CASAC MEETING NOVEMBER 17, 2021
Discussion by Richard L. Smith

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- Member of EPA's Science Advisory Board (SAB)
- Member of National Academies Committee on *Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards*
- The study I am going to report was partially financed by an industry sponsor
- The views I express here are entirely my own views and do not reflect the opinions of UNC, the SAB, the National Academies or the industry sponsor

First, I would like to thank the EPA and CASAC for organizing this public comment session. As a member of the SAB, I have often found the public comments to be very helpful in orienting the discussion. I hope you find today's comments similarly helpful.

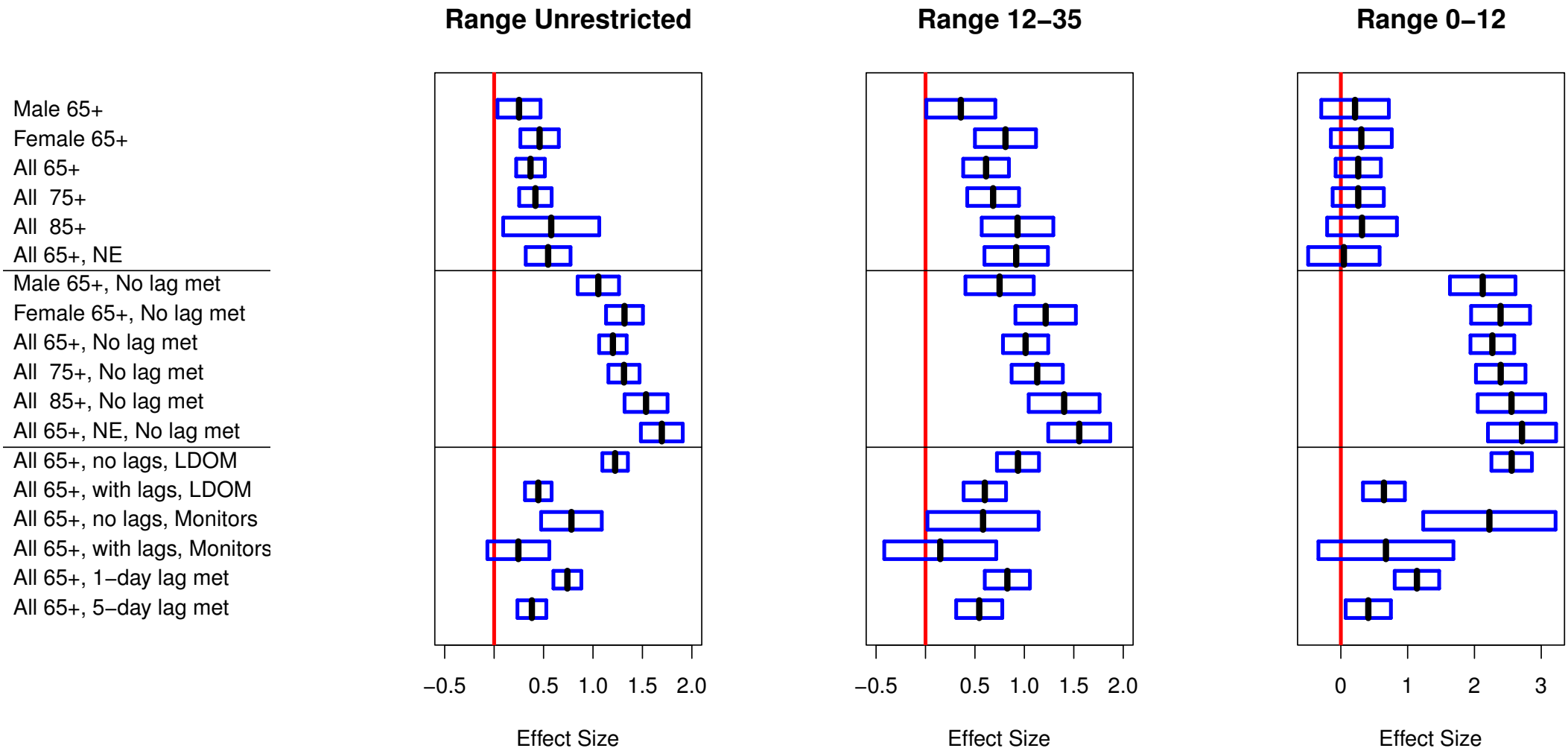
My Study

- Short-term mortality associations with $PM_{2.5}$ above and below 12 $\mu g/m^3$ (the current long-term standard)
- Medicare data: $\approx$16 million deaths, 1999–2013
- $PM_{2.5}$ data from EPA data product (RSIG), and monitors
- Temperature and dewpoint data from NOAA (GSOD)
- Analysis by case-crossover method with 28-day comparison window
- Concentration-response functions: linear, non-linear or "broken stick" model (two straight lines joined at 12 $\mu g/m^3$), applied to $PM_{2.5}$, mean of day 0 and day 1 lags
- Meteorological adjustment: nonlinear functions of temperature and dewpoint both current day and average of 3 lagged days

