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Proceedings of an HEI Workshop on Further Research to Assess the Health Impacts of Actions Taken to Improve Air Quality

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Communication 15

Health Effects Institute

Boston, Massachusetts

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ABOUT HEI

The Health Effects Institute is a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the effects of air pollution on health. To accomplish its mission, the institute

- Identifies the highest-priority areas for health effects research;
- Competitively funds and oversees research projects;
- Provides intensive independent review of HEI-supported studies and related research;
- Integrates HEI's research results with those of other institutions into broader evaluations; and
- Communicates the results of HEI's research and analyses to public and private decision makers.

HEI receives half of its core funds from the U.S. Environmental Protection Agency and half from the worldwide motor vehicle industry. Frequently, other public and private organizations in the United States and around the world also support major projects or certain research programs. HEI has funded more than 280 research projects in North America, Europe, Asia, and Latin America, the results of which have informed decisions regarding carbon monoxide, air toxics, nitrogen oxides, diesel exhaust, ozone, particulate matter, and other pollutants. These results have appeared in the peer-reviewed literature and in more than 200 comprehensive reports published by HEI.

HEI's independent Board of Directors consists of leaders in science and policy who are committed to fostering the public–private partnership that is central to the organization. The Health Research Committee solicits input from HEI sponsors and other stakeholders and works with scientific staff to develop a Five-Year Strategic Plan, select research projects for funding, and oversee their conduct. The Health Review Committee, which has no role in selecting or overseeing studies, works with staff to evaluate and interpret the results of funded studies and related research.

All project results and accompanying comments by the Health Review Committee are widely disseminated through HEI's Web site (*www.healtheffects.org*), printed reports, newsletters and other publications, annual conferences, and presentations to legislative bodies and public agencies.

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Proceedings of an HEI Workshop on Further Research to Assess the Health Impacts of Actions Taken to Improve Air Quality

CHAPTER 1. INTRODUCTION

OVERVIEW

As HEI's current program of research to assess the health consequences of actions taken to improve air quality nears completion, interest in this issue has never been higher among HEI's sponsors and the broader international community of HEI stakeholders. This interest reflects an increased awareness of the magnitude and global distribution of the burden of disease attributable to air pollution, and the tightening of guidelines and standards designed to reduce human exposure, even in locales that enjoy comparatively good air quality. Increasingly, this interest also reflects a growing appreciation among stakeholders and the scientific community of the need to assess the health impacts of actions taken to slow climate change.

In 2003, the Health Effects Institute published Communication 11, *Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research* (HEI Accountability Working Group 2003). In its six chapters, this document defined the concepts of *accountability* and *accountability research*; set the historical and regulatory context for their application; considered methodologic issues; and offered a research agenda for accountability. While not explicitly defining accountability, it offered a general framework — the "chain of accountability" — for considering accountability research and the implication of its findings (Figure 1). Communication 11 guided the development of a research program related to accountability, a portfolio that includes nine studies.

The goals and preliminary findings of these studies were reviewed in Communication 14, *HEI's Research Program on the Impact of Actions to Improve Air Quality: Interim Evaluation and Future Directions* (van Erp and Cohen 2009). The studies funded by HEI are detailed in the table in Appendix A in this volume, and other relevant studies are summarized in Table D.1 in Appendix D (available on the HEI Web site). The studies can be characterized by time domain (shorter- and longer-term) and by the nature of the intervention investigated: changes in fuels or combustion technology; changes in sources and in traffic; and whether or not multiple actions were taken. They have been conducted in the United States and other countries. These studies provide a wide range of experiences for identifying "lessons learned."

This publication summarizes the findings of a workshop held December 17–18, 2009, at the Massachusetts Institute of Technology's Endicott House in Dedham, Massachusetts (see Agenda in Appendix B in this volume), which reviewed the current state of accountability research being carried out by the Health Effects Institute. A multidisciplinary group reviewed the nine HEI studies implemented to date, along with other studies, in the context of the framework developed in Communication 11. The review was timely, as five of the studies had been completed and the remaining four were nearing completion. The workshop also afforded an opportunity to revisit the framework of accountability research proposed in Communication 11 and to consider methodologic issues related to accountability.

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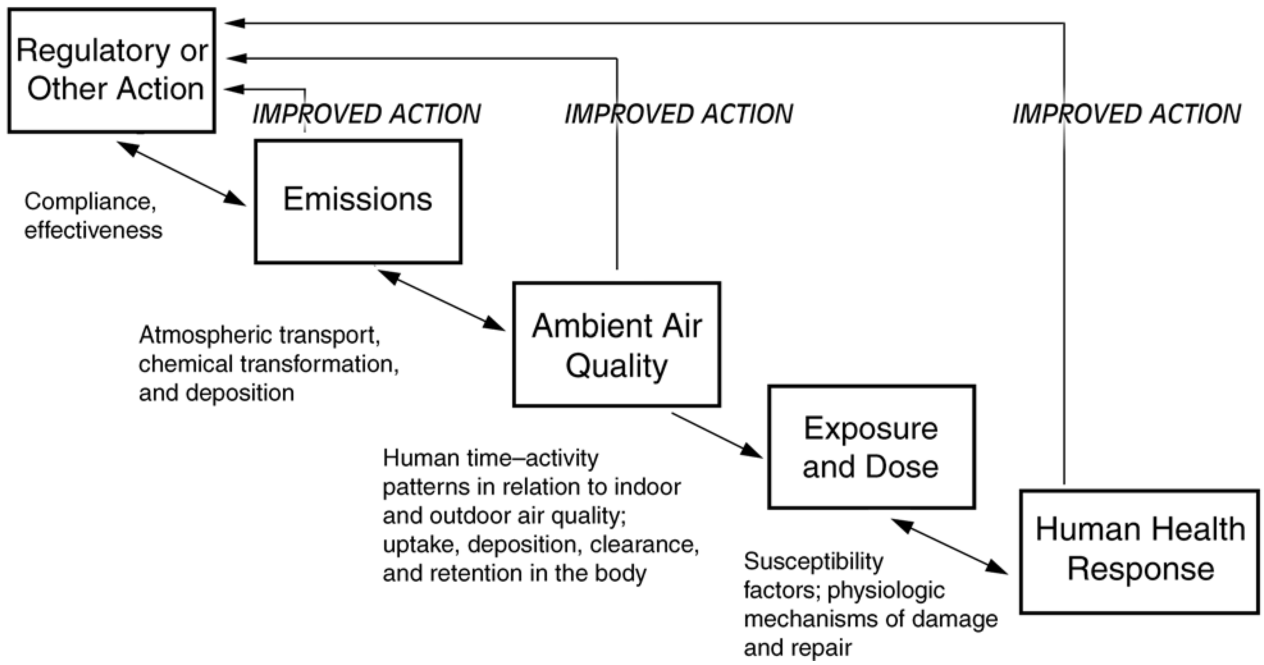

Figure 1. The chain of accountability. Each box represents a stage in the process between regulatory action and human health responses to air pollution. Arrows connecting the stages indicate possible directions of influence. The text below the arrows identifies factors affecting the effectiveness of regulatory actions (referred to as "accountability") at each stage. At several of the stages, knowledge gained from accountability studies can provide valuable feedback for improving regulatory or other actions (from HEI Accountability Working Group 2003).

WORKSHOP OBJECTIVES AND PROCEDURES

The workshop objectives were as follows:

1. Review the current state of knowledge, based on the work supported by HEI and others
   - With regard to concepts and methods for accountability research;
   - With regard to findings and "lessons learned" from accountability research conducted to date;
2. Revisit, and possibly revise, the research model and strategic vision presented in Communication 11 in light of experience to date; and
3. Recommend strategies, methods, and targets of opportunity for further research to assess the health impacts of actions taken to improve air quality, and develop a list of key recommendations (to be included in HEI's Strategic Plan for 2010–2015) and workshop proceedings.

As with the earlier Communication 11, this publication is intended both to inform HEI's research planning and to play a leading role in guiding the development of research methods and the setting of research priorities for the broader research and policy communities.

The two-day workshop was limited to about 25 participants, comprising key contributors to Communication 11, current members of the HEI Health Research and Review Committees, and others, including selected HEI-funded investigators who have contributed to our current accountability research program (see the list of Contributors). Jonathan Samet of the University of Southern California chaired the workshop.

Before the workshop, participants received an overview table that described the approaches and results of about 20 accountability studies that have been conducted to date (see Table D.1 of Appendix D, available on HEI's Web site), a list of specific topics and questions to guide the discussions, and a white paper (see Appendix C, available on HEI's Web site) that was written especially for the workshop. Following presentations on key issues related to accountability research (see Appendix E, available on HEI's Web site), the workshop participants divided into smaller groups to discuss three specific topics: exposure contrasts, shorter-term and small-scale actions, and longer-term actions.

Working Group 1: Role of Exposure Contrasts in Accountability Research

As some of the first wave of accountability studies have demonstrated, changes in air quality in relation to an intervention are sometimes difficult to show, especially if the action was not specifically designed to reduce air pollution (e.g., measures to reduce traffic congestion). The charge to this working group was to discuss how much (anticipated) reduction in pollutant concentrations and/or exposures is sufficient to warrant an evaluation of the health impacts and whether there are recent advances in exposure measurement and modeling that are particularly useful to accountability research.

Working Group 2: Evaluating Shorter-Term and Small-Scale Actions

Many of the studies funded so far have looked at relatively small-scale actions implemented over a shorter-term time frame that aimed to achieve relatively rapid improvements in air quality. The charge to this working group was to discuss what we have learned from such studies in terms of their design and the availability and quality of data on air quality and health. Will additional small-scale studies be useful in the future, and if so, which kinds of research questions would be most interesting to pursue, and which kinds of interventions might be expected to provide the most useful data?

Working Group 3: Accountability Assessment of Longer-Term Regulatory Actions

Regulatory agencies are most interested in evaluating longer-term programs to improve air quality that are implemented over many years and produce gradual changes in air quality. The charge to this working group was to discuss what approaches are available to assess such longer-term changes, taking into account other changes that take place over the same time frame, such as changes in demographics, socioeconomic factors, health care status, exposure to other environmental pollutants, and other factors, such as diet and smoking status.

Following the workshop, selected participants prepared the proceedings. The writing groups were asked to (1) evaluate the current HEI program and summarize lessons learned; (2) review other relevant research; (3) assess which areas of research proposed in Communication 11 have been covered well and which have not; (4) consider which types of studies have been most informative; and (5) propose research priorities going forward, specifying on what types of research HEI should focus. The discussions and recommendations from the three working groups are presented in chapters 2 through 4.

The next section addresses general issues that extend across the three areas covered in this report.

COMMUNICATION 11 REVISITED

Workshop participants revisited the broad concepts set out in Communication 11. The term *accountability* had been used in that document largely because of its currency at the time. Its use, in part, reflected the call on the part of decision makers and stakeholders for an "accounting" of the benefits of continually improving air quality in the United States (and elsewhere). Communication 11 defined *accountability research* to indicate research that provides analyses and estimates relevant to the following regulatory-related questions:

- Was the regulation implemented as specified?
- Did it achieve the intended reductions of pollutant concentrations and a subsequent reduction of the exposure of human populations?
- Did it have the anticipated public health benefits?
- What remains to be done?

The concept of accountability research was broadened in Communication 11 to include evidence relevant to consequences of interventions for population exposure to pollutants and to causal inference. In the chain of causation, changes in exposures consequent to interventions are a needed step in the pathway to a reduction of health risks; consequently, studies of exposures in relation to measures intended to improve air quality fit within the scope of accountability research. Communication 11 also noted that research directed at measures anticipated to alter sources and/or exposures in a stepped fashion in time could provide evidence useful for causal inference and for characterizing exposure–response relationships. Such stepped changes in sources and/or exposures may provide an opportunity to characterize the effect of a particular pollutant or source class by altering the relationships of the targeted pollution or source with other pollutants or sources.

"LESSONS LEARNED" FROM WORK TO DATE

Communication 14 offered an assessment of issues and challenges that could be identified across the studies supported by HEI:

- Type of action: The consequences of shorter-term actions have proved to be more readily characterized than those of longer-term actions.
- Timing of study: Studies carried out retrospectively using available data can be conducted quickly and at relatively low cost, although they are potentially limited by the scope and quality of the data in hand. In studies

carried out prospectively, researchers can put into place mechanisms for collecting data in a targeted fashion.

- Magnitude of the change in air quality: Given the range of air pollution sources in many locales and the key role of weather, it may be difficult to detect a change in air quality associated with an intervention/regulation. If there is a specific marker — for example, lead in gasoline or sulfur in fuels — then sensitivity to finding a change will be enhanced.
- Suitability of air quality monitoring and exposure assessment: Routinely collected data from central ambient air quality monitors may lack the granularity in space and time needed to characterize the consequences of an intervention/regulation.
- Causal inference: Studies of the consequences of removing an exposure source can provide information relevant to causal inference, particularly for those pollutants for which the evidence to date has not achieved sufficient strength to infer causality.
- Timeline of change: Communication 14 identified several studies in which the timeline for implementing the intervention, and subsequent changes in air quality, had not been as rapid as projected, leading to more limited sensitivity of the study to changes in health outcomes than anticipated at the time of implementation.
- Populations studied: The extent of generalizability is often an issue in accountability research, particularly for those studies limited to a particular population and intervention (e.g., the Olympic Games in Atlanta).
- Health outcomes studied: Health outcomes have been studied at various levels of disease expression. This range can provide coherence to results from observational studies but adds the additional challenge of the necessity of integrating findings on outcome measures that range from biomarkers of exposure and response to bioassays to mortality and morbidity.
- Methods development: Further development of appropriate analytic tools is needed.
- Multiple stages of the accountability chain: Few accountability studies to date have addressed all of the multiple steps along the accountability chain.

Beyond these points, workshop discussions highlighted several broad issues that are fundamental to the decision to carry out accountability research studies. First, the potential usefulness of the evidence that would be generated by the particular accountability research should be identified. This need for careful planning is in line with the framework for risk assessment set out in the recent National Research Council Report, *Science and Decisions: Advancing Risk Assessment* (National Research Council 2009). That report proposed an initial phase of planning and scoping so as to assure that the findings of a risk assessment have the greatest value possible for decision makers. The body of accountability research conducted to date includes examples where such scoping might have led to a more informative study or to a decision not to carry out a study. The reports from the working groups (chapters 2–4) identify empirical research on study sensitivity and precision of findings that would be one element of such scoping.

Second, it is important for HEI and other research funders to appreciate and maintain the distinction between studies of the health impacts of actions taken to improve air quality (sometimes referred to as *accountability studies*) and accountability research more broadly. Communication 11 offered the following definition of the goal of accountability studies that HEI might fund: "[To] evaluat[e] the extent to which air quality regulations improve public health…part of a broad effort — termed *accountability* — to assess the performance of all environmental regulatory policies" (p. i of the Executive Summary). This definition of accountability studies implies the generation of new knowledge, while much of the domain of accountability research is focused on more straightforward program evaluation (e.g., did a particular regulation reduce emissions from a particular source). Future studies undertaken within the HEI accountability research program should focus on generating new knowledge about the effects on health of reductions in levels of air pollution, rather than the type of program evaluation just described.

REVISITING THE CONCEPTUAL FRAMEWORK

The framework for HEI's accountability research has been based on the concept of the chain of accountability illustrated in Figure 1. That concept has proved useful for characterizing research with regard to specific stages between implementation of a regulation and its ultimate effect. Communication 14 relied on this framework as the basis for its review of current studies, and it has proved useful to other agencies and to the research community. The framework is also useful for setting out evaluation strategies.

The chain of accountability also makes data needs explicit for each of its steps, and it offers a framework for prospective implementation of data collection. It has links to the parallel and evolving concept of *environmental public-health tracking,* in which ongoing data collection and analysis inform public-health decision makers as to the risks sustained by the covered populations at levels that might range from local to global (Matte et al. 2009).

The methodologic aspects of environmental public-health tracking of air pollution effects were addressed in a 2008 workshop (Matte et al. 2009), supported in part by HEI. Several examples were covered that illustrate the need for prospectively collecting the "right" data (Medina et al. 2009; Talbot et al. 2009). In addition, that workshop identified a need for sustained discussion with the various agencies and health care systems that collect the data used in accountability research. There are issues of harmonization (e.g., coding of places) that could be prospectively discussed, as could potential problems in data access. In Europe, the Air Pollution and Health — A European Information System (Apheis*) project recently established a data system for tracking and accountability research (Medina et al. 2009).

