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Exposure-Response Relationships for Coal Mine Dust and Obstructive Lung Disease Following Enactment of the Federal Coal Mine Health and Safety Act of 1969

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Underground U.S. coal miners were studied cross-sectionally for the association of respirable coal mine dust exposure with pulmonary function and symptoms of airways obstruction. The study group included 1,185 miners participating in Round 4 of the National Study of Coal Workers' Pneumoconiosis who had started mining in or after 1970 when comprehensive exposure regulations first came into effect. Quantitative estimates of cumulative exposure, derived using respirable dust measurements taken by the Mine Safety and Health Administration over the entire study period, were used in linear and logistic regression models on indicators of pulmonary function and chest symptoms while controlling for smoking status, pack-years, and other potential confounders. Statistically significant associations between log cumulative exposure and decrements in FVC, FEV_1, and FEV_1/FVC were observed. In logistic models, statistically significant associations of cumulative exposure with increasing prevalence of FEV_1 and FEV_1/FVC less than 80% predicted and symptoms including chronic phlegm, chronic bronchitis, breathlessness, wheeze, and wheeze with shortness of breath were found. It is concluded that exposures to respirable coal mine dust present in U.S. mines since 1970 continue to affect respiratory health in underground miners.

Key words: coal mining, coal dust, respirable dust, chronic obstructive lung disease, black lung, pulmonary function, chronic bronchitis, exposure-response studies

INTRODUCTION

The U.S. Coal Mine Health and Safety Act (CMHSA) of 1969 required the reduction of respirable dust exposures in coal mines to below 3.0 mg/m^3 beginning January 1, 1970 and a reduction to under 2.0 mg/m^3 three years later [U.S. Congress, 1969]. The choice of these levels was driven largely by data from British studies regarding the prevention of coal workers' pneumoconiosis (CWP) [Jacobsen et al.,

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1970]. However, the potential effectiveness of this exposure standard in preventing another recognized coal-related pulmonary effect, obstructive lung disease, is less certain. This study considers the exposure-response relationship between cumulative respirable coal mine dust exposure and indicators of obstructive lung disease in a group of miners who have been exposed only to the historically low concentration of dust present in U.S. mines since the CMHSA took effect. The ability to conduct this analysis stems from the availability of quantitative exposure data collected by the Mine Safety and Health Administration (MSHA) and health data from the National Study of Coal Workers Pneumoconiosis (NSCWP) conducted by the National Institute for Occupational Safety and Health (NIOSH).

MATERIALS AND METHODS

The cohort for this analysis was derived from Round 4 (R4) of the NSCWP which has been previously described [Attfield, 1990]. R4 was conducted in 1985–1988 and was designed to follow-up a subgroup of miners who participated in Round 1 (R1) or Round 2 (R2) of the study in the early 1970s, and who were not expected to have reached retirement age (58 years) before R4 (Fig. 1). From the 9,081 miners surveyed in R1 and 9,343 surveyed in R2, 7,387 miners under retirement age were identified as having participated in R1 or R2. For R4, miners having worked primarily in anthracite mines were excluded because there were too few of them for analysis, and miners from sparsely populated regions were excluded to improve the efficiency of data collection. The resulting population targeted for study in R4 was composed of 5,452 current and ex-miners.

NIOSH made a substantial effort to contact and elicit participation by repeated mailings and telephone contact with the eligible group. At active mine sites, presentations were made to the current miners to elicit their participation. Of the 5,452 targeted miners, 9% had moved away or died before contact and 7% could not be located, leaving a total of 4,580 available for study. Of these, 3,037 were examined.

For this study, R4 participants who started mining work in 1970 or later were selected. On the basis of the first mining job reported in the R4 work history, 1,270 such miners were identified. Among these 1,270, two women, 43 miners with unacceptable or missing pulmonary function tests, and 40 miners whose work history obtained at R2 suggested that they actually had worked prior to 1970 were excluded, leaving 1,185 in the cohort.

The NSCWP R4 examination included a chest radiograph, spirometry, and a questionnaire administered by NIOSH personnel. The questionnaire included a brief medical history, a smoking history, a detailed work history, and a modified British Medical Research Council (BMRC) questionnaire on respiratory symptoms [DHEW, 1971].

Spirometry was conducted according to the 1979 American Thoracic Society criteria [ATS, 1979] using an Ohio rolling seal, volume displacement spirometer. Up to 10 maneuvers were elicited in order to obtain at least three meeting acceptability requirements. Timed expiratory volumes were based on back-extrapolated calculations to time zero. In accordance with the 1987 ATS recommendations for spirometry [Gardner et al., 1987], no reproducibility criteria were applied for this analysis, although a comparison of the reproducible and non-reproducible spirometry results is

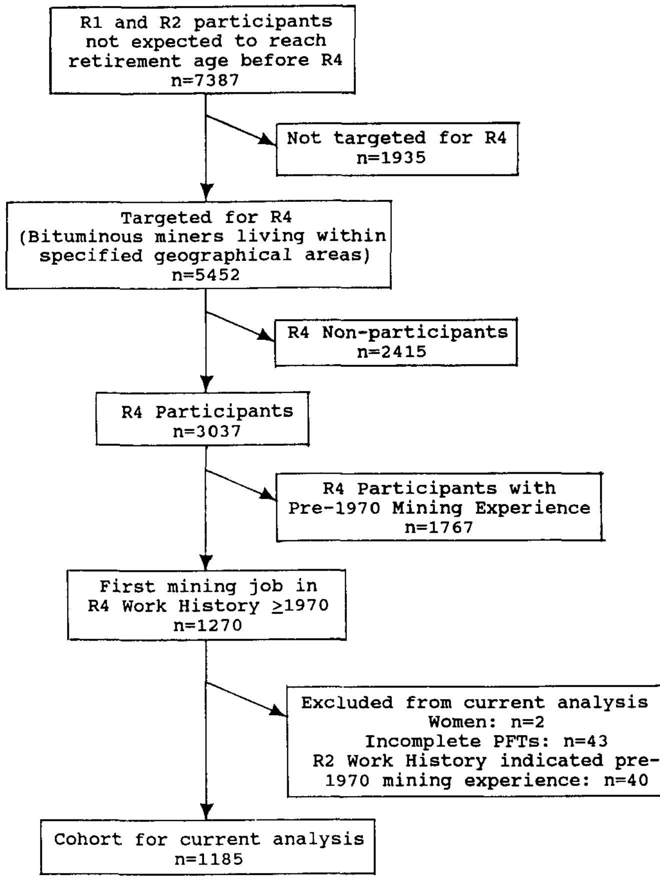

Fig. 1. Derivation of the National Study of Coal Workers' Pneumoconiosis cohort for the current analysis.

presented. Reproducible PFTs were defined as having the second largest value within 5% of the largest, for both FVC and FEV_1.

