So Why Did We Invite You All to Today's Session, Anyway?

The Policy Questions We Hope to Help Answer

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What are the policy-relevant questions we are trying to help answer?

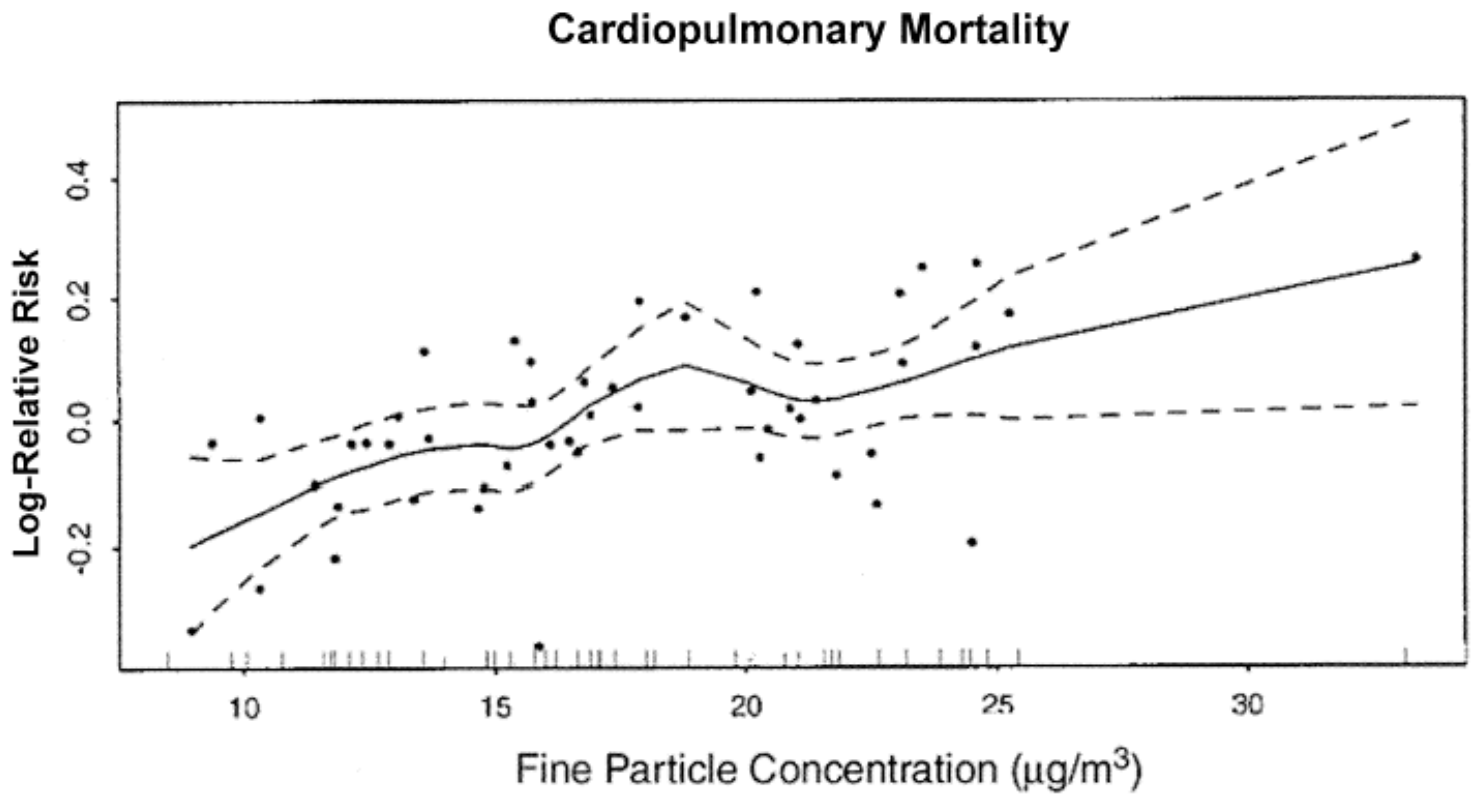
- Concentration-Response relationships can help contribute to:
  - Understanding the shape of the relationship, especially at very low and very high levels
    - E.g. is there a threshold, and at what level?
  - Helping to assess whether a particular exposure may cause a specific effect, and
  - Estimating the public health burdens from an exposure
- They also can help inform at least two important policy questions:
  1. At what level should we set ambient air quality standards?
  2. To what level of exposure should we estimate health impacts?