CHAPTER 2. ROLE OF EXPOSURE CONTRASTS IN ACCOUNTABILITY RESEARCH

INTRODUCTION

The primary purpose of air pollution control is to reduce risks to human health; additional goals may relate to human welfare and environmental consequences of air pollution. Relatively few studies, however, have been conducted to examine the success of air pollution control measures and to quantify any reductions in health risks. In part, the relative paucity of studies reflects the difficulty of doing such studies. Not only must human exposure to air pollution be demonstrably reduced and be measurable, but health benefits from these reductions also must be measurable and separable from those of other factors that may change as the measures are implemented.

Despite these difficulties, a growing number of accountability studies have been conducted that have quantified the health benefits of measures to reduce air pollutant concentrations. As discussed in Communication 11, these studies follow a variety of study designs dependent on the reduction measure, and the conduct of these studies and interpretation of their findings have sometimes been difficult. The most informative of these studies have assessed step changes in pollutant concentrations, as in the evaluations of the Utah steel mill closing (Pope 1989) and the Dublin coal sales ban (Clancy et al. 2002). Step changes in pollutant concentrations may result from programs that are implemented at one point in time and that have an immediate and large impact on air pollution emissions. The Utah steel mill was closed at a particular point in time as a result of a labor dispute, and the Dublin coal sales ban similarly came into effect on a particular date. With such abrupt changes in major sources, parallel changes in the concentrations of index pollutants were readily identified.

When the time frame of measures to improve air quality becomes more prolonged or less defined, as with the implementation of new diesel emission standards, the challenge to accountability research generally increases, because of the need to document accurately changes in air pollutant concentrations and to take account of other outcome determinants that may be changing over time as well. Studies have utilized a variety of strategies to contend with these challenges, including having large study populations and using variation on both temporal and spatial scales. Through these varied strategies and designs, accountability studies conducted to date have advanced our understanding of the challenges inherent in estimating changes in pollutant concentrations associated with particular actions. They have helped to reaffirm research strategies set forth in earlier accountability documents and communications (HEI Accountability Working Group 2003; National Research Council 2004; van Erp and Cohen 2009) and have illustrated how novel exposure assessment methods, tools, and approaches can be used to improve the design of future accountability studies. The rest of this chapter gives a brief description of some of these lessons learned.

HOW MUCH (ANTICIPATED) EXPOSURE REDUCTION IS SUFFICIENT TO WARRANT AN EVALUATION OF HEALTH IMPACTS?

HEI Communication 14 stated that pollutant concentrations need to be reduced by a factor of 1.5 to 2 in order to reliably detect the health effects of measures to improve air quality. This factor range was determined based on concentration ranges typically reported in the epidemiologic literature on the health effects of air pollutants. Some HEI accountability studies have so far shown reductions of similar magnitudes in a variety of interventions taken to improve air quality, for example, the coal sales bans in Ireland (Clancy et al. 2002). However, studies on measures to reduce traffic intensity or traffic emissions have shown much smaller reductions (Tonne et al. 2008; Kelly et al. 2010, in press; Peel et al. 2010). Recent work in the United States by Pope and colleagues on longer-term air quality changes and gains in life expectancy (Pope et al. 2009) investigated reductions of concentrations of particulate matter (PM) with an aerodynamic diameter ≤ 2.5 µm ($PM_{2.5}$) over a 20-year period by a factor of approximately 1.5, on average, with absolute reductions ranging from 0 to 14 µg/m^3 from baselines varying between 10 and 30 µg/m^3.

* A list of abbreviations and other terms appears at the end of the document.

Although studies conducted to date have shown reductions in pollutant concentrations within the stated range, thus far, the findings demonstrate that the magnitude of the reductions alone is insufficient to determine how informative a given study may be. Any epidemiologic study needs to be adequately powered to detect an effect on population health. The power of the study is a function of factors such as anticipated size of the reduction in concentrations/exposures, exposure misclassification, size and underlying susceptibility of the study population, other sources of environmental pollution that affect human health, and size of anticipated health response. As the anticipated size of concentration/exposure reduction resulting from an action is only one consideration, it is not possible to calculate the minimum concentration reduction without taking other determinants of study power into consideration. If an accountability study is focused on the change in risk to health, considerations beyond exposure need to be taken into account at the design stage.

ARE THERE RECENT ADVANCES IN EXPOSURE MEASUREMENT AND MODELING THAT MAY BE PARTICULARLY USEFUL FOR ACCOUNTABILITY RESEARCH?

The continual improvement of measurement techniques and air pollution modeling has enhanced accountability studies. Nonetheless, the exposure estimation approaches used need to be tailored to the particular research question and the exposures of interest.

Measurement Techniques

Currently instrumentation is available for fast-response-measurements of trace gases at a frequency of 1 Hz (i.e., every second on average), using, for example, tunable infrared laser absorption spectrometers. Fast-response instrumentation is also available for measuring aerosol composition and size, using aerosol mass spectrometers. Operating in fixed-site locations, these fast-response techniques can detect local-source emission contributions within averaged ambient urban or regional levels, providing knowledge of the temporal variability in concentrations for a variety of pollutant species (e.g., nitrogen dioxide [NO_2], carbon monoxide [CO], formaldehyde [H_2CO], sulfur dioxide [SO_2], sulfate [SO_4], and organic fractions of PM). Applications that deploy these fast-response measurement systems on mobile platforms (e.g., in vans or trucks) can be used to perform spatial mapping — for example, of ambient concentrations in the vicinity of the intersection of major traffic sources and local neighborhoods — providing improved knowledge of the temporal and spatial concentration gradients of these pollutant species and how they vary among neighborhoods with different emission sources. Such measurements are of significant interest in assessing traffic-related pollutant exposures in urban environments (Canagaratna et al. 2004; Kolb et al. 2004; Herndon et al. 2005; Kittelson et al. 2006).

Air Quality Monitoring and Modeling

Atmospheric dispersion models have been supplemented with land-use regression models and satellite observations in order to estimate air pollution concentrations at temporal and spatial scales that are relevant to evaluating proposed or already-implemented measures to improve air quality.

Advancements in mesoscale meteorologic models and physicochemical air quality modeling systems, and their coupling, raise expectations as to the role that these modeling systems may play in improving exposure estimates for health-outcome–related air quality assessments. The application of nested-grid air quality models and the incorporation of improved spatially resolved roadway source emissions indicate that air quality model predictions at 1- to 2-km resolution are feasible, but await detailed field evaluations.

Traffic in urban environments is of particular interest for accountability research. Historically, the roadside monitoring network in the United States was designed to address compliance in meeting the CO standard, and thus, typically only CO monitors were operated at these sites. Since most urban metropolitan areas are now compliant with the National Ambient Air Quality Standards (NAAQS) as a result of major reductions in CO exhaust emissions, many of these sites have been decommissioned. As outlined in HEI Special Report 17, *Traffic Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and Health Effects* (HEI Panel on the Health Effects of Traffic-Related Air Pollution 2010), traffic-related pollution contributes significantly to the population exposure in major metropolitan areas, and the potential public health significance of this contribution suggests a need to rethink monitoring strategies. The traffic-influenced environments should be characterized through a broad suite of measurements of pollutants (e.g., CO, NO_2, nitrogen monoxide [NO], ozone [O_3], H_2CO, carbon dioxide [CO_2], $PM_{2.5}$, PM components, and particle number and size distribution) performed at a combination of permanent fixed-site roadside monitors and systematic periodic deployment of mobile or fixed measurement systems to capture the pollution gradients within 500 m of major urban highways. Design and implementation of several pilot measurement studies in several major metropolitan areas should be considered to inform the development of a national traffic-related monitoring strategy.

Recently, several models that combine measurements, geographic information systems (GIS), and statistical smoothing techniques have been developed and validated for obtaining time- and space-varying estimates of exposure. For example, Yanosky and colleagues (2008) developed GIS-based spatiotemporal models to estimate monthly outdoor PM ≤ 10 µm in aerodynamic diameter (PM_{10}), $PM_{2.5}$, and coarse particle ($PM_{10-2.5}$) concentrations at discrete locations within 13 Northeastern and Midwestern U.S. states. Validation procedures showed that these models represented a significant improvement over traditional methods, such as those simply assigning the value of the nearest ambient air quality monitor, since they are able to account for pollution gradients (both within and between cities) and to predict time- and space-varying pollutant concentrations. These improvements have substantial and important implications for epidemiologic studies of chronic air pollution exposures. As demonstrated for the Nurses' Health Study participants living in the Northeastern and Midwestern United States (Puett et al. 2008), the time-and space-resolved exposure estimates provided by the models were better able to detect associations between PM exposures and mortality than the more traditional closest-monitor and kriging approaches.

HOW CAN FUTURE ACCOUNTABILITY RESEARCH EVALUATE EFFECTS FROM MULTIPLE POLLUTANTS AND PM COMPONENTS?

Some observed health effects may be due to exposures to complex mixtures of air pollutants. These mixtures may include fresh source emissions and aged emissions that undergo chemical and physical interactions with urban or regional background pollution, for which current criteria pollutants may serve as prominent markers. The chemistries associated with SO_2, NO_2, O_3, and $PM_{2.5}$ and its components share reaction pathways and, in many cases, common precursors and sources. There are most likely economies of scale in implementing a multipollutant air quality management approach that addresses the NAAQS holistically and considers the interactive processes and associated trade-offs that may arise with emission control strategies to meet the standards (National Research Council 2004; Hidy et al. 2010, in press).

Although the health effects community has identified causal relations between individual NAAQS pollutants and health outcomes, it is not yet clear how causal inference can be drawn for pollutant mixtures. Indeed, it is not clear that these associations are strictly with the pollutants with which they are identified (i.e., how much of the association attributed to the pollutant is due to the mixtures in which it frequently finds itself). Current multipollutant analyses are inadequate to address this question. In order to assess the causal effects of mixtures and of individual mixture components, careful exposure characterization is needed to take advantage of opportunities based on interventions. Measurements and models can make significant contributions in estimating multipollutant exposures and in identifying conditions during which pollutants of interest do and do not covary in time and space and populations are exposed to combinations of fresh emissions and aged pollutants.

Results from large epidemiologic studies conducted to date point to the significant challenges in studying multipollutant exposures and separating their health impacts, especially when the particles and gases originate from the same source (McConnell et al. 2003; Lippmann et al. 2006; Bell et al. 2009; Peng et al. 2009; Zanobetti et al. 2009). For these cases in particular, ambient concentrations of many pollutants are strongly correlated, which makes it difficult to establish which of the mixture components (and in what relative or absolute concentrations) may contribute to the observed health outcomes. The importance of doing so, however, is clear. Multicity studies of acute PM effects show that the relation between ambient PM and hospital admissions varies by city (Schwartz 1999; Janssen et al. 2002; Dominici et al. 2006) and attribute this variation in part to differences in particle composition but also to other factors such as the percentage of homes equipped with central air conditioning. Correspondingly, recent epidemiologic and toxicologic studies have also shown that health risks differ by particle component (e.g., Ito et al. 2007; Chen et al. 2010). However, the components posing the greatest concern have generally varied by study and health outcome, even when studies were conducted within the same city, thus complicating interpretation of study results because of the issue of multiple comparisons in data analysis and the noncomparability of study populations.

These concerns have been addressed using a variety of methods. Focusing on exposures, investigators in several studies have conducted simultaneous measurements of ambient concentrations and personal exposures for multiple pollutants over time (Sarnat et al. 2001, 2006; Weisel et al. 2005; Turpin et al. 2007). These studies have generally shown strong longitudinal associations between ambient concentrations and personal exposures to $PM_{2.5}$ and its component SO_4, moderate to weak associations with elemental carbon (EC), and limited associations with the criteria gases, particularly O_3. However, other studies have shown stronger associations with reflectance (as a surrogate for EC) than for PM mass itself (Brunekreef et al. 2005).

Some studies (Laden et al. 2006; Ryan et al. 2009) have addressed the issue of multiple pollutants through source apportionment techniques, which effectively group pollutants according to how their concentrations covary from day to day, presumably because of generation by common sources. Other studies have tried to assign the health effects to the various pollution sources by taking advantage of the different spatial profiles for regional as compared with local pollutants, with regional pollutants being more homogeneous over space and local sources demonstrating higher spatial variability (Miller et al. 2007; Brunekreef et al. 2009). Studies have done so using spatiotemporal modeling techniques to estimate local pollutant concentrations in their health effects analysis. Given a good model for exposure, this approach may yield more accurate measures of spatially heterogeneous exposures than central site monitoring.

RECOMMENDATIONS

- During the design phase, future accountability studies should consider carefully the predicted pollutant concentration and anticipated exposure reductions following an intervention. If only a limited reduction is expected, emphasis might be given to the "upstream" components of the accountability chain — emission reductions, air quality improvements, and perhaps also personal exposure — before a decision is made whether the direct measurement of health outcomes will provide meaningful results. However, even when the expected exposure reduction is small, one can always conduct a health impact assessment estimating the health benefits using existing exposure–response functions.
- During the design phase of future accountability studies, careful assessment of available monitoring sites is needed. The number and location of monitors, which pollutants are measured, and the frequency of sampling may determine the power of the study to detect changes in air quality. This is especially true of traffic interventions, which may cause relatively small changes in urban background air quality and require measurements of specific chemical species at high temporal resolutions at roadside locations (i.e., more frequently than hourly at roadside monitors).
- Advances in exposure estimation and air quality modeling may be useful to some research approaches depending on the type of intervention and study design. Researchers would do well to include the appropriate multidisciplinary expertise on their teams to take full advantage of such developments.
- The development of a national traffic-related monitoring strategy is desirable. The design and implementation of several pilot measurement studies in several major metropolitan areas should be considered, including the deployment of advanced high-precision and time-resolution instrumentation.
- Agreement is needed within the research and monitoring communities as to which pollutant parameters require priority consideration for routine monitoring in order to improve multipollutant exposure estimates and track progress in mitigation strategies.
- Further development of approaches is needed to improve the understanding of how health outcomes are associated with specific components of air pollution mixtures. Special consideration should be given to the evaluation of possible synergistic effects. Accountability studies may provide useful information about the health effects of specific sources. In addition, they may provide information about the health effects of specific components of mixtures if they find that reductions in certain mixture components resulting from specific air quality actions are associated with reductions in health outcomes.
- The design and implementation of emission control strategies to achieve NAAQS compliance should include a measurement plan to track the progress and effectiveness of controls and the potential collateral benefits (i.e., reduced emissions in co-emitted species, e.g., metals in the scrubbing of SO_2 from power plants).

CHAPTER 3. EVALUATING SHORTER-TERM AND SMALL-SCALE ACTIONS

INTRODUCTION

This working group discussed lessons learned from prior studies of the health effects of shorter-term actions that could inform the planning and design of future efforts. While the group reached consensus that studies of shorter-term actions may be useful, the group noted challenges identified in prior studies, many of which were discussed in Communication 14. For example, experience to date has documented the problem of inadequate data to assess the consequences of gradual or limited changes in air quality. The group attempted to clarify definitions, goals, and study design issues and made recommendations to improve future studies of shorter-term actions.

DEFINITION OF SHORTER-TERM ACTION

For this chapter, the group defined shorter-term actions as those that are expected to cause a fairly abrupt (over a period of days to less than a year) "step change" in air quality. In this time frame, the air quality change occurs over such a brief interval that changes in population health due to other factors (e.g., shifts in demographics, health-related behaviors, or the health care system) are unlikely to have occurred. A study will also be more informative if the change in the targeted index is large and persistent in comparison with the largely weather-related temporal variation of pollution concentrations observed in typical time-series studies. It should be noted that while most studies of shorter-term actions have involved actual or assumed reductions in emissions and improvements in air quality, actions that produce an abrupt worsening of air quality could also present opportunities for evaluation (Gilbreath et al. 2008; Moore et al. 2008).

Shorter-term actions could be permanent — for example, the coal sales ban in Dublin (Clancy et al. 2002) — or short-lived (reversible) — for example, traffic restrictions during the 1996 Atlanta Summer Olympic Games (Friedman et al. 2001; Peel et al. 2010). The group noted that there is no bright line separating the time scales of shorter- and longer-term actions. Additionally, shorter-term actions that are permanent create opportunities for the evaluation of longer-term impacts, to which other design and interpretation challenges apply. The challenges of conducting and interpreting such longer-term studies are presented in chapter 4.

