	FVCs not within 5% or 100 ml (n = 880)	FVCs within 5% or 100 ml (n = 6,910)	FEV ₁ s not within 200 ml (n = 748)	FEV ₁ s within 200 ml (n = 7,042)
Deaths: %	10.6	8.3	8.2	8.6
Crude odds ratio	1.30 (1.04-1.64)†		0.94 (0.72-1.24)	
Adjusted odds ratio*	1.03 (0.79-1.28)		1.00 (0.75-1.33)	

* The odds ratios are adjusted for age, pack-years of smoking, and years of coal mine dust exposure.

† Miettinen (6) test-based 95% confidence intervals in parentheses.

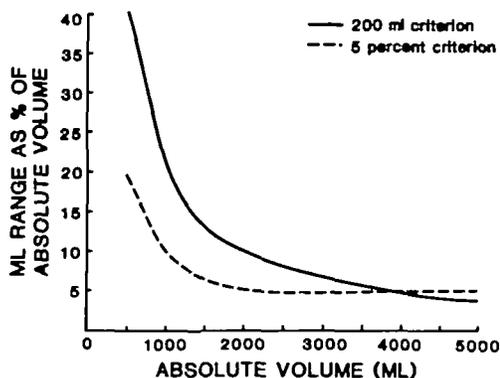


FIGURE 1. The variability ranges, expressed as per cent of absolute volumes, imposed by the 200 ml and 5 per cent criteria, for miners in the first round of the National Coal Study, 1969-1971. The absolute volumes in this study are FEV₁ for the 200 ml criterion and FVC for the 5 per cent criterion.

range which is equivalent to 13 per cent of his absolute forced expiratory volume of 1,500 ml. However, to meet the proportional 5 per cent or 100 ml criterion, the same miner would have to repeat his two best FEV₁s or FVCs within a 100 ml range which is equivalent to only 6 per cent of his absolute forced expiratory volume of 1,500 ml. In addition, to meet the absolute 200 ml criterion, a miner with a relatively high forced expiratory volume of 4,500 ml would have to repeat his best two FEV₁s or FVCs within a 200 ml or a range equivalent to 4 per cent of his absolute forced expiratory volume. However, to meet the proportional 5 per cent criterion, the same miner would have to repeat his FEV₁s or FVCs within a 225 ml range, equivalent to 5 per cent of his 4,500 ml forced expiratory volume.

Therefore it is not only less difficult for miners with low forced expiratory volumes to meet the 200 ml criterion than the 5 per cent criterion, but it is also relatively more difficult for miners with higher forced expiratory volumes to meet the 200 ml criterion than the 5 per cent criterion. As a direct consequence, in contrast to use of the 5 per cent criterion, use of the absolute 200 ml criterion tends to eliminate two different subgroups of miners: those with low forced expiratory volumes and high variability, and those with relatively high forced expiratory volumes and low varia-

bility. In our study the mean for FEV₁ in the 200 ml criterion failure group reflects the average of values for FEV₁ of these two subgroups of miners. In contrast, the group mean of FEV₁ for the 5 per cent criterion failure group primarily reflects lower values of FEV₁ for the group of miners unable to meet the narrower range of variability imposed by this criterion on the lower FEV₁ values.

While our study was cross-sectional in design, our findings for the effects of use of the 200 ml criterion on lung function are consistent with those reported from a prospective study by Eisen et al. (2, 3). Our cross-sectional study findings are most comparable to their group who failed the 200 ml criterion at one of six annual surveys. Eisen et al. reported that the one-time failure group, compared with the group who met the 200 ml criterion at all six annual surveys, were younger (mean age of 39.4 vs. 40.0 years), had the same predicted levels of FEV₁ (96 per cent vs. 96 per cent), and lower annual decrements in FEV₁ (37.2 ml vs. 45.9 ml). In addition, Eisen et al. reported higher annual decrements in FEV₁ values for workers who persistently failed the 200 ml criterion on at least two of the six annual surveys. Since our study was cross-sectional we have no data for a persistent failure group comparable to the findings for the persistent failure group reported by Eisen et al. However, it seems reasonable that it would be the subgroup of miners with low FEV₁s and high variability in our 200 ml criterion failure group who might persistently fail the 200 ml criterion if given the opportunity to do so during subsequent surveys in a prospective study. This subgroup would, as reported by Eisen et al. for the persistent failure group, have a lower group mean for FEV₁ and probably higher annual decrements in FEV₁ levels as well.

Of the four respiratory symptoms analyzed in this study, the pathophysiology of severe shortness of breath is the most closely associated with airflow obstruction. The finding of the highest odds ratio for this symptom in miners who failed the 5

per cent criterion, further suggests that the mechanism underlying the association observed between spirometry variability and respiratory symptoms is airflow obstruction. Our findings for symptoms are consistent with those reported by Eisen et al. (4) for groups of cotton textile workers and machinists failing the 5 per cent or 100 ml criterion applied to the FEV₁.

The group of miners who failed the 200 ml criterion, in addition to having a higher group mean for FEV₁ also had an increased risk of severe shortness of breath. If airflow obstruction does mediate the effects of spirometric variability on respiratory symptoms, one would expect these miners to have a lower, rather than the observed higher risk of severe shortness of breath. However as previously noted, it is quite likely that the group of miners who failed this criterion was made up of two subgroups: those who had very good lung function or higher FEV₁s but failed to reproduce them within the proportionately narrower range of variability imposed by this criterion, and those who had very poor lung function or lower FEV₁s and had increased variability in reproducing them (figure 1). It is the latter subgroup that one would expect to contribute to the increased risk of severe shortness of breath in the 200 ml failure group.

FEV₁ is known to be a good predictor of death (10). One might expect the inverse correlation between level of FEV₁ and probability of death to explain the observed increased risk of death found for miners who failed the 5 per cent criterion. After adjustment for age, pack-years of smoking, and years of coal mine dust exposure, the odds ratio for death was 1.03, suggesting that the increased risk of death had been due to one or a combination of these three variables. However, given the association between FEV₁ level with age and smoking, adjustment for these two variables also indirectly adjusted for the effects of FEV₁ on risk of death.

The findings of this study as well as those reported by Eisen et al. (2-4) clearly demonstrate that intrasubject variability in spi-

rometry testing reflects test subjects' health status. Our comparison of the difference in selection bias effects resulting from the use of the 200 ml and 5 per cent criteria indicates that the use of either criterion introduces selection bias. However, due to the different ranges of variability imposed on relatively low and high lung volumes by the two criteria, use of one or the other of the criteria could lead to quite different selection bias effects.

To minimize the selection bias effects of use of a spirometry variability criterion and still ensure the validity of spirometry data, the current American Thoracic Society 5 per cent or 100 ml criterion ought to be relaxed—perhaps to a 10 per cent level. In addition, study data for subjects who fail to meet the variability criterion ought to be carefully analyzed and compared with that for subjects who meet the criterion.

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