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HEI's Research Program on the Impact of Actions to Improve Air Quality: Interim Evaluation and Future Directions

Annemoon M. van Erp and Aaron J. Cohen

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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 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.

CONTRIBUTORS

HEI Project Staff

Annemoon M. van Erp, *Lead author, Senior Scientist*

Aaron Cohen, *Coauthor, Principal Scientist*

Robert O'Keefe, *Vice President*

Rashid Shaikh, *Director of Science*

HEI Publications Staff

Barbara Gale, *Director of Publications*

Flannery McDermott, *Editorial Assistant*

Leah Shriro, *Consulting Science Editor*

COMMUNICATION 14

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INTRODUCTION

The goal of most air quality regulations is to protect the public's health by implementing regulatory actions or providing economic incentives that help reduce the public's exposures to air pollutants. If this goal is met, ambient concentrations and exposure to air pollution should be reduced, and indicators of public health may improve, or at least not deteriorate. Because air quality management focuses on reducing ambient concentrations of air pollutants by reducing emissions, and because there are many other factors that affect public health, it is important to assess whether the air quality regulations have succeeded in reducing exposure to air pollution and in protecting public health.

Evaluating the extent to which air quality regulations succeed in protecting public health is part of a broader effort — variously termed "accountability research," "research on regulatory effectiveness," or "outcome studies" — designed to assess the performance of environmental regulatory policies in general. In recent decades, air quality in the United States and Western Europe has improved substantially, and this improvement is attributable to a number of factors, including increasingly stringent air quality regulations. However, the cost of the pollution-control technologies and mechanisms needed to implement and enforce these regulations may be considerable. It is therefore prudent to ask whether the regulations have in fact yielded demonstrable improvements in public health and to provide information to inform future efforts to do so.

Although this document was produced with partial funding by the United States Environmental Protection Agency under Assistance Award CR-83234701 to the Health Effects Institute, it has not been subjected to the Agency's peer and administrative review and therefore may not necessarily reflect the views of the Agency, and no official endorsement by it should be inferred. The contents of this document also have not been reviewed by private party institutions, including those that support the Health Effects Institute; therefore, it may not reflect the views or policies of these parties, and no endorsement by them should be inferred.

The National Research Council (NRC)* in its report *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (National Research Council 2002) has concluded that there is a lack of direct evidence about the extent to which air quality regulations have improved health (measured as a decrease in premature mortality and excess morbidity). The California Air Resources Board (ARB), the U.S. Environmental Protection Agency (U.S. EPA), the U.S. Centers for Disease Control and Prevention (CDC), and other agencies have also indicated that there is a need for studies to provide such direct evidence.

In 2003, the Health Effects Institute published Communication 11, *Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research* (Health Effects Institute 2003). This monograph was written by members of HEI's multidisciplinary Accountability Working Group after a 2001 workshop on accountability. Communication 11 set out a conceptual framework for accountability research and identified the types of evidence required to demonstrate the effects of air quality regulations on health and the methods by which the evidence should be obtained. It has also guided the development of HEI's Research Program to Evaluate the Impact of Air Quality Actions, which is discussed below.

Between 2002 and 2004, HEI issued four Requests for (Preliminary) Applications (RFAs) soliciting studies to evaluate the effects of actions taken to improve air quality. A total of nine studies were funded: At this time, five studies have been completed and are nearing publication; four studies are ongoing and are projected to be completed later in 2009 and in 2010.

This document provides an interim evaluation of HEI's Research Program within the framework of Communication 11. Based on the results obtained to date, we attempt to address what can be learned from this first group of studies and summarize the difficulties encountered while

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

conducting them. We also draw from knowledge obtained in similar studies funded by other agencies and institutes, acknowledging that this document is not an exhaustive overview of accountability studies conducted to date. We then look toward the future, identifying possible opportunities for studying the effectiveness of actions to improve air quality, taking into account the issues discussed here.

BACKGROUND

CONCEPTUAL FRAMEWORK

The NRC's Committee on Research Priorities for Airborne Particulate Matter set out a conceptual framework for linking air pollution sources to adverse health effects (National Research Council 1998). This framework can be used to identify factors along a "chain of accountability" (see figure), each stage of which affords its own opportunities for making quantitative measurements of the intended improvements.

At the first stage (regulatory action), one can assess whether controls on source emissions have in fact been put into place. At the second stage (emissions), one can determine whether controls on sources have indeed reduced emissions, whether emitters have changed their practices, and whether there have been unintended consequences, e.g., emissions of nontargeted compounds have accidentally increased. At the third stage (ambient air quality), one can assess whether controls on sources and reductions in emissions have resulted in improved air quality. At the fourth stage (personal or population exposure), one can assess whether the improvement in air quality has reduced people's actual exposure and whether susceptible subpopulations (those most likely to experience adverse health effects) have experienced reduced exposure. At this stage, it is important to take into account changes in time–activity patterns that could either increase or reduce exposure. The actual dose that an individual's organs may be exposed to should also be considered (i.e., whether reductions in exposure have led to reductions in concentrations in body tissues such as the lung). Finally, at the fifth stage (human health response), one can assess whether risks to health have declined, given the evidence about changes in health outcomes such as morbidity and mortality that have resulted from changes in exposure. The challenge at this stage is to investigate the health endpoints that are most directly related to exposure to air pollution.

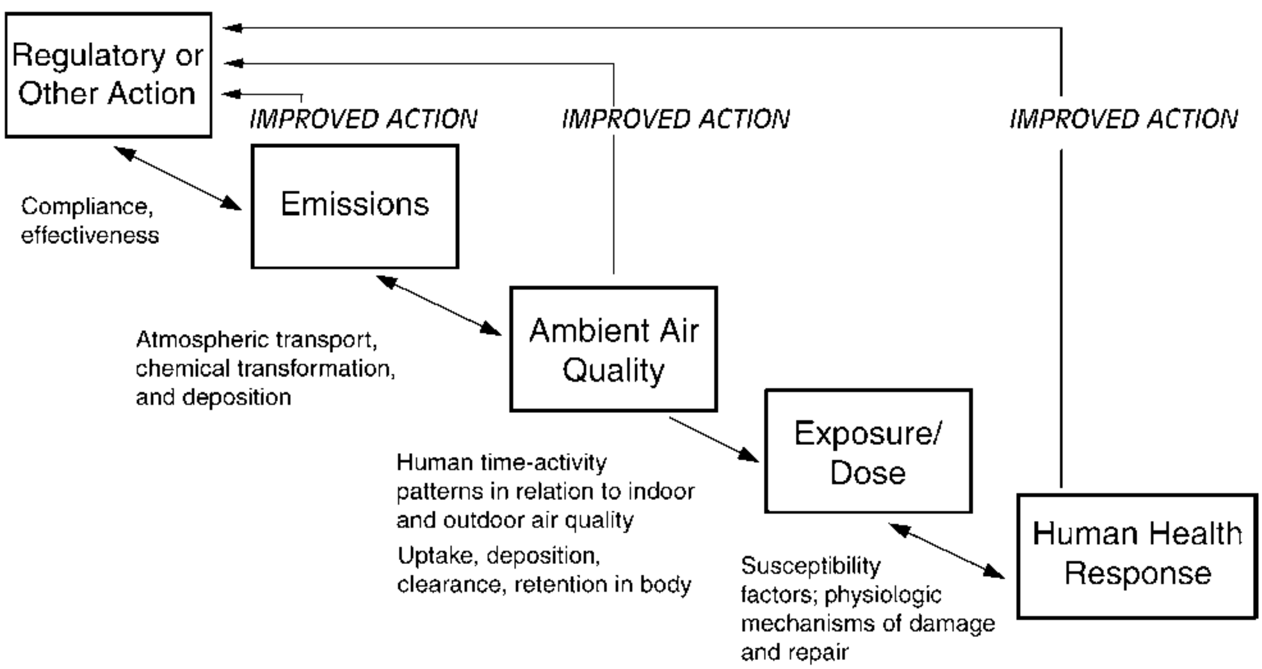

Figure 1. The Chain of Accountability. Each box represents a stage in the process between regulatory action and human health responses to air pollution. Arrows connecting the stages indicate possible directions of influence. The text below the arrows identifies factors affecting the effectiveness of 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 Health Effects Institute 2003, Figure 1.2).

