Executive summary of *Research Priorities for Airborne Particulate Matter: IV. Continuing Research* Progress, National Research Council (2004)

The following pages contain the executive summary of Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress. *At the request of Congress and EPA, the National Research Council (NRC) Committee on Research Priorities for Airborne Particulate Matter was established in 1998 and given the charge of developing a research agenda for this purpose and monitoring progress. This report, the committee's fourth, evaluates research progress since the first report, evaluates possible barriers to continued progress, and makes recommendations for future research directions and research management. The series of four reports served as a major source of guidance for the both the original PM Centers Request for Applications (RFA) in 1998 and the second RFA in 2004.*

This executive summary of the fourth volume of the series assesses the status of PM research and outlines research recommendations for the future. Additionally, the report describes the "Challenges for the Years Ahead", including moving from a PM research program to a multi-pollutant research program.

Research Priorities for Airborne Particulate Matter

·IV·

Continuing Research Progress

Committee on Research Priorities for
Airborne Particulate Matter

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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Washington, D.C.
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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This project was supported by Contract No. 68-C-98-003 between the National Academy of Sciences and the U.S. Environmental Protection Agency. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

Library of Congress Control Number 2004112036

International Standard Book Number 0-309-09199-3 (Book)
0-309-53170-5 (PDF)

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Dedication to the Memory of Professor Glen Cass (1947-2001)

We dedicate this report to the memory of our late colleague and fellow committee member, Professor Glen Cass. Glen represented superbly the multidisciplinary research approach that we advocate in this report. Over the past two decades, from his Ph.D. research on sulfates to subsequent work on ozone, nitrates, primary and secondary carbon, visibility reduction, and indoor air quality, Glen and his research group unraveled the sources, atmospheric processes, toxicity, and emission controls needed to curtail the detrimental impacts of particulate matter on public health and welfare. Glen had a unique ability to combine elegant scientific approaches with sound engineering judgment to arrive at practical solutions that have been incorporated into air quality management practices in Los Angeles, the northeastern United States, and Asia. His legacy includes a large body of research and a rigorous, yet practical, approach to training a generation of air pollution scientists, who continue to lay the foundation needed for science-based decisionmaking. As a colleague, a friend, and an inspiration, we all sorely miss him.

Preface

Under the Clean Air Act, particulate matter (PM) is one of the major air pollutants for which National Ambient Air Quality Standards (NAAQS) are to be established on the basis of the scientific evidence on risks to human health. The U.S. Environmental Protection Agency (EPA), other federal and state government agencies, and nongovernment organizations are conducting a major multiyear research effort to improve scientific understanding of airborne PM and its effects on human health. An overall objective is to reduce uncertainties in the scientific evidence used to set the NAAQS for airborne PM in the United States. At the request of Congress and EPA, the National Research Council's Committee on Research Priorities for Airborne Particulate Matter was established in 1998 and given the charge of developing a research agenda for this purpose and then monitoring research progress. Biosketches of the committee members are presented in Appendix A. This report, the committee's fourth, comes 6 years after its first report, which proposed a 13-year research portfolio. This report evaluates research progress since the first report, evaluates possible barriers to continued progress, and makes recommendations for future research directions and research management.

The first of the committee's four planned reports, *Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio*, was published in 1998. It identified 10 high-priority research topics linked to key policy-related scientific uncertainties and presented a 13-year "research investment portfolio" containing recommended short-term and long-term phasing and estimated costs of research on each topic. Congress, EPA, and the scientific community gave strong support to the committee's recommendations and implemented substantial changes in research efforts in response to them.

The committee's second report, *Research Priorities for Airborne Particulate Matter: II. Evaluating Research Progress and Updating the Portfolio,* published in 1999, described the committee's plans for monitoring the progress of research. In addition, the research recommendations from the committee's first report were updated, and recommendations related to emissions and air quality models were substantially revised.

The committee's third report, published in 2001, monitored the progress of the research begun in 1998 or later to address the priority research topics identified by the committee. Although much research had been initiated, not enough time had elapsed by then for many of the projects to be completed and their results reported. The third report should be viewed as a preliminary assessment of research progress.

In this final report, the committee faced the challenge of gauging research progress on each of its 10 research topics. It developed an approach for characterizing the degree to which new evidence has reduced uncertainty and then gathered and evaluated the evidence coming from research over 5 years since the first report. The committee was assisted by the many individuals (listed below) who participated in workshops and public sessions of committee meetings held for the purpose of learning about relevant findings. Research progress reflects not only the creativity and efforts of researchers but also the efficiency of research management. This report also provides recommendations for future consideration of research on PM, as this committee's work is now finished.

The committee received oral or written presentations or both from the following individuals:

John Bachmann, U.S. Environmental Protection Agency; Tina Bahadori, American Chemistry Council; John Bailar, University of Chicago; David V. Bates, University of British Columbia; William Bennett, University of North Carolina at Chapel Hill; Michael Brauer, University of British Columbia; Richard Burnett, Health Canada; Lilian Calderon-Garciduenas, University of North Carolina at Chapel Hill; Aaron Cohen, Health Effects Institute; Daniel Costa, U.S. Environmental Protection Agency; Robin Dennis, U.S. Environmental Protection Agency; Robert Devlin, U.S. Environmental Protection Agency; Douglas Dockery, Harvard School of Public Health; Francesca Dominici, Johns Hopkins Bloomberg School of Public Health; Ed Edney, U.S. Environmental Protection Agency; Mark Frampton, University of Rochester; John Froines, University of California at Los Angeles; Patrick Gaffney, California Air Resources Board; Chris Geron, U.S. Environmental Protection Agency; Frank Gilliland, University of Southern California; Ian Gilmour, U.S. Environmental Protection Agency; John Godleski, Harvard School of Public Health; Judy Graham, while at the U.S. Environmental Protection Agency, currently at the American Chemistry Council; Jack Harkema, Michigan State University; Bruce Harris, U.S. Environmental Protection Agency; James Hogg, University of British Columbia; Patrick Kinney, Columbia University School of Public Health; Michael Kleinman, University of California at Irvine; Jane Koenig, University of Washington; Timothy Larson, University of Washington; Allen Lefohn, A.S.L. & Associates; Chuck Lewis, U.S. Environmental Protection Agency; Joellen Lewtas, U.S. Environmental Protection Agency; Morton Lippmann, New York University School of Medicine; Phillip Lorang, U.S. Environmental Protection Agency; Robert Mason, National Jewish Medical and Research Center; Andrew Miller, U.S. Environmental Protection Agency; Fred Miller, CIIT Centers for Health Research; David Mobley, U.S. Environmental Protection Agency; D. Warner North, NorthWorks; William Ollison, American Petroleum Institute; Wayne Ott, Stanford University; Pedro Oyola, Chilean National Commission for the Environment; Joseph Paisie, U.S. Environmental Protection Agency; Giovanni Parmigiani, Johns Hopkins University; Robert Phalen, University of California at Irvine; C. Arden Pope III, Brigham Young University; Peter Preuss, U.S. Environmental Protection Agency; Charles Rodes, Research Triangle Institute; Joseph Rodricks, ENVIRON International Corporation; Armistead Russell, Georgia Institute of Technology; Richard Scheffe, U.S. Environmental Protection Agency; Kenneth Schere, U.S. Environmental Protection Agency; John Seitz, while at the U.S. Environmental Protection Agency, currently at Sonnenschein, Nath & Rosenthal, LLP; Linda Sheldon, U.S. Environmental Protection Agency; Lianne Sheppard, University of Washington; Dean Smith, U.S. Environmental Protection Agency; Paul Solomon, U.S. Environmental Protection Agency; Helen Suh, Harvard School of Public Health; Joseph Tikvart, U.S. Environmental Protection Agency; Paige Tolbert, Emory University; Sverre Vedal, National Jewish Medical and Research Center; James Vickery, U.S. Environmental Protection Agency; Russell Weiner, U.S. Environmental Protection Agency; Ronald Williams, U.S. Environmental Protection Agency; William Wilson, U.S. Environmental Protection Agency; and Denis Zmirou, French Institute of Health and Medical Research.

We are grateful for the assistance of the NRC staff in preparing the report. We wish to thank Raymond Wassel, project director, and James Reisa, director of BEST. Scientific and technical information was provided by Eileen Abt, Kulbir Bakshi, K. John Holmes, Karl Gustavson, Amanda Staudt, Mirsada Karalic-Loncarevic, and Rachel Hoffman. Invaluable logistical support was provided by Emily Brady. The report was ably edited by Ruth Crossgrove.

Finally, I would like to thank all the members of the committee for their dedicated efforts throughout the development of this report.

Jonathan Samet, Chair
Committee on Research Priorities for
Airborne Particulate Matter

Acknowledgment of Review Participants

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

Carol Henry, American Chemistry Council; George Hidy, ENVAIR; Morton Lippmann, New York University Medical Center; Ronald Low, University of Medicine and Dentistry of New Jersey; D. Warner North, NorthWorks; Robert Phalen, University of California at Irvine; C. Arden Pope, Brigham Young University; and Armistead Russell, Georgia Institute of Technology.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Annetta Watson, Oak Ridge National Laboratory. Appointed by the NRC she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Contents

Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress

Summary

This report is the fourth in a series by the Committee on Research Priorities for Airborne Particulate Matter. The committee was convened by the National Research Council (NRC) in January 1998 at the request of the U.S. Environmental Protection Agency (EPA) following directions from Congress in EPA's fiscal year 1998 appropriations report. The congressional request for this study arose from the need to reduce uncertainties in the scientific evidence considered by EPA in reaching the July 1997 decision to establish new National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) less than 2.5 micrometers (µm) in aerodynamic diameter ($PM_{2.5}$). Anticipating information needs of the required reviews of the PM NAAQS every 5 years, Congress appropriated substantial funds for a major research program to reduce the scientific uncertainties. It also directed EPA to arrange for this independent NRC study to provide guidance for planning the research program and then monitoring research progress. This report focuses on the progress since early 1998 in reducing scientific uncertainties.

THE PARTICULATE MATTER RESEARCH PROGRAM

EPA initiated a substantial program that largely followed the 13-year research portfolio set out over 5 years ago by this committee in its first report. The portfolio identifies 10 high-priority research topics linked to key scientific uncertainties relevant to those sources that cause adverse health effects (see Box S-1). Table S-1 shows funding levels budgeted during fiscal years 1998-2003 by Congress for EPA's PM research and related technical work. Much of the research called for by the committee has been carried out by EPA investigators, but many scientists from academia and research institutes in the United States and in other countries are also involved.

REVIEW OF PROGRESS AND STATUS OF RESEARCH

In preparing this final report, the committee matched PM research and resulting contributions to the scientific literature from projects sponsored by EPA and other institutions against the committee's recommended research portfolio. It assessed the extent to which completed and ongoing research is addressing gaps in the evidence on major issues that decision-makers will consider as they review the scientific evidence relevant to the PM NAAQS. The committee systematically reviewed progress made between 1998 and mid-2002 in PM research on its topics 1-10. Review updates were performed over the next year as this report was written. Brief summaries for each topic follow.

