Conflicts between Two Cultures: Implications for Epidemiologic Researchers in Communicating with Policy-Makers

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During the 1990s policy-makers, including the US Congress, increasingly called for evidence-based decisions on environmental and other policy issues (1, 2). By implication, this appeal implies that scientific evidence has not always played a major role in decisions affecting public health because of gaps in the evidence and even prejudice against public health data as “soft.” Some would now argue that science can and does have an impact on policy decisions. They would place epidemiology as the foundation of public health science. Since epidemiologic data measure risks directly in humans, findings of epidemiologic research are perceived by many as the most relevant indicators of adverse effects in humans. Because of the immediate relevance of human data, epidemiology probably engenders the most commentary and criticism of all the public health sciences. The discussion is fueled by the inability of epidemiologists to “control” their research as toxicologists can control their experiments, and, consequently, the results of observational research are inherently subject to uncertainty and imprecision. Recent debates over acceptable levels of risk for radon, air pollution, mercury, and lead—for which much epidemiologic data are available—exemplify the debate that may arise when major policy decisions are largely driven by epidemiologic data.

Discussions and even heated debates about the adequacy and interpretation of scientific evidence are frequent and now inherent to policy debates, seemingly creating a conflict and a gulf between science and policy (3–5). The decision-makers sometimes find it difficult to understand and to use the scientific evidence, especially in the context of the inevitable limitations and uncertainties clouding any scientific evidence. While the recent movement toward evidence-based policy has been positive in its policy implications, it has also inadvertently to increased distrust of science and scientists on the part of policy-makers who want more from scientific evidence than they believe they are getting. This distrust has spawned conflicts between science and policy which need to be resolved to improve the basis for decision-making. Both disciplines need to expand their efforts to understand their different roles in policy-making. The following presentation will focus only on suggestions for scientists, especially epidemiologists, which may help reduce some of the conflicts.

In order to reestablish credibility, scientists must define their roles and the role of science in decision-making and educate the policy-makers regarding these roles. Science alone does not drive policy decisions, it is simply one source of information. Epidemiologists, as well as other public health scientists, need to better understand the role that epidemiologic evidence may assume at a policy level and to learn how to interact with policy-makers. As an initial step, they need to understand the framework for decision-making. Since science and policy often meet over environmental issues, examples of this framework’s use in environmental policy decisions will be highlighted in this presentation.

FRAMEWORK FOR DECISION-MAKING

In the past, science only entered the arena of policy and decision-making at the point of risk assessment (6). Policy-setting was done by managers who interpreted the science which was handed over to them. Goals were often set without discussions with scientists. More recently, the Presidential/ Congressional Commission on Risk Assessment and Risk Management has characterized the steps leading to the development of an environmental policy and ultimately to making a final decision (7). The framework developed by the Commission suggested that stakeholders be involved at all stages of policy-making, from description of the problem to evaluation of the outcomes resulting from policy. However, the recommendations did not emphasize the importance of scientific input throughout the process.

The Science Advisory Board of the US Environmental Protection Agency arrived at similar conclusions when considering the decision-making process within the Agency. The Science Advisory Board noted that it is particularly important to have stakeholder involvement at the earliest stage of policy development—when identifying the nature of the environmental problem. The stakeholders need to understand and consider the scientific basis for problem definition, risk identification, and delineation of options (8). The Science Advisory Board further noted that, to be useful to decision-makers, science must inform all steps in the decision process and scientists must be actively engaged and interact at every step. Both scientists and policy-makers have had difficulty in accepting and implementing a mean-
Cultural Conflicts Between Epidemiology and Policy


If scientists are only involved after a policy is developed, decisions could have already been made that are not soundly based in scientific evidence and, hence, not likely to be supported by scientists. One inevitable consequence of not involving both stakeholders and scientists at the earliest stages of goal-setting and problem definition is that conflicts arise over scientific evidence after policy is set. Unfortunately, decision-makers, having selected a policy option, may choose to give science less weight at that point, or to even disregard it if it does not support the selected decision (9–11).

