Applied Occupational and Environmental Hygiene

ISSN: 1047-322X (Print) 1521-0898 (Online) Journal homepage: https://www.tandfonline.com/loi/uaoh20

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To cite this article: Eileen D. Kuempel , Randall J. Smith , Michael D. Attfield & Leslie T. Stayner (1997) Risks of Occupational Respiratory Diseases among U.S. Coal Miners, Applied Occupational and Environmental Hygiene, 12:12, 823-831, DOI: 10.1080/1047322X.1997.10390616

To link to this article: https://doi.org/10.1080/1047322X.1997.10390616

Published online: 25 Feb 2011.

Risks of Occupational Respiratory Diseases among U.S. Coal Miners

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The excess (exposure-attributable) risks of certain respiratory diseases and outcomes were estimated for U.S. coal miners exposed to respirable coal mine dust for various durations and concentrations, including a 45-year working lifetime at the current 2-mg/m³ standard. Multiple linear and logistic regression models were used to compute predicted prevalence and excess risk of disease, using data and regression results from published epidemiological studies of U.S. coal miners. Disease outcomes evaluated include simple coal workers' pneumoconiosis, progressive massive fibrosis, and clinically significant deficits in lung function, measured as forced expiratory volume in 1 second of <80% or <65% of predicted normal values. Point estimates of excess risk of progressive massive fibrosis ranged from 1/1000 to 167/1000 among coal miners exposed to respirable coal mine dust at a mean concentration of 2 mg/m³ for 45 years. This range reflects coal rank and study differences. Point estimates for an excess risk of forced expiratory volume in 1 second of <65% of predicted normal values ranged from 9/1000 to 188/1000 among miners with the same exposures noted above (the range reflects smoking status, geographical region, and study differences). Excess risks for all disease outcomes studied exceeded 1/1000 among miners exposed to mean concentrations as low as 0.5 mg/m³ and durations as low as 15 years (most coal ranks). Sources of uncertainty associated with these results were considered. Based on these and previous analyses, U.S. coal miners are predicted to have a substantial risk of developing occupational respiratory diseases from working lifetime exposures to respirable coal mine dust at the current 2-mg/m³ standard. To reduce this risk, the National Institute for Occupational Safety and Health (NIOSH) recommends that worker exposures to respirable coal mine dust be kept below 1.0 mg/m³ during each work shift (as a time-weighted average concentration for up to 10 h/day during a 40-hour workweek). KUEMPEL, E.D.; SMITH, R.J.; ATTFIELD, M.D.; STAYNER, L.T.: RISKS OF OCCUPATIONAL RESPIRATORY DISEASES AMONG U.S. COAL MINERS. APPL. OCCUP. ENVIRON. HYG. 12(12):823–831; 1997. © 1997 AIH.

The current U.S. standard for respirable coal mine dust of 2 mg/m³, which was established in the Federal Coal Mine Health and Safety Act of 1969,[1] is based largely on studies of coal miners in the United Kingdom.[2–4] U.S. studies at that time did not include quantitative exposure data needed for exposure–response studies. The U.K. studies showed two important relationships. First, the risk of developing progressive massive fibrosis (PMF) was found to increase with increasing category of simple coal workers' pneumoconiosis (CWP), particularly among miners with simple CWP category 2 or greater.[3,4] Second, the quantitative relationship between cumulative exposure to respirable coal mine dust and the risk of developing simple CWP[2,5] or PMF[4] was described, and the probability of progression to simple CWP category 2/1 or greater was estimated to be essentially zero for miners with 35 years of exposure to an average concentration of 2 mg/m³. Thus, 2 mg/m³ was adopted as the U.S. standard for respirable coal mine dust.[1]

Although simple CWP is not necessarily associated with impaired lung function or disability, miners with simple CWP have a greater risk of developing PMF.[3,4,6] PMF has been associated with impaired lung function, disability, and early death.[7] Miners may also develop decrements in lung function, sometimes severe, as a result of their exposure to respirable coal mine dust, whether or not pneumoconiosis is present.[8–15]

In the United States, studies performed since 1969 have included both cumulative exposure estimates and medical data, thus enabling the direct evaluation among U.S. coal miners of exposure–response for simple CWP and PMF[16,17] and for deficits in lung function, including forced expiratory volume in 1 second (FEV_1).[13–15] In the United Kingdom, several additional epidemiological studies have been performed since 1969 to investigate the exposure–response relationships between cumulative exposure to respirable coal mine dust and simple CWP and PMF[6,18–20] and lung function deficits.[8–12] In Germany, exposure–response relationships for simple CWP have been reported.[21,22] These studies provide an important basis for comparison with the U.S. studies.

In general, risk estimates have been higher in studies of U.S. coal miners than in those in other countries. Because the U.K. studies were based on medical and personal exposure data collected specifically for epidemiological study,[23] the prevalence estimates from the U.K. studies may be more reliable. However, the U.S. studies are more relevant to conditions in the United States. Therefore, the U.S. studies were used to estimate excess risks for U.S. coal miners.

The objectives of this article are to summarize the risk estimates from previous epidemiological studies of U.S. coal miners and to estimate working lifetime excess (exposure-attributable) risks using data from these studies. In this article, the methods for computing these risk estimates are described; the results of excess risk estimates are presented; and the National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit (REL) for respirable coal mine dust, which was derived using these risk estimates, is described.

