TCEQ

Critique of EPA's Benefit Cost Analysis

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Director, Toxicology Division

Background

- March 2011 – EPA published "Benefits and Costs of the Clean Air Act from 1990 to 2020 (Second Prospective Study)"
  - Benefits ($2T) outweigh costs ($65B) by 30 to 1
    - TCEQ staff examined this analysis, focusing on:
      - The studies used
      - The assumptions made
      - The methods employed

Key = $PM_{2.5}$

- According to EPA:
  - Causally associated with Premature Mortality
  - No Safe Level of Exposure

"Particulate matter causes premature death. It doesn't make you sick. It's directly causal to dying sooner than you should…. If we could reduce particulate matter to healthy levels, it would have the same impact as finding a cure for cancer in our country…. We are actually at the point in many areas of this country where on a hot summer day, the best advice you can give is don't go outside. Don't breathe the air. It may kill you." - Lisa P. Jackson, Former EPA Administrator

Key to Understanding → PM2.5 NAAQS Basis

Clinical Studies and Toxicology

- Exposure of human volunteers to PM, CAPS, DE
- Exposure of mice to PM
  - ApoE model: susceptible to heart disease
    - Cholesterol levels 14 times higher than wild type mice (Plump et al. 1992)
- The majority of human clinical and animal studies show no significant effects
- Some studies show subtle changes in heart rate variability or markers of inflammation

Observational Epidemiology

- ACS (American Cancer Society)
  - Pope et al. 2002
  - Krewski et al. 2009
- HSC (Harvard Six Cities)
  - Laden et al. 2006

PM – particulate matter, CAPS – concentrated air particles, DE – diesel exhaust

Exposure of Human Volunteers to $PM_{2.5}$

Studies Conducted by EPA

<u>FOIA HQ-FOI-02235-11</u>

January 2010 – June 2011
41 Volunteers
Dose:35 – 750 µg/m³

<u>Results</u>:

1 individual: elevated heart rate
1 individual: irregular heart beat*
39 individuals: no clinical effects

<u>Additional Information:</u>

April 2010 Report to UNC IRB: ≥6,000 volunteers exposed to date

- one adverse reaction in exposure group
- two adverse reactions in clean air control group

FOIA # HQ-FOI-02235-11

Exposure Date	SUBJECT	Entered Chamber	Exited Chamber	Filter Conc (ug/m3)	Clinical Effects*
1/5/2010	OMC019	11:02	13:02	205.27	No clinical effects requiring follow-up observed
1/6/2010	KCN112	9:34	11:34	153.58	No clinical effects requiring follow-up observed
2/9/2010	OMC021	10:52	12:52	442.49	No clinical effects requiring follow-up observed
3/9/2010	OMC023	10:45	11:08	750.83	No clinical effects requiring follow-up observed
3/23/2010	OMC024	10:49	12:49	147.42	No clinical effects requiring follow-up observed
4/13/2010	OMC025	10:43	12:43	431.06	No clinical effects requiring follow-up observed
4/20/2010	OMC026	11:19	13:19	336.56	No clinical effects requiring follow-up observed
4/27/2010	OMC027	11:00	13:00	257.18	No clinical effects requiring follow-up observed
4/28/2010	KCN111	9:13	11:13	154.36	No clinical effects requiring follow-up observed
5/4/2010	OMC028	10:54	12:54	326.78	No clinical effects requiring follow-up observed
5/5/2010	KCN113	9:26	11:26	578.95	No clinical effects requiring follow-up observed
5/11/2010	OMC022	10:51	12:51	247.77	No clinical effe
6/8/2010	OMC030	10:48	12:48	257.12	No clinical effe
6/15/2010	OMC031	11:28	13:28	468.96	No clinical effe
6/29/2010	OMC033	11:04	13:04	321.36	No clinical effe
7/13/2010	OMC034	10:49	12:49	177.02	No clinical effe
7/15/2010	XCE224	11:10	13:10	137.19	No clinical effe
8/10/2010	OMC035	11:00	13:00	411.98	No clinical effe
8/12/2010	XCE225	10:59	12:59	157.63	No clinical effe
8/25/2010	KCN114	9:55	11:55	232.91	No clinical effe
9/9/2010	XCE226	10:55	12:55	87.36	No clinical eff
9/23/2010	XCE228	11:05	13:05	174.61	No clinical effects requiring follow-up observed
10/6/2010	KCN115	9:31	11:31	131.50	No clinical effects requiring follow-up observed
10/7/2010	XCE227	11:21	12:10	111.68	Removed from chamber due to new onset of atrial fibrillation. Individual reverted to normal sinus rhythm approximately two hours later. Individual was admitted to the hospital overnight for observation and telemetry. Detailed in Ghio et al., 2011 Case Report, Environ Health Perspect doi:10.1289/ehp.1103877
11/18/2010	XCE229	11:14	13:14	59.09	No clinical effects requiring follow-up observed
12/2/2010	XCE231	10:55	12:55	35.60	No clinical effects requiring follow-up observed
1/6/2011	XCE233	11:05	13:05	43.65	No clinical effects requiring follow-up observed
1/24/2011	XCE232	10:47	12:47	150.63	No clinical effects requiring follow-up observed
1/31/2011	XCE234	11:03	13:03	90.95	No clinical effects requiring follow-up observed
2/3/2011	XCE236	11:12	13:12	57.91	No clinical effects requiring follow-up observed
2/10/2011	XCE235	11:12	11:35	66.26	Removed from chamber due to a short episode of an elevated heart rate during exposure. The individual denied any symptoms. This individual was provided with copies of the EKG and holter recording and referred to MD.
2/24/2011	XCE238	10:57	12:57	103.51	No clinical effects requiring follow-up observed
3/28/2011	XCE239	10:52	12:52	80.06	No clinical effects requiring follow-up observed
4/14/2011	XCE237	10:48	12:48	93.24	No clinical effects requiring follow-up observed
4/18/2011	XCE242	11:09	13:09	72.89	No clinical effects requiring follow-up observed
4/25/2011	XCE240	11:05	13:05	41.54	No clinical effects requiring follow-up observed
5/2/2011	XCE244	11:13	13:13	85.31	No clinical effects requiring follow-up observed
5/16/2011	XCE243	11:00	13:00	142.50	No clinical effects requiring follow-up observed
5/23/2011	XCE245	10:57	12:57	266.92	No clinical effects requiring follow-up observed
6/2/2011	XCE247	11:00	13:00	179.58	No clinical effects requiring follow-up observed
6/9/2011	XCE246	10:55	12:55	359.52	No clinical effects requiring follow-up observed

* Note : Clinical Effects is defined as requiring medical follow-up or referral to physician

Case Report:
Supraventricular Arrhythmia after Exposure to Concentrated Ambient Air Pollution Particles. Ghio et al. EHP. Feb. 2012. 120:275-277

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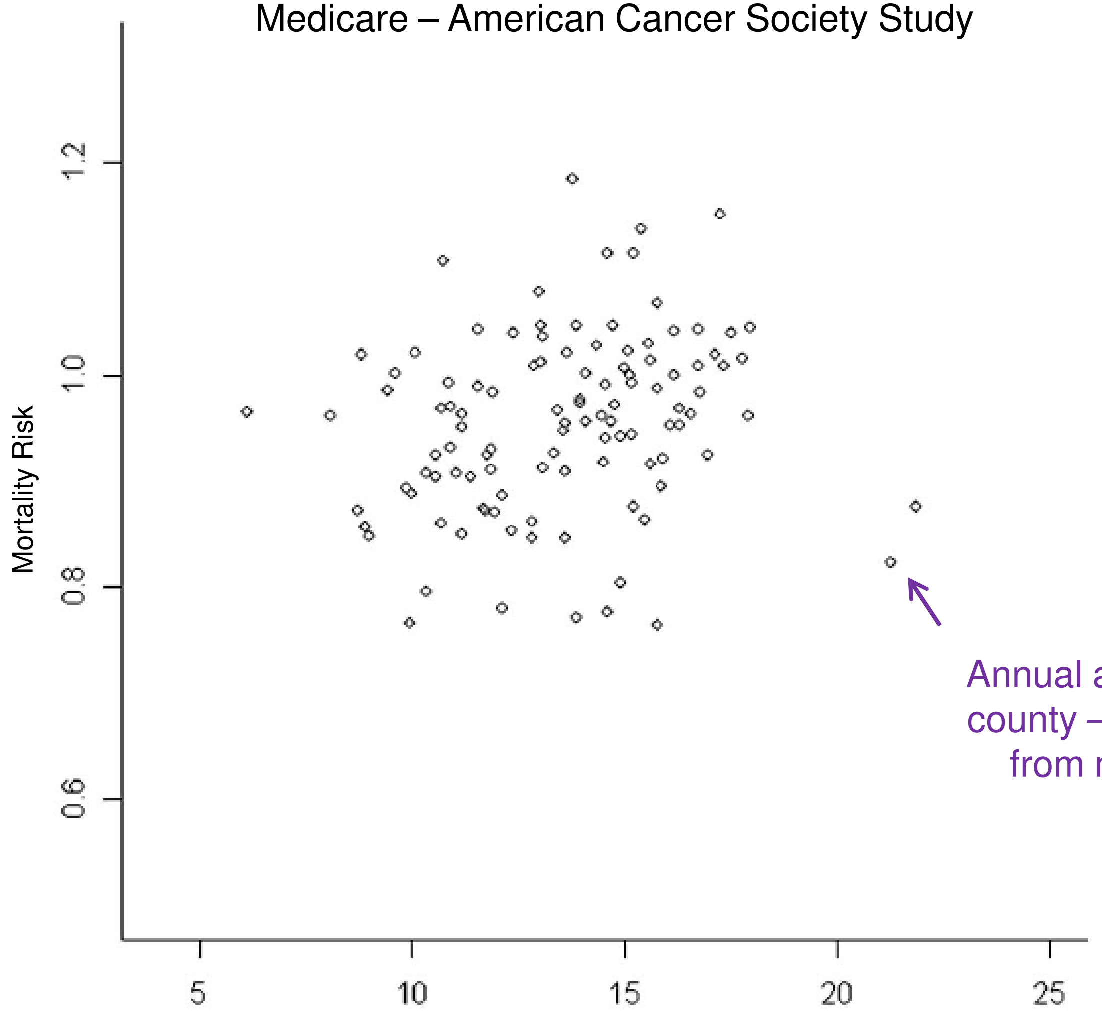
Observational Epidemiology Studies

