

MSHA's Draft Quantitative Risk Assessment (QRA) of RCMD:

Current flaws and possible fixes

Comments of
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On behalf of
The National Mining Association

2-15-11

Outline

- Hazard identification
- Exposure assessment
- Exposure-response relationship
- Risk characterization
- Uncertainty characterization
- Conclusions and recommendations

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- Hazard identification → omitted
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- Hazard identification → omitted
- Exposure assessment → incorrect/irrelevant
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- Risk characterization → incorrect
- Uncertainty characterization → omitted
- Conclusions and recommendations
 - Risk if present standards enforced: not quantified
 - Probability that tightening standard will *not* decrease risk: Not quantified

Outline

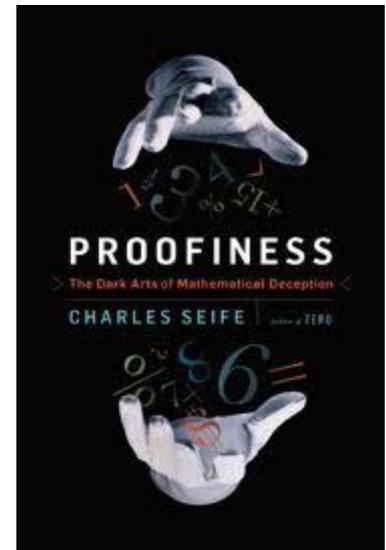
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- Conclusions and recommendations
 - Effects of single-shift sampling on risks, exposure threshold exceedance frequencies, enforcement error rates: not quantified

Hazard identification

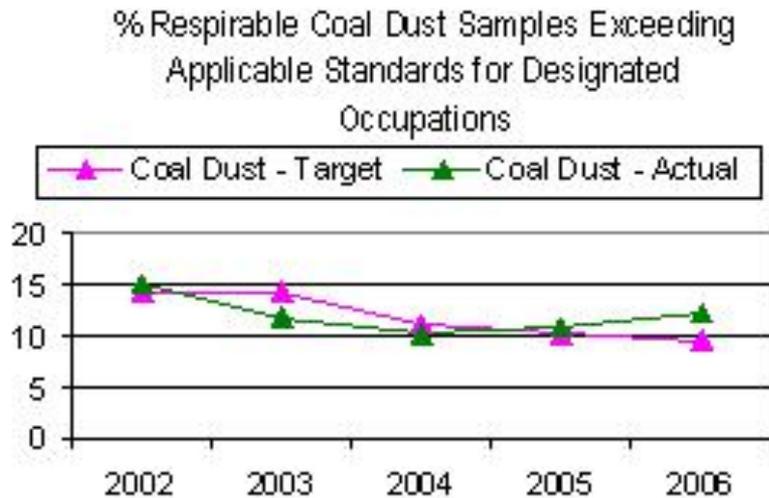
- Do *current levels* of RCMD create an excess risk of adverse human health effects?
 - What is the evidence, pro and con?
 - Toxicological, clinical, epidemiological
 - What is the weight of evidence?

Hazard identification

- Do *current levels* of RCMD create an excess risk of adverse human health effects?
 - What is the evidence, pro and con?
 - Toxicological, clinical, epidemiological
 - What is the weight of evidence?
- MSHA's QRA: *Assume yes*
- Supporting rationale/evidence/critical discussion: None
- QRA skips hazard identification
 - Proofiness: “The art of using bogus mathematical arguments to prove something that you know in your heart is true — even when it’s not”



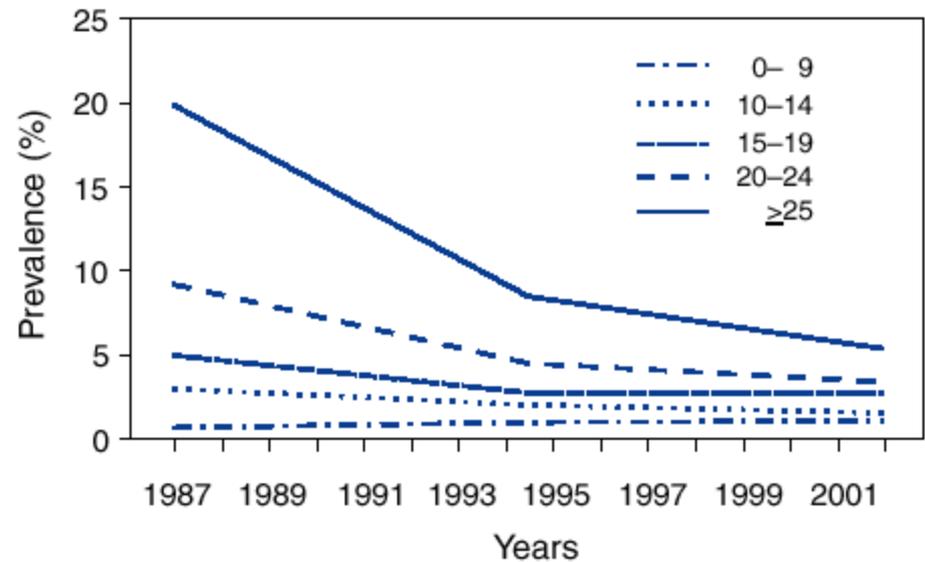
Regression of trends \neq causation



Exposure down

? \rightarrow ?