Shorter-term actions may affect large populations or be very focused on specific population subgroups in particular geographic areas. While spatial scale affects sample size, the group did not feel it was a useful consideration in defining or classifying shorter-term actions.

The following taxonomy of shorter-term actions was proposed:

1. *Planned regulatory controls* designed to reduce community air pollution concentrations and to take effect fairly rapidly on a time frame no longer than one year (e.g., restrictions on sulfur in fuels);
2. *Other planned regulatory actions* that might be anticipated to reduce community air pollution abruptly (e.g., traffic restrictions to improve flow);
3. Other *nonregulatory events* that could be anticipated and that might lead to abrupt changes in air pollution exposures (e.g., strikes, industrial disruptions, economic downturns, major road construction, or maintenance shutdowns of power stations); and
4. *Unplanned events* that have the effect of suddenly changing air pollution exposures (e.g., accidents or natural disasters).

While planned regulatory controls arguably are the most policy-relevant actions to evaluate, each type of shorter-term action may present opportunities for informative research as well as challenges for design and interpretation.

GOALS OF HEALTH STUDIES OF SHORTER-TERM ACTIONS

Evaluation of Planned Regulatory Controls

In the case of planned regulatory controls, an air pollution intervention would be designed and implemented with a goal of achieving public health benefits. The regulatory and planning processes may have involved estimation of expected health benefits. In that case, the results of the action could be evaluated prospectively to assess the actual changes in air pollution and associated health benefits and to compare the actual to the predicted benefits based on prior observational epidemiologic studies. While many planned regulatory controls produce gradual emissions reductions and ambient pollution changes, some measures lead to shorter-term changes, especially regulations concerning fuels (Clancy et al. 2002; Hedley et al. 2002; Dockery et al. 2010). Under the right circumstances, shorter-term actions support “quasi-experimental” studies and provide particularly valuable evidence of the health benefits of air pollution controls. Admittedly, regulatory actions lack the important feature of randomization used in clinical trials. Nonetheless, an abrupt change in emissions and in the ambient concentration of pollutants of interest may reduce the potential for confounding by temporal or geographic factors relative to confounding in studies that rely on typical patterns of variation for exposure contrasts.

Air Pollution Benefits of Other Anticipated Actions, Regulatory or Otherwise

Some studies address the air pollution benefits, not of direct air pollution control interventions, but of regulatory actions that secondarily lead to air pollution reductions, known as co-benefits. Examples include traffic restrictions to improve flow (Tonne et al. 2008), and the removal of lead from gasoline to prevent contamination of catalytic converters (Annest et al. 1983). Other opportunities for studying shorter-term air quality changes may result from nonregulatory events that could be anticipated. For example, a planned strike could shut down a polluting industrial facility (Pope et al. 2007).

If air pollution benefits can be anticipated, studies can be planned to monitor exposure and health prospectively, potentially enabling more informative designs, as noted later in this chapter.

Air Pollution Benefits of Unplanned Events

Often events or actions that lead to air pollution reductions are recognized only in retrospect, thereby precluding the prospective planning of an optimal study. Therefore, studies based on such events are generally restricted to available surveillance data — air pollution and health data that are routinely collected for other reasons, typically without individual exposure and covariate information. In addition, an unanticipated event, such as a natural disaster, may influence health through other pathways, such as stress or service disruption.

Effects of Source-Specific Air Pollution

In epidemiologic studies of ambient air pollution, there may be difficulty in assessing the effects of specific sources on public health. Ambient air pollution exposures are the net results of the accumulated emissions from multiple sources, both stationary and mobile. Because these emissions are transported, diluted (diffused), chemically transformed, and removed, it is difficult to identify the specific contribution of any one source (or class of sources) to this pollutant mixture. On the other hand, controls are directed at specific sources. That is, abatement, fuel switches, or engineering controls are applied to single, specific sources or source classes. Such interventions, therefore, offer the unique opportunity to assess the benefits of controlling specific sources within the mixture of pollutants from multiple sources. A change in a single source may provide a research opportunity that is most closely analogous to an experimental design, as only the targeted source changes while the operation of others is unchanged. Examples of this scenario include the steel mill strike in Utah Valley (Pope 1989), the copper smelter strike in New Mexico, Arizona, Utah, and Nevada (Pope et al. 2007), and the Dublin ban on coal sales (Clancy et al. 2002).

Marine ports have distinctive emissions profiles related to the use of residual oil for bunkering as well as emissions from diesel equipment and trucks. Planned actions at some ports have the potential to produce abrupt changes in local emissions through fuel switching, provision of shore power, and emissions standards for trucks servicing the port. Similarly, a phaseout of the use of residual oil for heating being considered in New York City also has the potential to change ambient particle concentrations and composition. However, it is less clear whether this change could be rapidly implemented because of the number of facilities involved.

CHARACTERISTICS OF SHORTER-TERM ACTIONS THAT SUPPORT INFORMATIVE EVALUATIONS AND RESEARCH

To enable informative research, shorter-term actions must produce changes in exposure — decreases or increases — of sufficient size and spatial extent to produce an observable change in *an outcome measure of interest* in a target population, a particular cohort, or a study panel. Some planned actions may produce abrupt changes in emissions from a particular source, but the alterations to the source may not be large enough to substantially affect exposures and to support informative investigation.

A potential problem with shorter-term, small-scale changes is the limited precision with which consequences can be characterized. One way to overcome this limitation is to pool data across multiple locations and times. For example, while maintenance shutdowns of fossil-fueled power generation plants are common, individual stations may not have a large enough impact on population exposure to enable an adequately powered shorter-term study when operation is interrupted and restarted. In order to be able to pool data, the data need to be collected in a consistent manner across locations. By pooling population health data across many communities affected by such shorter-term interruptions in power station operation, an informative analysis might be possible. Major road construction projects that alter or divert traffic flow are also common, but may have too local an impact to be studied without such pooling.

STUDY DESIGN CONSIDERATIONS

Prospective vs. Retrospective Assessment

The timing of data collection in relation to the change in exposure is a key design consideration in obtaining the most informative measures and populations. When a shorter-term action is planned sufficiently far in advance, a prospective study can be designed and tailored to the nature of the action. This approach may include identifying a panel of vulnerable individuals and planning repeated measures of individual exposure, health outcomes, and potential confounders. This design allows for consideration of not only clinical events (e.g., strokes, myocardial infarctions, and asthma attacks) but also potentially more sensitive subclinical physiologic measures (e.g., blood pressure, heart rate variability, systemic inflammatory markers, and lung function) (Zhang et al. 2010) or symptoms (e.g., asthma attacks, wheezing, and shortness of breath). Retrospective studies are generally restricted to surveillance data collected previously for other purposes (e.g., deaths, hospital admissions, emergency department visits, insurance payments, and school absences). Note that the compilation and analysis of such surveillance data can also be planned prospectively. However, such surveillance data typically do not allow for the evaluation of individual time-varying covariates (i.e., potential confounders or modifiers).

Defining the Affected Population

For some shorter-term actions, the timing of the exposure change and the population affected can be readily identified. For example, the ban of coal sales within the city of Dublin occurred before the 1990 heating season, and the widespread use of coal for residential heating meant that changes in emissions would potentially affect exposures across the city. Emissions changes at a power station or large industrial facility, on the other hand, might affect only downwind populations. For example, after sulfur restrictions in Hong Kong were implemented, the population downwind from affected point sources was the most affected by the change (Hedley et al. 2002).

Moreover, some actions can take place over mixed spatial and time scales. Consider studies of woodstove interventions: effects on individual households participating in the woodstove change-out program (resulting in a change in air quality inside the home) could be immediate, while effects on community air quality could be extended over a considerable amount of time during which individual households are enrolled and stoves are retrofitted (Noonan et al. 2010).

The temporal and spatial changes in pollution from shorter-term actions affecting traffic can be especially complex. For example, the restriction of traffic on particular roads or in selected areas could divert traffic and congestion to other locations. Additionally, the populations maximally affected by near-source exposure to primary pollutants, such as ultrafine particles and nitrogen oxides (NO_x), may differ from those affected by changes in concentrations of secondary pollutants, such as O_3. The latter impacts may be too small to measure across a larger urban area, while impacts from near-source primary pollutant exposure could be significant on households adjacent to traffic routes being affected. Measures that affect traffic may have greater effects on weekdays than on weekends.

Tracking Multiple Links in the Chain of Accountability

While this discussion focuses largely on studies to evaluate exposure–response relations, it should be noted that the ideal study of a planned shorter-term action will evaluate several steps in the causal pathway linking a regulation or other action to health. For example, the evaluation of a traffic-congestion mitigation action should examine changes in traffic flow, estimated emissions, ambient pollution concentrations, and effects on health.

Health Endpoints

Surveillance Data For the same reasons that air pollution time-series studies of daily counts of adverse events (e.g., deaths, hospital admissions, and emergency department visits) have been so powerful in demonstrating the acute effects of air pollution exposure, such routinely collected health data are also an important resource for analyses of the effect of planned or unplanned interventions. Because these adverse events are relatively infrequent, effective use of this approach requires either inclusion of large populations being affected or collection of records over multiple years. This scarcity of events implies that large populations affected by the shorter-term action are required in order to be able to quantify an impact with good precision. In the case of designing a study around planned regulatory controls, if the control strategy has been designed to affect a specific health endpoint (e.g., reduced myocardial infarctions or asthma emergency visits), then studies of the health impacts should focus on such endpoints, while including others that might also be relevant.

Panel Studies with Repeated Measures An alternative to the surveillance of health events such as emergency department visits would be the repetition of physiologic measures of intermediate outcomes, such as heart rate variability or pulmonary function, in a panel of people over time. These studies can gain power by repeating sensitive measures of response in the same subjects, but are necessarily limited in size (i.e., tens to hundreds of subjects). For example, Zhang and colleagues (2010) made repeated measures of physiologic outcome indicators and biomarkers in medical students in Beijing, before, during, and after the 2008 Summer Olympic Games. In terms of advancing our understanding of the mechanisms and pathways of the benefits of air pollution control, these intermediate biologic markers of response can be particularly informative.

Multiple Endpoints One of Bradford Hill's criteria for causation is *specificity*, that is, whether or not the exposure is uniquely associated with a specific health endpoint (Hill 1965). However, the health effects of concern in these studies are usually common chronic conditions with multiple etiologies. Thus, we should not expect to see specificity; and, in fact, it is lack of specificity that leads to a need to characterize other determinants of the outcome of interest. A more relevant criterion proposed by Hill is *coherence*, that is, consistency of the observed associations "with the generally known facts of the natural history and biology of the disease." Showing consistent benefits in a coherent set of population outcomes (e.g., cardiovascular mortality, cardiovascular hospital admissions, and cardiovascular emergency department visits) and in relevant physiologic measures among a panel of study subjects can strengthen the case for a causal relationship. Studies based on surveillance data have an advantage in that multiple outcomes can be readily abstracted from available data with minimal extra costs. In prospective studies that use repeated physiologic measures of individuals, each additional endpoint measured may add costs.

Identifying Vulnerable Populations Subgroups of the population (e.g., the elderly, diabetics, and patients with prior myocardial infarctions) could be expected to experience greater benefits from air pollution reductions (or harm from increases) because of their underlying disease status. Vulnerable subpopulations may also be identified by greater exposures to the emissions targeted by a shorter-term action. For example, traffic controls would most dramatically affect those living immediately adjacent to the affected traffic routes. Populations with low socioeconomic status (SES) may also be more vulnerable to air pollution effects (O'Neill et al. 2003; Forastiere et al. 2007; Ou et al. 2008), possibly because of reduced access to health care, suboptimal medical management of underlying cardiopulmonary disease, or greater or differentially toxic exposure.

To fully capture the effects of shorter-term actions, vulnerable populations for whom exposure–response relations may be greater than in the general population should be included in studies in sufficient numbers for stratified analyses. The inclusion of such populations is also motivated by concerns about disparities in exposure profiles. Options for identifying vulnerable subpopulations in surveillance data may be limited (e.g., for analyses stratified by age or neighborhood SES); however, these options may be without significant additional cost. For repeated-measure studies of individuals, it is feasible — and in fact highly desirable — to select vulnerable individuals based on prior conditions or characteristics. While selection of vulnerable subjects can increase the likelihood of finding a response, and therefore add power to the study, it obviously limits the generalizability of the results to the general population.

Identifying Appropriate Control Scenarios

Shorter-term studies naturally focus on assessing changes over time in the population affected by a shorter-term action. Because shorter-term changes in population health may occur for other reasons (e.g., influenza activity), the potential for confounding can be reduced by comparing trends in health outcomes with trends observed during the same time period in locations not affected by the shorter-term action under study. Such designs require careful attention to ensure the comparability of the different locations with regard to factors related to temporal trends in health outcomes.

Identifying Potential Temporal Confounders

Shorter-term actions that abruptly change emissions may produce or coincide with changes in other factors that could affect the health outcomes of interest. For example, a strike that closes an industrial facility could be associated with social unrest and economic distress. Traffic changes can affect both air quality and noise exposure. The influence of such temporal confounders may be difficult to avoid completely but should be anticipated and measured where possible and considered in interpreting results.

Ambient Concentration Change as an Outcome

If a shorter-term action does not have a large enough impact on population exposure to support a health outcome study, such an event may nonetheless provide an opportunity to evaluate models and assumed relations among sources, emissions, and ambient concentrations. An example would be the evaluation of changes in near-roadway pollutant concentrations in relation to an abrupt interruption or change in traffic flow.

IMPLEMENTATION ISSUES

Developing a Clearing House for Prospective Identification of Planned Actions and Regulations

When shorter-term actions are anticipated, studies can be scoped (as outlined in the next section), planned, and resourced, if appropriate. Unfortunately, there is currently no systematic approach to identifying planned shorter-term actions so that their potential to support accountability research can be explored. Therefore, it is recommended that HEI explore, with air quality managers and transportation officials at the federal and state level as well as with researchers, development of a system, or clearinghouse, to identify and disseminate information about planned actions. The goal of such a clearinghouse would be to alert researchers, funders, and others to upcoming actions with enough lead time to determine if an accountability study might be desirable and feasible. Funding mechanisms with expedited application and review processes are needed to support such work.

Advanced Planning of Studies: Modeling Emissions and Ambient Pollutant Concentration Changes

Shorter-term actions provide opportunities for useful research only if they are anticipated to have a substantial impact on ambient concentrations of pollutants of interest. Before investing in resources to design and conduct a shorter-term study, investigators should use available information to estimate changes in emissions and, where feasible, ambient concentrations. If estimated impacts (signal) are meaningful relative to baseline concentrations and variation (noise), an evaluation study may be informative.

Another goal of advanced planning is to identify the affected geographic area, the populations potentially benefitting or harmed by the planned action, and relevant available ambient monitoring and health surveillance data. It also may be possible during the planning process to identify existing cohorts, panels, or other populations suitable for a prospective study. Based on this information and prior knowledge of concentration–response relations, plausible health outcomes, background incidence rates, and a range of realistic effect sizes, investigators can estimate study power.

In assessing study power, the relevant null hypothesis will depend on the goal of the investigators in evaluating the shorter-term action. If the goal is simply to strengthen causal inference about the presence of health effects of a pollutant concentration being reduced (or increased) because of the shorter-term action, a null hypothesis of no effect is appropriate. If, on the other hand, the goal is to compare the observed impact of the shorter-term action with that predicted by prior analyses (e.g., regulatory impact analysis), then the appropriate null hypothesis is the predicted impact. The power to detect all but large deviations from predicted impacts may be limited.

Phased Study Implementation

An extension of the recommendation to plan studies in advance is a recommendation to fund and conduct studies in a phased manner when feasible, as was the case with the HEI-sponsored evaluation of the London congestion-charging scheme (Kelly et al. 2010, in press). In this example of a planned traffic mitigation action, the first step was to confirm that a change in the source occurred — in this case, there were changes in traffic volume and flow. Second, ambient monitoring data were evaluated, and emissions and dispersion models were used to estimate the change in concentrations of relevant pollutants attributable to the changes in traffic. The third phase of the project would have been to analyze electronic health records to estimate health benefits associated with the change in air quality. However, the estimated air quality impacts of congestion charging were judged to be too small (Kelly et al. 2010, in press) to justify a study directly evaluating changes in morbidity resulting from congestion charging.

