A Review of the Scientific Basis for MSHA's Proposal for Lowering the Coal Mine Dust Standard

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What We Will Cover

- Objectives of this presentation are to summarize the epidemiological evidence regarding risk factors associated with:
  - “Sentinel health" events of rapidly progressive CWP.
  - Exposure-response relationships of CMD and CWP.
- Our summary includes consideration of other risk factors
  - Exposures to quartz.
  - Differences in pulmonary fibrogenicity due to coal rank.
- Plus bias and confounding in studies evaluated.
  - Low participation rates.
  - Biased exposure estimates of CMD.
- The results from our evaluation are then used to assess whether the current coal mine dust standard protects miners from developing CWP and whether the proposed lowering of the standard is scientifically based.

MSHA/NIOSH Rationale for the Proposed Lowering of the CMD

- In the past decade, there have been reports of a slight increase in the prevalence of CWP.
- Moreover, there have been reports of rapidly progressive CWP.
  - Occurring in younger miners.
  - Often exposed for a relatively short time period.
- According to NIOSH, new exposure-response estimates for predicting the occurrence of CWP at various cumulative exposure levels have provided estimates greater than previously shown.
- These three points appear to be the main rationale for the proposal to lower the current CMD standard to 1.0 mg/m^3.

Summary of Rapidly Progressive CWP Studies

- RP CWP cases are clustered in the southern Appalachian region (SAR).
- RP CWP cases are more characteristic of silicosis than CWP and are associated with r-type opacities on the chest radiograph.
- For the SAR, prevalence of both r-type opacities and PMF increased each decade.
  - Effect of increased risk noted in small mines (<50 miners).
- The evidence is convincing that increased quartz exposure is an important, if not the explanatory factor in these rapidly progressive cases of CWP.

Studies On Rapidly Progressive CWP

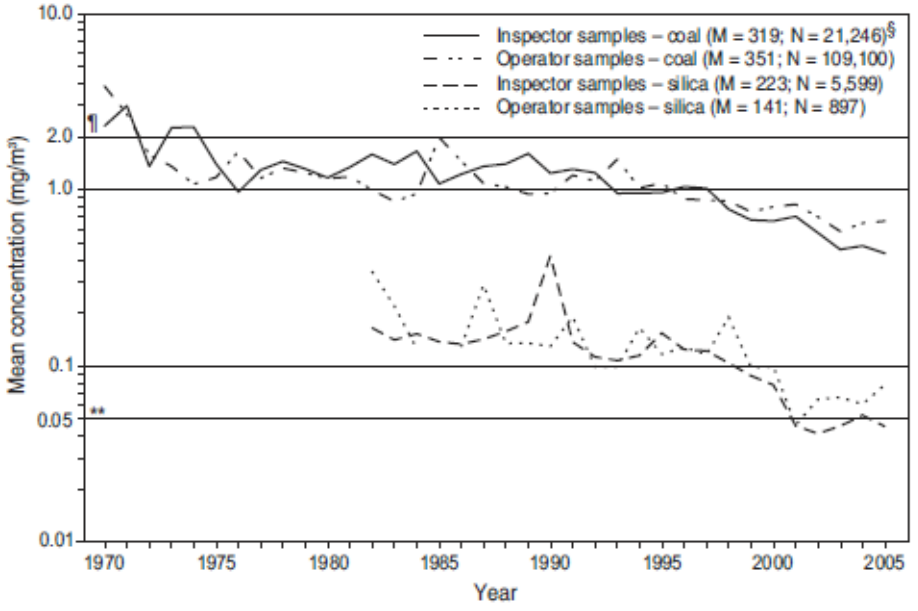
- Beginning in the mid-1990s an increase in more severe and RP CWP was noted.
- Despite the apparent stability in CMD exposure levels.
- The change of RP CWP occurrence was identified as a “sentinel health” event.
  - Occurred in the southern Appalachian region (“SAR”) of eastern Kentucky, western Virginia and southern West Virginia.
- Several potential causal factors have been investigated in an attempt to explain these changes in RP CWP severity and progression as well as why it is most common in the SAR.

The NIOSH Authors Propose Several Hypotheses Regarding These Cases

- CMD Standard Too High.
  - CMD levels in these 2 counties were:
    - Below the standard from 1972 to 2005
    - Below the REL of 1.0 mg/m^3 since 1995.
- Dust levels are actually above the MSHA and Operator data.
  - Compliance samples may be biased and underestimate exposure levels (Boden and Gold 1984; Weeks 2003).
  - 1970-2005 about 2.5% of individual samples on average were greater than 2.0 mg/m^3 .
- Silica might be a contributing factor.
  - Sampling for silica from the 1980s and remained above the standard of 0.1 mg/m^3 until about 1998 (18 years).
    - ~ 65% of silica samples 1982-2000 exceeded the NIOSH REL of 0.05 mg/m^3 .
    - Only since 2001 have mean county levels been below the NIOSH REL for quartz.

