

Critical Review of Scientific Basis for Lowering Coal Mine Dust Exposure Level. iii. Exposure-Response Studies of Radiographic CWP

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Abstract

Implementation of the coal mine dust ("CMD") interim standard of 3.0 milligrams per cubic meter ("mg/m³") in 1970 was reduced to 2.0 mg/m³ in 1972 and produced a steady decline in dust levels and prevalence of coal workers pneumoconiosis ("CWP"). Beginning in the mid-1990s, an apparent increase was reported in what was thought to be severe and rapidly progressive CWP and PMF despite stability in CMD levels. These "sentinel health" events led to further investigation and stimulated the 2010 MSHA proposal to lower the current CMD standard from 2.0 mg/m³ to 1.0 mg/m³. The purpose of this study is to summarize exposure-response associations between CMD and CWP to evaluate evidence for a revised standard.

There are five cohorts of UK and US coalminers with exposure-response analyses useful for assessing a proposed coal mine dust standard. Two major biases confound such an evaluation. Exposure misclassification bias occurs for exposures occurring before standards and before sampling surveillance was initiated. This bias is most obvious in the US studies where sample results collected after initiation of the standard were back-extrapolated to pre-standard time periods. The bias introduced produces a spurious steeper exposure-response slope due to over-estimation of risk at higher exposure levels (>4 mg/m³) and under-estimation of risk at lower exposures. Participation bias occurs in one of the US studies when survey participation rates dropped below 50% in rounds 1-4.

Exposure-response evidence suggests a coal mine dust standard of 2 mg/m³ appears to be protective from occurrence of CWP ≥2 for low rank coals. However there is excess CWP ≥2 in miners exposed to high rank coal, suggesting a lower exposure standard is needed to protect these miners.

Keywords: Bias; Coal mine dust (CMD); Coal rank; Coal workers pneumoconiosis (CWP); Exposure-response; Radiographic category

Abbreviations: CMD: Coal Mine Dust; CWP: Coal Workers Pneumoconiosis; ILO: International Labour Office; MSHA: Mine Safety And Health Administration; BNCB: British National Coal Board; NIOSH: National Institute Of Occupational Safety And Health; NSCWP: National Study Of Coal Workers' Pneumoconiosis; NMRD: Nonmalignant Malignant Respiratory Disease; PMF: Progressive Massive Fibrosis; REL: Recommended Exposure Limit

Introduction

CWP was first identified in a 1928 study of the Coal Trimmers Union in Cardiff, South Wales where there were excesses of bronchitis and pneumonia, but no excesses from TB. ¹Case studies showed a radiological pattern similar to silicosis. This led to an understanding of a CWP entity distinct from silicosis and the modern era of studies into CWP [1].

The US Public Health Service completed an important study of anthracite coal miners in Pennsylvania in 1936 [2]. Radiographs identified "anthracosilicosis" in 23% of the miners and a clear exposure-response relationship that led to a recommended standard of 50 mppcf. Most of the recommendations were not implemented and several studies in the 1940s suggested fairly low prevalences of CWP among bituminous miners in Appalachia and Utah.

¹Coal trimmers were workers who shoveled coal in the holds of ships to evenly spread the coal from side to side. Originally pulmonary disease in coal miners was thought to be a result of silica exposure in the CMD. Since the coal being loaded on ships had been cleaned and the silica admixed in the coal had been largely removed this was the first recognition that CMD without silica was related to a pneumoconiotic disease.

The next important study was in Raleigh County, WV in 1963 which established that CMD exposure was producing a high occurrence of CWP (46%) and PMF (7%) that was related to tenure [3]. This study led to a flurry of studies to document the prevalence of CWP in the US, UK and Germany.

In the 1960s the Pennsylvania Board of Health found an increasing gradient of CWP from 11% in Western Pennsylvania to 35% in Central/Eastern Pennsylvania [4-6]. In Appalachian counties nearly 10% of working miners (9% with PMF) and 18% of nonworking miners had CWP. The 1969-71 first round of the NIOSH NSCWP of 31 mines and over 9000 miners found a very high prevalence of CWP: 60% in anthracite coal, 30% in Appalachia, 25% in the Midwest, and 10.5% prevalence in Western coal.

These high prevalences were thought to be in part attributable to the use of a new classification system and standard radiographic films for classifying chest x-rays for the pneumoconioses developed by the Union for International Cancer Control and the University of Cincinnati Radiology Department, referred to as the UICC/Cincinnati 1968 classification. CWP prevalence was markedly reduced in the

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second round using the 1971 ILO/UC classification system and different B readers for the pneumoconiosis, but this change was not considered to have contributed to lower prevalences [1].

Prior to 1969, detailed research regarding coal miners' health in the United States was meager and dispersed. In 1968, a coal mine explosion in Farmington, WV took the lives of 78 miners and was a major impetus for action by Federal and State governments. At the federal level, the Farmington explosion led to a massive revamping of the Nation's coal mine safety laws and a federal program to prevent occupational diseases in US coal miners, especially CWP, and passage of the Federal Coal Mine Health and Safety Act of 1969 (the "1969 Mine Act"). A centerpiece of the coal miner health provisions of the 1969 Mine Act was the establishment of mandatory CMD standards in the Nation's coal mines. Effective in 1970, under the 1969 Mine Act, the average concentration of CMD in underground coal mines was to be maintained at or below 3.0 mg/m³ through 1972, after which the CMD standard was reduced to 2.0 mg/m³. The provisions of the 1969 Mine Act remained largely intact under the 1977 Mine Act.

Prior to the passage of the 1969 Mine Act, research in Britain at the Institute of Occupational Medicine was well underway with work known as the Interim Standards Study. Before publication of the results, consultation between US and UK researchers, and evaluation by various US Congressional Committees and others resulted in portions of the Interim Standards Study results being utilized for setting the above noted CMD standard in the US.

The basis for setting the US CMD from the Interim Standards Study was that a miner exposed at 2.0 mg/m³ over a working lifetime of 35 years would have zero risk of developing Category 2 simple CWP as defined by the International Labor Office ("ILO") Guidelines for the Classification of Radiographs of Pneumoconioses. This was a logical deduction as the likelihood of a miner contracting the more disabling and sometimes fatal condition known as progressive massive fibrosis ("PMF") would be dramatically reduced or eliminated if ILO Category CWP 2 was never reached.

The first exposure-response study of CWP using gravimetric sampling of respirable coal mine dust was in the UK [7]. There were 10-years of observation of 4,122 coal face miners in 20 collieries selected in 1953. The results suggested negligible risk of CWP ILO Category 2/1 over a working lifetime when coal mine dust levels were below 2.0 mg/m³. Smoking was not associated with CWP prevalence. These results were the basis of the current MSHA dust standard of 2.0 mg/m³.

Since the passage of the 1969 Mine Act, measured dust exposures in US coal mines have been reduced to a considerable degree, with a large majority of coal mines being in compliance with the 2.0 mg/m³ dust standard. Likewise, the reported prevalence of CWP has decreased from around 30 % to about 3%.

The Mine Safety and Health Administration ("MSHA") published on October 19, 2010 its proposed rule for "Lowering Miners' Exposure to Respirable Coal Mine Dust. Including Continuous Personal Dust Monitors" (the "NPR"). The major provisions of the NPR are: (1) lower the existing exposure limits for respirable coal mine dust from 2.0 milligrams per cubic meter (mg/m³) to 1.0 mg/m³; (2) provide for the use of a single full-shift sample to determine compliance under the mine operator and MSHA's inspector sampling programs; (3) require the use of a new technology, the Continuous Personal Dust Monitor ("CPDM") for exposure monitoring; and (4) expand requirements for medical surveillance.

The purpose of this report is to critically evaluate pertinent scientific information on the subject of respirable coal mine dust ("CMD") and coal workers pneumoconiosis (CWP), and in particular exposure-response studies to ascertain if the proposed standard of 1.0 mg/m³ is supported by the epidemiological evidence. We have reported on other factors including the potential role of quartz [8] and coal rank. Under some conditions background prevalence is as high as CMD-attributable CWP, so it is important to adjust for it. In this report we focus on exposure-response studies with radiographic CWP as the response variable, with particular focus on hidden uncertainties such as bias and confounding that affect estimation of a safe exposure level. We believe the studies evaluated in our critique constitute the seminal studies providing the weight of evidence for assessing the rationale for lowering the exposure limit for CMD from 2.0 mg/m³ to 1.0 mg/m³. These key studies are summarized here and detailed comments on each are presented.

Methods

Cumulative exposure is the exposure metric (mg/m³-years) used in an exposure-response analysis, but a standard is based on daily exposure level (mg/m³). To evaluate a daily exposure level we assume a 40-year working lifetime at 2.0 mg/m³. Any part of the exposure-response curves to the right of 80 mg/m³-years indicates coal miners are working at lifetime exposures above the standard of 2.0 mg/m³. We suggest there may be a 5% background prevalence of CWP. So in the figures showing exposure-response trends there are four quadrants with different implications for determining a safe standard:

**Upper right quadrant* indicates excess CWP prevalence and exposure levels are out of compliance with the standard. These data are not relevant for setting a new standard as the excess occurred at working levels above the standard.

**Lower right quadrant* relates to working at exposures above the standard of 2.0 mg/m³ and cumulative exposures above the 80 mg/m³-years. But prevalence of CWP in this quadrant is not elevated above expected, or above background. These data are not relevant for lowering the standard, but suggest that under some conditions exposures greater than the standard do not produce an increased risk of radiographic CWP.

**Lower left quadrant* shows conditions where exposure is below the allowable cumulative standard of 80 mg/m³-years (40-years x 2 mg/m³) and prevalence of CWP is not above expected. A proportion of all miners has worked under these conditions and suggests safe working conditions for these miners.

**Upper left quadrant* provides data suggesting that the 2.0 mg/m³ standard is possibly too high and should be lowered. Data in this quadrant indicate cumulative exposures are below the standard and there is an excess prevalence of CWP ≥ 2 .

Results

Results of exposure-response studies are summarized and critically reviewed. They are stratified by country (UK, US, other).

Exposure-response studies of radiographic CWP in the UK [10,11]

These are studies of 2,600 British coal miners in 10 collieries with at least 20-years exposure and category 2/1 or greater CWP. Most attended the 1st, 3rd and 5th surveys of the PFR. Estimated cumulative exposure was derived from the 20-year sampling results beginning

at the first survey. Pre-1953 exposure was based on averages for each work group from the post-1953 sampling results. Exposure samples in the first 10 years were measured with an early sampling device, the Standard Thermal Precipitator, with concentrations expressed as ppcm (particles per cubic centimeter) for particles 1-5 μm in size. Side-by-side sampling with the MRE gravimetric sampler were conducted to convert ppcm units to gravimetric units (mg/m^3). The MRE sampler was used in the second 10 years of the study. Individual results for cumulative exposures assumed a 1740 working hours/year and were in gh/m^3 units.