RECOMMENDATIONS

- Studies of shorter-term actions should continue to be conducted. Studies of intentional interventions to improve air quality as well as other actions will remain useful under specified circumstances, depending on the nature of the action and the magnitude of the expected changes in air quality and in the health outcomes of interest. Although particular emphasis should be given to studies of planned actions intended to improve air quality — arguably the most policy-relevant actions to evaluate — all types of shorter-term actions offer opportunities for informative research and challenges for design and interpretation. However, the value of conducting additional retrospective studies of temporary actions may be limited, especially if the time period is very short (e.g., the duration of the Olympic Games).
- We recommend using available information to estimate expected changes in emissions and, where feasible, ambient concentrations, before investing resources in the design and conduct of a shorter-term study. If the estimated impacts (signal) are meaningful relative to baseline concentrations and variation (noise), an evaluation study may be informative. A staged approach may be useful, in which the first step is to measure air quality changes, before deciding to continue to measure changes in exposure or health outcomes.
- Future research should continue to capitalize on abrupt changes in emissions leading to approximate step changes in ambient concentrations of pollutants. In such situations, the potential for confounding by temporal or geographic factors is reduced relative to that in studies that rely on the ”usual” variation in ambient levels in the design of exposure contrasts.
- Studies of control measures aimed at particular sources should be a high priority. These measures could include abatements, fuel switches, or engineering controls. Such measures offer the unique opportunity to assess the benefits of controlling specific sources within the mix of pollutants from multiple sources. For example, studies of planned reductions in emissions from diesel engines in major marine ports may offer considerable potential for future research.
- Opportunities for coordinated (“pooled”) studies of the same action in multiple locations or time periods should be explored as a way to increase the precision of estimates of the effect of a particular type of action. For example, major road construction projects that alter or divert traffic flow are common, but any particular project may have too small an impact to be studied alone. Pooling population health data across many communities affected by such shorter-term actions could allow for a more informative analysis.
- To facilitate such coordinated research, HEI should explore, with air quality managers and transportation officials at the federal and state level as well as with researchers, the development of a system, or clearinghouse, to identify and disseminate information about planned actions. The goal of such a clearinghouse would

be to facilitate coordinated research and timely identification of planned actions by alert researchers, funders, and others with enough lead time to determine if a study is desirable and feasible.

- In studies of shorter-term actions planned far in advance, and if measurable air pollution benefits are expected, every effort should be made to monitor exposure and health prospectively. Prospective studies could include identifying a panel of vulnerable individuals and repeatedly measuring individual exposure, health outcomes, and potential confounders.
- Study designs must be based on an explicit definition of the population affected by a given action, especially when such actions take place on varying temporal and spatial scales. For example, studies of traffic restrictions may affect residents of contiguous areas as a result of the diversion of traffic from the target area. In general, it is important to specify the appropriate reference location or population for "counterfactual" comparison (i.e., assessment of health outcomes in the absence of a particular action).
- If particular policy actions are intended to reduce particular adverse health effects (e.g., asthma or myocardial infarction), then studies of their health impacts should be designed to estimate effects on those endpoints.
- For shorter-term actions, studies of intermediate physiologic measures of response (such as heart rate variability or pulmonary function) should be considered. They provide an alternative to the surveillance of health events such as emergency department visits and could advance understanding of the mechanisms and pathways underlying health outcomes affected by air pollution control measures.
- Future studies need to take seriously, and design against, the potential for confounding. For example, an event such as a labor dispute or a natural disaster may influence health through other pathways, such as stress or service disruption. Although such confounding may be difficult to avoid completely, it should be anticipated, measured where possible, and considered in interpreting results (e.g., by comparing trends in health outcomes in affected areas with trends during the same time period in locations not affected by the shorter-term action under study).
- To fully capture the effects of shorter-term actions, vulnerable populations for whom exposure and/or exposure–response relations may be greater than for the average population should be included in studies in sufficient numbers to allow valid and precise effect estimates. A focus on such populations is justified by concerns about environmental injustice and racism resulting in disparities in exposure profiles between less and more advantaged populations, and by the evidence for larger effects of exposure in the elderly and those with preexisting medical conditions, including children with asthma.

CHAPTER 4. ACCOUNTABILITY ASSESSMENT OF LONGER-TERM REGULATORY ACTIONS

INTRODUCTION

Air quality in the United States has improved since the mid-twentieth century, particularly since the promulgation of the 1970 Clean Air Act (CAA) Amendments and the implementation of independent regulatory actions at the state level (Bachmann 2007). There have also been marked improvements in population health, including reductions in cardiovascular morbidity and mortality and increases in life expectancy over that same interval on a national scale (Ezzati et al. 2008). The extent to which these improvements in population health were the direct result of regulatory clean air programs, given trends in major risk factors over the same time frame, is uncertain. Therefore, quantifying the health impacts of air quality regulatory programs is a priority of stakeholders in the air regulatory process, although not currently mandatory.

The CAA mandates that NAAQS be promulgated for specified pollutants so as to protect the public health with an "adequate margin of safety" and has required that the U.S. Environmental Protection Agency (U.S. EPA) assess the benefits and costs of meeting those standards (Section 812 of the CAA Amendments of 1990). The U.S. EPA conducted several assessments to that end estimating health benefits under alternative regulatory scenarios using health risk information from epidemiologic studies. These assessments provide evidence of large benefits from reductions in air pollution attributable to the CAA (U.S. EPA 1997, 1999).

There have been few studies, however, that directly evaluate the effects on health of large-scale regulatory programs. Several studies report results that suggest that national regulatory programs have been responsible for measurable improvements in health (Chay and Greenstone 2003; Laden et al. 2006; Pope et al. 2009; Rava et al. 2010, in press), but others do not (Chay et al. 2003; Janes et al. 2007; Peng et al. 2008; Greven et al. 2010, in press). These mixed results are not surprising and have multiple explanations (Dominici et al. 2007). In estimating the benefits of regulatory programs, the analysis needs to take into account other changes in determinants of health within the same time frame, many of which are more important than air pollution. However, if available, the data on these other factors may be imperfect, thereby limiting the extent to which they can be controlled for. These other determinants include economic factors (such as unemployment), medical treatment and quality of and access to health care, diet, tobacco smoking, and demographic changes that result in changes in population susceptibility. In addition, population migration, changes in the built environment, and the geographic distribution of major pollution sources may contribute to error in the measurement of exposure, causing apparent differences among risk estimates (Rothman et al. 2008; Greven et al. 2010, in press).

More robust research designs and statistical methods better suited to estimating the health effects of longer-term regulatory programs and other determinants of longer-term changes in health outcomes are clearly needed, but there is reason for optimism. Improvements in epidemiologic and statistical methods in air pollution epidemiology and — more generally — in environmental epidemiology over the past 20 years have led to advances in knowledge and methodology (Thomas 2009). The application of Bayesian hierarchic models and spatial statistics and of other geographic methods has led to better estimates of the risks of adverse health outcomes associated with longer-term exposure to air pollution (Zeger et al. 2008; Krewski et al. 2009). The evaluation of the public health impact of air quality regulations is challenging, in part because it must account for both temporal and spatial patterns in the data and confounding bias (HEI Accountability Working Group 2003; van Erp and Cohen 2009). This added complexity may well require new approaches, including computationally intensive methods from other disciplines not currently employed in air pollution epidemiology.

However, improvements in methods will go only so far in improving the evaluation of the public health impact of air quality regulations unless there are also improvements in the extent and quality of data. The limitations imposed by data availability and quality noted earlier can be overcome only by a concerted effort to assemble and make widely available longitudinal data on major health outcomes, air pollution concentrations, and, critically, factors that may confound or modify estimates of the effects of air quality regulations.

Such improvements in population health as may have occurred on a national scale because of air quality regulation may not have been equally distributed across geographic locations. Large spatial differences in levels and trends in population health and life expectancy have been documented in the United States (Ezzati et al. 2008), which may reflect the effects of factors correlated with SES and changes in population susceptibility, as well as changes in air quality over time. For this reason, a purely national research focus often obscures important inequalities in the distribution of health benefits of air quality improvement, with possible implications for the design of future regulatory action. Research strategies designed to explore the distribution of the health effects of air quality regulation and its determinants in more detail is needed.

In this chapter, we recommend approaches to strengthening research to estimate the health impacts of longer-term, large-scale regulatory actions. Our recommendations include improvements with respect to all the major components of such research. Specifically, we discuss the strengths and weaknesses of using existing retrospective studies of major regulatory actions, and we then describe the needs for (1) a national data warehouse; (2) simulation and/or feasibility studies to assess whether existing data can be informative for detecting the potential reduction of the burden of adverse health effects attributable to regulatory actions; and (3) the development of statistical methods and/or the tailoring of existing statistical methods to analyze data for this purpose. These approaches should include methods for causal inference and the supplementation of Bayesian approaches with new machine-learning algorithms to account for model uncertainty. Finally, we discuss how to best take advantage of the opportunity to generate useful evidence when a new regulatory action is undertaken.

TAKING ADVANTAGE OF EXISTING RETROSPECTIVE STUDIES OF MAJOR REGULATORY ACTIONS

Retrospective studies of planned or unplanned interventions that may fall into the category of "accountability" studies are of two types, each of which has strengths and limitations: (1) studies that evaluate relatively short-term, abrupt, intervention-related changes due to regulatory actions that lead to declines in specific pollutants over short periods of time as discussed in chapter 3; and (2) studies that evaluate regulatory actions with effects extending over long periods, because these actions come into play over prolonged periods of time. The latter type of study speaks directly to the priority of quantifying the health impacts of air quality regulatory programs noted in the introduction to this chapter.

Accountability studies that address the first type of regulatory change can be relatively straightforward provided that there are reasonable exposure and health data for sufficiently long periods of time before and after the time-specific intervention, as was the case for the studies of the Utah Valley steel mill strike (Pope 1989) and Dublin coal sales ban (Clancy et al. 2002) (see chapter 3).

Accountability studies that address the second type of regulatory changes are more complex. For these types of studies, the lengthy time period of interest requires consideration of (1) the time lag between the propagation of a regulatory change and the time at which any effect of the regulation can be expected to occur; (2) longer-term temporal trends in population structure (e.g., demographics) that alter the susceptibility of the population to various adverse health outcomes; (3) changes in medical and public health practices that lead to improved outcomes for particular diseases; (4) changes in the distribution of health-related behaviors within and among populations; (5) effects of regulatory changes for a given pollutant on the overall mixtures to which populations are exposed; and (6) the often heterogeneous patterns of change in pollutant levels due to a regulatory action across time and space.

Epidemiologists have used several approaches to study the health impacts of complex, longer-term changes in air quality. Further development of these approaches for accountability research will need to capitalize on their strengths and mitigate their weaknesses.

Cohort Studies

Cohorts of individuals enrolled at a given point or points in time and followed up to ascertain health outcomes have been a principal source of information on the risks of longer-term exposure to air pollution (Laden et al. 2006; Krewski et al. 2009). These cohorts are closed populations to which new members cannot be added. With sufficient follow-up, risks can be examined within successive time intervals so as to assess whether the risk of air pollution has changed over time. Analyses of such cohorts may be limited by informative censoring and effects related to survivorship in the cohort, the occurrence of pollutant exposures before the inception of the cohort, and overall attrition of the cohort. Survivor and attrition effects can be complex and are particularly problematic when relative risk (hazard) measures are used. Subjects who survive to later periods in the life of a cohort generally are relatively less vulnerable to the exposures under study and have higher baseline hazard for competing risks. However, background morbidity and mortality progressively increase in an aging cohort, such that, even in the face of continuing adverse risk due to air pollutants, relative risks (hazards) will decline. Therefore, the overall risks/hazards from such studies are somewhat arbitrary and dependent on the age structure of the cohort and when the follow-up periods of the cohort ended. Studies based on open, or dynamic, populations (Zeger et al. 2008; Pope et al. 2009; Moore et al. 2010) may be less subject to these problems, because new members can join the population throughout the study period.

Aggregate-Level Studies

Aggregate-level (or *ecologic*) studies do not collect information on individual subjects, but instead compare incidence or mortality rates for geographic regions distinguished by different overall levels of air pollution. The effects of air pollution exposure, or exposure reductions, can be estimated from aggregate-level data, but the interpretation of these estimates is more complicated than for estimates derived from cohort studies where data on disease occurrence and health risk factors are available for individuals. The major limitations of aggregate-level studies are the lack of data on inter-individual and between-region differences in important potential confounders and effect modifiers and the lack of sufficiently detailed spatial data on the pollutants of interest (Morgenstern 2008). These complex issues are clearly illustrated in the recent studies by Pope and colleagues on national trends in life expectancy (Pope et al. 2009) and by two studies sponsored by the California Air Resources Board on asthma hospital discharges (Moore et al. 2008) and cardiovascular mortality (Moore et al. 2010). Studies of open populations, such as the studies based on data in the Medicare database (Dominici et al. 2006; Zeger et al. 2008), can address some of the problems with respect to confounding and sources of heterogeneity, but still may suffer from a lack of adequate spatial–temporal exposure data and adequate adjustment for unmeasured confounders (Greven et al. 2010, in press).

Recent advances in analytic methods for intervention research can potentially be applied to data generated by both study designs. Though not currently the standard approach, these methods are designed to address explicitly the kinds of questions accountability studies seek to answer concerning the impact of regulatory action on health. For example, one recent paper extended earlier methods designed for randomized clinical trials to provide marginal estimates of the effect of interventions at the population level, in other words, estimates based on averaging over-all exposure and covariates within a given target population or within specific subsets of that population in order to address potential differences in response to a given population-level intervention (Hubbard and van der Laan 2008). Another paper provided an example of the application of a closely related method in an aggregate-level study of asthma hospital admissions and air pollution (Moore et al. 2008).

Regulatory changes that result in discrete-time interventions are targets of opportunity. To the extent that plans for such studies are known in advance (e.g., the Dublin coal sales bans), some planning can take place with respect to needed exposure and health data (see the recommendation on anticipating and preparing for major upcoming regulatory actions at national and state levels, listed in the Recommendations section at the end of this chapter). Accountability studies that intend to evaluate regulatory changes whose impact can be addressed only over the longer-term mandate careful planning. For studies of open cohorts, countries with national health care systems across entire populations (e.g., United Kingdom, Scandinavia, and Canada) or segments thereof (e.g., the U.S. Medicare system) or health care providers with large, diverse populations (e.g., Kaiser, a private company in the United States) are preferred to fixed cohorts for reasons noted earlier. The planning in these types of studies mainly involves the establishment and maintenance of exposure measures over space–time sufficient to provide the least bias and more reliable estimates of exposure within the constraints of resources.

Close cooperation between teams with access to these data, those who develop monitoring networks for regulatory compliance, and investigators working in a particular area who have developed reasonably dense space–time monitors should be a high priority for these types of studies. This is particularly true since regulatory levels are beginning to approach background concentrations in many developing countries. In general, as pollution levels decline and regulatory efforts result in smaller and/or less abrupt changes in pollution concentrations and exposures, the signal-to-noise ratio will decline. Therefore, the development of new databases integrating the characteristics of air quality regulatory programs with existing national databases on ambient pollution levels, mortality, morbidity, and key confounders is a necessary step for accountability research.

DEVELOPMENT OF PUBLICLY AVAILABLE PLATFORMS FOR KEY RESEARCH DATA

Of critical importance for accountability research is the availability of easily accessible data sets that characterize and quantify the impact of regulatory actions for public health research. For example, an ideal situation would be to develop a “national environmental health data warehouse” for accountability research. Ideally, this data warehouse would include data on (1) the major national and local air quality regulations; (2) trends in health outcomes; (3) trends in indicators of health care quality (such as neonatal mortality); (4) trends in exposure indicators (e.g., in ambient concentrations of PM, other criteria pollutants, and speciated PM); and (5) trends in confounders and modifiers (e.g., in health care practice and new technologies).

