Models for Funding and Implementing Coordinated Research
The Case of Air Pollution and Health

Dan Greenbaum, President
Health Effects Institute

Beebe Symposium
Future of Low Dose Radiation Research in the United States
National Academies of Science, Engineering, and Medicine
May 9, 2019
Models for Funding and Implementing Coordinated Research
*The Case of Air Pollution and Health*

- Setting the Context: Creating the Strategic and Funding Climate for Research
- Two Examples:
  - The NRC Committee on Research Needs for Airborne Particulate Matter
  - The Health Effects Institute
- Concluding Thoughts
Setting the Context…

• Key elements that can lead to sustained funding of research to inform public health and environmental policy:
  • First, it helps to have controversy and a need for better science...
  • Second, identifying and/or creating a trusted institution to
    • Organize the scientific community to identify the highest priority research needs
    • Build a strategic plan for investment in the research
    • Implement and/or monitor progress
  • Third, a sustained effort to communicate results to key audiences,
    • And continue to identify remaining gaps....
A Multi-Year Program of Research on Airborne Particulate Matter

• The Genesis: Regulatory Controversy...
  • 1997 EPA proposal for a new National Ambient Air Quality Standard for fine particulate matter (PM2.5)
  • Limited science in place; a highly controversial proposal
  • Consensus by all parties – agencies, industry, environmentalists, scientists - that further research was needed
“To this end, the conferees have included bill language which specifically provides $49,600,000 for particulate matter research, and further provides that within 30 days of enactment of this Act, EPA shall enter into a contract or cooperative agreement with the National Academy of Sciences (NAS) to develop a comprehensive, prioritized, near- and long-term particulate matter research program, as well as a plan to monitor how this research program is being carried out by all participants in the research effort. The conferees intend the NAS to develop a near-term research plan within four months of execution of the contract with EPA and expect a long-term plan to be completed within twelve months of execution of the contract. Both plans should be developed on as close to a consensus basis as is practicable following consultation and comprehensive discussions with, but not limited to, representatives of the EPA, the National Institute of Environmental Health Sciences (NIEHS), the Department of Energy (DOE), and the National Oceanic and Atmospheric Administration (NOAA), as well as representatives from such organizations as the Health Effects Institute (HEI), the North American Research Strategy for Tropospheric Ozone (NARSTO), the Chemical Industry Institute of Technology (CIIT), the Lovelace Inhalation Toxicology Research Institute, the American Lung Association, the Electric Power Research Institute (EPRI), EPA’s Science Advisory Board and Clean Air Scientific Advisory Committee, and other qualified personnel representing government, industry, and the environmental community. Upon completion of the research plans, the NAS shall simultaneously provide copies to the Congress, to EPA, and to all participating parties.”
This 1997 Controversy launched extensive new research planning – The National Research Council’s PM Committee – as well as extensive research
Committee Membership

Jonathan Samet (Chair), Johns Hopkins University, Baltimore, MD

Judith Chow, Desert Research Institute, Reno, NV

Bart Croes, California Air Resources Board, Sacramento

Robert Forster, University of Pennsylvania, Philadelphia

Daniel Greenbaum, Health Effects Institute, Boston, MA

Philip Hopke, Clarkson University, Potsdam, NY

Petros Koutrakis, Harvard University, Boston, MA

Daniel Krewski, University of Ottawa, ON

Paul Lioy, University of Medicine and Dentistry of New Jersey, Piscataway

Joe Mauderly, Lovelace Respiratory Research Institute, Albuquerque, NM

Roger McClellan, Albuquerque, NM

Günter Oberdörster, University of Rochester, NY

Rebecca Parkin, The George Washington University Medical Center, Washington, DC

Joyce Penner, University of Michigan, Ann Arbor

Richard Schlesinger, Pace University, New York, NY

Frank Speizer, Harvard Medical School, Boston, MA

Mark Utell, University of Rochester, NY

Ronald White, Johns Hopkins University, Baltimore, MD

Warren White, University of California, Davis

Ronald Wyzga, Electric Power Research Institute, Palo Alto, CA

Terry Yosie, American Chemistry Council, Arlington, VA
Committee’s Four Reports

First report, March 1998
Presented a conceptual framework and recommendations for a 13-year integrated research program relevant to evaluating, setting, and implementing PM NAAQS.

Second report, August 1999
Updated the research portfolio and discussed the criteria and approaches that the committee planned to use in evaluating research progress over the next few years.