One year at $1 \text{ gh}/\text{m}^3 = 0.57 \text{ mg}/\text{m}^3\text{-years}$ cumulative exposure. Average years worked were 33-years. This conversion is used subsequently so units are presented as $\text{mg}/\text{m}^3\text{-years}$ rather than $\text{gh}/\text{m}^3\text{as}$ in the paper.

Mean cumulative exposure to coal dust was $104 \text{ mg}/\text{m}^3\text{-years}$ and 14% of the cohort had exposures $>100 \text{ mg}/\text{m}^3\text{-years}$ (or average exposure of 3.2 and $>5.2 \text{ mg}/\text{m}^3$ respectively based on average tenure of 33 years). There are two notable features of the cumulative exposure data. First, there is high variability overall and within each colliery, indicating a wide range of individual exposures and some very high exposures for some miners. Second, there are evident differences in mean exposure levels between collieries. Quartz exposures are much less variable within a colliery, and differences in quartz exposure are usually due to differences between mines rather than within mines.

The prevalences of CWP 0/1 and $\geq 2/1$ were 13.5% and 3.1% respectively using the independent randomized method for classifying X-rays. The prevalence ranged from 0% in Colliery P to 13.8% in Colliery T. There is a clear overall exposure-response trend for all ten coal mines and many of the individual collieries had the same general pattern (Figure 1).

Two collieries had clearly divergent patterns. Colliery T showed high risk with an overall prevalence of 13.8% and a threshold at about $55 \text{ mg}/\text{m}^3\text{-years}$. Prevalence was 20% or higher at exposures ranging from 120-190 $\text{mg}/\text{m}^3\text{-years}$, but there was only one miner in the highest exposure group. Colliery Q was an outlier with very low risks. The overall prevalence was 0.8% with two cases at the highest exposure

category of $>205 \text{ mg}/\text{m}^3\text{-years}$ and a threshold at about $180 \text{ mg}/\text{m}^3\text{-years}$ not considering background prevalence (Figure 1). Similar relationships were observed for CWP 1+ but these data were not shown.

Exposure-response trends for the eight combined collieries, excluding T and Q, shows a higher threshold ($100 \text{ mg}/\text{m}^3\text{-years}$) and steeper slope (Figure 2) compared to the combined exposure-response trend from all ten collieries (Figure 1).

There may have been selection bias at Colliery T as many miners left before the fifth survey because of imminent closure of the mine. So the "excess at colliery T was inflated by an underestimation of the miners' exposures accumulated before the first medical survey"

Mean cumulative quartz exposure was 5.02 (SD = 3.3) $\text{mg}/\text{m}^3\text{-years}$ and was highly correlated ($r = 0.77$) with mixed dust overall. The authors suggest there was little evidence quartz influenced CWP development overall. Mineral characteristics at each mine were similar. Quartz content at Colliery T was the same as the overall average (5%), while it was 6.4% at low risk Colliery Q.

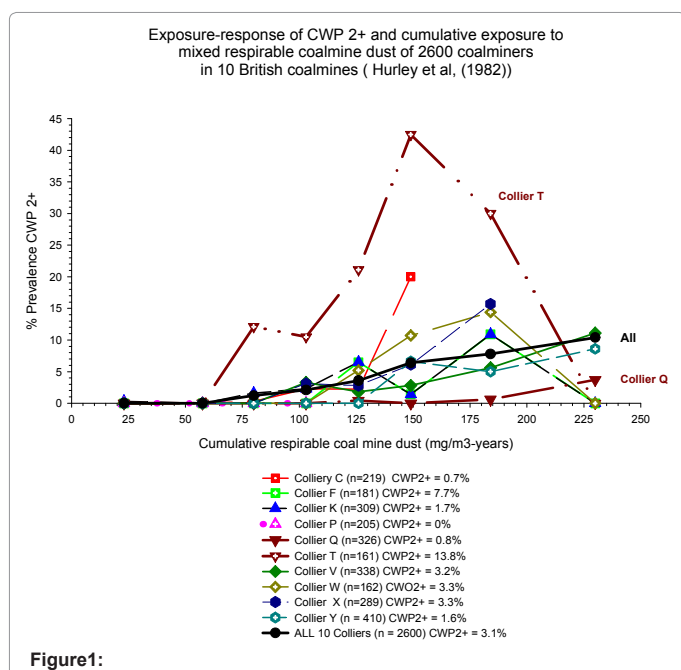
The comparison of quartz and CMD alone is suggestive of a general effect of quartz exposure. For example, the exposure-response trend for quartz is not linear but at exposures $>6 \text{ mg}/\text{m}^3\text{-years}$ quartz and $>150 \text{ mg}/\text{m}^3\text{-years}$ CMD the quartz effect appears to be associated with about a 5% prevalence of CWP ≥ 2 . At lower exposure levels of quartz and CMD the associations with prevalence appear to be equivalent. On the other hand, the correlation is so high ($r = 0.77$) it may not be possible to distinguish the separate effects of CMD and quartz alone, except at dust levels $<150 \text{ mg}/\text{m}^3\text{-years}$ (Figure 3).

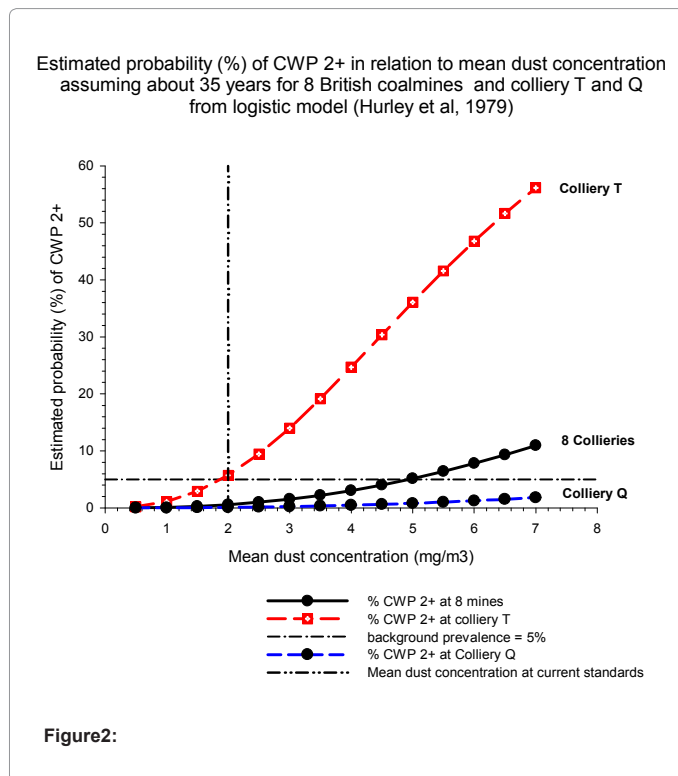
The authors conclude there are very large variations in medical responses between collieries despite similar dust exposures. The reasons for these differences are "not yet known," but they do not seem explicable on the basis of different quartz levels at the collieries. There is a subset of miners that show rapid progression over a short time-period (ten years) that is related to high quartz exposure [11]. The issue of rapid progression of CWP ≥ 2 in a small subset of miners is discussed elsewhere [8]. Finally, radiographic classifications (categories 2/1 and greater) were "clearly associated" with measures of CMD exposure.

Critique of Hurley et al. [10,11]

All coal miners had >20 -years latency and adequate time to develop CWP. There were generally clear exposure-response trends for all collieries, although Collieries Q and T did not fit the general pattern with unusually low and high risks respectively. There was a clear threshold above about $100 \text{ mg}/\text{m}^3\text{-year}$ cumulative exposure for eight collieries, excluding collieries Q and T. With an average working life-time of 33 years underground in this cohort, the threshold for development of CWP ≥ 2 was about $1.8 \text{ mg}/\text{m}^3$ ($60 \text{ mg}/\text{m}^3\text{-yrs}/33\text{-years}$) for all collieries and about $3 \text{ mg}/\text{m}^3$ ($100 \text{ mg}/\text{m}^3\text{-years}/33\text{ years}$) for the eight collieries (excluding Q and T) in this study.

The low risks found in Colliery Q had been expected based on earlier results [12]. Evidence was presented of bias with regard to Colliery T. Selection bias occurred because many miners left prior to the fifth survey because of imminent closure of the pit. The remaining "survivor" population may be the result of an "unusual pattern of selection." The authors also note there was evidence suggesting exposures were underestimated prior to the first survey. Thus, it seems plausible that the data considered should exclude Colliery T because of bias. The reason for excluding Colliery Q is less obvious, perhaps on the basis of being an outlier. At any rate, the data from the remaining eight collieries appear to be the least biased and most reliable. These data show a threshold at

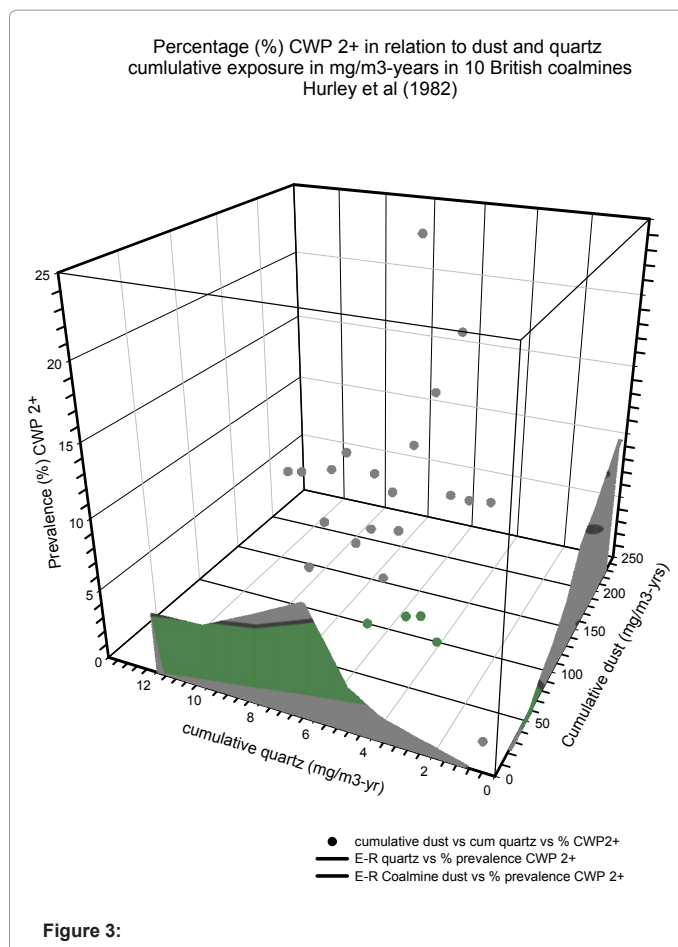




100 mg/m³-years and no excess prevalence of CWP below about 2.5 mg/m³ exposure for 40 years (Figure 2).