TABLE 1. Epidemiological Exposure–Response Studies of U.S. Coal Miners

Disease Outcome Evaluated and Study Reference	Number of Miners	Date of Medical Examination
Simple CWP or PMF		
Attfield and Morring[16]	9078	1969–71
Attfield and Seixas[17]	3194	1969–71; follow-up in 1985–88
Lung function deficits[A]		
Attfield and Hodous[13]	7139	1969–71
Seixas et al.[14,15][B]	1185 or 977	1969–71 or 1972–75; follow-up in 1985–88

[A]FEV_1 <65% or <80% of predicted normal values.
[B]Study of miners new to coal mining during or after 1970.

Methods

The working lifetime excess risk estimates for certain respiratory diseases and outcomes among coal miners were computed using results from the published exposure–response studies of U.S. coal miners[13–17] (Table 1). These diseases and outcomes, which are defined in terms of standardized criteria for interpreting chest radiographs and spirometry results, include simple CWP, PMF, and decrements in FEV_1. In a population of individuals without exposure to respirable coal mine dust, there is some age-related "background" prevalence of either small radiographic opacities[24] or lung function values below predicted normal levels.[25] These "background" prevalences in the coal miner cohort can be predicted, for individuals with given values of covariates and assumed zero exposure to respirable coal mine dust, from the linear and logistic regression models describing exposure–response.[13–17] The excess (exposure-attributable) risk is obtained by subtracting the predicted prevalence among individuals with assumed zero exposure from the predicted prevalence among individuals with a given cumulative exposure to respirable coal mine dust (but otherwise with the same covariate values).

Data Used

The studies used in this analysis (Table 1) include health effects data from the National Study of Coal Workers' Pneumoconiosis (NSCWP) and exposure data from sampling programs of the Mine Safety and Health Administration (MSHA) and Burêau of Mines (BOM).[26] The NSCWP is an epidemiological research program that includes data from the medical examinations and work histories of more than 17,000 U.S. coal miners from 1969 through 1988.[27] The BOM data include measurements of respirable coal mine dust collected during a survey in 1968 and 1969 of 29 underground coal mines across the United States.[26,28] The MSHA data of respirable coal mine dust were collected from 1970 to 1988 (and continuing) as part of a mandated sampling program.[1]

Two separate cross-sectional surveys of the NSCWP were examined in these published studies (Table 1): Round 1 (1969–1971)[13,16] and Round 4 (1985–1988).[14,15,17] Round 4 is a follow-up study of current miners and ex-miners who had participated in Round 1. The medical examinations at each round included a chest X-ray, spirometry, and a questionnaire on work history, smoking history, and respiratory symptoms. Study populations of miners (all male) consisted of the following: 9078 miners from 31 mines across the United States;[16] 7139 whites of age 25 years or older[13] (subset of Attfield and Morring[16]); 3194 underground bituminous coal miners and ex-miners[17] (follow-up study of Attfield and Morring[16]); and 977 of the 1185 miners new to mining in 1970[14,15] (subset of Attfield and Seixas[17]).

The chest radiographs were classified according to the International Labour Office classification scheme (discussed in Attfield and Morring[16] and Attfield and Seixas[17]). Response variables for chest X-ray findings in this study include the following: simple CWP category 1 or greater (indicates any chest X-ray presenting major category 1, 2, or 3 small opacities and/or any category of large opacities); simple CWP category 2 or greater (indicates major category 2 or 3 and/or large opacities); and PMF (indicates any category of large opacities).

Lung function response variables evaluated in this study include FEV_1 of either <80% or <65% of predicted normal values. Predicted normal values were computed as the mean of the distribution of FEV_1 values in the coal miner cohort with given values of covariates and with cumulative exposure equal to zero (Figure 1). These percentages were selected because they may indicate clinically important deficits. For example, FEV_1 of <80% of predicted normal values is approximately equal to the lower limit of normal, defined as the 5th percentile of the distribution of lung function values in a normal population.[25,29] FEV_1 of <65% of predicted normal values (also estimated in a study of U.K. coal miners)[10] is approxi-

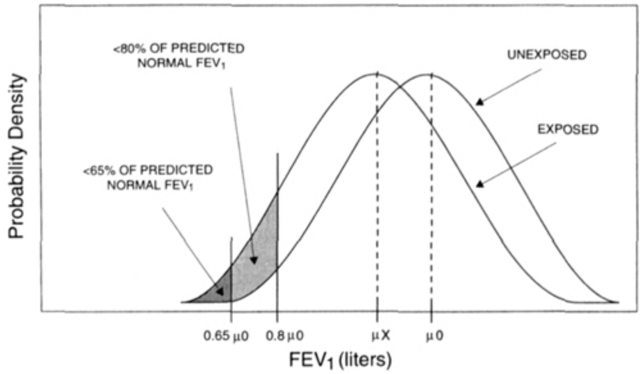

FIGURE 1. The effect of cumulative exposure to respirable coal mine dust on FEV_1. The effect illustrated is a shift in the distribution of FEV_1 values among individuals without exposure to respirable coal mine dust toward lower values of FEV_1. The shaded regions thus represent the excess (exposure-attributable) risk of having FEV_1 <80% or <65% of the predicted normal value ($\mu 0$), as described in equation (4).