Medicare – American Cancer Society Study

Based on death certificates collected in the county

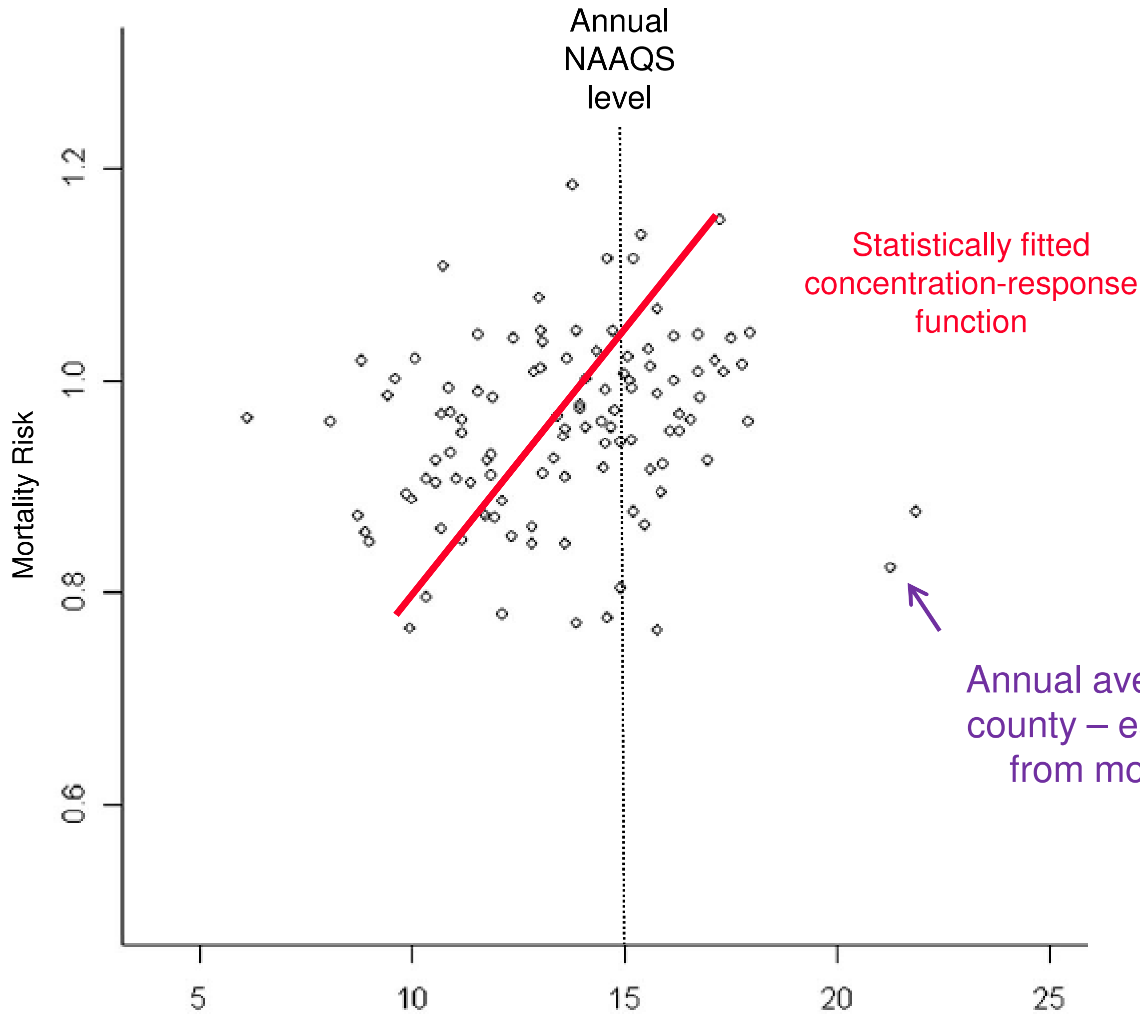


Annual average for county – estimated from monitors

Average Annual $PM_{2.5}$ (Eftim et al. 2008)

Observational Epidemiology Studies

Based on death certificates collected in the county



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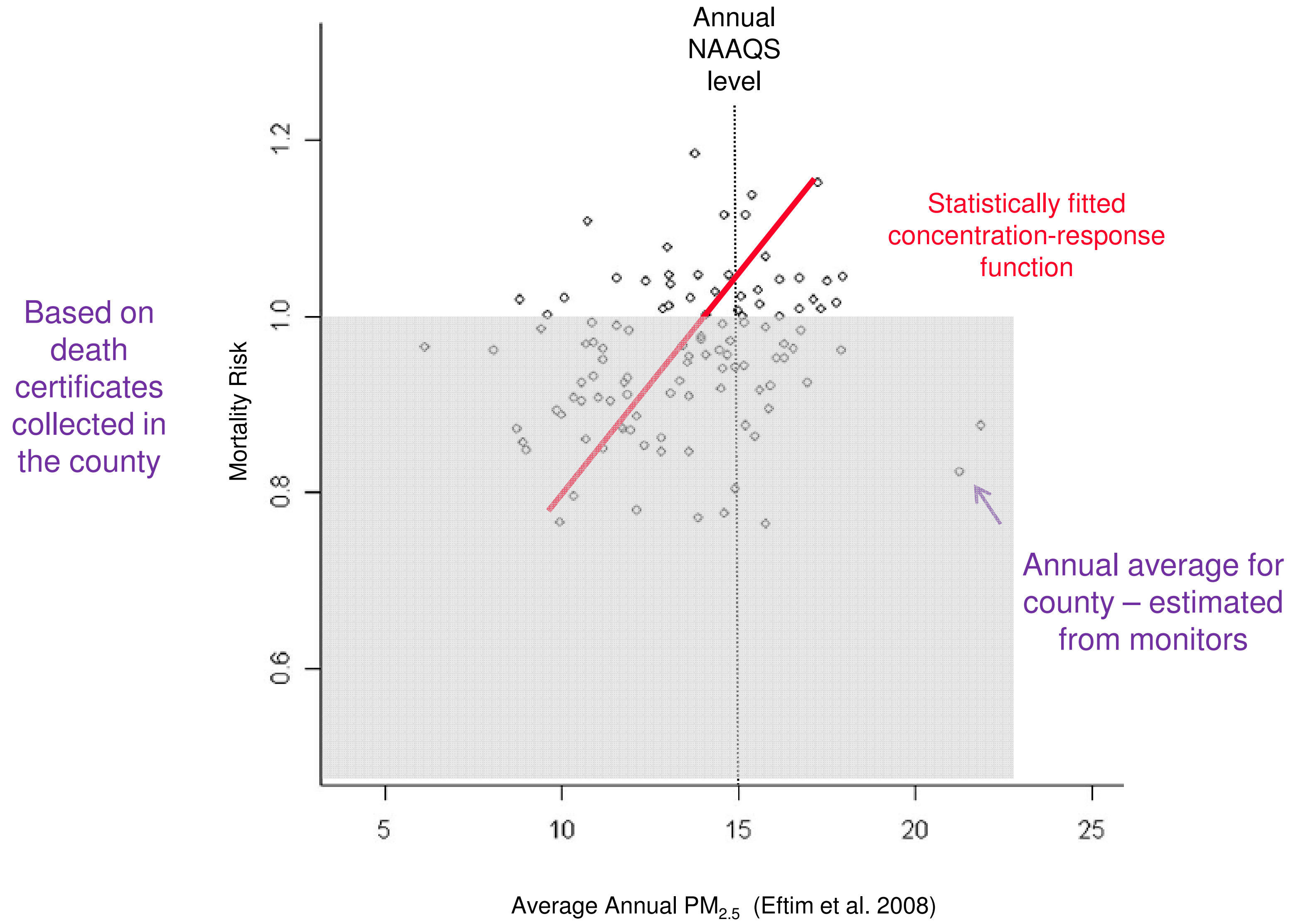