Research to evaluate the effectiveness of air quality actions can focus on any of the stages described here. For example, investigators may decide to evaluate the impact of an air quality action on reducing exposure without detailed evaluation of the impact on ambient pollutant concentrations. However, research that includes an assessment of multiple stages provides more persuasive evidence on the effectiveness of the action to improve air quality.

APPROACHES TO STUDYING THE IMPACT OF AIR QUALITY ACTIONS

Approaches to studying accountability are as diverse as the actions or regulations they are trying to evaluate. They might include modeling air quality under several scenarios and predicting the health benefits of those scenarios, field studies that monitor pollutants in a person's breathing zone, measuring specific health outcomes in a group of participants, and a range of other possibilities. As required under section 812 of the Clean Air Act, the U.S. EPA has been making systematic efforts to calculate health benefits and associated economic benefits resulting from implementing the Act. The Agency performed a retrospective evaluation of the period from 1970 to 1990 (U.S. EPA 1997) as well as a prospective evaluation for the period from 1990 to 2010 (U.S. EPA 1999), with further plans to extend the analysis to 2020 (U.S. EPA 2003). More recently, the U.S. EPA conducted a similar prospective evaluation of the Clean Air Interstate Rule (U.S. EPA 2005). Such efforts are valuable but would benefit from additional studies that collect data on air quality and health outcomes, to measure actual changes that have taken place after the regulations went into effect.

Obviously, large-scale national research studies are difficult to conduct. Thus it is not surprising that early, well-known studies include smaller-scale, local efforts, such as the effects of a ban on the sale of coal in Dublin on mortality (Clancy et al. 2002) and of restricting sulfur in fuel for motor vehicles as well as power plants in Hong Kong (Hedley et al. 2002). There are also examples of unplanned actions, so-called "natural experiments," such as the temporary closure of a steel mill in the Utah Valley, which improved air quality and respiratory disease (Pope 1989), and a nationwide copper smelter strike that affected the air quality and mortality in the southwestern states of New Mexico, Arizona, Utah, and Nevada (Pope et al. 2007). Although these were not regulatory actions, they have provided valuable insights. Air quality changes during periods of economic recession (Chay and Greenstone 2003) or large-scale societal and economic changes, such as those that have been occurring in Eastern European countries (Krämer et al. 1999; Heinrich et al. 2002), provide additional interesting opportunities for research. Conducting such retrospective studies may, however, be limited due to a potential lack of adequate air quality data, health data, or both. Thus, studies that are planned prospectively are needed, to monitor interventions as they take place and to collect all necessary data. Also needed are studies that evaluate interventions at the regional and national levels.

When HEI issued its RFAs to evaluate the impact of air quality actions, the aim was to solicit applications for studies designed to take advantage of (1) planned actions at the local to national level that were specifically designed to improve air quality, or (2) other actions that could result in changes in air quality although they might not necessarily have been designed to do so. The RFAs recommended that proposed studies measure both changes in air quality resulting from these actions and changes in health status or health effects in the affected populations, evaluating either recent past changes (using a retrospective study design) or estimating future changes (using a prospective study design).

In its RFAs, HEI listed the following examples of opportunities for study:

- Planned actions designed to reduce a source of air pollution (e.g., traffic) or air pollution itself (e.g., fuel substitution at industrial facilities or power plants) that could be used to assess changes in health effects;
- Specific changes in policy (for other than air quality purposes) that result in changes in air pollution levels and that could be used to assess anticipated, ongoing, or even past changes in air pollution and public health; and
- Events not planned to result in changes in air quality or population exposure, but which would have that effect.

In addition, HEI also considered proposals for studies that would:

- Measure changes in exposure using established human biomarkers instead of an actual health endpoint, when the latter would be extremely difficult to measure (e.g., studying biomarkers of benzene exposure rather than cancer, the ultimate health endpoint); or
- Characterize changes in either exposure or air quality that could be linked to specific measures of health changes.

HEI encouraged novel, creative, interdisciplinary approaches and recommended that the studies involved a research team with broad expertise: public health experts, epidemiologists, physicians, statisticians, biochemists, exposure experts, and others. HEI also encouraged partnerships with all levels of government (domestic and international), as well as studies that use existing data-collection systems to assess changes in health or air pollution.

SUMMARY OF HEI-FUNDED STUDIES

HEI funded nine accountability studies that used a variety of approaches to evaluate diverse regulatory actions and natural experiments (van Erp et al. 2008). They included both shorter-term actions that may have caused a relatively sudden change in air quality over several days or months as well as medium- to long-term actions that were implemented in stages over a number of years and may have resulted in more gradual changes. Some studies spanned different time scales: For example, a study of a wood stove change-out would be expected to see short-term effects on indoor air quality in homes but longer-term effects on ambient air quality at the community level.

Most actions included in the accountability studies were specifically designed at the local or regional level to permanently improve air quality, targeting either a specific source of emissions, such as traffic or cleaner fuel, or multiple sources. Other actions may have been designed with a different purpose but had the beneficial side effect of improved air quality. This category included natural experiments, such as the temporary closure of an industrial facility. Some of the actions were temporary, such as steps taken to improve traffic flow and air quality during the Olympic Games in Atlanta and Beijing, which were reversed after the events were completed. Those kinds of events provide a dual opportunity to study pollution levels as they go down and again when they increase to levels similar to those experienced before the event.

The nine HEI-funded studies are described in more detail below. Each section describes the action or opportunity the study targeted, the approach, the results to date, and the challenges encountered during the study.

SHORTER-TERM ACTIONS

Actions to Improve Fuels and Combustion Technologies

Curtis Noonan: Woodstove Change-Out Program in Montana Noonan and colleagues are prospectively evaluating a community intervention project, conducted by the Montana Department of Environmental Quality and other parties, to reduce emissions of particulate matter with an aerodynamic diameter ≤ 2.5 µm ($PM_{2.5}$) from domestic wood stoves in Libby, MT. To reduce winter levels of particulate matter (PM) in the community, the program targeted approximately 1200 uncertified high-emission wood stoves and 100 wood-burning boilers and furnaces and replaced them with certified (i.e., cleaner and more efficient) appliances. The woodstove change-out was planned to take place from 2005 through 2007.

Approach Noonan and colleagues are evaluating whether this specific targeted action led to reduced exposure and improved respiratory health in children. They are measuring concentrations of $PM_{2.5}$ and some of its components (e.g., markers for wood smoke) outdoors, inside schools during different seasons, and in a small number of homes during the winter months. In parallel, they are tracking parent-reported respiratory symptoms as well as illness-related school absences in children. Changes in reported wintertime symptoms and variations in school absences will be evaluated in relation to changes in ambient $PM_{2.5}$ levels in successive years. Sampling was continued through the winter of 2009. The study is assessing three stages of the chain of accountability: ambient air quality, exposure/dose, and human health response; in addition, the investigators followed closely how the program was implemented.

Outcome Ambient winter levels of $PM_{2.5}$ were 25% lower in the winter of 2007/2008 compared with the winter of 2005/2006, and the number of times the National Ambient Air Quality Standards for $PM_{2.5}$ was exceeded was reduced (Noonan et al. 2009). Levels of levoglucosan, a chemical marker of wood smoke, were decreased significantly starting in the winter of 2005/2006 compared to previous winters and continued to decline in 2006/2007. Sampling inside 20 homes before and after installation of a cleaner woodstove indicated a mean 71% decrease in 24-hour average indoor $PM_{2.5}$ concentrations (51.2 ± 32.0 µg/m^3 before versus 15.0 ± 20.8 µg/m^3 after change-out); maximum $PM_{2.5}$ concentrations in the homes were lowered by a mean 76% (434 ± 419 ng/m^3 before versus 103 ± 167 ng/m^3 after change-out) (Ward and Noonan 2008). Preliminary results based on surveys obtained from parents of about 380 children in grades 1 through 8 indicated a reduction in respiratory symptoms in the winter of 2006/2007 compared to 2005/2006, although symptoms slightly increased again in the winter of 2007/2008 (Noonan et al. 2009). School absences did not seem to be affected. Collection of ambient air quality and health data has been continued through the winter of 2008/2009, and additional homes were sampled as well.