FIGURE 2. Trends in coal workers' pneumoconiosis prevalence by tenure among examinees employed at underground coal mines — U.S. National Coal Workers' X-Ray Surveillance Program, 1987–2002



Disease down

Proofiness: Attribute decline in lung diseases to tighter RCMD standards

Regression of trends \neq causation

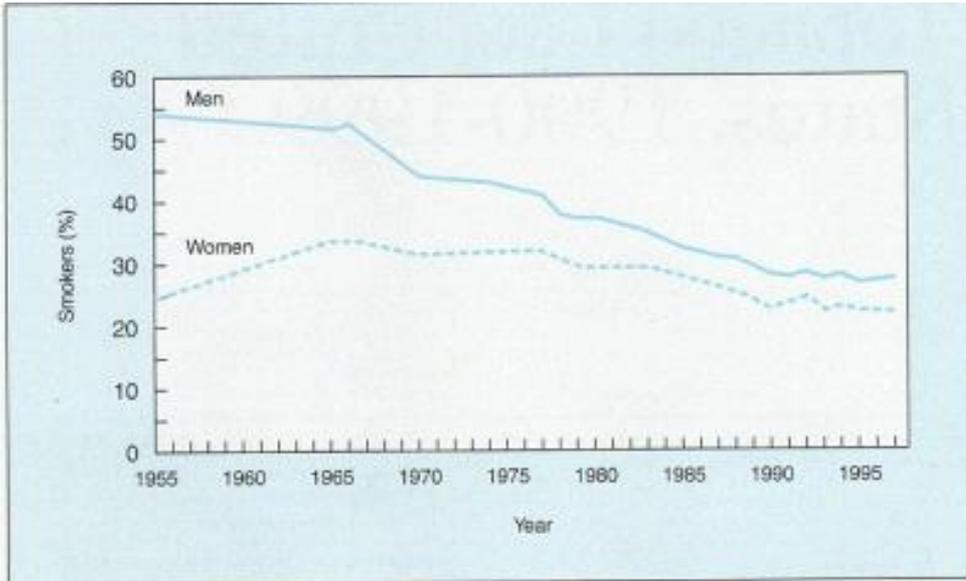


Figure 2: Trends in Cigarette Smoking Among Persons \geq 18 Years Old, by Gender—United States, 1955-1997—Before 1992, current smokers were defined as persons who reported having smoked \geq 100 cigarettes and who currently smoked. Since 1992, current smokers have been defined as persons who reported having smoked \geq 100 cigarettes during their lifetime and who reported smoking every day or some days. Source of data: 1955 Current Population Survey, National Interview Survey, 1965-1997.

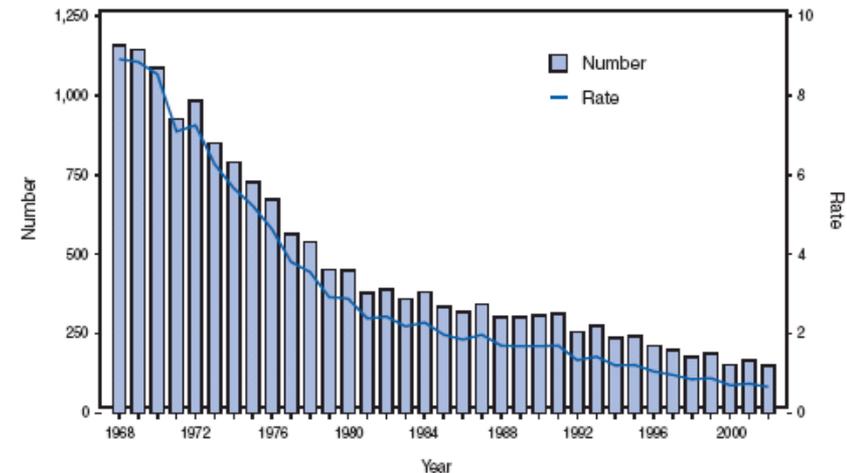
Smoking down

? \rightarrow ?