The Commission’s framework suggests that there is an orderly process which advances from identifying problems through risk assessment, identifying management options, and finally making a decision that will lead to policy formulation and subsequent action. In the area of environmental policy, the process, however, is quite different. The Science Advisory Board found the process often to be non-linear, multifactorial, and driven by interactions among factors. Figure 1 depicts some of the interactive factors that can influence environmental policy decisions (8). The relative weight of their influence may vary across policy issues. For some, there may be little scientific evidence. Even when informative evidence is available, public opinion or other interests—including specific lobbying groups—may have a stronger influence on policy than scientific data. As indicated in figure 1, the decision-maker faces a seemingly chaotic array of information, opinions, and pressures, all having weight in shaping policy and action.

CULTURAL CONFLICTS AND TENSIONS

In addition to understanding the general framework for environmental (or other) policy decisions, epidemiologists should understand perspectives of policy-makers regarding both scientists and their scientific evidence. When faced with a complex policy, decision-makers will look for a “right” answer from scientific data. If no clear answer is forthcoming, policy-makers may be more influenced by non-scientific factors which require no interpretation by experts. For scientists, particularly epidemiologists, it may be difficult to draw a clear conclusion from scientific evidence that would support a particular policy option. The policy-relevant data from epidemiologic studies are often subject to more uncertainties than animal data, but certainly not more than the overriding issue of extrapolation from an animal model to humans.

Inherent variability, both within and across individuals, further complicates interpretation of the data. The ever-present possibility exists that some relevant factor has not been controlled, a virtually generic criticism of epidemiology. As a result, doubt may be cast on the research findings, regardless of the study’s quality. From the policy-maker’s perspective, the apparent vagueness and ambiguity of epidemiology as a method for scientific inquiry is frustrating and provides the main source of conflict between epidemiologic researchers and policy-makers. Other factors relating to epidemiology also contribute to tensions between the two cultures, including relevance of human data, culture of epidemiology, collection of exposure information, confounding factors, methods of analysis, and advocacy.

Relevance of human data

Epidemiologic data are derived from observations of human beings in real-world situations, and, therefore, are viewed as having direct relevance for estimating human

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**FIGURE 1.** Factors influencing policy decision-making.
health risk and for risk assessment. For example, the International Agency for Research on Cancer has defined the category of Group 1 human carcinogens as agents having “sufficient evidence” of carcinogenicity in humans, where the “sufficient evidence” is on the basis of evidence from epidemiologic studies (12). Given the strength of human data, the more influence an epidemiologic study has in setting a particular policy, the more the study’s scientific merit is scrutinized, criticized, and questioned by decision-makers, the public, industry, and other non-scientists.

Epidemiology culture

The epidemiology discipline engenders tension in itself unrelated to interactions with policy-makers. The conduct of epidemiologists has created a culture that fosters extensive criticisms of epidemiologic studies by colleagues. These criticisms are often proffered without adequate consideration of the policy impact of uncertainties associated with studies. Without any concept of the boundaries or standards for the criticisms, critics within epidemiology may leave the impression that epidemiologic data are so flawed as to be useless for policy development, especially if the policy requires a quantitative risk assessment. Only animal or other toxicologic data may remain as scientific evidence. Ironically, uncertainties in extrapolating to human risks from animal studies may provide a greater source of uncertainty in evaluating environmental risks than epidemiologic studies (13).

Estimated exposure information

Limits of exposure data collected in epidemiologic research afford another point of tension. Past exposure information is difficult to reconstruct in any epidemiologic study. The data may only exist for a subset of the population and may be subject to bias. The study may be the first investigation of a suspect risk and many other exposures may have been investigated in the same study. Thus, an initial review of risks may only dichotomize exposures. An exposure-response relation based on crude measures may be developed to suggest causation. For policy purposes, this approach is not enough. The main goal of the policy-maker is to set safe levels of exposures, and epidemiologists often do not provide exposure estimates that could lead to quantitative risk estimates. Epidemiologists shy away from exposure estimates which have large uncertainties. The discordance between the epidemiologist’s approach to collecting exposure data and the needs of the risk assessor and decision-maker remains a source of conflict between the two cultures that could be addressed by further interaction and communication between the two groups.