Challenges During the first winter of the study not as many woodstoves were replaced as planned, leading to a more prolonged change-out phase and thus a more gradual change in air quality. Sampling in the homes was complicated because stove usage varied in relation to differences in ambient temperature. To solve this problem, Noonan added additional sampling on days with ambient temperatures that matched those on the previous sampling days, both before and after the change-out. In addition, variation in indoor $PM_{2.5}$ concentrations could also have been due to variation in stove operation. Another complication was that some of the homes with woodstoves were heated with electric or propane heaters and therefore could not be included in the analyses. Although ambient levoglucosan levels were reduced, other markers for wood smoke such as resin acids did not consistently track with indoor $PM_{2.5}$ levels. Analysis of parent-reported respiratory symptoms might have been complicated by other temporal trends, such as temperature and influenza, that are difficult to control for. Possible reporting bias (for example, over-reporting) of respiratory symptoms was evaluated by analyzing the reporting of other symptoms that had not been expected to be affected by the wood stove change-out.

Status Preliminary results were presented at the HEI Annual Conferences of 2007 through 2009. The study is expected to be completed in the spring of 2010.

Chit-Ming Wong: Reducing Sulfur in Fuel in Hong Kong

In 1990, regulations went into effect in Hong Kong that required power plants and vehicles to use fuel with a sulfur content of less than 0.5%. Sulfur dioxide (SO_2) concentrations decreased from an average 44.2 ± 40.1 $\mu g/m^3$ during the 5 years before the intervention to 20.8 ± 9.9 $\mu g/m^3$ during the first year after the intervention (a 53% reduction) and to an average of 24.5 ± 12.2 $\mu g/m^3$ during the 5 years after the intervention (a 44.7% reduction). No significant changes were observed in concentrations of PM_{10} (PM with an aerodynamic diameter ≤ 10 µm) or nitrogen dioxide (NO_2), but ozone (O_3) concentrations increased significantly, from 18.5 ± 7.5 $\mu g/m^3$ before the intervention to 23.8 ± 11.4 $\mu g/m^3$ during the 5 years after the intervention (a 28.3% increase; Hedley et al. 2002). A substantial reduction in mortality was observed over 5 years after the intervention; notably, the expected peak in mortality rate during the cool season was absent in the first year after the intervention (Hedley et al. 2002). The authors reported that a greater decline in mortality was noted in areas with a higher reduction in SO_2 concentrations during the first 2.5 years after the intervention than in areas with smaller reductions in SO_2.

Approach In this retrospective follow-on study, Wong and colleagues evaluated changes in mortality and life expectancy in more detail and studied the effects of subsequent regulations on mortality. They used existing pollutant and mortality data collected by government agencies to evaluate the effects of changes in the mixture of pollutants (SO_2, NO_2, O_3, PM mass, and the chemical composition of PM) on mortality, while accounting for spatial variation of those changes in their analyses. Part of the study was devoted to improving current methodology to assess changes in life expectancy. In addition, Wong and colleagues determined the relationship between short-term and long-term benefits associated with improved air quality. They evaluated mortality data from 1985 through 2005 for the general population and for people older than 65 years of age. The study assessed two stages of the chain of accountability: ambient air quality and human health response.

Outcome Preliminary results indicated that PM composition changed during the study period; decreases in nickel and vanadium occurred close to the timing of the intervention. Analyses to date indicate that the impact of reductions in concentrations of PM_{10} and SO_2 were significantly associated with reductions in nonaccidental mortality. The size of the observed SO_2 and PM_{10} effects on mortality were similar in magnitude (Wong et al. 2009). The investigators indicated that the estimates of life expectancy changes were consistent when different definitions of mortality rate and different reference populations were used, and were consistent with the results of other cohort studies.

Challenges Long-term mortality trends in populations are complicated by changes in age distribution as the population ages. In addition, possible changes in sources and composition of pollutants during the study period need to be evaluated, in particular the possible role of nickel and vanadium. Although the regulation was implemented in the short term, its effects are permanent and may be seen over many years. As stated by the investigators, the changes in PM composition may have contributed to the health gains observed after the intervention: Sulfur was not the only compound affected by the intervention.

Status Preliminary results were presented at the HEI Annual Conferences of 2007 through 2009. The study was completed in 2009 and is expected to be published in 2010.

Actions to Reduce Vehicular Traffic

Frank Kelly: Congestion Charging Scheme in London

Kelly and colleagues studied air quality changes associated with the implementation of the Congestion Charging Scheme (CCS) in London in February 2003. The CCS mandates that vehicles must pay a fee (initially £5, now £8) to enter the inner city of London from 7 AM to 6 PM on weekdays, to ease traffic congestion. When the CCS was implemented, authorities added bus routes and increased the frequency of existing routes to provide additional public transportation. Predicted air quality changes included a 1.7 ppb decrease in nitrogen oxides (NO_X) concentrations and a 0.8 $\mu g/m^3$ decrease in PM_{10} concentrations inside the zone, although an increase in primary NO_2 emissions was also predicted due to the installation of particle traps on diesel buses.

Approach A substantial part of this retrospective study was devoted to developing methods to model aspects of air quality, including the modeling of meteorological influences; a statistical approach to detecting a step change in pollutant levels; incorporating emissions data, to model exposure at a fine spatial scale; and exploring at what time scale (weeks, months, or years) surrounding the CCS implementation data should be analyzed. Another novel aspect of the study was the evaluation of the oxidative potential of particles collected on filters inside and outside the CCS zone to account for possible changes in particle composition. The study assessed three stages of the chain of accountability: emissions, ambient air quality, and exposure/dose with plans to evaluate a fourth stage (human health response) if a clear improvement in air quality can be detected.

Outcome Implementation of the CCS did not lead to a change in roadside or nonroadside concentrations of NO_x during the hours of operation of the CCS nor in nonroadside concentrations of NO_x. Some evidence showed that nonroadside concentrations of nitrogen oxide (NO) may have decreased, whereas NO_2 slightly increased within the zone. Nonroadside concentrations of PM_{10} and carbon monoxide (CO) decreased within the zone compared to the control area. None of these small changes in air quality could be causally attributed to the CCS per se. Although there were differences in the oxidative potential of filter samples collected across the city, no clear patterns emerged, with one exception: The oxidative potential of PM collected on filters was highest at roadside locations. The oxidative potential of the filter samples at the one site within the zone did not change after introduction of the CCS (Kelly et al. 2009a).

Challenges The CCS was not specifically designed to improve air quality. The size of the zone (the inner city of London) is quite small relative to the greater London area — even with the Western Extension that went into effect in 2007 — and the number of air quality monitors was thus limited as well. In addition, the increased numbers of bus and taxi trips to carry passengers not in other vehicles may have partly offset potential air quality benefits. Also, 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.

Because the air quality changes were small, the power to detect changes in health outcomes was deemed too low to allow an analysis of health outcomes. However, a separate study not funded by HEI calculated — based on modeled annual average NO_2 and PM_{10} concentrations — that, in theory, benefits could be expected of 183 additional life-years per 100,000 population inside the zone compared to 18 life-years among surrounding areas, and that in London overall, 1888 additional life-years per 100,000 population could be gained (Tonne et al. 2008).

Status Preliminary results were presented at the HEI Annual Conferences of 2005 through 2009. The study was completed in 2007 and is expected to be published by the end of 2009.

Jennifer Peel: Traffic Measures During the 1996 Olympic Games in Atlanta During the 1996 Olympic Games in Atlanta, several measures were taken to improve traffic flow while accommodating the large number of visitors expected. So-called "intelligent transportation systems" were implemented to provide up-to-date traveler information, including information on congestion, alternative routes, and how to get to the Olympic Village and where to park. In addition, businesses provided telecommuting options or forced employees to take a vacation, reducing the number of regular commuters traveling in Atlanta. A study by Friedman and colleagues (2001) showed a decrease in acute-care visits for pediatric asthma during the period of the Olympic Games, based on Medicaid records. The study also showed a 27.9% decrease in peak ozone concentrations and a 22.5% reduction in peak weekday morning traffic counts. Peel proposed to extend the study by Friedman by looking at different health outcomes and contrasting the findings in Atlanta with findings in the surrounding region.