Disease down

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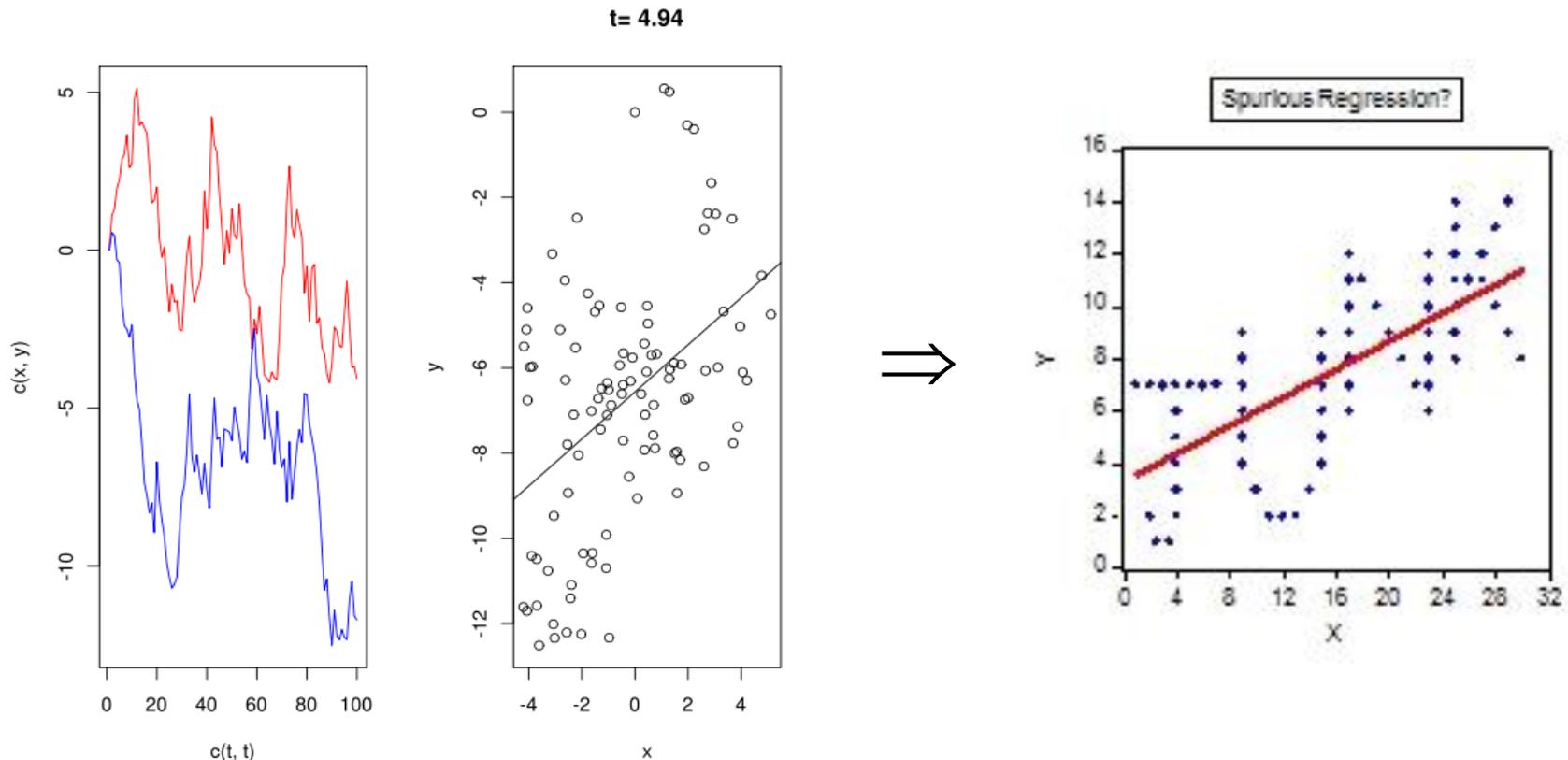
FIGURE 1. Number of silicosis deaths and age-adjusted mortality rate*, by year — National Occupational Respiratory Mortality System, United States, 1968-2002



* Per million persons aged \geq 15 years.

Regression: Wrong tool for the job

- Regressing *trend variables* against each other makes even independent variables (random walks) look “significantly correlated”!