mately equal to FEV_1 deficits that have been associated with severe exertional dyspnea in U.K. miners.[9]

Individual cumulative exposures were estimated for each miner from the time of starting work until the date of the medical examination. For miners participating in Round 1 of the NSCWP (1969–1971),[13,16] cumulative exposures were estimated by computing the sum of the products of the mean concentration of respirable coal mine dust for a given job and the years worked in that job.[26] Mean concentrations by job were estimated from BOM exposure monitoring data during 1968–1969 and from MSHA compliance data during 1970–1972.[26] For miners participating in Round 4 of the NSCWP (1985–1988),[14,15,17] cumulative exposure estimates after 1970 were computed using the sum of the products of time worked in each job with dust concentration data from the exposure matrix developed by Seixas et al.[30] For miners participating in Round 4,[14,15,17] cumulative exposures from working before 1970 were estimated using the same approach as for Round 1 participants.[26] In two studies[13,16] the cumulative exposure estimates were expressed as gram-hours per cubic meter (g-hr/m^3) (as in the U.K. studies) by using the factor of 1740 h/yr/1000 milligrams per gram (mg/g). For these analyses, the inverse of that factor was used to express the cumulative exposure estimates as milligram-years per cubic meter (mg-yr/m^3) for consistency with the other U.S. studies.

Statistical Methods

SIMPLE CWP AND PMF. The excess risk estimates are based on the fitted models from the published studies (Table 1). Attfield and Seixas[17] and Attfield and Morring[16] used logistic regression models to compute prevalence estimates for simple CWP and PMF among miners with given values of age and cumulative exposure. The prevalence for given values of age and cumulative exposure, $P(\text{Age}, X)$, was thus modeled using the following logistic regression equation:

$$P(\text{Age}, X) = \exp(\beta_0 + \beta_{age} * \text{Age} + \beta_{Xr}*X)/[1 + \exp(\beta_0 + \beta_{age} * \text{Age} + \beta_{Xr}*X)] \quad (1)$$

where the coefficients to be estimated are β_0, the intercept; β_{age}, the coefficient for age at the time of medical examination; and β_{Xr}, the coefficient for cumulative exposure to respirable coal mine dust (X) of a type identified by r. The index, r, identifies the rank of coal or the region of the United States where it is mined (five coal ranks were evaluated in Attfield and Morring[16] and two coal ranks were evaluated in Attfield and Seixas[17]). The logistic model is based on the assumption that the data have a binomial distribution (for a given set of covariate values). Separate models were fitted for simple CWP category 1 or greater, simple CWP category 2 or greater, and PMF. Additional information is provided in Attfield and Seixas[17] and Attfield and Morring.[16]

A property of these models is that they predict a positive prevalence associated with any given age or exposure (including prevalence among those without dust exposure, i.e., zero exposure). For a given age and cumulative exposure, the model permits the prevalence to be either increased ($\beta_{Xr} > 0$), decreased ($\beta_{Xr} < 0$), or unchanged ($\beta_{Xr} = 0$) relative to no exposure.

In this study, the excess (exposure-attributable) risk for a given age and cumulative exposure, $ER(\text{Age}, X)$, was determined by the difference in the prevalence of disease among individuals either with or without exposure to respirable coal mine dust as follows:

$$ER(\text{Age}, X) = P(\text{Age}, X) - P(\text{Age}, 0) \quad (2)$$

where Age, X, and $P(\cdot,\cdot)$ are given in equation (1) and $ER(\text{Age}, X)$ is the corresponding excess prevalence.

FEV_1. Attfield and Hodous[13] and Seixas et al.[14,15] used linear regression to model the FEV_1 data of U.S. coal miners for given values of age, cumulative exposure, and other covariates. The following is a summary model of the variables used in each study, with covariates described for each model. The expected mean value of FEV_1, $E(FEV_1|\text{Age} \ldots X)$, is determined from this model for persons with given values of cumulative exposure to respirable coal mine dust (including zero exposure) and covariates:

$$E(FEV_1|\text{Age} \ldots X) = \beta_0 + (\beta_{age} * \text{Age}) + (\beta_{ht} * \text{Ht}) + (\beta_{reg} * \text{Reg}_i) + (\beta_{race} * \text{Race}_i) + (\beta_{csmok} * \text{Csmok}_i) + (\beta_{exsmok} * \text{Exsmok}_i) + (\beta_{pkyr} * \text{Pkyr}) + (\beta_X * X) \quad (3)$$

where the β's are regression coefficients associated with each predictor variable to be estimated; Age (years) is the miner's age at medical examination; Ht is height (inches); Reg_i is an indicator for the eastern (1) or western (0) region as defined in Attfield and Hodous[13] (this variable is not included in Seixas et al.[15]); Race_i is an indicator for black (1) or other (0) as defined in Seixas et al.[15] (not needed in Attfield and Hodous[13]); Csmok_i is an indicator of a current smoker at the time of the medical examination (1) or not (0); Exsmok_i is an indicator of an ex-smoker (1) or not (0) at the time of the medical examination (in Seixas et al.,[15] not in Attfield and Hodous[13]); Pkyr is the pack-years (packs per day × years smoked); and X is cumulative exposure to respirable coal mine dust (mg-yr/m^3). The estimated values of the coefficients are as listed in Seixas et al.[15] and Attfield and Hodous,[13] except for the following corrections to the estimated β's in Attfield and Hodous[13] (personal communication from M. Attfield to E. Kuempel, 11/93): $\beta_0 = -1544$; $\beta_{csmok} = -208$; and $\beta_{reg} = -212$ (computed as the average of the eastern regions relative to the west).