Statistical analyses using logistic models presented different ways of presenting exposure-response to better assess the effect of various factors. One model confirmed that miners working longer had a higher prevalence of CWP ≥ 2 than those at the same cumulative exposure category but with shorter tenure. Adding quartz did not substantially improve the model and is consistent with a general lack of response to quartz in CMD in this study. This does not appear to be consistent with the (green) quartz exposure-response trend observed in Figure 3.

Air samples were available for a 20-year period for each occupational group. The work history prior to the first survey was obtained by interview, and average concentrations based on samples collected from 1953-1973 were used for estimating pre-1953 CMD exposures. As a result a potentially large portion of a workers' cumulative exposure could be under- or over-estimated, most likely under-estimated. The authors indicated there was evidence of under-estimation for these exposures for Colliery T. For example, on average the miners had about 13 years of dust exposure prior to the start of surveys, or about 40% of their cumulative dust exposure was estimated from samples collected after the initial 13 years of underground work. It is quite likely early exposures were really higher than estimated -- thus resulting in an over-estimate of CWP risks. The authors acknowledge this. Nonetheless, it appears that an exposure-response trend does exist, but it may not be as severe as indicated. This bias is also likely to further reduce the threshold to some level greater than 2.5 mg/m³.



It is important to note that the (implied) dust threshold relates to category $\geq 2/1$ and this threshold might be quite different if related merely to the development of category $\geq 1/0$. Attfield et al., however, showed no apparent difference in an implied threshold for categories ≥ 1 and ≥ 2 overall [13]. Adding the effect of high ranked coal, however, produced a higher threshold for CWP ≥ 2 than for CWP ≥ 1 , which is an expected result. The apparent lack of a quartz effect in this study and the authors' comment that CWP ≥ 2 and CWP $\geq 0/1$ had generally similar results are suggestive that thresholds may also be similar.

Like most studies of this type, much depends on the dust exposure estimates. However, exposure estimates from the British Surveillance Program are thought to be the most complete in the coal industry. Like the US studies, portions of the work history are based on extrapolations backward to high exposures early in the work life of the miners and before the initial medical surveys.

In summary, this study indicates no apparent excess prevalence of CWP below about 2.5 mg/m³.

Exposure-response studies of radiographic CWP among ex-miners in the UK [14]

Previous studies had examined exposure-response associations among working miners without consideration of miners who left the industry (ex-miners) [10, 15]. The ex-miners left the industry for various reasons, some of which could be for health reasons or because they had greater responses to coal dust than working miners. The purpose of this study was to assess whether ex-miners' exposure-response associations of CWP and CMD exposure were similar to those of working miners.

The sample of miners was selected from men examined at the first round survey 1953-1958 at 24 collieries. All 3,645 miners with category 1 or greater CWP and 14,093 miners randomly selected from the remaining participants were selected for inclusion in the study. After 22 years follow-up there were 2,255 miners and 3,896 ex-miners still

alive and who attended follow-up medical exams, including X-ray and work history. This is the cohort that was assessed for exposure-response relationships between CWP and coal dust exposure.

The results of these analyses indicated no “systematic or statistically significant difference between men who stayed and men who left in the quantitative relations between dust exposure and simple pneumoconiosis. Present estimates of risk of simple pneumoconiosis in relation to exposure to mixed respirable dust in working miners adequately describe the relation found in men who have been miners but have left the industry.”

This conclusion is consistent with Figures 4 and 5 that show no substantive differences between exposure-response curves for miners and ex-miners for different age groups for CWP ≥ 1 and CWP ≥ 2 .

Critique of Soutar et al. [14]

This may be the only study of ex-miners, and it suggests that exposure-response of miners and ex-miners are similar enough that exposure to CMD did not pose any greater risk to ex-miners than it did to miners. Thus, there appears to be no reason for a lower standard because of this potentially more susceptible population. The issue becomes clear in Figures 4 and 5 showing that exposure-response curves for miners and ex-miners were fairly parallel and mimicked each other closely. These curves support the authors’ conclusions that indicate “whatever standard is adequate to protect miners, should also apply to ex-miners”.

Interpretation of the two sets of figures is problematic. Figure 5 (= Figures 1 and 2 from Soutar, et al.) are the observed prevalence of CWP vs. dust exposure by age group under 65. Figure 6 (= Figures 3 and 4 from Soutar, et al.) are logistic regressions of predicted prevalence for smokers only and adjusting for collieries. It appears the predicted prevalence would be the adjusted model for exposure-response curves displayed in Figure 5, which are not adjusted for potential confounding. If so, the predicted exposure-response curves in Figure 6 are extrapolations beyond the data because maximum exposure levels are greater (= 600 gh/m³) than in the observed data where the maximum values for different groups ranges from <200 to 450 gh/m³ as shown in Figure 5.

Figures 5 and 6 suggest a possible threshold of about 100 gh/m³ (57 mg/m³-years) for CWP. The usefulness of category $\geq 0/1$ is questionable because a diagnosis of CWP below category 2/1 may not be reliable, has high background prevalence, and “could be the result of disease other than pneumoconiosis, since in other, non-mining populations, age related small rounded opacities of low profusion may be shown.” This reference is to a cohort of polyvinylchloride workers where two readers found no association of category $\geq 0/1$ with dust but a background prevalence of about 2%. If the third reader is included, the background would be higher [16].

The gh/m³ units used by the British to estimate exposure remain confusing. The authors only refer to “dust exposure,” making it unclear whether the exposure-response relationships refer to average shift air concentrations or to cumulative exposure. Mean dust exposure ranged from 73 to 140 gh/m³ (and SD from 71 to 118) in their Table 1 among the categories of miners, ex-miners and unexamined. The maximum exposures are in the range of about 600 gh/m³, which seem high for mean levels (intensity) and low for cumulative exposure levels.

The increased prevalence occurred primarily in two collieries where prevalences for all categories were 1.3% and 2.3%. For category

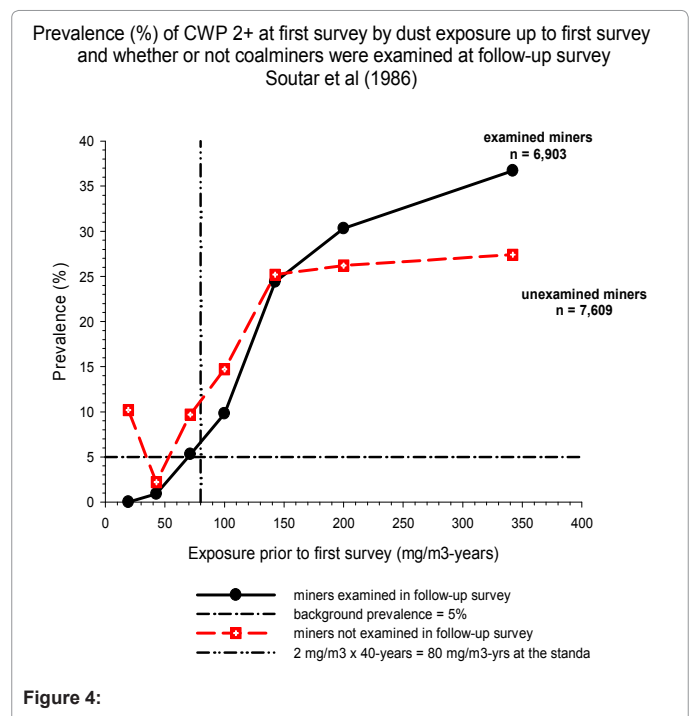


Figure 4:

≥ 2 , prevalences were 0.5% and 1.2% respectively. Possible causes for these increases in the last years of the 20th Century focused on the two collieries designated as A and B. Characteristics of each are listed (Table 2).

Furthermore, X-rays were interpreted by a panel of “self-trained readers.” Readings from such a panel are reproducible and adequate for the purposes of this study. In fact, this procedure of using lay readers was followed at NIOSH’s Appalachian Laboratory for Occupational Safety and Health years ago. In this study a test comparison was conducted with a subset of the lay readings compared to readings from a panel of three experienced and medically qualified readers. Results showed that the self-trained panel recorded higher prevalences of simple CWP. This difference, thus, may have affected the CWP category $\geq 0/1$, but not category ≥ 2 and the relationships with dust.

Exposure-response studies of radiographic CWP in the UK [17]

This study reports on CWP occurrences for the colliery population in the UK under the Periodic X-ray (“PXR”) scheme for the years 1998–2000. Since the beginning of this program in 1959 the prevalence of CWP 1 and CWP ≥ 2 has dropped dramatically, until the last survey when prevalence increased (Figure 7). Prevalence of CWP in UK from 1959–2000 under the Periodic X-ray (PXR) Scheme [17]

Age changes in the UK coal mine population may also have produced some changes in CWP. In the early part of this 40-year period most miners retired at age 65. As the industry got smaller and pits closed the older miners tended to leave so the average age decreased. In the last few years the trend has reversed with age increasing because miners are tending to stay longer and ex-miners are returning. Up to 1997 at least, dust control was the cause for the decreases in CWP prevalence, and a younger age distribution was not a major cause for decreasing CWP because prevalence reductions were similar in all age categories (Table 1).

Round	Years	No. X-rayed	Category 1		Category 2+		All Categories	
			No.	Prevalence	No.	Prevalence	No.	Prevalence
1	1959-63	462999	32608	7	23401	5	56009	12.1
3	1969-73	238759	16389	6.9	7888	3	24277	10.2
5	1978-81	198055	6256	3.2	1902	1	8158	4.1
7	1986-89	76802	453	0.6	65	0.1	518	0.7
8	1990-93	36970	138	0.4	10	0.01	148	0.4
9	1994-97	6378	13	0.2	0	0	13	0.2
	1998-2000	4647	26	0.6	9	0.2	35	0.8

Table 1: Categories of miners.

Characteristic	Colliery A	Colliery B
Use of respiratory protection equipment	Slightly > national average	Significantly < national average
Dust Levels	Not excessive over last 10 years but some increase last 10-years	Dusty
Places of Work		Most of those affected had worked in geological faults & cutting through stone may have led to increased quartz exposure
Mining methods		Recent introduction machinery to cut through rock previously removed by explosives requiring removal of miners when firing, & lower exposures.
Working hours	Cases worked longer than non-cases & standard work week. Work week time doubled in extreme cases & 7 days/wk, 12 hr shifts common. Considered most significant factor leading to increased CWP incidence in collieries A & B.	

Table 2: Main findings from focused investigation on Collieries A and B [17].

Critique of Scarisbrick and Quinlan [17]

This study may be useful in assessing possible reasons for the recent increases in incidence and rapid progression of CWP. In these two pits the primary possible causes for increased CWP included:

- Much longer working hours and, therefore, higher exposures;
- Increased quartz exposure in Colliery B due to increased cutting through stone; and
- Change in mining methods employing new mining equipment that can cut through rock that in past was removed by explosives (Colliery B)

This study is consistent with findings in the US of reduced prevalence of CWP and a recent but slight increase in rapidly progressive pneumoconiosis. It may be useful in explaining possible reasons for the recent increase in CWP prevalence. This study is not useful for assessing exposure-response or developing a standard.