Research Topic 1. Outdoor Measures Versus Actual Human Exposures

Substantial progress has been made in addressing topic 1, in part because of leadership by EPA in this area. The committee was able to identify a large number of studies initiated after its first report, and for most, the field work is now complete, and results are being published in peer-reviewed literature. Advances in personal monitoring made data collection feasible not only for healthy adults but also for children and persons with chronic heart and lung diseases. Monitoring studies of groups of individuals measured at successive points in time supported the conclusion that ambient (outdoor) particle concentrations are a key determinant of variation in personal exposure to particles. Such an association of ambient concentrations with personal PM exposures supports the use of ambient concentrations in time-series analyses and as a relevant metric for public health.

Although substantial monitoring data have been collected and analyzed, understanding remains incomplete on the quantitative relationships between outdoor measures of airborne PM and actual personal exposures to PM. Monitoring data should also be used to evaluate existing exposure models and develop new models when necessary. In addition, there is still only sparse information about the exposures of susceptible individuals for example, those with chronic heart and lung diseases to particles and other air pollutants. However, studies on such individuals might best be deferred

BOX S-1 Research Priorities and Questions Recommended by this NRC Committee

Research Topic 1. Outdoor Measures Versus Actual Human Exposures
What are the quantitative relationships between concentrations of particulate matter and gaseous copollutants measured at stationary outdoor air monitoring sites and the contributions of these concentrations to actual personal exposures, especially for subpopulations and individuals?

Research Topic 2. Exposures of Susceptible Subpopulations to Toxic Particulate Matter Components
What are the exposures to biologically important constituents and specific characteristics of particulate matter that cause responses in potentially susceptible subpopulations and the general population?

Research Topic 3. Characterization of Emission Sources
What are the size distribution, chemical composition, and mass emission rates of particulate matter emitted from the collection of primary-particle sources in the United States, and what are the emissions of reactive gases that lead to secondary formation through atmospheric chemical reactions?

Research Topic 4. Air Quality Model Development and Testing
What are the linkages between emission sources and ambient concentrations of the biologically important components of particulate matter?

Research Topic 5. Assessment of Hazardous Particulate Matter Components
What is the role of physiochemical characteristics of particulate matter in eliciting adverse health effects?

Research Topic 6. Dosimetry: Deposition and Fate of Particles in the Respiratory Tract
What are the deposition patterns and fate of particles in the respiratory tract of individuals belonging to presumed susceptible subpopulations?

Research Topic 7. Combined Effects of Particulate Matter and Gaseous Pollutants
How can the effects of particulate matter be disentangled from the effects of other pollutants? How can the effects of long-term exposure to particulate matter and other pollutants be better understood?

Research Topic 8. Susceptible Subpopulations
What subpopulations are at increased risk of adverse health outcomes from particulate matter?

Research Topic 9. Mechanisms of Injury
What are the underlying mechanisms (local pulmonary and systemic) that can explain the epidemiological findings of mortality and morbidity associated with exposure to ambient particulate matter?

Research Topic 10. Analysis and Measurement
To what extent does the choice of statistical methods in the analysis of data from epidemiological studies influence estimates of health risks from exposures to particulate matter? Can existing methods be improved? What is the effect of measurement error and misclassification on estimates of the association between air pollution and health?

Sources: NRC 1998, 1999, 2001.

TABLE S-1 EPA Funding for PM Research and Related Technical Work (in millions of dollars)

	Fiscal Year Budgets					
	1998	1999	2000	2001	2002	2003
PM research	42.0	47.3	53.7	59.0	61.1	58.1
Related technical work	8.2	8.3	8.7	6.3	6.6	8.8
TOTAL	50.2	55.6	62.4	65.3	67.7	66.9

until monitoring methods can be enhanced to characterize exposures to specific PM components.

Research Topic 2. Exposures of Susceptible Subpopulations to Toxic Particulate Matter Components

A small number of studies have included measurements of personal exposures to various particulate constituents, including sulfate, nitrate, ammonium, elemental and organic carbon, and other substances. However, research conducted to date on such exposures has focused on methods development. These efforts will be useful in initial chemical characterizations of exposure of potentially susceptible subpopulations and in directing the design of future exposure studies. However, before implementing research on this topic, the committee's sequence of research calls for substantial advances in identifying biologically relevant PM characteristics.

Research Topic 3. Characterization of Emission Sources

Although critically important for implementation of new PM NAAQS, a comprehensive and cohesive emissions characterization program (previously recommended by the committee) has not yet been implemented by EPA or other responsible sponsors, including state agencies. Characterizing PM emission sources requires accurate measurements of mass emission rates, composition, and size distributions from a representative sample of an individual source type. In addition, accurate emission rates of reactive precursor gases, such as sulfur dioxide, are needed. Since 1997, the committee has identified several advances, the greatest of which has been improvement in estimating on-road mobile-source emissions (particularly from heavy-duty diesel trucks) of PM mass, ultrafine particles with diameters less than 0.1 μm, ammonia, and semivolatile organic vapors. Additional test methods and testing are needed for the many other sources that contribute major fractions of ambient PM (such as residential wood combustion, wildfires, cooking, and nonroad engines). Both direct and precusor sources of carbon emissions are the most poorly characterized of the emissions contributing to PM. Also, more efforts are needed to understand the uncertainties in emissions inventory estimates. As the committee emphasized in its third report, EPA should develop a comprehensive plan for systematically translating new source-test methods into a completed, comprehensive national emissions inventory based on contemporary source tests of comparable quality. The first step in planning the source-test program would involve the systematic creation of a master list of the representative sources that should be given highest priority. The timeline for this testing must allow for incorporation of revised and updated data into an overall emissions inventory of predetermined quality and completeness before the next round of PM implementation plans are drafted.