In addition to new, linked data sources, we also need adequate epidemiologic and statistical methods for estimation. As an example, the existing Internet-based Health and Air Pollution Surveillance System (iHAPSS) regularly accesses, analyzes, and disseminates policy-relevant data about the association of air pollution and mortality in U.S. cities (*http://www.ihapss.jhsph.edu/*). However, for accountability research, the iHAPSS would need to be substantially revised, with an update of the data sets already posted and with added linkage to many others. Regardless, in addition to the many benefits to the accountability field from having relevant data available, the potential challenges and data limitations encountered in developing this proposed data warehouse would provide insight and suggest approaches for future research.

SIMULATION STUDIES TO SET REALISTIC EXPECTATIONS FOR FUTURE STUDIES OF CARDIOVASCULAR DISEASE AND OTHER COMPLEX, MULTIFACTORIAL HEALTH OUTCOMES

As the effect on health of further reductions in air pollution in developed countries might be small, it is important to develop a reasonably sophisticated perspective on whether future studies will have the power to detect and quantify an effect if there is one and to describe null effects with enough precision for policy purposes. Many studies will, of necessity, be retrospective, and the size of the study population will be fixed. Therefore, it will be critical to pay serious attention to the sensitivity of statistical inference to model specification and time-varying confounding.

Model Uncertainty

Statistical inference, especially statistical hypothesis testing, is model based (Leamer 1978). That is, parameter estimates depend on the specified statistical model and the sample of data collected. Uncertainty about a particular parameter estimate representing some scientific hypothesis is typically computed by estimating a sample distribution for that estimate based on the entire estimated statistical model. For example, suppose we specify a very simple statistical model in which the risk of cardiovascular disease (CVD_r) is expressed as a linear function of cumulative exposure to some air pollutant (Exp), Age, and SES:

$$\text{CVD\_r} = \beta_0 + \beta_1 \text{ Exp} + \beta_2 \text{ Age} + \beta_3 \text{ SES} + \epsilon \qquad (1)$$

In this model, the parameter β_1 expresses the dependence of CVD_r on Exp, “controlling for” Age and SES. Estimating the model with ordinary least squares (purely for purposes of illustration), we can compute a standard error for $\widehat{\beta_1}$, the estimate of β_1, which allows us to compute inferential statistics such as the *P* value: the probability of estimating a value for β_1 as large or larger than $\widehat{\beta_1}$, given that $\beta_1 = 0$.

If we want to interpret this probability as reflecting the scientific uncertainty about the *predictive* dependence of CVD risk on exposure, then we must also assume that the rest of the model is specified correctly. That is, we must assume that (1) CVD_r is indeed a *linear* function of Exp, Age, SES, and other factors ϵ; (2) ϵ is *homoscedastic*; (3) ϵ is normally distributed, etc.

If we want to interpret this probability as reflecting the scientific uncertainty about the *causal* dependence of CVD risk on exposure, then we must also assume that exposure is before CVD_r and that, given Age and SES, the relationship between Exp and CVD_r is unconfounded. That is, we must assume that the causal model is implicit in the above regression equation but made explicit by the appropriate causal graph*, in which Exp, Age, and SES are freely correlated with each other but uncorrelated with $\tilde{\epsilon}$ (Figure 2).

Regression models are statistically indistinguishable from many other causal models over the same variables, and in general, many causal structures are indistinguishable from observational data.[†]

For example, in Figure 3, we show two alternative causal models for these variables that would be indistinguishable in a sample involving only Age, Exp, SES, and CVD_r.

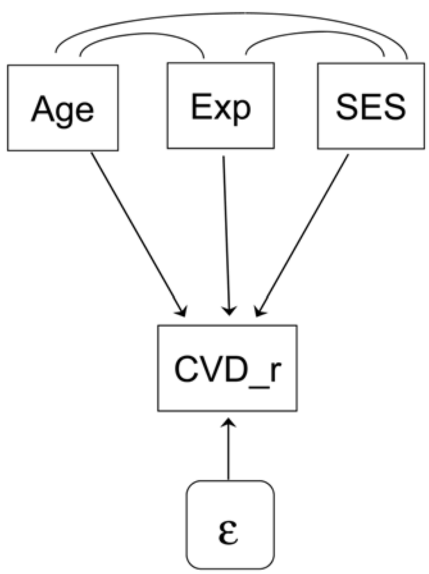

Figure 2. Regression model as causal model. Exp, Age, and SES are freely correlated with each other but uncorrelated with $\tilde{\epsilon}$.

* Causal graphs are directed acyclic graphs over a set of variables *V* that constrain the probability distributions over *V* and provide a semantics for how the system would respond to interventions and manipulations (Pearl 2000; Spirtes et al. 2000).

† See chapter 4 in Spirtes et al. (2000) for an axiomatic discussion of statistical indistinguishability for causal structure.

‡ See Kevin Murphy's excellent compendium "Software Packages for Graphical Models/Bayesian Networks" (last updated 5/28/10). *http://www.cs.ubc.ca/~murphyk/Software/bnsoft.html*. Accessed 7/1/10.

In model 1, the assumption of nonconfounding is satisfied, but in model 2, it is not (ϵ is composed of ϵ' and an unmeasured common cause of CVD_r and Exp). Many machine learning algorithms for searching for indistinguishable causal structures are now available.[‡]

Assuming that all relationships are linear and that the true causal dependence of CVD_r on Exp is ϕ in model 1, and zero in model 2, then the expectation of the parameter estimate, $\widehat{\beta_1}$, even if the statistical assumptions are all satisfied, is ϕ in model 1 and γ in model 2.

The implication is clear: scientific uncertainty arises from sampling variability *and* from model uncertainty. Standard statistical inference captures only chance sampling variability (Hoeting et al. 1999). How can model uncertainty also be included when estimating overall scientific uncertainty? In the best case, we might be uncertain about the correct model, but we might be able to narrow consideration to a small set of possible models and even have degrees of belief about which of these models is likely to be true. For example, we might believe that one of the models pictured in Figure 3 is true and that there is a 60% chance of model 1 being correct and a 40% chance of model 2 being correct. We could then apply a weighted average of the parameter estimate for the causal dependence of CVD_r on Exp:

$$0.6 \times (\text{estimate from model 1}) + \\ 0.4 \times 0 \times (\text{estimate from model 2}) \qquad (2)$$

This technique is called *Bayesian model averaging* and has been used in a variety of social science contexts (Raftery et al. 1997; Hoeting et al. 1999). We might also attach a parameter to a particular type of model uncertainty, for example, the amount of unmeasured confounding. In that case, we could do a sensitivity analysis for the parameter of interest as a function of the parameter representing the amount of unmeasured confounding (Rosenbaum 2002; Dominici et al. 2004). The smaller the size of the effect being considered, the more necessary it is to properly take account of model uncertainty.

Time-Varying Confounders

Even if we are reasonably confident of a model specification, certain parameters of a model can influence the power the data will have on estimating others. For example, suppose that we specified model 1 in Figure 3 and were reasonably confident that this model specification was accurate. Suppose we wanted enough statistical power to determine if, after standardizing all variables to have mean 0 and variance 1, ϕ is above 0.2. The power will depend on the size of γ and λ and in general on the variance and level of the factors besides exposure. If the variance in CVD_r is almost

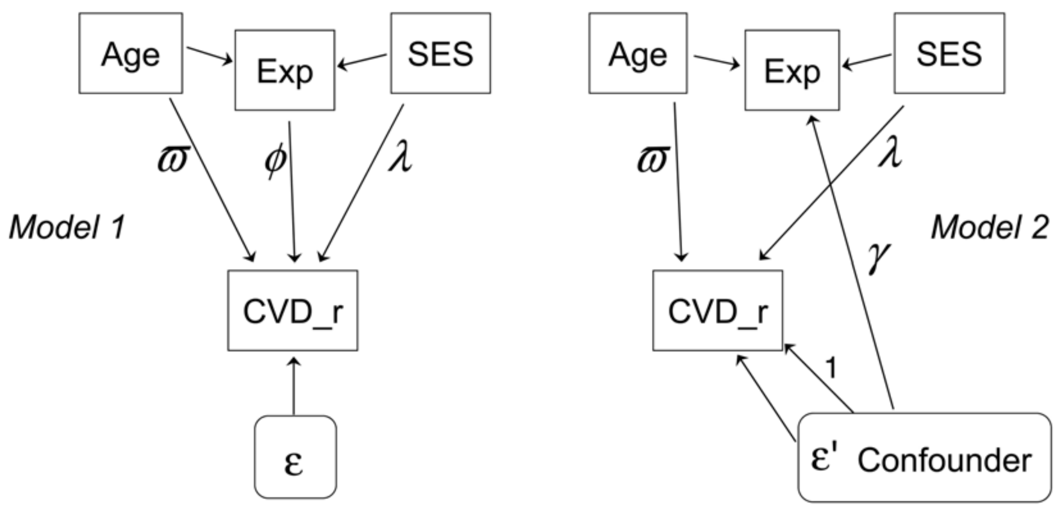

Figure 3. Alternative causal models. In model 1, the assumption of nonconfounding is satisfied; in model 2, it is not.

entirely due to variation in SES and Age, then the effect of Exp is relatively small and will be hard to detect. In the specific case of heart disease, over the last four decades, the decrease in smoking rates, the improvements in treating hypertension, and the advent of cholesterol-lowering drugs have all had a major effect on reducing mortality due to all causes (Feinleib 1984; Kannel and Thom 1984). Thus, if a factor beyond air pollution can be expected to vary over time, and it is a sufficiently strong predictor of change in disease risk, then it is important to account for such changes in any model of the power of a future study. Standard statistical techniques exist for both of these problems, but they might be best handled with an appropriately sophisticated simulation tool that could construct alternative models that represent the extent of our current uncertainty and varying levels of other influences on outcomes of interest, including the possibility of time-dependent confounding.

ANTICIPATING AND PREPARING FOR MAJOR UPCOMING REGULATORY ACTIONS

The U.S. EPA is currently implementing a number of major regulatory actions, including on-road and off-road diesel rules, rules covering locomotives and marine vessels, and the existing Clean Air Interstate Rule (CAIR). In addition, the U.S. EPA is considering a number of new regulations, including Maximum Achievable Control Technology (MACT) standards for utilities and industrial boilers, and a replacement for CAIR. Individual states and regions are also implementing or planning regulations covering a number of important sources of air pollution, including those in ports and transportation corridors.

The process of incorporating accountability research into policy development may include an iterative cycle of prospective and retrospective analysis, whereby potential outcomes of policies are evaluated using exposure and risk assessment models during the initial policy development phase, and the results of policies are evaluated once air pollution reduction strategies have been implemented. In planning for these types of linked analyses, it is useful to consider prospective and retrospective analyses in parallel (see Hidy et al. 2010, in press, for a more complete discussion of this concept). Figure 4 diagrams this type of parallel structure and shows the linkages between the different phases of analyses that support the prospective and retrospective assessments of regulatory actions. As noted in the NARSTO report (Hidy et al. 2010, in press), adoption of a parallel analytical process provides for more frequent evaluation of the effects of regulations at different levels (e.g., regulatory compliance, emission reductions, and air quality change) in order to determine whether the assumptions that went into the prospective analysis are being realized as projected and, if not, what the implications of realized differences are for the outcomes of the regulation.

Large-scale regulations provide unique opportunities to address a number of accountability questions (in terms of expected emissions reductions), including emissions and air quality modeling sensitivities, changes in exposure associated with changes in ambient air quality, and changes in health outcomes associated with changes in the levels and/or composition of air pollution. Because regulations often target specific sectors or emissions types (e.g., mobile-source diesel emissions or utility SO_2 emissions), certain types of accountability questions can be asked about the regulations that cannot be asked about other

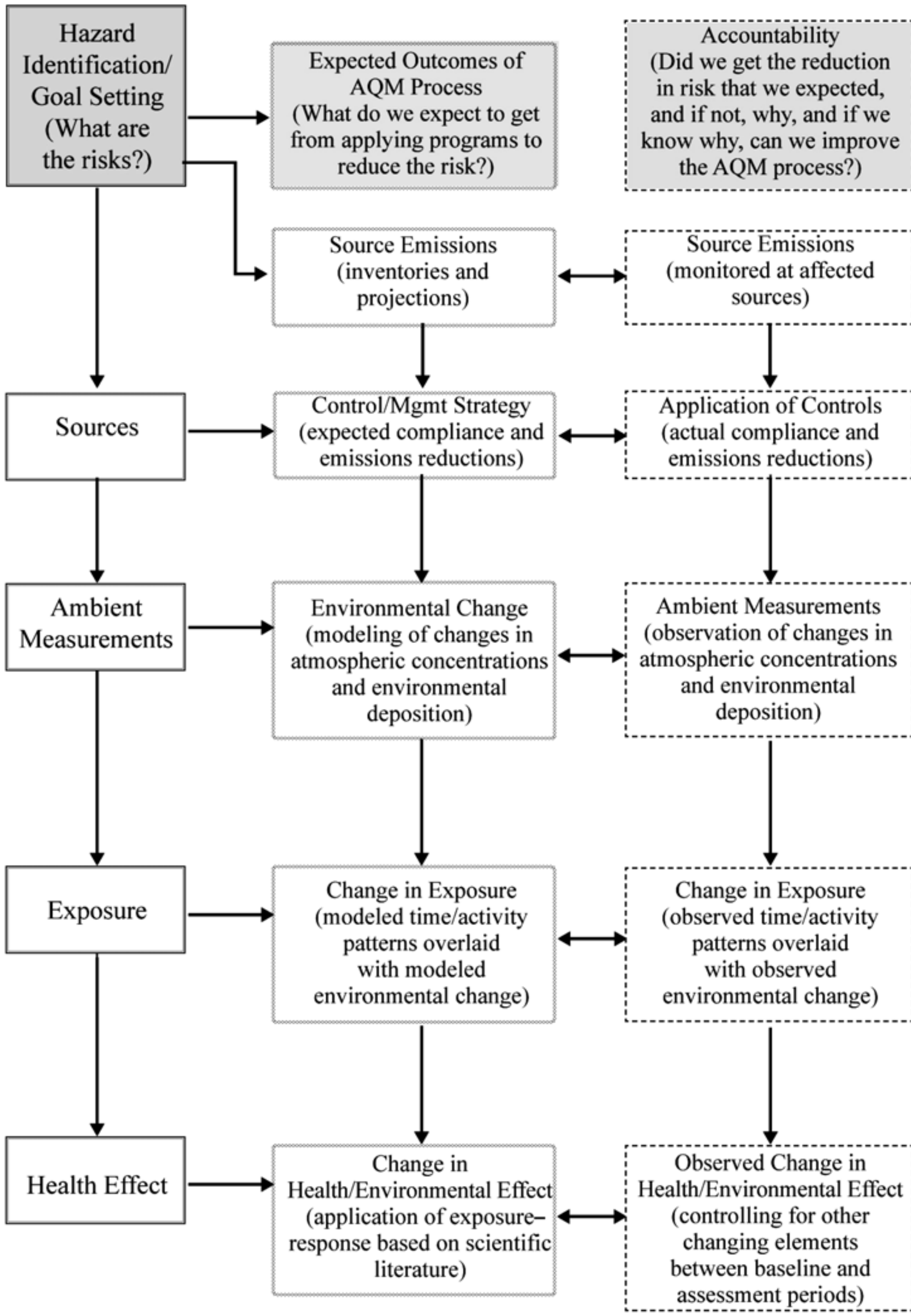

Figure 4. Parallelism between prospective (risk analysis and air quality management [AQM]) and retrospective (accountability) assessments of regulatory outcomes. Reprinted from Hidy et al. 2010 (in press), with permission of Springer Science & Business Media.

types of interventions. For example, one important accountability question might be, Does reducing SO_2 emissions from power plants lead to the reduction in mortality risk associated with longer-term exposure to $PM_{2.5}$ mass? By focusing on the utility SO_2 emissions regulations, which are likely to disproportionately affect the sulfate component of $PM_{2.5}$, it may be possible to determine how SO_2 reductions affect the $PM_{2.5}$ mixture and mortality outcomes. Identifying upcoming regulations and understanding the types of changes in emissions, air quality, exposure, and health expected as a result of the rule can lead to opportunities for answering these types of questions and can improve planning for accountability assessments by setting up parallel prospective and retrospective risk analyses.

RECOMMENDATIONS

The main objective of accountability research is to create methods and obtain knowledge relevant to the evaluation of environmental regulation. We have discussed four recommendations on how to better achieve this objective.