Exposure-Response Studies of Radiographic CWP in the US [18]

This study derived estimates of cumulative CMD exposures applicable to the exposures prior to the first round of the NSCWP. These estimates were subsequently used in two morbidity studies [13,19] and a mortality study [20]. These exposure estimates may not have a significant effect on the relative toxicities of coal rank, but are critically important in the derivation of exposure-response associations in US coal studies.

Estimates of pre-1970 job exposures were derived from MSHA compliance sample data collected 1970-72 and then back-extrapolated to pre-1970 (1968-69) levels by estimating a conversion factor from BOM data collected in 17 mines prior to 1970 [21] to convert lower post-1970 sample data to higher pre-1970 CMD exposure levels.

Ratios of BOM data by job ÷ MSHA job exposure provided the relative difference between pre- and post-1970 job exposures. The average of these ratios, or the *conversion factor*, was calculated to be 2.3. The conversion factor provided the estimate that pre-1970 exposures were 2.3 times greater than post-1970 job exposures on average. This ratio was used to derive intensity of exposure for each job, which was then used in the calculation of cumulative exposure.

Cumulative exposure for individual miners was calculated from work histories obtained by interview in the first round of the NSCWP (around 1970). The summation of years spent in each job x intensity exposure for each job gives cumulative exposure in mg/m³-years. Mean job exposure in mg/m³ was derived from the back-extrapolation of MSHA data.

The authors' noted that "the resulting estimated exposures have been shown to correlate well with various measures of respiratory morbidity."

Critique of Attfield and Moring [18]

A concern with the NIOSH data is the recall ability of miners on the work history. No validation of recall ability has been made, and neither the direction nor magnitude of the bias is known.

The greatest limitation is the systematic bias built into the procedure for developing pre-1970 CMD exposures, which was the primary objective of this paper. That is, the purpose was to convert 1970-2 MSHA data to pre-1970 CMD exposure levels.

After 1970 in the US a CMD dust standard was initiated and CMD exposure levels rapidly declined. Pre-1970 exposure data were from Bureau of Mines (BOM) sampling in 17 mines from 1968-1969. The BOM data are important as they provide the best estimates of pre-1970 CMD exposures when exposures were high and unregulated. Unfortunately, these converted estimates appear to be biased relative to

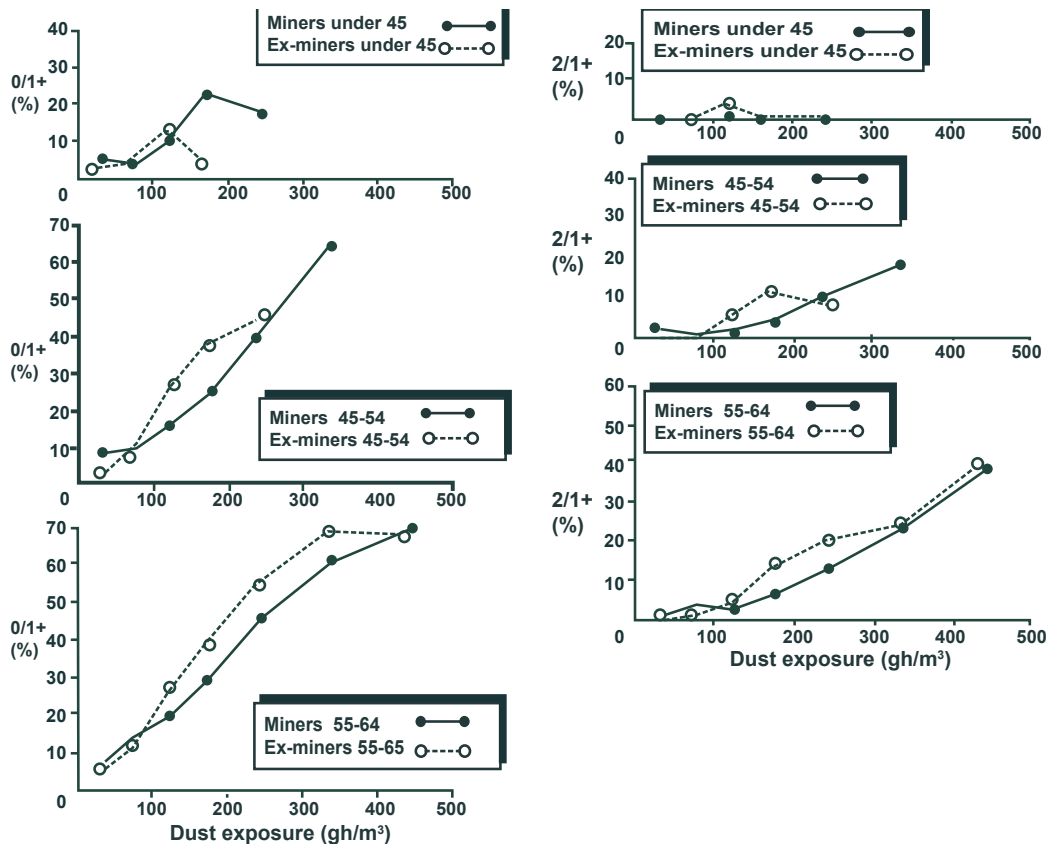


Figure 5: Exposure-Response for Observed Prevalence of CWP $\geq 0/1$ and CWP $\geq 2/1$ versus dust exposure (gh/m^3) for miners and ex-miners by age groups (Figures 1 and 2 from [14]).

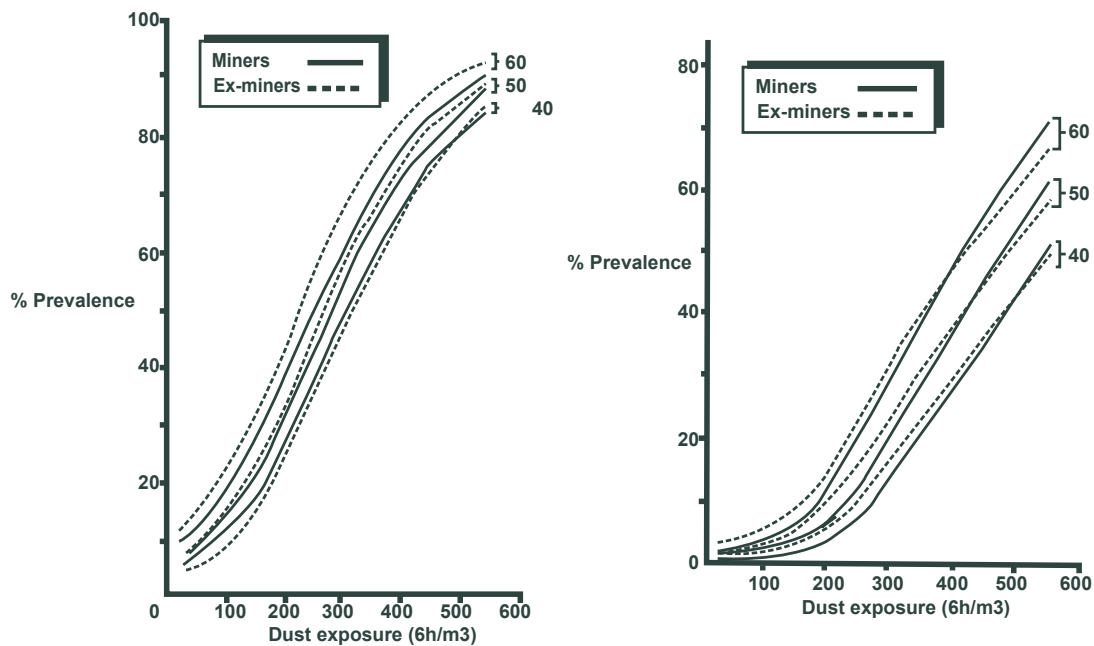


Figure 6: Predicted prevalence of CWP $\geq 0/1$ and $\geq 2/1$ in relation to dust exposure (gh/m^3) and by age group using logistic regression for miners and ex-miners who smoke. Figures 3 and 4 from [14].

the BOM data. Assuming the pre-1970 data provide the best exposure estimates for this time period, the effects of this bias are to elevate the slope of exposure-response curve above 4 mg/m³ and reduce slope below 4 mg/m³, thereby spuriously over-estimating risk. The logic and arithmetic of this procedure are discussed.

The BOM data collected in 1968-69 were the first gravimetric sampling done in US mines. Seventeen of these mines were part of the NSCWP. The differences in CMD levels between BOM and MSHA data were calculated for each job (and were calculated from the authors' Table 1). The BOM data are also discussed in [21]. An overall mean ratio of 2.3 was calculated using the formula: conversion factor (CF) = mean pre-1970 exposure levels (BOM) ÷ mean post-1970 exposure (MSHA) = 2.3. Thus, pre-1970 exposures from BOM data were on average about 2.3 times greater than MSHA post-1979 exposures levels for the same jobs. This conversion factor of 2.3 was then used to back-extrapolate from the MSHA post-1970 compliance data and used as the measure of pre-1970 exposures in place of the BOM exposure data. Or stated in a slightly different manner, the 1970-72 MSHA job-specific mean dust levels were divided by a factor of 2.3 and thereby back-extrapolated to constitute pre-1970 exposures.

This procedure produced different results for each job as shown in the example of continuous miner operator using the NIOSH method versus direct use of the BOM data.

- The BOM data for a continuous miner operator indicated a mean concentration of 6.8 mg/m³.
- The MSHA data for 1970-72 indicated a mean concentration of 2.4 mg/m³.
- The calculated conversion factor for a continuous miner operator would be 6.8 ÷ 2.4 = 2.8.
- Using this conversion factor, the estimated exposure concentration would be 2.8 x 2.4 = 6.7 mg/m³.
- Rather than using job specific conversion factors or the actual BOM sample results, NIOSH calculated a universal factor of 2.3 from the mean of all 25 job-specific conversion factors (calculated from the authors' Table 1).
- Using the NIOSH universal conversion factor, the estimated exposure concentration for a continuous miner operator calculated and used in NIOSH studies would be 2.3 x 2.4 = 5.5mg/m³.
- Thus, for the continuous miner operator job category, the NIOSH approach would underestimate the exposure by 22% compared to the BOM data.

These back-extrapolations are biased because they are based on an average ratio rather than job-specific ratios. The biases are displayed in Figures 8 and 9, which also show that exposures are generally underestimated in high exposure jobs and under-estimated in low exposure jobs.

Figure 8 shows the universal conversion factor of 2.3 and the BOM job-specific data points above and below this line. Points below the line are lower exposure jobs based on the BOM data. When their MSHA exposure is multiplied by 2.3 to estimate pre-1970 exposure, the MSHA exposure is larger than the BOM estimate. That is, exposure is greater than expected so risk is over-estimated or biased upward.