Cases of RP CWP in Lee & Wise Counties, Virginia

FIGURE. Mean concentrations of respirable coal mine dust and crystalline silica in coal mine dust* for underground workers at the coal face† — Lee and Wise counties, Virginia, 1970–2005



Not Consistent with the Data

MMWR Morb Mortal Wkly Rep 55:909-13

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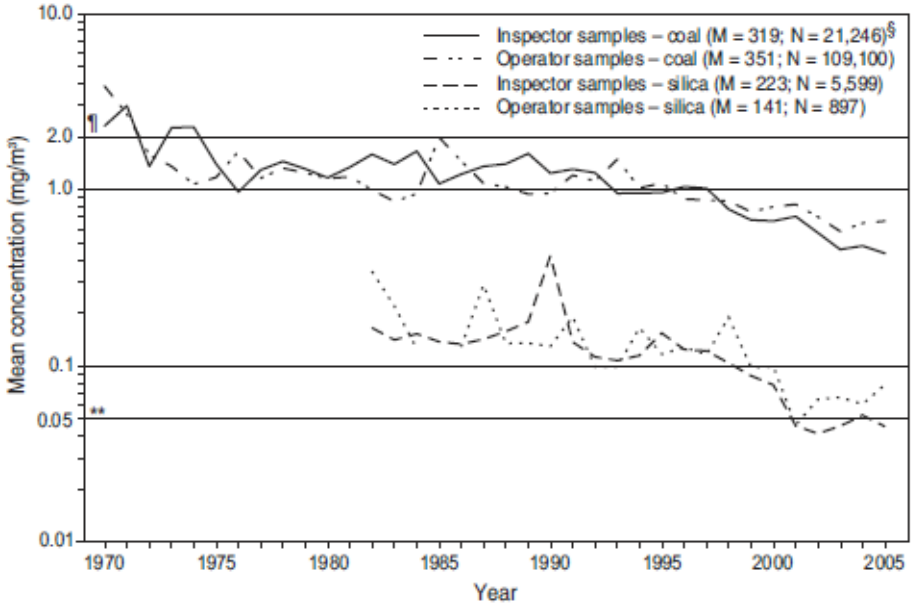

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Silica is the Major Contributing Factor

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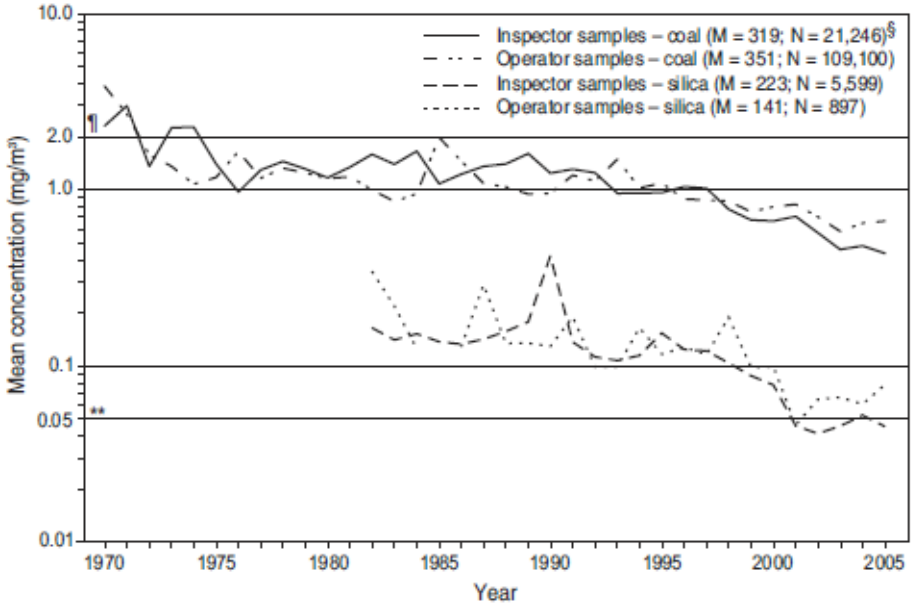

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ORIGINAL ARTICLE

Rapidly progressive coal workers' pneumoconiosis in the United States: geographic clustering and other factors

- A subset of a nationwide study of 29,521 miners in CWXSP (1996-2002) and Miners Choice Program (1999-2002).
- Study includes miners with at least 2 chest X-rays with most recent ≥ 1/1.
- Rapidly progressive CWP (RP CWP) defined as > 1 ILO subcategory over 5-years and/or development of PMF after 1985.
- Study group is 277 miners.

	N	Age	Tenure	Small Mines <50	Face Tenure
Rapid	277	48 ±6	27 ±6	OR= 1.5 (1.2-2.0)	19 ±10
Non Rapid	506	51 ±6	28 ±	OR = 1.0	17 ±10

Antao, V. S., E. Petsonk, et al. (2005) Occup Environ Med 62: 670-674.

ORIGINAL ARTICLE

Rapidly progressive coal workers' pneumoconiosis in the United States: geographic clustering and other factors

- Table 1 reports there were 295 RP CWP cases in 25 counties, which comprised over 40% of all RP CWP cases (at odds with text 277).
- Miners with rapidly progressive CWP:
  - were younger than miners without rapid progression (48 vs. 51 years of age),
  - were more likely to have worked in smaller mines (>50 miners),
  - did not differ with respect to mean underground tenure,
  - reported longer mean tenure working at the face
  - Geographical clustering in eastern Kentucky and western Virginia.
    - Clustering of RP CWP previously reported in Appalachian region (Amandus, Reger et al. 1973).
- Cases of rapidly progressive CWP can be regarded as sentinel health events, indicating inadequate prevention measures in specific regions.

Antao, V. S., E. Petsonk, et al. (2005) Occup Environ Med 62: 670-674.