Pulmonary function parameters addressed in this analysis were forced vital capacity (FVC), forced expiratory volume in 1 second (FEV_1), and their ratio, FEV_1/FVC. In addition, the percent of predicted, based on age and height, for these three measures were calculated using the prediction equations of Crapo et al. [1981]. Analyses examining pulmonary function used either absolute values and simultaneously controlled for age, height and race/ethnicity, or alternatively, used percents of predicted. A cut-off of less than 80% predicted was adopted as an indicator of a clinically significant decrement [Boehlecke, 1986].

Seven measures of symptom-based health outcome were derived from the BMRC questionnaire responses. The outcomes used were defined as follows:

1. Cough: Answered yes to *either* 1) Do you usually cough first thing in the morning (on getting up) in the winter? *or* 2) Do you usually cough during the day (or at

night) in the winter? *and,* 3) Do you cough like this on most days (or nights) for as much as 3 months each year?
2. Phlegm: Answered yes to *either* 1) Do you usually bring up any phlegm from your chest first thing in the morning (on getting up) in the winter? *or* 2) Do you usually bring up any phlegm from your chest during the day (or at night) in the winter? *and,* 3) Do you bring up phlegm like this on most days (or nights) for as much as 3 months each year?
3. Chronic Bronchitis: Fulfilled the definitions of *both* cough and phlegm.
4. Obstructive Bronchitis: Fulfilled the definition of chronic bronchitis *and* had an FEV_1 less than 80% of predicted.
5. Breathlessness: Answered yes to, Do you get short of breath walking with other people of your own age on level ground?
6. Wheeze: Answered yes to both: 1) Does your chest ever sound wheezing or whistling? *and* 2) Do you get this on most days or nights?
7. Wheeze with Shortness of Breath (SOB): Answered yes to: Have you ever had attacks of shortness of breath with wheezing?

Initial analyses of the effect of exposure were conducted by categorizing cumulative exposure into three levels approximating the lowest quartile (low: <11.0 mg/m^3-years), the middle two quartiles (medium: 11.0–20.0 mg/m^3-years), and the highest quartile (high: >20.0 mg/m^3-years). To avoid potential confounding by race/ethnicity, these analyses were conducted only on whites, and to minimize potential confounding by age, pulmonary function parameters were considered as the percent of predicted.

Multiple regression analyses were conducted to simultaneously control for age, height, cigarette smoking status (current, not current), pack-years of cigarette smoking, race/ethnicity (white, black, Hispanic), mining status (current, ex), and years of dust exposure before mining. For symptoms related to asthma (wheeze and wheeze with SOB), self-report of history of asthma was included as a predictor. Age, height, pack-years, previous exposure, and cumulative exposure were entered into the models as continuous variables; current smoking, mining status and race/ethnicity (white, black, Hispanic) were represented by dummy variables (0,1). For continuous outcomes (FVC, FEV_1, and FEV_1/FVC), multiple linear least squares regression was conducted. For categorical outcomes, multiple logistic regression was used. Cumulative exposure was included in each model but all other variables were selected by a simple forward stepwise procedure (p for inclusion <0.2). All selected variables with p between .1 and .2 were then evaluated to determine their effect on the cumulative exposure coefficient. If removal of the variable resulted in a change in the coefficient for cumulative exposure greater than 10%, then the covariate remained in the model. The model fit was evaluated by examining residual plots for outliers, by exploring the same models stratified by age categories, and with the use of dummy variables for categories of cumulative exposure and age. As a result of these analyses, it was determined that a logarithmic transformation of cumulative exposure appeared to model decrements in pulmonary function better than simple linear models. The linear regressions were rerun using the natural log of exposure. The potential for interaction of log exposure with age and smoking status was then tested.

To help assess the potential for selection bias occurring over the course of the study, a preliminary analysis was conducted which examined miners who had participated in R2 and were believed to have started work in 1970 or later. Since the R2 work histories only included summary measures of years of mining in various categories, selection of eligible miners (i.e., started working after 1970) was done indirectly. If the reported number of years mining at R2 was not greater than the time between January 1, 1970 and the R2 interview date, the miners were considered eligible for participation in this study. The health status at R2 of the eligible miners who participated in R4 was then compared with those eligible miners that did not participate.

Methods by which cumulative exposures were estimated for the cohort have been described in detail elsewhere [Seixas, 1990; Seixas et al., 1990a,b]. Briefly, exposure data collected for legal compliance purposes under the auspices of the Mine Safety and Health Administration (MSHA) were used. The data used for the analysis included only personal samples collected on miners over the period 1970 through 1987 in the 36 mines from which the R4 cohort was originally selected. Several potential biases in the data were identified and, where possible, corrections were made to account for them [Seixas et al., 1990b]. Mean exposures were estimated within strata defined by mine, occupation, and year, and for decreasingly specific stratifications by occupation/year, mine/year (within occupation group), and year (within occupation group). To minimize the variance of means for occupation/mine/year strata with very few samples, the three-way means were combined with two-way (occupation/year) means so as to minimize the mean squared error [Seixas et al., 1990a]. Cumulative exposure was estimated for each cohort member by matching the oral work histories obtained at R4 and the estimated mean exposures. Matching was conducted first to the three-way stratification, and then, as required, to the decreasingly specific stratifications.

RESULTS

Exposure-Response Analysis

Personal characteristics and outcome indices are presented for the whole group and stratified by smoking status in Table I. The age, race/ethnicity distribution, and cumulative exposure were similar among current, ex, and never smokers. Cumulative exposure was reasonably symmetrically distributed between 0.6 and 40.8 mg/m^3-years, with a mean of 15.6 mg/m^3. Approximately 16% of the group noted some previous occupational (non-coal) dust exposure with an average duration of 0.9 years. Mean FEV_1 was lower than predicted, with current smokers having the lowest values. Symptoms of cough, phlegm, and wheeze appeared relatively common, again with current smokers being most often affected.

Initial examination of the effect of exposure was conducted on 1,103 whites by categories of cumulative exposure (Fig. 2A–C). There were 280, 552, and 271 miners in the low, medium, and high exposure categories, respectively. The three exposure groups were similar with respect to age (mean 40.8, 39.4, and 40.1 years, respectively). Members of the high exposure group were slightly more likely to be current smokers than other cohort members (42.1 for current vs. 36.1 and 40.0 for ex and never, respectively), but on average had fewer pack-years (20.8 vs. 24.6 and 21.9 pack-years, respectively).