BOM data points above the 2.3 conversion factor are higher exposure jobs. When the MSHA job mean is multiplied by 2.3 to

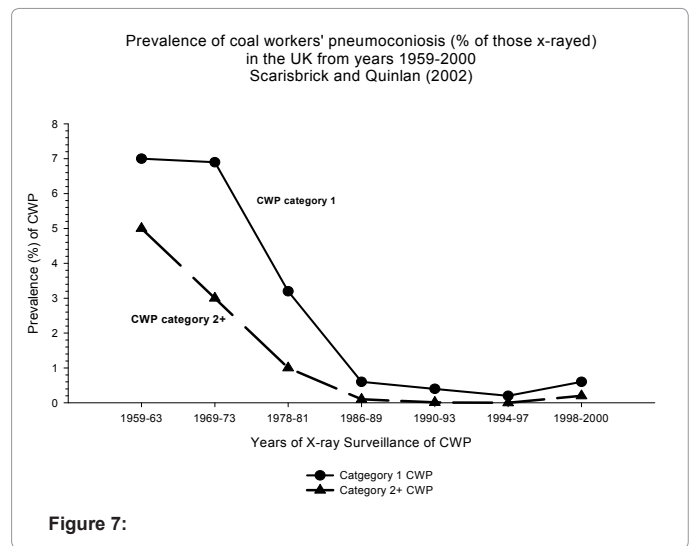


Figure 7:

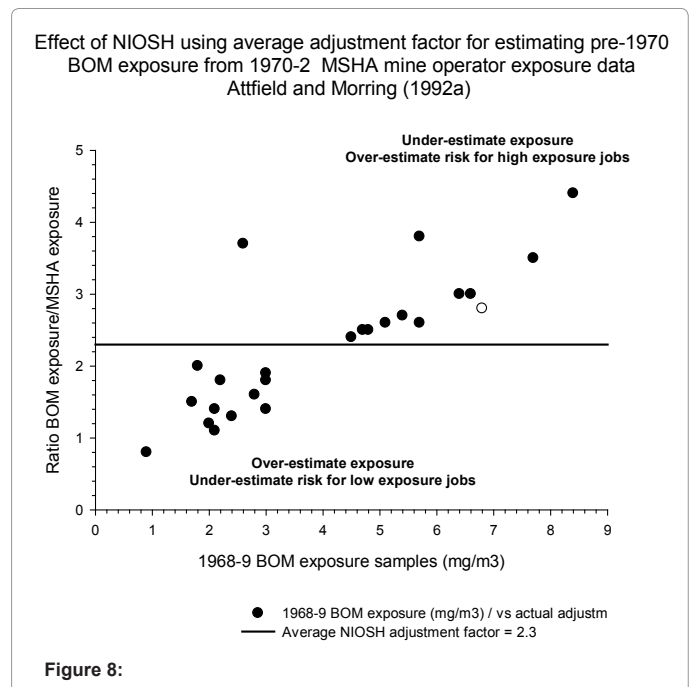


Figure 8:

estimated pre-1970 exposures, the calculated NIOSH estimate is less than the BOM mean. That is, the NIOSH estimated exposure underestimates exposure, which produces a biased increased risk.

Cumulative CMD exposure is estimated by the summation of tenure x job exposure. Since job exposure is biased, cumulative exposure will be biased in the same directions. There is a rough breaking point for higher and lower exposure jobs at about 4 mg/m³. Metaphorically, 4 mg/m³ is a kind of fulcrum. To the left of this point, the exposure-response curve is biased downward. To the right of 4 mg/m³ the exposure-response curve is biased upward. The overall effect is a spuriously steeper slope and spuriously increased risk at higher exposures. If the biases were adjusted or removed, the exposure-response slope becomes flatter and the association weaker.

This bias is applicable to the first morbidity study of CWP [19] and the last mortality study [20] where only pre-1970 data are used. The other morbidity study used both pre- and post-1970 exposure [13].

The latter authors noted the potential for the under-estimation bias in exposure via “probable systematic underestimation of higher dust levels brought about by certain mine operator sampling practices over the years” and special sampling exercises that showed “operator sampled dust levels were indeed systematically lower than those collected by inspectors” [13]. This operator bias increases the effect of the NIOSH calculation bias. Because of these biases, estimated risks from these studies will be spuriously high and actual effects of CMD exposure will be somewhat less than those derived from the exposure-response data as presented.

There were more post-1970 than pre-1970 data available, but it is not clear this advantage provides adequate rationale for a procedure that produces exposure estimates that are systematically biased. The actual BOM pre-1970 sample data appear to offer a direct estimate of pre-1970 exposures, and may be preferable to a back-extrapolation based on ratios of two incomparable data sets. The data sets are incomparable with regard to time (1968-9 vs. 1970-2) and sample source (BOM-collected samples vs. operator-collected samples).

Exposure-response studies of radiographic CWP in the US [19]

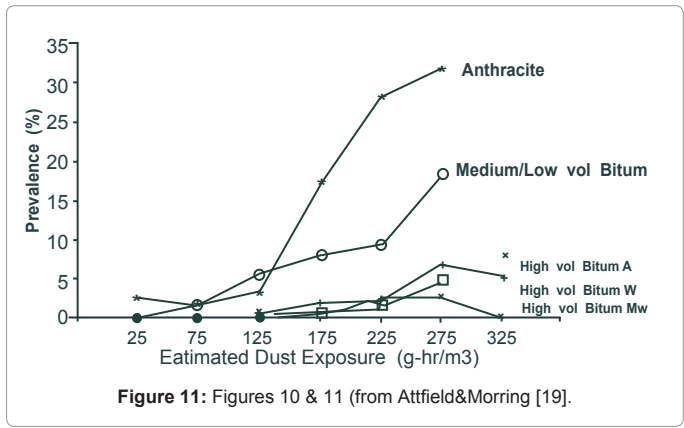
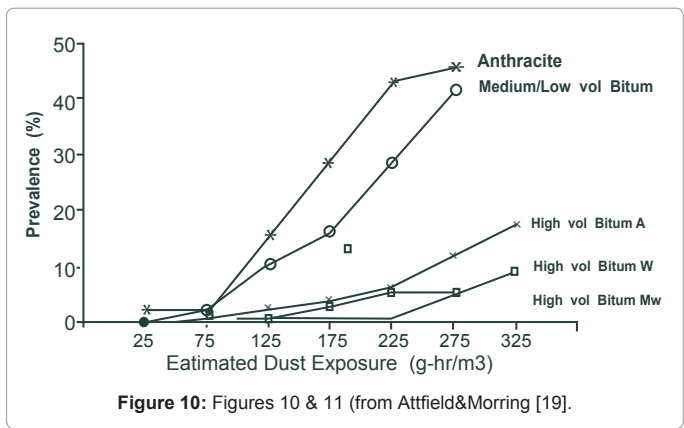
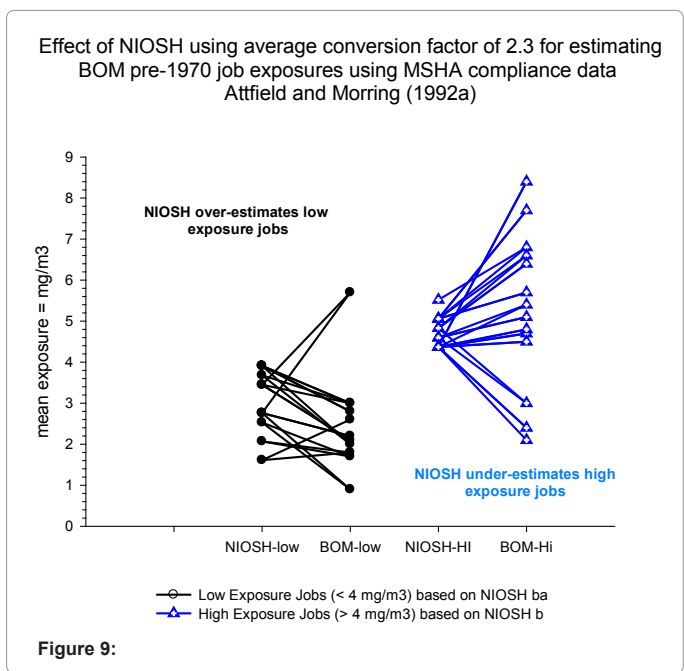
This is the first exposure-response study of US coal miners using quantitative estimates of exposure (gh/m^3) instead of tenure or job. The present exposure limit of $2.0 \text{ mg}/\text{m}^3$ is largely based on results from studies of British miners. The prime objective of this study was to develop exposure-response relationships between CWP and CMD in US coal mines.

The cohort consisted of miners from 31 underground US mines examined in 1969-1971 as part of the first round of the NSCWP. The relevant parts of the examination for this study included chest radiograph, spirometry, work and smoking histories.

Three data sets were utilized to estimate cumulative CMD exposures that occurred prior to the miners’ examinations; viz. the work histories from the miners in the NSCWP 1969-1971, MSHA compliance data 1970-1972, and BOM data 1968-1969. The BOM data were collected at 17 of the mines included in this study and are the only body of gravimetric data prior to 1970 that were available for this study. Exposure estimates used in exposure-response analyses were based on 1970-72 compliance samples and back extrapolated to pre-1970 miner work experience by using an average factor derived from the ratio of job specific BOM/MSHA data and then applying this factor to the MSHA compliance data in 1970-1972. This procedure and these estimates are reviewed in the previous article of Attfield and Moring [18].

Each coal mine was classified into one of five rank categories with Rank 1 = anthracite, Rank 2 = medium/low volatile bituminous (89-90% carbon) coal in central Pa, and southeastern West Virginia; Rank 3 = High volatile “A” bituminous coal (80-87% carbon) in western Pennsylvania, West Virginia, eastern Ohio, eastern Kentucky, western Virginia and Alabama; Rank 4 = High volatile Midwestern coal in western Kentucky and Illinois; Rank 5 = High volatile West in Utah and Colorado.

There are clear, strong associations of CWP 2+ and exposure to high rank coals 1 and 2 with excess prevalence occurring at exposures below the current standard. Associations with coal ranks 3 and 4 are weaker with excess prevalences at exposures above the current exposure standard. There is no apparent association with coal rank 5 as the exposure-response curve is flat with some separation from rank 3 beginning around $70 \text{ mg}/\text{m}^3\text{-years}$. The exposure-response slopes for ranks 3-5 from the logistic regression models are similar but with slopes



becoming less steep with each increase in rank for category CWP 2+ (Figures 10, 11, 12).

Critique of Attfield and Moring [19]

The authors’ note a limitation of this study in that there was only

one reader of chest films, although the similarity with readings from the UK provided some comfort that it should not lead to major errors in prevalence or exposure-response relationships.

CWP ≥ 2 is more reliable than CWP ≥ 1 and should be the response-variable used to establish exposure-response trends. We say that because profusion of small opacities can be from other causes (e.g. smoking and lung conditions other than CWP). Classification of CWP ≥ 2 is a relatively clear and reliable indicator of CWP when coupled with CMD exposures.