Confounding factors

Policy-makers may be further frustrated as critics and researchers argue over the potential influence of confounding variables on observed effects. It is always possible to list factors that might differ between exposed and unexposed populations in most epidemiologic studies. Such lists, however, do not identify true confounding factors—those that are related to both the outcome of interest and the exposure in the population. Critics of a proposed policy will produce a generic list of potential confounding factors which are intended to negate the value of studies for making policy. However, they never estimate the magnitude of the associations between confounder and outcome or confounder and exposure that must be present to create meaningful bias in the estimated risk. Criticism over unexamined “confounders,” without substantiative estimates of their potential effects on risk estimates, leaves policy-makers with the mistaken impression that all epidemiologic studies fail to address important confounders.

Methods of analysis

Increasingly sophisticated statistical methods have allowed epidemiologists to carry out complex, multivariable data analyses. To decision-makers, and sometimes to other epidemiologists, these approaches may seem like a “black box” analysis where little is known about the actual relations. The epidemiologist must be able to explain to the decision-maker all aspects of the analysis in policy-relevant terms that the non-scientist can understand. This effort should enhance the usefulness of epidemiologic analysis for policy decisions. Interpretation of scientific information will only improve when epidemiologists and policy-makers openly discuss the interpretation and use of scientific data.

Advocacy

Tension between science and policy can arise when epidemiologists step beyond their roles of researchers and interpreters into the role of advocates. Investigators may offer their recommendations on potential policy issues because they recognize the strong public health implications of risks identified from human data. Policy recommendations from epidemiologists are almost always based on estimated risks, without consideration of the costs of the recommended action or the public’s attitude toward the policy. The environmental policy arena is a complicated one, with many interrelated factors that need to be considered and many players with suggestions and opinions. The scientist must recognize that science is not the only consideration that leads to a decision. The scope of the scientist’s role should be to carry out the scientific work required to address the issues at hand, and to be an active participant in all steps of the decision-making process to help interpret science and answer questions.

BARRIERS TO USING EPIDEMIOLOGIC DATA IN POLICY-MAKING

Environmental hazards risk assessment exemplifies a major policy-making process that desperately needs communication between epidemiologists and policy-makers. In most environmental risk assessments, the risk assessment team may have had little involvement of epidemiologists.
even when information from their studies is used in the assessment. Often, risk assessors avoid the use of "messy" epidemiologic data, preferring instead to use toxicologic data from experiments conducted under strict protocols with carefully controlled exposure scenarios. Classically, epidemiologists have approached health problems, such as smoking or measles, from a standpoint of elimination of exposure or prevention (i.e., vaccination), which is essentially an "all or none" approach. Many environmental problems, however, do not fit into that public health paradigm. For example, mercury cannot be eliminated from water and particulates cannot be completely removed from air. For most environmental exposures, the only recourse is to mitigate adverse health effects to an acceptable level by setting "safe" levels of exposure through the use of quantitative risk assessment. To enhance the use of epidemiology in quantitative risk assessment, epidemiologists will need to provide specific data that meshes directly with the risk assessment paradigm (6).

The ideal multidisciplinary risk assessment team should include both toxicologic and epidemiologic expertise to help the risk assessor in examining human and animal data, interpreting pharmacokinetic models, and pointing out differences and similarities between the two sources of information. This interaction would provide for better interpretation of the full range of scientific information that is available to the risk assessor. While this multidisciplinary approach would require additional time and effort of participating scientists, the risk assessment will be strengthened, and cross-disciplinary understanding of problems by team members will be improved.

The types of data and the level of detail needed by the risk assessor are driven by key elements of the process. To set an acceptable level of exposure for the general population, the risk assessor must often extrapolate using data from populations with high-level exposures to estimate the effect on a population exposed at low levels. Risks observed in the workplace may be extended to the general population (14). For example, the risk of radon in homes has been estimated using data from underground miners, most having exposures far beyond those from typical indoor exposures (14). Policy-makers need explanations for the rationale behind this type of extrapolation and its implications for policy development. One of the dangers in extrapolating from high occupational exposures to low general exposures are the differences between the two exposure populations, such as susceptibility, that might influence risk. For example, high exposure occupational studies usually do not include pregnant women or children who may have substantially different susceptibility compared with employed, healthy workers. Evident sources of uncertainty, such as the role of cigarette smoking or other exposures, must be addressed (15). In the example of radon and lung cancer, researchers advanced the possibility of no risk at lower levels of exposure due to cellular repair processes that mitigate effects below some threshold dose (16). Debates such as that regarding the miner-based risk model can undermine any policy process and might have been lessened by greater interactions between scientists and policy-makers.