Observational Epidemiology Studies

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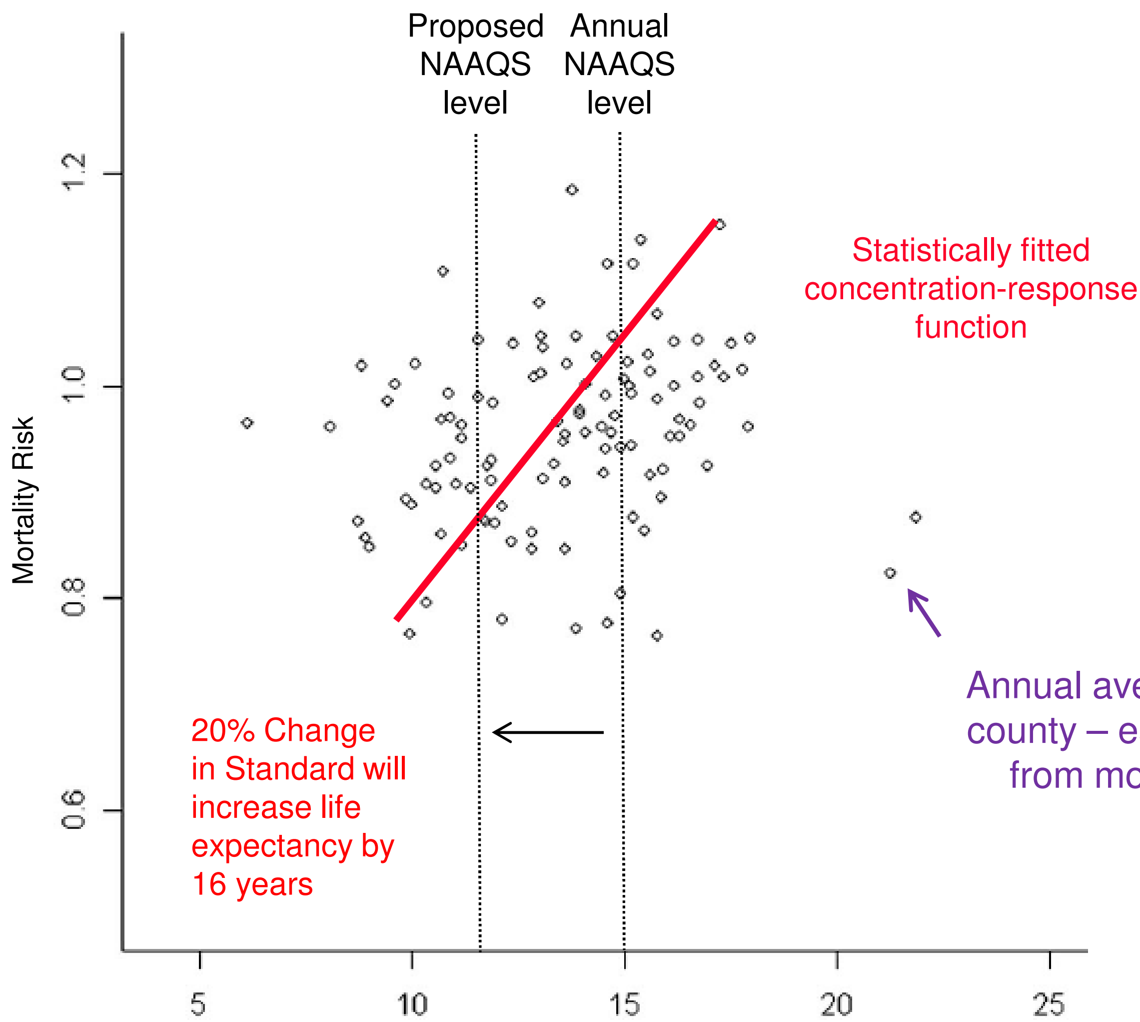


Annual average for county – estimated from monitors

Average Annual $PM_{2.5}$ (Eftim et al. 2008)

Data from Harvard Six Cities Study

Laden et al. 2006

Laden et al. HSC Study 2006

1 statistically significant result (that is no longer significant)

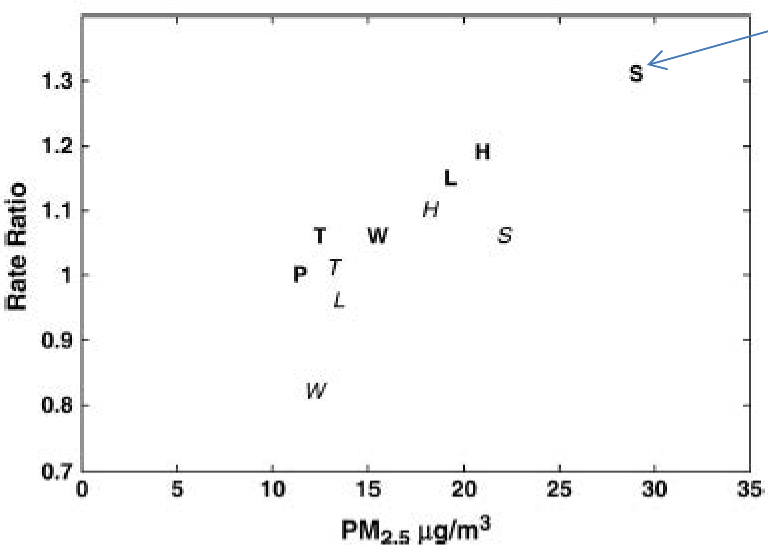
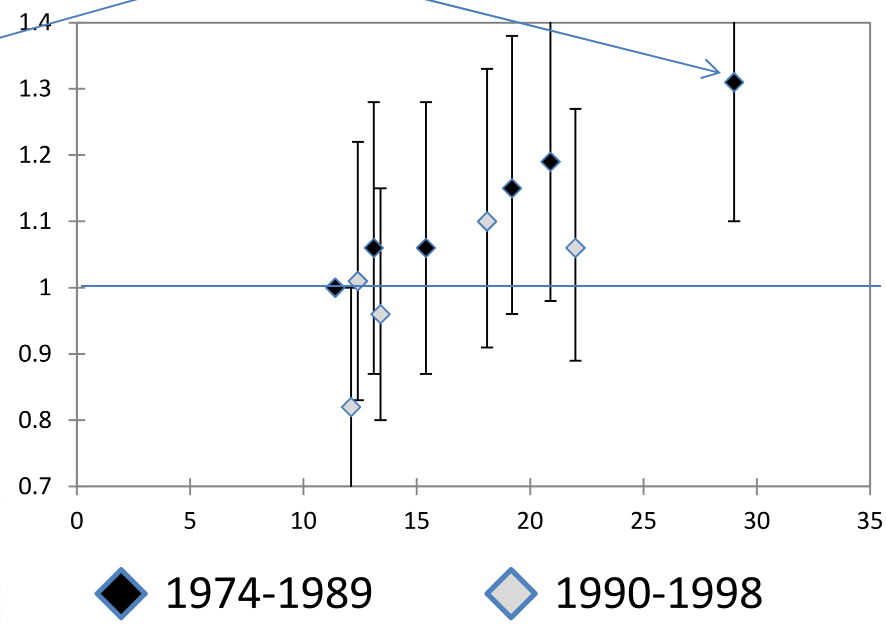
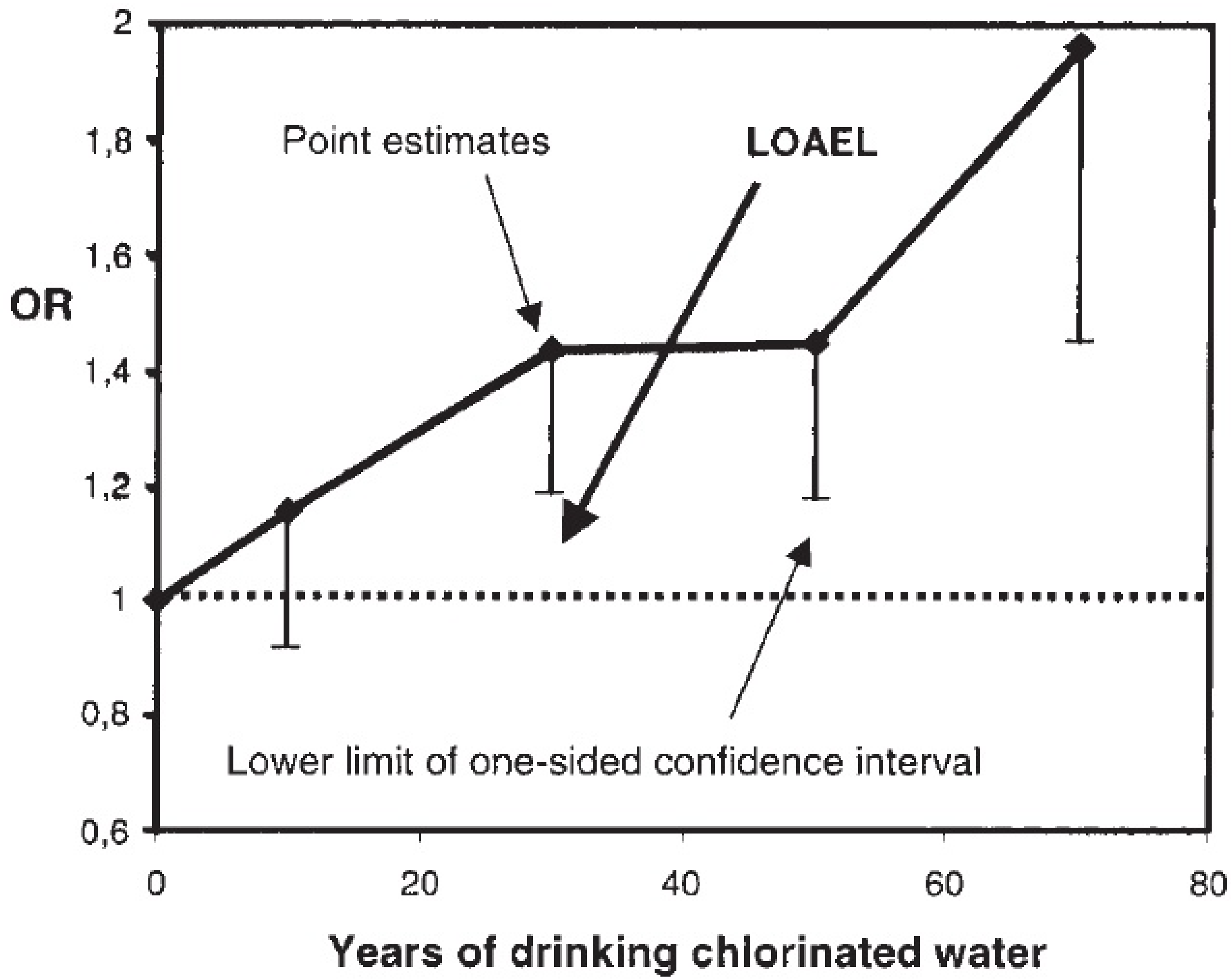