The background level of CWP is estimated to be about 5% [13]. At this background level there is no excess PMF for low ranking coal 3-5 and no excess CWP ≥ 2 for low ranking coal below 110 mg/m³-years, (Figures 10, 11, and 12).

Figure 13 shows the effect of coal rank on prevalence of different categories of CWP. This graph is based on statistical models predicting prevalence based on the effects of a 40-year work life at 2 mg/m³. There appears to be no excess prevalence of categories CWP 1 and CWP 2 for ranks 3-5 when background levels of abnormal radiographs are taken into account. The predictions are also based on exposures prior to 1970, a time when concentrations could be as high as 8 mg/m³.

A major limitation of this (and other US studies) is that exposure is based on sample results taken about the time the 3.0 mg/m³ standard was being initiated. The period before about 1970 was a period of high exposures with 21 of 25 jobs above the current standard and ranging as high as 8.4 mg/m³[18].

The last sentence in the abstract admits possible weaknesses in the exposure estimates, but indicated the results are in general agreement with data from the UK, except for somewhat higher predictions of CWP prevalence. The US predictions are quite high and well above background prevalence and general findings from other studies. The authors contend that between 2% and 12% of workers exposed to 2.0 mg/m³ are predicted to have category 2 or greater CWP after a 40-year working life. Smaller prevalence is noted for PMF, but it too is very high.

These are unexpected results compared with the original British Interim Standards which the US adopted to stop miners from progressing to category 2 or greater. It is noted in the body of the paper that exposure-response estimates would permit more precise assessment of health risks. Very true, but this assumes that both the environmental exposure and the biological response are measured accurately or nearly so.

This study was done to derive exposure-response estimates based on US data because there was concern regarding extrapolation of UK information to the US experience. The miners of choice were from the 1st round of the NSCWP and the x-ray readings were from one reader and only rounded opacities were considered. This is reasonable as only rounded opacities were used in the earlier UK studies. The use of one x-ray reader in the US could be of great concern, but the similarity of the one reader with median British readers was reassuring to the authors. It is appropriate that the readings from the other two readers were discarded, although concern regarding the use of a single reader lingers.

The authors' Figure 2 shows exposure-response by coal rank and clearly shows prevalence is associated with both dust exposure and rank. Alternate statistical models produced no improvement. They are similar to UK models where the exposure is a continuous variable and begins at zero exposure. There are no threshold estimates in this study,

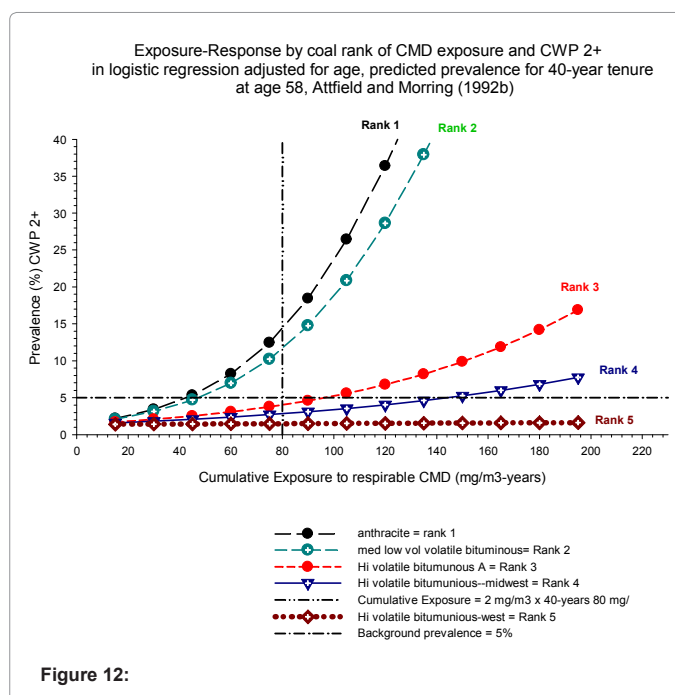


Figure 12:

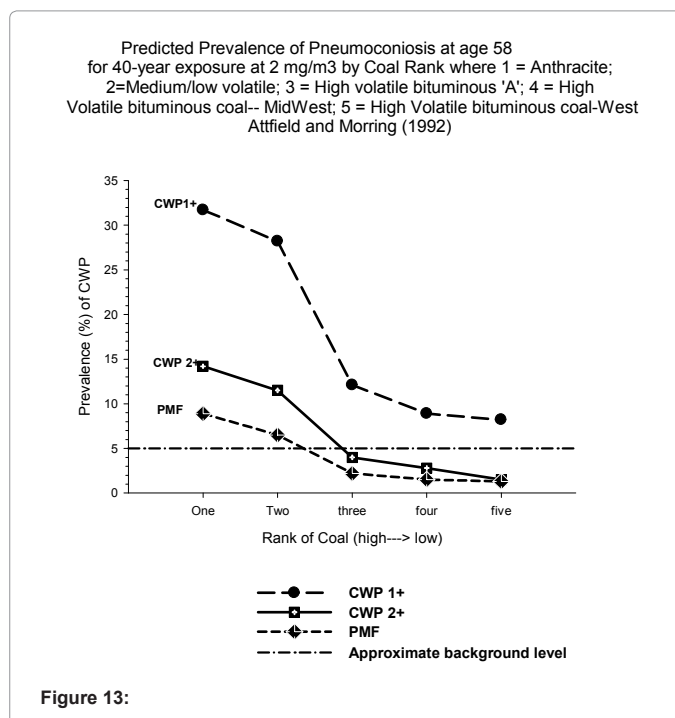


Figure 13:

but the authors comment that their models may be inadequate at very low exposure levels. Exposure-response trends are clear and consistent, but prevalence estimates of CWP in the US are dramatically higher than for the UK. Reasons for the gross disparity are not resolved. Thus, the authors advise caution in using the information in this report. (See[13] for comparison.)

The data in this report provide strong evidence that rank of coal is an important factor to be considered and seems implicated in the etiology of CWP (see [9] for further discussion of rank).

Exposure-response studies of radiographic CWP in the US (13)

This is a cohort study of 7,281 US underground miners and examiners who participated in Rounds 1 and 2 of the NSCWP begun in 1970. There were 3,194 (44%) participants selected for study who were <59 years old in 1985 and were examined in Round 4. Miners excluded from the study were from areas where it was not feasible to conduct further surveys.

Mines were divided into three broad categories of coal rank. The high coal rank category of miners were from Pennsylvania and southwestern West Virginia (about 2000); the low rank group was from Kentucky, Illinois, Colorado and Utah (about 2200); the medium rank comprised all the other states including Ohio (350), Tennessee (100), and Virginia (600).

Cumulative exposure ranged from 0 to 211 mg/m³-years with a mean of 34 and standard deviation of 32 mg/m³-years. Most (75%) of the cohort had low exposures of 13-41mg/m³-years.

The overall prevalence of CWP ≥ 1 (all major categories) was 4% (n = 131). For CWP ≥ 2 (categories 2, 3) prevalence was 0.7% (n=23) and for PMF was 0.8% (n= 28). Age and cumulative dust exposure were significant factors affecting prevalence of CWP ≥ 1 , CWP ≥ 2 and PMF. There were clear exposure-response trends of increasing CWP with increasing cumulative coal dust exposure. The exposure-response slope became even steeper from the added effect of exposure to high rank coal dust (Figure 14).

Critique of Attfield and Seixas [13]

These data show clear exposure-response trends for CWP to increase with increasing cumulative exposure. The logistic regression models suggest no excess prevalence of CWP ≥ 2 and PMF for low rank coal at exposures below the standard. There was excess prevalence of CWP ≥ 1 when exposed to high rank coals. There is a clear and large effect of rank, with high rank coal showing strong steep trends, while lower ranks generally had shallow slopes except for CWP ≥ 1 (Figure 14).

There are categorical analyses of CWP ≥ 1 and ≥ 2 in the authors' Figure 2, which suggests a threshold for median readings of CWP ≥ 1 at about 30 mg/m³-years, and about 80 mg/m³-years for CWP ≥ 2 at the 5% background prevalence. These data are suggestive of no measurably increased risk of CWP at coal dust exposures less than about 30 mg/m³-years without consideration of background prevalence.

However, background prevalence of CWP does not appear to be zero. The authors reported a predicted prevalence of 5% category CWP ≥ 1 among non-exposed coal miners. Predicted prevalences were 0.9% for CWP ≥ 2 and 0.5% for PMF (their Table 4). From the categorical analysis (the authors' Figures 2 & 3) prevalence of CWP ≥ 1 is 2-3% up to about 30 mg/m³-years. Citing unpublished work of Castellan, et al., (from blue-collar cohort [22]) the prevalence of category 1/0 among unexposed blue collar workers about 56 years old was 1.4% (SE = 0.8%) or an upper limit of about 3%, which obviously is less than the 5% predicted in this study. The authors cite Figure 2 of Collins, et al.(23)showing a 5% prevalence of category $\geq 0/1$ small irregular opacities (90% being $\geq 1/0$) among 60-year old smokers. The authors conclude that "inclusion of small rounded opacities, in order to derive a... [background] estimate for all opacity types, as studied in this report, would naturally raise this prediction above 5%, although it is not possible to calculate a figure from the information given."

Meyer et al. [23] conducted a literature analysis of prevalence of category $\geq 1/0$ among workers with no exposure to dust. There were nine study populations in Europe and North America that had unexposed workers or control groups for analysis. The population prevalence was 5.3% (2.9-7.7%), and was significantly greater in Europe than North America; the contrast was 11.3% (10.1-12.5%) vs. 1.6% (0.6-2.6%). The prevalence among males was 5.5% (3.4-7.6%). Prevalence remained higher in Europe than North America by age category >50-years, being 11.7% vs. 2.3%. Age, gender and smoking did not explain these differences in prevalences. Reader variability and environmental or unaccounted occupational exposures were considered as possible causes of the large differences between Europe and North America.

Based on these data, a background prevalence of 5% for category $\geq 1/0$ appears reasonable in the absence of a non-exposed control group in the studies reviewed.

Potential limitation in the exposure estimates noted by the authors include potentially incomplete work histories based on interviews and "deficiencies in recalling work history." Mine operator samples (especially from mines with <125 miners) tend to underestimate exposures. However most of the mines in this study were larger than 125 miners so this bias may not be large. Both of these biases, however, can produce over-estimates of the pulmonary fibrogenicity of CMD and produce radiographic changes at lower exposure levels than actually occur (Table 3).

A probable limitation relates to exposures prior to 1970 which were included in the overall estimates of cumulative exposure. Both pre- and post-1970 time periods contributed to the development of CWP ≥ 1 in the combined low and medium coal rank groups. However, there is convincing evidence that pre-1970 exposure estimates may be seriously underestimated (data from Doyle 1970(21) are shown below).

