



Air Resources Board



Linda S. Adams
Secretary for
Environmental Protection

Mary D. Nichols, Chairman
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Arnold Schwarzenegger
Governor

September 9, 2010

Daniel S. Greenbaum, President
Health Effects Institute
101 Federal Way, Suite 500
Boston, Massachusetts 02110-1817

Dear Mr. Greenbaum:

Thank you for forwarding the analysis that Dr. Daniel Krewski conducted for the California Dump Truck Owners Association and other parties. We agree with your assessment and Dr. Krewski's that these analyses have very limited statistical power and utility due to the small number of cities (4 to 7) and participants (40,000 to 50,000) that could be included and the complete lack of peer review. You also note that the Health Effects Institute's (HEI) Research Committee would likely not have funded this analysis for these reasons. The 2009 study by Dr. Krewski and his colleagues that the U.S. Environmental Protection Agency used as the primary basis for a PM2.5 risk assessment of the entire U.S. and fifteen cities (including Los Angeles and Fresno) does not share these limitations. The 2009 Krewski study includes about 110 more cities and 450,000 more participants, and was peer reviewed through HEI's careful and thorough process.

We will honor your request to post your letter on ARB's webpage for our February 26, 2010 symposium on estimating premature deaths from long-term exposure to PM2.5. If you have any additional questions, please contact me at (916) 323-4519 or bcroes@arb.ca.gov.

Sincerely,

Bart E. Croes, P.E., Chief
Research Division

cc: Daniel Krewski, Ph.D., MHA
University of Ottawa

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, see our website: <http://www.arb.ca.gov>.

California Environmental Protection Agency

September 7, 2010

Mr. Bart Croes
Chief, Research Division
California Air Resources Board
1001 I Street
Sacramento, California 95814

Dear Bart,

I am forwarding results of analyses prepared by Dr. Daniel Krewski of a California-specific analysis of American Cancer Society (ACS CPS II) data for the California Metro Statistical Areas; this was follow-up to the work presented in HEI Research Report 140 using the same methods and approaches, and performed in response to a request to HEI for facilitating data access to this study by the California Dump Truck Owners Association and other parties.

The data underlying these analyses is owned by American Cancer Society which has provided access by specific investigators for researching particular research questions. The ACS was willing to provide permission for data access to Dr. Krewski for these additional analyses and he agreed to perform them. I am attaching a letter from Dr. Krewski which explains how the analyses were performed and limitations in their interpretation. Given potential broader interest in any such results, HEI is forwarding these supplementary analyses to CARB, with a request to post them on your website so that they are available to the larger community.

Dr. Krewski notes the limitations of conducting such an analysis with very limited statistical power; HEI's Research Committee would likely not have funded this analysis given its limited power and utility. I should also note that these specific supplementary results were not subjected to HEI's detailed and careful process by which we select research and investigators, engage outside data auditors to provide quality assurance, monitor progress of the research, independently review and evaluate every completed study, and prepare a commentary pointing to strengths and weaknesses of the study. In as much as this work was a direct extension of the research presented in Report 140 (which did go through our detailed research and review processes), and also based on our experience of working with Dr. Krewski in the past, we have no reason to believe anything but that the analyses were performed using all the appropriate methods and safeguards. Nevertheless, these results have not been subjected to the detailed scrutiny to which HEI would normally put any research that it sponsors.

Please let us know if you have any questions and thank you for your attention to post these on the ARB website.

Sincerely,



Daniel S. Greenbaum, President

Cc: Dr. Krewski, University of Ottawa
Dr. Thun, American Cancer Society



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August 31, 2010

Dan Greenbaum
President
Health Effects Institute
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Dear Dan,

In response to your request of April 30, and subsequent telephone discussions with senior staff at both the Health Effects Institute (HEI) and the American Cancer Society (ACS), I have prepared a number of supplementary analyses pursuant to the presentation that I made at the workshop sponsored by the California Air Resources Board (CARB) on February 26, 2010 in Sacramento.