Forced vital capacity was unrelated to exposure status while trends of decreasing FEV_1 and FEV_1/FVC with increasing exposure were observed (Fig. 2A). Similar

TABLE I. Demographics, Pulmonary Function Findings, and Symptoms in Cohort of 1,185 Miners*

		Smoking status		
	Total	Current	Ex	Never
n	1,185	469	393	323
Age, years	40.0 (6.4)	39.6 (6.1)	41.1	39.2
Cum. exp, mg/m^3-yr	15.6 (6.5)	15.9 (6.4)	15.3 (6.4)	15.6 (6.6)
% (no.) with prev. exp.	16.5 (196)	17.1 (80)	18.8 (74)	13.0 (42)
Race				
White	93.1 (1103)	93.0 (436)	93.1 (366)	93.2 (301)
Black	4.1 (48)	3.6 (17)	3.8 (15)	5.0 (16)
Hispanic[a]	2.8 (34)	3.4 (16)	3.1 (12)	1.9 (6)
Pack-years[b]	21.8 (16.6)	18.9 (12.9)	25.4 (19.6)	—
PFTs				
FVC, liters	4.97 (0.84)	4.88 (0.82)	5.05 (0.84)	5.00 (0.86)
FEV_1, liters	3.86 (0.72)	3.70 (0.74)	3.96 (0.70)	3.97 (0.67)
FEV_1/FVC, fraction	0.78 (0.07)	0.76 (0.08)	0.78 (0.07)	0.80 (0.07)
% predicted				
FVC	96.8 (13.4)	95.4 (13.9)	98.4 (13.8)	96.9 (13.4)
FEV_1	92.3 (14.4)	88.7 (14.6)	94.9 (14.2)	94.5 (13.2)
FEV_1/FVC	95.5 (8.8)	93.1 (9.3)	96.6 (8.3)	97.7 (7.8)
<80% predicted				
FVC	10.1 (120)	11.7 (55)	7.6 (30)	10.8 (35)
FEV_1	18.2 (216)	26.7 (125)	13.0 (51)	12.4 (40)
FEV_1/FVC	5.5 (65)	9.0 (42)	4.3 (7)	1.9 (6)
Symptoms				
Cough	28.3 (335)	38.6 (181)	21.1 (8.3)	22.0 (71)
Phlegm	31.6 (375)	41.1 (193)	26.2 (103)	24.5 (79)
Chronic bronchitis	21.0 (249)	29.2 (137)	15.3 (60)	16.1 (52)
Obstructive bronchitis	5.7 (67)	9.2 (43)	3.6 (14)	3.1 (10)
Breathless	22.3 (263)	23.4 (109)	20.9 (82)	22.3 (72)
Wheeze	26.7 (316)	37.1 (174)	20.4 (80)	19.2 (62)
Wheeze with SOB	17.0 (201)	15.8 (74)	18.3 (72)	17.0 (55)

*Continuous variables—mean (S.D.). Categorical variables—percent (no.).
[a]Includes 33 Hispanics and 1 Native American.
[b]Average pack-years smoked for current and ex-smokers.

trends of increasing exposure with increasing prevalence of FEV_1 and FEV_1/FVC less than 80% of predicted were also observed (Fig. 2B). Trends of increasing exposure with increased prevalence of reported phlegm, chronic bronchitis, breathlessness and wheeze were also seen (Fig. 2C).

A similar analysis, stratified by smoking status, (not shown) indicated current smokers had the fewest clear associations of dust exposure with outcomes (trends were consistent only for FEV_1/FVC <80% predicted and phlegm). Ex and never smokers had consistent trends with exposure status for % predicted FEV_1, FEV_1/FVC, and prevalence of FEV_1 and FEV_1/FVC <80% predicted, as well as several of the symptom outcomes.

Linear regression models of pulmonary function outcomes indicated statistically significant associations of cumulative exposure with FEV_1 and FEV_1/FVC (Table II). The estimated relationship of FEV_1 with exposure was −5.5 ml per mg/m^3-year.