For some environmental agents, epidemiologic data have been sufficient to allow careful examination of population factors for susceptibility, as in the case of breast irradiation. Studies indicate that the risk for breast cancer after radiation varies substantially with the age at exposure (i.e., infancy, childhood, premenopause, and postmenopause) (16–21). The heightened risk for radiation in infancy and adolescence has direct relevance to risk assessment and risk management. However, epidemiologists generally prefer studies of representative population samples rather than concentrating only on small subsets and may eschew subgroup analyses because it is looked upon as excessive "mining" of data.

Epidemiologic data, along with toxicologic and other mechanistic data, may be informative with regard to the shape of the dose-response curve. Alternative dose-response curves (e.g., linear versus non-linear) may convey substantially different implications for risk assessment and management. In analyzing data, epidemiologists rarely characterize the extent to which the exposure-response evidence supports different risk models.

Questions about the quality of the data may also pose a barrier in using epidemiologic evidence for risk assessment (15, 22–25). Ideally, a quality control/quality assurance process will enhance confidence in the data, but the information is not always provided. Epidemiologists should be prepared to introduce evidence on quality control and make their data available for review by unbiased experts if appropriate. In a political climate that calls for balanced input from all sectors, the evaluation and interpretation of research findings often falls to a committee of scientists and non-scientists who may not have detailed knowledge of the research issue nor adequate time for in-depth review. Soliciting individual experts in the field may be a more equitable and informative approach for evaluating the research and providing an appropriate interpretation. This type of evaluation could also avoid the conflicts that may arise in committee reviews if members have their own separate agendas (8).

The final products of the risk assessment include a characterization of the hazard and of the uncertainties. Much like attributable risk estimation, the burden of disease in a risk assessment is estimated using a risk model and the exposure estimates for the population. Epidemiologists have generally not attempted to estimate the burden of disease for populations beyond the study population. Epidemiologic data and principles can be used for this purpose, however, even though uncertainties are inevitable (22). Improving the epidemiologist's understanding of risk assessment modeling can lead to awareness of the important items needed from epidemiologic data for risk assessment purposes.

CURRENT CHALLENGES FOR EPIDEMIOLOGISTS

As epidemiologic data are increasingly used for policy purposes, epidemiologists will face a series of challenges in carrying out research and participating in policy development. Exposure assessment is one of these challenges. While more detailed assessment of current environmental and occupational exposures requires significant resources, assessment of past exposures requires, in addition, estimation procedures based on modeling (16, 26, 27). Too often, investigators have reported dichotomous exposure status...
measures or relative exposure status, such as categories of high, medium, and low, because they feel there is less uncertainty related to this information. While this type of exposure information has been useful in identifying risk factors (particularly strong risk factors and their exposure-response relations), it is less useful for estimating general population risks. Risk assessors need to know the quantitative relations across exposure categories and not just relative rankings. For example, low, medium, and high categories might represent a linear or an exponential increase in exposure level.

Epidemiology can provide useful quantitative risk estimates despite many who argue to the contrary. One only needs to recognize that the major sources of risk assessment for the effects of radiation are epidemiologic data based on estimated exposures, as in the atomic bomb survivors and the uranium miner studies (14, 16). Both studies required the commitment of many scientists and large sums of money to arrive at appropriate exposure values for risk assessment. Both had the advantage that the biologic model for cancer from radiation was well accepted by scientists. Similar commitments of scientists’ time and funds are needed for evaluating other agents and their risks using epidemiologic data. These efforts require a basic understanding of the biologic action of the chemical in humans as compared with animals. It requires attention to the expected shape of the dose-response curve and comparison with the observed data. The epidemiologist must be prepared to expect that some chemicals and some outcomes may never show the usual cumulative dose-response curve, as with birth defects related to a specific exposure level at a unique time in pregnancy.