Figure 2. Estimated adjusted rate ratios for total mortality and $PM_{2.5}$ levels in the Six Cities Study by period. P denotes Portage, WI (reference for both periods); T = Topeka, KS; W = Watertown, MA; L = St. Louis, MO; H = Harriman, TN; S = Steubenville, OH. A term for Period 1 (1 if Period 2, 0 if Period 1) was included in the model. *Bold letters* represent Period 1 (1974–1989) and *italicized letters* represent Period 2 (1990–1998). In Period 1, $PM_{2.5}$ (µg/m^3) is defined as the mean concentration during 1980–1985, the years where there are monitoring data for all cities (18). In Period 2, $PM_{2.5}$ is defined as the mean concentrations of the estimated $PM_{2.5}$ in 1990–1998.

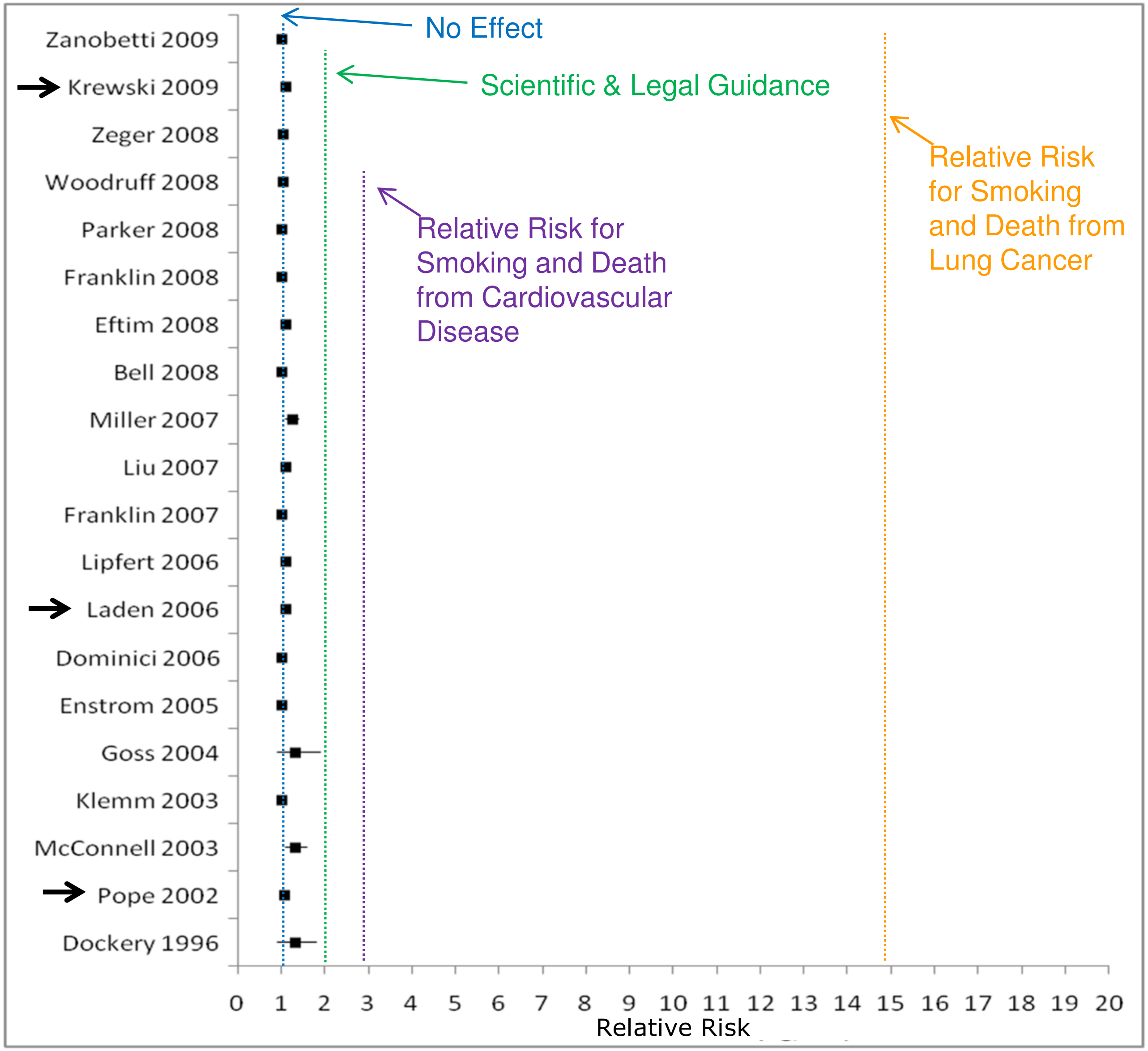


What the Curve Should Look Like



However, causality seems questionable, because neither the point estimate nor the lower confidence intervals are above a relevance limit of efficacy of 2.5,… Hothorn, 1999

Relative Risks <2 ≠ Causality



Reference Manual on Scientific Evidence

Third Edition, National Academies Press, 2011

"In general, studies that find a relative risk less than 2.0 should not be sufficient for causation…[r]elative risks of less than 2.0 may readily reflect some unperceived bias or confounding factor…If the relative risk is near 2.0, problems of bias and confounding in the underlying epidemiologic studies may be serious, perhaps intractable."

Interpreting Epidemiology Studies – EPA Water Program

Journal of Water and Health | 04.Suppl 2 | 2006

Table 6 | Assessing the strength of an epidemiologic association[a]

Rate ratio (increased risk)	Rate ratio (decreased risk)	Strength of association
1.0–1.2	0.9–1.0	None
1.2–1.5	0.7–0.9	Weak
>1.5	< 0.7	Moderate to strong

[a]Adapted from Monson (1990).