Hazard identification

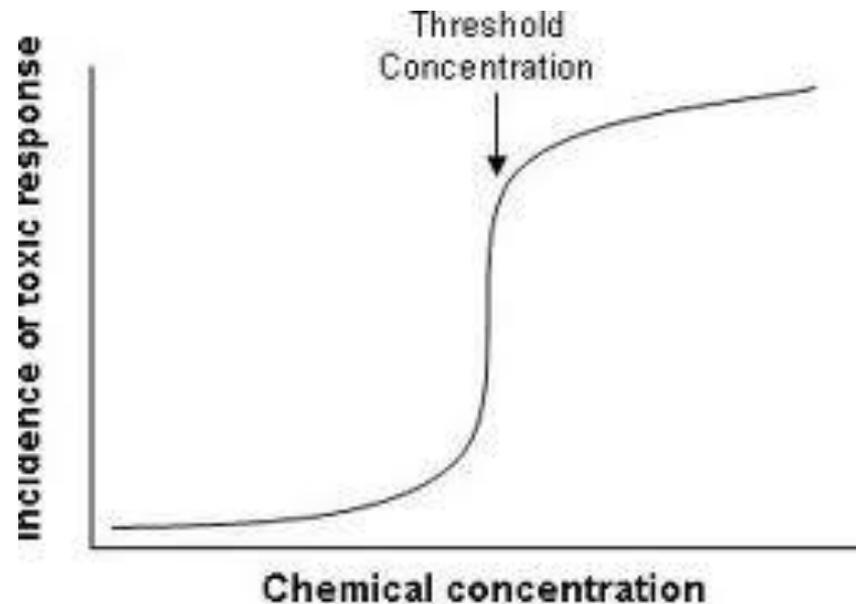
- What would a sound hazard identification show?
- Weight of evidence is that inflammation-mediated lung diseases caused by poorly soluble particulates have *exposure-response thresholds*.
 - E.g., “Tissues and cells respond to mild oxidative stress by increasing antioxidant defenses. However, high levels of ROS/RNS may overwhelm antioxidant defenses, resulting in oxidant-mediated injury or cell death” ([Comhair and Erzerum 2002](#))

Hazard identification

- What would a sound hazard identification show?
- Weight of evidence is that inflammation-mediated lung diseases caused by poorly soluble particulates have *exposure-response thresholds*.
- A useful risk assessment should address how current and proposed future standards affect exposures compared to such exposure-response thresholds (or steep nonlinearities).
 - Would tighter standards create incremental health benefits, beyond those from enforcing current standards?
 - MSHA's QRA does not address thresholds → No answer

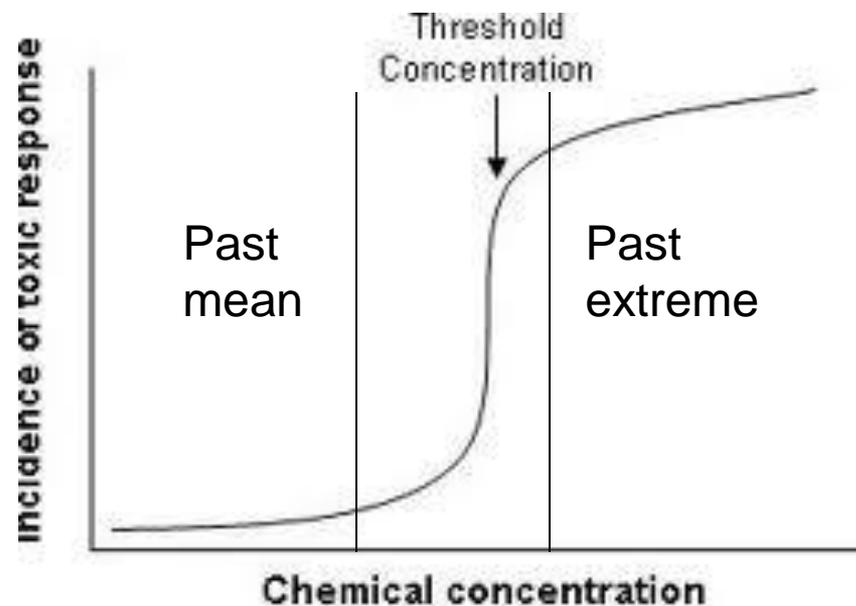
Exposure assessment

- *Key question: Do currently permitted levels of exposure increase risk of harm?*



Exposure assessment

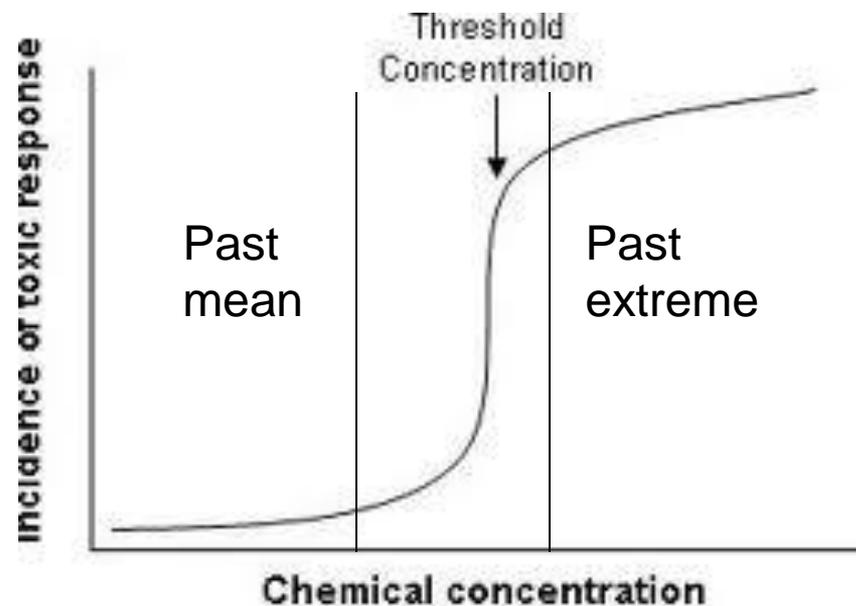
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Exposure assessment