These supplementary analyses are being provided to you with the approval of ACS in the interests of being responsive to requests received by HEI for additional California specific results. The supplementary analyses included Tables 1 and 2 attached are identical to national analyses given in Tables 33 and 34 in HEI Report No. 140, *Extended Follow-up and Spatial Analyses of the American Cancer Society Cohort Linking Particulate Air Pollution and Mortality*, published in May, 2009, but are specific to the State of California. The supplementary analyses for California were prepared using the same analytical methods used for the national analyses that are described in HEI Report No. 140, but are restricted to ACS participants residing in metropolitan statistical areas within California.

These analyses have been conducted by the McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa, and have not been reviewed by other members of the research team that prepared the national analyses summarized in our HEI Report. There will be no charges to HEI for preparing these results.

It is important to note that although these analyses show results for cardiopulmonary mortality that are similar to those in the national analysis, these analyses are subject to a number of limitations, the most important of which is the very small number of metropolitan statistical areas for which fixed site ambient monitoring data are available in California. A more fulsome analysis of the ACS data specific to California is currently being conducted under an agreement between CARB and the University of

California at Berkeley, for which Dr. Michael Jerrett is Principal Investigator. This analysis will involve a much more sophisticated assessment of exposure to ambient air pollution throughout California, thereby providing a firmer basis for the assessment of the impact of air pollution on population health in that state. The final report will include a detailed evaluation of the study results, which is necessary for a proper interpretation of the findings.

With the ongoing CARB sponsored study nearing completion, further ad hoc analysis of the ACS data of the type included in the attached two tables would appear to be counterproductive, and of limited utility for assessing the population health risks of ambient air pollution. As such, the McLaughlin Centre would prefer not to receive requests for additional ad hoc analyses of this type from HEI.

Having worked with the ACS data since 1998, we are aware of the challenges involved in analyzing, evaluating, and interpreting complex data of this type. If there remains interest in exploring regional variation in mortality associated with ambient air pollution within the United States, it might be preferable to address such variation on a national scale. However, this would be a nontrivial undertaking, which would require time and resources to complete.

I understand that HEI has made arrangements with CARB to have these supplementary analyses posted on their website.

With best regards,



Daniel Krewski, PhD, MHA
Professor and Director
MacLaughlin Centre for Population Health
Risk Assessment
University of Ottawa

Cc Dr. Michael Thun, American Cancer Society

Table 1

HRs by Cause of Death for a 10-ug/m³ Change in PM_{2.5} Covering Three Follow-Up Time Periods, Using the Same Number of MSAs and Study Participants Within PM_{2.5} Exposure Categories, and With and Without Adjustment for the Seven Ecologic Covariates (State of California)^{a,b}

