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Editorials

Protecting Public Health in the Face of Uncertain Risks: The Example of Diesel Exhaust

Formal risk assessments, required for setting occupational and environmental health standards in the United States, often pose a severe burden on regulatory agencies and in many cases have caused delays in the development of effective standards. As a result, some environmentalists have questioned the utility of risk assessments for addressing current public health problems.[1] Their concern is that the requirement for risk assessments has become a mathematical straitjacket for regulatory agencies who increasingly appear to be in a state of "paralysis by analysis."

What makes the risk assessment process so difficult for regulatory agencies? The problem is that all stages of the risk assessment process[2] (hazard identification, dose–response analysis, exposure assessment, and risk characterization) are fraught with uncertainty, which frequently leads to acrimonious debates among scientists and others about whether there is a risk and about how best to quantify it.

Performing risk assessments for occupational and environmental exposures to diesel exhaust is a current example of the problems facing regulatory agencies. The data available for assessing the risk of diesel exhaust exposure are extensive, including publications from over 40 epidemiological studies and numerous chronic animal bioassays and in vitro toxicological studies. Despite this extensive database, there remain substantial challenges in using these data for characterizing human risks, making it difficult for regulatory agencies to complete their risk assessments and to fully develop regulatory policies for diesel exhaust.

The History of Diesel Exhaust Risk Assessment

In 1989 the California Environmental Protection Agency (EPA) initiated a risk assessment of diesel exhaust, releasing a first draft in 1994. The quantitative risk assessment in the first draft relied primarily on a dose–response model of a rat inhalation study of diesel exhaust particulates[3] and a simple model of an epidemiological cohort study of railroad workers.[4] A second draft of the California EPA risk assessment was released in 1997, which included quantitative risk assessments based on the animal bioassay data, the railroad cohort study, and a case–control study of railroad workers.[5] The final version, recently published,[6] presented estimates of risk based on analyses of both of the railroad studies and on a meta-analysis of the epidemiologic studies by Lipsett and Campleman.[7]

Although it took the California EPA nearly 10 years to finish its risk assessment, this is in some sense a success story when compared with attempts by the federal EPA, which has been struggling for nearly 20 years with this issue and still has not finalized its cancer risk assessment for diesel exhaust. Concern in the 1970s over the increasing use of diesel-powered vehicles as a result of the energy crisis led the federal EPA to initiate a research program on diesel exhaust particulates, which led them to identify diesel exhaust as a mutagen and a potential human carcinogen. In 1982 the federal EPA initiated an effort to regulate diesel exhaust, and a quantitative risk assessment using a comparative potency approach with in vitro diesel exhaust studies was published by EPA staff,[7] although this publication was not considered an official EPA risk assessment. A more comprehensive health risk assessment for diesel exhaust exposure was initiated by the EPA in

Editor's Note. Please see related article by Lipsett and Campleman (p 1009) in this issue.

1987 following the publication of several toxicological and epidemiological studies indicating a possible increased risk of lung cancer. A review of the first draft was conducted in 1990, a second draft was reviewed in 1995, and a third draft was reviewed in 1998. The EPA's Clean Air Scientific Advisory Committee concluded that the 1998 draft "was not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines."[8]

The Occupational Safety and Health Administration (OSHA) has not put diesel exhaust on its regulatory agenda and thus has not developed a corresponding risk assessment. However, the Mine Safety and Health Administration (MSHA) recently published a proposed diesel exhaust rule for coal,[9] metal, and nonmetal[10] miners. This effort was initiated in 1988 when an advisory committee recommended that MSHA promulgate standards limiting underground coal miners' exposure to diesel exhaust. In 1988, MSHA also requested that NIOSH perform a quantitative risk assessment for diesel exhaust exposure in response to these recommendations. NIOSH completed and submitted a quantitative risk assessment to MSHA in 1990[11] and an update of this assessment last year,[12] which was used by MSHA in developing its proposed rules.

In our final assessment, we at NIOSH chose not to emphasize one set of data or one modeling approach but rather to present risk estimates from different models and studies that had been used previously. The risk estimates from these different approaches ranged over 2 orders of magnitude, which reflects the influence of the large assumptions and uncertainties underlying the alternative analyses. However, the estimates of lung cancer risk from these different analyses were all high by most contemporary standards (≥1 excess lung cancer case per 1000 workers) at the diesel exhaust particulate levels in some mines (e.g., ≥1 mg/m^3).[12]

The Nature of the Debate

What has caused these agencies to stumble in completing their risk assessments for diesel exhaust exposure? The answer to this question is simply that intense scientific debates over the data and methods used in these risk assessments have raised a cloud of uncertainty over analyses that have been performed to date. Not only has there been an ongoing debate about how to conduct risk assessments for diesel exhaust exposure, there has also been some debate about the qualitative determination that diesel exhaust is a potential human carcinogen. Reviews of this issue have lead several national and international organizations to conclude that diesel exhaust should be regarded as a potential or probable human carcinogen.[13–17] The meta-analysis published in this issue of the Journal by Lipsett and Campleman adds to the evidence that exposure to diesel exhaust should be regarded as potentially carcinogenic.[6] There remain, however, some authors who are skeptical of whether there is risk to humans from such exposure.[18]

The larger debate has been about what methods and particularly what data can be used to quantify the risk. Fundamentally, the problems in this and all quantiative risk assessments are related to the quality of the available data and our need to extrapolate either from animals to humans or from high to low exposure levels. The early risk assessments conducted by NIOSH, the California EPA, and the federal EPA relied on modeling of the rat chronic inhalation bioassay data.[3] Subsequent research has indicated that the response in rats may be related to overload of lung clearance mechanisms in the rat.[19] The authors of these studies have suggested that this mechanism is unique to the rat and that these data cannot be used for predicting human risk.[19] The more recent risk assessments conducted by these agencies have developed estimates of risk based on epidemiological data; however, this approach has also been controversial.