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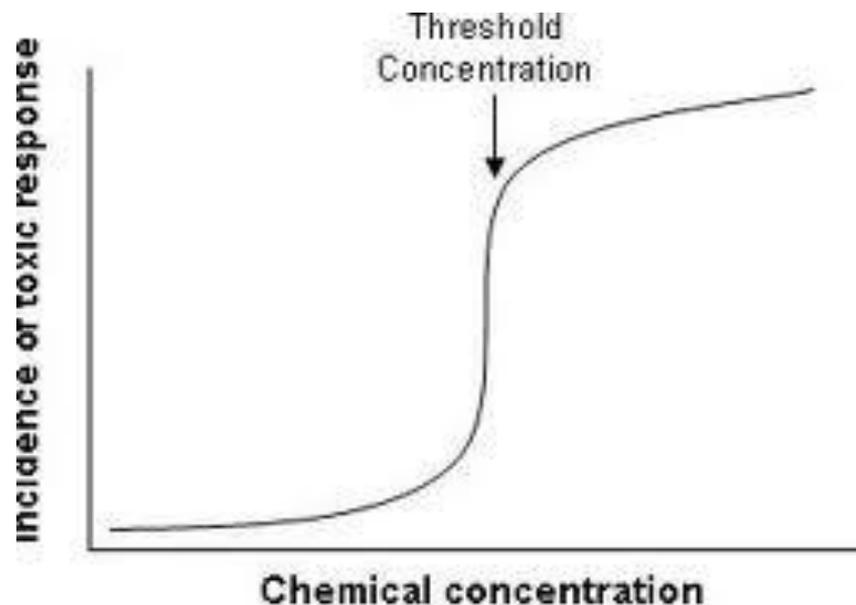
Risks attributed to past mean exposures may have been caused by much higher extreme exposures.

Exposure assessment

- *Key question: Do currently permitted levels of exposure increase risk of harm?*
- QRA does not actually address this question
 - QRA estimates future cumulative mean exposures, but not past variances or response thresholds
 - Cumulative mean exposures have no known relevance to risk
 - QRA simply assumes that the answer is yes.
 - Attributes harm to RCMD, without showing any causation
- Past harm may have resulted from higher-than-currently-permitted exposures
 - Such exposures have not been estimated

Exposure assessment

- Estimates of mean cumulative exposures are inappropriate for risk assessment
 - Proposed measures that decrease exposure mean but increase variance could still increase risk
 - Need to quantify *upper tail* of exposure distribution