1. *At what level should we set ambient air quality standards?*

- There are different legislative mandates for this.
  - In the US, for example, the Clean Air Act calls for the EPA Administrator to set the National Ambient Air Quality Standards at "***a level requisite to protect the public health with an adequate margin of safety***"
- This has *not* meant that there are necessarily no effects below the standard
- In the preamble to the 2012 PM NAAQS final rule EPA noted:
  - "[a]s both the EPA and CASAC recognize, in the absence of a discernible threshold, health effects may occur over the full range of concentrations observed in the epidemiological studies." (78 FR 3149, 15 January 2013).
  - "EPA concludes that it is not appropriate to place as much confidence in the magnitude and significance of the associations over the lower percentiles of the distribution in each study, as at and around the long-term mean concentration." (78 FR 3154, 15 January 2013).
- So a standard *may* be set where the confidence of effects is highest, not necessarily at the lowest level where associations are seen.

EPA = Environmental Protection Agency
PM NAAQS = Particulate Matter National Ambient Air Quality Standard
CASAC = US EPA's Clean Air Scientific Advisory Committee
FR = Federal Register

HOW DO WE SET THESE?
Long-term analysis of "Concentration-Response"
American Cancer Society
HEI Reanalysis Results for $PM_{2.5}$ (Krewski et al 2000)