- Is sufficient information available to estimate the magnitude (e.g. PAR) of an increased risk of endemic AGI or a specific disease (e.g. cryptosporidiosis) that may be associated with drinking water systems in the United States or another developed country?
- If so, can the risk be generalized to the national population? Are certain populations (e.g. the elderly) at greater or less risk?
- What factors (e.g. water source and treatment processes) may modify the risk?
- What are the uncertainties associated with estimating the

Confounding in $PM_{2.5}$ Epidemiology

Risk Factor	Effect Size	Relative Risk or Hazard Ratio	Reference	Controlled for in Krewski et al. 2009
High Dietary Trans Fats	1.4	RR	Danaei et al. 2009	not trans fat specific, measured as "dietary fat"
Low Fruit/Veg Intake	1.04	RR	Danaei et al. 2009	not fruit/veg specific, measured as "dietary fiber"
Low Omega 3 Intake	2.18	RR	Danaei et al. 2009	
Tobacco Use	M: 5.51 F:3.78	RR	Danaei et al. 2009	√
High Cholesterol	2.11[A]	RR	Danaei et al. 2009	
High Blood Pressure	2.04[B]	RR	Danaei et al. 2009	
Overweight	1.14[C]	RR	Danaei et al. 2009	√ (as BMI)
High Blood Glucose	1.42[D]	RR	Danaei et al. 2009	
Psychiatric Disorders (Bipolar)	5.55	HR	Gale et al. 2012	
Temperature >93.2°F	1.09	RR	Hondula et al. 2012	
Multivitamin Use	1.07[E]	HR	Park et al. 2011	
Stress	1.43	HR	Russ et al. 2012	
Shift Work	1.24	RR	Vyas et al. 2012	

Note:
Covariate data was from the 1982 ACS Enrollment Questionnaire

Relative Risk for $PM_{2.5}$ exposure and premature mortality:
1.115 (1.003–1.239)

A – per mmol/l increase
B – per 20 mmHg increase
C - per kg/m2 increase
D – per mmol/l increase
E - nonsignificant

Confounding in $PM_{2.5}$ Epidemiology

Epidemiology:
July 2007 - Volume 18 - Issue 4 - pp 416-423
doi: 10.1097/EDE.0b013e31806462e9
AIR POLLUTION: Original Article

Trends in Air Pollution and Mortality: An Approach to the Assessment of Unmeasured Confounding

Janes, Holly; Dominici, Francesca; Zeger, Scott L.

- The existing body of epidemiological literature linking $PM_{2.5}$ and premature mortality appears to be affected by confounding

An Approach to the Estimation of Chronic Air Pollution Effects Using Spatio-Temporal Information

Sonja GREVEN, Francesca DOMINICI, and Scott ZEGER

Journal of the American Statistical Association
June 2011, Vol. 106, No. 494, Applications and Case Studies
DOI: 10.1198/jasa.2011.ap09392

Greven, Dominici, and Zeger: Estimation of Chronic Air Pollution Effects

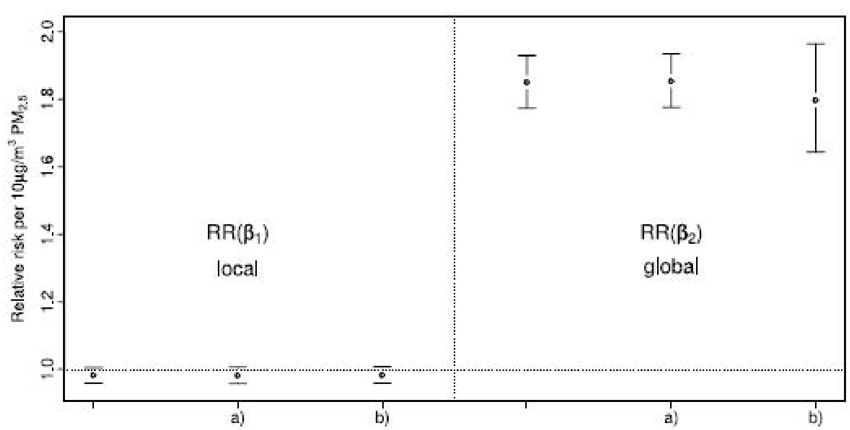
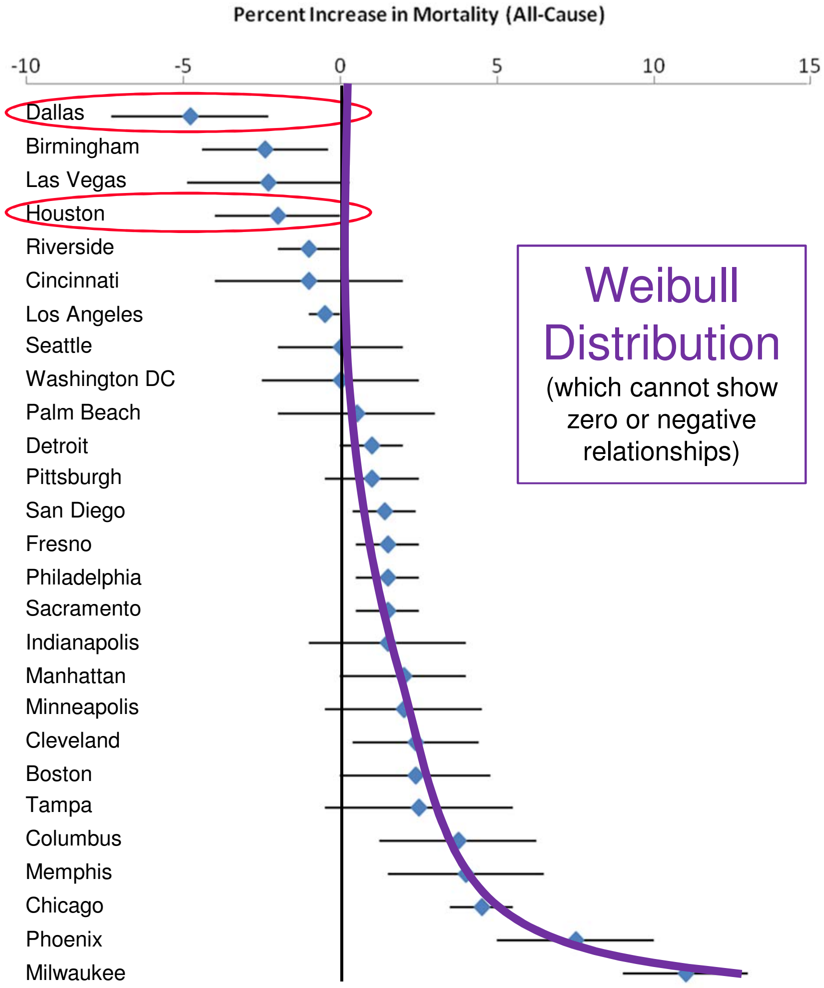


Figure 5. Sensitivity analysis using data on 173 locations with additional variables from the BRFSS-SMART survey. The left-most estimate shows estimates $\widehat{\beta}_1$ and $\widehat{\beta}_2$ from model (3) for this subset of the data. a) indicates the analysis including additional variables on the level of the monitor's county: the proportion of current smokers and of nonwhites, and the mean income and body mass index. b) gives the results for the same analysis allowing separate coefficients for the four variables' global and local trends.

Correct Statistical Analysis?