In the current study, the linear regression model was used to estimate the expected proportion of miners (with given values of covariates) having a response defined as FEV_1 below a certain percentage of the predicted normal FEV_1. The predicted normal FEV_1 was computed internally from the coal miner cohort data, using regression results from the fitted models[13,15] in which the values of age and other covariates were fixed at given values and cumulative exposure was set to zero. Thus, predicted normal FEV_1 was defined as the mean of the distribution of FEV_1 values, assuming zero exposure to respirable coal mine dust. The fixed values used for the variables—other than the indicator variables, which are described in equation (3)—include: Age = 65 years; Ht = 70 inches; Pkyr = 0 (never smoker) or 45 (smoker); and $X = 0$ (unexposed) mg-yr/m^3. Values for 80% and 65% of the predicted normal FEV_1 were then computed. The estimated percentage of miners whose FEV_1 values fall below either 80% or 65% of the predicted normal mean FEV_1 was then derived using the standardized Normal cumulative distribution (described below). In computing the excess risk estimates (equation 4), an assumption of the original models[13,15] was used, that is, the distribution of the observed values about their regression means was modeled as having a normal distribution with constant variance.

The excess (exposure-attributable) risk of having FEV_1 below a given percentage of the predicted normal FEV_1 (i.e., among coal miners with given values for age and other covariates and with assumed zero cumulative exposure), *ER*(*X*), was modeled as follows:

$$ER(X) = \Phi[F\mu_0 - \mu_x)/\sigma] - \Phi[(F\mu_0 - \mu_0)/\sigma] \quad (4)$$

where $\Phi(\mu)$ is the standardized normal cumulative distribution function, computed using the PROBNORM function[31]; F is fraction of interest (in this case, $F = 0.8$ or 0.65); μ_0 is the mean of the distribution of FEV_1 values among unexposed individuals (computed from equation 3); μ_x is the mean of the distribution of FEV_1 values among exposed individuals (computed from equation 3) with $X = 22.5$ to 90 mg-yr/m^3; and σ is the standard deviation, which was estimated using the root mean square error (RMSE) from the regression model. The value of RMSE for the Attfield and Hodous[13] model is 552 mL (corrected value for Attfield and Hodous,[13] personal communication from M. Attfield to E. Kuempel, 11/93). The value of RMSE for the Seixas et al.[15] model in Table 3, FEV_1, of Seixas et al.[15] is 0.538 L (personal communication from N. Seixas to E. Kuempel, 1/95). Equation (4) is illustrated in Figure 1.

Results

Simple CWP and PMF

Table 2 provides the excess risk estimates of simple CWP radiographic category 1 or greater, category 2 or greater, or PMF among U.S. coal miners at age 65 following exposures to mean concentrations of 0.5, 1.0, or 2.0 mg/m^3 of respirable coal mine dust during a 45-year working lifetime. Excess risk estimates are provided for both Round 1[16] and Round 4[17] of the NSCWP. Results are also presented separately for exposure to dust of different ranks of coal. Figure 2 shows the excess risk estimates of PMF among miners with 45-year exposures to respirable coal mine dust, based on data from both Round 1[16] and Round 4[17] of the NSCWP.

The point estimates of risk based on data from Round 1 or Round 4 of the NSCWP are similar for exposure to dust of similar ranks of coal (Table 2, Figure 2). For high-rank bituminous coal, 45-year working lifetime excess risk estimates of simple CWP category 1 or greater are 41/1000, 108/1000, and 338/1000 for exposure to a mean concentration of 0.5, 1.0, or 2.0 mg/m^3, respectively, while those from Round 4 are 48/1000, 119/1000, and 341/1000. Excess risk estimates of PMF are 13/1000, 34/1000, and 114/1000 for Round 1 compared to 13/1000, 36/1000, and 15/1000 for Round 4 (same exposures and coal rank as above).

The risk of PMF for durations of exposure less than 45 years was also evaluated in this study. Figure 3 illustrates the fitted relationship between excess risk of PMF and mean concentration of respirable coal mine dust among miners aged 65 who had been exposed for either 15, 30, or 45 years to respirable dust of either high-rank or medium/low-rank bituminous coal (as defined by Attfield and Seixas[17]; see Table 2, first footnote). Figure 3 shows that the excess risk of developing PMF by age 65 increases with increasing duration of employment and with increasing intensity of exposure. At any given duration and intensity of exposure, excess risk estimates are higher for miners exposed to dust of higher-rank coal. The mean concentration of 2 mg/m^3 and durations of 15 and 30 years are well within the range of the data.[32] At a mean concentration of 2.0 mg/m^3, the point estimate of excess risk of PMF at age 65 exceeds 1/1000 for all durations of exposure and coal ranks evaluated, with a range of risk estimates from 6 to 155 per 1000, depending on duration and coal rank. A risk of 1/1000 was described as a significant risk in the U.S. Supreme Court benzene decision.[33]

FEV_1

Table 3 provides the excess risk estimates of decreased lung function among U.S. coal miners at age 65 following exposure to a mean concentration of 0.5, 1.0, or 2.0 mg/m^3 of respirable coal mine dust during a 45-year working lifetime. Excess risk estimates are provided for white miners who participated in Round 1[13] and for all miners who participated in Round 4 and who were new to mining in Round 1 or later (and who also participated in Round 2).[15] Excess risk estimates are provided separately by region (east or west) for miners in the Attfield and Hodous[13] study. For miners in both studies, excess risk estimates are provided separately for ever smokers and never smokers. In computing the predicted normal FEV_1 values for smokers, the effects of smoking were included in the statistical model with the other covariates. Thus, the estimates of excess risk represent those attributable to cumulative exposure to respirable coal mine dust.