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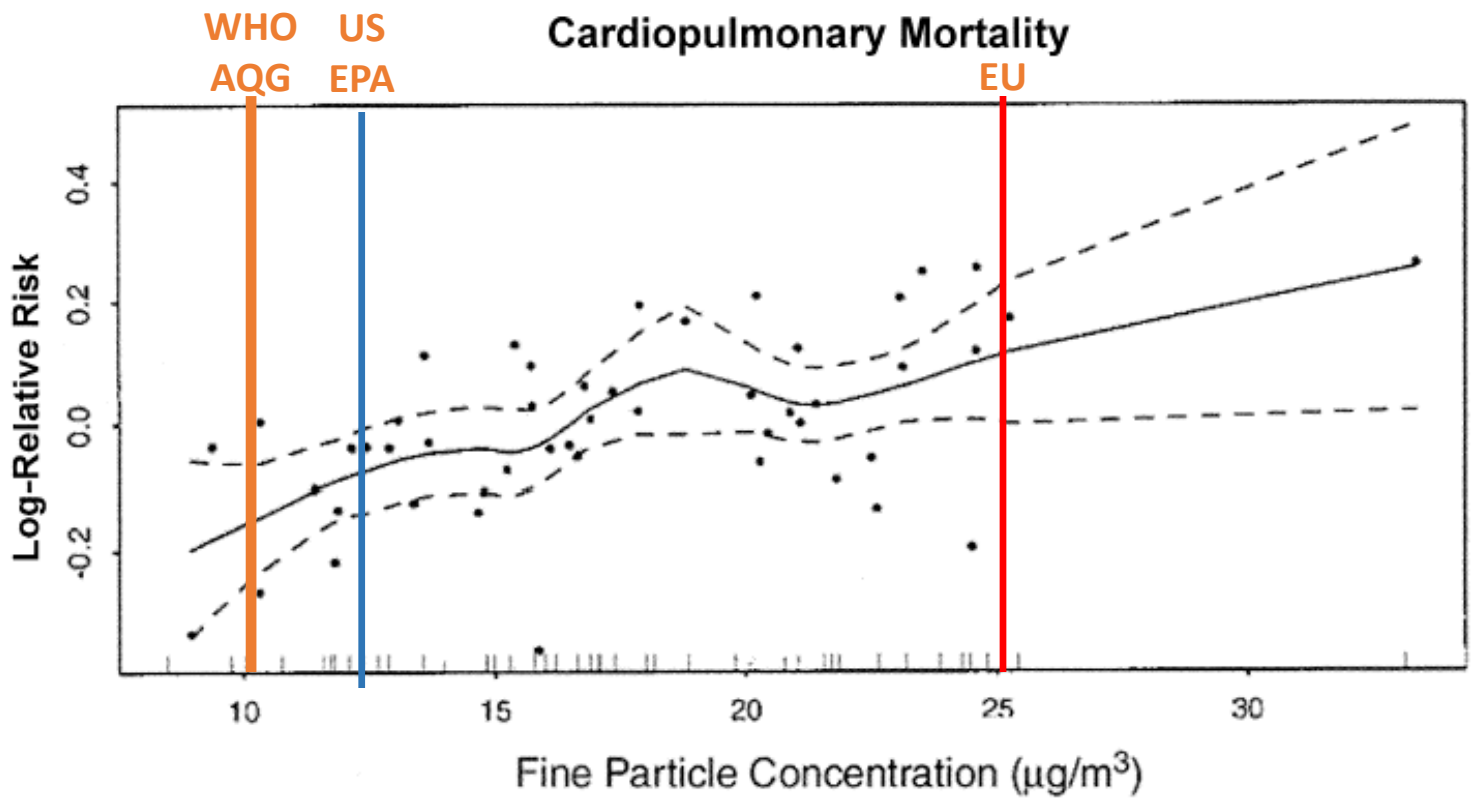
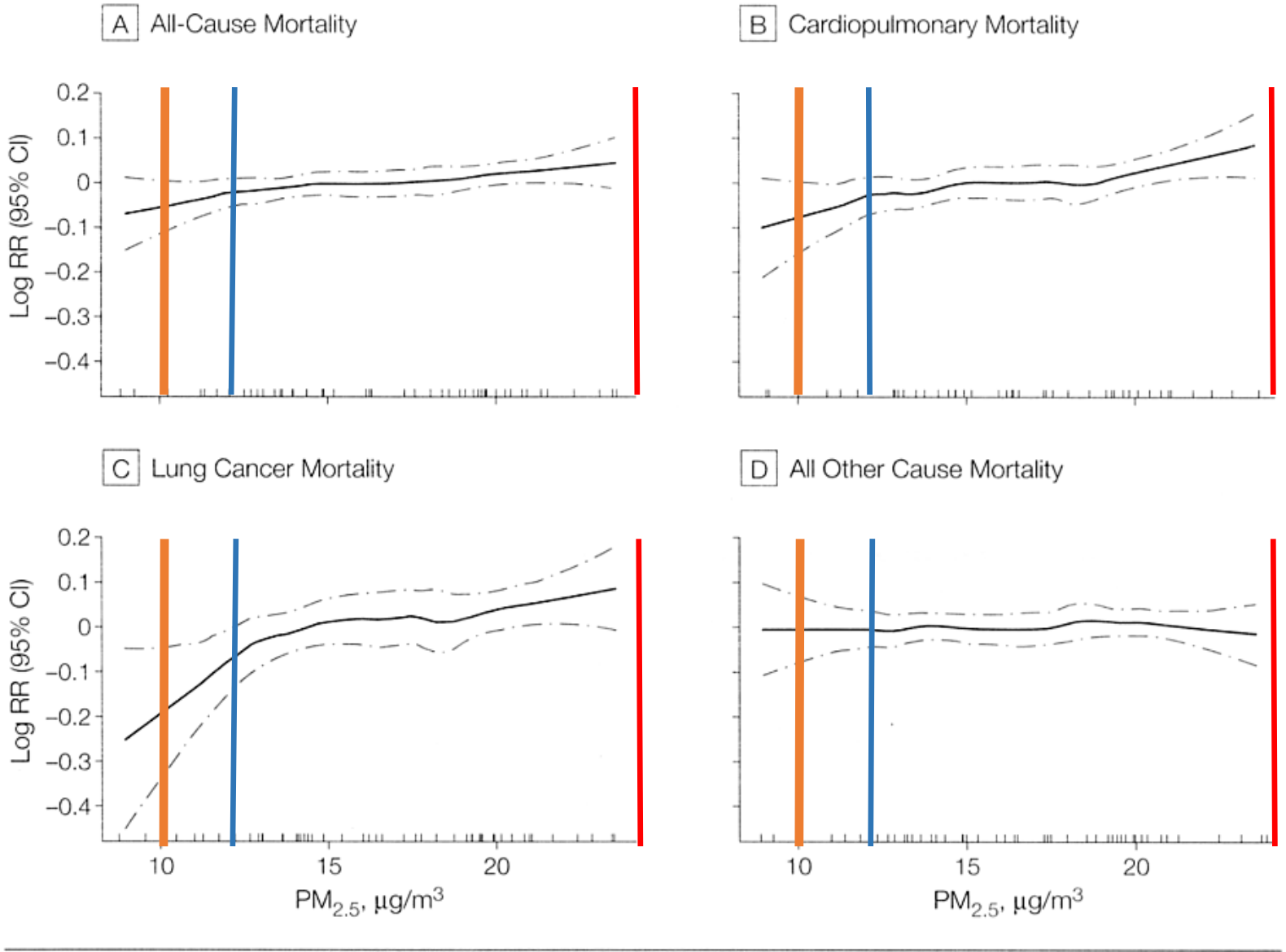