Third report, January 2001
Assessed initial research progress made in addressing key scientific uncertainties for PM regulation.

Final report, March 2004
Further evaluation of PM research progress.
The Key Criteria for Identifying Priorities

- Scientific Value
- Decision-making Value
- Feasibility and Timing
Research Priorities Recommended by the Committee

Research Topic 1. Outdoor Measures Versus Actual Human Exposures
Research Topic 2. Exposures of Susceptible Subpopulations to Toxic Particulate Matter Components
Research Topic 3. Characterization of Emission Sources
Research Topic 4. Air Quality Model Development and Testing
Research Topic 5. Assessment of Hazardous Particulate Matter Components
Research Topic 6. Dosimetry: Deposition and Fate of Particles in the Respiratory Tract
Research Topic 7. Combined Effects of Particulate Matter and Gaseous Pollutants
Research Topic 8. Susceptible Subpopulations
Research Topic 10. Analysis and Measurement
A General Framework for Integrating PM Research

Sources of airborne PM or gaseous precursors → Ambient PM → Personal exposure → Dose to target tissues → Human health response

Topic 3
Topic 4
Topic 1
Topic 2
Topic 6
Topic 5
Topic 7
Topic 8
Topic 9
Topic 10
A 13-year Plan for Research

With estimated costs

Staged to answer questions in logical order

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*The committee's rough but informed collective-judgment cost estimates for the highest-priority research activities recommended in this report. See Chapter 4 for explanations.
**Research management includes research planning, budgeting, oversight, review, and dissemination, cumulatively estimated by the committee at 10% of project costs.
**EPA Funding for PM Research and Related Technical Work (in millions of dollars)**

*From the 4th report (2004); Funding Continues to this day (~$95 million in FFY 2019)*

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<td>62.4</td>
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MANAGING SCIENCE TO ADDRESS THE KEY QUESTIONS

• Committee sought, and obtained, first EPA Multi-Year Research Program (MYP) ever
  • With National Program lead and integration of extramural and intramural programs into one plan
  • First for PM, has continued to this day for the Air and Energy program
  • And extended throughout EPA research program with National Leads and MYPs for Water, Chemical Risk, Sustainable Communities, and more.

• Committee also sought a better integrated national program across all agencies (e.g. DOE, NOAA, NIEHS, NSF, others)
  • That was NOT as successful – multiple priorities and complicated funding
In Sum

- Controversy generated interest in and funding for targeted research on a wide range of topics
- A carefully drawn, multi-year plan guided investment
- Expert plan development and continued monitoring of progress enhanced the credibility of the results
- Improvement occurred not just in knowledge but in the way science was managed over multiple years
  - i.e. the MYPs and also the HERO evergreen database of all relevant and environment and health literature
- And continued attention to the regulatory issues has sustained financial support
The Health Effects Institute
A Public-Private Model to Obtain Impartial Science
HEI - The Idea

• 1977: Clean Air Act Requirements (s.202a4)
  • Auto companies to test health effects of emissions
  • EPA-Industry relationship poor
    • Dueling, defensive science
    • Not advancing understanding
• 1978-79: EPA Administrator and Industry CEOs
  • There must be a better way to produce science we can trust
• 1980: The Health Effects Institute launched
About the Health Effects Institute

Nearly 40 years providing impartial, high-quality science on health effects of air pollution to inform often controversial decisions

Initially, and still today, joint core funding (~$10 million/year) from:
  Government (U.S. EPA)
  Industry (Worldwide Vehicle and Engine Manufacturers)

Also expanded partnerships with:
  European Union, WHO, California, other agencies
  Oil (API, CONCAWE), Chemical, other industries
  Foundations, Development Banks (Global Work)

HEI structured to maintain credibility & transparency
  Balanced government and industry funding
  Independent Board and Expert Science Committees
    Board agreed to by EPA Administrator and core industry sponsors
    Board appoints:
      Research Committee selects all research competitively
      Separate Review Committee intensively peer reviews all results
    All results and data – both positive and negative – reported

Does not take policy positions

Trusted Science ● Cleaner Air ● Better Health
Targeted Research and Reanalysis
Over 350 Studies on a wide variety of air pollutants: PM, ozone, diesel, air toxics, others
Exposure, Toxicology, Epidemiology
Accountability Research