Approach Peel's retrospective study conducted more in-depth analyses of seasonal and regional changes in air quality, extending the time frame to the years before and after the Games. She also expanded the original findings by studying emergency department visits for respiratory and cardiovascular conditions, using data from the Study of Particles and Health in Atlanta (SOPHIA) project. The study assessed two stages of the chain of accountability: ambient air quality and human health response.

Outcome Peel reported that overall daily traffic counts in Atlanta were not substantially reduced during the Olympics period, although peak morning rush hour counts were somewhat lower compared to the weeks before and after.

Ozone levels were approximately 30% lower during the Olympics period compared to the four weeks before and after, but similar reductions in O_3 concentrations were observed throughout the southeastern United States. Peel reported little or no evidence of reduced emergency department visits during the Olympics period; she indicated that the findings were sensitive to the choice of analytic model and to the method of adjusting for temporal trends (Peel et al. 2009). Peel also found an unexplained increase in hospital admissions for chronic obstructive pulmonary disease (COPD). There were too few data on ventricular arrhythmias to draw conclusions.

Challenges The relatively short period of the Olympics and temporary nature of the measures to improve traffic flow required careful analyses of variations that may have confounded the association between air pollution and health outcomes. The decrease in O_3 concentrations was a regional phenomenon and thus is unlikely to be related to traffic measures during the Olympics. Peel's approach included analyzing different time windows surrounding the Olympics and comparing them to the same time period in surrounding years (e.g., analyzing summer data as opposed to data from an entire year). Results varied when different time windows were analyzed. In addition, broadening the geographic area to include other parts of Georgia as well as metropolitan cities in neighboring states strengthened the conclusion that a decrease in O_3 concentrations was a regional phenomenon not attributable to the traffic measures in Atlanta.

Status Preliminary results were presented at the HEI Annual Conferences of 2006 through 2009. The study was completed in 2008 and is expected to be published in early 2010.

Multiple Actions

Junfeng Zhang: Air Quality Improvements During the 2008 Olympic Games in Beijing The local government took substantial efforts in the period leading up to the 2008 Olympic Games to reduce emissions from traffic and industrial sources in Beijing. The authorities targeted both stationary and mobile sources and used a two-tiered approach by (1) keeping high-emitting vehicles off the road and restricting operations of high-emitting industries during an extended period surrounding the Olympics (July 25–September 17, 2008) and (2) placing emissions-control restrictions on additional vehicles and industrial facilities during the actual competition (August 8–24, 2008). Such restrictions affected the construction industry, smelters, cement plants, the petro-chemical industry, power plants, and nonattainment boilers. In addition, certain vehicles and trucks were banned, 70% of government-owned vehicles were kept off the streets, and other vehicles could travel through the city only on alternating days, the day determined by whether the license plate was even- or odd-numbered.

Approach Zhang 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, i.e, before (June 10–July 6), during (August 4–29), and after (October 6–31) the Games. The study is assessing three stages of the chain of accountability: ambient air quality, exposure/dose, and human health response.

Outcome During the two weeks of the Olympic Games, an improvement in air quality was observed, with a 39% to 57% decrease in concentrations of $PM_{2.5}$, NO_2, NO_x, SO_2, and CO during the Games compared to the weeks before. Ozone was the only pollutant that showed an increase in 24-hour average concentration and in 1-hour maximum concentration during the Games. Preliminary analyses, based on measurements obtained before and during the Games, show marked changes in biomarkers of oxidative stress (Zhang et al. 2009).

Challenges Potential difficulties include the range of actions taken over a relatively long period of time, starting up to a year before the Games. In addition, regional sources of pollution and weather patterns contribute significantly to pollution levels in Beijing (Wang et al. 2008). 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. However, if the observed substantial changes in pollution can be credibly linked to changes in health outcomes, such information would be useful in and of itself.

Status Preliminary results were presented at the HEI Annual Conferences of 2008 through 2009. The study is expected to be completed by early 2010.

MEDIUM- TO LONG-TERM ACTIONS

Actions to Reduce the Impact of Mobile, Area, or Stationary Sources

Douglas Dockery: Coal Bans in Irish Cities Dockery and colleagues based their study on a real-world experiment that took place in Ireland during the last two decades. During the 1980s, air quality had deteriorated due to a switch from oil to coal for domestic use. To improve air quality, in 1990 the Irish government banned the marketing, sale, and distribution of coal in Dublin. Soon after that, a substantial drop in ambient concentrations of particles (black smoke) occurred, and a significant decrease in rates of mortality from cardiovascular and respiratory diseases was observed (Clancy et al. 2002). Subsequently, the Irish government extended the ban to other major Irish cities, with the expectation that air quality and health would improve as it did in Dublin. First, a ban was put in place in Cork in 1995, followed by bans in 10 other cities in 1998 and 2000.

Approach In this retrospective, interrupted time-series study, Dockery and his Irish colleagues are evaluating mortality and hospital admission rates in Dublin and 11 other Irish cities before and after the city-specific ban on sales of coal. Major questions asked are whether an effect of a coal ban could be observed in smaller towns, and how it might contrast with trends in the rest of the country where no coal ban was in effect. In addition, the original observation in Dublin on mortality was expanded to include hospital admissions data, to provide further support that improved air quality led to public health benefits. The study is assessing two stages of the chain of accountability: ambient air quality and human health response.

Outcome The original study showed a 70% immediate reduction in concentrations of black smoke in Dublin in 1990. Dockery and colleagues found that similar changes occurred in the other cities: Reductions in black smoke were substantial — ranging from 45% to 70% — and were largest during the heating season, reducing the occurrence of winter peaks that were prominent before the bans went into effect. Levels of SO_2 seemed to be less affected by the bans; reductions ranged from 4% to 57% with one exception, a 24% increase in Cork. The largest SO_2 reductions were observed in locations with the highest SO_2 concentrations before the ban (Goodman et al. 2009).

Preliminary analyses of the coal bans suggested that reductions in hospital admissions for cardiovascular or respiratory disease were detectable in some of the communities, although other temporal trends may have complicated the observed patterns (Dockery et al. 2006). Dockery and colleagues reported significant reductions in cardiovascular mortality rates and nonsignificant reductions in respiratory and other mortality rates in County Cork after the 1995 ban (Rich et al. 2009). The investigators reported that the reductions in cardiopulmonary mortality were similar to those seen in Dublin after the 1990 ban.

Challenges The much smaller population in cities other than Dublin raised the question of whether the expected changes in mortality risk estimates were large enough to be statistically significant. Because the largest air quality changes occurred in winter (the heating season), the largest changes in health outcomes were expected to occur at that time of the year. Also, although evaluating specific health outcomes, such as hospital admissions for ischemia, stroke, or COPD, allowed the investigators to observe effects on specific diseases, when the time period and the disease outcome, or both, were narrowed down, the number of cases included in the analyses became quite low. In an attempt to increase the power of the study, Dockery and colleagues are pooling data across cities.

In terms of study design, it was unclear whether the rural population in Ireland provided an adequate control population because there may have been socioeconomic and other differences between that population and the people living in cities. An additional challenge that arose during the study was that the bans implemented in 1998 and 2000 resulted in less improvement to air quality than there had been in Dublin because air pollution concentrations were lower at those starting points, because of earlier bans and other long-term trends. Because of these factors and because the period evaluated after the later bans is shorter than that after the original ban, it is proving more difficult than anticipated to show health changes associated with the later bans. Finally, the investigators noted a long-term decline in mortality rates starting before the ban in Dublin and inconsistencies in the registration of deaths and hospital admissions in the period leading up to the ban in County Cork (unpublished observation, Dockery et al. 2007), which complicate the comparison of hospital admissions before and after the ban. To address these coding issues, the investigators have indicated that they will focus their analyses on county-level data with sensitivity analyses of city-level data. They have also tried to avoid complications resulting from longer-term changes in death rates by comparing summer and winter data within the same year (to evaluate the impact of the heating season).

Status Preliminary results were presented at the HEI Annual Conferences of 2003 through 2007 and 2009. The study is expected to be completed in the fall of 2009.