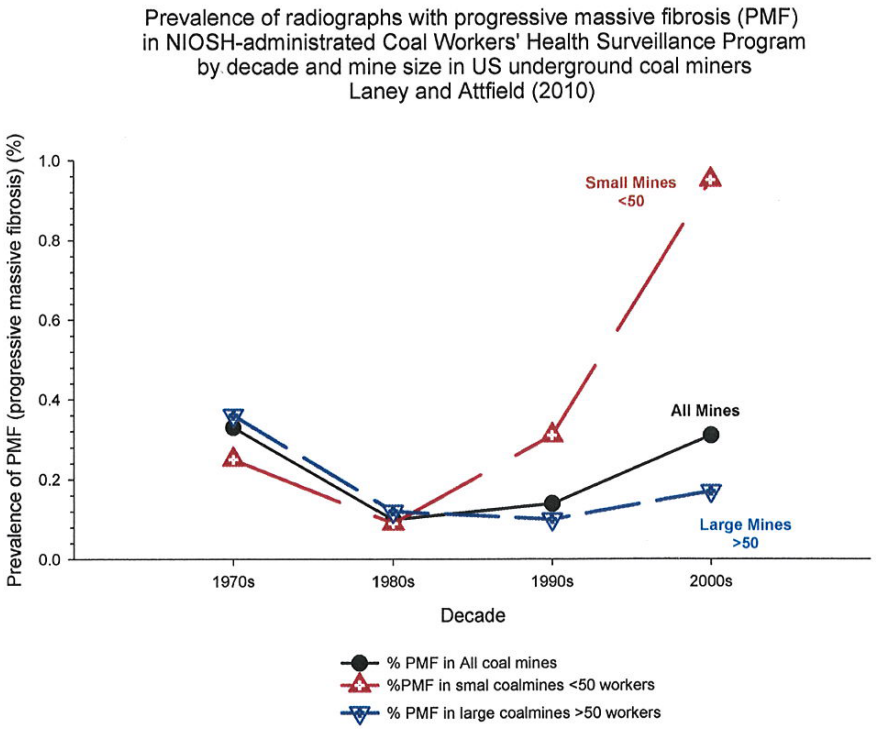
Limitations of Antao, et al. (2005)

- Inter-reading variability because of independent readings by different readers at different times (separated by 5+ years).
- Selection bias may be occurring.
  - Participation rate was about 31%.
  - Are rapid progressors more likely to participate?
  - Or, not participate?
  - Since it is unknown why miners were more, or less, likely to choose to participate it is pure speculation as to which way this might bias the study.
- No E-R relationships so not useful in determining safe exposure levels.

Antao, V. S., E. Petsonk, et al. (2005) Occup Environ Med 62: 670-674.

CWP and PMF Are More Prevalent in Small UG Coal Mines (< 50 miners)

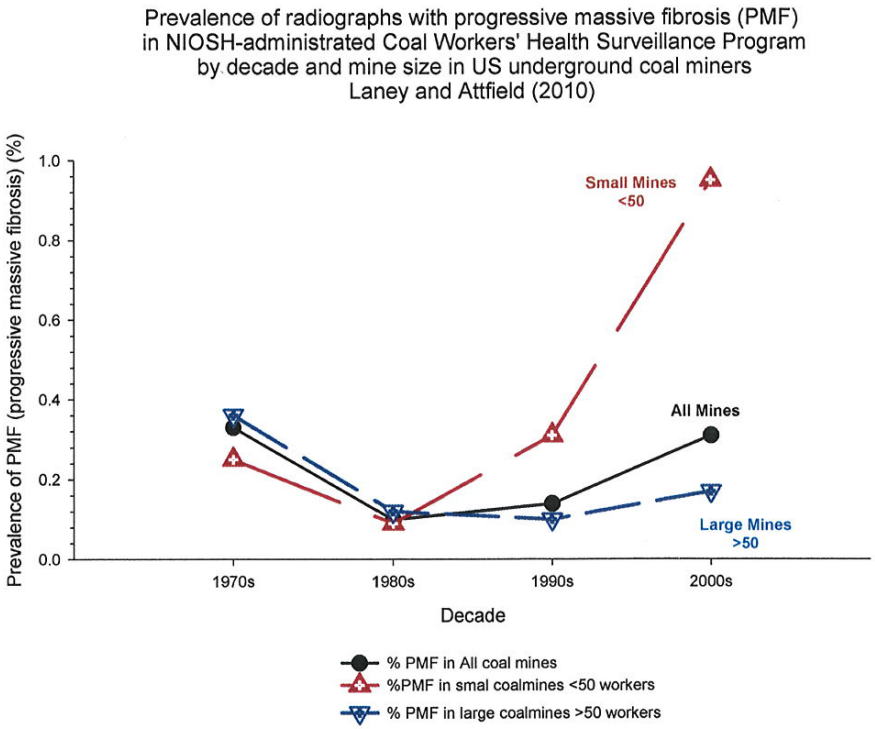
- Analysis included 145,512 miners' X-rays taken 1970-2009 with size and location of the mine.
- Prevalence of CWP was higher among large mines in the 1970s.
- Similar prevalence in the 1980s.
- But changed dramatically in the 1990s and 2000s when CWP became increasingly higher in small mines
- Adjusting for age, miners from small mines were five times more likely to have PMF than miners from large mines.



Laney and Attfield, 2010

CWP and PMF Are More Prevalent in Small UG Coal Mines (< 50 miners)