Research Topic 4. Air Quality Model Development and Testing

EPA's ultimate goal should be to have integrated, flexible, and well-tested aerosol models available for development of emission-control strategies for ambient PM management. It is still not clear that EPA is making appropriate commitments to develop models for local air quality management. Taking into consideration limited progress on emissions characterization and on source- and receptor-oriented models, the committee remains concerned about the air quality management community's access to fully operational tools for the NAAQS implementation tasks to be undertaken in the coming years.

Although instruments needed to monitor air quality are largely in place, much remains to be done if the resulting data are to be used effectively. Access to these data by researchers and other potential users outside of EPA should be made easier.[1] Users of the data also face the difficulty of accounting for substantial sampling and analytical uncertainties in the measurement of major particle components—most critically, organic material.

[1]The internet portal that once served this function has been replaced since 2001 by a notice to submit a Freedom of Information Act request to EPA to obtain hourly or daily monitoring values.

Various models earmarked for regulatory application will be operationally useful only to the extent that data needed to support them are routinely available. Characterizing emissions is a major need for both source- and receptor-oriented modeling. The rigorous evaluation of source-oriented models will also require large-scale, three-dimensional field studies, because spatially limited measurements are insufficient to challenge a model's mass accounting. Although data sets from already-completed efforts may be adequate in some locations, additional studies are needed in regions of differing climate and emissions. The committee also recognizes the need to improve bridging between geographic scales typically used for PM source-oriented modeling and those needed to conduct exposure assessment.

Although EPA alone might not have adequate resources for model evaluation, it can participate in, and coordinate, efforts involving other government agencies and private institutions with substantial field monitoring programs, enhancing such efforts in ways that synergistically increase the value of the resulting data for its own applications. EPA leadership is needed for a coordinated effort to document and compare models and to identify capabilities and limitations of models for decisionmaking purposes.

Research Topic 5. Assessment of Hazardous Particulate Matter Components

The current NAAQS for PM is both size and mass-based and implicitly assumes that all particles of a given size have the same toxicity per unit mass, irrespective of chemical composition. In the committee's judgment, this mass-based NAAQS greatly oversimplifies complex biological phenomena. Progress on assessment of hazardous PM components is central to the national research portfolio and to any refinement of the current mass-based NAAQS for PM. Without progress on topic 5, targeted exposure studies cannot be developed under topic 2, nor can emission inventories and models be refined under topics 3 and 4. Also, new information on hazardous PM components would help to guide efforts to better understand the deposition and fate of relevant particles (topic 6). Research on biological mechanisms (topic 9) and identification of susceptible populations (topic 8) could be enhanced by research accomplishments in topic 5. A better understanding of characteristics that modulate toxicity could lead to targeted control strategies specifically addressing those sources having the most significant adverse effects on public health.

The diversity of PM characteristics and the array of possible health effects define a potentially large and complex matrix for investigation; in fact, different features of particles might be relevant to different health outcomes. Since the committee's first report in 1998, even though progress in assessing specific hazardous characteristics of PM has been fragmented, an increasing number of studies have been published that address specific characteristics of particles, including size and chemistry. The resulting evidence provides some new insights concerning toxicity for many of the specific particle characteristics related to size and chemical composition, as discussed in this report. However, there is a large variety of possible relationships between PM characteristics and health outcomes and, to date, those relationships have not been approached systematically.

Epidemiological research has been limited by the lack of detailed ambient monitoring data on particle characteristics collected over periods of time and thought to be relevant to exposure and health effects. The research has also been limited by the high correlations among some particle components. Given the complexity of the hypotheses to be tested, large data sets with rich detail on particle characteristics are needed to reduce uncertainties related to topic 5. Also, the sustained research efforts to obtain air quality monitoring data to estimate exposures for study participants and communities for epidemiological studies are only now coming into place. The initial toxicological studies are providing promising findings, pointing to possible roles for the ultrafine fraction of PM, metals, and other components of the PM mixture in air.

Despite the large number of research projects directed at this issue, progress since 1998 has been modest, reflecting the challenging set of scientific questions to be addressed. The matrix of relationships between particle composition and possible health responses has been only partially explored. Researchers have focused on PM collected from specific emission sources or on PM components of their particular interest, or they have focused on popular hypotheses or suggestive experimental evidence. A more systematic approach will be required to ensure that research encompasses a broader range of potentially important PM characteristics and yields data that can be used to establish the relative toxicity of different components.

Research Topic 6. Dosimetry: Deposition and Fate of Particles in the Respiratory Tract

Dosimetry provides a critical link between exposure to atmospheric concentrations of particles and the doses of particles reaching critical sites in the respiratory tract, the clearance of particles from those sites, and the movement of particles from the respiratory tract to other organs. The greatest policy-relevant advance in the understanding of PM dosimetry since the committee's first report is the convergence of evidence from studies in multiple laboratories that demonstrate an increase in the portion of inhaled $PM_{2.5}$ depositing in the respiratory tracts of people having obstructive lung disease (a highly prevalent condition). The available evidence on dosimetry confirms earlier work suggesting that abnormalities of airway structure or intrapulmonary gas distribution are likely to increase the total deposited dose for a given exposure concentration.

The greater deposition fraction and the heterogeneity of deposition in abnormal lungs offer one possible mechanism for increased susceptibility of persons with underlying lung disease to inhaled particles—increased lung dose to localized lung regions—in comparison with persons having normal lungs. Differences in fractional and regional deposition associated with aging have not yet been adequately characterized. Clearance has been less well studied than deposition, and the effects of gender, age, and respiratory abnormalities on clearance remain largely uncertain. Translocation of PM or PM constituents from the lung to other organs has been demonstrated, but this phenomenon has not yet been well characterized. Evidence is more limited for specific size fractions of particles, such as ultrafine particles and particular chemical components of particles. Additionally, more information on dosimetry in animal models of human disease is needed to facilitate extrapolation of findings from these models to humans.