- Continue to conduct retrospective epidemiologic studies to estimate the health impacts of changes in air quality attributable to longer-term, large-scale regulatory actions. These should entail close cooperation among those with access to study populations; agencies at national, state, and local levels responsible for developing air quality monitoring networks for regulatory compliance; and investigators working in particular areas who have developed high-density spatio–temporal monitoring platforms.
- Develop a national environmental health data warehouse for accountability research. Ideally, the data warehouse would include data on (1) the major national and local air quality regulations; (2) trends in health outcomes; (3) trends in indicators of health care quality; (4) trends in air pollution exposure indicators; and (5) trends in key potential confounders and modifiers.
- Conduct simulation studies to set realistic expectations for future studies of CVD and other complex, multifactorial health outcomes. It will be critical to explore in advance the sensitivity of statistical estimation and inference to model specification and time-varying confounding in any major proposed study.
- Anticipate and prepare for major upcoming regulatory actions at national and state levels. The process of incorporating accountability research into policy development may include an iterative cycle of prospective and retrospective analysis, which may be conducted in parallel. Regulations aimed at achieving large-scale reductions in particular emissions can provide unique research opportunities. Because such regulations often target specific sectors or emissions types (e.g., mobile-source diesel emissions or utility SO_2 emissions), certain types of accountability questions can be asked about the regulations that cannot be asked about other types of interventions.

Our recommendations are designed to provide key components of the evaluation of environmental regulations, including data, methods, and analyses that quantify (1) the tracking of the regulatory process and its characteristics; (2) location-specific estimates of trends in air pollution levels, taking appropriate account of measurement error; and (3) methods for estimating adverse health risks associated with longer-term exposure to air pollution accounting for time-varying confounders and model uncertainty.

The results of studies of longer-term interventions could potentially be used in risk assessments designed to estimate the number of deaths and hospital admissions that would be prevented by the implementation of increasingly stringent air quality regulations. We recognize important limitations inherent in any approach for assessing the health effects of government regulations and in the use of a causal framework in particular. These "causal" estimates of preventable mortality and morbidity are often based on strong and unverifiable assumptions (as are many more conventional models). For example, we often need to assume that the trends observed in the locations affected by a regulation can be used to predict what trends would have occurred in those locations absent regulation. Often, these types of limitations can be addressed by sensitivity analyses.

In summary, controlling air pollution to protect the public health has become increasingly challenging: outdoor levels of key pollutants have declined but epidemiologic studies continue to show adverse effects. Regulators need increasingly refined information concerning the sources of pollutants contributing most substantially to risk for adverse effects in order to create cost-efficient and focused control strategies. The rationale for accountability research in this context is evident: we need to know if projected benefits of control measures are being realized, and if the costs of controls can be supported by their benefits to public health. Surprisingly, the concept of accountability is still nascent, and new data and methodologies for accountability research still need to be formally developed.

CHAPTER 5. CROSS-CUTTING ISSUES AND RECOMMENDATIONS

CROSS-CUTTING ISSUES

Accountability research involves an implicit comparison: a comparison of what took place after an action to what would have taken place absent the action. This comparison scenario is referred to as the *counterfactual,* a term reflecting that it is counter to the actual facts. The notion of the counterfactual has formed the basis for causal thinking as far back as David Hume in the 18th century. Along the chain of accountability (see Figure 1), counterfactuals might be proposed for each of the elements: for example, what would the source mix have been, absent an intervention that changed sources (or fuels)? Or, what would pollution concentrations have been, without a change in regulation? The assumed counterfactual takes on particular relevance for interpretation when the study design is quasi-experimental and involves a "before-and-after" approach. In the example of the Provo, Utah, steel mill strike, the shutdown and reopening of the facility offered a powerful opportunity to compare outcomes during the shutdown to those before *and* after the cessation of operations.

The selection of a counterfactual becomes problematic for longer-term actions, where typically other factors may be changing over the time period of interest and also contributing to changes in the occurrence of the outcome. Is the appropriate counterfactual, then, the conditions at the time of implementation of the intervention? What is the appropriate counterfactual for an intervention that comes into play over an extended period of time, such as a change in a National Ambient Air Quality Standard? A complete working through of issues related to the counterfactual should be a component of the screening phase of accountability research. Approaches to address these questions are already available, such as history-adjusted marginal structural models (Petersen et al. 2007).

Workshop participants recommended a broadening of the application of the accountability framework to better acknowledge the heterogeneity of risks across the population. Much of the accountability research to date has considered population-level consequences of interventions without assessing the extent to which particular subgroups are affected. The participants recommended that analysis be deepened to consider how risks to particular subgroups within populations may be changed by interventions, particularly with the consideration of environmental justice and of the contribution of air pollution to health disparities. Such considerations should enter into the planning phase for an accountability study.

Some actions provide an opportunity to gain evidence that may be useful for strengthening causal inference. The symmetric finding of a benefit to health from exposure reduction complements the findings of increased risk to health at higher exposures. A targeted intervention (e.g., one aimed at reducing traffic) provides information about a specific source, while a step change in concentration/exposure reduces concern about confounding in estimating the effect of a source or pollutant. These considerations regarding causation should be given greater specificity by being set in the concentration/exposure/dose range at which they occur. For airborne PM, for example, there is considerable certainty as to the risks of very high level exposures, but increased uncertainty at the lower levels experienced in many countries today. Accountability studies can be informative as to whether effects persist at exposures of current interest, although beyond speaking to whether there is a threshold exposure for effects, they will not offer information for characterizing the form of the exposure–response relation.

Chapters 2 to 4 highlight the need for data and information resources. The research community needs to be aware of opportunities for accountability research, particularly if data collection systems need to be designed prospectively. Many interventions are in progress or planned, and even if they do not offer sufficiently robust evidence by themselves, multisite protocols might be informatively implemented. However, as noted in the previous chapters, there does not appear to be any ongoing compilation of interventions that would support such research. HEI could take the lead in developing a system for capturing such opportunities.

The studies to date illustrate the complexity of accountability research and the high likelihood of obtaining results that are uninformative or ambiguous. While HEI and its sponsors remain interested in carrying out accountability research, experience to date suggests that the approach to designing such research should be cautious and phased. The empirical research on study sensitivity will enhance informed decision making on whether to conduct particular studies. The proceedings of this workshop along with the findings of the recommended empirical studies should be used to refine HEI's agenda for accountability research.

Should further accountability research be funded at present? This topic was not directly addressed by the workshop participants, some of whom were engaged at the time in accountability studies. Given the "lessons learned," HEI might reasonably await the completion of the currently funded projects, while evaluating specific proposals for their potential to make significant contributions. As a research funder, HEI might choose to not fund studies that are unlikely to generate scientific evidence that addresses key uncertainties.

RECOMMENDATIONS

In this section, we recap the recommendations from each working group.

Recommendations Related to Exposure Assessment in Accountability Research (Chapter 2)

- During the design phase, future accountability studies should consider carefully the predicted pollutant concentration and anticipated exposure reductions following an intervention. If only a limited reduction is expected, emphasis might be given to the "upstream" components of the accountability chain — emission reductions, air quality improvements, and perhaps also personal exposure — before a decision is made whether the direct measurement of health outcomes will provide meaningful results. However, even when the expected exposure reduction is small, one can always conduct a health impact assessment estimating the health benefits using existing exposure–response functions.

- During the design phase of future accountability studies, careful assessment of available monitoring sites is needed. The number and location of monitors, which pollutants are measured, and the frequency of sampling may determine the power of the study to detect changes in air quality. This is especially true of traffic interventions, which may cause relatively small changes in urban background air quality and require measurements of specific chemical species at high temporal resolutions at roadside locations (i.e., more frequently than hourly at roadside monitors).
- Advances in exposure estimation and air quality modeling may be useful to some research approaches depending on the type of intervention and study design. Researchers would do well to include the appropriate multidisciplinary expertise on their teams to take full advantage of such developments.
- The development of a national traffic-related monitoring strategy is desirable. The design and implementation of several pilot measurement studies in several major metropolitan areas should be considered, including the deployment of advanced high-precision and time-resolution instrumentation.
- Agreement is needed within the research and monitoring communities as to which pollutant parameters require priority consideration for routine monitoring in order to improve multipollutant exposure estimates and track progress in mitigation strategies.
- Further development of approaches is needed to improve the understanding of how health outcomes are associated with specific components of air pollution mixtures. Special consideration should be given to the evaluation of possible synergistic effects. Accountability studies may provide useful information about the health effects of specific sources. In addition, they may provide information about the health effects of specific components of mixtures if they find that reductions in certain mixture components resulting from specific air quality actions are associated with reductions in health outcomes.
- The design and implementation of emission control strategies to achieve NAAQS compliance should include a measurement plan to track the progress and effectiveness of controls and the potential collateral benefits (i.e., reduced emissions in co-emitted species, e.g., metals in the scrubbing of SO_2 from power plants).

Recommendations Related to Evaluating Shorter-Term and Small-Scale Actions (Chapter 3)

- Studies of shorter-term actions should continue to be conducted. Studies of intentional interventions to improve air quality as well as other actions will remain useful under specified circumstances, depending on the nature of the action and the magnitude of the expected changes in air quality and in the health outcomes of interest. Although particular emphasis should be given to studies of planned actions intended to improve air quality — arguably the most policy-relevant actions to evaluate — all types of shorter-term actions offer opportunities for informative research and challenges for design and interpretation. However, the value of conducting additional retrospective studies of temporary actions may be limited, especially if the time period is very short (e.g., the duration of the Olympic Games).
- We recommend using available information to estimate expected changes in emissions and, where feasible, ambient concentrations, before investing resources in the design and conduct of a shorter-term study. If the estimated impacts (signal) are meaningful relative to baseline concentrations and variation (noise), an evaluation study may be informative. A staged approach may be useful, in which the first step is to measure air quality changes, before deciding to continue to measure changes in exposure or health outcomes.
- Future research should continue to capitalize on abrupt changes in emissions leading to approximate step changes in ambient concentrations of pollutants. In such situations, the potential for confounding by temporal or geographic factors is reduced relative to that in studies that rely on the "usual" variation in ambient levels in the design of exposure contrasts.
- Studies of control measures aimed at particular sources should be a high priority. These measures could include abatements, fuel switches, or engineering controls. Such measures offer the unique opportunity to assess the benefits of controlling specific sources within the mix of pollutants from multiple sources. For example, studies of planned reductions in emissions from diesel engines in major marine ports may offer considerable potential for future research.
- Opportunities for coordinated ("pooled") studies of the same action in multiple locations or time periods should be explored as a way to increase the precision of estimates of the effect of a particular type of action. For example, major road construction projects that alter or divert traffic flow are common, but any particular project may have too small an impact to be studied alone. Pooling population health data across many communities affected by such shorter-term actions could allow for a more informative analysis.

- To facilitate such coordinated research, HEI should explore, with air quality managers and transportation officials at the federal and state level as well as with researchers, the development of a system, or clearinghouse, to identify and disseminate information about planned actions. The goal of such a clearinghouse would be to facilitate coordinated research and timely identification of planned actions by alert researchers, funders, and others with enough lead time to determine if a study is desirable and feasible.
- In studies of shorter-term actions planned far in advance, and if measurable air pollution benefits are expected, every effort should be made to monitor exposure and health prospectively. Prospective studies could include identifying a panel of vulnerable individuals and repeatedly measuring individual exposure, health outcomes, and potential confounders.
- Study designs must be based on an explicit definition of the population affected by a given action, especially when such actions take place on varying temporal and spatial scales. For example, studies of traffic restrictions may affect residents of contiguous areas as a result of the diversion of traffic from the target area. In general, it is important to specify the appropriate reference location or population for "counterfactual" comparison (i.e., assessment of health outcomes in the absence of a particular action).
- If particular policy actions are intended to reduce particular adverse health effects (e.g., asthma or myocardial infarction), then studies of their health impacts should be designed to estimate effects on those endpoints.
- For shorter-term actions, studies of intermediate physiologic measures of response (such as heart rate variability or pulmonary function) should be considered. They provide an alternative to the surveillance of health events such as emergency department visits and could advance understanding of the mechanisms and pathways underlying health outcomes affected by air pollution control measures.
- Future studies need to take seriously, and design against, the potential for confounding. For example, an event such as a labor dispute or a natural disaster may influence health through other pathways, such as stress or service disruption. Although such confounding may be difficult to avoid completely, it should be anticipated, measured where possible, and considered in interpreting results (e.g., by comparing trends in health outcomes in affected areas with trends during the same time period in locations not affected by the shorter-term action under study).
- To fully capture the effects of shorter-term actions, vulnerable populations for whom exposure and/or exposure–response relations may be greater than for the average population should be included in studies in sufficient numbers to allow valid and precise effect estimates. A focus on such populations is justified by concerns about environmental injustice and racism resulting in disparities in exposure profiles between less and more advantaged populations, and by the evidence for larger effects of exposure in the elderly and those with preexisting medical conditions, including children with asthma.

Recommendations Related to Evaluating Longer-Term Regulatory Actions (Chapter 4)

- Continue to conduct retrospective epidemiologic studies to estimate the health impacts of changes in air quality attributable to longer-term, large-scale regulatory actions. These should entail close cooperation among those with access to study populations; agencies at national, state, and local levels responsible for developing air quality monitoring networks for regulatory compliance; and investigators working in particular areas who have developed high-density spatio–temporal monitoring platforms.
- Develop a national environmental health data warehouse for accountability research. Ideally, the data warehouse would include data on (1) the major national and local air quality regulations; (2) trends in health outcomes; (3) trends in indicators of health care quality; (4) trends in air pollution exposure indicators; and (5) trends in key potential confounders and modifiers.
- Conduct simulation studies to set realistic expectations for future studies of CVD and other complex, multifactorial health outcomes. It will be critical to explore in advance the sensitivity of statistical estimation and inference to model specification and time-varying confounding in any major proposed study.
- Anticipate and prepare for major upcoming regulatory actions at national and state levels. The process of incorporating accountability research into policy development may include an iterative cycle of prospective and retrospective analysis, which may be conducted in parallel. Regulations aimed at achieving large-scale reductions in particular emissions can provide unique research opportunities. Because such regulations often target specific sectors or emissions types (e.g., mobile-source diesel emissions or utility SO_2 emissions), certain types of accountability questions can be asked about the regulations that cannot be asked about other types of interventions.

REFERENCES

Annest JL, Pirkle JL, Makuc D, Neese JW, Bayse DD, Kovar MG. 1983. Chronological trend in blood lead levels between 1976 and 1980. N Engl J Med 308:1373–1377.

Bachmann J. 2007. Will the circle be unbroken: A history of the U.S. National Ambient Air Quality Standards. J Air Waste Manag Assoc 57:652-697.

Bell ML, Ebisu K, Peng RD, Samet JM, Dominici F. 2009. Hospital admissions and chemical composition of fine particle air pollution. Am J Respir Crit Care Med 179:1115–1120.

Brunekreef B, Beelen R, Hoek G, Schouten L, Bausch-Goldbohm S, Fischer P, Armstrong B, Hughes E, Jerrett M, van den Brandt P. 2009. Effects of Long-Term Exposure to Traffic-Related Air Pollution on Respiratory and Cardiovascular Mortality in the Netherlands: The NLCS-AIR Study. Research Report 139. Health Effects Institute, Boston, MA.

Brunekreef B, Janssen NAH, de Hartog JJ, Oldenwening M, Meliefste K, Hoek G, Lanki T, Timonen KL, Vallius M, Pekkanen J, van Grieken R. 2005. Personal, Indoor, and Outdoor Exposures to $PM_{2.5}$ and Its Components for Groups of Cardiovascular Patients in Amsterdam and Helsinki. HEI Research Report 127. Health Effects Institute, Boston, MA.

Canagaratna MR, Jayne JT, Ghertner DA, Herndon S, Shi Q, Jimenez JL, Silva PJ, Williams P, Lanni T, Drewnick F, Demerjian KL, Kolb CE, Worsnop DR. 2004. Chase studies of particulate emissions from in-use New York City vehicles. Aerol Sci Technol 38:555–573.

Chay K, Dobkin C, Greenstone M. 2003. The Clean Air Act of 1970 and adult mortality. J Risk Uncertainty 27: 279–300.

Chay K, Greenstone M. 2003. The impact of air pollution on infant mortality: Evidence from geographic variation in pollution shocks induced by a recession. Quart J Econom 118:1121–1167.