Rapid Scientific Review
E.g. The Health Effects of Exposure to Traffic

Global Health
North America, Europe
Developing Asia

NEW Energy Research Program
Potential Exposures and effects from unconventional oil and gas development
HEI Organization: Research Committee

Impartial, internationally-regarded subject experts
  Exposure, biostatistics, medicine, epidemiology, engineering

Responsibilities:
  Identifies research agenda (Five Year Strategic Plan)
  Prepares Requests for Applications
  Selects investigators through competitive process
    • Intensively oversees quality and timeliness of research
    • Independent QA/QC Audits, Site Visits
    • Detailed report by investigators

Current Chair Dr. David Savitz, Brown University
HEI Organization: Review Committee

Separate panel of respected, impartial experts
All of the same expertise as the Research Committee
But no involvement in selection or oversight of HEI research projects

Responsibilities
Independently peer review comprehensive reports of studies
Publish detailed critique of studies
Publish detailed commentary outlining:
• how research has or has not contributed to the state of knowledge in a given area, and
• the implications for policy/regulations

Current Chair Dr. James Merchant, University of Iowa
HEI’s Strategic Plan

Guides HEI’s research and review activities;

Responds to the needs of HEI industry & government sponsors, and other interested parties;

Anticipates future policy and technology events; and,

Evolves over time to adapt to changing knowledge and events.
Choosing the Future

**POTENTIAL TOPICS**

**Major Opportunities**
- Informing Tough Upcoming NAAQS/Limit-Values Decisions
  - Effects of long-term exposure to low levels of air pollution
  - Further analyses in the NPACT and ESCAPE studies
  - Cardiovascular effects of ozone
- Examining Exposure and Health Related to Traffic and Ports
  - Enhanced and innovative exposure assessment
  - New health studies of road and port exposures
  - Evaluation of sensitive populations
  - Exposure components of special interest
  - A possible updated HEI Traffic Special Review
- Improving Science for Decisions: Accountability and Transparency
  - New methods
  - At-risk communities
  - Improving transparency and data access
- Climate, Air Quality, and Health
  - Evaluation of fuel-efficient vehicles
  - Global decisions on air quality and climate

**STRATEGIC PLANNING PROCESS**

**Input from**
- Sponsors
  - U.S. EPA
  - Motor vehicle industry
  - Oil and other industries
- HEI scientific committees and board
- The scientific community
- The environmental community
- International agencies
- Others

**Selection criteria:**
- Importance to
  - Public health
  - Regulation and technology (short- and long-term)
  - Science
- Research activities by others

**THE HEI STRATEGIC PLAN 2015–2020**

...and beyond

**Informing Decisions on Air Quality and on Climate-Driven Technology**
- Multipollutant Science (low dose, statistics, traffic)
- Accountability and Transparency
- Emerging Fuels and Technologies
- Global Health Science
- Cross-Cutting Issues
  - Statistical models
  - At-risk populations
  - Enhanced exposure
  - Climate change
  - New biologic techniques
  - New health outcomes

**Lower-Priority Items**

(which will not be a focus)
- Single-pollutant research programs
- Life-cycle analysis
- Broader climate change issues and effects
The HEI Strategic Plan 2015–2020... and beyond

Informing Decisions on Air Quality and on Climate-Driven Technology

Cross-cutting Issues

- Multipollutant Science (Low Dose, Traffic Statistics)
- Accountability, Transparency
- Fuels and Technologies
- Global Science (E.U., Asia)

Better Decisions

- Air Quality Standards (U.S., E.U., Asia)
- Vehicle Fuels and Emissions
- Vehicle GHG Standards
- GHG Source Health Effects

Statistical Models, At-Risk Populations, Enhanced Exposure Assessment, Climate Change, New Biologic Techniques, and New Health Outcomes
Implementation of the Strategic Plan 2015 – 2020

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**Multipollutant Science**

- Complete MOSES: Review, publish, and disseminate
- Complete traffic exposure studies: Publish and disseminate
- Effects at low levels: Select studies, Conduct research, Publish and disseminate
- Plan for mid-term Committee and mid-updates of Traffic Review
- Workshop on research carried out in IMPACT and ESCAPE
- Communicates Diesel Epidemiology Review results
- Complete Second-Wave Health Outcomes studies
- Accountability Workshop: Synthesize new studies on long-term interventions and effects, Continue new methods development, Publish and disseminate
- Synthesis of past decade of accountability research: Lessons for future actions