Epidemiologists must begin to examine paradigms for exposure-outcome interrelations other than the ones typically based on the classic responses to radiation or asbestos. They should emphasize the inclusion of all data in their analysis rather than focusing only on the highest and lowest exposed groups (28–30). Potential confounding variables may be a greater source of uncertainty in this type of analysis, as small exposure subgroups are more likely to differ from the total population in regard to these factors. This could occur even though adjustment for confounding was carried out for the total population.

Epidemiologists have tended to utilize only data that included the majority of the study population and provided point estimates of exposure for each person. Individuals without information are excluded. Omission of part of the population may produce bias, and epidemiologists must begin to use estimation tools to provide missing data. For example, missing exposure data may be associated with age, death, time last worked, or other factors which also relate to outcome. Omitting these subjects may lead to bias in risk measures. To avoid such bias, estimation procedures may be used—e.g., distribution-based approaches for estimating exposure levels—to provide values for the missing exposure data (26, 27). Epidemiologists must be willing to estimate a quantitative risk for each individual based, perhaps, on a few measured doses and a series of assumptions about changing risks. They must be willing to test the validity of these assumptions using a small subset of the population with measured values. Policy-makers need to know the sensitivity of any dose-response values to alternative selection of variables, assumptions, or models. The impact of risks in specific subgroups of possibly susceptible populations on the overall dose-response curve is important. Investigation of these subsets should not be regarded as an inappropriate step in the usual epidemiologic study. Acknowledging and characterizing uncertainty is another challenge for epidemiologists to make their research more relevant to policy-making. Sources of uncertainty should be addressed fully and their consequences considered carefully. Rarely have epidemiologists been called upon to test the uncertainties in a statistical model they have used for analyzing data. They have evaluated the influence of statistical variation in dose data, especially at the extremes of the curve. They have not tested the impact of different assumptions about confounding variables or use of different models on the overall dose response. Decision-makers need to be fully cognizant of the range of uncertainty around the risks of interest and the extent to which different factors contribute to that range. Many policy-makers already understand the concept of variation stemming from the statistics of the analysis. Formal uncertainty analysis is an informative tool that allows one to examine all aspects of the assumptions and figures that are part of the risk assessment. A high degree of variation or uncertainty from a specific factor may indicate a need for research to reduce uncertainty before a decision is made.

The conclusion from these suggestions is that epidemiology must move forward to use many different types of analysis in attempting to quantitate risks in populations. This will require use of multidisciplinary teams, as well as additional time and funding to complete the study. All studies may not need all of these in-depth analyses but, for important environmental agents, these steps are essential. The scientists will need to work with the policy-makers throughout this process to enhance general understanding of the results.

In addition, several studies may have key data on subsets of the total study population but the size of any investigator’s group may be too small to provide an adequate sample for analysis. Under the new provisions of the Office of Management and Budget that require government sponsors of research to make data available for policy-setting, these data should be made available for combined analysis. This activity requires even more time and resources of the investigator. However, planned funding in advance might allow provision of these data on an accessible web site or through collaboration of several investigators and risk assessors to provide appropriate analysis. These activities are becoming an expanding effort of all epidemiologic investigations today.

To generate data as relevant as possible for environmental policy-making, epidemiologists should understand the various regulations that underlie many policy decisions. For example, the US Environmental Protection Agency functions under a complex web of laws and regulations that govern exposures and manage risk assessment issues (2, 31). The Clean Air Act of 1970 (32) and the Clean Water Act of 1977 (33) each have their own separate constraints and requirements for compliance which the decision-maker must meet. Gaining an understanding of environmental regulations may be challenging for epidemiologists, who are
NEW ROLES FOR EPIDEMIOLOGISTS

With the changes in the political and social climate over the past decade, including the movement toward evidence-based policy, the roles and responsibilities of epidemiologists have been redefined (8). These roles and responsibilities will continue to change as the regulatory and legal frameworks related to environmental factors and human health issues continue to evolve. Epidemiologists have so far been urged to make their studies more useful to decision-makers and to minimize clashes over the science during the policy-making process through communication, education, and team participation. Additionally, epidemiologists need to gain a broader perspective beyond their own discipline and prepare to assume roles they had not considered previously, which include new responsibilities in the decision-making process where an epidemiologic approach is needed.