Chen LC, Hwang JS, Lall R, Thurston G, Lippmann M. 2010. Alteration of cardiac function in $ApoE^{-/-}$ mice by subchronic urban and regional inhalation exposure to concentrated ambient $PM_{2.5}$. Inhal Toxicol 22:580–592.

Clancy L, Goodman P, Sinclair H, Dockery DW. 2002. Effect of air-pollution control on death rates in Dublin, Ireland: An intervention study. Lancet 360:1210–1214.

Dockery DW, Rich DQ, Ohman-Strickland P, George P, Kotlov T, Goodman PG, Clancy L. 2010. Effect of air pollution control on mortality and hospital admissions in Ireland. Presentation at Health Effects Institute 2010 Annual Conference. April 25–27, 2010. Alexandria, VA.

Dominici F, McDermott A, Hastie T. 2004. Improved semiparametric time series models of air pollution and mortality. J Am Stat Assoc 468:938–948.

Dominici F, Peng RD, Bell ML, Pham L, McDermott A, Zeger SL, Samet JM. 2006. Fine particulate air pollution and hospital admission for cardiovascular and respiratory diseases. JAMA 295:1127–1134.

Dominici F, Peng RD, Zeger SL, White RH, Samet JM. 2007. Particulate air pollution and mortality in the United States: Have the risks changed from 1987 to 2000? Am J Epidemiol 166:880–888 (with discussion).

Ezzati M, Friedman AB, Kulkarni SC, Murray CJ. 2008. The reversal of fortunes: Trends in county mortality and cross-county mortality disparities in the United States. PLoS Med 5:e66.

Feinleib M. 1984. The magnitude and nature of the decrease in coronary heart disease mortality rate. Am J Cardiol. 54:2C–6C.

Forastiere F, Stafoggia M, Tasco C, Picciotto S, Agabiti N, Cesaroni G, Perucci CA. 2007. Socioeconomic status, particulate air pollution, and daily mortality: Differential exposure or differential susceptibility. Am J Ind Med 50:208–216.

Friedman MS, Powell KE, Hutwagner L, Graham LM, Teague WG. 2001. Impact of changes in transportation and commuting behaviors during the 1996 summer Olympic Games in Atlanta on air quality and childhood asthma. JAMA 285:897–905.

Gilbreath S, Yap P, Garcia C. 2008. Changes in cardiovascular mortality during a 2002 port strike in Southern California. American Public Health Association 136th Annual Meeting & Exposition. October 25–28, 2008. San Diego, CA. Available at *http://apha.confex.com/apha/136am/webprogram/Paper182571.html*. Accessed 7/2/2010.

Greven S, Dominici F, Zeger SL. 2010, in press. An approach to the estimation of chronic air pollution effects using spatio-temporal information. J Am Stat Assoc. Available at *www.bepress.com/jhubiostat/paper190/.*

HEI Accountability Working Group. 2003. Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research. Communication 11. Health Effects Institute, Boston, MA.

HEI Panel on the Health Effects of Traffic-Related Air Pollution. 2010. Traffic-Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and Health Effects. Special Report 17. Health Effects Institute, Boston, MA.

Hedley AJ, Wong CM, Thach TQ, Ma S, Lam TH, Anderson HR. 2002. Cardiorespiratory and all-cause mortality after restrictions on sulphur content of fuel in Hong Kong: An intervention study. Lancet 360:1646–1652.

Herndon SC, Shorter JH, Zahniser MS, Wormhoudt J, Nelson DD, Demerjian KL, Kolb CE. 2005. Real-time measurements of SO_2, H_2CO, and CH_4 emissions from in-use curbside passenger buses in New York City using a chase vehicle. Environ Sci Technol 39:7984–7990.

Hidy GM, Brook JR, Demerjian KL, Molina LT, Pennell WT, Scheffe RD, eds. 2010, in press. Technical Challenges of Multipollutant Air Quality Management. Springer, Dordrecht, The Netherlands.

Hill AB. 1965. The environment and disease: Association or causation? Proc Royal Soc Med 58:295–300.

Hoeting JA, Madigan D, Raftery AE, Volinsky CT. 1999. Bayesian model averaging: A tutorial. Statist Sci 14: 382–417.

Hubbard AE, van der Laan MJ. 2008. Population intervention models in causal inference. Biometrika 95:35–47.

Ito K, Thurston GD, Silverman RA. 2007. Characterization of $PM_{2.5}$, gaseous pollutants, and meteorological interactions in the context of time-series health effects models. J Expo Sci Environ Epidemiol. 17(Suppl 2):S45–S60.

Janes H, Dominici F, Zeger SL. 2007. Trends in air pollution and mortality: An approach to the assessment of unmeasured confounding. Epidemiology 18:416–423.

Janssen NA, Schwartz J, Zanobetti A, Suh HH. 2002. Air conditioning and source-specific particles as modifiers of the effect of PM(10) on hospital admissions for heart and lung disease. Environ Health Perspect 110:43–49.

Kannel WB, Thom TJ. 1984. Declining cardiovascular mortality. Circulation 70:331–336.

Kelly FJ, Anderson HR, Armstrong B, Atkinson R, Barratt B, Beevers S, Derwent R, Green D, Mudway IS, Wilkinson P. 2010, in press. Congestion Charging Scheme in London: Assessing Its Impact on Air Quality. HEI Research Report 155. Health Effects Institute, Boston, MA.

Kittelson DB, Watts WF, Johnson JP, Schauer JJ, Lawson DR. 2006. On-road and laboratory evaluation of combustion aerosols: Part 2. Summary of spark ignition engine results. J Aer Sci 37:931–949.

Kolb CE, Herndon SC, McManus B, Shorter JH, Zahniser MS, Nelson DD, Jayne JT, Canagaratna MR, Worsnop DR. 2004. Mobile laboratory with rapid response instruments for real-time measurements of urban and regional trace gas and particulate distributions and emission source characteristics. Environ Sci Technol 38:5694–5703.

Krewski, D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi Y, Turner MC, Pope C A III, Thurston G, Calle EE, Thun MJ. 2009. Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality. HEI Research Report 140, Health Effects Institute, Boston, MA.

Laden F, Schwartz J, Speizer FE, Dockery DW. 2006. Reduction in fine particulate air pollution and mortality: Extended follow-up of the Harvard Six Cities study. Am J Respir Crit Care Med 173:667–672.

Leamer EE. 1978. Specification Searches: Ad Hoc Inference with Nonexperimental Data. John Wiley & Sons, New York, NY.

Lippmann M, Ito K, Hwang JS, Maciejczyk P, Chen LC. 2006. Cardiovascular effects of nickel in ambient air. Environ Health Perspect. 114:1662–1669.

Matte TD, Cohen A, Dimmick F, Samet J, Sarnat J, Yip F, Jones N. 2009. Summary of the workshop on methodologies for environmental public health tracking of air pollution effects. Air Qual Atmos Health 2:177–184.

McConnell R, Berhane K, Gilliland F, Molitor J, Thomas D, Lurmann F, Avol E, Gauderman WJ, Peters JM. 2003. Prospective study of air pollution and bronchitic symptoms in children with asthma. Am J Respir Crit Care Med. 168:790–797.

Medina S, Le Tertre A, Saklad M; on behalf of the Apheis Collaborative Network. 2009. The Apheis project: Air Pollution and Health — A European Information System. Air Qual Atmos Health 2:185–198.

Miller KA, Siscovick DS, Sheppard L, Shepherd K, Sullivan JH, Anderson GL, Kaufman JD. 2007. Long-term exposure to air pollution and incidence of cardiovascular events in women. N Engl J Med 356:447–458.

Morgenstern H. 2008. Ecologic studies. In: Modern Epidemiology, 3rd ed. (Rothman KJ, Greenland S, Lash TL, eds.) Lippincott Williams & Wilkins, Philadelphia, PA.

Moore K, Neugebauer R, Lurmann F, Hall J, Brajer V, Alcorn S, Tager I. 2010. Ambient ozone concentrations and cardiac mortality in Southern California 1983–2000: Application of a new marginal structural model approach. Am J Epidemiol 171:1233–1243.

Moore K, Neugebauer R, Lurmann F, Hall J, Brajer V, Alcorn S, Tager I. 2008. Ambient ozone concentrations cause increased hospitalizations for asthma in children: An 18-year study in Southern California. Environ Health Perspect 116:1063–1070.

National Research Council (U.S.). 2004. Air Quality Management in the United States. National Academies Press, Washington, DC.

National Research Council (U.S.). 2009. Science and Decisions: Advancing Risk Assessment. National Academies Press, Washington, DC.

Noonan CW, Ward TJ, Navidi W, Sheppard L. 2010. Community intervention for woodstove-generated PM: Impact on ambient air and respiratory symptoms. Presentation at Health Effects Institute 2010 Annual Conference. April 25–27, 2010. Alexandria, VA.

Ou CQ, Hedley AJ, Chung RY, Thach TQ, Chau YK, Chan KP, Yang L, Ho SY, Wong CM, Lam TH. 2008. Socioeconomic disparities in air pollution-associated mortality. Environ Res 107:237–244.

O'Neill MS, Jerrett M, Kawachi I, Levy JI, Cohen AJ, Gouveia N, Wilkinson P, Fletcher T, Cifuentes L, Schwartz J. 2003. Health, wealth, and air pollution: Advancing theory and methods. Environ Health Perspect 111:1861–1870.

Pearl J. 2000. Causality: Models, Reasoning and Inference. Cambridge University Press, New York, NY.

Peel JL, Klein M, Flanders WD, Mulholland JA, Tolbert PE. 2010. Impact of improved air quality during the 1996 Olympic Games in Atlanta on multiple cardiovascular and respiratory outcomes. Research Report 148. Health Effects Institute, Boston, MA.

Peng RD, Bell ML, Geyh AS, McDermott A, Zeger SL, Samet JM, Dominici F. 2009. Emergency admissions for cardiovascular and respiratory diseases and the chemical composition of fine particle air pollution. Environ Health Perspect. 117:957–963.

Peng RD, Chang HH, Bell ML, McDermott A, Zeger SL, Samet JM, Dominici F. 2008. Coarse particulate matter air pollution and hospital admissions for cardiovascular and respiratory diseases among Medicare patients. JAMA 299:2172–2179.

Peters A, Breitner S, Cyrys J, Stölzel M, Pitz M, Wölke G, Heinrich J, Kreyling W, Küchenhoff H, Wichmann H-E. 2009. The Influence of Improved Air Quality on Mortality Risks in Erfurt, Germany. Research Report 137. Health Effects Institute, Boston, MA.

Petersen ML, Deeks SG, Martin JN, van der Laan MJ. 2007. History-adjusted marginal structural models for estimating time-varying effect modification. Am J Epidemiol. 166:985–993.

Pope CA III. 1989. Respiratory disease associated with community air pollution and a steel mill, Utah Valley. Am J Public Health 79:623–628.

Pope CA III, Ezzati M, Dockery DW. 2009. Fine-particulate air pollution and life expectancy in the United States. N Engl J Med 360:376–386.

Pope CA III, Rodermund DL, Gee MM. 2007. Mortality effects of a copper smelter strike and reduced ambient sulfate particulate matter air pollution. Environ Health Perspect 115:679–683.

Puett RC, Schwartz J, Hart JE, Yanosky JD, Speizer FE, Suh H, Paciorek CJ, Neas LM, Laden F. 2008. Chronic particulate exposure, mortality, and coronary heart disease in the nurses' health study. Am J Epidemiol 168:1161–1168.

Raftery AE, Madigan D, Hoeting JA. 1997. Bayesian model averaging for linear regression models. J Am Stat Assoc 92:179–191.

Rava M, White R, Dominici F. 2010, in press. Does attainment status for the PM_{10} National Ambient Air Quality Standards change the trend in ambient levels of particulate matter? Air Quality, Atmosphere and Health.

Rosenbaum PR. 2002. Observational Studies, 2nd ed. Springer-Verlag, New York, NY.

Rothman KJ, Greenland S, Lash TL. 2008. Modern Epidemiology, 3rd ed. Lippincott Williams & Wilkins, Philadelphia, PA.

Ryan PH, Bernstein DI, Lockey J, Reponen T, Levin L, Grinshpun S, Villareal M, Hershey GK, Burkle J, LeMasters G. 2009. Exposure to traffic-related particles and endotoxin during infancy is associated with wheezing at age 3 years. Am J Respir Crit Care Med. 180:1068–1075.

Sarnat SE, Coull BA, Schwartz J, Gold DR, Suh HH. 2006. Factors affecting the association between ambient concentrations and personal exposures to particles and gases. Environ Health Perspect 114:649–654.

Sarnat JA, Schwartz J, Catalano PJ, Suh HH. 2001. Gaseous pollutants in particulate matter epidemiology: Confounders or surrogates? Environ Health Perspect 109:1053–1061.

Schwartz J. 1999. Air pollution and hospital admissions for heart disease in eight U.S. counties. Epidemiology 10:17–22.

Spirtes P, Glymour C, Scheines R. 2000. Causation, Prediction, and Search. 2nd ed. MIT Press, Cambridge, MA.

Talbot TO, Haley VB, Dimmick WF, Paulu C, Talbott EO, Rager J. 2009. Developing consistent data and methods to measure the public health impacts of ambient air quality for Environmental Public Health Tracking: Progress to date and future directions. Air Qual Atmos Health 2:199–206.

Thomas DC. 2009. Statistical Methods in Environmental Epidemiology. Oxford University Press, New York, NY.

Tonne C, Beevers S, Armstrong B, Kelly F, Wilkinson P. 2008. Air pollution and mortality benefits of the London congestion charge: Spatial and socioeconomic inequalities. Occup Environ Med. 65:620–627.

Turpin BJ, Weisel CP, Morandi M, Colome S, Stock T, Eisenreich S, Buckley B, and Others. 2007. Part II. Analyses of concentrations of particulate matter species. In: Relationships of Indoor, Outdoor, and Personal Air (RIOPA). Research Report 130. Health Effects Institute, Boston, MA.

U. S. Environmental Protection Agency. 1997. The Benefits and Costs of the Clean Air Act 1970 to 1990. EPA-410-R-97-002. Office of Air and Radiation, Washington, DC.

U.S. Environmental Protection Agency. 1999. The Benefits and Costs of the Clean Air Act 1990 to 2010: EPA Report to Congress. EPA-410-R-99-001. Office of Air and Radiation, Washington, DC.

van Erp AM, Cohen AJ. 2009. HEI's Research Program on the Impact of Actions to Improve Air Quality: Interim Evaluation and Future Directions. Communication 14. Health Effects Institute, Boston, MA.

Weisel CP, Zhang J, Turpin BJ, Morandi MT, Colome S, Stock TH, Spektor DM, and Others. 2005. Part I. Collection Methods and Descriptive Analyses. In: Relationships of Indoor, Outdoor, and Personal Air (RIOPA). Research Report 130. Health Effects Institute, Boston, MA.

Yanosky JD, Paciorek CJ, Schwartz J, Laden F, Puett R, Suh HH. 2008. Spatio-temporal modeling of chronic PM_{10} exposure for the Nurses' Health Study. Atmos Environ 42:4047–4062.

Zanobetti A, Franklin M, Koutrakis P, Schwartz J. 2009. Fine particulate air pollution and its components in association with cause-specific emergency admissions. Environ Health 8:58.

Zeger SL, Dominici F, McDermott A, Samet JM. 2008. Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000–2005). Environ Health Perspect 116:1614–1619.

Zhang J, Kipen HM, Zhu T, Huang W, Wang G, Rich DQ, Zhu P, Wang Y, Hu M, Lu S-E, Ohman-Strickland P. 2010. Biological responses to drastic changes in air pollution during the Beijing Olympics. Presentation at Health Effects Institute 2010 Annual Conference. April 25–27, 2010. Alexandria, VA.