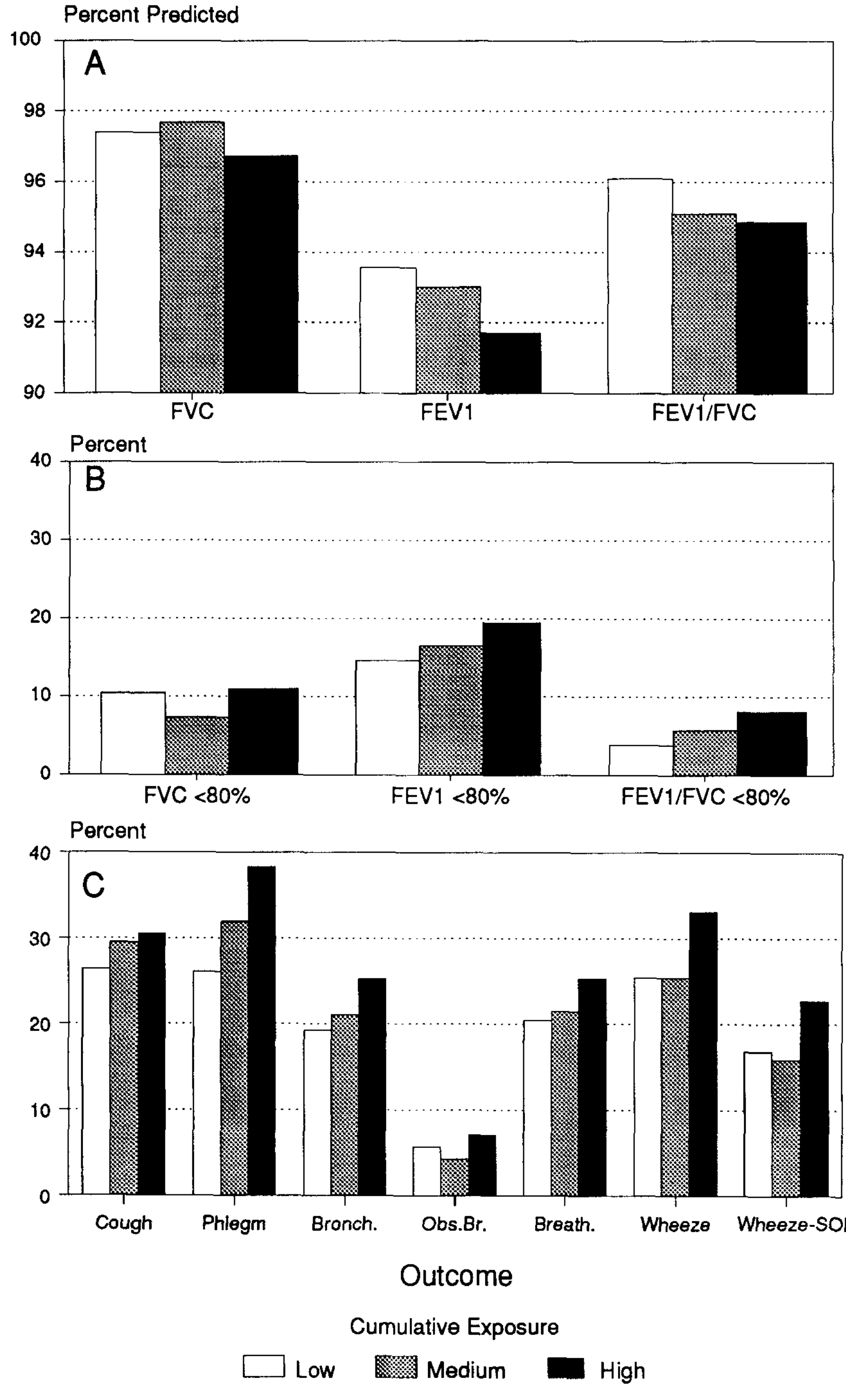

Fig. 2. Outcomes by categories of cumulative exposure to respirable coal mine dust for 1,103 white male coal miners. **A:** Percent predicted pulmonary function indices. **B:** Prevalence of pulmonary function indices < 80% predicted. **C:** Prevalence of symptoms. Exposure categories are: low, <11.0 mg/m^3-years; medium, 11.0–20.0 mg/m^3-years; and high, >20.0 mg/m^3-years.

TABLE II. Linear Regression Models for Pulmonary Function Outcomes (n = 1,185 Males)*

	FVC (liters)	FEV_1 (liters)	FEV_1/FVC
Model r^2	0.409	0.426	0.149
Constant	−5.1475 0.5754 (<.001)	−2.7395 0.4909 (<.001)	0.9190 0.0140 (<.001)
Age, years	−0.0390 0.0030 (<.001)	−0.0434 0.0027 (<.001)	−0.0028 0.0003 (<.001)
Height, cm	0.0665 0.0031 (<.001)	0.0483 0.0026 (<.001)	
Current smoker (0 = no, 1 = yes)	−0.1293 0.0387 (<.001)	−0.2425 0.0331 (<.001)	−0.0304 0.0041 (<.001)
Pack-years		−0.0020 0.0010 (.050)	−0.0004 0.0001 (<.001)
Black (0 = no, 1 = yes)	−0.9085 0.0959 (<.001)	−0.5612 0.0810 (<.001)	0.0308 0.0100 (.002)
Hispanic (0 = no, 1 = yes)		0.2005 0.0985 (.042)	0.0400 0.0121 (.001)
Cumulative exposure mg/m^3-yr	−0.0010 0.0030 (>.2)	−0.0055 0.0025 (.030)	−0.0009 0.0003 (.005)

*Results shown are: estimated coefficient, standard error (p-value).

Alternative models including an additional indicator variable, to distinguish ex and never smokers or excluding miners who left employment for health reasons, gave very similar results. However, examination of the nature of the exposure-response relationship suggested that a log transformed exposure variable would be more appropriate. For FVC and FEV_1, inclusion of interaction terms between log exposure and age, and log exposure and smoking status, further improved the model fit. The final regression models selected for pulmonary function outcomes are presented in Table III. The associations of log cumulative exposure with FVC, FEV_1, and FEV_1/FVC were statistically significant ($p < .02$). To aid in interpretation of these models, predicted FEV_1 is presented in Figure 3 for current and not current smokers aged 30, 40, and 50 years over the range of cumulative exposures in the study. A decline of FEV_1 with increasing exposure is predicted for all cases except for current smokers aged 50 years. The estimated linear association (at age 40) of exposure with FEV_1, −5.5 ml per mg/m^3-years (Table II), is also displayed in Figure 3.

Logistic regression functions were fitted for categorical outcomes and are shown in Table IV. In these models, cumulative exposure was a statistically signif-

TABLE III. Regression Models for Pulmonary Function Outcomes (n = 1,185 Males)*

	FVC, liters	FEV_1, liters	FEV_1/FVC
Model r^2	0.412	0.433	0.150
Constant	−3.5460 0.8588 (<.001)	−1.2781 0.7276 (.079)	0.9365 0.0165 (<.001)
Age, years	−0.0715 0.0157 (<.001)	−0.0701 0.0132 (<.001)	−0.0028 0.0003 (<.001)
Height, cm	0.0661 0.0031 (<.001)	0.0480 0.0026 (<.001)	
Current smoker (0 = no, 1 = yes)	−0.4581 0.1979 (.021)	−0.6140 0.1667 (<.001)	−0.0305 0.0041 (<.001)
Pack-years		−0.0020 0.0010 (.053)	−0.0004 0.0001 (<.001)
Black (0 = no, 1 = yes)	−0.9186 0.0958 (<.001)	−0.5736 0.0808 (<.001)	0.0299 0.0100 (.003)
Hispanic (0 = no, 1 = yes)		0.1952 0.0979 (.046)	0.0393 0.0121 (.001)
Ln CE (ln mg/m^3-yr)	−0.5960 0.2476 (.016)	−0.5651 0.2083 (.007)	−0.0116 0.0038 (.002)
LnCE × age	0.0125 0.0060 (.036)	0.0102 0.0050 (.042)	
LnCE × current smoker	0.1231 0.0732 (.093)	0.1392 0.0616 (.024)	

*Results shown are: estimated coefficient, standard error (p-value).

icant ($p < .05$) predictor of FEV_1 <80%, FEV_1/FVC <80%, phlegm, breathlessness, wheeze, and wheeze with SOB. The trends for chronic bronchitis and obstructive bronchitis were of borderline statistical significance ($.05 < p < .1$) and, although the trend for cough is in the expected direction, the coefficient did not reach statistical significance ($p > .1$). Additional models were fit using categorical variables for exposure levels, and the results indicated that the linear functions for exposure adequately fit the data. Log transformation of cumulative exposure did not substantially improve the fit nor were interaction terms significant.

To translate these logistic regression coefficients into more easily interpretable measures, odds ratios for each of the measures are given in Table V. The ratios represent the increased odds for each increase in 1 and 20 mg/m^3-years of cumulative exposure. The estimated odds ratios for 20 mg/m^3-years of exposure are substantial. Note that 20 mg/m^3-years represents exposure at an average exposure of 1 mg/m^3 for 20 years.