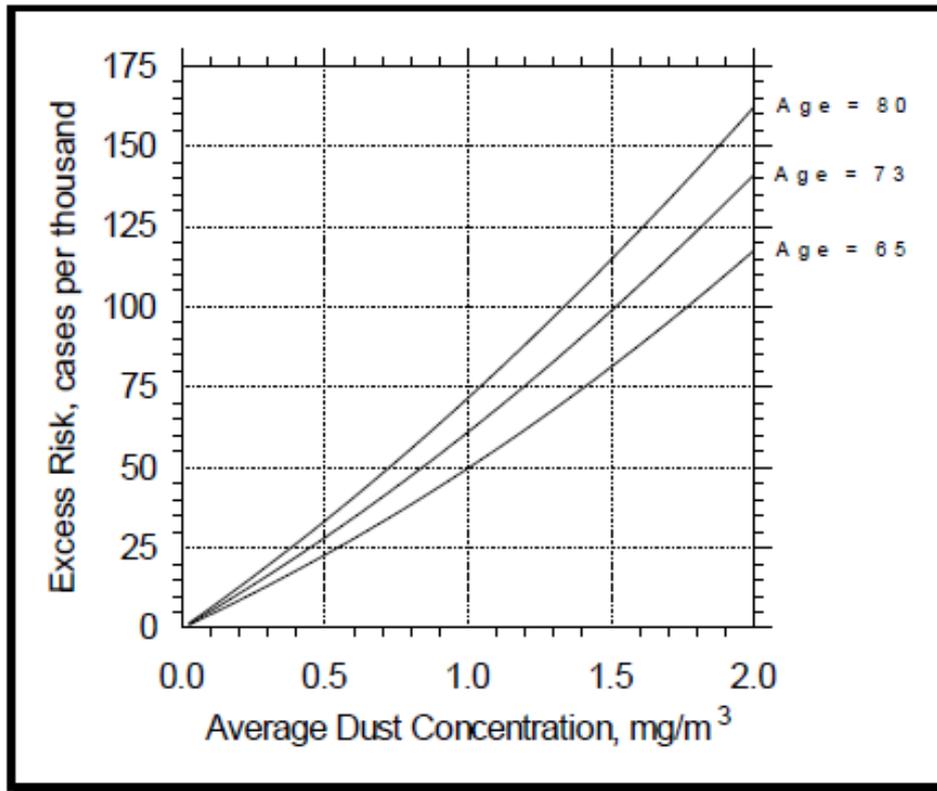


Exposure-response modeling

- *Purpose:* Quantify the probability that each exposure level causes illness
- *Status:* Not done.
 - QRA uses statistical (descriptive) regression equations, not causal (predictive) models, to attribute risk to exposure
 - No exposure-response relation established
 - Exposure estimation uncertainty not accounted for
 - Treats estimated exposures as true exposures
 - Creates potentially large, unquantified biases

Exposure-response modeling

- This is *not* an exposure-response relation!



Plotting predicted hypothetical responses against hypothetical mean exposures does not create (or provide evidence of) a valid exposure-response relation.

Figure 14. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and excess risk of developing emphysema severity corresponding to FEV₁ < 65% of predicted normal value, for white, never-smoking U.S. coal miners at ages 65, 73, and 80 years.

Attribution vs. Causation

- The risk “*attributable*” to a source (in epidemiology) is not the risk *caused* by it (and is often much larger)
 - The QRA treats them as the same thing
 - Attributes a relative risk of 4.4 to coal even when exposure = 0
 - Use with caution (MSHA QRA) vs. Don’t use!
 - Assigns some risks from smoking to RCMD
 - Attributable risk can be positive even when exposure does no harm

Risk characterization

- *Purpose:* Show the frequency and severity of health effects with and without proposed rule.
- *Status:* MSHA has not performed a risk characterization for effects of proposed action
 - Estimates are provided only for hypothetical exposure scenarios and obsolete conditions (smoking, etc.).
 - No causal modeling → No accurate or validated predictions

Risk characterization: Bogus claims

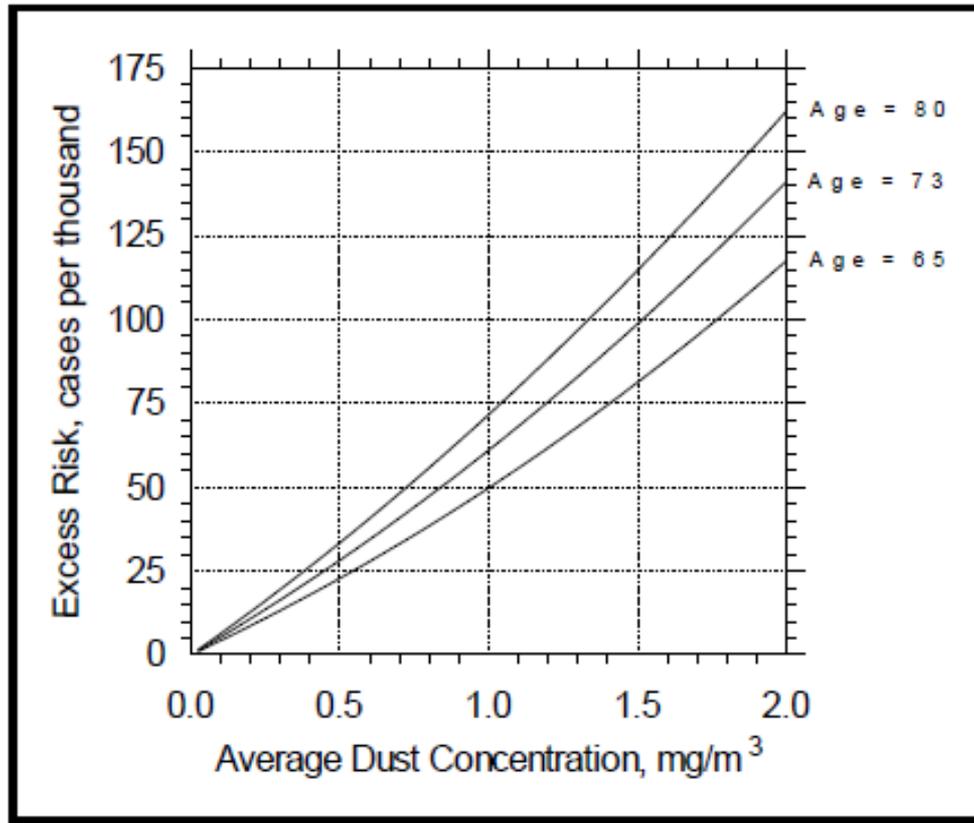


Figure 14. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and excess risk of developing emphysema severity corresponding to $FEV_1 < 65\%$ of predicted normal value, for white, never-smoking U.S. coal miners at ages 65, 73, and 80 years.