Frank Kelly: London Low Emission Zone Baseline Study Kelly and colleagues prospectively studied a Low Emission Zone (LEZ) that is being implemented in stages across greater London. The first stages — which were to restrict entry of the most polluting trucks and buses — went into effect in February and June 2008. Later stages, planned for 2010 and 2012, will restrict entry of large vans and minibuses. Vehicles must comply with increasingly tight European Union emissions standards or pay a considerable daily fee (£200 for large vehicles and £100 for smaller vehicles) to enter the city.

Approach Through modeling, Kelly identified citywide locations that were predicted to show the greatest air quality changes and installed or upgraded monitoring capability at those locations. His team then collected data up to the first stage of LEZ implementation in February 2008. Kelly and colleagues built on the approaches developed in his study of the CCS (described above) and established an approach to link health data to exposure estimates at the postcode level. They also collected filter samples (of both PM_{10} and $PM_{2.5}$) to evaluate their oxidative potential, which they hypothesized might change because of possible changes in the composition of the air pollution mixture after changes in the vehicle fleet. The study assessed three stages of the chain of accountability: emissions, ambient air quality, and exposure/dose. A fourth stage, human health response, would be assessed in a follow-on study. In addition, the investigators were involved in analyzing different implementation scenarios during finalization of the regulations.

Outcome Before the study started, Kelly and colleagues worked with local authorities to evaluate the number and capability of monitors in the area most likely to be affected by the LEZ. They upgraded and added several monitors to ensure better coverage. The investigators predicted decreases in NO_2 concentrations of at least 3 $\mu g/m^3$ and in PM_{10} concentrations of 0.75 $\mu g/m^3$ after the first stage of implementation. Kelly and colleagues confirmed that health data could be obtained from a large number of general medical practices (primary care physicians) and that those data could be linked to estimated pollution data at the postcode level (Kelly et al. 2009b). They observed large variability in oxidative potential across filter samples, with filters collected at roadside locations exhibiting higher activity. Preliminary analyses indicate that oxidative activity was linked largely to PM metal composition, with the coarse-particle fraction being more closely linked to tire and brake wear as opposed to tail-pipe emissions.

Challenges 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. In addition, changes 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.

Status Preliminary results were presented at the HEI Annual Conferences of 2006 through 2009. The study was completed in 2007 and is expected to be published in early 2010.

Richard Morgenstern: Air Quality Improvement Under Title IV of the 1990 Clean Air Act Amendments Morgenstern and colleagues are assessing the effectiveness of U.S. EPA regulations that were designed to improve air quality east of the Mississippi River by requiring power plants to reduce their emissions of SO_2 and NO_x. These regulations, called for by the Clean Air Act Amendments of 1990, were issued in 1993 under Title IV. Phase 1 called for reduction of emissions in the largest, dirtiest power plants; phase 2 required reductions from all power plants not already affected by this regulation.

Approach Morgenstern and colleagues planned to assess the impact of the regulation on changes in emissions of SO_2 and NO_x using the U.S. EPA's annual emissions inventories and the detailed database of emission transactions that the U.S. EPA maintains, to establish for each source where and when emissions occurred. They would then trace those changes in emissions to changes in air quality (PM_{10}, $PM_{2.5}$, and sulfate concentrations) using two kinds of techniques, a statistical model linking sources and receptors and a weather-mediated source–receptor matrix based on a large-scale regional atmospheric model. Finally, Morgenstern and colleagues planned to estimate what the air pollutant concentrations would have been in the absence of this policy and compare them with the observed concentrations. At a later stage in the study, the investigators expected to evaluate whether adverse health effects were avoided by the air quality improvement. The study is assessing three stages of the chain of accountability: emissions, ambient air quality, and human health response.

Outcome Morgenstern and colleagues aimed at connecting changes in average monthly ambient $PM_{2.5}$ concentrations at selected air quality monitors in the eastern United States with average monthly changes in SO_2 and NO_x emissions from electric utility generators subject to the SO_2 emissions caps. For each of 220 ambient monitors, 32 spatial zones were defined in terms of direction in relation to, and distance from, the generators, and the monthly sum of SO_2 and NO_x emissions from the utility sources was calculated. Preliminary modeling results using a Bayesian belief net suggested a statistical link between particular sources and receptors. Subsequent, still preliminary, analysis using parametric statistical models found and quantified relationships between receptor concentrations and aggregate emissions in many of the 32 direction-and-distance zones described above. The next and final step is to calculate the effect of the emission reductions required by Phase 2 on the concentrations and distribution of $PM_{2.5}$ throughout the eastern United States.

Challenges The multistage modeling approaches used to estimate the effects on air quality of the Clean Air Act Amendments are complex. More mundane aspects of the research — such as collecting air quality data and identifying and characterizing how data gaps might affect the results — also presented considerable challenges, the most serious of which was the incompleteness of the ambient re-ceptor data. In analyzing the effect of gaps in monitoring data, Morgenstern concluded that data gaps in a given month would contribute imprecision and bias to that month's estimate of average emissions, with larger gaps producing greater bias (Harrington et al. 2009). 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 readings 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 was relaxed.

Status Preliminary results were presented at the HEI Annual Conferences of 2006 through 2009. The study is expected to be completed by the end of 2009.

Multiple Actions

Annette Peters: Air Quality Improvement After German Reunification In the decade after the reunification of Germany in 1990, many legislative and socioeconomic changes occurred that affected air quality. Pollution levels decreased significantly over this period due to stricter environmental regulations as well as modernization of industries, transportation, and household heating. For example, natural gas replaced brown coal for home heating and power plants, and the number of diesel vehicles increased. During this period of gradually, but substantially, improving air quality (Ebelt et al. 2001), a concomitant decrease in children's nonallergic respiratory symptoms and an improvement of their lung function was observed (Krämer et al. 1999; Heinrich et al. 2002; Sugiri et al. 2006).

Approach Peters and colleagues retrospectively studied the health benefits of these long-term changes, focusing on daily mortality and air pollution in the city of Erfurt, building on previous studies of air pollution and health in that city (Wichmann et al. 2000). In the current study, Peters used a complex but innovative modeling method (time varying coefficient model [TCVM]) to evaluate changes in relative risk over the period studied. The study assessed two stages of the chain of accountability: ambient air quality and human health response.

Outcome Peters observed a clear, gradual decrease in both gaseous and particulate pollutants from 1990 through 2002. The largest reduction was observed in concentrations of SO_2 (from 64 µg/m^3 in 1992 to 4 µg/m^3 in 2001); concentrations of PM_{10}, $PM_{2.5}$, and CO were reduced by more than 50%. Concentrations of NO_2, O_3, and ultrafine particles were decreased to a lesser extent. Peters and colleagues reported an association between daily mortality and ultrafine particles and CO, with a lag of 3 to 4 days; an association between daily mortality and ultrafine particles and O_3, with a lag of 2 days; and a marginal association between daily mortality and NO_2. No consistent associations were observed for PM_{10}, $PM_{2.5}$, or SO_2. The TCVM approach was successful in showing that the relative risks of mortality per unit of exposure to nearly all pollutants (except O_3) were at their lowest near the end of the study period; the highest relative risks were observed in the transition period (1995 through 1997) when pollutant sources were changing most rapidly (Peters et al. 2009).

Challenges The relatively small size of the population in Erfurt may have limited the ability to detect statistical differences. In addition, many of the socioeconomic and demographic changes related to the reunification may have affected mortality rates. It is unclear why an effect was found for ultrafine particles but not for $PM_{2.5}$ or PM_{10}. Peters analyzed specific single-day lags but did not report multiday or distributed lags*; relative risks for mortality varied substantially from little or no association with some lags to significant associations with selected lags. The observation that mortality was associated with exposure to ultrafine particles 3 to 4 days earlier (and not for other lag times) currently relies only on indirect evidence of a plausible biological explanation.

Status The study was completed in 2006 and was recently published (Peters et al. 2009).

* Additional distributed lag analyses were conducted and showed similar effects (Peters, personal communication 2009).