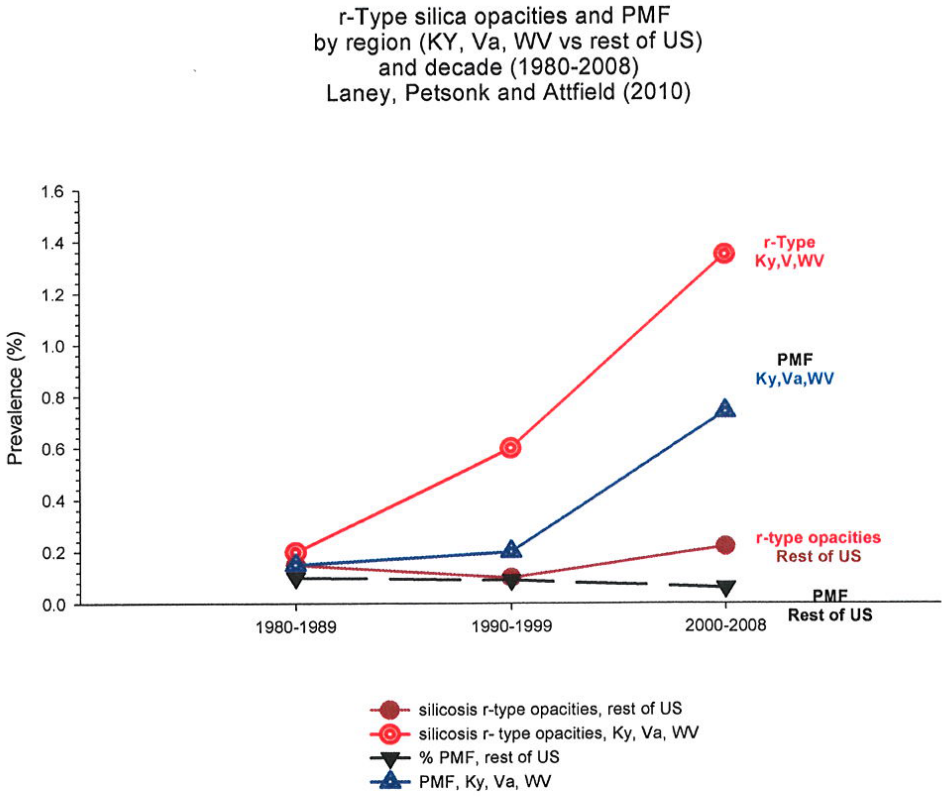
- Reasons for the prevalence shift from large to small mines cannot be assessed in this study.
- Small mines may have higher actual dust levels than operator samples indicate.
- MSHA inspectors sampled dust levels at the face, and compared them to operator samples.
- At large mines the results were comparable.
- At small mines the difference between operator and MSHA samples became larger.
- At the maximum spread MSHA samples were about two-fold greater than operator samples (MSHA 1993)



Laney and Attfield, 2010

Pneumoconiosis among UG coal miners…is silicosis becoming more frequent?

- CWP commonly does not progress rapidly, and requires a long latency period.
- On the other hand, silicosis has these characteristics, particularly at high concentrations well above the quartz standard
- R-type opacities are plausible indicators of excessive quartz exposure based on autopsy findings of classical silicotic nodules.



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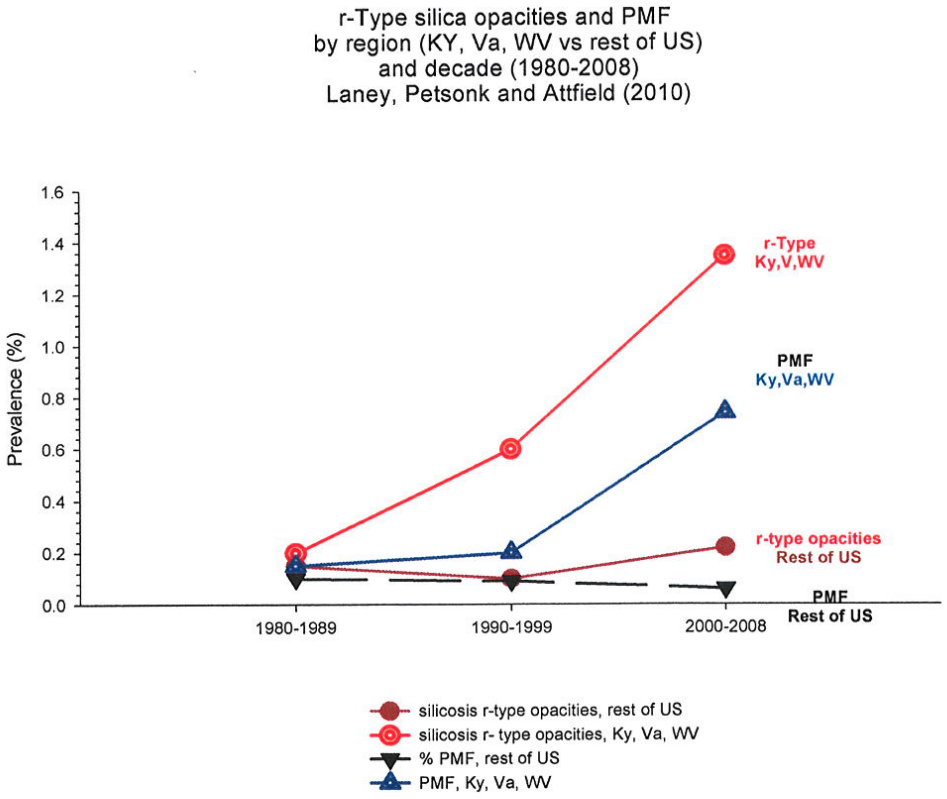
Pneumoconiosis among UG coal miners…is silicosis becoming more frequent?

- Of 90,973 (1980-2008) radiographs, 2868 (3.2%) demonstrated a profusion of category ≥ 1.
- There were 321 (0.35%) X-ray readings showing r-type opacities (1° and 2°).
- For the SAR, prevalence of both r-type opacities and PMF increased each decade with a 7.6-fold increase in r-type lesions in 2000-2008 compared to the 1980s.
- For the rest of the US there was no trend for r-type opacities to increase, and slight downward trends for PMF.