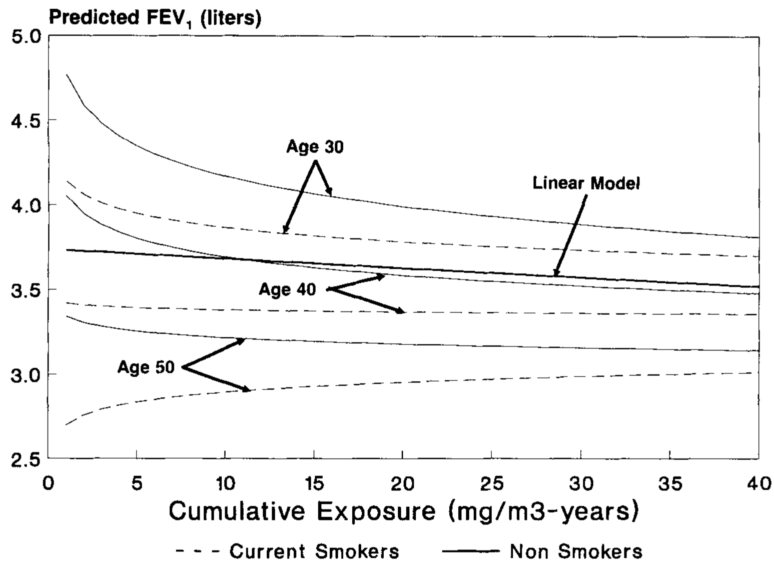

Fig. 3. FEV_1 by cumulative exposure to respirable coal mine dust for current and non smokers aged 30, 40, or 50 years, as predicted by the model given in Table III and the linear model (at age 40) given in Table II.

To further examine the interrelationships of smoking history and dust exposure, the cohort was stratified by smoking status (current, ex, never) and separate regressions were done for each of the outcomes. The models used for these regressions were the same as those given in Tables III and IV, with the smoking status variables removed for each group. For the never smoking group, pack-years was also removed. The resulting coefficients for cumulative exposure from these models are shown in Tables VI (linear models) and VII (logistic models). FEV_1 was significantly associated with log cumulative exposure in ex and never smokers and FEV_1/FVC was associated with log exposure in ex smokers (Table VI). For current smokers, only phlegm and breathlessness were significantly associated ($p < .05$) with exposure (Table VII). For most of the symptoms observed (cough, phlegm, chronic bronchitis, wheeze, and wheeze with SOB), a more marked association was observed for never smokers. FEV_1 predicted by the stratified model for never smokers is presented in Figure 4 for 30, 40, and 50 year old miners. A decline of function is predicted for the two younger age groups.

Examination for Potential Selection Effects

To assess the potential for selection bias occurring between R2 and R4, a separate analysis was conducted comparing the R2 health status of R4 participants and non-participants. Of the 7,387 miners from R1 or R2 not expected to reach retirement before R4 (Fig. 1), 4,225 were from R2 and were selected for study in R4. An additional 189 not selected for R4 participated in the R4 mine surveys giving a total of 4,414 eligible for examination at R4. On the basis of their R2 work histories 1,882 of these miners had started work after 1970. Thirty-seven of these miners had

TABLE IV. Logistic Regression Models for Categorical Outcomes (n = 1,185 Males)*

Variable	FEV_1 <80%	FEV_1/FVC <80%	Cough	Phlegm	Chronic bronchitis	Obstructive bronchitis	Breathlessness	Wheeze	Wheeze with SOB
Constant	−0.5400	−0.6435	1.5025	1.0867	3.3718	−7.0039	1.0077	0.2172	0.4493
	2.4903	4.0294	2.0292	1.9697	2.1353	0.9087	2.1760	2.0898	2.4445
	(>.2)	(>.2)	(>.2)	(>.2)	(.114)	(<.001)	(>.2)	(>.2)	(>.2)
Age	0.1057	0.0869	0.0194	0.0237		0.0777	0.0502	0.0405	0.0469
	0.1237	0.0208	0.0104	0.0100		0.0183	0.0107	0.0106	0.0121
	(<.001)	(<.001)	(.062)	(.018)		(<.001)	(<.001)	(<.001)	(<.001)
Height	−0.0364	−0.0434	−0.0207	−0.0202	−0.0295		−0.0257	−0.0196	−0.0247
	0.1347	0.0216	0.0108	0.0105	0.0119		0.0117	0.0112	0.0131
	(.007)	(.045)	(.056)	(.056)	(.013)		(.028)	(.079)	(.060)
Current smoker (0 = no, 1 = yes)	1.1062	1.1308	0.8313	0.7296	0.7733	1.1217		0.9099	
	0.1679	0.2801	0.1332	0.1292	0.1459	0.2683		0.1383	
	(<.001)	(<.001)	(<.001)	(<.001)	(<.001)	(<.001)		(<.001)	
Pack years		0.0207							
		0.0067							
		(.002)							
Black (0 = no, 1 = yes)	1.9339					1.0702			
	0.3361					0.4549			
	(<.001)					(.019)			
Hispanic (0 = no, 1 = yes)	−0.9924		−1.3272	−1.3544	−1.2990		−1.3383	−2.0048	−2.0570
	0.5851		0.5505	0.5050	0.6221		0.6268	0.7460	1.0303
	(.090)		(.016)	(.007)	(.037)		(.033)	(.007)	(.046)
Current miner (0 = no, 1 = yes)			−0.2135		−0.2912	−0.4905	−0.3737	−0.3892	−0.3089
			0.1383		0.1514	0.2709	0.1484	0.1431	0.1680
			(.124)		(.054)	(.070)	(.012)	(.007)	(.066)
Asthma[a] (0 = no, 1 = yes)								1.2037	2.1997
								0.0315	0.3218
								(<.001)	(<.001)
Cumulative exposure	0.0312	0.0463	0.0149	0.0301	0.0229	0.0358	0.0307	0.0253	0.0312
	0.0126	0.0202	0.0108	0.0101	0.0118	0.0204	0.0115	0.0112	0.0130
	(.014)	(.022)	(.165)	(.003)	(.052)	(.079)	(.008)	(.024)	(.016)

*Results shown are: estimated coefficient, standard error, (p-value).
[a]History of asthma reported. Only entered models for Wheeze and Wheeze with SOB.

died before R4 and are excluded from this analysis. Of the 1,845 R2 miners available for consideration of selection bias in R4, 1,092 participated in R4 and 753 did not.

The comparison of the eligible participants and non-participants is shown in Table VIII. R4 non-participants were slightly younger and were more likely to be current smokers. Non-participants appeared to have slightly higher symptom prevalence; however, pulmonary function measures did not show a similar relationship. In summary, only small differences were seen between the two groups in the R2 data.

PFT Reproducibility

Of the 1,185 members of the study cohort, 98 did not have reproducible PFTs. A comparison of the reproducible and non-reproducible PFT groups is given in Table IX. Miners with non-reproducible PFTs were slightly older and less likely to be a current smoker. They had substantially lower FVC and FEV_1 with little difference in the ratio.