OTHER EFFORTS

In addition to the completion, review, and publication of the nine accountability studies described here, HEI has also funded the development of two Web sites intended to enhance transparency and provide other researchers with access to extensive data and software from HEI funded studies, including the following:

1. Data and software from the National Morbidity, Mortality, and Air Pollution Study (NMMAPS), as described by Zeger and colleagues (2006) (data available at the Web site of the Johns Hopkins Bloomberg School of Public Health, *www.ihapss.jhsph.edu*); and
2. Data from the National Particle Components Toxicity Initiative (NPACT) on concentrations of components of $PM_{2.5}$ collected at or near the 54 sites in the U.S. EPA's $PM_{2.5}$ Chemical Speciation Trends Network (STN) (data available at the Web site of Atmospheric and Environment Research, Inc., *http://hei.aer.com*).

The data on pollution and health from a large number of U.S. cities, as documented and regularly updated by the NMMAPS team and made available on the Internet-based Health and Air Pollution Surveillance System (iHAPSS) Web site, constitute a valuable resource that allows other researchers to undertake additional analyses, possibly including further accountability studies. The STN Web site provides scientists with an opportunity to investigate specific questions about concentrations of $PM_{2.5}$ components and their association with adverse health effects in regions covered by the STN network and to address questions related to accountability when interventions in these regions are being planned.

EVALUATION

This section discusses a set of common issues and challenges identified across studies, such as issues of data access and quality and confounding factors, and also addresses issues specific to the type of action, time period, or health outcomes analyzed. These considerations may provide guidance in planning for future studies.

TYPE OF ACTION

In this first wave of accountability research, many studies have evaluated short-term actions on a local scale because such studies have been able to capitalize on unique events, have direct implications for a specific community, and are relatively easy to conduct. The studies of the Olympic Games in Atlanta and Beijing were unique because they evaluated a short window of improved air quality, after which air pollution levels were expected to increase to preintervention levels. Such studies provide an opportunity to evaluate the association between air pollution and health twice, once as air quality improved and again when air quality deteriorated once the actions ended. Even though the actions were temporary, the related studies provide a window on how results can be achieved in the future with a clear plan and a dedicated effort. In contrast, longer-term studies, such as those conducted by Peters, Dockery, Morgenstern, and Wong, may be more difficult to conduct but may help advance the field by evaluating and developing improved research approaches. These longer-term studies will likely provide better insight into how to account for trends over time in mortality and societal factors. Further, these studies may improve approaches for assessing air quality changes associated with a number of sequential actions taken over several years.

RETROSPECTIVE VERSUS PROSPECTIVE STUDIES

HEI funded several retrospective studies that were based on earlier findings. Because such studies start with previously collected data, they can be conducted at relatively low cost and may provide valuable additional insight. On the other hand, researchers may encounter data-access and quality issues. Dockery is expanding the findings related to a coal ban in Dublin to other cities in Ireland, but has encountered unforeseen difficulties in obtaining health data from the additional cities. Wong is extending the original observations in Hong Kong to include evaluation of life expectancy, adding important additional evidence. Peel conducted a study based on the previous study by Friedman related to traffic measures during the 1996 Olympics; she examined additional health outcomes and also explored different time windows and compared air quality changes in Atlanta with changes in surrounding regions. This study exemplifies the need to consider multiple factors when critically assessing the impact of interventions that may contribute to air quality improvements, especially those that are temporary in nature.

Prospective studies, such as those conducted by Noonan and Zhang, provide an opportunity to collect detailed baseline data before the planned regulation or action takes effect. Prospective studies can thus include the evaluation of biomarkers and personal exposure, which are usually unavailable in retrospective studies. The challenge with prospective studies, however, is having advance knowledge of the upcoming intervention and sufficient lead time to develop a study protocol and have funding in place.

BACKGROUND LEVELS AND WEATHER

One of the main issues that has come to the foreground is the ability, or inability, to detect significant air quality improvements when regional background concentrations of pollutants and weather patterns change. For example, in the London CCS study, the investigators expected to find a fairly rapid improvement in air quality when the congestion charging went into effect, based on an immediate reduction in the number of cars entering the center of London. However, during that time a weather inversion caused an increase in regional background concentrations of PM that may have obscured any air quality improvement associated with the CCS. In addition, an increased number of bus routes and trips into the inner city of London may have partly offset the gains from the reduced numbers of cars. In Atlanta, Peel found that the observed decrease in O_3 concentrations was regional in nature, making it unlikely that that change in air quality could be attributed to measures to improve traffic flow in downtown Atlanta during the 1996 Olympic Games. In Beijing, weather patterns during the 2008 Olympic Games influenced air quality considerably, complicating the evaluation of the extent to which measures to reduce emissions from traffic and stationary sources may have contributed to observed changes in air quality during the Games. Thus it remains important to firmly establish the extent to which the actions have actually improved air quality, instead of solely relying on predicted air quality scenarios or measured concentrations of air pollutants. Because weather patterns cannot be predicted, studies should adequately control for unexpected changes by evaluating multiple time windows surrounding the intervention and by comparing changes at the study location against those in the surrounding areas.

AIR QUALITY MONITORING AND EXPOSURE ASSESSMENT

The past decade has seen the development of new approaches to estimating exposure to air pollution for epidemiologic research, including geographic information systems and land use regression models, in which measurements of ambient pollution concentrations are combined with other data in statistical models to estimate the average exposure of populations. These approaches may help alleviate exposure misclassification resulting from the use of pollutant concentrations measured at central monitors to estimate people's exposures. Though not all of the properties of these complex approaches are well understood, additional research comparing and contrasting exposure estimates obtained with these approaches for the purpose of studying accountability would be informative. The requirements of such methods for air pollution monitoring networks are different, and more demanding in some ways, than for approaches that allow the measurements from a small number of monitors to represent the exposure of large populations. Thus, it becomes increasingly important to evaluate existing monitoring networks and determine whether they are adequate (in terms of the number and location of monitors and the pollutants covered) for the purposes of the planned analytical approach. This issue is especially important when studying the effect of traffic measures, when more roadside monitors may be needed in addition to central ambient monitors.

Based on experience obtained during the London CCS study, Kelly negotiated with Transport for London to improve and install additional monitors before the LEZ baseline study started, to provide better coverage. Similarly, officials in New York City are currently conducting a one-year community air quality survey at about 150 street-level locations to support the evaluation of a range of planned initiatives to improve air quality, including a possible congestion charging scheme similar to the one in London (The City of New York 2007). Peters and Zhang conducted their own air quality sampling to supplement available data from central ambient monitors; Peters obtained detailed measurements of ultrafine particles that are not normally included in central monitoring, whereas Zhang conducted sampling close to where the study participants were spending the majority of their time. Monitoring specific components of the air pollution mixture may be helpful in identifying the impact of changes in specific sources; for example, Noonan included levoglusan as a tracer of wood smoke. In addition, in certain cases it may be appropriate to obtain detailed air quality measurements inside people's homes (e.g., the Noonan study) or to conduct personal monitoring (i.e., monitoring the exposure of individual people).

Even when fairly adequate coverage is obtained with a particular monitoring network, however, exposure modeling remains complex because of the many factors that are included and the uncertainties associated with them. For example, the London LEZ baseline study used exposure modeling to estimate exposure to different pollutants at the postcode level, based on data from ambient monitors, weather patterns and dispersion models, emissions from traffic, distance from roadways, and so on. These kinds of approaches are important to reduce uncertainty in the exposure estimates, but they require further validation.

CAUSALITY

To estimate the health benefits accrued from actions taken to improve air quality, many current health assessments use concentration-response functions from observational epidemiologic studies. These estimates generally assume that causal effects will apply "in reverse" when exposure is reduced (U.S. EPA 1997, 1999; World Bank/SEPA 2007). The tenability of that assumption rests on the strength of the collective epidemiologic evidence, evaluated via systematic, critical, and quantitative review (e.g., meta-analysis) (WHO 2000a,b). The stronger the evidence in support of a causal relationship between air pollution and disease, the stronger the inference that reducing exposure will result in health benefits. To improve the strength of evidence, it is critical to address measurement error in exposure estimates and health outcomes, confounding factors, and other biases. Only a handful of studies have tried to estimate directly the impacts of specific actions, as exemplified by the London CCS and LEZ studies and the study of coal bans in Ireland. Given the cost and effort involved in collecting data to provide direct estimates, it is likely that future assessments will continue to use relative risk estimates from the broader epidemiologic literature to quantify the impacts of actions taken to improve air quality.