Figure 4 shows the excess risk estimates of FEV_1 <65% of predicted normal values among miners aged 65 with 45-year exposures to respirable coal mine dust, based on data from Round 1[13] of the NSCWP for both smokers and nonsmokers (never smokers). Among miners with 45-year working lifetime exposures to a mean concentration of 2 mg/m^3 respirable coal mine dust, the estimated excess risk of <65% FEV_1 is 9/1000 for never smokers in the western region and 12/1000 for the eastern region (Table 3, Figure 4). Among smokers, those estimated risks are 15/1000 and 19/1000, respectively. The risk estimates from the Seixas et al.[15] study are several times higher (Table 3). This is considered further in the Discussion under "New Miners Study."

Discussion

Predicted Prevalence and Excess Risk Estimates

The excess risk estimates for certain respiratory diseases and outcomes among U.S. coal miners described in this study are, by definition, lower than the predicted prevalences from the published studies[13,15–17] for given cumulative exposure to respirable coal mine dust and given values of covariates. This is because the excess risk estimates, by definition, are adjusted for

TABLE 2. Excess (Exposure-Attributable) Prevalence of Simple CWP or PMF among U.S. Coal Miners at age 65 Following Exposure to Respirable Coal Mine Dust Over a 45-Year Working Lifetime

		Cases/1000 at Various Mean Dust Concentrations		
Study and Coal Rank	**Disease Category**	**0.5 mg/m^3**	**1.0 mg/m^3**	**2.0 mg/m^3**
Attfield and Seixas[17]A				
High-rank bituminous	CWP ≥ 1	48	119	341
	CWP ≥ 2	20	58	230
	PMF	13	36	155
Medium/low-rank bituminous	CWP ≥ 1	27	63	165
	CWP ≥ 2	9	22	65
	PMF	4	10	29
Attfield and Morring[16]B				
Anthracite	CWP ≥ 1	45	120	380
	CWP ≥ 2	17	51	212
	PMF	17	46	167
High-rank bituminous (89% carbon)	CWP ≥ 1	41	108	338
	CWP ≥ 2	15	43	168
	PMF	13	34	114
Medium/low-rank bituminous (83% carbon)	CWP ≥ 1	18	42	111
	CWP ≥ 2	6	15	42
	PMF	4	9	21
Medium/low-rank bituminous (Midwest)	CWP ≥ 1	12	26	64
	CWP ≥ 2	4	9	22
	PMF^C	1	3	6
Medium/low-rank bituminous (West)	CWP ≥ 1	7	14	32
	CWP ≥ 1	<1	<1	1
	PMF^C	<1	<1	1

^A Attfield and Seixas[17] define the coal rank groups as follows:
1. High-rank bituminous (89–90% carbon): central Pennsylvania and southeastern West Virginia.
2. Medium/low-rank bituminous (80–87% carbon): medium rank—western Pennsylvania, northern and southwestern West Virginia, eastern Ohio, eastern Kentucky, western Virginia, and Alabama; low rank: western Kentucky, Illinois, Utah, and Colorado.

^B Attfield and Morring[16] define the coal rank groups as follows:
1. Anthracite: two mines in eastern Pennsylvania (about 93% carbon).
2. Medium/low volatile bituminous (89–90% carbon): three mines in central Pennsylvania and three in southeastern West Virginia.
3. High-volatile A bituminous (80–87% carbon): 16 mines in western Pennsylvania, northern and southwestern West Virginia, eastern Ohio, eastern Kentucky, western Virginia, and Alabama.
4. High-volatile Midwest: four mines in western Kentucky and Illinois.
5. High-volatile West: three mines in Utah and Colorado.

Coal rank groups 4 and 5 contained mines for which the rank of the coal was generally lower than in the high-volatile A bituminous group.

^C The coefficients of the logistic regression models (which were used to compute excess prevalence estimates) were not statistically significant ($P > 0.4$) for these outcomes.

the background risks predicted from the statistical models among individuals with assumed zero exposure.[32] Although none of the coal miners actually had zero exposure to respirable coal mine dust, the concept of *background* disease prevalence is consistent with the observation of small radiographic opacities and lung function deficits among persons not employed in coal mining.[32]

An analysis of observed versus predicted disease prevalences showed reasonable agreement.[32] In that analysis, the model-predicted prevalence estimates for simple CWP from Attfield and Morring[16] are consistent with the observed occurrence of small opacities among participants of a medical surveillance program.[32] This suggests that the original model[16] provides a reasonable basis for predicting actual disease prevalences and for computing excess risk estimates. Although similar analyses are not currently available for the other studies[13,15,17] used here for excess risk estimation, a comparison of risk estimates from these and other published studies provides some means of evaluation. For example, given exposure to dust of similarly ranked coal, the predicted prevalences of simple CWP and PMF are consistent in studies of Round 4 NSCWP participants[17] and Round 1 NSCWP participants,[16] as are the excess risk estimates (Table 2). These predicted prevalences of U.S. coal miners are higher than those reported in studies of U.K. coal miners.[19,32] Regarding lung function decrement (FEV_1), the predictions from one study of U.S. miners[13] are consistent with the predictions from studies of U.K. coal miners.[10,12] The predictions from other U.S. studies[14,15] are several times higher (Table 3), as discussed under "New Miners Study."