The previously developed linear regression models (Table II) for FEV_1 and

TABLE V. Odds Ratios for Exposure to 1 and 20 mg/m^3-Years Coal Mine Dust Based on Logistic Regression Models

	OR_1[a] (95% C.I.)[a]	OR_{20}[a]
FEV_1 <80%	1.03 (1.01,1.06)	1.9
FEV_1/FVC <80%	1.05 (1.01,1.09)	2.5
Cough	1.02 (0.99,1.04)	1.4
Phlegm	1.03 (1.01,1.05)	1.8
Chronic bronchitis	1.02 (1.00,1.05)	1.6
Obstructive bronchitis	1.04 (1.00,1.08)	2.0
Breathlessness	1.03 (1.01,1.05)	1.8
Wheeze	1.03 (1.01,1.05)	1.7
Wheeze with SOB	1.03 (1.01,1.06)	1.9

[a]Odds ratio as determined by the logistic models given in Table III for the increase in exposure of 1, and 20 mg/m^3-years.

TABLE VI. Comparison of Effects of Cumulative Dust Exposure on Pulmonary Function Estimated on Smoking Status Sub-Groups of the Cohort of Coal Miners*

	Smoking status		
	Current	Ex	Never
n	469	393	323
FVC			
Ln CE	−0.6437	−0.3030	−0.6362
SE	0.3953	0.4047	0.5212
p	(.014)	(>.2)	(>.2)
Ln CE × age	0.0171	0.0055	0.0134
SE	(0.0100	0.0095	0.0131
p	(.089)	(>.2)	(>.2)
FEV_1			
Ln CE	−0.2672	−0.5795	−0.8449
SE	0.3556	0.3310	0.4075
p	(>.2)	(.081)	(.039)
Ln CE × age	0.0062	0.0098	0.0180
SE	0.0090	0.0078	0.0103
p	(>.2)	(>.2)	(.079)
FEV_1/FVC			
Ln CE	−0.0075	−0.0201	−0.0067
SE	0.0062	0.0066	0.0067
p	(>.2)	(.002)	(>.2)

*Provided are the coefficients, standard errors and p-values for cumulative exposure or log cumulative exposure obtained from the models given in Table III, run on the specified smoking subgroups.

FEV_1/FVC were rerun excluding miners with non-reproducible PFTs. The coefficient for the association of cumulative dust exposure with FEV_1 was -0.0044 ± 0.0025 ($p = .087$) and for FEV_1/FVC, it was -0.0008 ± 0.0003 ($p = .016$). Both coefficients are slightly smaller than the coefficients for the linear models run on the group including miners with non-reproducible results (−0.0055 and −0.0009 for ml FEV_1 and FEV_1/FVC, respectively).

TABLE VII. Comparison of Effects of Cumulative Dust Exposure on Smoking Status Sub-Groups of the Cohort of Coal Miners for Logistic Models*

	Smoking status		
	Current	Ex	Never
n	469	393	323
$FEV_1 < 80\%$	0.0171	0.0537	0.0375
SE	0.0176	0.0256	0.0267
p	(>.2)	(.036)	(.160)
$FEV_1/FVC < 80\%$	0.0278	0.0718	0.0965
SE	0.0262	0.0386	0.0582
p	(>.2)	(.063)	(.097)
Cough	0.0119	0.0092	0.0452
SE	0.0159	0.0208	0.0212
p	(>.2)	(>.2)	(.033)
Phlegm	0.0301	−0.0247	0.0412
SE	0.0153	0.0185	0.0200
p	(.049)	(.183)	(.040)
Chronic bronchitis	0.0204	−0.0013	0.0519
SE	0.1701	0.0234	0.0238
p	(>.2)	(>.2)	(.029)
Obstructive bronchitis	0.0356	0.0389	0.0462
SE	0.0261	0.0466	0.0483
p	(>.2)	(>.2)	(>.2)
Breathlessness	0.0367	0.0517	0.0100
SE	0.0183	0.0215	0.0211
p	(.045)	(.016)	(>.2)
Wheeze	0.0082	0.0128	0.0787
SE	0.0161	0.0215	0.0235
p	(>.2)	(>.2)	(<.001)
Wheeze with SOB	0.0207	0.0297	0.0495
SE	0.0215	0.0230	0.0242
p	(>.2)	(>.2)	(.040)

*Regression Coefficients for Cumulative Exposure or Ln cumulative exposure (coefficients, standard errors, p-values) estimated from linear and logistic regression models as specified in Tables II and III. Units in Ln Cumulative Exposure (ln mg/m^3-years).

DISCUSSION

The results of this analysis indicate an association of respirable coal mine dust with pulmonary function and chest symptoms consistent with airways obstruction. Age, race/ethnicity, and smoking-adjusted statistically significant associations with dust exposure were found for decrements in FVC, FEV_1, and FEV_1/FVC, the odds of FEV_1 and FEV_1/FVC less than 80% predicted, and the odds of developing symptoms of chronic bronchitis, breathlessness, and wheeze. The cohort had been exposed for a maximum of 18 years and had an estimated average cumulative exposure of 15.6 mg/m^3-years. The detection and quantification of such effects for coal mine dust at these exposure levels has not been previously demonstrated.

The models which best describe the associations of exposure and pulmonary

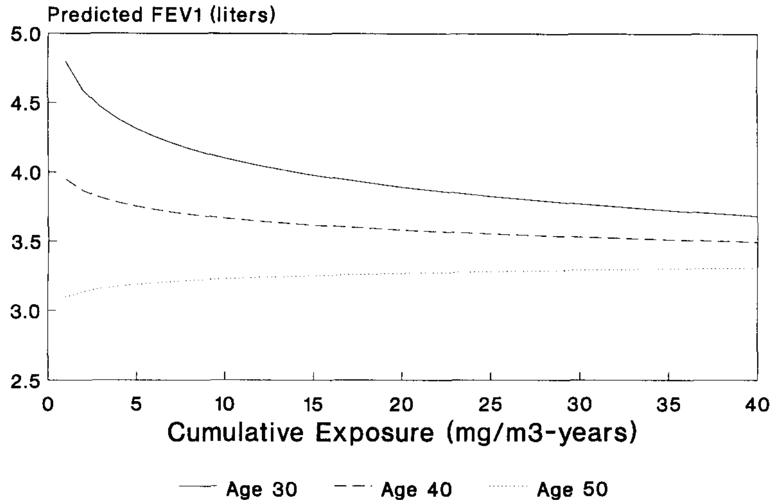

Fig. 4. FEV_1 by cumulative exposure to respirable coal mine dust for never smokers aged 30, 40, or 50 years, as predicted by the model presented in Table VI.

function outcomes are complex. The logarithm of cumulative exposure was linearly related to decrements in pulmonary function, suggesting a proportionately greater response at low cumulative exposures than at high ones. In addition, significant interactions were observed between log exposure and age and smoking status. These results suggest that the dust-related decrements in function are greater in younger miners and in non-smokers (Figs. 3, 4). Although the model predicts that, in older smokers, there is actually a reverse effect of exposure (greater exposure predicts higher lung function), the magnitude of the effect for older smokers was very small. This reverse effect could have easily arisen from imprecision in the estimates of the coefficients. In fact, in an analysis restricted to miners aged 42 years or older, the effect of exposure was not statistically significant.

