Public Workshop on Updating the Methodology for Estimating Premature Death Associated with PM2.5 Exposures

August 21, 2006

Sacramento, California

Air Resources Board

Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

Agenda Summary

- Background on ARB's health impacts analysis
- U.S. EPA's expert elicitation
- Overview of ARB's analysis plan
- Public comments and questions
- Conclusions

ARB's Health Impacts Analysis

- Estimate health impacts due to air quality levels that do not meet State ambient air quality standards for ozone and PM
- Estimate benefits associated with proposed diesel PM regulations to reduce emissions
  - Numerous diesel PM airborne toxic control measures
  - Ports and Goods Movement emissions reduction plan

Why Update the Methodology?

- Pope 2002 (ACS) study for premature death and PM2.5 used by ARB
- New studies emerged since 2002
  - Jerrett 2005: subset of ACS in Los Angeles region
  - Laden 2006: follow-up to Harvard 6-cities
  - Intervention studies
- Need to consider all health studies on the subject

Advisors

- Dr. Jonathan Levy, Harvard University
- Dr. Bart Ostro, Office of Environmental Health Hazard Assessment
- Dr. Arden Pope, Brigham Young University

U.S. EPA's Expert Elicitation

- Formal process to capture the current state of knowledge on PM-mortality relationship
- Draws on a wide array of evidence

EPA's Expert Elicitation of the Association of $PM_{2.5}$ Exposures to Mortality

Presented to:
California Air Resources Board
Public Workshop
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Outline

- Background on Expert Elicitation
- EPA's use of Expert Elicitation to Characterize Uncertainty
- How We Conducted the new PM-Mortality Expert Elicitation

Background

- Congress asked the National Academies of Science (NAS) to review how EPA estimates the benefits of air pollution regulations
- NAS completed their Report to Congress in 2002
  - Commends EPA on the approach to estimating PM benefits
  - Well thought-out and scientifically defensible
- Key finding in NAS report is that EPA could improve upon its characterization of uncertainty
  - Recommends more exploration of quantified approaches to fully characterize uncertainty
    - Typically using empirical data from statistical analyses
    - Provide the Expected Outcome (the mean or average) and the uncertainty range around that estimate
      - Expressed in a distribution of probabilities of each outcome
  - Probability distributions should be obtained from experts where data are limited, or where understanding precludes the use of conventional statistical techniques. NAS specifically states:
    - Expert elicitation recommended as one of several methods to characterize uncertainty in benefit analyses
    - When expert judgment is used, it should be clearly identified and rationales and bases for judgments should be made available
    - Expert Elicitation results should be compared to empirically-derived results when possible

What is Expert Elicitation?

- Eliciting the judgments of experts on a topic using a survey instrument
  - A protocol provides the script for questions to ask of the experts
    - Well-thought out; passes clairvoyance test; avoids biases or leading questions
  - Experts use empirical data from a variety of sources, past experience, and judgment in giving their answer
- Expert Judgment is a quantitative expression of what an expert knows and doesn't know about a subject
- Judgment expressed as probabilities - degree of belief
- Also provides a description of the underlying basis for their judgment – evidence, theory