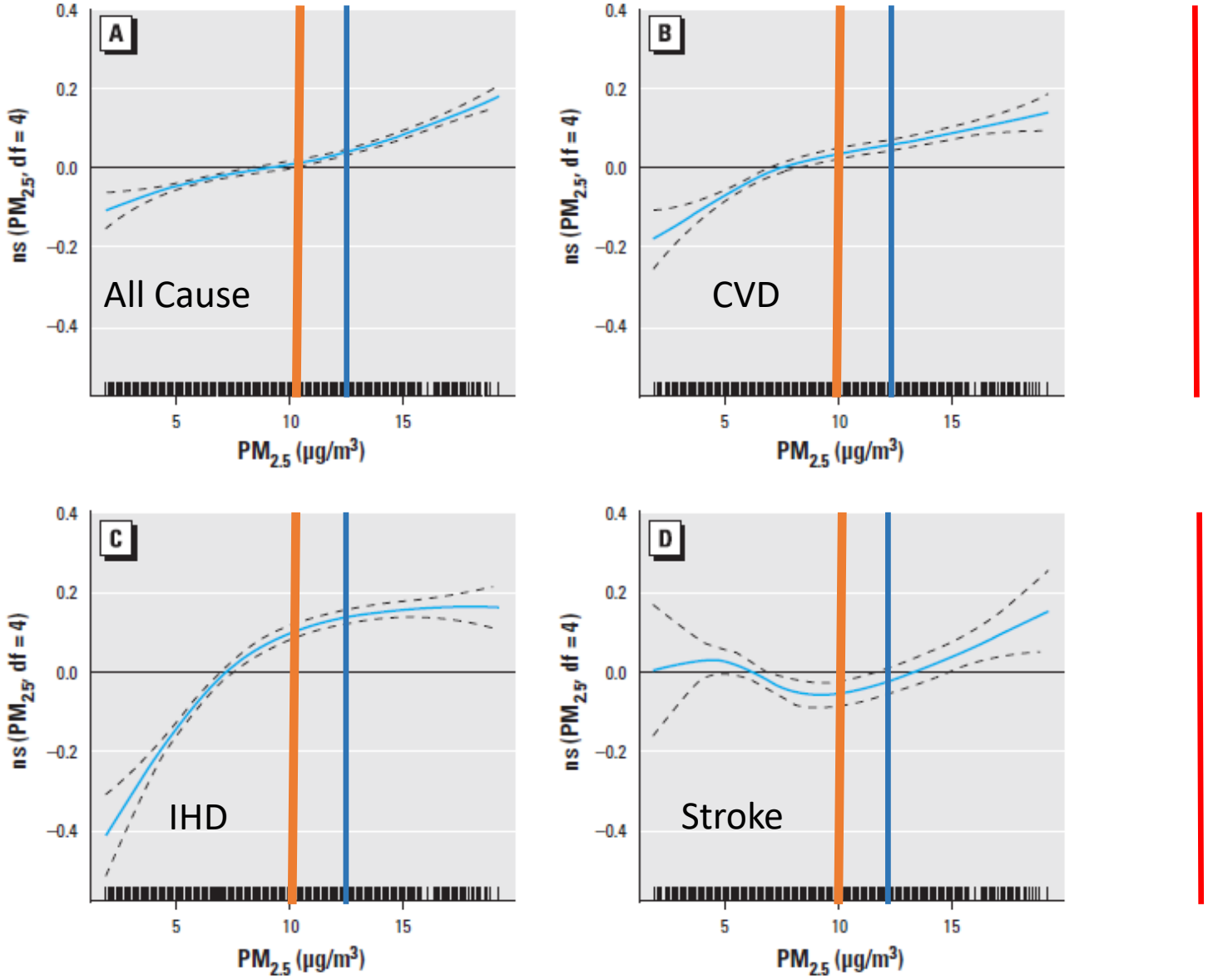