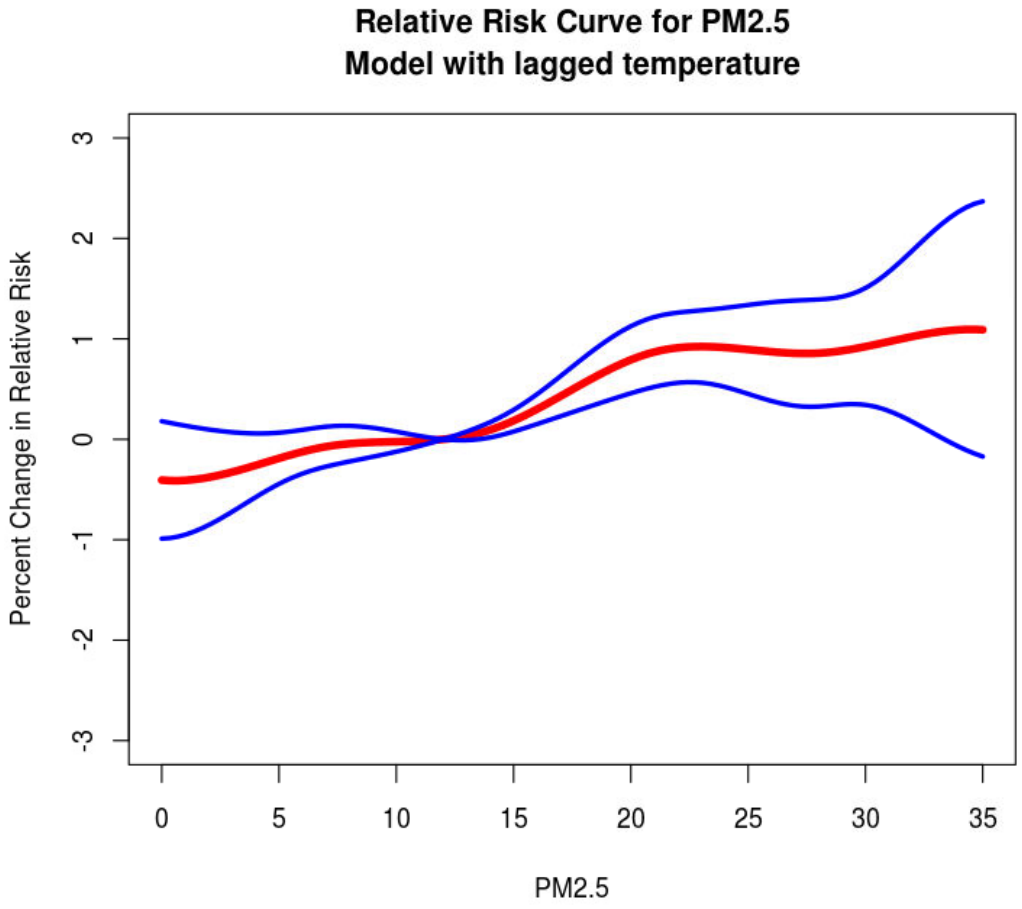
Results

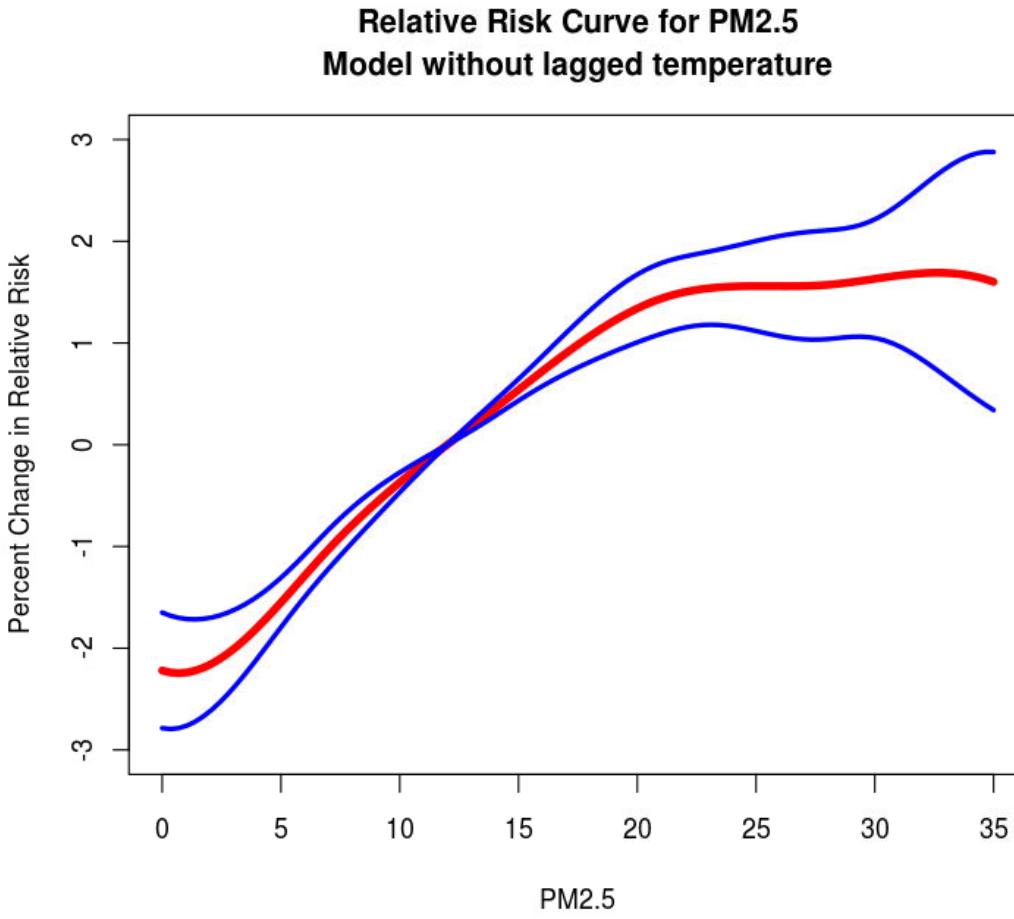
- Positive (statistically significant) dependence between mortality and $PM_{2.5}$ when linear C-R function is fitted to full range or broken stick model above 12 $\mu g/m^3$
- No significant effect below 12 $\mu g/m^3$
- But if lagged meteorology is omitted, the effects are larger across the board, and statistically significant in all ranges
- These results are robust across various sensitivity analyses
- Non-linear C-R curves confirm a similar discrepancy between the results that do or do not include lagged meteorology

Percent Increased Mortality Per 10 μg/m^3 Increase in $PM_{2.5}$



Nonlinear risk curves: percent change in mortality compared with a reference level of 12 μg/m^3 $PM_{2.5}$, with pointwise 95% confidence limits





Relevance to the ISA

- There is another study that included many of the same variables. This study was highly cited in the ISA (and the PA)
- This study:
  - Used Medicare data from almost the same time period
  - Different constructions of $PM_{2.5}$ and meteorology
  - Similar but not identical statistical and computational methodology
  - Included nonlinear meteorology effects for day of death, but *not* for lagged days
  - This study found highly statistically significant effects for $PM_{2.5}$ both above and below 12 $\mu g/m^3$
- I believe this study was deficient. If they had investigated the confounding effect of lagged meteorology, they would have found the same thing as I did

Discussion

- This is *not* about discrediting that particular group of researchers. They are a very well known group who have made many creative contributions to air pollution epidemiology
- Rather, I believe this highlights the generic problem with all observational studies: the results can sometimes be highly sensitive to seemingly minor changes in the statistical methodology