Research Topic 7. Combined Effects of Particulate Matter and Gaseous Pollutants

This research topic addresses the extent to which the effects of PM on health are independent of coinciding effects of other pollutants and the possibility that PM effects vary with concentrations of other pollutants. Research is complicated by the possibility that modification of the effects of PM by other pollutants could vary among health outcomes.

The committee's review found little new direct evidence related to topic 7, other than newer observational studies that have continued to demonstrate an independent effect of particles that is robust to statistical adjustment for other pollutants. Assessments of effect modification in epidemiological and toxicological studies have provided little evidence to indicate whether PM effects vary with concentrations of other major pollutants in ambient air. The committee concludes that further research is needed to address topic 7, while acknowledging the challenges in carrying out such studies whether based on epidemiological observations or toxicological experiments.

Modification of PM effects by other pollutants, particularly ozone, can be more powerfully explored in planned larger studies, such as extensions of the approach used in the National Morbidity, Mortality, and Air Pollution Study (NMMAPS). More comprehensive characterization of mixtures considered in source-oriented exposure studies would make such studies more informative. A better understanding is needed of why some mixtures and potentially those from different sources have different effects in different diseases.

Research Topic 8. Susceptible Subpopulations

Research on susceptible populations is needed to ensure that all populations are protected against risks from PM, including those groups who might be most susceptible. There have been several new findings relevant to susceptible subpopulations. Research results show that following PM exposures,

- Persons with diabetes might be at increased risk for adverse health effects, including increased mortality.
- Persons with asthma or chronic obstructive pulmonary disease (COPD) exhibit greater deposition of inhaled fine and ultrafine PM, resulting in higher doses and associated risks.
- Older adults experience adverse changes in cardiac physiology.
- Older adults show hematological changes that are relevant to risk for cardiovascular disease (for example, changes in blood coagulation factors).

Animal models are yielding consistent findings. Dogs with coronary occlusion and hypertensive rats demonstrate adverse cardiac and vascular effects when exposed to PM. Studies involving rodent models of aging show enhanced susceptibility to PM and an increase in the effect of PM with infection.

To obtain evidence needed to understand the impacts of PM on susceptible subpopulations, research should more effectively address different time scales of exposure (from short-term peaks [acute] to long durations [chronic]), characteristics of exposure, cellular and molecular mechanisms, the range of potential adverse health effects, and potential effect modifiers.

Some current concerns focus on whether chronic PM exposures relate to the development of disease and of organ dysfunction, the extent to which ultrafine particles induce adverse effects in asthma and COPD patients, and the magnitude of life-shortening from PM exposures.

Research Topic 9. Mechanisms of Injury

The major potential biological processes suggested to underlie the reported human health effects from ambient PM exposures include oxidative stress and pulmonary or systemic inflammation. Among the postulated physiological consequences of injury by PM are increased airway hyperreactivity; alterations in the cardiovascular system, such as changes in blood viscosity, heart rate, and rhythm; and heart rate variability. Since 1997, research has broadened to address more subtle pulmonary responses relevant to current exposures and also cardiovascular responses to inhalation of PM. Investigators have begun to consider the respiratory tract as a portal of entry for particles producing systemic effects rather than simply as a target organ for PM.

Results from epidemiological, clinical and animal studies are converging to indicate that PM exposures, both to $PM_{2.5}$ and ultrafine particles, have adverse cardiovascular effects. Although research has provided some leads on potential mechanisms underlying these effects, uncertainty remains regarding the role of copollutants. It is becoming more evident from clinical and toxicological studies that ambient fine PM induces respiratory and cardiovascular events that in susceptible, compromised people can explain the morbidity and mortality observed in epidemiological studies. Research has documented that components of hypothesized mechanistic sequences do actually take place, supplying a biological basis for explaining some effects of PM observed in susceptible subpopulations.

Despite substantial research since 1997, uncertainties remain concerning potential mechanisms underlying the various adverse effects of PM observed in epidemiological studies. In part, these uncertainties reflect the limitations of extending findings from toxicological studies that by necessity use small sample sizes to human studies in which large populations are studied to detect effects. Efforts to apply toxicological findings include the challenges of extrapolating from in vitro systems and high-dose animal experiments at concentrations sometimes orders of magnitude greater than those received by people from ambient exposures. There is also uncertainty about mechanistic observations based on nonphysiological exposure routes, such as intratracheal instillation. The next step is to more clearly understand mechanisms underlying exposure-dose-response relationships, recognizing that it is likely that most mechanisms will have some element of exposure (dose) dependence. The findings from the clinical, animal, and in vitro experimental work have often not addressed exposure-dose-response relationships, which may provide critical insights into the relevance of the experimental findings for interpreting epidemiological research. In addition, similar physiological, cellular, and molecular responses to PM in different species help to provide a mechanistic underpinning to the epidemiological observations.

Another major uncertainty relates to the lack of understanding of the relationships between the mechanisms responsible for acute versus chronic health effects. As the focus shifts to findings from epidemiological studies on chronic health effects, a similar shift will be required of the mechanistic studies. At present, it is unclear how the mechanisms characterized in the acute health-effects studies relate to the mechanisms underlying chronic health effects.

