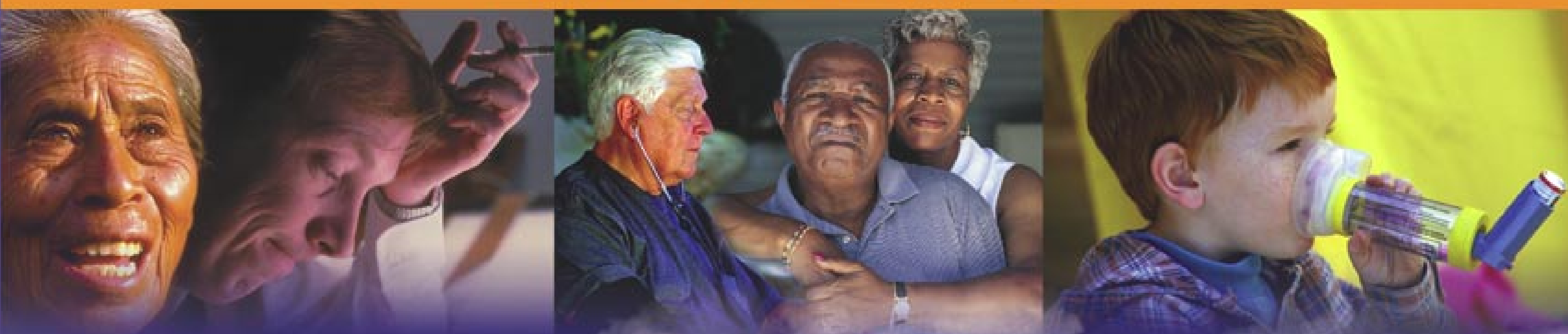
United States Environmental Protection Agency

research & development

The EPA Particulate Matter Research Program

What Have We Learned About PM Since 1997?



EXECUTIVE SUMMARY

The air in every American community will be safe and healthy to breathe. In particular, children, the elderly, and people with respiratory ailments will be protected from health risks of breathing polluted air.

—EPA Strategic Plan 2000

EPA 600/S-04/057
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The EPA Particulate Matter Research Program

What Have We Learned About PM Since 1997?

EXECUTIVE SUMMARY

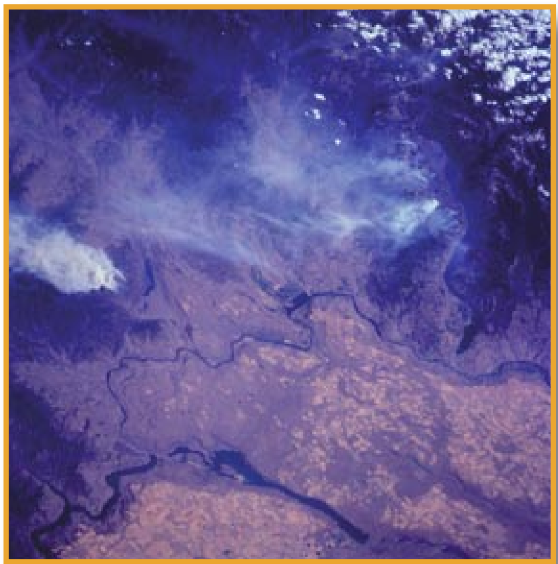
US Environmental Protection Agency
Office of Research and Development
Washington, DC 20460

The U. S. Environmental Protection Agency (EPA, or the Agency) Clean Air Goal aims for every American community to have safe and healthy air. However, research has shown that exposure to particulate matter (PM) air pollution continues to be linked to increases in respiratory health problems, hospitalization for heart or lung disease, and even premature death. The set of National Ambient Air Quality Standards (NAAQS) for PM, promulgated by EPA in 1997, was designed to respond to this research and move the nation closer to achieving the Clean Air Goal. Currently, EPA estimates that its regulations to reduce air pollution will prevent tens of thousands of premature deaths and reduce hospitalizations for cardiovascular and respiratory illness by tens of thousands more people each year. The monetary benefits of reducing mortality alone are estimated to be up to approximately $100 billion per year; the benefits of reducing illness and minimizing the number of lost workdays and consequences of restricted activity are estimated to provide savings of billions more dollars each year.

EPA views the reduction of PM emissions through its NAAQS as key to accomplishing its Clean Air Goal. By expanding its PM Research Program over the last five years, EPA's Office of Research and Development (ORD)[1] is successfully strengthening the science base for the NAAQS and facilitating its implementation.

The PM Research Program

In 1997, EPA revised the NAAQS for PM, with the most significant change being a new standard for PM smaller than 2.5 μm in aerodynamic diameter ($PM_{2.5}$ or fine PM). Developed largely on the basis of epidemiological studies that found consistent associations between ambient PM concentrations and various adverse health effects, the revised standards were shadowed by concerns regarding the true public health significance and credibility of the adverse effects of ambient PM. In 1998, these concerns led Congress to increase the President's recommended EPA budget for the PM Research Program of $27.8 million by $22.4 million per year—an increase that was largely sustained for the ensuing five years. EPA's specific charge was to accelerate its investigation of the role of PM in health effects associated with air pollution and to strengthen the science to support implementation of scientifically defensible regulatory actions.



Smoke plumes from wildfires. EPA's PM Research Program is working to develop more accurate estimates of PM emissions from wildfire events and other sources to help state and local agencies develop effective plans to achieve air quality standards for PM.

[1] *EPA research programs include both intramural components (ORD laboratories) and extramural components [Science To Achieve Results (STAR) Program grants, cooperative agreements, and other mechanisms]. References to ORD work in this document apply to both its intramural and extramural work.*

As a result of this intensified research program:

- Credibility has replaced skepticism concerning the nature and extent of ambient PM's effects on cardiopulmonary disease and mortality.
- Scientists are uncovering the many of the complex interactions involving PM attributes and human characteristics, among other factors, that contribute to unwanted health outcomes.
- Clear advances have been made in characterizing air pollution sources and atmospheric processes. This information is needed to plan and implement effective emission reductions to reduce PM.

The emergence of this new information was the result of a comprehensive, national research endeavor involving the coordinated planning efforts of EPA's intramural scientists, extramural investigators funded by EPA, and EPA partners such as the Health Effects Institute (HEI). Other federal organizations (including the National Institutes of Health and the Department of Energy) and others participating in the Air Quality Research Subcommittee of the Federal Committee on Environment and Natural Resources (CENR) joined in a coordinated effort to enhance the research addressing PM. This research has been performed within a scientific framework developed by the National Research Council (NRC) of the National Academy of Sciences, an independent committee of experts assembled at the request of EPA. The NRC Committee on Research Priorities for Airborne Particulate Matter (NRC Committee) issued a series of reports that outlined a research agenda to address the key scientific questions about PM and provided periodic assessments of progress.

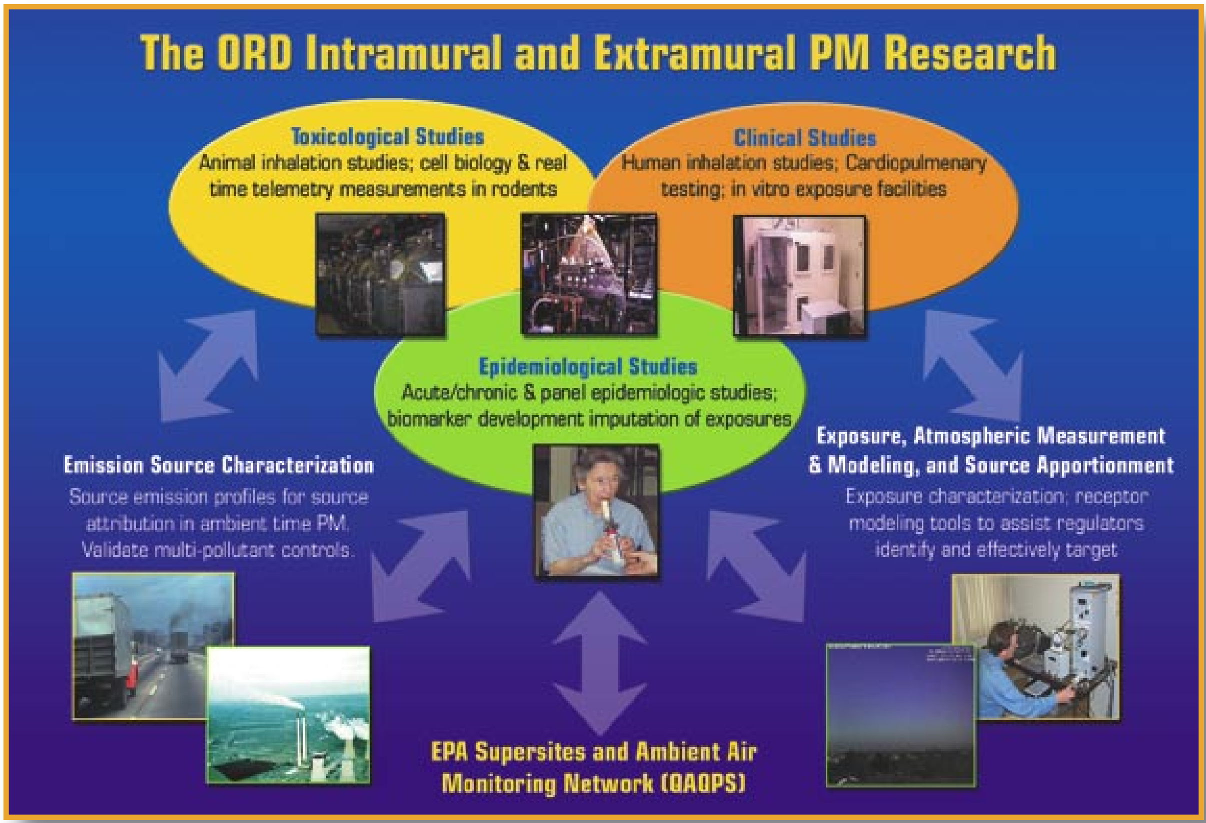
> In three reports, the NRC Committee identified important research topic areas and recommended to EPA a multi-year research portfolio and plan of the highest priority research topics designed to strengthen and expand the scientific understanding of the links between ambient PM and adverse health effects. ORD has relied upon these priorities in setting its PM research agenda.

The NRC Committee's first report (Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio, March 1998) set the stage for the evolution of EPA's PM Research Program. EPA quickly focused the expertise of both intramural and extramural scientists to address the NRC priorities. Intramurally, the program adjusted its priorities in keeping with the NRC recommendations and established goals, time-lines, and associated internal funding support. The STAR Program, an extramural grant program managed by the EPA's National Center for Environmental Research (NCER), developed Requests for Applications (RFAs) for PM research in numerous environmental science, exposure, engineering, and health areas. This included the establishment of five PM Research Centers that, together with the EPA intramural program, could broadly address the PM issue. A major goal of the program has been to communicate and coordinate new findings and research priorities with partners and other Federal agencies. For example, the basic PM

Research Program analyses and other analyses conducted independently by the HEI have yielded significant contributions that have advanced and refined our knowledge of PM. The integration of EPA's PM Research Program with the programs of partners and other Federal agencies and the communication among them have been key elements in achieving significant scientific and regulatory advances.