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Conclusion of RP CWP Studies

- The greater severity of RP CWP are more characteristic of silicosis than CWP and are associated with r-type opacities on the chest radiograph.
- Geographic clustering of RP CWP is found in the SAR.
- For the SAR, prevalence of both r-type opacities and PMF increased each decade.
  - A 7.6-fold increase in r-type lesions in 2000-2008 compared to the 1980s.
  - For the rest of the US there was no trend for r-type opacities to increase, and slight downward trends for PMF.
- Effect of increased risk noted in small mines (<50 miners).
  - In the 1990s three times as likely to have PMF.
  - In the 2000s miners at small mines 5 times more likely to have PMF.
  - MSHA samples were about two-fold greater than operator samples at small mines (MSHA 1993).
- The evidence is convincing that increased quartz exposure is an important, if not the, explanatory factor in these rapidly progressive cases of CWP.
  - Essentially these are likely cases of silicosis being misdiagnosed as CWP.
  - This experience offers no support for reducing the CMD standard.

Data source for US exposure-response studies

Need exposure-response studies to establish a standard

- Morbidity
  - CWP Attfield/Morring, 1992b;
  - Attfield/Seixas, 1995

- Mortality
  - Attfield/Kuempel, 2008

  - These three studies have problems of bias from exposure misclassification and low participation
  - Background prevalence must be considered when interpreting these studies

Exposure-Response, Coal Rank and Bias

- There are clear exposure-response associations between CWP and coal mine dust.
- The current data suggests no excess CWP at exposures below the current standard for coal ranks 1-3
- Adjustments for bias in exposure estimates should reduce risks.

Background Prevalence

- Background prevalence should be taken into account when assessing risk of increased CWP.

- NIOSH says 5 % is an appropriate background prevalence

- Prevalence data should be collected during study to be used as control for background

Background Prevalence in Older Unexposed Workers

Attfield & Seixas (1995)

- Category 1/0 + (Blue collar) 1.4% (0.8) = **3%**
- Predicted: CWP 1+ = **5%;**
  (Attfield/Seixas, 1995)
- Predicted: CWP1+ = **5.5%**
  (Attfield/Morring, 1992b)
- Category 0/1+: (small + irregular) (60 yrs) **7.5%**
  (Collins et al, 1988)
- Category 1+ : (Meyer et al, 1997)
  - EU = **11.7%**
  - North America = **2.3%**
  - All = **5.3% (2.9-7.7%)**

Background prevalence rate from age & non-occupational causes (Attfield/Seixas, 1995) **5%**

Exposure Misclassification Bias

- "Any underestimation (or overestimation) in the MSHA data would have little effect on the pre-1970 portions of the exposure." (Seixas et al, 1991)
-
- *We suggest bias has large effect on exposure estimates*

Exposure Bias

- Pre-1970 exposure estimates are biased to produce a spuriously steep slope and overestimate risk.

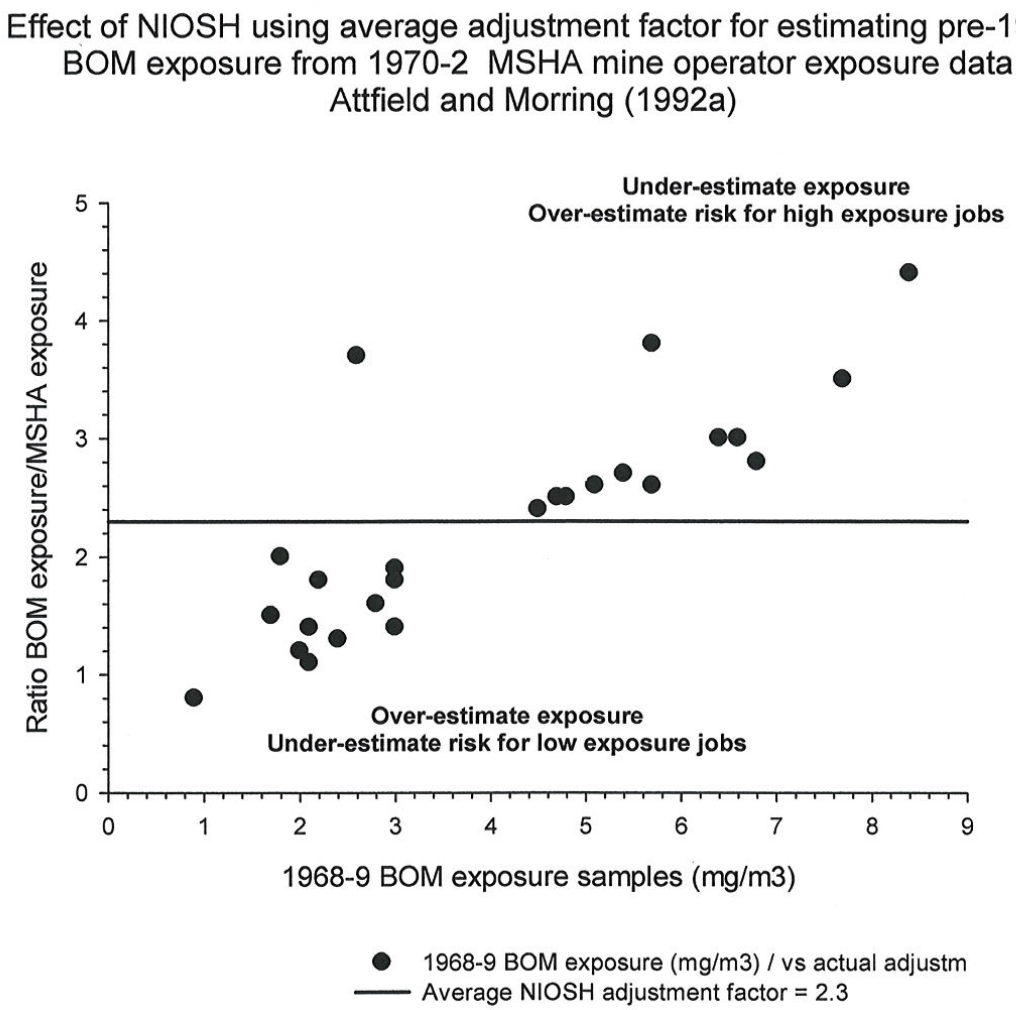
- If upward bias in exposure estimates were to be adjusted there may be no increased CWP occurring below the current standard for any rank of coal.