Research Topic 10. Analysis and Measurement

In its previous reports, the committee outlined several methodological issues needing further study. The issues included the sensitivity of findings in epidemiological studies to the statistical models used, the consequences of measurement error in epidemiological studies, and the analytical approaches to addressing the degree of life shortening associated with PM exposures. Since 1997, several new statistical methods have been introduced to analyze the temporal association between air quality measures and health. These models have been used to examine large national databases and to pool evidence across multiple locations. Although the committee's previous reports had found substantial progress related to this topic, recent findings on the sensitivity of time-series results to modeling approaches are an indication that further methodological research is needed. After the committee's third report, a problem was recognized in the application of a widely used statistical package in time-series analyses, resulting in extensive reanalyses of several studies that were central to characterizing the short-term risks of air pollution. These reanalyses yielded somewhat lower estimates of the effect of PM on risk for hospitalization and mortality. Nonetheless, time-series studies are likely to remain important for estimating the health effects of air pollution on populations, and a more complete understanding of the implications of modeling approaches is needed. In adddition, the issue of "harvesting" or mortality displacement[2] needs further investigation. It would also be important to understand any relationship between the results of the times-series studies and the cohort studies.

A framework was also developed to address measurement error–the difference between the actual exposure and the measured exposures of individuals in a study. The framework implies that measurement error per se will not create the positive associations found between air pollution and health effects. More precise estimates of the magnitudes and statistical distributions of measurement error need to be incorporated into multipollutant models to provide more reliable quantitative estimates of the impact of measurement error and of the relative importance of various pollutants on health impacts. Greater consideration of this issue would give more credence to risk assessments used to support regulatory decisions.

LOOKING ACROSS THE RESEARCH TOPICS

As the context for PM research has evolved, five cross-cutting issues have emerged.

An Increasing Number of Adverse Health Outcomes Associated with PM and the Related Susceptible Subpopulations

Research results under the topics of outdoor measures versus actual human exposures, dosimetry, combined effects of PM and gaseous pollutants, susceptible subpopulations, and mechanisms of injury indicate a broadening scope of health concerns since the committee's 1998 report. At that time, emphasis was largely placed on total morbidity and mortality from respiratory causes, such as exacerbation of chronic respiratory diseases, including COPD and asthma, and the respiratory health of children. Subsequently, the list of particle-related health outcomes has broadened and now includes several adverse cardiac outcomes, such as changes in heart rate variability, cardiac arrhythmias, ischemic events, and congestive heart

[2] The terms "harvesting" or "mortality displacement" refer to questions of whether deaths from air pollution occur in people who are highly susceptible and near death (and die a few days earlier because of air pollution than they otherwise would have) or whether air pollution leads to the death of people who are not otherwise near death.

failure, as well as reproductive outcomes. Health-outcome research has also focused on many susceptible subpopulations, such as those with preexisting cardiopulmonary illnesses, children, and older adults. Although findings on several of these outcomes remain preliminary and inconsistent, interest has grown in investigating these outcomes and exploring new ones.

Particle Toxicity in Relation to Different Particle Characteristics and Emission-Source Types

Ambient particles contain a large spectrum of individual compounds. Research findings from the Supersites Program and other atmospheric characterization studies have elegantly demonstrated the complexity of ambient particle characteristics. Research to assess hazardous PM components seeks to understand the comparative toxicity of particles in relation to their specific characteristics (for example, size or composition). Information needed to relate particle characteristics to their potential health risk remains largely incomplete, and the committee views this as a critical gap. Identifying toxicity-determining components of PM is the cornerstone for moving from strategies directed at particles generally to those directed at particular sources of more toxic particles. Such information is helpful for the development of effective controls on emission sources.

Increasing Emphasis on Exposure-Dose-Response Relationships

Emphasis needs to be shifted from research directed primarily at the question of whether particles are causing particular health effects (that is, hazard identification) to characterizing exposure-dose-response relationships (that is, the form of the quantitative relationship between exposure and risk for an outcome). Knowledge of exposure-dose-response relationships is important in establishing the NAAQS for PM and implementing effective control strategies. This quantitative understanding can guide decisionmaking, offering a foundation for estimating the burden of morbidity and mortality caused by particles and comparing the benefits of alternative scenarios of air quality management. The design of research directed toward characterization of exposure-dose-response relationships may differ from that directed toward hazard identification. In particular, information on exposure-dose-response relationships is needed across a range of particle exposures relevant to those received by people at contemporary concentrations. The incorporation of approaches that will allow examination of exposure-dose-response relationships for in vitro systems and laboratory animal experiments will be critical in further research evaluating the comparative toxicity (potency) of PM components.

Considering PM Health Effects within the Broader Context of Other Pollutants in the Ambient Air

For some time, investigators have recognized that surrogates for "dirty air" have been derived from assessing one pollutant at a time, and possible health effects attributed to a single pollutant have often been used in part to make regulatory decisions. However, in recent years, scientists and regulators have been concerned that, except in specific occupational settings, humans are exposed to air pollutant mixtures. In addition, the recognition of a broader range of health impacts as being putatively related to ambient pollution raises the possibility that single pollutants may be acting together to increase risk through interactive mechanisms. Research findings on the combined effects of particles and gaseous copollutants, susceptible populations, mechanisms of injury, and human exposures have implications that extend beyond PM. The finding of interactions between PM and the other five criteria pollutants listed in the Clean Air Act could provide a rationale for more integrated standards reflecting realistic atmospheric mixture exposures to populations at risk and reflecting the potential for overall mixture toxicity.

Designing PM Research Programs to Inform Most Effectively the Setting and Implementing of the PM NAAQS

Important PM research needs have implications for the setting of the PM NAAQS. Research results on exposure assessment, emissions characterization, development and testing of air quality models, assessment of hazardous PM components, assessment of the combined effects of PM and gaseous pollutants, and understanding the mechanisms of injury may have significant impacts on the four elements of the NAAQS for PM, namely, the pollutant indicator, averaging time, numerical level of the indicator, and the statistical form of the standard. Measurements of source emission rates for PM and precursor gases as well as evaluations of models are needed as states begin the process of developing NAAQS attainment plans.