It is unlikely that selection effects account for the observed relationship between cumulative exposure and respiratory effects. Attfield (1990) found some evidence that R4 participants had slighty better health status than non-participants. In this analysis of the sub-cohort employed after 1970, R4 participants had similar pulmonary function and slightly lower prevalence of symptoms at R2 than R4 non-participants (Table VIII). These observations indicate that the studied cohort was similar, or perhaps slightly healthier than eligible miners that were not surveyed. Perhaps most importantly, it is difficult to hypothesize a plausible mechanism by which miners with poorer baseline respiratory health would have selected into higher exposure occupations. Nonetheless, the possibility of selection effects pre-dating R2 cannot be excluded completely with the available data, and it is not possible to quantitatively determine if the studied miners' responsiveness to dust exposure differs from miners in general.

Researchers using cross-sectional data from the British Pneumoconiosis Field Research have estimated the effect of cumulative respirable dust exposure (not log transformed) to be about 1.0 to 1.6 ml FEV_1 per mg/m^3-year [Soutar, 1987] (assuming 1,740 hours worked per year as derived from the British Pneumoconiosis

TABLE VIII. Comparison of Health Status of Coal Miners at Round 2 for Round 4 Participants and Non-Participants*

	Participants	Non-participants
n	1,092	753
Age, years	27.6 (6.6)	26.4 (6.0)[a]
% white	95.8	94.0[b]
Years mining	2.2 (1.3)	2.1 (1.3)
Smoking status (%)		
current	57.4	62.2[b]
ex	16.8	12.2
never	25.8	25.6
Pack-years	6.22 (8.40)	5.99 (7.69)
% predicted		
FVC	103.8 (12.6)	103.0 (12.6)
FEV_1	98.6 (12.8)	98.8 (13.3)
FEV_1/FVC	95.0 (8.5)	95.9 (8.2)[a]
% <80% predicted		
FEV_1	7.7	8.2
FEV_1/FVC	5.2	3.7
% with symptoms		
Cough	13.8	15.1
Phlegm	19.0	21.1
Chronic bronchitis	9.5	10.9
Obstructive bronchitis	1.0	1.6

*Continuous variables—mean (S.D.). Categorical variables—percent (No.).
[a]Two sample t-test, $p < .05$.
[b]Chi-square test of association, $p < .05$.

Field Research studies [Hurley et al., 1982]). The corresponding estimate in the current analysis, based on a similar type of linear model, was considerably greater at 5.5 ml per mg/m^3-year. Although the linear model with the log of exposure and interactions demonstrated a more complex relationship, the average linear relationship fits well with the data over most of the range of exposures (as demonstrated in Fig. 3).

The causes of the difference in estimated effects on the FEV_1 in this study and the British studies may be related to a combination of several factors. Non-linearities in exposure-response with respect to cumulative exposure, age, time since beginning of exposure, or concentration could play a role, and the improved fit of the models using the log of exposure is consistent with these hypotheses. The population in the current study differs in several respects from that of the British studies which estimated the annual loss of FEV_1. For example, in the study reported by Soutar and Hurley [1986], the population was older (mean age 53 years as compared to 40 years in the current study), exposed to a higher dust concentration (mean of 3 vs. 1.2 mg/m^3), and had worked for longer periods of time (mean of 33 vs. 13 years). If exposure early in a miners' career and/or at a young age were associated with a steeper exposure-response than later (as suggested by the current data), this could explain some of the differences. An interaction between dust exposure and age which may be consistent with this finding has been observed previously [Rogan et al.,

TABLE IX. Comparison of Sub-Groups of Cohort of Coal Miners With and Without Reproducible PFTs*

	Reproducible PFTs	
	Yes	No
n	1,087	98
Age (yr)	39.8 (6.3)	41.7 (6.5)
% (no.) white	93.5 (1,016)	88.8 (87)
Cumulative exposure (mg/m^3-yr)	15.7 (6.5)	14.4 (5.8)
Smoking status		
current	40.4 (439)	30.6 (30)
ex	33.0 (359)	34.7 (34)
never	26.6 (289)	34.7 (34)
Pack-years	21.6 (16.4)	24.6 (19.2)
% predicted		
FVC	97.5 (13.0)	88.6 (15.1)
FEV_1	93.1 (14.0)	83.8 (16.3)
FEV_1/FVC	95.6 (8.8)	94.6 (9.2)
<80% predicted		
FVC	8.7 (95)	25.5 (25)
FEV_1	16.6 (180)	36.7 (36)
FEV_1/FVC	5.4 (59)	6.1 (6)

*Reproducible PFTs defined as second highest FVC and FEV_1 within 5% of the highest. Continuous variables—mean (S.D.). Categorical variables—percent (no.).

1973]. Because of the complexity of the final models, it would not be prudent to extrapolate the findings beyond the range of exposures observed in this study.

Other potential causes of the difference in the effect estimate could include systematic under-estimation of U.S. exposure levels and/or systematic over-estimation of British exposure levels. Because of evidence of under-estimation of exposure by U.S. mine operator-collected samples [Seixas et al., 1990b; Boden and Gold, 1984], an upward 13% adjustment was made in these estimates. However, there is substantial uncertainty regarding the level of adjustment needed. A recent court decision [MSHA, 1991a] and regulatory actions [MSHA, 1991b] citing systematic tampering with samples to produce low results by over 500 mining companies highlights this uncertainty. Real differences in either the inherent toxicity of U.S. vs. British coal dust, or in the respective populations' susceptibility to the dust also could have contributed to the apparent discrepancies. Finally, chance could play a role since the 95% confidence interval on the linear estimate from this analysis (−0.6, −10.4 ml per mg/m^3) includes the exposure-response estimates from the British studies (−1.0 to −1.6 ml per mg/m^3).

The relevance of these results to clinically significant impairment bears examination. While having an FEV_1 slightly less than 80% predicted may not be associated with any significant impairment, it may portend additional losses in pulmonary function which would be associated with impairment and increased risk of mortality. If those individuals with greater than average loss continue to lose function, they may develop substantial impairment within their working lifetime. Of course, such extrapolation of effects would be based on an assumption of continued loss over time which cannot be ascertained with the current data. Nevertheless, there remains a possibility that at least some sub-groups may be affected to a sufficient degree to present chronic problems.

The regression coefficients relating age to FVC and FEV_1 (decrements of 39 and 43 ml per year of age), shown in Table II, are somewhat larger than the values frequently observed in population-based cross-sectional studies (20 to 30 ml per year) which report pulmonary function prediction equations [Crapo et al., 1981; Knudson et al., 1983; Morris et al., 1971]. However, the coefficients for age are comparable to those observed by other investigations of coal miners' respiratory health. Rogan et al. [1973] reported a coefficient of −47 ml FEV_1 per year of age and Soutar and Hurley [1986] reported a decline of 42 and 41 ml for FVC and FEV_1, respectively, per year of increased age.