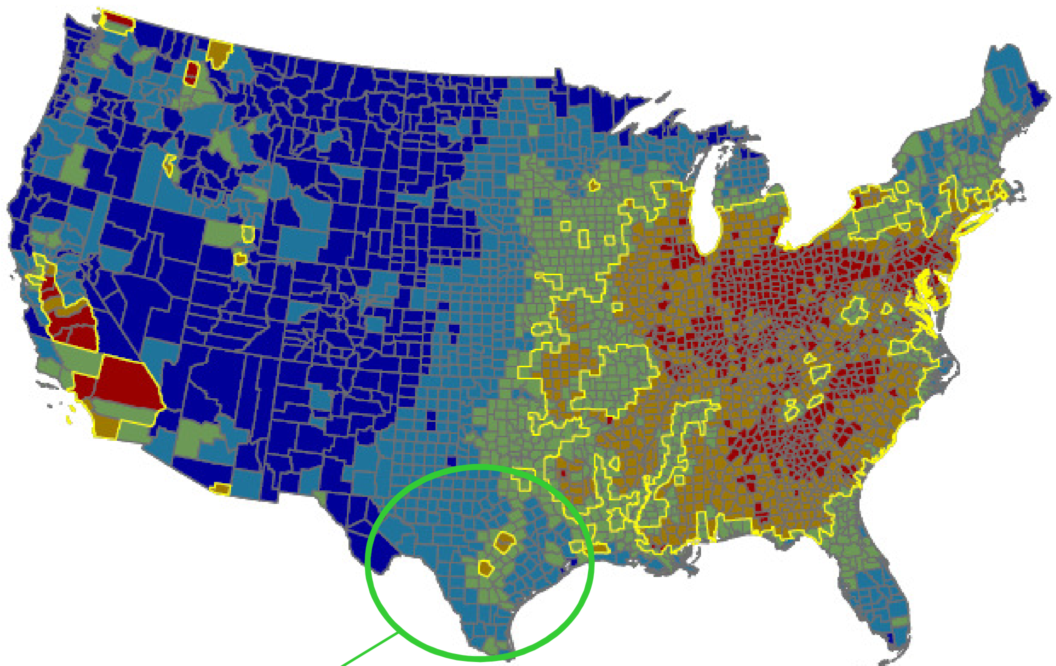
PM $_{2.5}$ -Mortality Coefficient Estimates and 95% CI
Adapted from Franklin et al. 2007



Estimates of the percent Increase in all-cause mortality with a 10 µg/m^3 increase in previous day's concentration PM $_{2.5}$

Extrapolation of Mortality Estimates

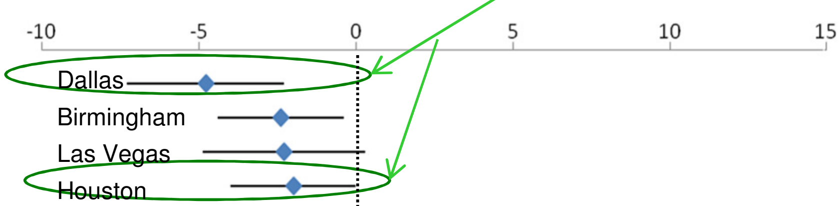
Figure C-2. Distribution of $PM_{2.5}$ Mortality Risk in 2005



$PM_{2.5}$ -Mortality Coefficient Estimates and 95% CI

Adapted from Franklin et al. 2007

Percent Increase in Mortality (All-Cause)



Percentage of total deaths due to PM2.5

- 0.85% to 2.6%
- 2.3% to 3.9%
- 4% to 5.1%
- 5.2% to 6.1%
- 6.1% to 9%
- Counties at or above the median risk level in 2005

From EPA – Regulatory Impact Analysis of the Proposed Toxics Rule: Final Report – March 2011

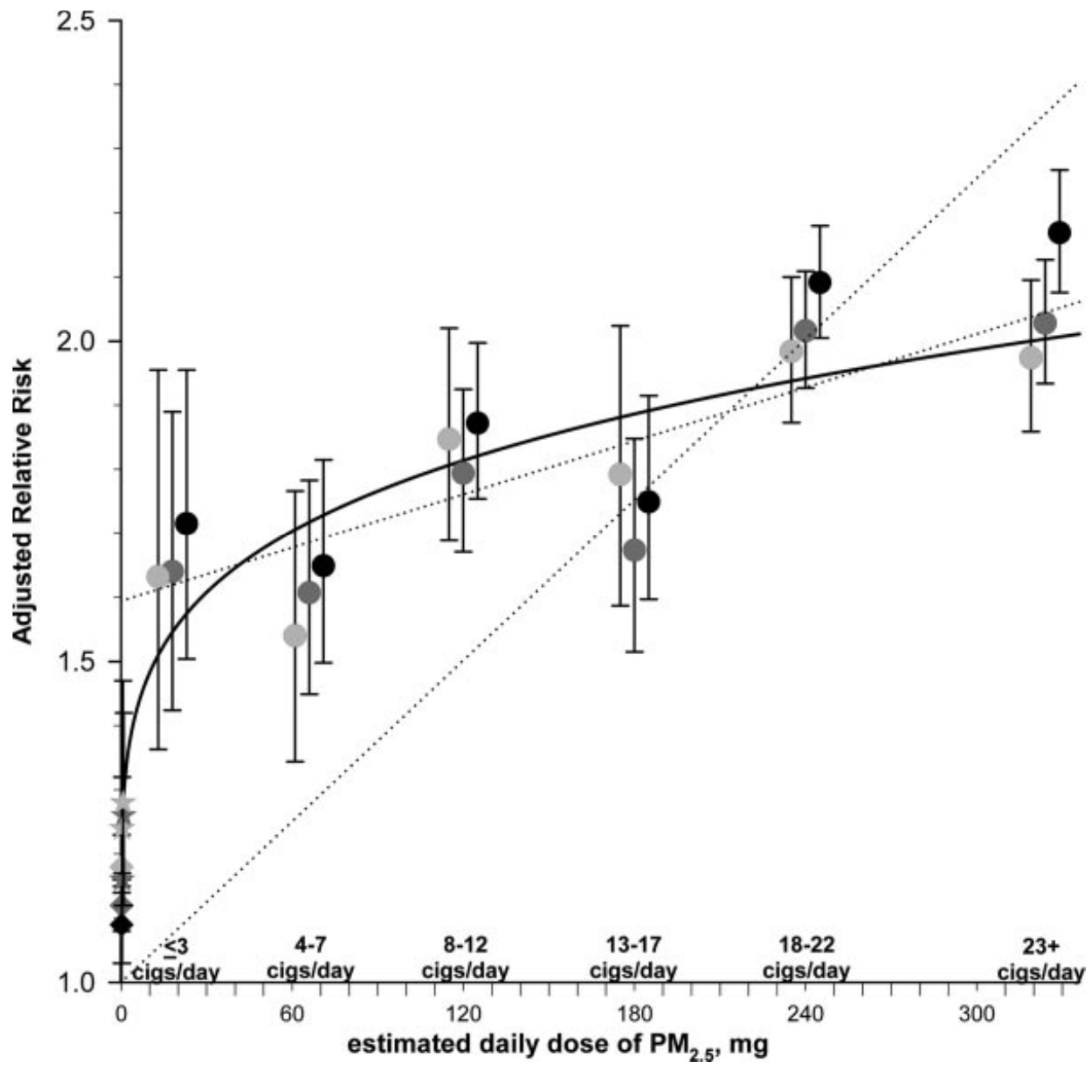
Expert Elicitation Study

Name	Academia	Other	EPA funded at the time	Funding Notes	Co-author ACS or HSC
Doug Dockery	Harvard		yes	center grant	yes
Kaz Ito	NY Univ.		yes	center grant	yes
Daniel Krewski	Univ, Ottawa		yes	author of center grant-supported paper	yes
Nino Kuenzli	Univ. Southern California		yes	center grant	no
Morton Lippmann	NY Univ.		yes	center grant	no
Joe Mauderly	Lovelace		yes	center grant	no
Bart Ostro		CALEPA	yes	grant	yes
Arden Pope	Brigham Young Univ.		yes	author of center grant-supported paper	yes
Richard Schlesinger	Pace Univ.		yes	center grant	no
Joel Schwartz	Harvard		yes	center grant	yes
George Thurston	NY Univ.		yes	center grant	yes
Mark Utell	Univ. of Rochester		yes	center grant	no

Authors of papers with contradictory data (19)	
Abbey	Lebowitz
Baty	Lipfert
Beeson	McDonnell
Breslow	Miller
Carmody	Nishino
Chen	Perry
Enstrom	Peterson
Ghamsary	Shavlik
Kabat	Wyzga
Knutsen	

6/12 panel members did not include the following studies with contradictory data
Enstrom 2005
Lipfert 2000, 2003, 2006
Abbey 1991, 1999
McDonnell 2000
Chen 2005

$PM_{2.5}$ More Toxic Than Cigarette Smoke



Value of Statistical Life

- "Lives Saved" vs. "Life-Years Added"
  - Deaths "prevented or avoided" do not occur, since reducing $PM_{2.5}$ does not confer immortality

TABLE 5-8. LIFE YEARS GAINED AND LIFE EXPECTANCY GAIN ESTIMATES FROM THE POPULATION SIMULATION MODEL

AGE COHORT		LIFE-YEARS GAINED IN SPECIFIC YEARS (ANNUAL)		CUMULATIVE LIFE YEARS GAINED THROUGH TARGET YEAR		LIFE EXPECTANCY GAINS (YEARS)		
START AGE	END AGE	2020	2040	2020	2040	2010	2020	2040
30	39	17,000	18,000	260,000	620,000	0.65	0.87	0.91
40	49	60,000	71,000	910,000	2,300,000	0.63	0.84	0.88
50	59	150,000	180,000	2,000,000	5,400,000	0.59	0.79	0.84
60	69	330,000	380,000	3,500,000	11,000,000	0.53	0.71	0.76
70	79	470,000	840,000	5,000,000	20,000,000	0.44	0.59	0.64
80	89	470,000	1,200,000	6,000,000	23,000,000	0.32	0.43	0.48
90	99	320,000	800,000	3,600,000	14,000,000	0.19	0.25	0.27
100+		60,000	200,000	490,000	3,100,000	0	0	0
	Total	1,900,000	3,800,000	22,000,000	80,000,000			

Note: Column entries to not add to totals due to rounding. Life expectancy results are incremental period conditional life expectancy gains at the start age of the cohort.