Appendix A. HEI's Accountability Research Program[a]

RFA / Investigator (Institution)	Study Title	Intervention	Approach	Challenges
RFA 02-1				
Douglas Dockery (Harvard School of Public Health, Boston, Mass.)	"Effects of Air Pollution Control on Mortality and Hospital Admissions in Ireland" (in review)	After a ban on the sale of coal in Dublin, Ireland, in 1990 was shown to effectively reduce particulate air pollution levels, similar bans were implemented in Cork (1995) and 10 other Irish cities (1998).	*Retrospective study.* Previous analyses of mortality in Dublin showed that total and cause-specific death rates fell by 8% after the ban. Dockery and colleagues extended those analyses to 11 other cities. They aimed to quantify in each city the effect of the coal bans on concentrations of black smoke and sulfur oxide, total and cause-specific mortality, and cardiovascular and respiratory hospital admissions. The time period studied was 1994–2000.	· The additional cities are much smaller than Dublin. Instead of calculating city-specific estimates, the investigators pooled data across cities to obtain a sufficient number of cases. · It was not clear if the rural population was an appropriate control population because of economic and other differences. · There was a smaller air quality impact from the later bans because of lower levels of air pollution. · The investigators observed a general decline in mortality over the time period studied. · The investigators encountered considerable difficulties in obtaining mortality data.
Annette Peters (GSF–National Research Center for Environment and Health[b], Neuherberg, Germany)	"Improved Air Quality and Its Influences on Short-Term Health Effects in Erfurt, Eastern Germany" (Peters et al. 2009)	Environmental protection and industrial modernization programs after German Reunification in 1990 brought substantial changes in air quality in the East German city of Erfurt. Changes in sources included a switch from brown coal to natural gas for home heating and power plants, and changes in the motor vehicle fleet.	*Retrospective study.* Peters and colleagues obtained ambient monitoring data for gaseous and particulate pollutants of varying size fractions and cause-specific mortality data from 1991–2002. Controlling for time-varying confounders, they compared daily mortality at various lagged times with levels of the pollutants of interest using a time-varying coefficient model to arrive at a dynamic estimate of mortality risk spanning the study period.	· Erfurt is a relatively small city. There was insufficient statistical power to be certain of effect estimates. · There were likely other demographic changes during the time period studied. · Changes were a mixture of planned and unplanned actions; thus, it is difficult to ascribe changes in air quality to specific actions.

Table continues next page

[a] Abbreviations: CCS = Congestion Charging Scheme; LEZ = Low Emission Zone; NO_2 = nitrogen dioxide; NO_x = nitrogen oxides; O_3 = ozone; PM = particulate matter; $PM_{2.5}$ = PM ≤ 2.5 µm in aerodynamic diameter; PM_{10} = PM ≤ 10 µm in aerodynamic diameter; RFA = request for applications; RFPA = request for preliminary applications; SO_2 = sulfur dioxide.

[b] As of 2008, GSF–National Research Center for Environment and Health is now the Helmholtz Zentrum München–German Research Center for Environmental Health.

Appendix A (*Continued*). HEI's Accountability Research Program[a]

RFA / Investigator (Institution)	Study Title	Intervention	Approach	Challenges
RFA 04-1				
Frank Kelly (King's College London, London, U.K.)	"Congestion Charging Scheme in London: Assessing Its Impact on Air Quality and Health" (in press)	Measures were implemented to reduce traffic congestion in inner city London by charging vehicles £5 (now £8) to enter during business hours.	*Retrospective study.* Kelly and colleagues investigated whether congestion charging led to improved air quality (with a focus on NO_x and PM) in inner city London. They used a number of approaches, including modeling of air quality, evaluation of monitoring data, and evaluation of oxidative potential of PM collected on filters. Evaluation of health outcomes was postponed until the investigators could show a clear improvement in air quality.	· The CCS was not designed to improve air quality. · The size of the zone (inner city London) is quite small relative to the greater London area, and the number of air quality monitors was thus limited as well. · The observed reduction in the number of cars entering the zone was partly offset by increased taxi and bus trips. · A change in the typical weather pattern during implementation of the CCS in February 2003 caused regional background concentrations of PM to increase, which made it difficult to identify changes in air quality that may have been associated with the CCS. · Overall, it was concluded that the scheme was too small to achieve a direct air quality benefit in such a major urban area. Thus, the power to detect changes in health outcomes was deemed too low to allow an analysis of health outcomes.

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Appendix A (*Continued*). HEI's Accountability Research Program[a]

RFA / Investigator (Institution)	Study Title	Intervention	Approach	Challenges
RFA 04-4				
Frank Kelly (King's College London, London, U.K.)	"The London Low Emission Zone Baseline Study" (in press)	Measures to reduce pollution levels in greater London by charging heavy-duty vehicles not meeting certain Euro emissions standards a substantial fee (£100–£200 per day) to enter the Low Emission Zone (LEZ). The first stage went into effect in 2008; later stages were being planned for 2010 (postponed) and 2012.	*Prospective study.* Kelly and colleagues collected baseline air pollution and health data in anticipation of the implementation of the LEZ in greater London (expected early 2008). Before the study started, they expanded the monitoring system to make sure there was adequate coverage of several major traffic arteries. They conducted a feasibility study to obtain data from general practices on doctor visits and medication use as an alternative approach to using hospital data. As was done in the CCS study, they collected filter samples for determination of oxidative potential. After conducting the baseline study, the investigators planned to apply for funding to conduct a health study.	· The air quality modeling at the postcode level — based on emissions calculations, traffic density, weather, and other factors — is quite complicated and has many uncertainties. · The air quality changes due to the LEZ may be relatively small, making it difficult to observe significant health benefits. · The changes also may be gradual due to the different stages of implementation and the fact that turnover of the fleets of trucks and buses is expected to happen over a period of time leading up to the date the regulation goes into effect. · In addition, using health data from general practices presents challenges in obtaining the data and in assuring data quality in terms of consistent interpretation of diagnoses and medication prescriptions.

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Appendix A (*Continued*). HEI's Accountability Research Program[a]

RFA / Investigator (Institution)	Study Title	Intervention	Approach	Challenges
RFA 04-4				
Richard Morgenstern (Resources for the Future, Washington, D.C.)	"Accountability Assessment of Title IV of the Clean Air Act Amendments of 1990" (in review)	U.S. EPA regulations that were designed to improve air quality east of the Mississippi River were implemented, requiring power plants to reduce their emissions of SO_2 and NO_x.	*Retrospective study.* Morgenstern and colleagues used the U.S. EPA's annual emissions inventories and a detailed database of emissions transactions to establish for each source where and when emissions occurred. They then used two methods to develop source-receptor matrices to model a causal relationship between the emission reductions and the improvement in air quality, and then used the models to develop one or more "no policy" counterfactuals, against which the observed reductions in ambient $PM_{2.5}$ and SO_4 concentrations could be compared. A possibility to add a health effects component (focused on daily mortality) remained open, depending on initial results.	· The multistage modeling approaches are complex. · Collecting air quality data and identifying and characterizing how data gaps might affect the results also presented considerable challenges. · Incompleteness of the ambient receptor data was a serious problem. The researchers' initial criteria for data quality resulted in the inclusion of only a very small number of receptors whose records were without gaps over the entire 84-month study period. To increase the number of receptors, the investigators explored the feasibility of using composite data-pooling from all monitors within a reasonably small radius, but this strategy failed to increase the number of complete monitor records appreciably. Thus to have an adequate sample of receptor sites, the data gap requirement had to be relaxed.
Curtis Noonan (University of Montana, Missoula, Mont.)	"Assessing the Impact on Air Quality and Children's Health of Actions Taken to Reduce $PM_{2.5}$ Levels from Woodstoves" (under way)	A community-based program reduced winter-time PM levels by replacing uncertified woodstoves and boilers with EPA-certified woodstoves and boilers in Libby, Montana, during 2005–2007.	*Prospective study.* Noonan and colleagues measured PM and some components in ambient air as well as inside schools and selected homes. They evaluated changes in children's exposure and health based on parent-reported respiratory symptoms and school absences.	· A prolonged change-out has made it more difficult to distinguish between pre- and post-intervention. · Stove use varied with ambient temperatures, requiring additional in-home sampling. · Stove operation affects efficiency and emissions. · There were possible reporting bias and temporal trends, such as for influenza.

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Appendix A (*Continued*). HEI's Accountability Research Program[a]

RFA / Investigator (Institution)	Study Title	Intervention	Approach	Challenges
RFA 04-4 (*Continued*)				
Jennifer Peel (Colorado State University, Fort Collins, Colo.)	"Impact of Improved Air Quality During 1996 Atlanta Olympic Games on Multiple Cardiorespiratory Outcomes" (Peel et al. 2010)	Temporary measures were implemented to reduce traffic congestion during the 1996 Summer Olympic Games in Atlanta.	*Retrospective study.* Peel and colleagues expanded an earlier evaluation that had shown concurrent reductions in ozone concentrations and pediatric acute care events related to asthma. They corrected for potential seasonal and spatial confounding by evaluating wider time windows (the preceding year and following years; 1995 and 1997–2000), evaluating a larger geographic area that included rural areas in Georgia and major urban areas in the southeastern United States, and including other respiratory and cardiovascular outcomes in children and adults.	· The intervention was short and temporary. · There was a lack of $PM_{2.5}$ data; PM_{10} data were available only every 6 days. · There were not enough data on cardiac arrhythmias in patients with an implantable defibrillator to allow a meaningful analysis. · The decrease in O_3 concentrations was a regional phenomenon and thus is unlikely to be related to traffic measures during the Olympics.
Chit-Ming Wong (University of Hong Kong, Hong Kong)	"Impact of the 1990 Hong Kong Legislation for Restriction on Sulfur Content in Fuel" (in review)	A reduction in fuel sulfur content to less than 0.5% was implemented in Hong Kong on July 1, 1990.	*Retrospective study.* Following an initial evaluation of the regulation that showed a rapid decrease in SO_2 concentrations and mortality, Wong and colleagues developed methods to assess changes in life expectancy and years of life gained. They also evaluated changes in mortality associated with changes in pollutant composition (with a focus on PM composition) and the relation between short-term and long-term benefits of improved air quality. They evaluated mortality data from 1985–2005.	· Changes in sources and composition of pollutants (e.g., nickel and vanadium) were observed in addition to changes in SO_2. · There were geographic differences in fuel properties and air pollution changes. · Long-term mortality trends in populations are complicated by changes in age distribution as the population ages.

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Appendix A (*Continued*). HEI's Accountability Research Program[a]

RFA / Investigator (Institution)	Study Title	Intervention	Approach	Challenges
RFPA 05-3				
Junfeng (Jim) Zhang (University of Medicine and Dentistry of New Jersey, Piscataway, N.J.)	"Molecular and Physiological Responses to Drastic Changes in PM Concentration and Composition" (under way)	Extensive measures were implemented to improve air quality during the 2008 Summer Olympic Games in Beijing, starting several months in advance. Tier 1 (July 25–Sept. 17): keeping 1 million high-emitting vehicles off the road; suspending operation of the Capital Steel Company; restraining operation of other high-emitting factories/power plants; ceasing construction work and exterior spray painting; reducing resuspension of road dust. Tier 2 (Aug. 8–Aug. 24): restricting the use of 1 million additional vehicles and closing additional factories.	*Prospective study*. Zhang and colleagues followed a panel of 131 medical students before, during, and after the Olympic Games to measure blood coagulation, oxidative stress, and systemic inflammation. The participants lived and worked on a campus of a university hospital located in central Beijing. Air pollution measurements were taken on campus during each of six visits made by the participants. Biomarkers were measured twice during each period: before (June 10–July 6), during (Aug. 4–29), and after (Oct. 6–31) the Games.	· Multiple actions were taken over a relatively long period of time, starting up to a year before the Games. · Regional sources of pollution and weather patterns contribute significantly to pollution levels in Beijing. · Local meteorology also played an important role in affecting ambient concentrations of air pollutants, which makes it more difficult to assess the extent of the effectiveness of the efforts to improve air quality.

[a] Abbreviations: CCS = Congestion Charging Scheme; LEZ = Low Emission Zone; NO_2 = nitrogen dioxide; NO_x = nitrogen oxides; O_3 = ozone; PM = particulate matter; $PM_{2.5}$ = PM ≤ 2.5 µm in aerodynamic diameter; PM_{10} = PM ≤ 10 µm in aerodynamic diameter; RFA = request for applications; RFPA = request for preliminary applications; SO_2 = sulfur dioxide.

APPENDIX B. Agenda of December 2009 Workshop

HEI Workshop on Further Research to Assess the Health Impacts of Actions Taken to Improve Air Quality

December 17–18, 2009

MIT Endicott House, Dedham, MA

AGENDA

THURSDAY, DECEMBER 17

Block 1: Presentations

8:30 Introductions, goals

9:00 **Jon Samet:** The Chain of Accountability as a conceptual model and template for future research

9:20 Discussion

9:40 **Annemoon van Erp:** Evaluation of HEI's program to date

10:00 Discussion

10:20 **Arden Pope:** Looking to the future — where can accountability research go next?

10:40 Discussion

11:00 Break

Block 2: Presentations

11:20 **Tom Matte:** What data sources are currently available?

11:40 Discussion

12:00 **Bert Brunekreef:** Role of exposure contrasts in accountability research

12:20 Discussion

12:45 Lunch

Block 3: Presentations

1:30 **Ira Tager:** Accountability assessment of long-term regulatory actions

1:50 **Francesca Dominici:** Response

2:00 Discussion

2:20 **Jennifer Peel:** Evaluating shorter-term and small-scale actions

2:40 **Doug Dockery:** Response

2:50 Discussion

3:10 Break

Block 4: Break-Out Groups

3:30 Charge to the break-out groups

3:45 Start discussions: Set goals for the break-out group; define the main topics and issues that need to be considered; brainstorm about each issue

- Group 1: Exposure contrasts
- Group 2: Shorter-term and small-scale actions
- Group 3: Long-term assessments

5:45 *Adjourn*

FRIDAY, DECEMBER 18

Block 5: Break-Out Groups

8:00 Check in with the groups; goals for the day

8:15 Continued discussions: Write key recommendations for each of the issues defined the previous afternoon; start an outline for proceedings chapter; prepare to report the key recommendations to the main group.

- Group 1: Exposure contrasts
- Group 2: Shorter-term and small-scale actions
- Group 3: Long-term assessments

10:45 Coffee break

Block 6: Summary & Recommendations

11:00 Report by Group 1, discussion

11:45 Report by Group 2, discussion

12:30 *Working lunch*

12:45 Report by Group 3, discussion

1:30 Final discussion and wrap-up: assign tasks following the workshop, timeline for completing chapters

2:30 Adjourn

APPENDICES AVAILABLE ON THE WEB

Appendix C. Accountability Studies of Air Pollution and Human Health: Where Are We Now and Where Does the Research Go Next? *C. Arden Pope III* (white paper)

Appendix D. Overview of Published Accountability Studies

Appendix E. Workshop Presentations:

- What Has Accountability Done for Us? *Jonathan M. Samet*
- Evaluating the Effectiveness of Air Quality Interventions: HEI's Research Program on Accountability, *Annemoon van Erp*
- Data Sources and Access: A Street Level View from a City Health Department, *Thomas Matte*
- Accountability Studies: Exposure Contrasts, *Bert Brunekreef*
- Accountability Assessment of Long-Term Regulatory Action: Warm Season O_3 and Cardiac Mortality, *Ira B. Tager*
- Statistical Methods for Accountability Research, *Francesca Dominici*
- Accountability Studies: Evaluating Shorter-Term and Small Scale Actions, *Jennifer L. Peel*
- Evaluating Shorter-Term and Small Scale Actions, *Douglas W. Dockery*

ABBREVIATIONS AND OTHER TERMS

Apheis	Air Pollution and Health—A European Information System
AQM	air quality management
CAA	Clean Air Act (U.S.)
CAIR	Clean Air Interstate Rule
CO	carbon monoxide
CO_2	carbon dioxide
CVD	cardiovascular disease
CVD_r	risk of cardiovascular disease
EC	elemental carbon
EPA	U. S. Environmental Protection Agency
Exp	exposure
GIS	geographic information system
H_2CO	formaldehyde
iHAPSS	Internet-based Health and Air Pollution Surveillance System
MACT	Maximum Achievable Control Technology
NAAQS	National Ambient Air Quality Standards
NO	nitrogen monoxide
NO_2	nitrogen dioxide
NO_x	nitrogen oxides
O_3	ozone
PM	particulate matter
$PM_{2.5}$	PM ≤ 2.5 µm in aerodynamic diameter
PM_{10}	PM ≤ 10 µm in aerodynamic diameter
$PM_{10-2.5}$	PM ≤ 10 µm and ≥ 2.5 µm in aerodynamic diameter
SES	socioeconomic status
SO_2	sulfur dioxide
SO_4	sulfate

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