Thresholds?

Confounding?

- Smoking
- SES

High exposures?
(Right tail)

Variance?

Uncertainties?

- Confidence?
- Model?

Proofiness: Hypothetical statistical relation presented as real causal relation.

Risk characterization

- *Recommendations:*
 - Extend risk characterization to address realistic frequency distributions of exposure histories and smoking histories.
 - Remove effects of confounders, estimation errors, etc.
 - Use validated causal models instead of attribution

Uncertainty characterization

- MSHA's QRA omits this step.

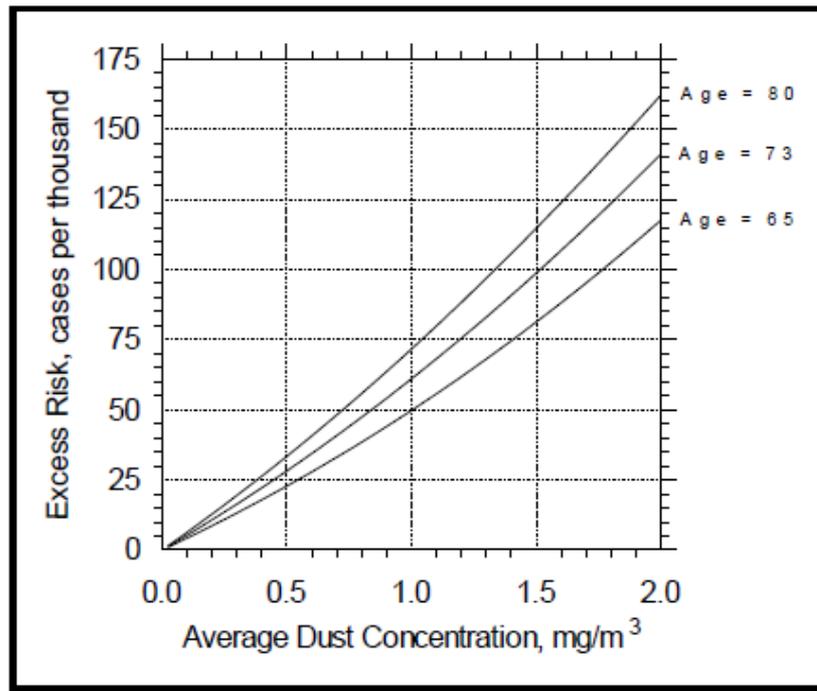


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Proofiness: Show a single answer – all exposure kills! – as the only possibility.

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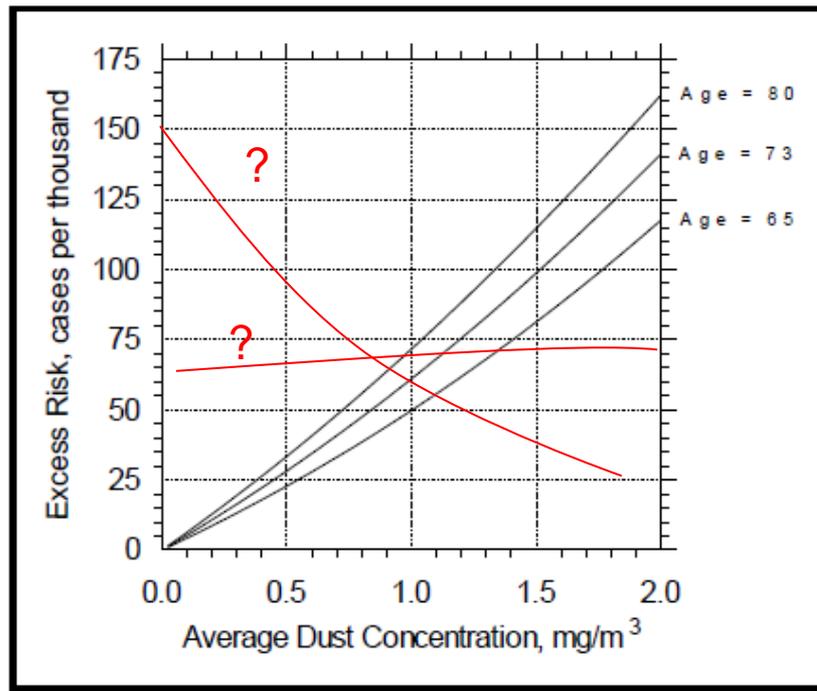


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What is probability that the proposed measure would...