- For the remainder of this presentation, I want to focus on two broader issues
  - Publication bias
  - Reproducibility/replicability

Publication Bias

- This paper was submitted to one of the major epidemiology journals
- The referees found no fault with the paper
- Nevertheless, the editor rejected it
- After extensive correspondence with the editor, I felt I had no choice but to withdraw the paper
- The paper is now (about to be) resubmitted to another journal
- I do not dispute the right of journal editors to select papers for publication as they see fit, but I believe this creates a distinct bias in the EPA assessment process

Transparency/Reproducibility

- The previous Administrator of EPA introduced a "Transparency Rule", ostensibly to insure that data from air pollution studies would be available for reanalysis
- Numerous scientific commentators, *including his own Science Advisory Board*, objected that the rule was unworkable
- The rule was reversed by the current Administrator
- Despite these developments, there has been no progress towards insuring greater reproducibility (or replicability) in EPA studies

Recommendations

- EPA should establish a public database of air pollution studies that have been approved by an IRB or equivalent body
  - The results of these studies should be retained in a public database, regardless of their outcome
  - If this system had been in place, the results of my study would have been available two years ago, and there would be no argument about their eligibility for the ISA
- EPA should set aside funds for reanalysis of air pollution studies when appropriate, preferably through open competition among academic researchers
- CASAC should include "replicability" as an explicit criterion for weighting air pollution studies. For some of the papers in the ISA, it's very hard for me to see how they could ever be replicated

THANK YOU FOR YOUR ATTENTION!