This report highlights and summarizes the salient scientific advances in PM-related health, exposure, and implementation research conducted by ORD and EPA-funded researchers since 1997. The following discussions are organized by the priority research needs stated in the three NRC Committee reports (Research Priorities for Airborne Particulate Matter I–III) and in the context of the program and regulatory needs of EPA's Office of Air and Radiation (OAR).

EPA's PM research is conducted through intramural and extramural research partnerships.



Overview of major research areas being addressed by EPA's PM Research Program.

Air monitoring equipment used in EPA's PM Supersites Program.

Outdoor Measures Versus Actual Human Exposures

What are the quantitative relationships between concentrations of particulate matter and gaseous co-pollutants measured at stationary outdoor air-monitoring sites and the contributions of these concentrations to actual personal exposures, especially for subpopulations and individuals?

Understanding the relationship between ambient $PM_{2.5}$ concentrations and personal PM exposure is fundamental to assessing the health effects of air pollution. In 1997, it was difficult to quantitatively link outside measurements of PM at ambient monitoring sites to what individuals were actually exposed, especially because people spend about 90% of their time indoors.

Initially, EPA designed studies that focused on understanding the relationship between PM mass measured at ambient monitors and local outdoor, indoor, and personal exposure concentrations. Likewise, the effects that human activities, housing characteristics, and other factors had on these relationships were also investigated. Longitudinal exposure studies were conducted in eight locations around the country representing diverse conditions in weather, housing, and pollution sources. Researchers studied potentially susceptible subjects with asthma, chronic obstructive lung disease, or cardiovascular disease.

The exposure studies revealed a number of important relationships between personal PM exposure estimates and data from community monitors. Associations between the ambient monitor and personal exposure are strongest for fine particle sulfate—which forms a substantial fraction of $PM_{2.5}$ in the eastern part of the nation—followed by $PM_{2.5}$ mass, and then PM_{10} (PM smaller than 10 μm in aerodynamic diameter) mass. The strength of the association between ambient concentrations and estimates of personal exposure demonstrated in these studies has verified that, for fine PM mass and sulfate, measurements at central monitoring sites should serve as an adequate surrogate for personal exposure to ambient $PM_{2.5}$ mass in community-based epidemiological studies.

> ...results from the longitudinal exposure studies have verified that for fine PM mass and sulfate, the ambient monitoring site should serve as an adequate surrogate for personal exposure...

Although pooled analysis of the results shows a strong relationship between exposure and central site concentrations, results for individuals show high variability. Much of this variability is due to the varying effect of outdoor particles on indoor environments. Building type and ventilation strongly influence the penetration of ambient PM indoors. Although until recently particles were assumed to readily penetrate into buildings, studies have shown that this is often not the case, and that penetration efficiencies vary by city and season. Not surprisingly, the greater the air turnover in a dwelling (via open windows, air leaks, or mechanical systems), the better the indoor $PM_{2.5}$ reflects the $PM_{2.5}$ measured by the outdoor monitor. PM_{10} and ultrafine (< 0.1 μm) PM (most often associated with recently generated or "fresh" combustion emissions) penetrate less well under similar circumstances and penetrate especially poorly into relatively well-sealed dwellings. High levels of ultrafines in many homes appear to be associated with human activity and specific indoor sources (e.g., cooking, space heaters, cigarette smoking), which can also contribute to co-pollutant exposure.

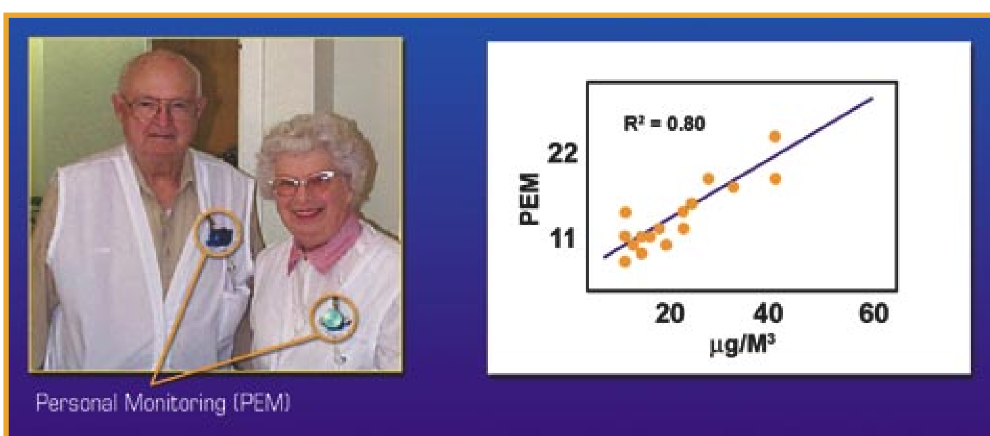
Because individuals typically spend most of their time indoors, they are exposed to lower levels of ambient PM than would be predicted by central site monitors; thus, the strength of the associations between ambient PM concentration and adverse health effects may be underestimated. Even with this variability in the relationships between ambient PM and personal exposure, recent studies have not shown significant differences in personal exposure to ambient PM as a result of health condition.

Gases such as NO_2, O_3, CO, and SO_2 are found along with PM in pollutant mixtures and may complicate the assessment of health outcomes associated with PM. Strong correlations were found to exist between ambient $PM_{2.5}$ concentrations and ambient gaseous co-pollutant concentrations (i.e., O_3, NO_2). However, only weak correlations existed between personal $PM_{2.5}$ exposure and personal exposures to gaseous co-pollutants. These data suggest that ambient gas concentrations do not significantly interfere with risk estimates for the effect of ambient PM exposure on health outcomes.

To assimilate these findings into a tool of use to state and regional regulators, EPA has developed the Stochastic Human Exposure and Dose Simulation (SHEDS) Model from laboratory and field data collected in the exposure studies. It is now being improved to incorporate the effect of emission sources on personal exposures and dose. This model will provide a relevant and sophisticated regulatory tool that will relate community monitoring or associated atmospheric modeling data to personal PM exposure.

The research activities associated with this topic have, by design, provided critical data to address fundamental questions regarding PM exposure. These data have now conceptually linked regulatory monitoring data with the health-outcome findings that were the basis of the initial PM studies. This research has also provided a platform from which to develop the predictive models needed to implement the NAAQS. As such, the original objectives of this topic area, as identified in the NRC Committee reports, are nearly complete. However, to provide more focused exposure estimates for health assessments, to guide model development, and to enable assessment of the regional variability associated with exposure to putative toxic components, data for particular PM constituents continue to be gathered in specific geographic areas.

Data from personal exposure monitors are highly correlated with measurements of $PM_{2.5}$ mass concentrations taken at ambient monitoring sites. This implies that changes in community-level ambient $PM_{2.5}$ mass concentrations are very similar to the changes in $PM_{2.5}$ concentration to which people are exposed, even when they spend most of their time indoors.



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?

This topic extends the Research Topic 1 research from exposure to PM mass to exposure to potentially toxic components of PM. Research in this area supports the hypothesis that health outcomes related to PM are determined by its specific physicochemical attributes. However, because current evidence suggests that health effects are likely to be associated with a significant number of the originally hypothesized toxic agents, the focus has shifted from evaluating individual components to evaluating the association between PM from specific sources and adverse health effects.

First, exposure research on individual PM species has been initiated without waiting for their toxic components to be definitively identified. Studies are being performed to investigate exposure relationships for as many of the hypothesized toxic components as are feasible with current technology. Results of these exposure studies can then be used to inform health studies. Second, source apportionment techniques are being incorporated into exposure research in order to evaluate the ambient-personal exposure relationship for PM from various sources as well as for individual PM constituents.

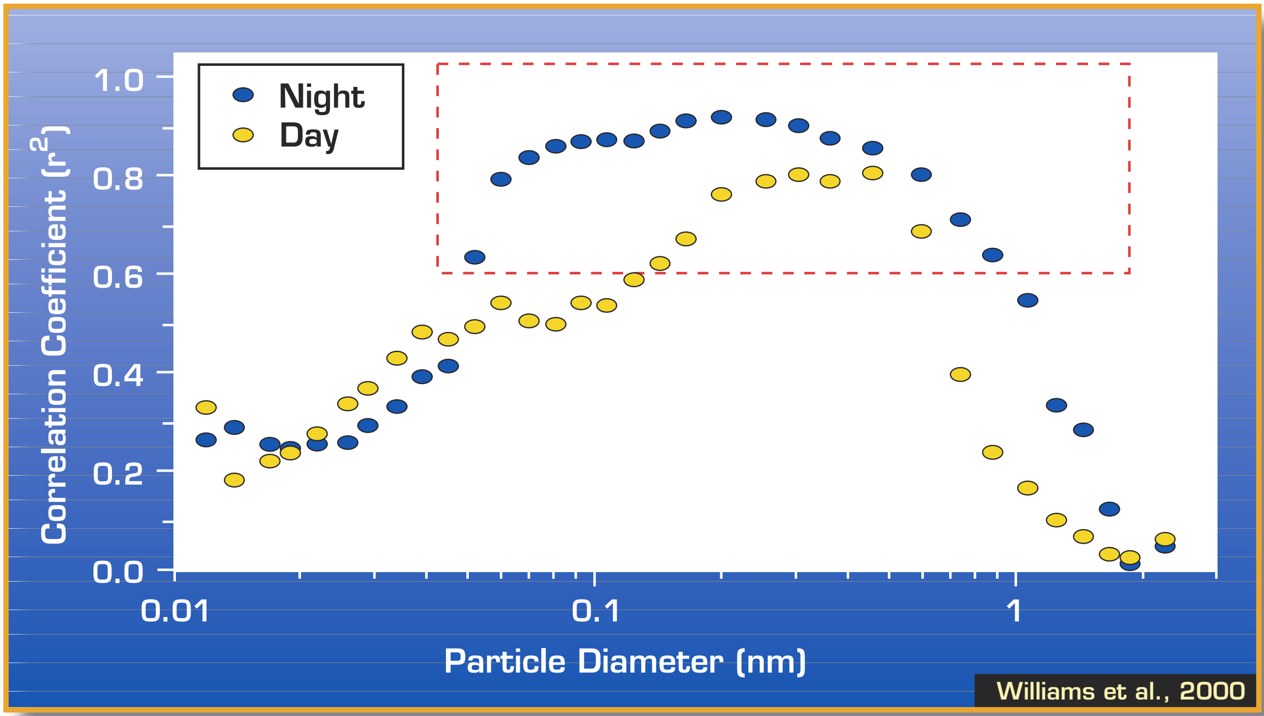
> Personal exposures to ambient PM are not substantially different for healthy and susceptible adult populations.

Initial work in this area has focused on developing methods for monitoring personal exposure to determining PM components and characteristics; identifying specific sources of PM; and developing lightweight, multi-pollutant samplers for susceptible individuals to use. EPA's support of improvements in analytical methods will improve the capability to identify sources of PM found in personal, residential, and ambient PM samples. Methods used to better define contributions to exposure from wood smoke and diesel and gasoline combustion are also being improved. Such methods have produced preliminary results showing that the high amounts of ultrafine particles near highways fall dramatically in relation to distance from the highway centerline and that ultrafine particles do not readily penetrate into buildings.