These quantitative risk assessments were based primarily on analyses of a cohort of railroad workers,[4] over which there has been a continuing controversy regarding whether this study exhibits a positive dose–response relationship. Analyses presented in the final California EPA risk assessment suggest that there is a positive dose–response relationship in this study,[16] whereas analyses performed for the federal EPA and for Mercedes Benz do not provide evidence of a positive dose–response relationship.[20] We at NIOSH have recently developed a new exposure–response model[21] based on our study of truck drivers exposed to diesel exhaust, which we used in our risk assessment for MSHA.[12]

Removing the Roadblocks

What can be done to remove the roadblocks that inhibit the completion of risk assessments and that impede decision making at regulatory agencies for diesel exhaust exposure and other hazards? We should first recognize that the problem is not so much with risk assessment as it is with our complicated regulatory decision-making process. Blaming risk assessment for our problems is analogous to killing the messenger when you don't like or fully believe the message. Risk assessment is a vital and irreplaceable tool for informing public health decision making. However, expecting risk assessment to provide definitive characterizations of human risk is naive and a recipe for procrastination in making important decisions for protecting the public's health. There will always be substantial uncertainties in risk assessments and substantial room for scientific debate about whether there is a risk and how best to quantify it.

While additional research may reduce the uncertainties in risk assessment for diesel exhaust exposure, it will not totally eliminate them. NIOSH has initiated an epidemiological study of miners exposed to diesel exhaust, and the Health Effects Institute recently funded a study to assess the feasibility of conducting a study of truck drivers. Although these studies were designed with the intent of clarifying the quantitative relationship between diesel exhaust and cancer, grounds for scientific debate will still remain. Given the large number of previous diesel exhaust studies, it is unclear whether any single new study will significantly alter our position on this issue. Furthermore, we must ask whether it is ethical to wait another 5 to 10 years for the results from these studies before making any decisions about protecting workers and the public from the potential hazards of diesel exhaust exposure. One hopes that most readers of this editorial would answer, "Clearly not."

Finally, we must recognize that risk assessment has become a battleground for powerful interests that are potentially affected by regulation. Organizations with ample resources have discovered that debates about the uncertainty of risk assessments can be a powerful tool for impeding regulations. However, as Sir Bradford Hill stated in his classic paper on determining causality in environmental epidemiology, "All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time."[22]

Scientists clearly recognize that all risk assessments are inherently uncertain and subject to change when new data are obtained. Regulators and other decision makers in our society must accept this as an inevitable consequence of the scientific process and not allow the acknowledgment of uncertainty to be used as an excuse for delay in developing policies to protect workers and the public from exposure to diesel exhaust and other hazards. Making decisions when the risks are uncertain will inevitably lead to errors. It is to be hoped that risk managers will continue to use conservative assumptions, with the result that any errors will be in favor of protecting workers and the general public from environmental hazards. □

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The Ebb and Flow of Radon

We are approaching an anniversary of sorts—radon became a public health issue almost 15 years ago. As those of us know who have been involved in radon research, levels of radon vary over time within homes, mirroring to some extent the fluctuation of the public's interest in the problem. Even in states with aggressive radon programs, such as my own New Jersey, we know that while much has been accomplished, much is left to be done.

Defining the Problem

In late 1984, Stanley Watras, a resident of Boyertown, Penn, employed at the Limerick Nuclear Generating Station, moved the issue of exposure to radon gas out of the realm of mines and contaminated sites and into the forefront of environmental health issues confronting the public.[1] Watras was an unlikely initiator of this transition. An electrical engineer, he worked in areas of the Limerick plant where he should not have come into contact with radioactive materials, but he nevertheless triggered contamination alarms when exiting the plant at the end of the workday. Once Watras established that he could trigger these alarms when arriving for work, Limerick and Pennsylvania state officials were able to identify radon decay products adhering to his clothing as the offending contaminants and the Watras home as the source.

Radon 222, the immediate decay product of radium 226, is part of the naturally occurring uranium decay series beginning with uranium 238 and ending with stable lead 206. Experience with underground miners and radium dial painters has shown it to be a human carcinogen, increasing the incidence of lung cancer in those exposed.[2] Because it is an inert gas with a 3.8-day half-life, radon moves freely in soils of suitable porosity under the influence of relatively small pressure gradients. The decay products of radon are isotopes of polonium, bismuth, and lead. Once created by the decay of radon, these metals can electrostatically collect on dust particles suspended in the air and, if these particles are inhaled and attach to lung tissue, produce high local radiation dose. Until the mid-1980s, assessing human exposure to radon and its decay products was largely the province of occupational hygienists employed in the mining industry and health physicists involved in remediating homes

Editor's Note. Please see related article by Alavanja et al. (p 1042) in this issue.