Coal rank has been shown to influence the disease risks in coal miners. Earlier studies showed that the prevalence of simple CWP and PMF was higher among miners exposed to dust of higher-rank coal.[4,34–36] Recent exposure–response studies found that the predicted prevalences of simple CWP and PMF are greater among miners with working lifetime exposures to respirable dust of high-rank coal.[16,17,19] Lung function deficits were found in one U.S. study to be greater

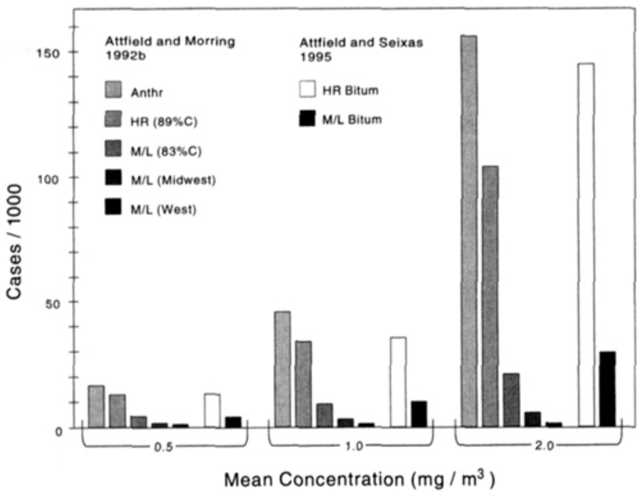

FIGURE 2. Estimated excess risk of PMF among miners aged 65 with 45 years of exposure by mean concentration of respirable coal mine dust of different coal ranks, including anthracite (Anthr), high-rank (HR) bituminous, and medium/low-rank (M/L) bituminous (defined further in the footnotes to Table 2). (Based on data from Attfield and Morring[16] and Attfield and Seixas.[17])

among miners exposed to respirable dust of medium-rank and high-rank bituminous coal in the midwestern and eastern United States than among miners exposed to respirable dust from low-rank bituminous coal in the western United States.[13] The excess risk estimates in this study reflect these coal rank differences (Tables 2 and 3).

Sources of Uncertainty

RISK ESTIMATES FROM CROSS-SECTIONAL DATA. Both predicted prevalence and excess risk estimates based on cross-sectional data may underestimate the true risk in the population. The risk of interest in this study is the expected proportion of a mining population beginning work at age 20 and intending to mine until age 65 who develop occupational respiratory disease. If miners who develop disease are more likely to leave mining before the time of cross-sectional examination than are miners without disease, then the prevalence estimates used to compute the excess risk estimates will be systematically lower than the true risk. The risk of PMF may also be underestimated because miners with simple CWP may progress to PMF after they leave mining.[37]

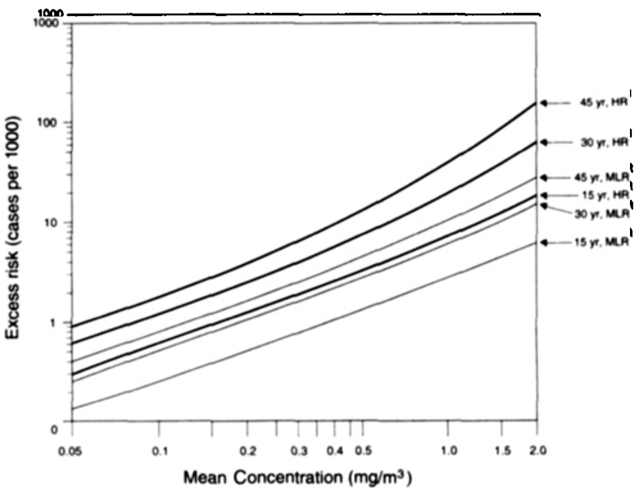

FIGURE 3. Estimated excess risk of PMF among U.S. miners at age 65 by intensity (concentration) and duration (years) of exposure to dust of high-rank (HR) coal or medium/low-rank (MLR) coal. (Based on data from Attfield and Seixas.[17])

PREDICTED NORMAL FEV_1. The predicted normal FEV_1 values were computed within the coal miner cohort. This approach avoids the problems of comparison with an external population, which may have different characteristics that affect lung function. This approach also allowed determination of the exposure-attributable risk of FEV_1 decrement. However, none of the coal miners actually had zero exposure, which could introduce bias in the risk estimates. Previous studies have estimated that the age-related decline in FEV_1 is greater in U.S. coal miners[13] than predicted from standardized equations.[38]

RANGE OF EXPOSURE AND DISEASE DATA. In contrast to the convention of using the upper 95% confidence limit of the mean to set exposure limits for the general population, the risk estimates evaluated in this study, as in other occupational risk assessments, are point estimates. Thus, for some individuals, the risks may be either lower or higher than predicted by the mean response. The predicted prevalence and excess risk estimates for miners with exposure to a mean concentration of 2 mg/m^3 are well within the range of the data. The data become sparse at mean concentrations near 0.5 mg/m^3 or durations of exposures near 45 years. Thus, risk estimates for miners with exposures near these values contain greater uncertainty than do risk estimates for miners with exposures that are well represented in the data.