Many of the samples that were collected as part of the longitudinal PM exposure studies of Research Topic 1 will be analyzed for the major PM constituents and size fractions and, in some cases, speciated organics. Preliminary results have shown that penetration efficiencies for ultrafine particles are very low and that, even in the absence of indoor sources, indoor-outdoor correlations are poor. Other studies have shown that outdoor concentrations of elemental carbon and several organic species are not homogenous across airsheds and are influenced by both mobile and stationary sources. For those species that show weak associations between central site concentrations and exposures or that are not well distributed across airsheds, data and models will be needed to develop better exposure surrogates for epidemiological studies and to conduct high quality exposure and risk assessments. Several models that refined the source attribution of PM fractions and their statistical applications are being expanded to be associated with health outcomes and the possible influence of the seasons. Research also includes development of new modeling techniques with which to evaluate exposure to PM constituents and sources.

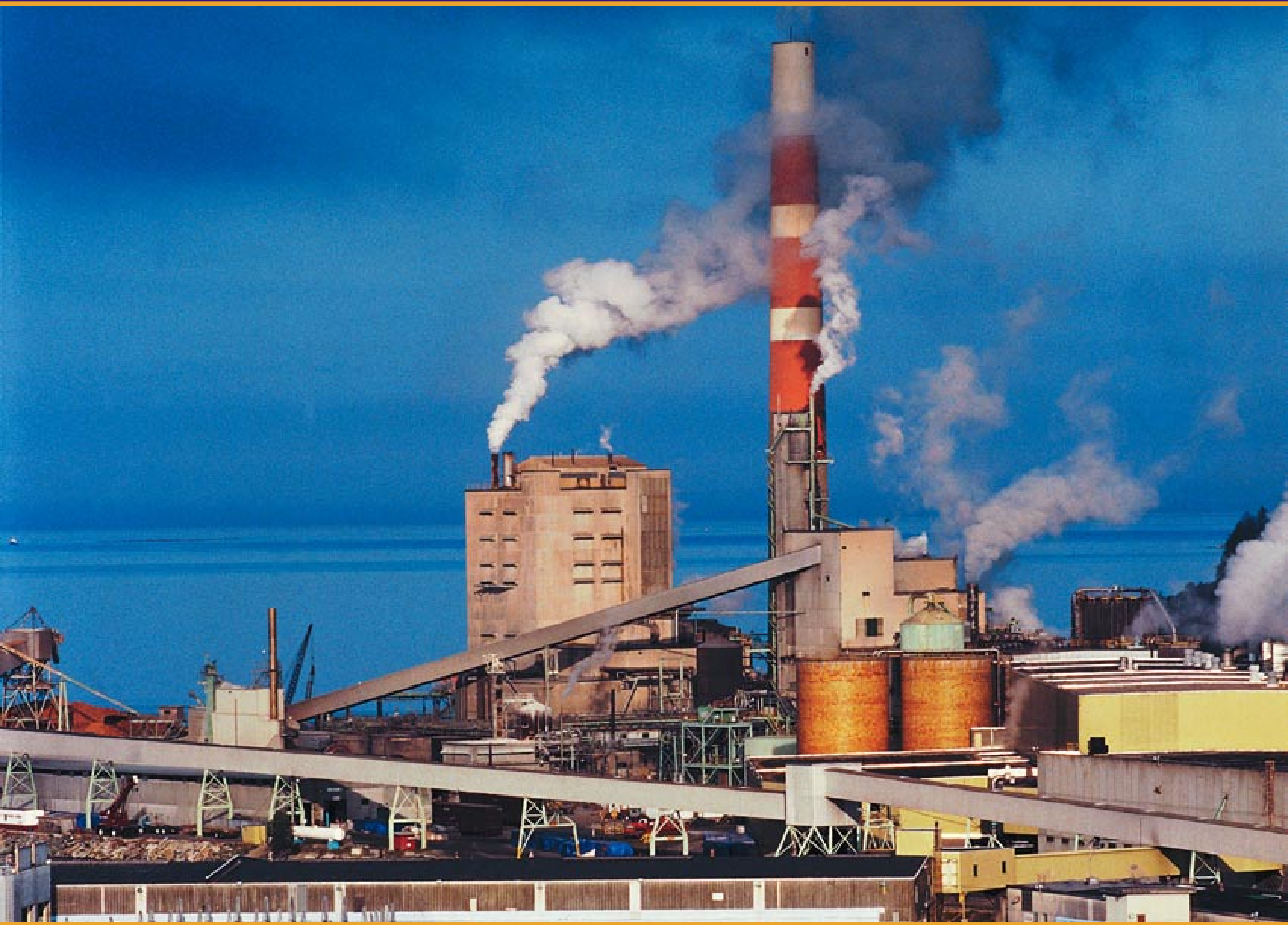
New field monitoring studies are being initiated to address the many remaining questions about personal exposures to PM with specific attributes or from specific source types and how these relate to what is measured at ambient monitoring sites. Based on the information from these studies, monitoring sites such as the PM Speciation Trends Network[2] sites can provide information about exposure to PM constituents across the country. This information will provide the basis for airshed-specific health studies which aim to explore specific associations with these measures and/or their predominant sources in order to improve associated risk assessments. Improvements in models directed at the spatial and temporal distributions of constituents and their source attribution will permit the development of models designed to predict exposure at community, residential, and personal scales.

...new studies are being planned and initiated to more fully understand and model exposures to PM constituents and PM from various sources.



The penetration of particles into the indoor environment is highly size dependent. Larger particles (>1 µm) are typically excluded by their inability to penetrate with the exchange of air. The smallest particles (<0.1 µm) easily adhere to surfaces and other items of contact and as a result also do not penetrate efficiently. Those particles between these sizes appear to penetrate most easily and also are highly respirable. While only slight differences in outdoor-indoor penetration exist between day and night, there are likely to be seasonal and behavioral differences, such as opened windows.

[2] *The Speciation Trends Network is a national network of approximately 50 ambient monitoring sites that has the capability to measure ambient levels of different chemical constituents of PM, including sulfates, nitrates, and elemental and organic carbon.*



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 particle formation through atmospheric chemical reactions?

ORD, in collaboration with OAR, has made substantial progress in compiling data on conventional (industrial) and less conventional (agricultural and other) sources of PM and PM-precursor emissions. Field and laboratory studies have significantly advanced our understanding of the chemical and physical characteristics of these source emissions resulting in new and revised "source profiles" that can be used to generate more complete and accurate airshed emissions estimates needed to allow air quality models to accurately predict ambient PM levels. Researchers are developing the specialized and complex measurement techniques needed to determine accurate particle sizes and compositions from diverse and often widely dispersed sources such as wildfires and concentrated animal waste facilities which have generally been underappreciated in terms of their contributions to ambient PM.

ORD's research efforts have focused on developing measurements and methods for the source types that are the most difficult to measure and to address areas for which the data currently available are highly uncertain.

Based on the NRC priorities and guidance from OAR and state and local regulatory agencies, EPA focused on five primary areas related to emission sources.

(1) Establish standard test methods to measure particle size and chemical composition for combustion sources. Scientists developed new or modified measurement approaches (hardware and operating procedures) for characterizing PM, including a dilution sampling system that collects emissions and allows the behavior of an exhaust plume to be modeled. The sampler also allows more relevant profiling of both organic and inorganic PM constituents than earlier versions. This work provided much of the technical foundation for EPA's new regulatory measurement methodology. Researchers also developed new methods to dynamically characterize the diesel exhaust from heavy-duty trucks during highway operation. This effort has provided especially valuable data concerning how PM emissions and characteristics change with fluctuations in real-world engine operation as well as on how PM evolves in an exhaust plume.

(2) Characterize primary particle size and composition of emissions. To develop or improve the emission profiles needed for modeling, ORD collected data to improve mass emission factors as well as PM composition and size information for many important emission sources. These sources have, to date, included residential wood combustion devices (including wood stoves), a heavy-duty diesel truck tested during highway operation, and various industrial boilers and combustors. The effects of fuel type and composition, as well as varied operating conditions, were determined for several of the above source types, along with performance data for pollution-control devices. Selected portions of this work also addressed questions about the toxicity of specific emission fractions with the future goal of associating toxicity with sources of ambient PM.

In cooperation with scientists from EPA Regions, ORD has addressed the effects of open biomass burning, which is common in the western U.S. The use of unique tracers or chemical fingerprints is being studied to estimate emission rates and assess how specific burning activities may influence local ambient air quality. ORD is also characterizing fugitive road dust contributions to the general air mix. Together, these data on primary emissions and precursors will update EPA's database of source chemical profiles and emission factors and will improve atmospheric models used to predict ambient concentrations and secondary particle formation.

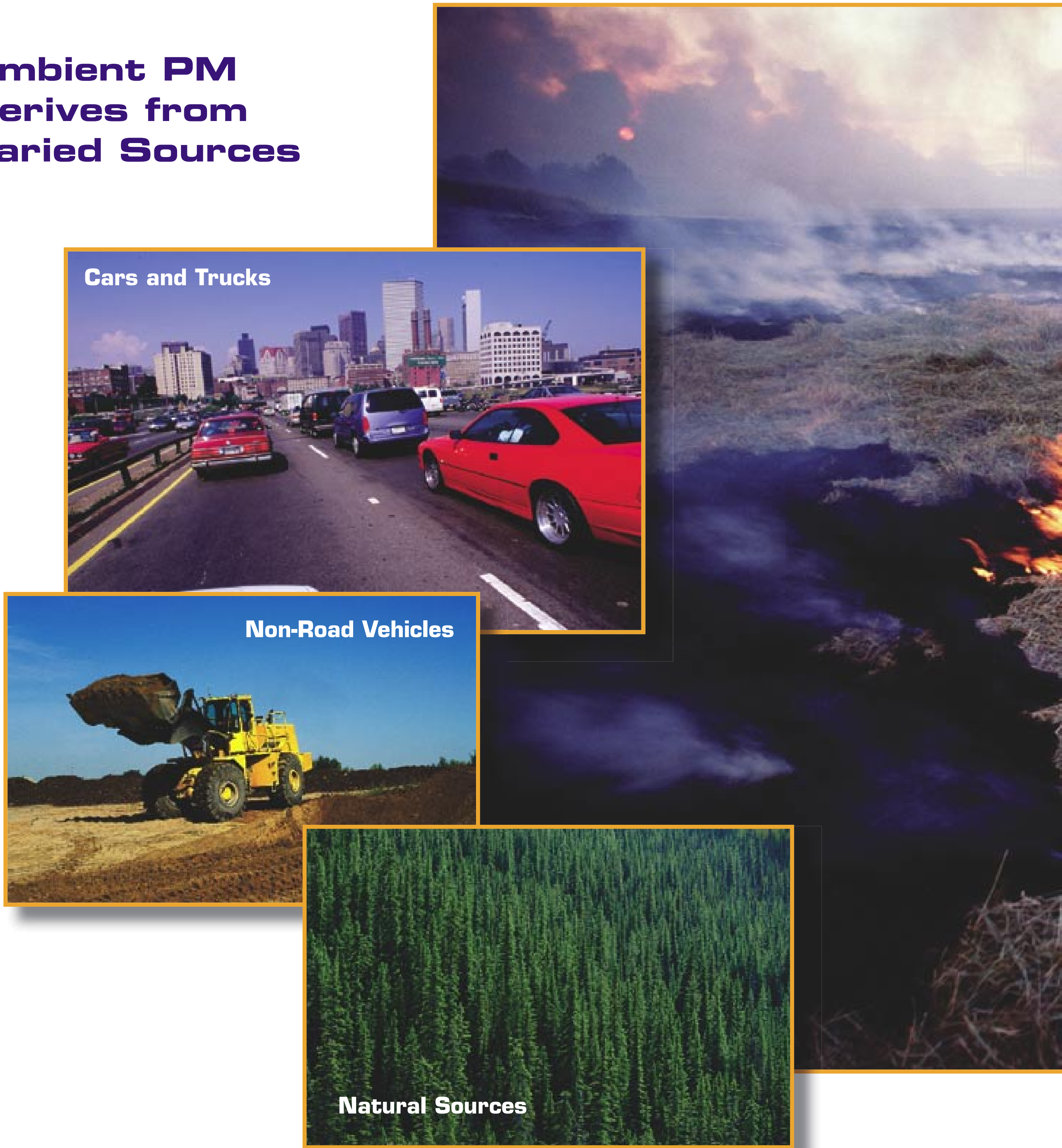
(3) Develop new measurement methods and collect data in order to characterize diffuse sources of gas-phase ammonia and organic vapors. Gas-phase ammonia is a critical co-pollutant in the evolution of ambient $PM_{2.5}$, especially in the eastern half of the country. ORD developed a method using a Fourier transform infrared (FTIR) laser system to measure ammonia emissions from hog barns and lagoons, which are significant sources of ammonia. Recent studies indicate that this same methodology can be used to measure other compounds, including methane and low molecular weight organic compounds from diffuse sources that usually cannot be measured by traditional stack-testing techniques.