JAMA®
The Journal of the American Medical Association

American Cancer Society Cancer Prevention Study II (ACS CPS-II) Cohort Study, (Pope et al 2002)

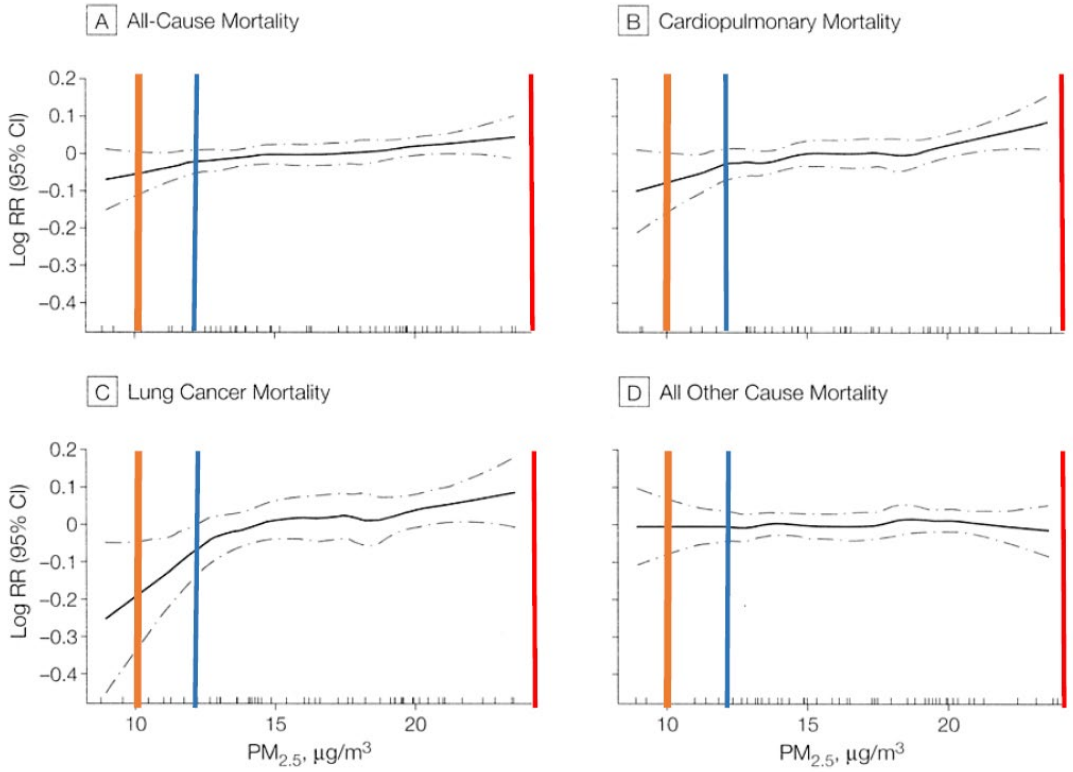




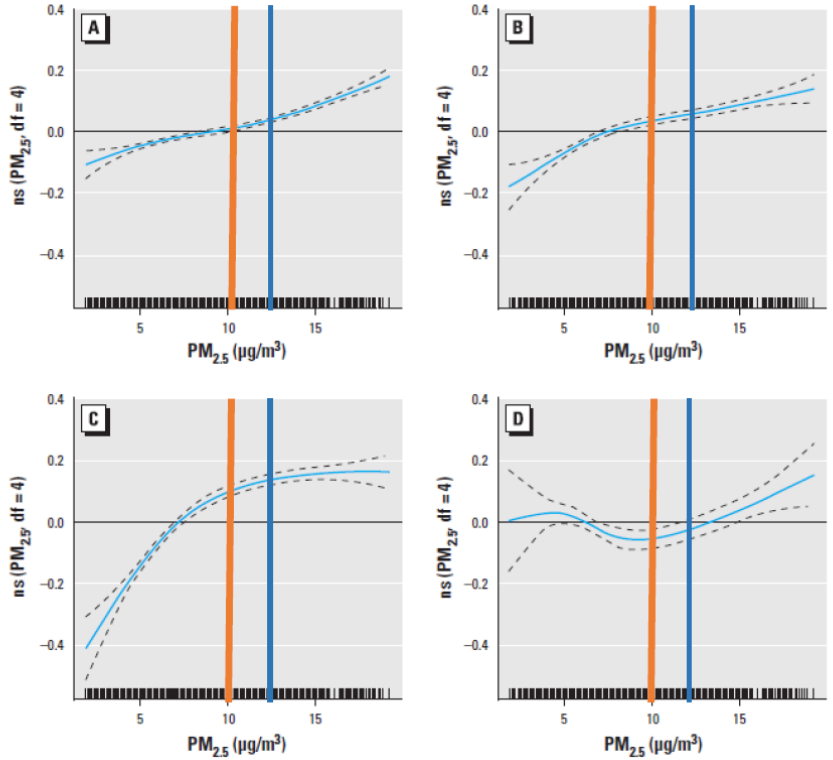
Risk of Nonaccidental and Cardiovascular Mortality in Relation to Long-term Exposure to Low Concentrations of Fine Particulate Matter: A Canadian National-Level Cohort Study 2012

Dan L. Crouse,[1] Paul A. Peters,[2] Aaron van Donkelaar,[3] Mark S. Goldberg,[4] Paul J.Villeneuve,[1,5] Orly Brion,[1] Saeeda Khan,[2] Dominic Odwa Atari,[2] Michael Jerrett,[6] C. Arden Pope III,[7] Michael Brauer,[8] Jeffrey R. Brook,[5,9] Randall V. Martin,[3,10] David Stieb,[1] and Richard T. Burnett[1]

In the end, will studies like one or another of these prove to be more robust and useful in these standard-setting discussions?



Pope 2002



Crouse 2012

These new Low Level Studies should help explore this question…

2. To what level of exposure should we estimate health impacts (and benefits of a reduction)?

- Three major metrics have been suggested:
  - There is no threshold (log-linear model)
  - Estimate down to the Lowest Measured Level (LML) of exposure in the studies being used
  - Estimate down to the current ambient air quality standard (where public health is ostensibly protected with an adequate margin of safety)
- These approaches can have significantly different results

First, given that few areas of the US* now exceed the $PM_{2.5}$ standard, the great majority of exposures and effects occur below the standard