CUMULATIVE EXPOSURE. There are several discussion points regarding uncertainty in the estimates of cumulative exposure to respirable coal mine dust. First, these data (described in Methods) are subject to error whenever the time-weighted average concentration derived from the job-specific measurements differs from the individual's unknown true value. The effect such errors would have on the excess risk estimates is unclear because information about such errors is lacking. Although attenuation of the regression coefficient toward zero under some classic models for error suggests a potential for underestimation of excess risk, the potential for overestimation is not discounted. Second, in some studies[14,15,17] the exposure estimates were based on compliance data, for which there is some evidence of bias[30]; in other studies[13,16] pre-compliance data were used.[26] In an analysis of bias in these compliance data, Attfield and Hearl[39] concluded that for the large mines used in these epidemiological studies, the bias was relatively small (10–15%) and consistent with the adjustment (13%) made by Seixas et al.[30,40] in estimating coal miners' cumulative exposures from these data. Finally, these data[26,30] represent the best available for estimating each miner's cumulative exposure to respirable coal mine dust, both before and after initiation of compliance sampling.

A further point relates to the use of cumulative exposure as the exposure metric. The exposure–response analyses that

TABLE 3. Excess (Exposure-Attributable) Prevalence of Decreased Lung Function[A] among U.S. Coal Miners at Age 65 Following Exposure to Respirable Coal Mine Dust Over a 45-Year Working Lifetime

Study and Region	Lung Function Decrement	Smoking Status	Cases/1000 at Various Mean Concentrations 0.5 mg/m³	1.0 mg/m³	2.0 mg/m³
Attfield and Hodous[(13)B]					
East	<80% FEV_1	Never smoked	10	21	44
		Smoker	12	24	51
West	<80% FEV_1	Never smoked	9	19	40
		Smoker	11	23	48
East	<65% FEV_1	Never smoked	2	5	12
		Smoker	4	8	19
West	<65% FEV_1	Never smoked	2	4	9
		Smoker	3	7	15
Seixas et al.[(15)C]					
	<80% FEV_1	Never smoked	60	134	315
		Smoker	68	149	338
	<65% FEV_1	Never smoked	18	45	139
		Smoker	27	67	188

[A]Decreased lung function is defined as FEV_1 <80% of predicted normal values. Clinically important deficits are FEV_1 <80% (which equals approximately the LLN, or the 5th percentile) and FEV_1 <65% (which has been associated with exertional dyspnea).
[B]Attfield and Hodous[(13)] define the following coal ranks and regions:
East: anthracite (eastern Pennsylvania) and bituminous (central Pennsylvania, northern Appalachia [Ohio, northern West Virginia, western Pennsylvania], southern Appalachia [southern West Virginia, eastern Kentucky, western Virginia], Midwest [Illinois, western Kentucky], South [Alabama]).
West: Colorado and Utah.
[C]Coal rank was not provided in Seixas et al.[(15)]. However, miners were included from bituminous coal ranks and regions across the United States, as described in Attfield and Seixas[(17)]:
1. High-rank bituminous (89–90% carbon): central Pennsylvania and southeastern West Virginia.
2. Medium/low-rank bituminous (80–87% carbon): medium rank—western Pennsylvania, northern and southwestern West Virginia, eastern Ohio, eastern Kentucky, western Virginia, and Alabama; low rank—western Kentucky, Illinois, Utah, and Colorado.

form the basis for the NIOSH REL for respirable coal mine dust[(32)] use cumulative exposure (intensity × duration) as the metric of exposure. Disease risk is assumed to be a function of cumulative exposure and not to depend on the specific values of intensity or duration used to compute cumulative exposure. For example, the exposure-related risk of a given disease is assumed to be equal among miners exposed to 2 mg/m³ for 20 years (i.e., 40 mg-yr/m³) and for miners exposed to 1 mg/m³ for 40 years (also 40 mg-yr/m³). Studies of coal miners suggest that this is a reasonable assumption provided that the duration of exposure has been sufficient[(41,42)]—usually considered to be 10 or more years for development of simple CWP.[(43)]

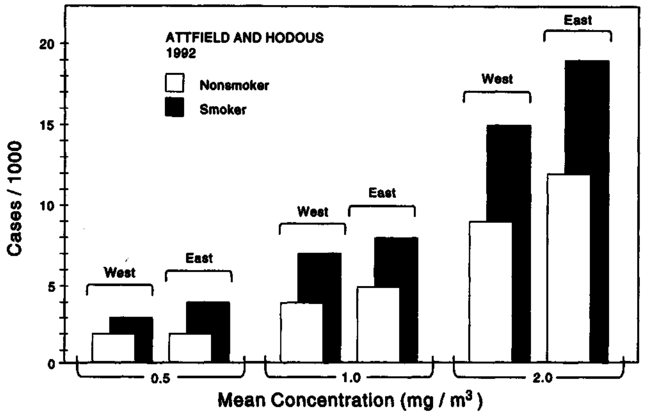

FIGURE 4. Estimated excess risk of FEV_1 <65% of predicted normal values by smoking status—smoker or nonsmoker (never smoker) at medical examination—among miners aged 65 with 45 years of exposure by mean concentration of respirable coal mine dust in the eastern or western United States (coal ranks associated with these regions defined in the footnotes of Table 3). (Based on data from Attfield and Hodous.[(13)])