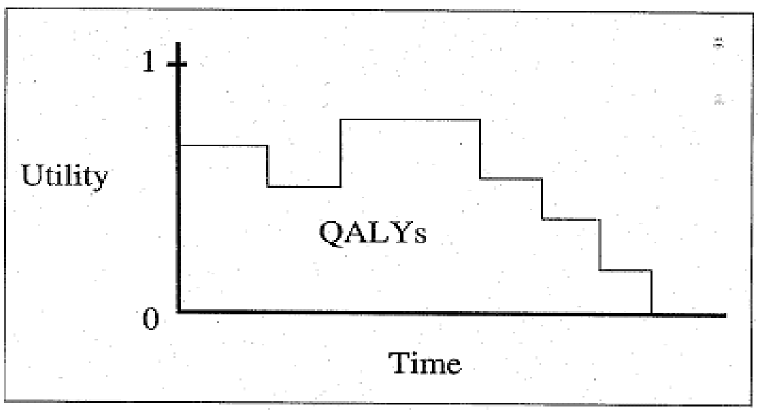


Figure: Determining Quality-Adjusted Survival—Length of life (time) is plotted against quality of life (utility). The area under the curve represents quality-adjusted survival measured in quality-adjusted life years (QALYs).

From Weeks 1995

- EPA estimates the median age of people who gain extra months of life from cleaner air is 79 years old.
- Adjustment of VSL for quality of life:
  - EPA VSL of $8,900,000 appropriate for healthy young adult (≈25)
  - 6:1 ratio for 25 vs. 80 year old
- Based on WTP studies, NOT economic value

Use of $PM_{2.5}$ in RIAs

- EPA uses estimates of benefits from reducing $PM_{2.5}$ in its RIAs for rulemakings under the Clean Air Act
  - This is called "co-benefits" because a $PM_{2.5}$ reduction is expected from efforts to reduce other air pollutants
- Trend towards using $PM_{2.5}$ as primary source of benefits in most RIAs since 1997
  - Even when regulation is not intended to protect public health from exposures to ambient $PM_{2.5}$

Table 2. Summary of Degree of Reliance on $PM_{2.5}$-Related Co-Benefits in RIAs Since 1997 for Major Non-$PM_{2.5}$ Rulemakings under the CAA
(RIAs with no quantified benefits at all are not in this table. Where ranges of benefit and/or cost estimates are provided, percentages are based on upper bound of both the benefits and cost estimates. Estimates using the 7% discount rates are used in all cases.)

Year	RIAs for Rules NOT Based on Legal Authority to Regulate Ambient $PM_{2.5}$	$PM_{2.5}$ Co-Benefits Are >50% of Total	$PM_{2.5}$ Co-Benefits Are Only Benefits Quantified
1997	Ozone NAAQS (.12 1hr=>.08 8hr)	×	
1997	Pulp&Paper NESHAP		
1998	NOx SIP Call & Section 126 Petitions		
1999	Regional Haze Rule	×	
1999	Final Section 126 Petition Rule	×	
2004	Stationary Reciprocating Internal Combustion Engine	×	
2004	Industrial Boilers & Process Heaters NESHAP	×	×
2005	Clean Air Mercury Rule	×	
2005	Clean Air Visibility Rule/BART Guidelines	×	
2006	Stationary Compression Ignition Internal Combustion		
2007	Control of HAP from mobile sources	×	×
2008	Ozone NAAQS (.08 8hr =>.075 8hr)	×	
2008	Lead (Pb) NAAQS	×	
2009	New Marine Compress'n-Ign Engines >30 L per	×	
2010	Reciprocating Internal Combustion Engines NESHAP	×	×
2010	EPA/NHTSA Joint Light-Duty GHG & CAFES		
2010	SO2 NAAQS (1-hr, 75 ppb)	×	> 99.9%
2010	Existing Stationary Compression Ignition Engines	×	×
2011	Industrial, Comm, and Institutional Boilers NESHAP	×	×
2011	Indus'l, Comm'l, and Institutional Boilers & Process	×	×
2011	Comm'l & Indus'l Solid Waste Incin. Units NSPS &	×	×
2011	Control of GHG from Medium & Heavy-Duty		
2011	Ozone Reconsideration NAAQS	×	
2011	Utility Boiler MACT NESHAP (Final Rule's RIA)	×	≥ 99%
2011	Mercury Cell Chlor Alkali Plant Mercury Emissions	×	
2011	Sewage Sludge Incineration Units NSPS & Emission	×	×
2011	Ferroalloys Production NESHAP Amendments	×	×

2009 Change in Methodology

From Smith, 2012 testimony

PM "Co-Benefits" in RIAs

	$PM_{2.5}$ NAAQS	Utility Boiler MACT	Mercury Air Toxics Standard	Sewage Sludge Incineration Units	Ferroalloy NESHAP	Total Costs millions ($2006)
Estimated Statistical Deaths	15,000	11,900	2,650	25	14	
Cost	6,400	10,600	9,329	17	4	26,350

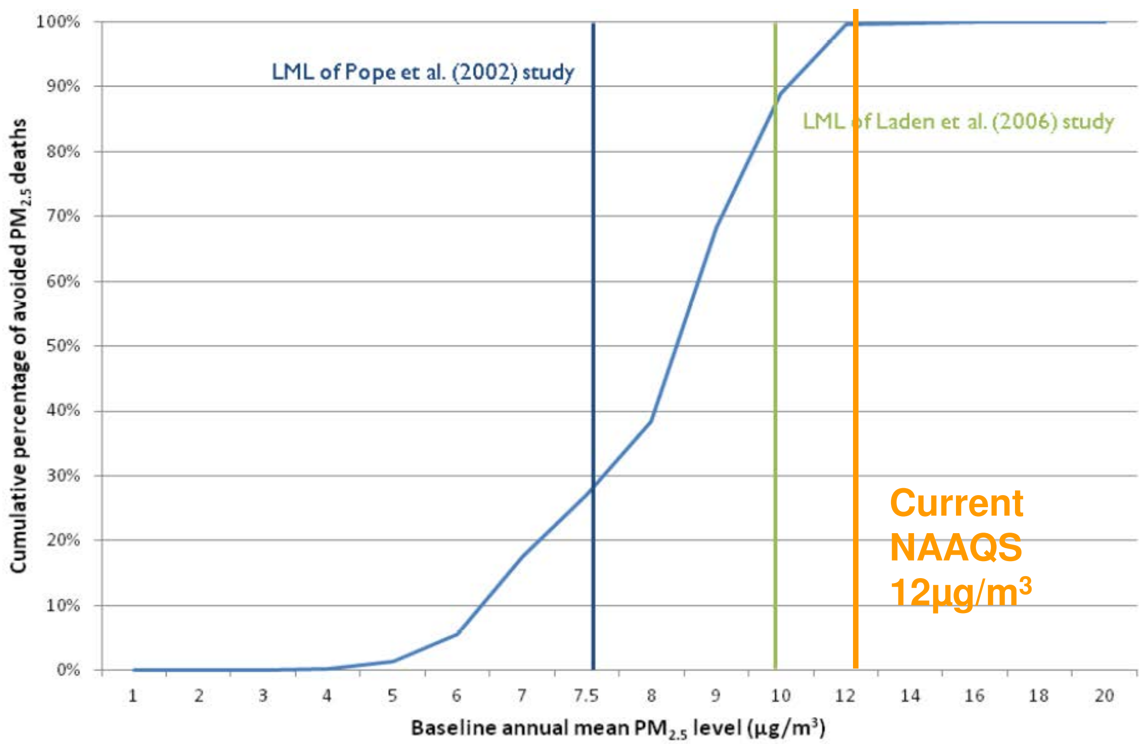
- Same statistical lives counted in multiple rules
- Different costs – unique to each rule

Risk Attributed to Ambient PM2.5

- "These benefits are incremental to an air quality baseline that reflects attainment with the 2006 $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS)", in other words EPA assumes risk from background levels.

  -*EPA, The Benefits and Costs of the Clean Air Act from 1990 to 2020, March 2011*

- ≈99% of the estimated mortality is due to concentrations less than the level deemed protective of public health.