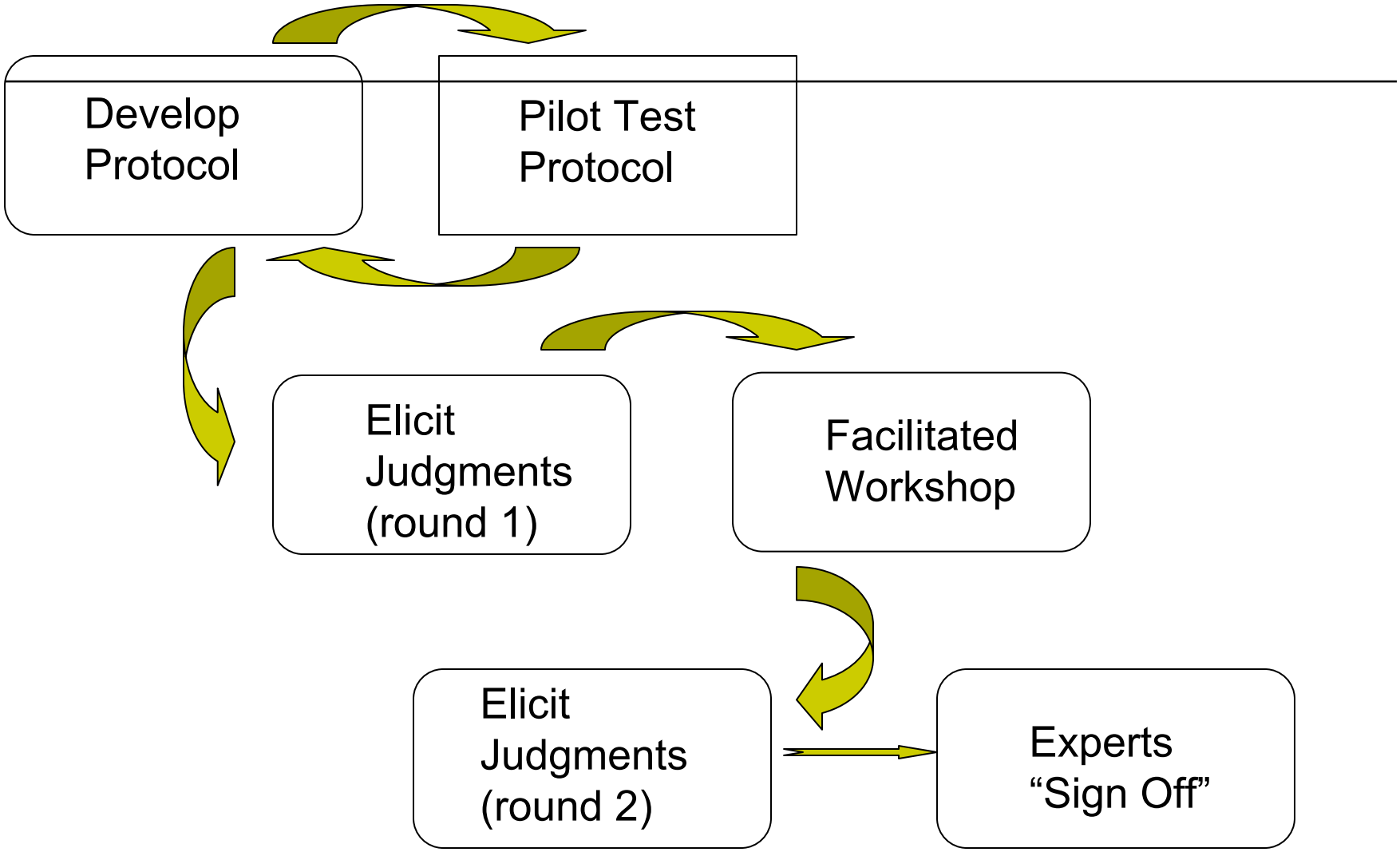
EPA'S History using Expert Elicitation

- ***OAQPS lead (Pb) health effects for ambient standards review (1985-1986)***
- ***OAQPS ozone chronic lung injury (1990-1992)***
- ***OAQPS/OMB Pilot Elicitation: particulate matter short- and long-term exposure mortality (2004)***
  - Pilot-scale project completed in one-year period
    - Small panel of experts selected from two known NAS committees
    - Truncated time precludes holding planning workshops to evaluate and inform development; or to explain expectations and prepare experts for the elicitation interview
    - Final report available at: www.epa.gov/ttn/ecas/benefits.html
- Why did we pick the PM2.5-mortality function for an elicitation?
  - Accounts for 85 – 95% of total benefits
  - Many empirical studies available, but no one study is able to capture the suite of issues surrounding the mortality estimate

Design Elements of an Elicitation

- Problem Definition -- Decision on Scope and Focus
- Protocol Development
  - Introduction: purpose and goal of elicitation
  - Background: scenario description, trends in air quality
  - Factors to consider relating to the estimation of PM-related mortality
  - Elicitation questions – quantitative probabilistic distributions
- Expert Selection
- Briefing Book
- Test Run of Protocol
- Pre-Elicitation Workshop
- Elicit Judgments
- Post-Elicitation Workshop
- Analysis of Results
- Peer Review

The Encoding Process



Scope and Focus of the PM-Mortality Elicitation

- To elicit judgments of the concentration-response function for mortality associated with exposures to annual PM2.5, including a probabilistic distribution of uncertainty.
  - Experts consider the influence of both short-term exposures and long-term exposures in providing an overall response.
  - Separate qualitative and quantitative questions on key factors considered in determining the overall response
    - Key studies used in forming their judgment
    - Detailed information on confounding, causality, and mechanisms, and effect modification
    - Shape of the Function and potential for thresholds

Protocol Development

- Improved upon experience from a Pilot Expert Elicitation completed in 2004
- Key assumptions prior to eliciting judgments
  - PM differs by location, however, we are eliciting views that can be applicable to the U.S. in general (all locations) – experts were to consider effects from high PM concentrations as well as low concentrations
  - EPA's intent was expressed in terms of uncertainty characterization in benefit analyses
    - Experts were told that the results would not be used for the setting the PM NAAQS standard
- Clearly defined questions for Factors to Consider
  - Effect Modification
  - Confounding
  - Exposure Misclassification
  - Causality – semi-quantitative format
  - Shape of C-R function & thresholds in effect