While no one can predict the future, epidemiologists can project future risks based on current trends and knowledge of changing risk factors in the population. Planning for future needs and setting goals to meet those needs will require population-based thinking, for which epidemiologists are well trained. This attention to future risks is essential in the area of environmental policy since many environmental problems cannot be easily remedied and often have very far-reaching effects. Projecting future risks involves the incorporation of evidence from various scientific disciplines (e.g., extrapolating animal toxicity data to human populations) and the integration of science into potential long-range policy decisions. Here, then, is a role for epidemiologists (and other scientists) to educate the members of the group involved in future thinking about the need for population-based projections of risk.

In taking the responsibility to consider future risks, the epidemiologist must also consider the effects of integrated risks. Scientists are already urging the US Environmental Protection Agency to examine risks in a comprehensive manner, rather than approaching each environmental agent as an isolated and separate hazard with consideration of one agent and one outcome as the risk (7, 8). As a result, the challenge to integrate risks has been mandated by the Food Quality Protection Act of 1996, which requires that all risks to children from all pesticides through all media must be considered when determining hazard (34). The difficulty of this challenge can be overwhelming. Few attempts have been made to assess the overall health impact of multiple risks from multiple sources, let alone to evaluate the best method of approaching this highly complex problem. The problem of integrating exposures and diseases remains a challenge for future epidemiologists.

Evaluation of environmental actions is one of the more immediate challenges which epidemiologists will need to address in the near future, since Congress is now demanding more proof of the effectiveness of interventions supported by public funds (35). The challenge becomes even greater when applying the integrated approach to environmental exposures and diseases (8). Congress will require better determination of exposures across populations, which means a need for better databases to assess human disease and ecologic health. Currently there are few databases that can be used to meet these future requirements, and none are designed to allow for evaluation of multiple diseases and exposures. Before designing new databases, researchers must address a number of questions: How will individual rights and control of information be managed? What are the basic needs for answering the important questions? How can the commitment be attained to provide the infrastructure and funding for long-term endeavors when the current emphasis is on short-term and transient goals? As with cancer registries, these long-term projects are costly and appear to offer little in return to those looking for quick results. Epidemiologists must, however, convince decision-makers of the need for such investments as this remains the most effective way to evaluate environmental health problems and intervention programs.

CHANGES FOR THE FUTURE

The concept of evidence-based policy has been embraced by both the policy-making and scientific communities. As sometimes happens with cross-cultural interactions, however, there are misunderstandings and conflicts. To improve evidence-based policy, the two cultures must improve communications with each other. Epidemiologists must take an active role in advancing communications and in working to
integrate their discipline with other scientists and with non-scientists in order to avoid conflicts during the decision-making process. Taking on this role requires hard work, an open mind, and good communication and educational skills. In practical terms, the role of the epidemiologist would entail serving on committees and teams to improve data for decision-making. Such committees should evaluate the environmental problems that are already on the horizon and plan for the toxicologic and epidemiologic data that would be needed to address the problems.

Before epidemiologists can commit feasibly to such a role in the policy-making process, a change must be made in how professional activities are rewarded. Funding agencies must recognize the importance of team efforts in making policy decisions by recognizing the time and money necessary to create the studies and policy-making environment that fosters active participation by the epidemiologist. At present, young scientists will gain little reward from committing time to committees and teams; they will gain little in terms of professional stature by trying to improve their communication skills if the long-standing rewards system remains inflexible.

The importance of the epidemiologist’s role in the policy-making process cannot be emphasized enough. Systematic and thoughtful planning, involvement of multiple disciplines and stakeholders in the planning process, and firm and long-term commitment to seeking the best scientific information for decisions will ultimately result in less controversy and conflicts. Scientists must be part of the decision-making team throughout all of its steps to achieve more rational and well-considered decisions for the future.

REFERENCES