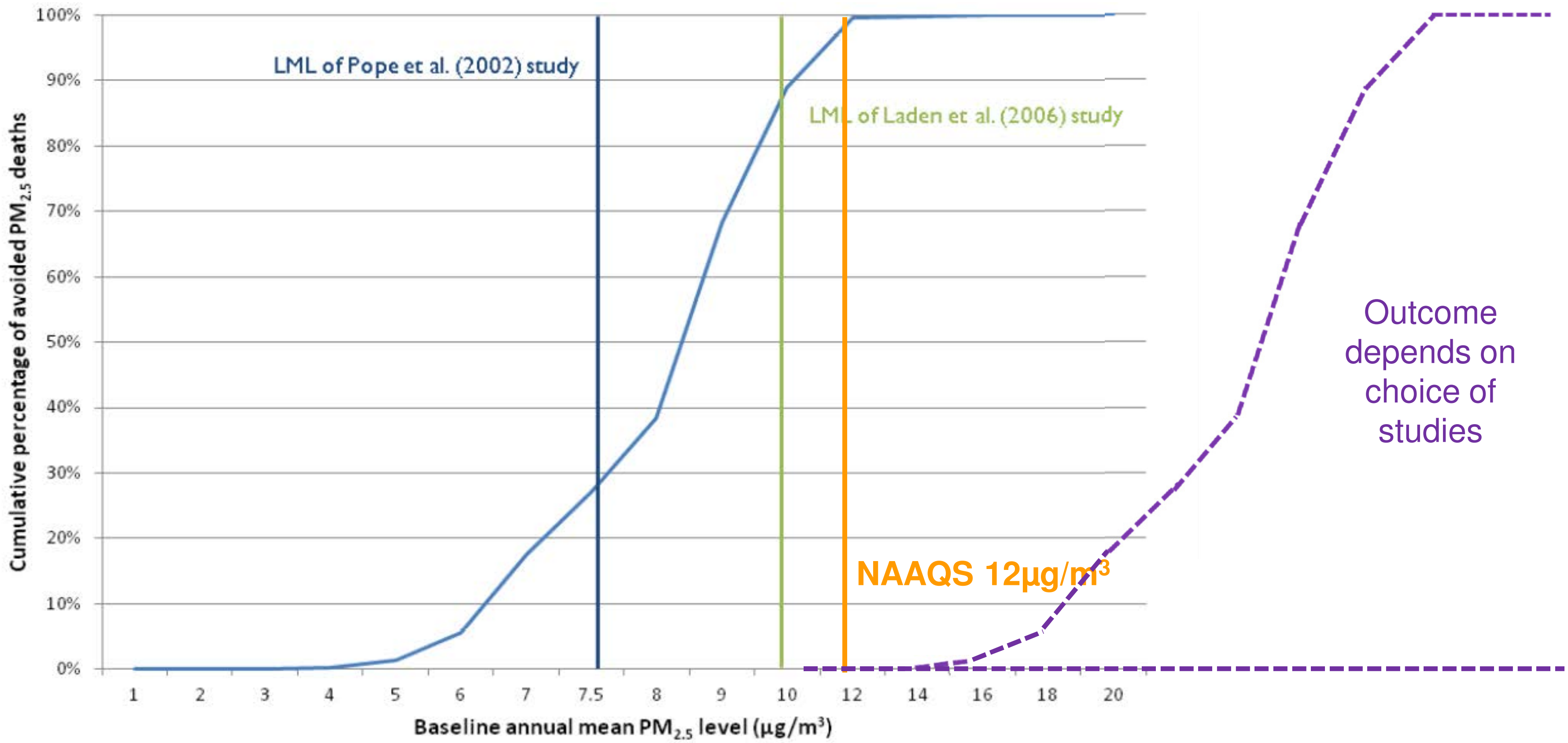


Of the total PM-related deaths avoided:

73% occur among population exposed to PM levels at or above the LML of the **Pope et al.** study.

11% occur among population exposed to PM levels at or above the LML of the **Laden et al.** study.

Risk Attributed to Ambient PM2.5



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EPA rules account for 64-87% of all "benefits" across all federal agencies

Report to Congress on the Benefits and Costs of Federal Regulations

2011

Office of Management and Budget
Office of Information and Regulatory Affairs

Table 1-1: Estimates of the Total Annual Benefits and Costs of Major Federal Rules by Agency, October 1, 2000 - September 30, 2010 (billions of 2001 dollars)

Agency	Number of Rules	Benefits ($ Billion)	Costs ($ Billion)
Department of Agriculture	6	0.9 to 1.3	1.0 to 1.34
Department of Energy	10	8.0 to 10.9	4.5 to 5.1
Department of Health and Human Services	18	18.0 to 40.5	3.7 to 5.2
Department of Homeland Security	1	< 0.1	< 0.1
Department of Housing and Urban Development	1	2.3	0.9
Department of Justice	4	1.8 to 4.0	0.8 to 1.0
Department of Labor	6	0.4 to 1.5	0.4 to 0.5
Department of Transportation (DOT)	26	14.6 to 25.5	7.5 to 14.3
Environmental Protection Agency (EPA)	32	81.8 to 550.7	23.3 to 28.5

Health Effects of Poverty and Unemployment

- Poverty and unemployment have been recognized as risk factors for morbidity and mortality since the 1800's (Virchow, 1848)
  - As of March 2012, there are 4,850 publications on this topic

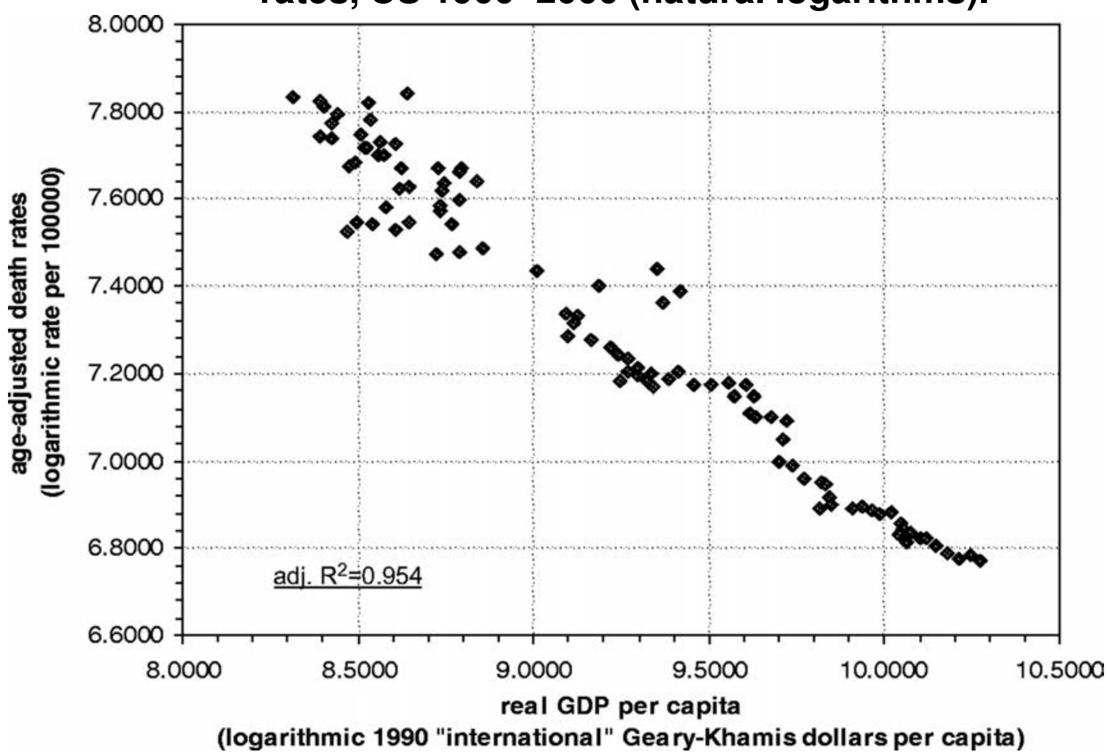
Unemployment and All-Cause Mortality

Meta-analyses stratified by gender and age [a]

Gender	Mean Age	HR (95% CI)
Women	Less than 40	1.73[b] (1.41, 2.11)
	40 to 49.9	1.34[b] (1.15, 1.56)
	50 to 65	0.94 (0.80, 1.11)
Men	Less than 40	1.95[b] (1.69, 2.26)
	40 to 49.9	1.86[b] (1.63, 2.12)
	50 to 65	1.17[c] (1.00, 1.36)

Roelfs et al. Soc Sci Med 2011; 72:840-54

Relation of real GDP per capita to age-adjusted death rates, US 1900–2000 (natural logarithms).



Brenner M H Int. J. Epidemiol. 2005;34:1214-1221