(4) Translate new source-test procedures and source-test data into comprehensive, national, emission inventories. EPA research has substantially contributed to development of comprehensive, national emission inventories by OAR and individual states. Directly, EPA provided updated emission factors and improved speciation and size-distribution data for use in national emission inventories. Indirectly, EPA provided expert consultation and guidance for data collection and analysis. The advances in source-test procedures and data were used in national emission inventories in 2002 and are being used currently; the results will reduce the uncertainty associated with both mass emission rates and size distribution for many source types.

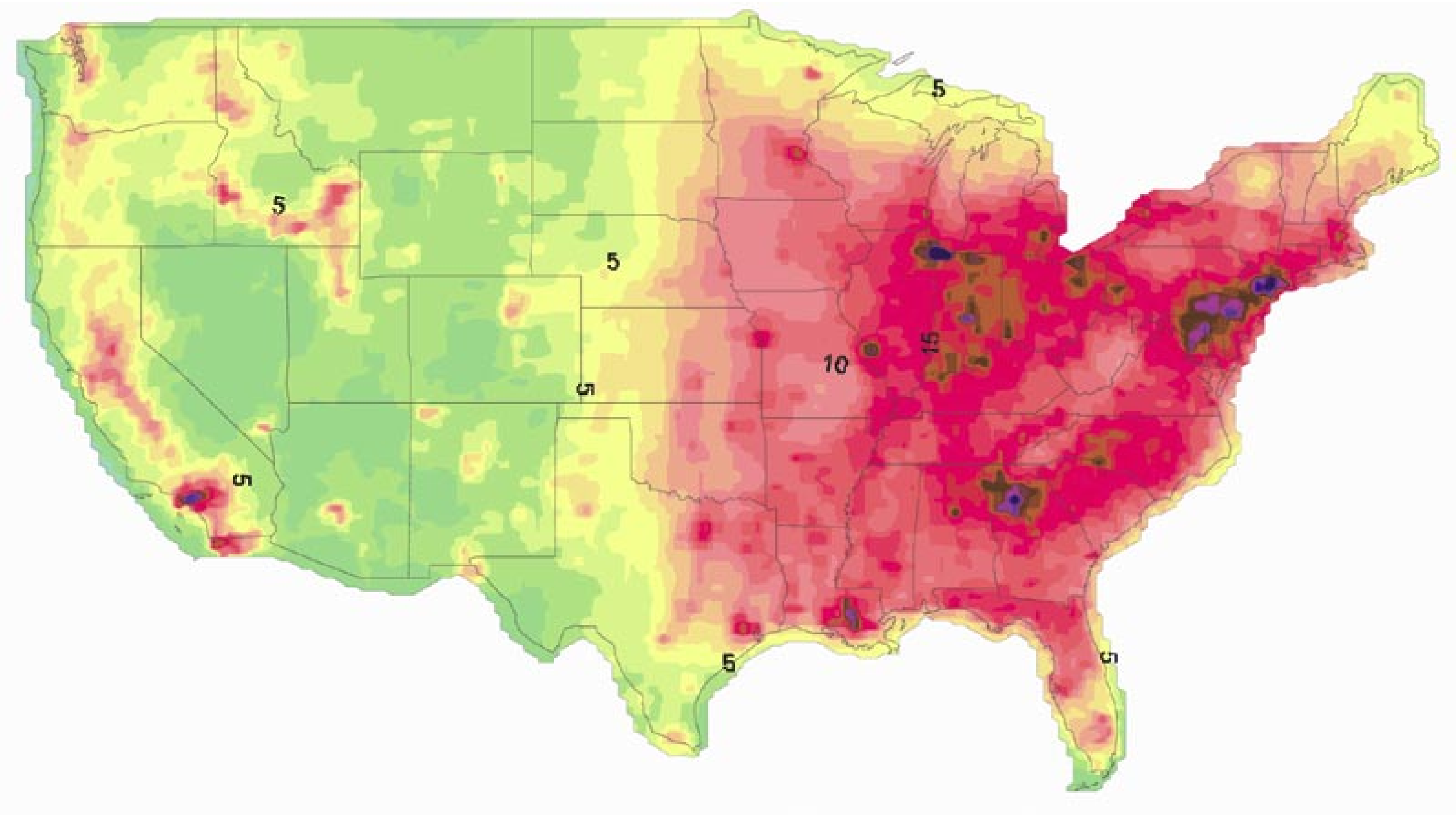
(5) Evaluation of PM and PM-precursor control technologies. Although the area of control technologies was not addressed by the NRC Committee report, ORD has conducted modest efforts to evaluate the performance of technologies to control PM and PM precursors to support the implementation of regulatory strategies to achieve the air quality standards. ORD has partnered with several other organizations, including industry, to leverage resources and expertise toward development of advanced PM control technologies.

Research has been and continues to be conducted to evaluate innovative approaches to improving the capture of fine PM from coal-fired power plants. By applying an electric field to a conventional baghouse, an electrostatically enhanced fabric filter system has been developed that can be retrofitted to plants currently using an electrostatic precipitator (ESP) or fabric filter system providing a cost-effective approach to incremental PM reductions. Work is also proceeding to address a potential problem associated with the installation of existing emissions reduction technologies at coal-fired power plants. In a limited number of cases, installation of SO_2 and NO_x controls can result in the formation of visible acid aerosol plumes. A review of current literature and available data has been conducted, and experiments are being performed to identify methods to prevent or eliminate the formation of these plumes.

Ambient PM Derives from Varied Sources




Industrial Sources
Heavy Duty Diesel Engines
Wood Burning Stoves
Agricultural Burning
Forest Fires



The CMAQ modeling system contains three types of modeling components: a meteorological modeling system for the description of atmospheric states and motions, emission models for man-made and natural emissions that are injected into the atmosphere, and a chemistry-transport modeling system for simulation of the chemical transformation and fate.

RESEARCH TOPIC 4

Air-Quality Model Development and Testing

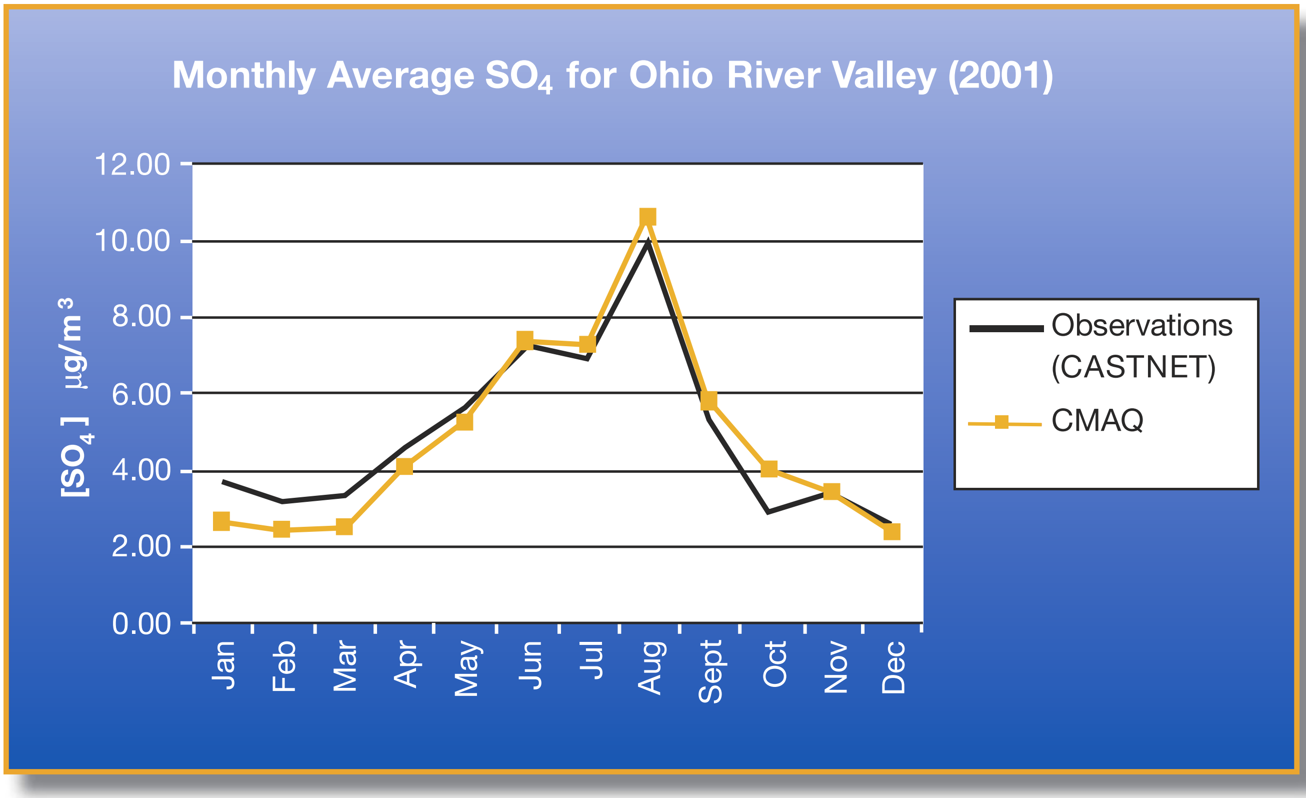
What are the linkages between emission sources and ambient concentrations of the biologically important components of particulate matter?