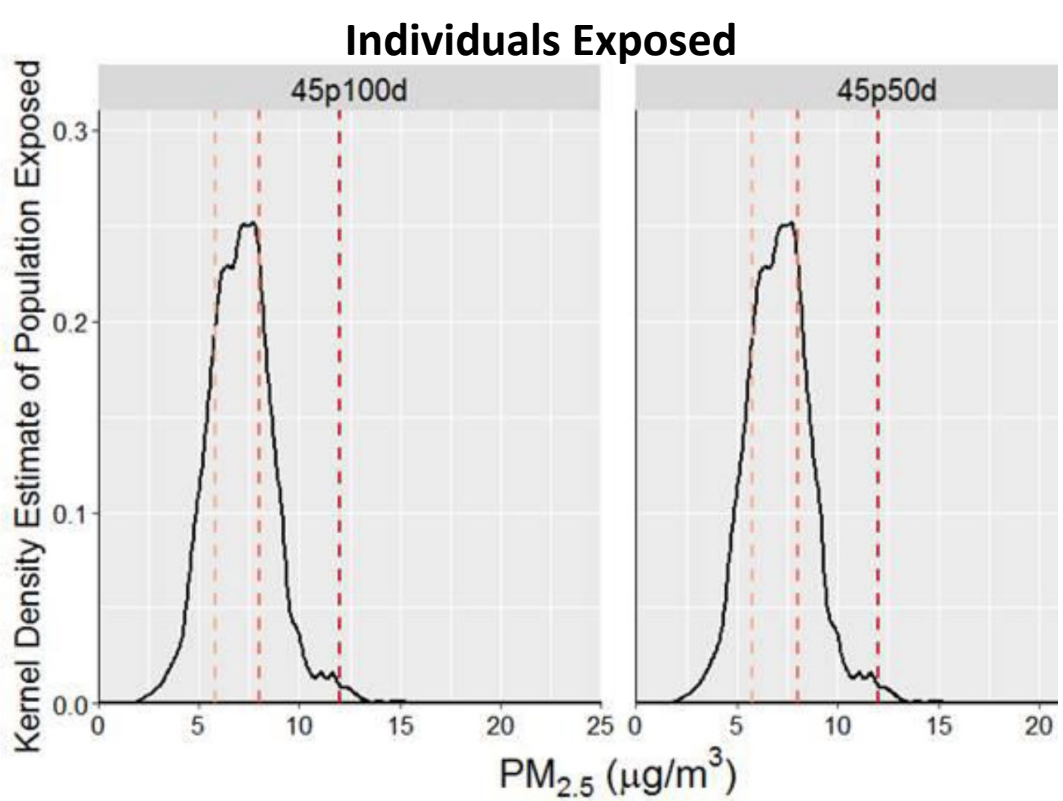


Figure 4-2 Number of Individuals Exposed According to Annual Mean $PM_{2.5}$ Concentration in 2030

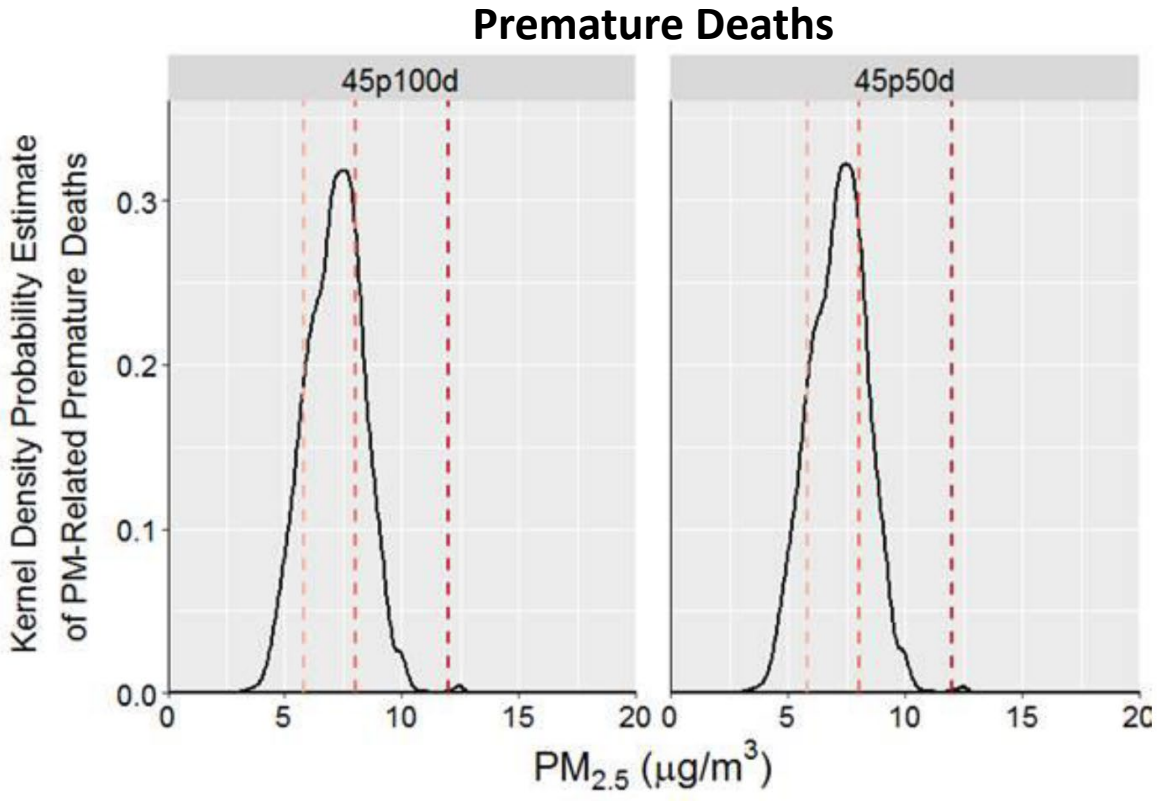


Figure 4-3 Number of $PM_{2.5}$-Related Premature Deaths According to $PM_{2.5}$ Concentration in 2030

