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Dear Dr. Niemeier:

Thank you for the opportunity to review the draft "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust." My comments focus primarily on technical aspects of pulmonary function testing and the gathering of related data since this is the area with which I am most familiar.

Comments

Appendix A:

An assessment of current and past cigarette smoking status should be included in the respiratory questionnaire, since smoking is the leading risk factor for the development of COPD. Since a smoking section is referred to on p. 164 of the document, I assume that this section was inadvertently omitted from the Appendix.

Pages 8 and 9, Sections 1.4.1.2, Spirometry Tests and 1.4.1.5, NIOSH-Approved Facilities:

The need for high quality technician training and skilled quality assurance reviews of spirograms cannot be overstated, since poor testing efforts can easily produce PFT results consistent with obstructive or restrictive impairment patterns.

Page 11, Section 1.4.2.2, Abnormal Pulmonary Function Values:

Since the evaluation of longitudinal changes in individuals is an area of respiratory medicine that is still not well standardized, it would be useful to refer to Hankinson and Wagner's 1993 article, which states explicitly how longitudinal change would be evaluated, rather than referring to the 1991 ATS Statement, which is vague about how a LLN for FEV_1 decline will be

computed. In addition, since length of follow-up is a critical factor in determining the stability of an estimate of change in FEV_1, as noted later on p. 183, should a minimum length of follow-up be required before longitudinal changes are evaluated as being above or below the LLN?

Page 84, Sections 4.1.2.1.3, Irregular Opacities on Chest Radiographs and 4.1.2.1.4, Radiographic Opacities among Nonminers:

I was puzzled why the controversial association between small irregular opacities and long term smoking was not mentioned in this section.

Page 94, Section 4.1.2.2.3, Dust-Related Loss of Lung Function:

A discussion of short term loss of FEV_1, in comparison with long term loss, should bear in mind the instability of estimates of FEV_1 loss when measured over a short time period.

Page 97, Table 4-10, Severity of Pulmonary Impairment:

The 1991 ATS Statement delegates the FEF_{25-75} to a strictly supporting role in the definition of pulmonary impairment. The FEF_{25-75} may be used to *confirm* the presence of obstruction if the FEV_1/FVC is borderline; the FEF_{25-75} "should not be used to diagnose small airway disease in individual patients"; and "abnormalities in ... FEF_{25-75} should not be graded as to severity when FEV_1 and FEV_1/FVC are within the normal range."

In addition, "FEV_1/FVC should be the primary guide for distinguishing obstructive from nonobstructive patterns" and "the severity of airway obstruction should be based on FEV_1 rather than FEV_1/FVC."

In light of this new and more cohesive approach to evaluating impairment, it might be wise not to present the Gold and Boushey table, since it reflects a classification scheme that is being replaced by the 1991 ATS approach.

Page 179, Section 5.2.5.4.1, Spirometry Tests: Number of Blows and Selection of Value:

The fact that the ATS (1987) still recommends selection of the maximal FVC and FEV_1 recorded from the test session's acceptable maneuvers should be stressed. If the choice of mean or maximum value has little effect on the reported result for the majority of subjects, I would think that one is wise to select an approach that was recommended in the interest of standardizing pulmonary function testing.

The fact that NIOSH, DRDS in Morgantown routinely requires 5 blows in its PFT studies should be part of the discussion in this section.

Page 180, Table 5-7, Proposed NIOSH Criteria for Interpreting Spirometry:

As I noted in my comment on the previous page, the ATS (1991) recommends grading the severity of obstruction using the FEV_1% predicted, not using the FEV_1/FVC ratio. A ratio below the LLN should be used to indicate that obstruction is present, but the level of obstruction should not be graded based on the level of the ratio. An alternative table is presented below:

	OBSTRUCTIVE		**RESTRICTIVE**
	FEV_1/FVC %Pred	FEV_1 %Pred	FVC %Pred
Normal	≥ LLN	---	≥ LLN
Borderline	< LLN	≥ LLN	---
Mild	< LLN	66 - < LLN	66 - < LLN
Moderate	< LLN	51 - 65	51 - 65
Severe	< LLN	≤ 50	≤ 50

Page 181, Section 5.2.5.4.2, Spirometry Tests: ATS Acceptability and Reproducibility Criteria:

The ATS acceptability and reproducibility criteria are *testing goals* to aim for while conducting the PFT; they have never been prescriptions for determining which subjects should be included and excluded from an epidemiologic analysis of data, although as the second and third paragraphs in this section indicate, this confusion has existed.

Last sentence, first paragraph: The ATS reproducibility criteria require that the difference between the two largest FEV_1s and two largest FVCs should not exceed 5% or 100 ml, whichever is greater.

If there are any questions, please contact me at 412/343-9946. Thank you.

Yours truly,

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Consultant