ORD has invested substantial effort in developing modeling approaches to address the links between ambient PM and emission sources that could contribute to health risks. Source-based models are predictive, forecasting the effects of emissions on primary (directly from the source) and secondary (chemically transformed) atmospheric PM. On the other hand, receptor-based models attempt to unravel the source attribution at the time of ambient measurements. When used together, these source- and receptor-oriented models provide regulators with the necessary data to develop, test, and evaluate the effectiveness of PM emission reduction strategies for State Implementation Plans (SIPs).

Source-based air quality models for PM were developed from earlier models designed for acid rain and ozone. These disparate models were integrated and updated with new information on atmospheric chemistry to create the initial Community Multiscale Air Quality (CMAQ) Model, which was released in 1998. The most recent version of the CMAQ Model, released in June 2002, incorporated the current state of the science in atmospheric processes at that time. The model is to be further evaluated with the $PM_{2.5}$ data now becoming available from air monitoring networks and large field studies. In addition, the CMAQ Model will also be improved through the incorporation of newly developed chemical modules that describe the complex PM chemistry with a specific focus on the formation of secondary organic aerosols. Through model evaluation and incorporation of improved atmospheric chemistry, significant improvements in the predictive capability of the CMAQ Model are planned by its next release in 2005. This release will provide a valuable tool for modeling air quality for states to use in developing their SIPs.

With SIP development beginning in 2004 and 2005, ORD has endeavored to provide user-friendly versions of available receptor-based models to state and local regulators. Two PC-based models have been developed: the Chemical Mass Balance (EPA CMB8.2) and Unmix (EPA Unmix2.3). CMB fully apportions exposure to the spectrum of sources and is highly dependent on the quality of the constituent-linked source-profile database. Unmix internally generates external source profiles from ambient data and will probably be a useful tool for handling the vast amount of data being generated by the national Speciation Trends Network. In addition to developing receptor modeling tools, EPA has also applied receptor-based models to identify the relative contributions of gasoline vehicles and diesel vehicles to ambient fine particle levels.

The Unmix model...[provided the first] quantitative estimation of the separate contributions of diesel and gasoline engines to ambient levels of $PM_{2.5}$



The CMAQ Model is able to predict changes in particulate sulfate levels by simulating how sulfur dioxide, the major precursor to particulate sulfate, is transported and transformed in the atmosphere. This comparison of measured sulfate levels (in black) with CMAQ Model results (in orange) shows the model is able to predict changes in particulate sulfate concentrations as meteorology and upwind emissions of sulfur dioxide change over the course of a year. The ability to identify how particle concentrations change as emissions change is crucial to developing effective air quality management strategies.

Assessment of Hazardous Particulate Matter Components

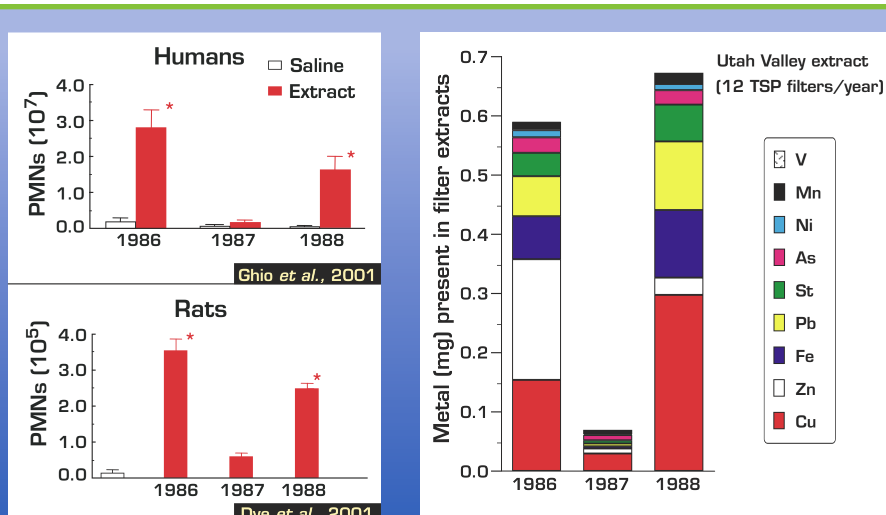
What is the role of physicochemical characteristics of particulate matter in eliciting adverse health effects?

Several hypotheses regarding the role of specific hazardous PM attributes[3] have emerged from ORD research since 1997. There now seems to be little doubt that there are adverse, PM-associated effects on human health and that several potential "active" attributes of the PM mixture may be involved.

The "causal" attributes of PM can be classified as either physical, chemical, or biological. EPA has conducted toxicological studies to build on previous epidemiological evidence that PM-related effects on cardiovascular or respiratory disease mortality and morbidity are strongly associated with exposure to smaller particles (effects of $PM_{2.5}$ > PM_{10} > total suspended particulate, or TSP). Some evidence also indicates that the smallest particles, the ultrafines, may have even greater potency. Further, in some instances, surface area may be a better dose metric than mass in evoking lung injury although not all ultrafine particles behave in a similar manner when comparably tested. Most epidemiological studies have found minimal effects on mortality risk for larger, coarser particles ($PM_{10-2.5}$), which are often of crustal origin. Yet time-series epidemiological studies of various morbidity end points, including respiratory symptom measurements and cause-specific hospitalization reports, have recently reported associations with both the fine and coarse PM fractions. It remains to be determined if health end points are differentially responsive to these size modes.

> Since 1997, empirical toxicological studies have provided important, albeit still limited, evidence indicting specific PM attributes as being primarily responsible for the cardiopulmonary effects linked to ambient PM.

The chemical composition of PM has received considerable scrutiny in toxicological studies; inorganic constituents have generated the most data to date. Sulfate and nitrate anions derived from combustion



A one-year closing of a steel-mill in Utah Valley provided a natural experiment to compare the effects of ambient PM in the Valley when the plan was and was not in operation. The composition of the PM suggested that metals played a role in its health impact.

[3] *"Hazardous" in this context does not refer to "hazardous air pollutants" as defined in the Clean Air Act, but is intended to convey the hypothesis that specific attributes of PM are responsible for the adverse health effects associated with exposure to ambient PM."*

emissions or atmospheric processes usually combine with other constituents in PM, especially the water-soluble materials. Although the intrinsic, independent toxicities of many sulfates and nitrates appear to be rather low, it is hypothesized that they may influence the toxicity or bioavailability of other PM components. Little is actually known about the cardiovascular effects associated with acidic aerosols or the possibility that they might mediate some of the reported PM effects, and this issue is now being explored in EPA-funded programs.

EPA toxicological studies have found that inhalation of certain metals results in inflammation in the lung and cardiac arrhythmias. While these studies were conducted with doses or concentrations of PM higher than typical ambient conditions, they demonstrate the potential for similar effects to occur in humans. Perhaps the most striking evidence for the importance of metals is from studies of PM-associated metals extracted from ambient filters in the Utah Valley at the site of a steel mill that was temporarily closed because of a labor dispute. Laboratory tests and human and animal exposure studies using material from particles collected when the plant was open and closed demonstrated similar patterns and types of effects. These EPA-supported studies corroborate the results of a separate study that found a decrease in hospital admissions for similar causes in the local population while the plant was closed. Extracts of the Utah Valley particles were tested in humans, animals, and *in vitro* cell cultures to compare the effects associated with particles collected during the periods when the plant was open and closed. Despite the relatively high doses used in these test systems, the experimental studies showed a pattern of response that was consistent with the reported epidemiological findings. Moreover, the experimental studies supported the hypothesis of a primary role for metals.

In a more focused analysis of the data from six U.S. cities, significant associations were found between mortality and two key sources of pollution—traffic and coal combustion—with the largest specific effect for the traffic factor.

EPA is investigating the toxicity of other chemical attributes of PM. Organic constituents are of particular concern due in large part to the contribution of various industrial sources as well as diesel and other mobile sources to the fine PM fraction. While not as overtly toxic as the some of the metallic compounds, some organic compounds appear to be able to generate oxidants that may cause delayed or subtle effects not readily measured by conventional methods.

Finally, EPA has begun to investigate the relationship between health outcomes and source-specific PM. If health effects can be linked to particular sources of air pollution, this information will prove useful for targeting control strategies. Field, epidemiological, and toxicological studies are emerging that can associate responses with sources. These studies are designed to help determine the PM components, characteristics, and sources most responsible for health effects. This information is required to ensure that control strategies are designed and focused on the PM sources that most strongly affect public health and to provide a sound scientific basis for the development of future PM standards.

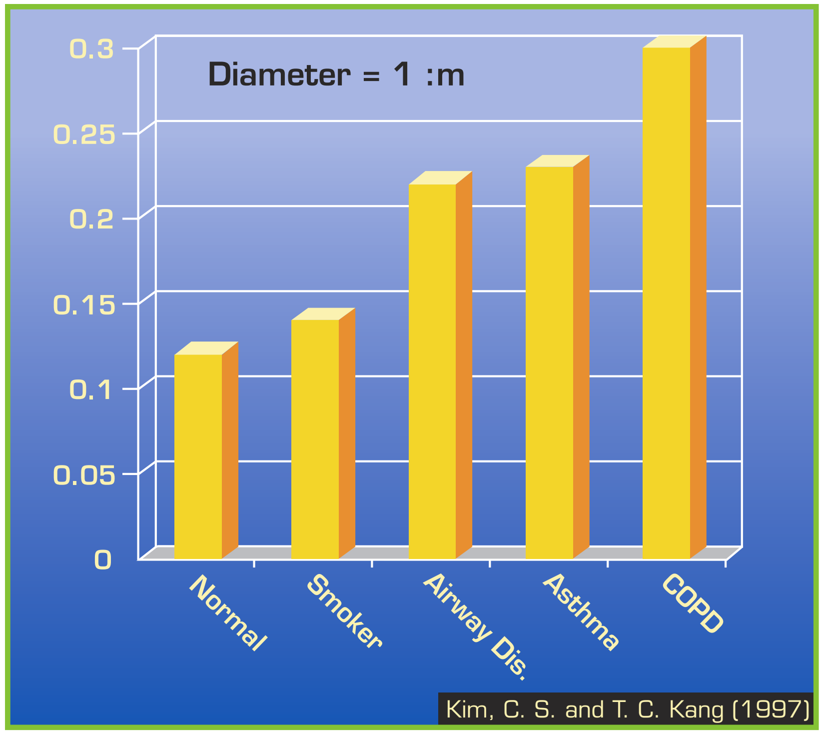
RESEARCH TOPIC 6

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?

Because the most relevant exposure measure of PM for health-risk assessment is the actual dose of particles in the lung, EPA developed a new, non-invasive method to measure the deposition of inhaled particles in different regions of the human lung. Studies using this method have significantly advanced our understanding of how different size classes of PM are deposited and the influence of age, gender, and respiratory diseases on the distribution of particle deposition within the lung.

Surprisingly, the smallest and largest of the potentially respirable PM, the ultrafine and coarse (PM_{10}-$PM_{2.5}$) PM fractions, are deposited in a healthy human respiratory tract in the same areas. It has long been understood that fine particles, including the ultrafine fraction, penetrate more deeply into the respiratory tract than coarse PM. However, it appears that the deposition patterns (as opposed to the penetration patterns) of ultrafine particles tend to be more similar to patterns of coarse particle deposition than to the patterns of fine particles. Clearly, the absolute dose deposited is different for different size fractions and depends largely on the size distributions of exposure aerosols. For urban aerosols with a dominant fine particle mode, mass deposition is similar for fine and coarse particles. While the number of ultrafine particles deposited may be much larger than the number of fine and coarse particles, the deposited mass of ultrafine particles tends to be negligible in most cases.



