

Comments on PM ISA

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1996/97 PM NAAQS Review

- First to focus on epidemiology to infer a causal PM-mortality relationship
- Previous NAAQS reviews relied mostly on controlled human exposures and toxicology to establish NAAQS
- Previously epidemiology studies were only considered secondarily if they supported human exposure and toxicology evidence because epidemiology cannot establish causality
- 1996/97 review weighed epidemiology more than toxicology or human exposure because toxicology and human exposure studies could not provide plausible biological mechanisms to explain EPA's PM-mortality conclusion
- Despite the lack of plausibility, EPA established stringent annual PM_{2.5} and 24-hour NAAQS

When Setting the PM_{2.5} NAAQS, EPA Acknowledge Many Uncertainties in 1996

- 1996 Staff Paper- “Staff believes it is important to emphasize the unusually large uncertainties associated with establishing standards for PM relative to other single component pollutants for which NAAQS have been set.”
- 1996 Staff Paper went on to identify 9 key uncertainties that needed to be resolved before the next review

Key Uncertainties Identified in 1996

1. Lack of biological mechanism
2. Uncertainties and biases introduced by measurement error
3. Confounding by copollutants
4. Uncertainty of attribution to size range or chemical constituent(s)
5. Uncertainty of shape of concentration-response (C-R) relationships
6. Unaddressed confounders and methodological uncertainties
7. Extent to which life is being shortened
8. Uncertainty of background concentrations
9. Lack of health studies on coarse fraction

Uncertainties Spawned Two Decades of Public and Private Research

- Blue Ribbon National Research Council Panel
- EPA established 5 PM Research Centers
- EPRI's PM Research Program
- Health Effects Institute (HEI) PM Research Program
 - Reanalysis Project
 - NMAAPS
 - APHENA
 - NPACT
 - Numerous other smaller studies

After Two Decades of Research: Remaining Uncertainties

Significant Uncertainties Remain

1. Lack of biological mechanism
2. Uncertainties and bias introduced by measurement error
3. Confounding by copollutants
4. Uncertainty of attribution to size range or chemical constituent(s)
5. Uncertainty of shape of C-R relationship
6. Unaddressed confounders and methodological uncertainties
7. Extent to which life is being shortened

Epidemiological Uncertainties Have Not Deterred EPA

- Two more stringent PM_{2.5} NAAQS adopted
 - 2006 24-hr NAAQS lowered to 35 µg/m³
 - 2012 annual NAAQS lowered to 12 µg/m³
- Ozone NAAQS lowered 2 times (2008 & 2015) based on epidemiology
- NO₂ and SO₂ NAAQS lowered in 2010 based on epidemiology
- EPA's estimated benefits from various adopted and proposed regulations are dominated by PM benefits

Areas of Draft PM ISA Deficiencies

- Dosimetry
- Toxicology
- Epidemiology
 - Confounding
 - Methodological Uncertainties

PM ISA Still Wedded to Assumption that Reported PM-Mortality Statistical Associations are Causal

This ignores the Evidence that:

- The choice of the statistical model determines the strength (and sometimes the sign) of the relationships. This is not consistent with a causal relationship
- Dosimetry and Toxicology cannot explain how such minute quantities of known species in PM_{2.5} could be causing the effects claimed by the epidemiological studies

Recent Studies with Different Conclusions

- Cox, LA Jr, Popken DA. Has reducing PM2.5 and ozone caused reduced mortality rates in the United States? *Annals of Epidemiology*. 2015 Mar;25(3):162-73
- Young, SS. Air quality environmental epidemiology studies are unreliable. *Regulatory Toxicology and Pharmacology*. 2017 86:177
- Cox LA Jr. Rethinking the meaning of concentration–response functions and the estimated burden of adverse health effects attributed to exposure concentrations. *Risk Analysis*. 2016 Sep;36(9):1770-1779
- Cox LA Jr. Do causal concentration-response functions exist? A critical review of associational and causal relations between fine particulate matter and mortality. *Critical Reviews in Toxicology*. 2017 Aug; 47(7): 603-631
- Young, SS, Smith, RL and Lopiano, KK. Air quality and acute deaths in California, 2000-2012. *Regulatory Toxicology and Pharmacology*. 2017 Jun; 88:173. doi: 10.1016/j.yrtph.2017.06.003
- Enstrom, JE. Fine particulate matter and total mortality in cancer prevention study cohort reanalysis. *Dose-Response: An International Journal*. 2017 Ja-Mar. DOI 10.1177/1559325817693345
- Cox, LA Jr, Liu X, Shi L, Zu K, and Goodman G. Applying nonparametric methods to analyses of short-term fine particulate matter exposure and hospital admissions for cardiovascular diseases among older adults. *Intern. J. Environ. Res. & Public Health*. 2017, 14, 1051; doi:10.3390/ijerph14091051