CHALLLENGES FOR THE YEARS AHEAD

In 1998, the committee recognized that meeting its research agenda would require a substantial investment as well as development of new research approaches to address complex scientific questions. In reviewing work carried out since its first report, the committee has identified seven remaining scientific challenges that should be of highest priority in further work to complete the PM research agenda. These challenges are central to the PM research agenda; meeting them may require the development of new research approaches and research management strategies.

Completing PM Emissions Inventory and Air Quality Models Necessary for NAAQS Implementation

Although the committee's charge is to provide independent guidance for planning and monitoring a long-term PM research program, it recognizes that this research program will also provide the tools needed for implementation of current and possible future PM NAAQS. In particular, improved emissions characterization and air quality model testing and development are critical for state implementation plans (SIPs) that detail steps that states and local air districts will use to attain the $PM_{2.5}$ NAAQS. Although some positive steps have been taken by EPA, rapidly approaching SIP deadlines require faster progress to ensure that these plans are based on the best available information. Research to improve emission inventories and air quality models will also support more targeted emission-control strategies as progress is made in characterizing hazardous PM components.

The specificity of the PM NAAQS on the solid phase of ambient pollutants poses significant scientific challenges for source-test methods. The partitioning of many substances between gas and particle phases is sensitive to environmental parameters, such as temperature and humidity, which typically differ greatly between effluent and ambient conditions. Emission-test methods have historically paid limited attention to such distinctions, thereby yielding particulate emission rates of uncertain relevance to ambient conditions. In its second report, the committee stressed the need for developing new dilution-based source-test methods that simulate ambient conditions and for systematically applying these to a wide array of sources. Implementation of PM NAAQS will require comprehensive national and local emission inventories of PM mass emission rates, composition, and size distributions, along with emission rates of reactive precursor gases (sulfur dioxide, oxides of nitrogen, ammonia, and volatile organic compounds). These inventories will in turn require measurements relevant to ambient conditions as a representative sample of an individual source type.

Understanding the relationships between emissions and ambient concentrations is also central to regulatory decisionmaking. The committee is concerned that implementation of emission controls to attain PM standards may rely on untested air quality models. There appears to be a tendency to view model development as a research activity that can be decoupled from the regulatory support functions of ambient monitoring and emissions tracking. However, emissions, ambient concentrations, and source-receptor relationships are closely interrelated in certain situations (as when a known source dominates ambient loadings); in such circumstances, there is an opportunity for cross-calibration and verification. The three activities of emissions tracking, air quality modeling, and ambient monitoring need to be viewed as elements of an integrated process. The committee recommends that the EPA PM program better acknowledge these interrelationships to promote iterative improvements in emission inventories, monitoring networks, and air quality models.

Developing a Systematic Program to Assess Toxicity of PM Mixture Components

This pivotal topic carries implications not only for research directions but also for PM-control strategies. Answering the key questions concerning hazardous components of PM will require a carefully coordinated, long-term multidisciplinary research effort that goes well beyond the work now under way. Although substantial relevant research has already been carried out, the committee's review showed a diffuse assemblage of evidence with little convergence. Also, the use of disparate approaches to assess hazardous PM components by investigators in the diverse research communities has been a barrier to interpreting the resulting evidence.

The research strategy for addressing this topic should be reconsidered, moving from solely investigator-initiated approaches toward more carefully structured ones. A more systematic evaluation of PM by characteristics, components, and health outcomes should be combined with investigator-initiated research that may follow resultant leads or focus more deeply on specific hypotheses. There is also a need for coherent and converging evidence from exposure and atmospheric characterization and from toxicological and epidemiological research that addresses specific components and health outcomes in parallel. Such integrative research would facilitate judging the extent to which toxicological observations, particularly those made at higher doses, can be generalized. This type of orchestrated programmatic research might be conducted by EPA, through the resources of the EPA PM research centers, or through other research mechanisms.

Barriers to implementing integrated research include scientific and administrative challenges. There is also a need to foster cross-disciplinary communication and collaboration. The costs for the needed research may substantially exceed those originally estimated for this topic by the committee, but these costs should not be a basis for deferring needed research, given the importance of the air pollution control topic.

Enhancing Air Quality Monitoring for Research

Meeting the key PM research priorities will require a shift in the current air monitoring paradigm, from primarily assessing compliance with the NAAQS toward serving multiple purposes, such as air quality forecasting, episode alerts, exposure characterization in populations at high risk, health studies, atmospheric process studies, evaluating emission-source zones of influence, and evaluating long-term effectiveness of control strategies. This shift implies less use of federal reference methods at urban locations and greater use of in situ continuous monitors and compound-specific integrated samples at locations representing background, boundary, transport corridor, regional, urban, and neighborhood spatial distributions.

Such an enhanced network should use continuous measures of appropriate indicators with real-time access, attempt to represent less-uniform micro- and middle-scale exposures, and encourage the completion of development of continuous monitors for indicators other than mass concentrations.

A carefully designed network serving multiple purposes could be accomplished using the same resources currently dedicated to compliance monitoring that would have much greater public-health and knowledge-creation benefit than the current filter-based network.

Investigating the Health Effects of Long-Term Exposure to Air Pollution

Long-term epidemiological studies are likely to remain central in assessing the public-health burden caused by air pollution. For quantitative risk assessment and cost-benefit analysis, estimates of the disease burden associated with exposure to particles are needed, and research approaches should continue to be developed on the basis of existing and new cohorts. Mechanisms are needed for enrollment and tracking of cohorts, including their exposures and health outcomes, that would provide an ongoing characterization of any impact of long-term exposure to air pollution on health.

It is not yet clear what role chronic exposure studies (that is, encompassing most or all of the life span) of animals could play in predicting human health effects or in enhancing the understanding of the mechanisms and exposure-dose-response relationships of long-term exposure to PM. A likely application of toxicological research to understanding the consequences of long-term human exposures to PM lies in the use of studies incorporating repeated exposures ranging from several days to a few months. Intermediate-term studies could help characterize long-term study needs and designs.