- Increase risk?
- Leave it unchanged?

MSHA's QRA does not show policy makers *any* uncertainties

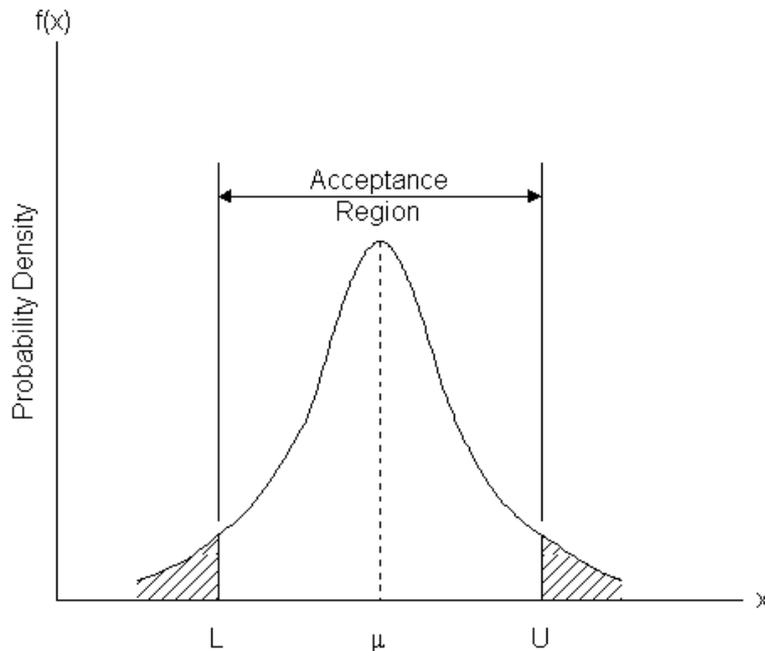
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Single-Shift Sampling: A bad idea

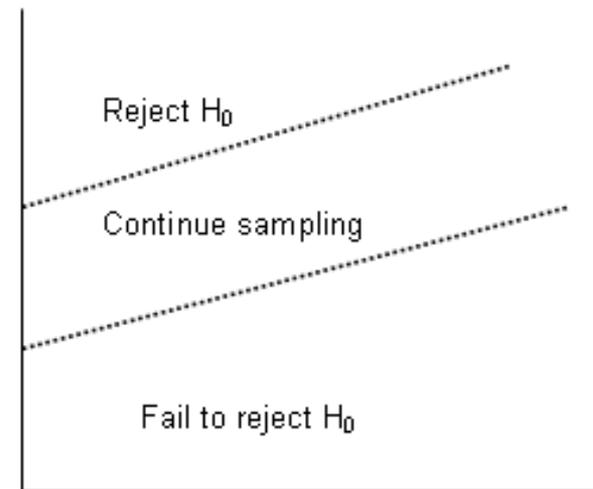
- QRA does not address *sample variance* around estimated means
- QRA provides no basis for risk-informed decisions.
 - Type 1 vs. type 2 errors?
 - Frequency of exceeding threshold?
 - Sampling and decision rules not designed to minimize errors or total cost/harm
- Basing enforcement criteria on less data is undesirable

Single-Shift Sampling: A bad idea

- *Recommendation:* Replace proposed single-shift sampling with well-designed *statistical sampling and decision rules* that reduce errors, rather than increasing them.



Sequential Probability Ratio Test



Summary

- Hazard identification → omitted
- Exposure assessment → incorrect/irrelevant
- Exposure-response relationship → omitted
- Risk characterization → incorrect
- Uncertainty characterization → omitted

Conclusions and Recommendations

- Correct or withdraw misleading claims and language. MSHA's QRA...
 - Does not obtain unbiased estimates
 - Does not assess risk from current exposures
 - Does not assess reduction in risk from reduction in exposure (causal effect)
- Add missing hazard identification section
- Add missing exposure-response modeling
- Add missing uncertainty characterization

Thanks!

Additional Materials

MSHA's QRA biases exposure and risk estimates upward

- Excludes post-abatement measurements
- “Adjusts” exposures upward, but not downward
 - Takes higher of two estimates
 - Creates an upward bias, even when current estimates are unbiased
- Does not counter-adjust the estimated exposure-response relations to reflect adjustments on exposure inputs
 - Creates upward bias in risk estimates

MSHA QRA's models are not validated for use in QRA

- Models produce conflicting predictions, so not all of them can be correct
- Models attribute risks to coal even when exposure is zero, so not good causal models
- Models use attribution formulas for *single* factors, but multiple factors (age, smoking, exposure, perhaps income and location) contribute to risk.
- Models do not explain historical data; not validated
 - Historical declines in exposure, changes in smoking, recent increases in risk