Fraction of inhaled small particles deposited in the lungs of human subjects. Those with various forms of airway and lung disease have a higher rate of deposition than normal healthy subjects.

This dosimetry information is important for understanding how a complex mixture of ambient PM may cause adverse health effects and why some people are more susceptible to adverse effects than others. Preliminary data suggest that some PM may, as a function of size and composition, migrate from the lung to other organs and tissues. Although these data need further confirmation, their potential implications are significant, especially in light of the cardiac effects attributed to PM.

PM deposition in healthy adults of different ages and in men and women was also studied. EPA researchers found that the respiratory dose in young and older adults is similar. Therefore, dose itself may not be responsible for differences in susceptibility to the health effects of PM by age. Similarly, overall respiratory dose is comparable in men and women but; in general, women tend to receive greater doses in their upper airway regions than men, possibly because their airways are somewhat narrower. This is consistent with some data that suggest women are more sensitive to irritant gases.

The respiratory dose of inhaled PM is unevenly distributed within the lung, and the actual dose in local airway regions can be many times greater than the average lung dose. People with impaired lungs may experience doses to airway "hot spots" that exceed those in a similar location of a healthy lung by a factor of 8 or 10. Therefore, exposure relationships alone may be inadequate to address responsiveness in potentially susceptible groups without some assessment of the dosimetry.

> The respiratory dose of inhaled PM is distributed unevenly within the lung, and the actual dose at local airway regions can be many times greater than the overall lung dose.

Generally, PM dosimetry in adult, healthy, human males has been well described by EPA researchers. Models have been developed to describe particle deposition for uniform breathing (both during rest or exercise) over a wide range of PM size. This idealized dosimetry has long been the standard for estimating lung doses of PM exposure. There are also analogous models for the laboratory rodents that are typically used in toxicological studies. These models are important for understanding exposure-dose relationships in toxicological studies conducted to address questions of mechanism, susceptibility, causality, and composition-specific effects on the lung. In contrast, dosimetry in impaired lungs is not well defined in animal models; consequently, its quantitative use in extrapolation to humans is limited.

The efforts in basic human dosimetry studies have waned in response to program priorities. ORD is now assessing the effect of cardiopulmonary diseases on the distribution of PM of various sizes in the various compartments of the respiratory system and how these distributions are mimicked in the animal models of these diseases.

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?

Much of what has been learned about the combined effects of PM and other air pollutants has emerged from the work done by extramural STAR Program grantees, PM Research Centers, and HEI. To date, these ORD-sponsored epidemiological and panel studies have found either no influences or only minor influences from co-pollutant exposure on the estimates of health risk from PM. The effects of PM appear to be independent from those of other criteria air pollutants.

Long-term health effects from PM that cause shortening of life, accelerated dysfunction, or exacerbated disease remain a major concern. At the time the PM regulations were set in 1997, two national-scale studies of long-term exposure to PM had been published in the peer reviewed literature. The Harvard Six Cities Adult Cohort Study and the American Cancer Society Cohort Study both reported significant associations between risk of premature mortality and long-term exposure to PM. To verify these results, HEI sponsored an extensive re-analysis effort which confirmed the findings of the original studies. Additionally, the ACS investigators extended the original study, doubling the follow-up time from 8 to 16 years; the results replicated the findings of increased cardiopulmonary risk and documented a significant association with mortality from lung cancer. Early methodological criticisms of these studies have been largely resolved, supporting the concerns about adverse effects of long-term exposure to PM.

Other studies in children exposed to a mixed oxidant-PM atmosphere suggest retardation of lung growth that is not fully reversible. Ongoing work at the U.S.-Mexico border suggests that asthma and economic status are important factors in the overall response. Work funded by the STAR Program is beginning to use established cohorts with the extensive medical histories or unique lifestyles that make them appropriate subjects for understanding the effects of long-term exposure to ambient PM.

This topic area, perhaps more than any other research priority identified by the NRC, is in its relative infancy due to the complexity, expense, and duration of longitudinal epidemiological studies of PM health effects and the lack of historical fine-particle monitoring data. Efforts are underway to address the effects of chronic exposure to ambient PM including new initiatives to study the health effects of long-term exposure

Pope et al. (2002) extended the original Adult Cohort Study by 8 years and replicated the findings of increased cardiopulmonary mortality risk, but in addition, reported a significant association with mortality from lung cancer.

initiated under STAR Program grants. Other initiatives to study chronic health effects in controlled animal studies have begun focusing on issues associated with the potential influence of the seasons and on identifying relevant biomarkers for long-term human studies. It is anticipated that the National Monitoring Network will be a key resource for many of the planned epidemiological studies and that laboratory animal studies will likewise attempt to use this rich database to assess specific causality and susceptibility hypotheses that link to potential chronic health outcomes.

A researcher checks the performance of a personal exposure monitor. Exposure research is helping EPA to understand when and how people are exposed to ambient PM, even when they spend significant amounts of time indoors.

Susceptible Subpopulations

What subpopulations are at an increased risk of adverse health outcomes from particulate matter?

Epidemiological studies in the 1990s indicated that risks of adverse effects from PM are higher in the elderly, children, and people with cardiovascular or respiratory disease. Children, infants, diabetics, and those with hypertension may also be at increased risk. EPA research, including clinical studies using human volunteers and novel animal models of disease, has begun to examine the biochemical and physiological mechanisms of PM-associated risks. For example, a number of studies have investigated the underlying biology of lung disease to understand why disease induces heightened sensitivity to PM. These studies used animal models of lung disease to show that animals with existing pulmonary inflammation may be intrinsically more responsive to PM. Similarly, a growing body of work has demonstrated PM-induced alterations in cardiac physiology in both humans and animals and has reinforced the hypothesis that PM exacerbates cardiovascular disease conditions. Studies in healthy elderly adults have demonstrated that exposure to concentrated ambient PM causes subtle changes in autonomic control of cardiac function and clotting factors. Although small, these changes are considered clinically significant based on other studies of cardiac disease progression.

Susceptible Subpopulations

Effect of PM_{10} (per 100 µg/m^3) Among People with Each Predisposing Condition

Individual Covariate Pattern	*Increase in Risk*	*95% Confidence Interval*
None of the five conditions	7.6%	(-2.9, 19.1)
Myocardial Infarction	23.7%	(-0.6, 53.8)
Diabetes	15.1%	(-1.6, 34.1)
Congestive Heart Failure	12.9%	(-1.0, 28.8)
COPD	5.8%	(-7.9, 21.5)
Conduction Disorder	6.8%	(-5.6, 20.8)

The risk of mortality associated with exposure to elevated levels of ambient PM increases, in some cases substantially, for people with pre-existing health problems. Researchers are studying why certain groups may be more sensitive to the effects of PM than others, which can help in the development of public health responses to air pollution events.

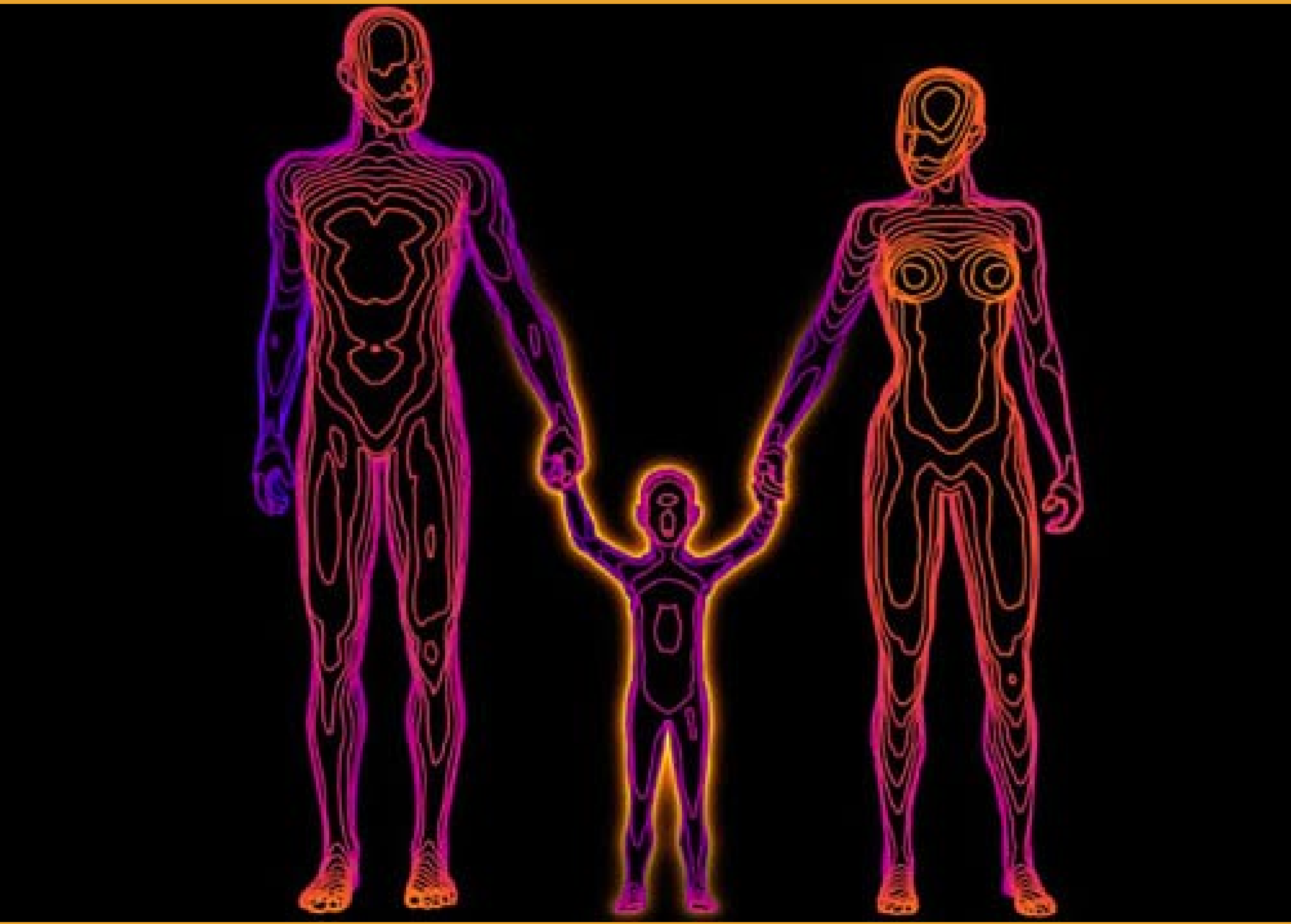
The results supported previous findings identifying those with pre-existing cardiopulmonary conditions at increased risk for ambient PM effects and implicated another possible risk factor—diabetes.

Epidemiological data are emerging on certain types of medical conditions that potentially predispose individuals to an increased risk of PM-associated mortality. Recent studies found that those with pre-existing cardiopulmonary disease or with diabetes were at increased risk for PM-related effects.