Studies of actions to reduce specific sources of pollution over a relatively brief interval may provide particularly strong evidence of a causal relationship because they evaluate the effects on health of removing or reducing exposure, one of Hill's ten criteria for assessing causality in epidemiologic studies (Hill 1965; Rothman and Greenland 1998). A prominent early example was the temporary closure of a steel mill in Utah (Pope et al. 1989), which provided strong evidence for the role of particles and transition metals in causing adverse health effects. Studies of actions to reduce specific sources of pollution can be expected to provide similar evidence. For example, the studies of the coal bans in Ireland are expected to provide further evidence for the role of black smoke in causing cardiovascular and respiratory mortality and morbidity. Studies of woodstove change-out programs may provide evidence for the role of wood-smoke components in causing respiratory symptoms in children similar to that found in studies of tobacco smoke. Even in those cases in which it may be difficult to directly attribute air quality improvement to a particular intervention, observations of improved health associated with improved air quality may still add to the larger body of epidemiologic evidence on causality.

TIMELINE OF CHANGE

As has been mentioned before, there is a clear distinction between a one-time step change in air quality and a more gradual change over time. Only a few actions have shown an immediate improvement (e.g., the reductions in Dublin black smoke and Hong Kong sulfur concentrations). When studying longer-term, gradual changes, the time window for evaluation needs to be defined carefully. Noonan's study of the woodstove change-out was complicated by the fact that the change-out occurred over three winters. In addition, that study dealt with changes on different time scales: air quality improvement inside each home was immediate, whereas ambient air quality in the community was more gradual, i.e., occurring over several winters. The second stage of the LEZ evaluation is complicated by the fact that the LEZ was implemented in two stages in 2008, followed by two additional stages in 2010 and 2012 to target different vehicle types. Because of the incremental effects and the focus on the most polluting sources at the first stages, the latter stages are expected to have diminished returns in terms of improved air quality. Even so, the overall impact of this series of regulations will be evident only after 2012. Thus it is difficult to design a study that captures incremental changes that differ in magnitude. A similar pattern has been emerging in the study of coal bans in Ireland, where the later bans showed smaller reductions than the initial ban in Dublin because the starting air pollution concentrations were lower. In addition, when a study is designed to assess changes after the implementation of multiple stages over several years, it may be affected when authorities unexpectedly change the schedule of the stages. For example, implementation of the first LEZ stage was delayed from 2007 until 2008, and the 2010 stage is being delayed as well (as of February 2009), complicating the timing of the evaluation of the air quality changes and their impact on health.

POPULATIONS STUDIED

Several studies have evaluated fairly small populations that are subject to a specific, local air quality intervention. Whereas the intervention itself may be relatively clear-cut in terms of air quality improvement, the number of people affected may be too low to allow detection of significant changes in health outcomes or it may be difficult to relate the results to the general population, or both. When the studied population is small, the ability to detect differences in health outcomes with a lower rate of occurrence, such as mortality rates for stroke, may become too limited, even when the outcomes are evaluated over a relatively long period (e.g., Dockery and Peters studies). Although one could argue that such considerations preclude informative research, the opportunity to study often unique and policy-relevant interventions have led HEI and others to support such research. How such studies might be designed to mitigate weaknesses due to small sample size has been the subject of recent HEI-supported workshops.

Some studies specifically investigated susceptible populations, which may be expected to show stronger responses to air pollution than the general population, and perhaps also greater improvement in health when air quality improves. For example, Noonan focused on respiratory symptoms in school age children; Peel evaluated pediatric emergency department visits, which are mostly due to asthma, and also the occurrence of arrhythmias in individuals with preexisting heart disease (although the latter group was too small to draw firm conclusions); Wong evaluated mortality rates of people older than 65 years of age and compared them to those of the general population.

HEALTH OUTCOMES STUDIED

The health outcomes that are being evaluated run the gamut of the potentially informative health endpoints identified in Communication 11 (Health Effects Institute 2003): from in-vitro assays of the oxidative potential of particulate matter collected on filters (Kelly study) to biomarkers obtained from panel study participants (Zhang study) and health questionnaires (Noonan study) to long-term average mortality (Dockery and Peters studies) and changes in life expectancy (Wong study). Because Communication 11 was equivocal about the utility of toxicologic indicators, the extent to which in-vitro assays make a substantial contribution will be of interest. A common epidemiological approach is to analyze mortality or hospital admission rates. Kelly used a different approach for gathering health data: He obtained data on primary care doctor's visits and medication use from a central database, which provided access to about 60 general practices with 300,000 to 400,000 patients in London. The data collected this way are from an earlier stage of disease development or management than are the data on hospital admissions or mortality. But this approach may introduce additional challenges in terms of teasing out information, for example, determining whether prescriptions for medicine were for treating acute episodes or were standard refills for long-term disease management.

METHODS DEVELOPMENT

Several studies have invested considerable effort into developing or adapting specific analytical approaches:

- Peters used a time-varying coefficient model to track gradual changes in relative risk over a decade.
- Wong devoted part of his study to improving current methodology to assess changes in life expectancy and to determine the relationship between short-term and long-term benefits associated with improved air quality.
- Noonan evaluated whether specific markers of wood smoke could be used to track source-specific changes in air quality inside homes as well as in ambient air.

MULTIPLE STAGES OF THE ACCOUNTABILITY CHAIN

Most studies described here are evaluating only two stages of the chain of accountability, i.e., changes in air quality and changes in health outcomes. Only a few studies are also evaluating other stages, such as reductions in source emissions and changes in exposure or dose. Morgenstern has taken several approaches to linking sources to emissions, using data from emissions inventories of individual sources and calculating their contributions to SO_2 and NO_2 concentrations measured at specific ambient monitors. As discussed above, Kelly used modeling approaches to estimate exposure at the postcode level. As is becoming evident from both studies, emissions-to-exposure modeling is challenging and introduces many uncertainties, making it difficult to trace the possible associations between emissions and exposures and health outcomes. Few studies are actually looking at measurements of personal exposure or the dose to organs and tissues. Noonan is including measurements of wood-smoke markers in order to trace exposure to source emissions inside homes as well as outdoors. Investigators designing future accountability studies should be encouraged to include more stages in their study designs in an effort to link the stages together.

FUTURE DIRECTIONS

Several organizations, including HEI, are taking a close look at the future of research on the health impact of actions to improve air quality. In 2007, the U.S. EPA issued a document, "Framework for Assessing the Public Health Impacts of Risk Management Decisions" (U.S. EPA 2007), the purpose of which was to "provide an understanding of the research needed to develop and validate indicators of the source-to-exposure-to-effect paradigm." The U.S. EPA framework concerns all environmental exposures, including exposures to air, water, and soil. The document states that the "U.S. EPA's Office of Research and Development (ORD) will produce an Air Accountability Framework by the end of 2009." In addition, the document indicates that "ORD and other members of the North American atmospheric research consortium under the North American Research Strategy for Tropospheric Ozone will complete an assessment of the technical capacity of the atmospheric science community to meet air accountability needs" (U.S. EPA 2007). More information can be found on the NARSTO Web site, which includes information on several workshops (*www.narsto.org/mpacc.src*).

In California, the ARB has been conducting several accountability efforts (see Kozawa et al. 2009 for details). For example, it is evaluating the effectiveness of regulations to reduce emissions from the transport sector (including trucking, marine shipping, and rail) in improving air quality and public health in areas surrounding ports; it is measuring key pollutants in communities around the Los Angeles and Long Beach Ports using a mobile platform (Gilbreath and Yap 2008). Further, the ARB recently conducted a study in the San Joaquin Valley — an area that suffers from poor ambient air quality, especially in winter — to evaluate regulations implemented in 2003 to reduce the impact of wood burning in the area, and found that the risk of mortality due to ischemic heart disease and cerebrovascular disease was reduced after the regulations went into effect (Gilbreath et al. 2008). In addition, the ARB evaluated the effects of the 2002 Los Angeles/Long Beach port strike (a natural experiment) on mortality of residents living close to the ports. During the strike period, pollutant concentrations actually increased due to an increasing number of idling ships at the port; a concomitant increase in cardiovascular deaths was observed (Moore et al. 2008). In addition, recurring studies of on-road motor vehicle emissions in the Caldecott tunnel in San Francisco have provided the ARB with the opportunity to study the impact of regulations affecting technology and fuels on average emission rates over several decades (e.g., Harley et al. 2006).