NIOSH Method of Estimating Pre-1970 CMD Exposures

Available Data

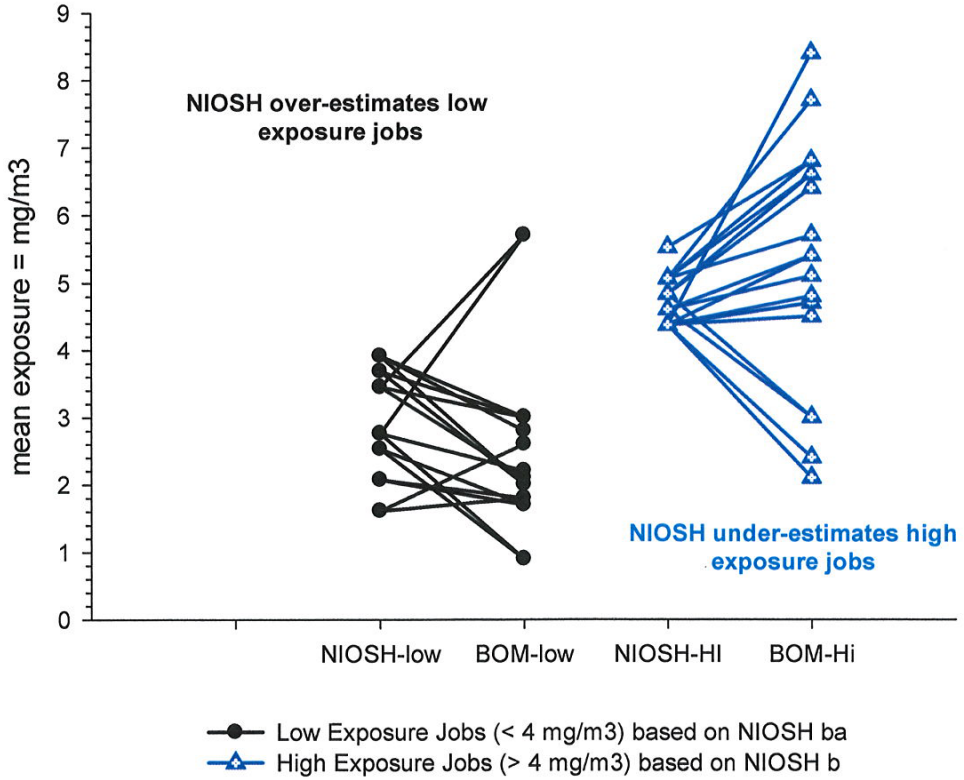
- Work histories from questionnaires during 1st round of NSCWP
- 1968-9 BOM: 29 large(17 in NSCWP), some small mines, mostly face, 10 shifts, no above ground
- 1970-2 MSHA compliance data from operators
- MSHA jobs combined to broader Lainhart job groups (25 jobs →12 jobs)

Exposure Misclassification Bias



Example of Bias for High and Low Exposure Jobs

Effect of NIOSH using average conversion factor of 2.3 for estimating
BOM pre-1970 job exposures using MSHA compliance data
Attfield and Morring (1992a)



Biases Due To NIOSH Using A 2.3 Average Conversion Factor

- High exposure: Average Under-estimate
  = 1.32 mg/m3 x 21 years tenure
  =**28 mg/m^3-years under-estimated exposure**
  - **Results in overestimates of risks**
- Low exposure: Average Over-Estimate
  = 1.30 mg/m^3 x 21 years tenure
  = **27 mg/m^3–years over-estimated exposure**
  - **Results in underestimates of risks**

Exposure-Response, Coal Rank and Bias

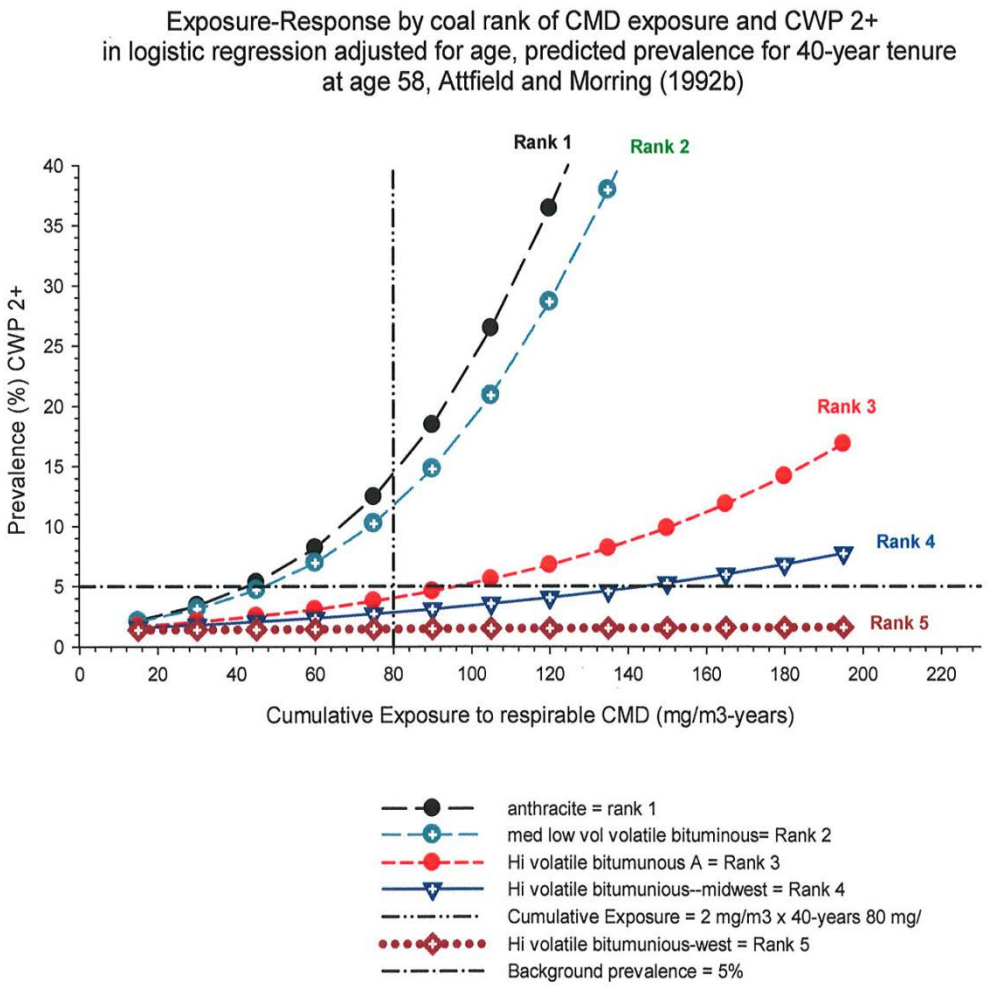
- There are clear exposure-response associations between CWP and coal mine dust.
- The current data suggests no excess CWP at exposures below the current standard for coal ranks 1-3
- Adjustments for bias in exposure estimates should reduce risks.

