Ethical Aspects of Fine Particulate Matter Epidemiology

James E. Enstrom, Ph.D., M.P.H.

Epidemiologist
UCLA School of Public Health & Jonsson Comprehensive Cancer Center

President
Scientific Integrity Institute
Los Angeles

American College of Epidemiology Annual Meeting
Chicago, IL
September 11, 2012
Fine Particulate Matter (PM$_{2.5}$)

PM$_{2.5}$ is defined by particle size ($\leq 2.5$ μm in diameter) and not by chemical composition, as in the case of a gaseous air pollutant like ozone. PM$_{2.5}$ is generated mainly by combustion processes. The major sources of PM$_{2.5}$ are forest fires, agricultural dust, industrial combustion, and diesel engines and these sources vary across the US.

PM$_{2.5}$ epidemiology has been used to establish the following two controversial regulations that have had multi-billion dollar economic impacts in the United States and California:

1) 1997 US Environmental Protection Agency Annual National Ambient Air Quality Standard (NAAQS) for PM$_{2.5}$ at 15 μg/m$^3$

2) 2008 & 2010 California Air Resources Board Truck and Bus Regulation of Diesel Vehicles in California
“Premature Deaths” Attributed to PM$_{2.5}$

An increased relative risk [RR > 1.00], based on increase in total (all cause) mortality risk for 10 $\mu$g/m$^3$ increase in PM$_{2.5}$ level, is interpreted by US EPA and CARB as evidence that PM$_{2.5}$ “causes” “premature deaths”

Because EPA assigns a lifetime monetary value of about $7-9$ million to each “death,” the health benefits of preventing these “deaths” exceed the compliance costs of the EPA and CARB regulations that are designed to reduce PM$_{2.5}$ levels and PM$_{2.5}$-related “premature deaths”

Without PM$_{2.5}$-related “premature deaths” the EPA and CARB regulations are not justified on a cost-benefit basis
Major Reasons for Lack of Proof that PM$_{2.5}$ “Causes” “Premature Deaths”

1) Small Variable Effect: the relative risk of death due to PM$_{2.5}$ is small (RR $\sim 1.10$), varies by time and place, and there is no consistent dose-response relationship.

2) Confounding Variables: confounders, including other pollutants, often reduce PM$_{2.5}$ effect to zero (RR $\sim 1.00$).

3) Ecological Fallacy: PM$_{2.5}$ measurements made at selected monitoring stations are imputed to individuals.

4) Variable PM$_{2.5}$: PM$_{2.5}$ is defined by specific particle size, but its composition varies greatly across the US.

5) Secret Data: major PM$_{2.5}$ studies (H6CS & ACS) cannot be independently analyzed, violating Data Access Act.
<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th>RR (95% CI)</th>
<th>Time Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>McDonnell 2000</td>
<td>AHSMOG</td>
<td>RR ~ 1.03 (0.95-1.12)</td>
<td>1976-1992</td>
</tr>
<tr>
<td>Krewski 2000</td>
<td>CA CPS II</td>
<td>RR = 0.87 (0.81-0.94)</td>
<td>1982-1989</td>
</tr>
<tr>
<td>Enstrom 2005</td>
<td>CA CPS I</td>
<td>RR = 1.04 (1.01-1.07)</td>
<td>1973-1982</td>
</tr>
<tr>
<td></td>
<td>(9 air sheds)</td>
<td>RR = 1.00 (0.98-1.02)</td>
<td>1983-2002</td>
</tr>
<tr>
<td>Zeger 2008</td>
<td>MCAPS “West”</td>
<td>RR = 0.99 (0.97-1.01)</td>
<td>2000-2005</td>
</tr>
<tr>
<td></td>
<td>(CA, OR, WA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Krewski 2010</td>
<td>CA CPS II</td>
<td>RR = 0.97 (0.92-1.02)</td>
<td>1982-2000</td>
</tr>
<tr>
<td>Jerrett 2010-11</td>
<td>CA CPS II</td>
<td>RR = 1.00 (0.99-1.01)</td>
<td>1982-2000</td>
</tr>
<tr>
<td>Lipsettt 2011</td>
<td>CA Teachers</td>
<td>RR = 1.01 (0.95-1.09)</td>
<td>2000-2005</td>
</tr>
</tbody>
</table>
Conclusions About PM$_{2.5}$ & Total Mortality in California and US

1) there is NO significant relationship between PM$_{2.5}$ and total mortality in California

2) there is substantial geographic variation nationally (West vs East) in the dose-response relationship between PM$_{2.5}$ and total mortality

3) there is no sound epidemiologic justification for setting a single national standard for PM$_{2.5}$ given the large and clear geographic variation in PM$_{2.5}$ mortality risk
US EPA Proposal to Lower National Ambient Air Quality Standard for Fine Particulate Matter

In spite of clear national geographic variation in PM$_{2.5}$ mortality risk and extensive persistent epidemiologic and statistical problems, US EPA issued proposed rule on June 29, 2012 to lower annual PM$_{2.5}$ NAAQS from 15 $\mu g/m^3$ to 12-13 $\mu g/m^3$ ([http://www.epa.gov/pm/actions.html](http://www.epa.gov/pm/actions.html)).

Lower NAAQS would impose multi-billion dollar compliance costs on impacted US industries ([http://online.wsj.com/article/SB10001424052702303822204577468371370095152.html](http://online.wsj.com/article/SB10001424052702303822204577468371370095152.html)).
Ethics and Epidemiologic Decision Making for Population Benefits

Professional ethical principles are paramount in determining the best approach to using epidemiologic data to benefit population health:

1) all available epidemiologic evidence must be fairly evaluated and used in decision making
2) population attributable risk must be calculated in a manner that is consistent with all the evidence
3) relationships should be used for regulations only if they satisfy the Hill causality criteria

Conclusion: Above principles and existing epidemiologic evidence indicate US EPA has no justification for lowering the PM$_{2.5}$ NAAQS