Covariates in Model ^c	Follow-Up Through 1989		Follow-Up Through 1998		Follow-Up Through 2000	
	1979-1983	1979-1983	1979-1983	1999-2000	1979-1983	1999-2000
PM _{2.5}						
MSAs (n)	4	4	4	7	4	7
Participants (n)	40,408	40,408	40,408	50,930	40,408	50,930
All Causes						
44 Individual	0.872 (0.805, 0.944)	0.958 (0.914, 1.003)	0.958 (0.914, 1.003)	0.975 (0.918, 1.034)	0.960 (0.920, 1.002)	0.968 (0.916, 1.022)
+ 7 Ecologic	0.927 (0.830, 1.035)	0.950 (0.890, 1.014)	0.950 (0.890, 1.014)	0.976 (0.912, 1.045)	0.949 (0.894, 1.008)	0.960 (0.902, 1.022)
CPD						
44 Individual	0.985 (0.877, 1.106)	1.056 (0.988, 1.128)	1.056 (0.988, 1.128)	1.101 (1.012, 1.197)	1.053 (0.991, 1.119)	1.084 (1.003, 1.171)
+ 7 Ecologic	1.119 (0.955, 1.311)	1.089 (0.995, 1.193)	1.089 (0.995, 1.193)	1.104 (1.003, 1.216)	1.081 (0.995, 1.175)	1.075 (0.984, 1.174)
IHD						
44 Individual	1.034 (0.876, 1.220)	1.126 (1.021, 1.242)	1.126 (1.021, 1.242)	1.306 (1.153, 1.480)	1.126 (1.028, 1.233)	1.258 (1.121, 1.410)
+ 7 Ecologic	1.131 (0.899, 1.422)	1.150 (1.005, 1.316)	1.150 (1.005, 1.316)	1.332 (1.155, 1.537)	1.144 (1.010, 1.296)	1.250 (1.097, 1.425)
Lung Cancer						
44 Individual	0.630 (0.485, 0.818)	0.887 (0.751, 1.046)	0.887 (0.751, 1.046)	0.889 (0.720, 1.099)	0.902 (0.772, 1.054)	0.900 (0.738, 1.097)
+ 7 Ecologic	0.746 (0.518, 1.074)	0.944 (0.750, 1.188)	0.944 (0.750, 1.188)	0.891 (0.699, 1.134)	0.941 (0.759, 1.168)	0.877 (0.700, 1.099)
All Other Causes						
44 Individual	0.797 (0.704, 0.901)	0.849 (0.789, 0.914)	0.849 (0.789, 0.914)	0.841 (0.765, 0.924)	0.856 (0.800, 0.916)	0.843 (0.773, 0.920)
+ 7 Ecologic	0.757 (0.635, 0.901)	0.780 (0.702, 0.866)	0.780 (0.702, 0.866)	0.849 (0.762, 0.947)	0.788 (0.715, 0.867)	0.847 (0.767, 0.936)

^a The analyses included in the above table are identical to national analyses given in Table 33 in HEI Report No. 140, *Extended Follow-up and Spatial Analyses of the American Cancer Society Cohort Linking Particulate Air Pollution and Mortality*, published in May, 2009 by the Health Effects Institute, but are specific to the State of California.

^b Based on a standard Cox model with the 44 individual-level covariates with and without adjustment for the seven ecologic covariates at MSA & DIFF levels. The baseline hazard function was stratified by age (1-year groupings), gender, and race. All analyses were conducted using the same 4 MSAs (40,408 participants) (Los Angeles, San Diego, San Francisco, San Jose) or 7 MSAs (50,930 participants) (Los Angeles, San Diego, San Francisco, San Jose, Fresno, Riverside, Sacramento) from the state of California. HRs are followed by 95% confidence intervals.

^c Data for the 44 individual-level covariates are from the ACS enrollment questionnaire. Data for the seven ecologic covariates were extracted from the 1980 U.S. Census Bureau database for the Nationwide Analysis of the current study.

Table 2

HRs by Cause of Death for a 10-ug/m³ Change in PM_{2.5} Based on Either a Standard Cox or a Random Effects Cox Model Covering Three Follow-Up Time Periods and Using the Same or Different Numbers of MSAs and Participants (State of California)^{a,b}