Exposure-response study of radiographic CWP in Germany [24]

This is an inception cohort of 1,369 coal miners who began work underground at two large German collieries during the period from 1974-1979 and had at least 0.5 years exposure underground. Miners were about equally divided between the Heinrich Robert Colliery, mining high rank coking coal used in steel production and the Walsum Colliery mining low rank gas and flaming coal used in energy production. By law each miner must receive a chest radiograph every other year and smoking histories are available on each miner. Over 36,000 stationary (or area samples) gravimetric dust measurements were collected from 1974-1998, which is the same time period as the follow-up.

Average CMD exposure was below 2.0 mg/m³ in the low rank mine and less than the 2.06 mg/m³ in the high rank coal mine. Intensity of quartz exposures were reversed with the higher average (and maximum) values in low rank coal compared to high rank coal. Years underground were similar in the two mines, so there is little difference in cumulative exposure between miners (Table 4).

There were no chest radiographs showing category CWP 1+ indicating no association between CWP and CMD.

Critique of Morfeld et al. [24]

This study shows no association between exposures to CMD at mean levels above the MSHA standard in high rank coal. In low rank coal, the mean was slightly below the MSHA standard, but a proportion

of miners had exposure levels above 2.0 mg/m³. Because there are zero cases of CWP ≥1 the best one can say about exposure-response is that the 2.0 mg/m³ standard appears to be protective in this cohort, and quartz exposures at the concentrations experienced also do not produce pneumoconiosis.

A limitation of this study is that latency may be too short for development of pneumoconiosis. The maximum latency in this study was 24 years with an average of 15 years. The relatively short latency for CWP may be an explanation for the absence of any apparent risk of developing CWP ≥1.

Three percent of the miners developed category 0/1, and all cases of 0/1 at the Walsum Colliery were either smokers or ex-smokers. These may be cases of the so-called “dirty lung syndrome” attributed to cigarette smoking and is the approximate baseline prevalence for 0/1 in this study. These data tend to support the German concept for considering category ≥1/1 a definite CWP category. Categories 0/1 and 1/0 are fraught with much variation and depending on how film reading is done can seriously affect outcomes in studies. Incidence of category 0/1 was not analyzed further in this study.

It is interesting that the authors compare their low risk estimates with US estimates and note the gross disparity in risk. They indicate that if personal dust sampling had been done it would have sharpened (increased) the discrepancy between the US and German findings. This refers to the general finding that area samples often are less than personal sampling results, and thus may underestimate individual exposure results.

Exposure-response study of radiographic CWP in South Africa [25]

This is a cross-sectional exposure-response study of a cohort of 684 current bituminous coal miners in the Mpumalanga province of South Africa. It is the first study to document the prevalence of CWP in a living South African cohort of coal miners.

The miner cohort consisted of all 684 current miners in three mines

and excluded all workers at or above grade 13, junior management level, administrative positions, etc. This is a cross-sectional study design in that only the most recent chest X-rays were used. Ex-miners were recruited for the study but because of the small number of former employees and the 11% non-participation rate this is not a major focus of this analysis.

The cumulative respirable CMD variable was categorized into tertiles of low exposure (0.62-20.1 mg/m³-years; n = 278), medium exposure (20.1-72.8 mg/m³-years; n = 285), and high exposure (72.8-259 mg/m³-years; n=294). Pack years was adjusted for in the exposure-response analysis. ²Average intensity of exposures was 0.2-0.3 mg/m³ on the surface and 0.9-1.9 mg/m³ at the face. Among mechanical miner operators, mean concentrations ranged from 1.2-2.8 mg/m³. Percent silica ranged from 1.2-2.8% at the face.

There was a clear exposure-response trend of CWP ≥1 and cumulative respirable CMD (trend test p=<0.001), but no trend with radiological emphysema (Figure 15). The exposure-response trend for CWP ≥1 was also significant using cumulative exposure as a continuous variable.

Critique of Naidoo et al. [25]

These data show a clear association of CMD and CWP ≥1, but low prevalence below 5% at high exposures. The mid-point of the high exposure range is 165 mg/m³-years and average tenure of 10 years for face workers suggest an average intensity exposure of about 16 mg/m³. At these concentrations the average intensity over a 40-year working lifetime would be 4 mg/m³. At an intensity of about 2.0 mg/m³ there would be a prevalence of <1% CWP ≥1 assuming 40 years tenure. While intensity of exposure is high, the prevalence of CWP is likely to be below background levels.

Such a low prevalence at high exposures may be due to inadequate latency for CWP to develop. Miners were classified into three groups by exposure, with the most exposed group being miners with 10+ years at the face. Maximum intensity of mean exposure at the face for all three mines was 1.9 mg/m³. A cumulative exposure of 165 mg/m³-years and

Occupation	No of mines	No of samples	Range (mg/m ³)	Mean (mg/m ³)
Continuous miner operator	21	178	0.02-21.44	4.08
Continuous miner helper	19	131	0.44-18.90	3.47
Cutting machine operator	15	98	0.71-15.42	3.69
Cutting machine helper	8	37	0.77-14.70	4.45
Coal drill operator	9	59	0.42-12.94	3.55
Loading machine operator	18	97	0.25-39.56	3.75

Table 3: Mine operator samples.

	Coal dust	Quartz	Time UG (yrs)	Approximately cumulative exposure = Intensity x yrs UG = mg/m ³ -yr
	Intensity (mg/m ³) Mean (max)	Intensity (mg/m ³) Mean (max)	Mean(max)	Mean (maximum) Coal Dust Quartz
Low rank coal(n = 699)	1.68 (6.91)	0.063 (0.88)	14.6 (23)	24.5 (159) 0.92 0.92 (20.2)
High rank Coal(n = 670)	2.06 (6.00)	0.038 (0.31)	14.9 (24)	30.7 (144) 0.91 (7.4)

Table 4: Exposure was dissimilar between the two collieries.

²Pack years is a term used in public health to measure the amount a person has smoked over a long period of time. It is calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked. For example, one pack year is equal to smoking 20 cigarettes per day for one year, or 40 cigarettes per day for half a year, and so on. A smoker who smoked one pack a day for 40 years would have a 40 pack year smoking history.

maximum intensity of 1.9 mg/m³ leads to an implausible tenure of 87 years. Maximum intensity of exposures (as opposed to mean) must have been well above the 2.0 mg/m³ MSHA standard.

The authors comment that the low 4.2% prevalence of CWP in South African miners is similar to the 4.5-6.8% reported in the US (26), but with about 50% lower average exposures in the US (34 mg/m³-years) than this study (57 mg/m³-years).

These data indicate an association of CWP ≥1 and cumulative respirable CMD exposure in this South African cohort. Prevalence is low even at high CMD exposure (and relatively low quartz exposure). At 2.0 mg/m³ intensity, these data suggest no increased prevalence; the finding of three cases (1.4%) at 20-73 mg/m³-years (or 0.5-1.8 mg/m³ for a 40-year working lifetime) could be due to chance. This chance finding could include a much higher intensity for relatively short periods at the face where it appears there are some individual exposures that could be 4 mg/m³ or more. If background prevalence is taken into account there are no significant excesses of CWP ≥1 at concentrations well above a 2.0 mg/m³ standard (Figure 15).

Prevalence of radiological emphysema was quite high, but showed no relationship with cumulative respirable CMD (Figure 15).

Discussion

The purpose of this study was to summarize exposure-response data using quantitative estimates of CMD exposure levels and CWP ≥2 as the response variable. The combined results of these are summarized in Figure 16. The figure is divided into 4 quadrants with the x-axis representing background prevalence and the y-axis representing 80 mg/m³-years or 40 years exposure to 2 mg/m³ CMD.

The upper left quadrant shows prevalences of CWP ≥2 at exposure levels greater than the current standard of 2 mg/m³. These data show that three of the five studies in this category involve exposure to high rank coals. The remaining seven curves do not show excess prevalence of CWP 2+ below the current standard considering background prevalence.

The US data are shown separately in Figure 17 to more easily visualize the associations in these data.

There are two US exposure-response studies in this group of coal worker cohorts [13, 19] (Figure 17). These studies have two limitations unique to NIOSH cohorts.

The first major limitation occurs in both studies and is systematic bias in pre-1970 exposure estimates where a mean adjustment factor was used to back-extrapolate 1970-72 compliance data to the miners pre-1970 work experience. This procedure produced over-estimates of risk in high exposure jobs, under-estimates of risk in lower exposure jobs and exposure-response that are biased upward. Another view of differences in CMD exposure is displayed in Figure 18, showing the large reduction in pre-1970 exposures compared to immediate post-1970 intensities and the continual reductions following institution of the federal coal mine dust standard.

The second limitation occurs from low participation in later rounds of the NSCWP. This potential selection bias applies to the more recent study where workers participating in the first and second rounds of the NSCWP were re-examined in the fourth round [13]. Low participation in rounds 2 and 4 could result in selection bias. If there was selection bias, there is inadequate information to determine its magnitude or direction. This limitation is relevant only for Attfield and Seixas where

participation involved coal miners from rounds other than round 1 of the NSCWP [13].

A large body of literature on CWP has been reviewed, with major emphasis on US studies and their relationship to the now existing MSHA dust standard of 2 mg/m³, and the current MSHA proposal to lower the standard to 1 mg/m³. The evaluation of other studies (largely from the UK) has been used to supplement and/or corroborate a point.

There is a natural progression of thought based in the epidemiological literature that leads to the current situation. Since the

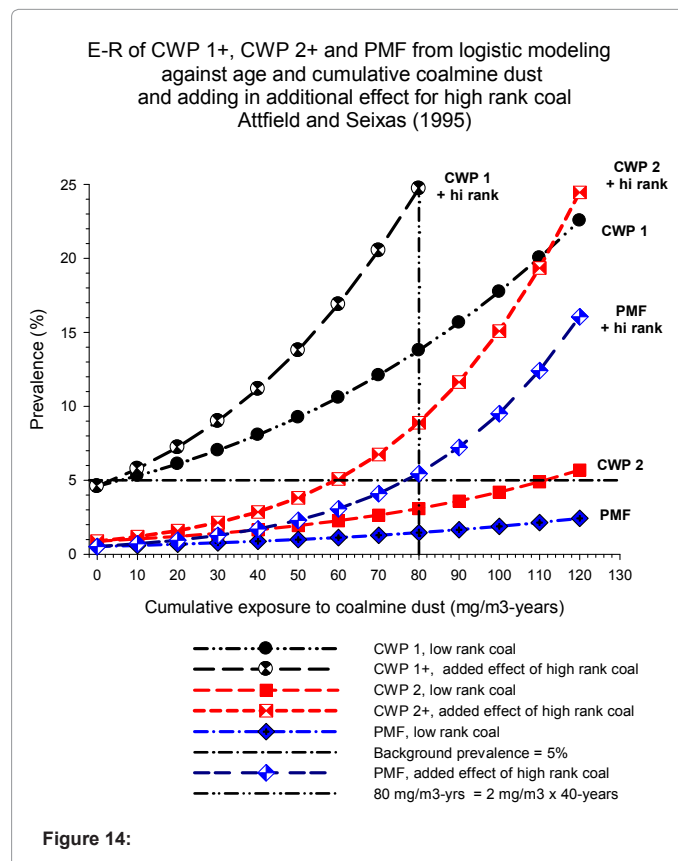


Figure 14:

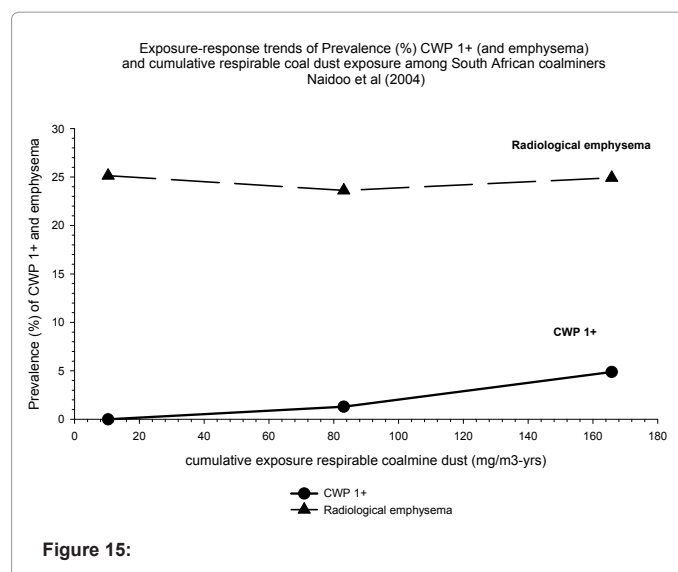


Figure 15:

1970s, when an X-ray surveillance program for coal workers in the US began and CMD standards were initiated, there was a rapid decline in the reported prevalence of CWP from around 30% to 3%, and this decline was coupled with decreasing CMD levels. However, from around 1970 to the 1990s, CMD appeared to stabilize at around 1 mg/m³ and then decrease slightly. In the 1990s and later there were reports that CWP prevalence was increasing slightly without concomitant increases in CMD exposure.

In the 2000s, NIOSH reported cases of rapidly progressive CWP. Some miners were described as developing dust-induced disease of high severity over short time periods, and some cases were among relatively young men. While the frequency of these sentinel events was low in absolute numbers, they were nonetheless a serious health concern calling for a determination of their cause and how to prevent their occurrence [8].

No studies have been conducted to identify specific etiological agents or factors associated with rapidly progressing cases such as a case-control study. The evidence that this reported outbreak of CWP is indeed CWP, and not silicosis, has not been adequately examined [8].

The current US dust standard is based on data from the UK coal fields; and in 1970, the US standard of 3.0 mg/m³ became operative, as a transition to 2 mg/m³ with less than 5% quartz in 1972.

The use of British coalmine data to set a US coal mine dust standard raised concerns about the relevance of that data for US mines. The UK has a similar range of quartz and coal rank as in US coal mines. However, both the reported and estimated CWP prevalence appears to be higher at similar exposure levels in the US than in the UK. Thus, the study of exposure-response associations of CMD and CWP in the US provides new data for a possible revised MSHA coal mine dust standard, data not used in the present standard.

Our review of this body of scientific studies has summarized methods, results, and critiques of exposure-response studies regarding CWP and CMD. Issues relating to “sentinel events” and likely quartz exposure [8] and rank of coal [9] have also been reviewed. Our main objective has been to assess the weight of the evidence regarding the proposed change of the CMD standard to 1.0 mg/m³.

Conclusion

This review has led to several overall conclusions regarding CWP and CMD. These are:

Conclusion 1

Prevalence (%) data from the NCWXSP are potentially biased by low participation. The direction and magnitude of the bias is not known. These data may be useful for assessing trends, but the actual prevalence of CWP in the US is unknown and data from this program remain questionable for use in research studies.

Conclusion 2

Estimates of pre-1970 CMD exposures are imprecise and biased. The use of an average adjustment factor applied to post-1970 compliance data to estimate pre-1970 data produced biased under-estimates of exposure and over-estimates of risk in high exposure jobs and the reverse in low exposure jobs. The effect is to bias exposure-response trends upward so the curves are inaccurate and produce spuriously low threshold levels of effect.

When adjustments are made for this bias, the associations of excess prevalence at exposures below the standard appear to disappear.

Summary of Exposure-Response studies of radiographic CWP category 2 with cumulative respirable coalmine dust (mg/m³-years) in US and UK Hurley (1979); Attfield-Seixas (1995); Attfield-Morring (1992); Soutar et al (1986); Miller et al, 1998

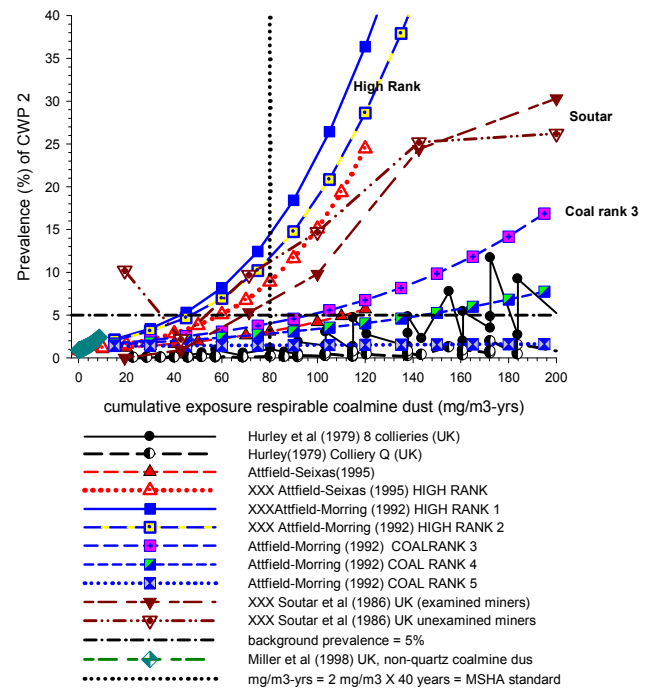


Figure 16:

Summary of US Exposure-Response studies of radiographic CWP 2+ and cumulative exposure to respirable coal mine dust Attfield and Morrings, (1992) and Attfield and Seixas (1995)

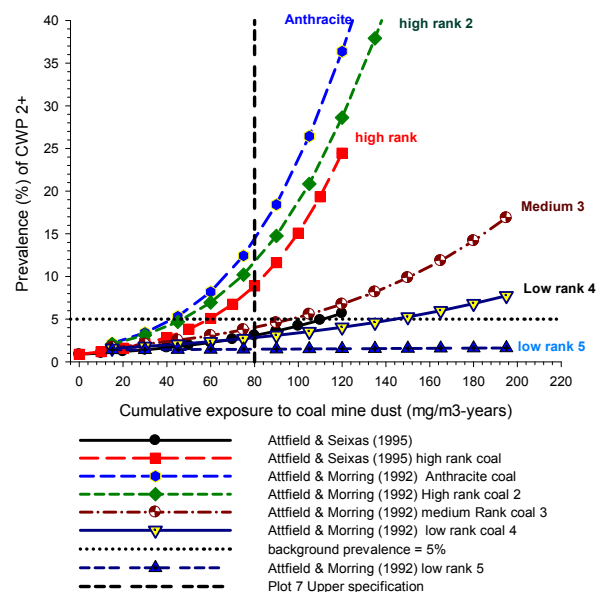
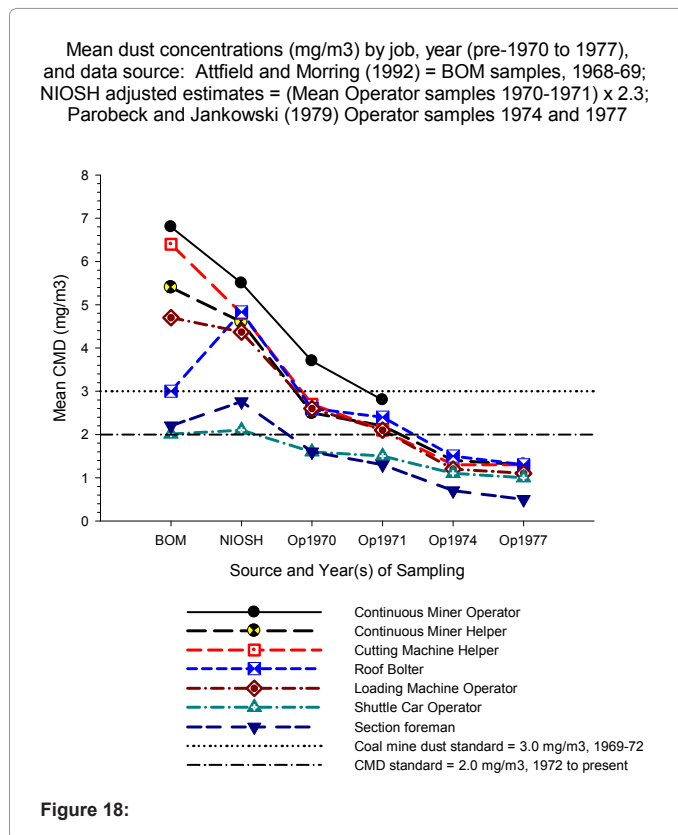


Figure 17:



NIOSH should conduct a properly designed analysis of pre-1970 exposures using (to the extent possible) available pre-1970 samples directly. Such an analysis may aid in overcoming limitations from indirect back-extrapolations and averaging that appear to produce biased exposure estimates and spuriously steep exposure-response slopes.

Conclusion 3

For there to be excess CWP among coal miners, the prevalence of CWP should be greater than background prevalence. A background prevalence rate of 5% for category 1 and greater has been suggested for US studies.

However this estimate seems implausibly high for CWP category ≥ 2 or PMF, and is at odds with some other data. Further details are needed to explain the derivation of this number. It is unfortunate background prevalence data on non-exposed individuals were not collected during the actual study periods.

The NIOSH exposure-response studies show a strong association between CMD and CWP ≥ 2 with excess pneumoconiosis at higher exposures. Excess CWP ≥ 2 was above background prevalence for coal miners exposed to high rank coal at concentrations below the current standard of 2 mg/m³. Exposure to low rank coal below the current standard was not associated with an increased risk of CWP ≥ 2 .

This conclusion is based on assuming 5% background prevalence, a 40-year working life, but does not take into account exposure misclassification bias that steepens the exposure-response relationship. Adjustments to the biased exposure-response models are suggestive there may be no increased risk of CWP at exposures below the current standard for low ranked coals.

Conclusion 4

Based on the data reviewed in this report, there is inadequate evidence supporting a reduction in the current standard for low rank coal because of increased risk of CWP morbidity. US exposure data are biased and risks over-estimated. Work is required to reduce this bias.

Research should be conducted to improved estimates of exposure. This research could include such things as the following:

- Reanalyze estimates of pre-1970 exposures of studies where the biased estimates were used for relationships with CWP;
- Case-control studies of post-1970 CWP cases to avoid potential biases from low participation and exposure misclassification.

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