Exposure-Response and Coal Rank for CWP in US NSCWP

Attfield and Morring (1992b)

- 90% participation of miners at 31 US mines 1969-71, n = 9023
- NIOSH back-extrapolation conversion to pre-1970 levels
  - Assumed no change in exposures from about 1920-1970
  - Nearly 10 % began working before 1930s
  - About 85% had average dust exposures > 2mg/m^3

Exposure-Response of CWP 2+ and CMD by Rank (1st Round NSCWP – Attfield & Morring, 1992b)

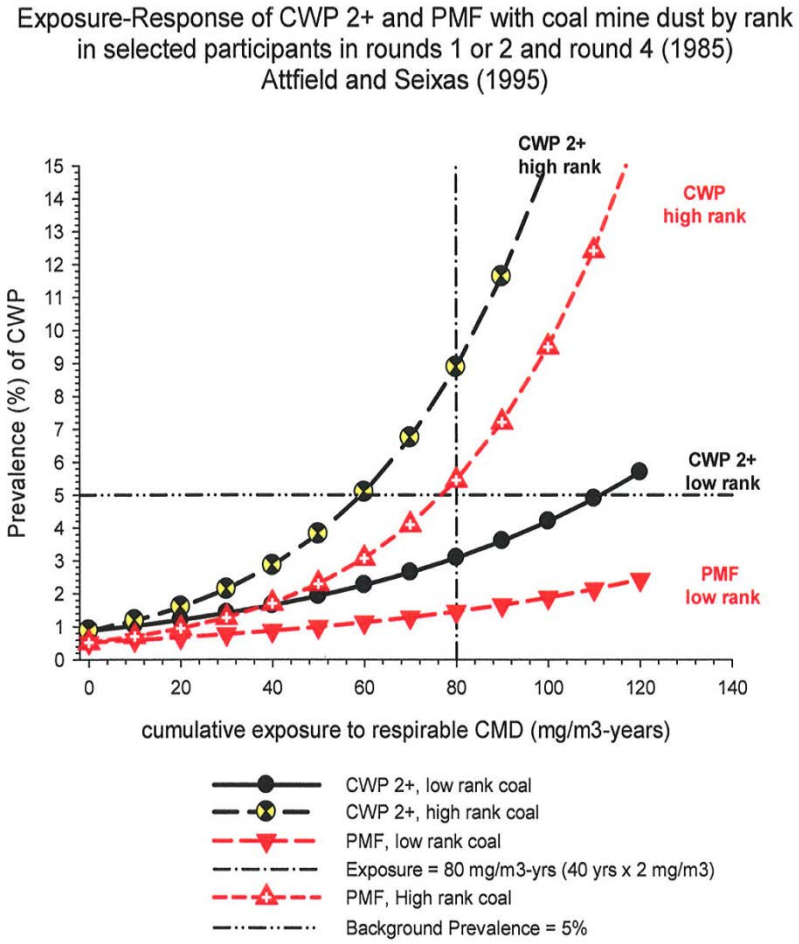


Exposure-Response and Coal Rank for CWP in US NSCWP

Attfield and Seixas (1995)

- 3,194 miners working in Rounds 1 or 2 and <58 years in 1985 (4th round)
- 7,281 miners eligible, 5,693 (78%) targeted, 3,280 (58%) participated
- About 50% first examined in Round 1, half in Round 2
- Low Participation in Rounds 2 and 4 may bias results in unknown direction and magnitude.
- Cohort may not be representative.