*While the situation in other places, e.g. Europe, will be different, the principle is the same

Source: US EPA Regulatory Impact Assessment (RIA) for Proposed Utility Greenhouse Gas Rule August 2018 (*Caveat: these are for a proposed rule and may not reflect what the final rule analysis will find*)

The No-threshold vs. Lowest Measured Level (LML) Approach can have a measurable impact on the estimates

Table 4-8 PM-Related Premature Deaths Estimated Using Alternative Approaches to Evaluate Uncertainty at Low-Concentations (95% Confidence Interval), Relative to Base Case (CPP)*

	No CPP	2% HRI at $50/kW	4.5% HRI at $50/kW	4.5% HRI at $100/kW
2025				
Log-Linear no-threshold model				
Krewski *et al.* (2009)	280 (190 to 370)	260 (170 to 340)	280 (190 to 370)	220 (150 to 300)
Lepeule *et al.* (2012)	640 (320 to 960)	590 (290 to 890)	630 (310 to 950)	510 (250 to 760)
Assuming PM effects below the LML of each study fall to zero				
Krewski *et al.* (2009) (LML= 5.8 μg/m^3)	240 (160 to 310)	220 (150 to 290)	230 (160 to 310)	190 (130 to 250)
Lepeule *et al.* (2012) (LML=8μg/m^3)	140 (67 to 200)	130 (64 to 190)	150 (74 to 220)	110 (57 to 170)

Source: US EPA Regulatory Impact Assessment (RIA) for Proposed Utility Greenhouse Gas Rule August 2018 (*Caveat: these are for a proposed rule and may not reflect what the final rule analysis will find*)

Estimating down to the current standard has further implications, especially in economic analysis

Table 4-9 Estimated Economic Value of Incremental $PM_{2.5}$ and Ozone-Attributable Deaths and Illnesses for Illustrative Scenarios & Three Alternative Approaches to Representing PM Effects in 2025, Relative to Base Case (CPP) (95% Confidence Interval; Billions of 2016$)[A]

		No CPP			2% HRI at $50/kW			4.5% HRI at $50/kW			4.5% HRI at $100/kW		
Ozone benefits summed with PM benefits:													
3% Discount Rate	No-threshold model[B]	$2.8 ($0.3 to $7.7)	*to*	$6.6 ($0.6 to $19)	$2.6 ($0.3 to $7)	*to*	$5.9 ($0.5 to $17)	$2.7 ($0.3 to $7.4)	*to*	$6.2 ($0.6 to $18)	$2.1 ($0.2 to $5.9)	*to*	$4.9 ($0.2 to $14)
	Limited to above LML[C]	$1.8 ($0.1 to $5.2)	*to*	$2.4 ($0.1 to $7)	$1.5 ($0.1 to $4)	*to*	$2.2 ($0.2 to $6)	$1.6 ($0.2 to $4.6)	*to*	$2.3 ($0.2 to $6)	$1.1 (-$.1 to $3.3)	*to*	$1.8 ($0.1 to $5)
	Effects above NAAQS[D]	$0.12 ($0 to $0.4)	*to*	$0.4 ($0 to $1.3)	$0.06 ($0 to $0.2)	*to*	$0.21 ($0 to $0.6)	$0.04 ($0 to $0.1)	*to*	$0.12 ($0 to $0.4)	-$0.07 (-$0.2 to -$0)	*to*	-$0.02 (-$0.1 to $0)

Source: US EPA Regulatory Impact Assessment (RIA) for Proposed Utility Greenhous Gas Rule August 2018 (*Caveat: these are for a proposed rule and may not reflect what the final rule analysis will find*)

So these studies could contribute significantly…

- This will be especially true if they:
  - Are able to harness successfully the large data sets to estimate exposure at the lowest levels;
  - Can consider potential confounders to the maximum extent possible
  - Apply a range of analytic approaches to test sensitivity to model selection – and possible causal inference
  - Capture and document the uncertainties that may propagate throughout the analysis
- Today, we will have the opportunity to learn of the work in progress, hear initial results, and get a first report of the HEI review panel.
- We look forward to hearing your questions, comments, and thoughts….

HEI

THANK YOU!

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