**Emerging Fuels and Technologies**

- Communicates ACE results
- Special Committee on Emerging Technologies, monitor key fuel and technology developments
- Exports review and identify best techniques for comparative toxicity screening: Inhale proof-of-concept testing: Disseminate
- Workshop/review Aromatics and PM
- Workshop/review CIDI and UFPs
- Workshop/review Fuels/Technology

**Global Health Science**

- Update and apply Global Burden of Disease to inform developing world source emissions
- Potential global cohort studies of full range of pollution exposure and/or source exposures and effects

**Cross-Cutting Issues**

- Identification and integration of at-risk populations into HEI studies
- Testing and validation of statistical models; enhanced exposure assessment; climate change; new biologic techniques; new health endpoints and modifying factors

**MID-TERM REVIEW: VISION 2020**
One Example: The HEI National Particle Component Toxicity (NPACT) Initiative

To answer Question 5 on the NRC PM Agenda:
Are all Particles created Equal?
Or are some more toxic than others?

Comprehensive Air Quality Data:
HEI created the most comprehensive, national web-based air quality database ever made available for PM studies

Quality Carefully Coordinated Science:
Open competition to find the best teams; applications from many top groups in the US and Europe; reviewed rigorously by an expert panel.
HEI Research Committee Detailed Oversight/Coordination
(Workshops, Site Visits, Quality Audits, Progress reports, Advice at key milestones from NPACT Advisory Committee)

UW/LRRI Team
- Integrated Toxicology and Epidemiology
  - Mouse studies of source exposures (LRRI)
  - In vitro studies (MESA cities)
  - Long Term Epidemiology (MESA-AIR ~ 9 cities)
  - Long term Epidemiology (WHI: 45 Cities)

NYUMC Team
- Integrated Toxicology and Epidemiology
  - Mouse Studies of CAPs exposure (6 sites)
  - In vitro Studies of CAPs, particle size
  - Long term Epidemiology (ACS: ~100 cities)
  - Short Term Epidemiology (Morbidity, Mortality) (15 – 20 cities)

Key Overlap
- Mouse Studies (CAPS and Sources)
- Long term Epidemiology (100+ cities)

COMPREHENSIVE REPORTS
(All Positive and Negative Findings, Data)

HEI NPACT Review Panel Intensive Peer Review
- Intensive toxicology, epidemiology, exposure and statistics review by experts on the HEI NPACT Review Panel
- HEI Commentary on science and relevance
- Synthesis of the implications of the results of all epidemiological and toxicological studies in both reports

Publication of Reports with Commentaries and Synthesis
A Systematic and Integrated Approach: Toxicology

NYU = 4 (+ 1) sites, 6-month CAPS exposures ApoE -/- mouse
LRRI = Albuquerque, 50-day defined exposures ApoE -/- mouse

Seattle:
Strong wood smoke signal, little sulfate,

Albuquerque (LRRI):
Lab studies of vehicles, secondary sulfate, nitrate, road dust

Irvine:
Few sulfates, strong traffic (gasoline)

East Lansing:
Suburban mix of sulfates, vehicles

Tuxedo, NY:
Rural, little traffic, strong sulfate

New York City:
Strong traffic (diesel) and sulfates
HEI’s National Particle Component Toxicity Initiative (NPACT)
Coordinated Epidemiology in Over 100 Cities
Intensive Review by A Specially Convened HEI Review Panel:

• Comprehensive Reports of Each Study
• Intensive review
• Commentary on each study
• Prepared cross study, multi-disciplinary synthesis distilling key findings
In Sum

• Controversy and distrust between major parties led to a public-private leveraged partnership for research investment
• Designed for maximum impartiality and credibility
• Guided by a carefully drawn, strategic research plan
• Renewal of the Plan and funding each five years provides opportunity to refresh, and refocus, the research
• Results: Nearly 400 research studies, re-analyses, and systematic literature reviews
  • Widely cited in the literature and in policy/regulatory deliberations
Setting the Context...

• Key elements that can lead to sustained funding of research to inform public health and environmental policy:
  • First, it helps to have controversy and a need for better science...
  • Second, identifying and/or creating a trusted institution to
    • Organize the scientific community to identify the highest priority research needs
    • Build a strategic plan for investment in the research
    • Implement and/or monitor progress
  • Third, a sustained effort to communicate results to key audiences,
    • And continue to identify remaining gaps....
THANK YOU!

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