Exposure-Response of CWP 2+ and CMD by Rank (1st, 2nd & 4th Round NSCWP – Attfield & Seixas, 1995)

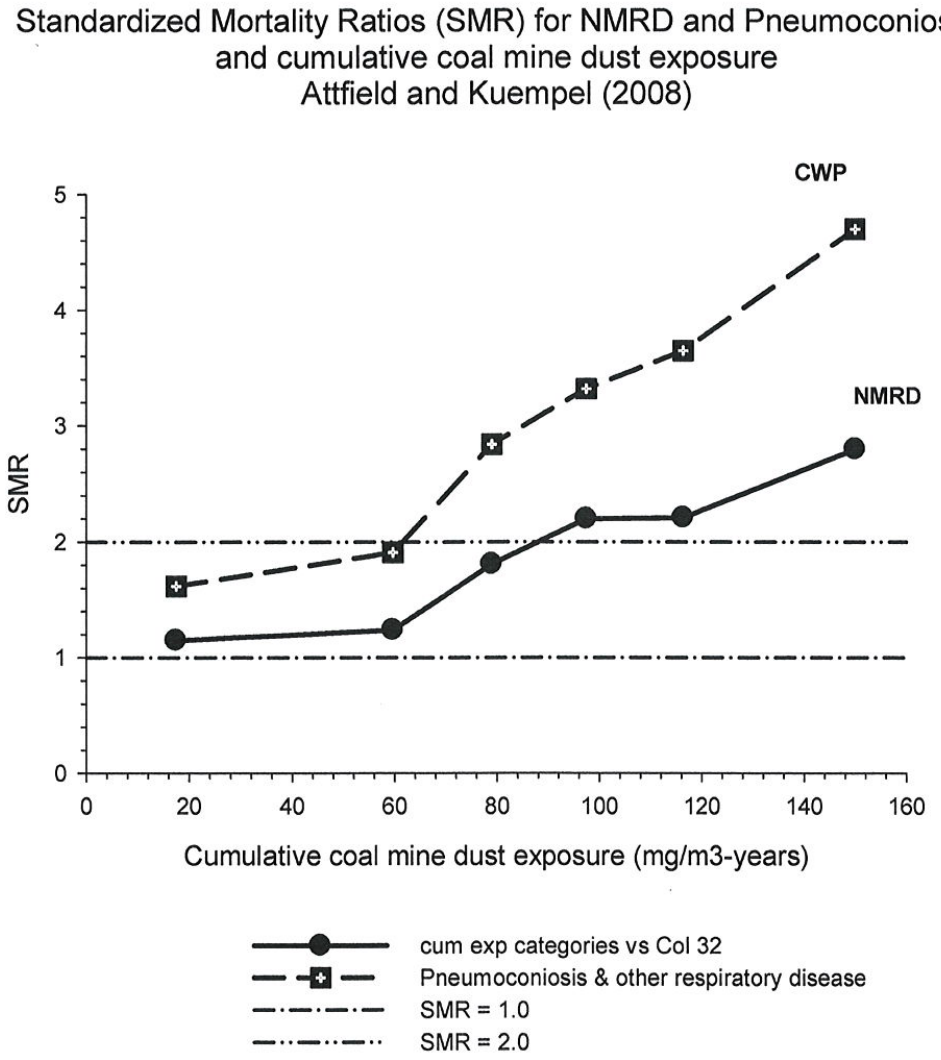


NMRD and CWP Mortality

We conclude:

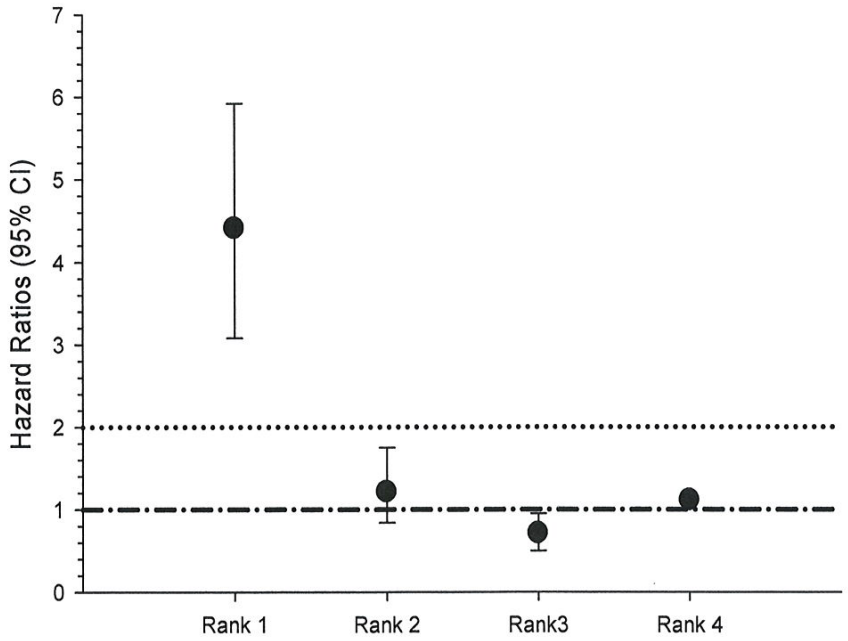
- Increased NMRD and CWP mortality significantly elevated at exposures below the current standard.
- Excess NMRD & CWP mortality may occur from exposure to high rank coal.
  - When stratified by rank, the excess NMRD mortality is confined entirely to miners exposed to anthracite.
- Exposure-response analyses with low rank coal should be conducted.

NMRD and CWP Mortality



NMRD Mortality and Coal Rank

Hazard Ratios (HRs) for mortality due to NMRD
as an underlying cause of death
Attfield and Kuempel (2008)



Rank 1 = anthracite; Rank = East Appalachia; Rank 3 = West Appalachia; Rank 4 = Mid-West

NMRD HR by Rank
HR = 1.0
HR = 2.0

Weight-of-Evidence and Coal Dust Standard

- Studies upon which MSHA relies, when viewed with silica and coal rank causation factors, demonstrate that the current standard is adequate.
- CWP is associated with high CMD exposures in high ranking coals.
- Bias related to background prevalence, exposure estimates and low participation may cause apparent effects below the standard.