NEW MINERS STUDY. The Seixas et al.[(14,15)] studies were based on a subset of miners who were new to mining after the enactment of the Federal Coal Mine Health and Safety Act.[(1)] The cross-sectional analyses[(14,15)] showed large initial exposure-related losses in lung function among new miners, but the longitudinal analysis[(15)] showed no additional exposure-related decline between Round 2 and Round 4 of the NSCWP. These studies suggest that individuals who are new to mining may experience greater rates of decline in lung function than do individuals who have been mining for longer periods of time. In addition, if the adjustment for bias in the cumulative exposure data[(30,40)] were insufficient, this could also contribute to the greater response observed in the new miners compared to the experienced miners studied previously both in the United States[(13)] and in the United Kingdom.[(10,12)] These factors may help to explain the higher excess risk estimates derived from Seixas et al.[(15)] (Table 3).

Statistical Models Evaluated

The epidemiological studies included in this study (Table 1) used either linear regression models (for FEV_1) or logistic regression models (for the presence or absence of a particular radiographic category). An assumption of these models is that the disease risks at all exposures are greater than zero. Hurley et al.[41,44] evaluated several models for describing the relationship between exposure to respirable coal mine dust and the development of simple CWP and PMF. They selected the logistic regression model using cumulative exposure because it best fit the data and best described the observed exposure–response relationship.

Bailer et al.[45] evaluated several model forms, including threshold models, for exposure–response between respirable coal mine dust and lung function deficits for miners who participated in Round 1 of the NSCWP. In a threshold model for FEV_1 of <80% of predicted normal FEV_1, a change point was suggested at a cumulative exposure to respirable coal mine dust of 22 mg-yr/m^3 (95% confidence interval = 0 to 55 mg-yr/m^3). These results indicate that the data are consistent with an exposure–response beginning at zero (nonthreshold) or beginning at a cumulative exposure as high as 55 mg-yr/m^3.

In this study, the assumed shape of the relationship between cumulative exposure to respirable coal mine dust and simple CWP category 1 or greater was evaluated by comparison of the original and alternative model forms. Logistic models using either the logarithm, square, or square root of cumulative exposure to respirable coal mine dust were compared to the model with cumulative exposure (data not shown). Comparison of the log likelihood estimates for the different models indicated that the original logistic regression model provided a slightly better fit to the data. This finding suggests that the original logistic model is adequate for summarizing these data.

NIOSH REL for Respirable Coal Mine Dust

The NIOSH recommended exposure limit (REL) for respirable coal mine dust is 1 mg/m^3 as a time-weighted average (TWA) concentration for up to 10 h/day during a 40-hour workweek.[32] The current U.S. exposure limit for respirable coal mine dust of 2 mg/m^3[1] is currently measured (as part of the mine operator bimonthly sampling program) as the average concentration of five consecutive 8-hour TWA measurements.[32] The NIOSH REL represents the upper limit of exposure for each worker during each work shift, and the REL was derived with consideration of the relationship between work shift exposures and long-term mean exposures, on which the risk estimates were based.[32] Additional information about the NIOSH sampling recommendations is provided elsewhere.[32]

The health basis for the REL is primarily the epidemiological exposure–response studies of occupational respiratory disease among U.S. coal miners.[13,15–17] Additional considerations included the sampling and analytical feasibility of monitoring exposures and the technological feasibility of reducing exposures. The intent of the REL (given the limits of technological feasibility) is to keep the daily exposures of workers low enough to reduce or eliminate the risk of impaired health or functional capacity over a working lifetime.[32] The REL has two important implications. First, the health-based need to reduce exposures to respirable coal mine dust is well supported by the risk estimates from the U.S. epidemiological studies. Second, the REL may not be sufficiently protective to prevent all occurrences of simple CWP, PMF, and lung function deficits among coal miners exposed for a working lifetime. Additional measures to protect miners' health, recommended by NIOSH,[32] are provided below.

Conclusions

The risk estimates from U.S. epidemiological studies suggest that miners with working lifetime mean exposures to respirable coal mine dust at the current U.S. standard (2 mg/m^3) have an elevated risk of developing simple CWP, PMF, or deficits in lung function. Further, these studies suggest that miners exposed to respirable coal mine dust at mean concentrations below 2 mg/m^3 and for less than a 45-year working lifetime have elevated risks of developing PMF by age 65.

Recommendations

To minimize the risk of occupational respiratory diseases among U.S. coal miners, efforts should be made to reduce daily exposures to respirable coal mine dust below the NIOSH REL through the use of engineering controls and work practices. To provide additional health protection to miners, NIOSH[32] recommends these additional measures: (1) participation of miners in the medical screening and surveillance program; (2) development and application of improved dust control techniques; (3) careful monitoring of exposures; and (4) use of personal protective equipment as an interim measure when exposures exceed the REL.

Acknowledgments

Those who contributed to the earlier published exposure–response studies of U.S. coal miners are gratefully acknowledged.

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