Researchers have begun to investigate the effects of PM exposures on physiological development in children. The Southern California PM Research Center is supporting assessment research on PM and traffic exposure for the ongoing California Children's Health Study, which has reported an increased risk of impaired lung development in children living in areas with higher levels of air pollution. Other studies are examining PM effects in young animals to identify possible effects of prenatal and postnatal exposures.

Thus, studies to date suggest that certain subpopulations are indeed more acutely responsive to PM, perhaps due to differences in lung deposition or to other biologic aspects of the cardiopulmonary system or disease. Emphasis on the identification and characterization of susceptible groups will continue, as will determining whether prolonged PM exposure moves one into a more susceptible state by impairing defenses or diminishing function. The role of genetic predisposition is largely unknown, but is potentially of great importance. Another key topic that has not yet been adequately addressed is individual risk and the elements that define or underlie that risk.

…there is sufficient evidence to conclude that certain groups are likely to be more sensitive or responsive to PM than others.



Mechanisms of Injury

What are the underlying mechanisms (local pulmonary and systemic) that can explain the epidemiological findings of mortality/morbidity associated with exposure to ambient particulate matter?

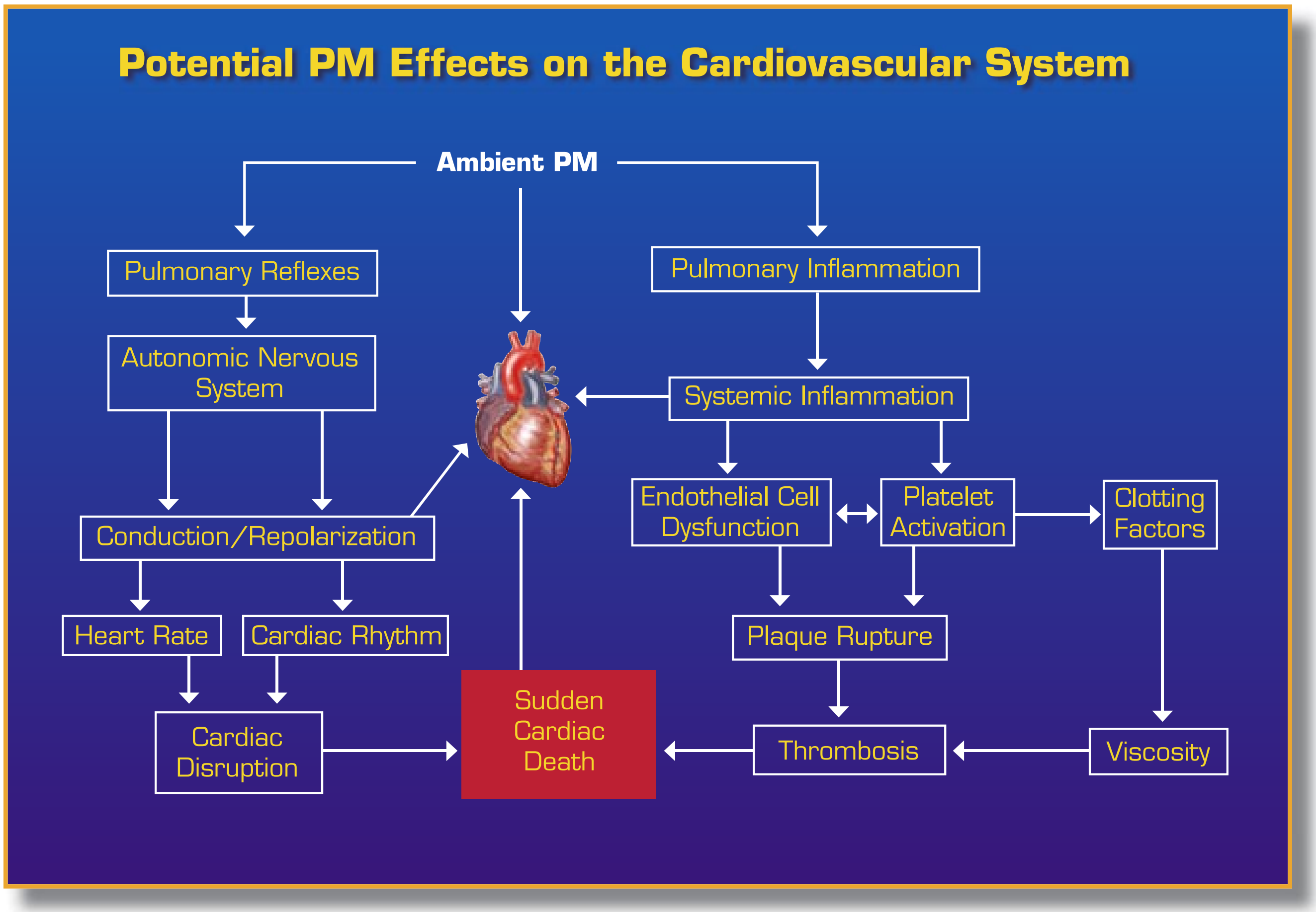
To understand the underlying biological mechanisms that explain how PM might cause adverse health effects, ORD has investigated several hypotheses. The mechanisms of PM toxicity are potentially quite complex and may involve interactions and/or interdependencies between several organ systems or tissues such as the lung, heart, vascular system, and autonomic nervous system. The primary portal of entry for PM air pollution is clearly the lung, and PM interactions with the lining of the lung may lead to immunologic and other responses that cause a wide range of pulmonary effects. These effects include lung injury, inflammation, and changes in resistance to infection or sensitivity to allergens. Exposure to PM or its reaction products may also alter respiratory rate and tidal volumes. Soluble components of PM may diffuse into the circulatory system and may be distributed systemically or may perhaps activate cells within the lung to secrete mediators that likewise can move throughout the body. Not surprisingly then, PM appears to exert a number of systemic effects, particularly on the cardiovascular system.

> The presence or absence of an inflammatory response is an important issue because inflammation may induce systemic effects.

The growing number of reports associating PM with cardiac death, morbidity, or altered cardiac function has spurred new thinking about how these problems could occur. One route under investigation by EPA is via neural mechanisms involving the autonomic nervous system. PM may act via direct pulmonary irritant reflexes in the airways or through reflexes activated during pulmonary inflammation. This effect could affect cardiac function via nervous system networks that operate to protect the lung or maintain homeostasis. Inflammatory changes in the heart or stimulation of bone marrow cells could modulate or impair normal function in an already diseased or stressed heart. Other studies report altered blood viscosity or circulation of cells, both of which are consistent with an increased risk of cardiac events. Because PM is a complex mixture of many different components, different components may stimulate different biochemical pathways or interact in other ways to alter the dose required to evoke a response. Thus, exposure to PM, depending on its chemical and physical makeup, may result in the activation of one or more pathways.

- Chapel Hill (NC) CAPs [concentrated ambient particles] cause mild pulmonary inflammation...
- Los Angeles CAPs [and] carbonaceous ultrafine particles provide evidence of systemic markers of inflammation.
- PM has also been shown to induce changes in conductance and repolarization of the heart.
- Some studies are reporting PM induced increases in several clotting and coagulation factors and vascular inflammatory cells...that might trigger cardiovascular events.

Five years ago, a description of PM health effects would typically include a caveat that the underlying biological mechanisms were unknown. Recent developments that led to multiple novel hypotheses indicate a rapid growth in our understanding of how PM can cause adverse effects. ORD, through its intramural and extramural programs, will be focusing specifically on early and primary events to separate the effects of PM from those of other stressors. Among various susceptible groups, there may be a common thread that explains what contributes to susceptibility to PM and why health effects occur.



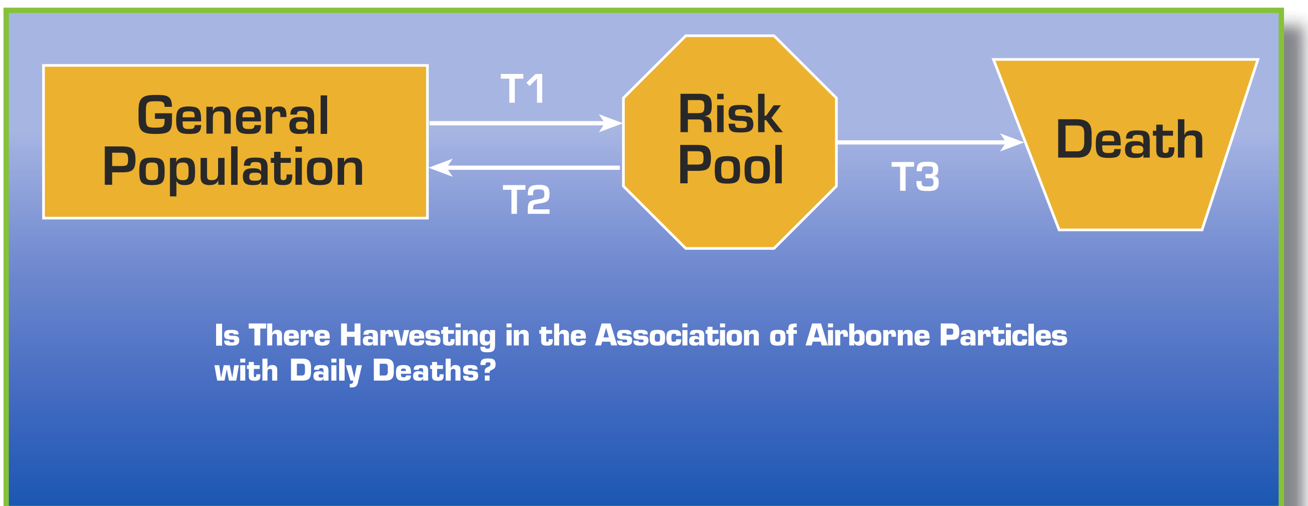
There are numerous pathways by which exposure to ambient PM can lead to cardiac events, including sudden cardiac death. EPA's research is examining these biological pathways to better understand how PM affects health.

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?

Since the early 1990s, more than 100 epidemiological studies have reported increases in mortality and morbidity associated with exposure to ambient PM. Most of these studies relied on novel statistical models or approaches and involved monitoring data not designed a priori for research use. To address these concerns and in response to recommendations in the first NRC Committee report, EPA and the University of Washington held a Workshop on Particulate Methodology in 1998. Since the workshop, many statistical concerns have been addressed by more detailed temporal and spatial segregation of important variables, independent re-analysis using alternate models, or a combination of databases for comparative or more rigorous evaluations. Basic issues such as the adherence to dose-response principles and testing for potential interactions with co-pollutants have also been addressed. Generally, investigators have concluded that the health effects of ambient PM are not the result of a statistical or methodological anomaly, but constitute a real and national problem.



Results of model analysis suggest that air pollution has a sustained impact on health. It increases the flow of people (T1) into the Risk Pool and reduces "recovery" (T2) further increasing the size of the Risk Pool as well as increasing the those who succumb and move into T3. (Schwartz 2001)

The developments in statistical methods have allowed researchers to evaluate specific questions concerning the nature of the mortality risks observed. For example, the question of whether deaths from air pollution observed in times-series studies occur only in very ill people who are days away from death, even if not exposed, has been addressed. These analyses indicate that individuals for whom death is imminent comprise only a small portion of the deaths associated with PM exposure and reported in the time-series studies.