As a part of its upcoming Strategic Plan 2010–2015, HEI will carefully examine opportunities for unique new contributions to accountability research. During this process, HEI is planning to hold a workshop with investigators and additional experts to more fully evaluate the current set of studies and identify challenges encountered as well as opportunities for further research. This workshop will likely be held in the fall of 2009. Questions it will pose are (1) What are the lessons learned from the challenges encountered in the first series of studies (documented above), and how can those lessons be incorporated into the design of new studies? (2) To what extent can additional studies of short-term actions deepen our knowledge about the effectiveness of actions to improve air pollution? (3) What are the best approaches to detect changes in health outcomes over the longer term? and (4) How can we stay abreast of policy development at the local, regional, and national levels, to identify future opportunities and quickly take advantage of those opportunities?

One conclusion reached, based on examining the current, largely opportunistic set of studies, is that it would be valuable to conduct studies in a more targeted manner with a longer-term commitment to a specific area of research or a specific type of intervention. Although opportunistic approaches may still be useful, there is a need for more systematic development of a body of evidence in specific areas of regulation and intervention, such as traffic control measures, switching to alternative fuels, reducing emissions surrounding ports, reducing exposure of susceptible populations, and recurring events, such as the Olympic Games or similar major events, for which authorities make efforts to reduce air pollution. The next generation of accountability studies should be systematically linked to the adoption of major new regulatory initiatives because those kinds of complex interventions remain understudied.

The results of discussions at the workshop, as well as discussions with federal and state agencies during the next few months, will provide information that will be incorporated into the HEI Strategic Plan 2010–2015.

SYSTEMATIC DATA COLLECTION AND AVAILABILITY

Recently, efforts to track environmental health have progressed with the systematic collection of health data at the state and federal level. In January 2008, HEI coorganized and cosponsored, with the CDC's Environmental Public Health Tracking Program and the U.S. EPA, a workshop entitled "Methodologic Issues in Environmental Public Health Tracking of Air Pollution Effects." HEI's involvement in the workshop was part of an effort to implement the initiative outlined in HEI's Strategic Plan 2005–2010 (Health Effects Institute 2005) to "build networks with the U.S. Centers for Disease Control and Prevention and state public health tracking programs to facilitate accountability research." The workshop built on the work of the CDC's Environmental Public Health Tracking Program (see the CDC Web site *www.cdc.gov/nceh/tracking/*) in the development of standardized measures of the effects of air pollution on health at the state and local levels in the United States. It brought together representatives of state and federal agencies and academic researchers to discuss methodologic issues in the development of such measures and made recommendations for their further development and application. The recommendations were provided in a September 2008 report to the CDC, and the proceedings will be published in the journal *Air Quality, Atmosphere & Health* in mid- to late 2009. HEI will continue to seek opportunities to work with the CDC and the U.S. EPA to apply newly developed methods for tracking public health to the assessment of the effectiveness of environmental regulations.

Long-term air quality monitoring is a critical component of environmental public health tracking; it is essential to evaluating the health impacts of regulatory and other actions to improve air quality. As part of the Environmental Public Health Tracking Project, the U.S. EPA has cooperated with the CDC to make such data available. Air quality indicators based on state-level air quality measurements have also been developed. As discussed earlier, HEI has funded the development of two Web sites intended to enhance transparency and provide other researchers with access to (1) extensive data and software from the NMMAPS study and (2) air quality data made available as part of the NPACT studies. If such databases can be maintained over the longer term at reasonable cost, they could contribute to and complement ongoing efforts by the CDC and the U.S. EPA to provide access to air quality data for public health tracking and program evaluation.

SUMMARY AND CONCLUSIONS

As the first set of studies that are evaluating whether actions to improve air quality have resulted in improved health outcomes is nearing completion, important lessons are emerging. As expected, these studies have encountered considerable challenges, many of which were described in detail in Communication 11 (Health Effects Institute 2003). At this time, we can conclude that conducting these kinds of studies remains challenging. When planning future research, the following observations should be taken into account:

- It remains important to establish air quality improvement before starting a study of health benefits if the study design allows for retrospective analyses. Careful review of a study's power to detect effects in terms of the size of the population studied, the rate of occurrence of specific health outcomes, and the expected or predicted magnitude of the intervention is essential before embarking on such challenging research. Any intervention that does not produce a sizeable change — of at least a factor of 1.5 to 2 — in air pollutant concentrations can hardly be expected to show evidence of improved health outcomes. Such exposure contrasts are usually taken into consideration when deciding whether epidemiologic research of air pollution and health is worth the effort; these kinds of considerations should be equally applied to accountability research.
- Flexibility and rapid but careful planning is needed to allow new prospective studies to take advantage of upcoming opportunities at the local level. If existing air quality monitoring, in terms of both the number and location of monitors, provides insufficient coverage, adding monitoring stations should be considered. To adequately capture the impact of changes in emissions from specific sources, it may be helpful to conduct additional monitoring of specific components of the air pollution mixture, such as levoglucosan as a marker for wood smoke. In certain cases, it may be appropriate to obtain detailed air quality measurements inside people's homes or to conduct personal monitoring.
- Unexpected events such as sudden changes in weather patterns and other variables remain an important challenge. In addition to obtaining adequate, detailed air quality monitoring data, study designs should include sensitivity analyses of multiple time windows surrounding the intervention as well as evaluations of areas surrounding the study location.
- Even if it is not clear whether a particular action has resulted in improved air quality (because the action was not designed as such, because the action was ineffective, or because the study could not demonstrate improved air quality definitively), studying it can still provide useful answers. For example, if a regional air quality improvement was observed that cannot be directly attributed to the local action, evidence of improved health across that region would still contribute to the larger body of evidence on the association between air pollution and health outcomes. In addition, there may be benefits (e.g., economic) other than health benefits.
- The majority of studies to date have focused on shorter-term actions and have evaluated only two stages of the accountability chain (i.e., air quality and health outcomes). There remains a need for (1) studies of longer-term, more complex interventions; (2) development of approaches to evaluate longer-term changes in light of other, concomitant changes in population or economic factors; and (3) studies that include evaluation of other stages of the accountability chain, such as reductions in emissions and exposure or dose, to provide a more comprehensive assessment of the effects of actions to improve air quality at different levels.

Looking ahead, HEI is looking forward to new opportunities for research studies and continued discussion of their outcomes as the field moves forward. Once all studies in the current HEI Accountability Program have been completed and reviewed, HEI expects to conduct a final evaluation of the program to date. Even as these future steps are being planned, investigators who have identified a distinctive opportunity to evaluate the effects of environmental regulations on air pollution and human health are encouraged to contact HEI.

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ABBREVIATIONS AND OTHER TERMS

ARB	Air Resources Board
CCS	Congestion Charging Scheme
CDC	U.S. Centers for Disease Control and Prevention
CO	carbon monoxide
COPD	chronic obstructive pulmonary disease
iHAPSS	Internet-Based Health and Air Pollution Surveillance System
LEZ	Low Emission Zone
NMMAPS	National Morbidity, Mortality, and Air Pollution Study
NO	nitrogen oxide
NO_2	nitrogen dioxide
NO_x	nitrogen oxides
NPACT	National Particle Components Toxicity Initiative
NRC	National Research Council
O_3	ozone
ORD	Office of Research and Development
PM	particulate matter
$PM_{2.5}$	PM with aerodynamic diameter $\leq$ 2.5 µm
PM_{10}	PM with aerodynamic diameter $\leq$ 10 µm
RFAs	Requests for (Preliminary) Applications
SO_2	sulfur dioxide
SOPHIA	Study of Particles and Health in Atlanta project
STN	U.S. EPA's $PM_{2.5}$ Chemical Speciation Trends Network
TCVM	time varying coefficient model
U.S. EPA	U.S. Environmental Protection Agency

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101 Federal Street
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Phone +1-617-488-2300
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