Development History

- Protocol development started in 2004 with input from health experts from EPA's Office of Research and Development, EPA'S Office of Air Quality Planning Standards; academia; as well as input from elicitation experts from OAQPS and academia
- Technical reviews by outside experts at a Symposium (April 2005)
- Test Run of the Protocol with independent, in-house experts
- Contracted with an elicitation expert, Dr. Katherine Walker, and a subject matter expert, Dr. Patrick Kinney, to conduct the elicitation

Briefing Book

- EPA's PM Criteria Document (CD)
- EPA's Air Quality Trends Report
- Articles on PM mortality issued after final CD
- WHO Report on PM and Ozone
- Committee on the Medical Effects of Air Pollution (COMEAP) Annual Report
- Also allowed for experts to identify additional relevant items - shared with all participating experts

What We Asked Experts to Provide – The Elicitation Question

- "What is your estimate of the true percent change in annual, all-cause mortality in the adult U.S. population resulting from a permanent 1 μg/m3 reduction in annual average ambient PM2.5 across the U.S.? In formulating your answer, please consider mortality effects of both reductions in long-term and short-term exposures. To characterize your uncertainty in the concentration-response relationship, please provide the 5th, 25th, 50th, 75th, and 95th percentiles of your estimate."

How We Selected Experts

- White Paper evaluated the optimal number of experts to select
  - Determined that 7 – 10 experts is typical in most elicitations
  - We chose to select 12 experts in a two-phase process
- Phase 1: Peer Nomination process
    - Harvard database of literature/authors
    - Ranking of nominees based on number of publications
  - Nominees provided lists of experts in four Categories for Nominations
    - Epidemiology
    - Toxicology
    - Up-and-Coming new scientists
    - PM policy experts
  - Nine experts selected (8 epidemiologists, 1 toxicologist)
- Phase 2: Peer Nomination for toxicologists
  - HEI nominated a list of 10 individuals from which we randomly selected 3 experts
- OVERALL: We selected 8 epidemiologists, 3 toxicologists/health scientists, and 1 clinician

Participating Experts

NAME	AFFILIATION
Dockery, Doug W.	Harvard School of Public Health
Ito, Kazuhiko	New York University School of Medicine
Krewski, Daniel	University of Ottawa
Kuenzli, Nino*	University of Southern California Keck School of Medicine (currently at Institut Municipal d'Investigació Mèdica - Center for Research in Environmental Epidemiology, Barcelona , SPAIN)
Lippmann, Morton	New York University School of Medicine
Mauderly, Joe	Lovelace Respiratory Research Institute
Ostro, Bart D.	California Office of Environmental Health Hazard Assessment
Pope, C. Arden III	Brigham Young University
Schlesinger, Richard	Pace University
Schwartz, Joel	Harvard School of Public Health
Thurston, George D.	New York University School of Medicine
Utell, Mark	University of Rochester School of Medicine and Dentistry

* Dr. Kuenzli was based in the U.S. at the time of expert selection, and subsequently began a sabbatical in Barcelona midway through the project.

Results & Peer Review

- Draft Report undergoing internal EPA review
- Peer Review begins August 25
  - Review of design and conduct of the elicitation
- Five reviewers have been selected
- Final report is expected by late September
  - Report of design, conduct, and findings by Industrial Economics, Inc. (IEc, 2006)
  - Peer Review report (RTI, 2006)
  - Application in the Benefits Chapter of the PM NAAQS RIA (EPA, 2006)

More Information:

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  Website of findings:
  www.epa.gov/ttn/ecas

Overview of ARB's Analysis Plan

- Develop a credible range
- Conduct sensitivity analysis
- Peer review evaluation
- Timeline

Develop a Credible Range

- Based on 12 distributions from EPA's elicitation process
  - Mean value describes central tendency
  - High and low values represent a reasonable uncertainty range
- Similar to ARB/OEHHA's derived range on the relationship between short-term exposures to ozone and premature death*

*Ostro B.; Tran H.; Levy J. The Health Benefits of Reduced Tropospheric Ozone in California, *JAWMA*, **2006**: 56, 1007-1021.

Sensitivity Analysis

- Pooling of 12 distributions by
  - Simple average
  - Monte Carlo methods
- Pooling of distributions without outliers
- Calculations based on actual study results

Peer Review Evaluation

- Independent evaluation of ARB's interpretation of expert opinions
  - *Has ARB staff applied the results in a reasonable manner?*
  - *Can these results be applied in a regulatory setting?*
- Currently working with University of California at Berkeley to select a peer review panel

Key Steps in ARB's Update of Methodology

Tentative Timeline

August 21, 2006	Public Workshop
October 2006	Draft report released
November 2006	Deadline for public comments
December 2006	Deadline for peer review comments
January 2007	Final staff report released
February 2007	Board update

Contact Information

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