The estimated effect of pack-years (2 ml per pack-year) was unexpectedly small. The reason for this remains largely unexplained, although in an alternative model employing an additional dummy variable separating the ex smokers from the never smokers, the pack-years coefficient was larger (4 ml per pack-year). This increase in the size of the coefficient occurred without any concomitant decrease in the magnitude of the dust exposure coefficient. In any event, the lower than expected value of the pack-years coefficient appears to be unlikely to be due to confounding or collinearity with dust exposure because, after controlling for age, there is a small negative correlation between exposure and pack-years. Moreover, the association between exposure and reduced FEV_1 was observed even in the never-smoking group.

Some additional questions may be raised which affect the interpretation of the models used. First, measurements of respirable coal mine dust were used to estimate dose. For the study of effects on the large airways (which FEV_1, FEV_1/FVC, chronic bronchitis, and wheezing may represent), dust depositing in the tracheo-bronchial region may be of equal or greater importance as a measure of exposure [ACGIH, 1985]. While this potential limitation is acknowledged, no estimates of total or tracheo-bronchial dust exposure are available. Because there is evidence that the ratio of tracheo-bronchial to respirable fraction dust does vary across occupations [Potts et al., 1990], the resulting misclassification may result in bias toward the null (if the ratios vary randomly) or away from the null (if the ratios are correlated with exposure level). It is not possible to determine which of these biases would be greater in the current analysis. The potential importance of exposure to the tracheo-bronchial dust fraction is currently being explored.

Second, cumulative exposure is only one of many potential summary measures to approximate the relevant dose. Models accounting for non-linear aspects of the exposure-disease relationship, including dust clearance mechanisms, peak exposures, and other toxicologic aspects of the exposure under study, might significantly alter the findings [Smith, 1985, 1992]. In further analyses of this data which included modeling of the effects at R2 [Seixas, 1990], the observed exposure-response functions were decidedly non-linear over time. Additional study of the temporal pattern of exposure is underway.

Third, the multiple regression models (linear and logistic) used for the analysis contain many assumptions about the shape of the response curve over the ranges of the variables. The appropriateness of the statistical models has been tested by observation of residuals, categorizing some continuous variables (e.g., cumulative exposure and age), and by observing the effect of interaction terms (between exposure and smoking variables). The final models incorporating the log of cumulative exposure and interaction terms fit the data well. It is, of course, always possible that exploration of additional models could provide additional improvements.

The overall obstructive pattern on PFTs observed in these data is indistinguishable from the typical effects of smoking, and an expected significant influence of smoking status on pulmonary function outcomes was observed in this cohort. In addition to looking at interaction between smoking and exposure, the cohort was stratified on smoking status and the linear (log of exposure) and logistic regression models were run on each sub-group (Tables VI, VII). It appears that non-smokers had a larger negative response to dust exposure than current smokers. For the pulmonary function outcomes, statistically significant effects of exposure were observed only for FEV_1 in the ex and never smoking groups. Soutar and Hurley [1986] also found slightly higher effects of dust in non-smokers in comparison to current smokers. One possible explanation for the larger effect in ex and never smokers compared to current smokers is that the effects of smoking mask the more variable effect of dust exposure.

The logistic regression models for the never smoked group also provide statistically significant associations with several of the symptom outcomes (Table VII), suggesting an effect of dust exposure on the airways, independent of smoking.

In conclusion, the implementation and enforcement of standards resulting in lowered concentrations of coal mine dust in U.S. coal mines does not appear to have been completely effective in preventing measurable adverse respiratory effects in this cohort. The obstructive patterns found on pulmonary function tests and the prevalence of obstructive symptoms were associated with measures of cumulative exposure. However, the mechanisms for the observed effects, and in particular, the temporal patterns of the exposure-disease relationships are complex, as suggested by nonlinearities and interactions observed in this analysis. Additional consideration of the temporal patterns of the exposure-response relationship will be the subject of a subsequent publication. Nevertheless, the findings of this analysis suggest that miners have experienced respiratory effects of dust exposure over the range of exposures present in mines after 1969.

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ADDENDUM

After completing the above manuscript, it was brought to our attention that an early programming error had miscalculated one of our variables, pack-years, for ex-smokers. We have rerun the models presented in the paper with the corrected quantity and observed no material effect on the results as they were presented. However, for the sake of accuracy, the following corrections should be noted.

Ex- and current smokers had an average of 16.9 (± 13.7) pack-years when the corrected value for ex-smokers, 14.5 (± 14.6), was used (Table I). A revised Table II is given below. As noted, no substantial change in any model parameter was observed. The effect of cumulative exposure on FEV_1 was −0.0057 (p = 0.024), rather than the originally reported −0.0055 (p = 0.030). In Table III, the estimated effect of pack-years on FEV_1 went from −0.0020 ± 0.0010 (p = .053) liters per pack-year to −0.0045 ± 0.0013 (p < 0.001), while none of the coefficients for exposure (ln CE and interactions) changed by more than 3%. Similarly, small changes were observed for the models presented in Table IV (FEV_1/FVC < 80%) and Table VI (Ex Smokers, FEV_1 and FEV_1/FVC).

We regret this error and hope that the minor corrections do not inconvenience the reader.

TABLE II. (Revised). Linear Regression Models for Pulmonary Function Outcomes (n = 1,185 Males)*

	FVC (liters)	FEV_1 (liters)	FEV_1/FVC
Model r^2	0.409	0.430	0.148
Constant	−5.1475 0.5754 (<.001)	−2.8076 0.4897 (<.001)	0.9187 0.0140 (<.001)
Age, years	−0.0390 0.0030 (<.001)	−0.0421 0.0027 (<.001)	−0.0028 0.0003 (<.001)
Height, cm	0.0665 0.0031 (<.001)	0.0485 0.0026 (<.001)	
Current smoker (0 = no, 1 = yes)	−0.1293 0.0387 (<.001)	−0.2022 0.0359 (<.001)	−0.0265 0.0045 (<.001)
Pack-years		−0.0045 0.0013 (<.001)	−0.0006 0.0002 (<.001)
Black (0 = no, 1 = yes)	−0.9085 0.0959 (<.001)	−0.5649 0.0807 (<.001)	0.0313 0.0100 (.002)
Hispanic (0 = no, 1 = yes)		0.1835 0.0984 (.062)	0.0393 0.0121 (.001)
Cumulative exposure mg/m^3-yr	−0.0010 0.0030 (>.2)	−0.0057 0.0025 (.024)	−0.0009 0.0003 (.005)

*Results shown are: estimated coefficient, standard error (p-value).

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