Improved Toxicological Approaches

The committee has previously recognized the need for complementary epidemiological and toxicological evidence. Toxicological approaches have been limited by the difficulty of replicating real-world inhalation exposures to PM in terms of chemistry, by the relatively high doses often used in animal studies, by the common use of instillation rather than inhalation of the particles, and by the inability to readily replicate human diseases associated with increased susceptibility. Using toxicological approaches to assess hazardous PM components has also proved to be especially challenging. Separating the potential effects of particle size from those of particle chemistry is difficult, because particles of different size might have different chemical characteristics and different rates or routes of clearance, which affect responses. Studies of appropriate design are needed, as are well-characterized particle samples for experimental exposures.

From a Particulate Matter Research Program to a Multipollutant Research Program

Another challenge to completing the committee's research agenda lies in the scientifically artificial separation of research on PM from research on air pollution generally. This separation follows the regulatory approach of setting ambient standards for six individual criteria pollutants and corresponding emission standards on precursors without adequate recognition of their interrelationships in determining their risk to health. Given the need to develop the evidence base for the NAAQS, research has too often been driven by a schedule reflecting the regulatory cycle of NAAQS review and by the scope of research being restricted to single pollutants rather than the air pollution mixture.

Although the PM research agenda has appropriately considered other pollutants, it has of necessity been directed at PM. Researchers have considered some other air contaminants, largely other criteria pollutants, as "copollutants" for their potential impact on PM effects. This research tests whether PM effects depend on the presence or concentrations of other pollutants without considering the overall toxicity of the air pollution mixture, as the characteristics of the mixture vary. For the future, there is an opportunity and a critical need to shift from the current single-pollutant focus to a multipollutant focus that begins by acknowledging that real-world exposures involve complex mixtures of hundreds of air contaminants falling into several physical-chemical classes.

A multiple air pollutant program can be carried forward in a manner that reflects the need to develop information relevant to the setting of standards and the development of air quality management strategies. It is important that research priorities be carefully established in such a research program. One potential payoff of a multipollutant science-based approach is the high likelihood that the resulting information will aid in understanding the relative importance of various pollutants (and thus sources) and their interactions in causing adverse health effects. This knowledge should have clear benefit in optimizing both the cost-effectiveness and the health benefits of future air quality management strategies.

Integrating Across Disciplines

The need for complementary evidence on PM from multiple disciplines was recognized early by the committee. It called for interdisciplinary research and proposed the PM research centers as one mechanism for fostering interdisciplinary collaboration. Although greater cross-disciplinary integration has occurred in some PM research topics, to a large extent the coordination of toxicological, epidemiological, exposure, and atmospheric research has received more discussion than actual implementation to date. Expanding multidisciplinary strategies and programs will be essential to implement a multipollutant approach.

At a minimum, such efforts should include the following:

- Active collaborative research design.
- A shift by funding agencies toward giving higher priority to research implemented by truly multidisciplinary teams.
- Adequate research funding for projects to allow the active involvement of a full team (including senior investigators from multiple disciplines, if needed).
- Fellowships or sabbaticals that will enable scientists to collaborate with groups outside their disciplines.
- Redoubled efforts of appropriate professional societies to hold joint workshops and meetings and to publish proceedings.

MANAGING SCIENCE TO ADDRESS THE KEY REMAINING QUESTIONS

Progress to date on several of the committee's priority research topics is encouraging and demonstrates that key uncertainties can be quickly addressed with targeted research initiatives, as in the example of research on outdoor measures of airborne PM versus actual human exposure (research topic 1). The committee has been impressed by EPA's quick incorporation of the PM research portfolio into its planning and its integrated approach to managing PM research within the agency. It is not surprising that much research remains to be done from the committee's original research agenda, as detailed in this report, and new research findings always invite new questions.

Beyond continuing to seek answers to those specific questions, the committee has identified some recent progress to address the seven challenges discussed above (for example, implementation of the nationwide speciation monitoring network), but those seven issues need careful attention as the PM research program continues. By addressing these challenges directly, the pace of scientific gain should be quickened and the quality of research evidence strengthened.

These challenges also pose significant challenges to the management of scientific research. To address them effectively, a series of steps should be taken to effectively manage this complex scientific enterprise:

First, an even higher level of sustained integration and interaction will be needed to successfully complete the research portfolio. This step must be taken among the scientific disciplines and among the full range of public and private research funding organizations.

Second, much stronger tools will be necessary to compile and synthesize the large amounts of new information being developed in this research program.

Third, and perhaps most important, sustained and substantially enhanced management of this program by EPA, accompanied by a continuing mechanism for independent review and oversight of the program, will be the only way to ensure that this investment is being soundly made. EPA has taken steps toward better management, but recent frequent transitions in management personnel of that effort and a substantial need for new management systems and administrative mechanisms for supporting research—especially on the topic of assessment of hazardous PM components—suggest that EPA will need to enhance its efforts. Also, it will be important to develop some form of continuing independent oversight to provide continued monitoring and guidance for EPA's and others' efforts.

Much has been learned from the research investment since 1998, and evidence gained by the investment is already being used in decisionmaking, which will continue even in the face of uncertainty. However, much is still to be learned. A failure to invest in developing greater understanding of the effects of PM and air pollution, in general, on health would result in not taking full advantage of the substantial research investment to date and in limiting the nation's ability to make evidence-based health policy and air quality regulatory choices in the future. Alternatively, continued enhancement of the air pollution and health research effort will undoubtedly yield substantial benefits for years to come. It is clearly the latter choice that offers the most promise to the nation in its effort to improve air quality and public health.