Model and Number of MSAs	Follow-Up Through 1989 ^c		Follow-Up Through 1998 ^d		Follow-Up Through 2000 ^e	
	1979-83	1979-83	1979-83	1979-83	1979-83	1999-2000
PM _{2.5} data						
Same ^f						
MSAs	4	4	7	4	7	
Participants	40,408	40,408	50,930	40,408	50,930	
Different ^f						
MSAs	4	4	7	4	7	
Participants	38,925	42,720	53,827	40,408	50,930	
All Causes						
Standard Cox						
Same	0.872 (0.805, 0.944)	0.958 (0.914, 1.003)	0.975 (0.918, 1.034)	0.960 (0.920, 1.002)	0.968 (0.916, 1.022)	
Different	0.893 (0.823, 0.969)	0.864 (0.798, 0.934)	0.861 (0.778, 0.952)			
RE Model						
Same	0.872 (0.805, 0.944)	0.958 (0.914, 1.003)	0.981 (0.903, 1.066)	0.960 (0.920, 1.002)	0.973 (0.899, 1.054)	
Different	0.893 (0.823, 0.969)	0.864 (0.798, 0.934)	0.868 (0.767, 0.983)			
CPD						
Standard Cox						
Same	0.985 (0.877, 1.106)	1.056 (0.988, 1.128)	1.101 (1.012, 1.197)	1.053 (0.991, 1.119)	1.084 (1.003, 1.171)	
Different	0.985 (0.874, 1.109)	0.970 (0.865, 1.088)	0.960 (0.830, 1.111)			
RE Model						
Same	0.985 (0.877, 1.106)	1.056 (0.988, 1.128)	1.101 (1.012, 1.197)	1.053 (0.991, 1.119)	1.084 (1.003, 1.171)	
Different	0.985 (0.874, 1.109)	0.970 (0.865, 1.088)	0.960 (0.830, 1.111)			
IHD						
Standard Cox						
Same	1.034 (0.876, 1.220)	1.126 (1.021, 1.242)	1.306 (1.153, 1.480)	1.126 (1.028, 1.233)	1.258 (1.121, 1.410)	
Different	1.034 (0.874, 1.223)	1.016 (0.864, 1.195)	1.151 (0.939, 1.411)			
RE Model						
Same	1.034 (0.876, 1.220)	1.126 (1.021, 1.242)	1.364 (1.132, 1.644)	1.126 (1.028, 1.233)	1.299 (1.086, 1.554)	
Different	1.034 (0.874, 1.223)	1.016 (0.864, 1.195)	1.246 (0.946, 1.642)			
Lung Cancer						
Standard Cox						
Same	0.630 (0.485, 0.818)	0.887 (0.751, 1.046)	0.889 (0.720, 1.099)	0.902 (0.772, 1.054)	0.900 (0.738, 1.097)	
Different	0.598 (0.460, 0.777)	0.620 (0.478, 0.805)	0.554 (0.398, 0.771)			

RE Model									
Same	0.630 (0.485, 0.818)	0.887 (0.751, 1.046)	0.889 (0.720, 1.099)	0.902 (0.772, 1.054)	0.900 (0.738, 1.097)				
Different	0.598 (0.460, 0.777)	0.620 (0.478, 0.805)	0.554 (0.398, 0.771)						
All Other Causes									
Standard Cox									
Same	0.797 (0.704, 0.901)	0.849 (0.789, 0.914)	0.841 (0.765, 0.924)	0.856 (0.800, 0.916)	0.843 (0.773, 0.920)				
Different	0.849 (0.747, 0.964)	0.789 (0.699, 0.891)	0.808 (0.690, 0.947)						
RE Model									
Same	0.797 (0.704, 0.901)	0.849 (0.789, 0.914)	0.848 (0.746, 0.965)	0.856 (0.800, 0.916)	0.847 (0.766, 0.937)				
Different	0.849 (0.747, 0.964)	0.789 (0.699, 0.891)	0.816 (0.595, 1.121)						

^a The analyses included in the above table are identical to national analyses given in Table 34 in HEI Report No. 140, *Extended Follow-up and Spatial Analyses of the American Cancer Society Cohort Linking Particulate Air Pollution and Mortality*, published in May, 2009 by the Health Effects Institute, but are specific to the State of California.

^b Models included the 44 individual-level covariates. The baseline hazard function was stratified by age (1-year groupings), gender, and race. HRs are followed by 95% confidence intervals.

^c Follow-up period used for the Reanalysis Project (Krewski et al. 2000).

^d Follow-up period used for the Updated Analysis (Pope et al. 2002, 2004).

^e Follow-up period used for this Extended Analysis.

^f Rows marked "Same" use the MSAs and participants from the current Nationwide Analysis (state of California Only). Rows marked "Different" use the MSAs and participants included in the earlier analyses (as outlined in Table 32).