In 2002, statisticians raised the concern that risk estimates for acute PM health outcomes had been overestimated because researchers had relied on a pre-programmed default assumption in a commonly used statistical model. To address this issue, ORD convened a workshop in November 2002 to consider the technical issues and to discuss how to overcome them. The studies deemed most relevant to the reassessment of the PM NAAQS process were subsequently re-analyzed using alternative statistical techniques. HEI conducted a peer review of the re-analyses and issued a report on its findings in May 2003. The re-analyses indicate that the relationship between PM exposures and adverse health outcomes remains statistically significant. The revised effects estimates were lower in most cases, although in some revised studies no decrease was noted in the effects estimates. The HEI peer-review panel concluded that the fundamental understanding of the association of adverse health effects with PM mass was not altered by the re-analyses.

In keeping with its basic health and implementation research efforts, ORD is attempting to associate outcomes with emission sources and with principal components of PM. Improvements in monitoring methods, exposure estimates, and data models/analyses will help refine risk assessments and will guide regulatory activities appropriately.

> [The ORD workshop]...led to a substantial clarification of the potential effects of problems in the use of general additive models...
> ...it appears that the existence of a statistical link between exposure to ambient PM and health outcomes remains valid...

Instrument for measuring PM concentrations.

Technical Support

Atmospheric Measurements and Methods[4]

[4] Projects and methods that support issues are addressed under Research Topics 3 and 4.

Since 1997, EPA has made significant advances in the development and field application of methods to measure PM. These efforts are broad-based, range from state-of-the-art methods development and validation to monitoring network design and PM characterization, and have relied upon coordinated activities across the Agency and with the broader scientific community to achieve the program's advances.

With the establishment of the $PM_{2.5}$ NAAQS, the refinement and standardization of a Federal Reference Method for monitoring $PM_{2.5}$ became paramount. The $PM_{2.5}$ methodology has now been validated in the field and used in the National Monitoring Network to collect the three years of data necessary for use in compliance determinations. With the anticipated need to specifically sample coarse PM, prototype samplers are entering their final testing phases. Ultimately, the goal for all these monitoring devices—which, at present, use filters and usually provide 24-hour measurements—is to achieve continuous, real-time measurement that can reveal rapid cycles and peaks not previously apparent.

In an effort to define new methods to advance monitoring technology and atmospheric science, EPA established the PM Supersites Program. These seven sites distributed throughout the nation were competitively selected to intensively characterize PM and associated co-pollutants and to provide opportunities to test the latest technologies in aerometric analyses. Early on, EPA made great efforts to coordinate with members of the private sector (the Electric Power Research Institute, or EPRI) and other Federal agencies, either directly or through CENR and NARSTO.[5] The five eastern sites were organized into the cooperative Eastern Supersites Program that designed intensive, seasonal studies over a 13-month period from 2001 to 2002. These data comprise the most extensive database on PM collected to date. Additionally, many new technologies were tested and validated, including approaches to making continuous measurements, single particle analyses, and others. The data from these studies are available on the web for public, scientific, and programmatic use.

PM measurement techniques have advanced, but much remains to be done to bring these techniques into wider application. Continuous and semi-continuous methods for PM mass (fine, coarse, and PM_{10}) and its major components are being developed. Likewise, with the emphasis on speciation of PM constituents, methods for measuring the chemical composition and physical properties of single particles are also emerging to complement more standard methods. In cooperation with the National Institute of Standards and Technology (NIST), EPA has been collecting samples to be used as Standard Reference Materials.

[5] *Formerly an acronym for the North American Strategy for Tropospheric Ozone, the term NARSTO is now commonly used to signify this tri-national, public-private partnership for dealing with multiple features of tropospheric pollution, including ozone and suspended particulate matter.*

Conclusions

Five Years of Progress

As the preceding pages have illustrated, the first five years of EPA's expanded research program have led to a wealth of new information and significant advances in PM science. EPA established a sound strategy, involved many partners, and successfully conducted high-priority research. Highlights of key accomplishments include the following:

Verification of PM-associated health effects: Studies showing that exposure to ambient PM can adversely affect human health have been replicated many times in a number of locations throughout the U.S. and the world. Generally, exposure to PM is associated with morbidity and mortality independent of the effects of other gaseous pollutants in the atmosphere. Recent studies have also underscored that the elderly with pre-existing cardiopulmonary disease appear to be most at risk. In addition, other groups such as the very young, asthmatics, and diabetics may also be susceptible to the effects of PM. Even more striking are the findings that suggest that extended exposure to PM can lead to chronic disease and/or shortened life span.

Confirmation of exposure measures: In 1997, the relationship between outside PM measurements and the concentrations to which people were actually exposed was not known. Results from exposure studies have verified that, for fine PM mass and sulfate, the central-site monitor should serve as an adequate surrogate for exposure in community-based epidemiological studies. While the strength of the correlation may vary by location, housing characteristics, and season, these data support the assumption used in health studies that measurements of outdoor $PM_{2.5}$ concentrations at central monitoring sites provide a valid representation of personal exposure to ambient $PM_{2.5}$. Exposure studies have also found that gaseous co-pollutants such as ozone and nitrogen dioxide measured outdoors can serve as appropriate surrogates for personal $PM_{2.5}$ and are not likely to interfere significantly with estimates of PM health risks.

Advances in dosimetry: Prior to the advent of the expanded PM Research Program, little was known about the deposition of fine particles in the impaired lung. Since then, laboratory studies have shown that inhaled PM is distributed unevenly in the respiratory tract and that actual dose at local airway regions can be many times greater than the average lung dose. These studies determined that as many as 10 times more particles are deposited in certain regions of the lungs of people with pulmonary disease. This may indicate that their increased susceptibility is due to exposure to a higher dose.

Plausible biological mechanisms: While scientists could not explain the observed effects in epidemiological studies from a biological basis five years ago, there are now multiple hypotheses describing the mechanisms by which very small concentrations of inhaled PM may produce the cardiovascular and pulmonary changes that contribute to increased illness and death. Similarly, laboratory studies and animal models that mimic human disease have stimulated several theories about how the physicochemical properties of PM produce toxicity. Somewhat surprisingly, there appears to be no single attribute that makes PM toxic, but size and certain chemical components (e.g., metals) appear to be involved. This is supported by both laboratory and field evidence.

Development of predictive models and evaluative tools to achieve reduction in PM: EPA is improving and developing tools to simulate and measure atmospheric processes and concentrations and is working to identify and characterize sources of PM. It is developing several models to address the links between ambient PM and emission sources. Such models are needed to estimate how much source-designated PM will reach populations likely to be affected. EPA's emission-inventory data and accurate air quality models are being applied to regions all around the country. The PM Research Program is also developing the specialized measurement techniques needed to determine the detailed particle sizes and compositions of PM from diverse and often widely dispersed unconventional sources such as wildfires.

Looking Ahead

As recognized by the NRC Committee in its original report, five years of expanded PM research are not sufficient to answer all of the most pressing questions. The first, very productive portion of this program has tackled many issues and laid the groundwork for addressing others. In addition, new research topics such as linking sources of PM to ambient concentrations and to health effects have emerged as promising areas for further research. Looking ahead, EPA will sustain its commitment to PM research to ensure that future reviews of the PM NAAQS are on the strongest scientific footing possible and that tools are available to implement the standards efficiently, effectively, and as inexpensively as possible. Highlights of future efforts include the following:

Effects of long-term exposure to PM: The role of long-term PM exposure in the development of chronic disease and how this long-term exposure combines with short-term fluctuations in PM levels to trigger acute events such as heart attacks is far from understood. In 2003, EPA issued a request for research grant proposals to conduct a 10-year longitudinal epidemiological study to examine the health consequences of long-term exposure to PM.

Biological mechanisms explaining susceptibility to PM effects: Now that several plausible mechanistic hypotheses have emerged, EPA will investigate their significance. These investigations will likely focus on human subpopulations and animal models with cardiopulmonary and associated systemic diseases that appear to contribute to PM sensitivity.

PM attributes and source apportionment of health effects: We still do not understand enough about the physicochemical properties of PM and how they relate to health outcomes. Source attribution of health effects is a growing area of interest, and ORD plans to expand exposure, toxicological, and epidemiologic research to pursue source-based linkages of hazardous components and effects. Through these efforts, the contributors to PM's adverse health effects can be more appropriately targeted for mitigation.

Air Quality Criteria Document (AQCD) for PM: By the end of 2004, EPA will complete its comprehensive assessment of PM science, the Air Quality Criteria Document for Particulate Matter. This document, which is required prior to the regulatory review of the NAAQS, will consider the findings of over 2,000 studies published since the last assessment in 1996. With completion of EPA's Office of Air Quality Planning and Standards (OAQPS) Staff Paper that evaluates the policy implications of the key scientific information, EPA will issue a decision concerning possible revision of the PM NAAQS based on the science delineated by the AQCD.

Human exposure to PM constituents and PM from specific source types: Exposure studies suggest that ambient concentrations provide an adequate surrogate for personal exposure to ambient fine particle mass and sulfate in community-based epidemiological studies. However, the same may not hold true for other components. Research is needed to evaluate exposures and health effects for those components associated with specific source types. EPA's exposure program will provide information to associate actual human exposure to ambient levels of PM components and PM from specific sources, which will provide the basis for more complete understanding of the relationships between source-specific PM and adverse health effects.

Tools for developing PM control strategies: With more than two years of $PM_{2.5}$ monitoring data now available from the National Monitoring Network, there is a pressing need for accelerated research related to the development of the tools and data needed by states and others for the development of approaches designed to achieve the PM standards. Such data includes the characterization of emissions and improved regional and local atmospheric modeling of $PM_{2.5}$. The next generation of analytical tools to help EPA and the states with NAAQS implementation was released by EPA in 2003. In 2004 and 2005, OAR will announce which states and regions are not in compliance with the NAAQS based on $PM_{2.5}$ monitoring and modeling data. This announcement will require the states and regions to develop plans and strategies that will enable them to meet the NAAQS. Additional EPA research will focus on likely causes of states and regions being unable to attain the standards beyond failure to implement current and pending regulations to reduce emissions such as local concentrations of carbonaceous particles.

Continuation of research partnerships: EPA's successes in the sciences that have expanded our understanding of pollutant emissions, transport, and transformation, as these relate to exposure and associated health effects of ambient PM have resulted from the combined work of EPA scientists, EPA-funded researchers, and our federal and academic partners. As the scope of studies increases, it becomes increasingly important to build upon these partnerships, such as with HEI, to achieve the goals of the program. Epidemiological research to evaluate the effects of PM and co-pollutants across multiple and diverse locations as a means to better understand how the emissions from specific source types are linked to health effects is one example of a large-scale effort that can benefit from strategic partnerships, and continue to provide the science needed to refine future air quality standards.

In addition to the research directions highlighted previously, EPA will rely on the final report of the NRC Committee to determine whether any additional changes in research direction are warranted. In this way, EPA's partnership between ORD and OAR remains an essential part of its efforts to achieve the Agency's Clean Air Goal. EPA will continue to integrate its diverse, yet targeted, health and implementation research agenda to ensure that air quality standards are scientifically sound and that approaches to achieving compliance with these standards are based on information and technical tools that are as accurate and effective as possible.

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