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Decision-Making Under Uncertainty in the Setting of Environmental Health Regulations

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INTRODUCTION

 SIR Austin Bradford Hill promulgated guidelines (1) for determining the likelihood that an association observed in a non-experimental study is causal. These guidelines are often used to weigh epidemiologic evidence in deciding whether or not to regulate exposures to chemical hazards. We argue that excessive reliance on his guidelines is inappropriate for many decisions bearing on the regulation of environmental exposures. We consider an alternative, explicitly Bayesian approach to regulatory decision-making, and we discuss the advantages and pitfalls of this approach. We conclude that a major advantage of the Bayesian approach is that it helps make explicit the non-scientific social and political determinants of public health decisions.

BRADFORD HILL'S GUIDELINES: STRENGTHS AND WEAKNESSES

In regulatory decision-making, substantial weight is given to evidence obtained from epidemiologic studies of human populations. Unfortunately, statistical associations observed between exposures and diseases in such studies may be either causal or non-causal. An observed association may reflect causality, or it may be due to the confounding effects of unmeasured risk factors, to various forms of bias, or to sampling variability. Conversely, failure to find an association may reflect either true lack of causality, or may result from confounding, bias or chance. In an attempt to systematize assessment of these issues, Sir Austin Bradford Hill promulgated guidelines for determining the likelihood that an association observed in an epidemiologic study is causal in nature.

In Bradford Hill's guidelines, the observed strength of an association between exposure and disease is the cardinal criterion of causality. When

assessing causality, the strength of the association is measured as the relative risk (the ratio of the rate of disease in an exposed group to that in an unexposed group). If a relative risk of 10 or greater is found in an epidemiologic study, it is difficult to imagine that unmeasured risk factors or unconsidered biases could account for such an extreme association. In such a case, scientific consensus on causality will almost certainly be reached. On the other hand, if a relative risk is found to be only 1.5, it is easy to suppose that uncontrolled biases or unmeasured risk factors could explain the observed association, and experts can be expected to disagree in their interpretation of such a result. This latter situation would pertain even if the study population were of sufficient size to produce a narrow confidence interval for the relative risk [e.g., (1.2, 1.4)] and an extreme p-value (e.g., $p < .01$). The problem is not simply one of statistical power; but rather, a deeper problem associated with the inherent limits of nonexperimental research. In any epidemiologic study in which the observed relative risk is less than 3 to 4, one may expect that consensus will never be reached among scientific experts that the observed association is truly causal in nature.

As we have implied, the application of Bradford Hill's guidelines is appropriate for determining whether or not scientific consensus can be reached. However, these same guidelines are often employed for a different purpose, i.e., to weigh the strength of epidemiologic evidence in establishing environmental regulations. We argue that these guidelines provide an inappropriate basis for such regulatory decisions. In general, the public health benefits of regulation are best measured in terms of the number of lives saved (or the amount of serious morbidity prevented) per thousand individuals exposed, i.e., in terms of attributable risk to each exposed individual rather than in terms of relative risk.

(More precisely, if we assume (1) that the total funds available for preventing environmental disease are fixed; (2) that the costs of regulating any given chemical increase linearly with the number of individuals exposed; and (3) that the regulatory cost per individual is the same for all chemicals, then regulating the exposures associated with the largest attributable risk per individual will maximize the number of lives saved. If the regulatory costs per individual differ for different chemicals, these costs must enter into the decision process as follows. Chemical A should be regulated in preference to a Chemical B whenever the product of the reciprocal of the regulatory cost per individual times the attributable risk per individual for Chemical A exceeds that for Chemical B. Thus, the public health benefits of regulation can still be summarized in terms of the attributable risk per

individual. If the costs of regulation do not increase linearly with the number of individuals exposed, the health benefits of regulation can no longer be simply summarized in terms of the attributable risk per individual when weighing regulatory costs against health benefits.)

Consider, for example, that the death rate from colorectal cancer is over 30 times that from soft tissue sarcoma (2). It is therefore more important (in terms of number of lives saved per thousand individuals exposed) to regulate an exposure associated with a true relative risk of 1.5 for colorectal cancer than to regulate an exposure associated with a true relative risk of 1.5 for soft tissue sarcoma [since $30 \times (1.5-1)$ is greater than $(1.5-1)$]. Given that the true relative risk for colorectal cancer is 1.5, it is likely that the observed relative risk will be less than 2 in any epidemiologic study with sufficient power to be seriously considered in the regulatory process. In these circumstances, using Bradford Hill's guidelines, scientists would be unable to reach a consensus that the true relative risk was greater than 1 and that true causality existed. Thus, a regulatory decision based strictly on Bradford Hill's guidelines (i.e., based on scientific consensus) would in this situation treat the true relative risk for colorectal cancer as no different from 1. In contrast, scientific consensus *would* exist on the need to regulate the exposure associated with the 1.5-fold increased risk for soft tissue sarcoma. As a result, the exposure which in actuality threatens fewer lives would be preferentially regulated. Essentially, then, a regulatory policy which is based strictly on a requirement for scientific consensus is equivalent to a policy not to regulate substances associated with true relative risks of roughly 3 or less, even when the associated attributable risks are quite large.

A BAYESIAN APPROACH TO REGULATORY DECISION-MAKING

We have argued for the need to consider regulating exposures for which the possibility of reaching scientific consensus on causality is unlikely or even inherently infeasible. As an alternative to an approach based on scientific consensus, we consider an approach to regulation which is based on Bayesian decision analysis. The use of the Bayesian approach to medical decision-making is not new. For example, Pauker and Kassirer (3) have recommended that decision making in clinical practice be based on a Bayesian approach. A clinician cannot wait for scientific consensus among experts regarding diagnosis before deciding whether or not to operate on a suspected case of appendicitis. Similarly, environmental regulators cannot delay regulating a suspected harmful exposure until scientific consensus

exists. In both instances, decision-making under uncertainty is necessary.

We describe briefly how a Bayesian approach to environmental regulation might operate. An expert hired by a regulatory agency would be asked to determine to the best of his ability (based on the available data) his subjective degree of belief (i.e., his personal probability) that the relative risk associated with an exposure E (at the dose in question) exceeds 1. He then is asked to *state explicitly* his degree of belief that the relative risk is between 1 and 1.3, that it is between 1.3 and 1.6, and so on. Suppose that such an expert states with probability 60% (i.e., has a degree of belief of 60%) that the relative risk for colorectal cancer is 1.0 with probability 30% that the relative risk is 1.5, and with probability 10% that it is 3.0. Using a Bayesian analysis, the expert would then calculate his expectation as to the number of excess deaths due to colorectal cancer per hundred thousand workers by multiplying 10% times the number of excess deaths that would occur if the true relative risk were 3.0 plus 30% times the number of excess deaths that would occur if the relative risk were 1.5. A simple calculation (Table 1) shows that from the perspective of this expert, more

TABLE 1
Calculations Demonstrating Expected Excess Deaths
for the Two Exposures Described in the Text

	<i>Personal probability of given relative risk</i>	×	<i>Proportion of excess deaths above death rate in the unexposed (equals relative risk - 1.0)</i>	×	<i>Annual death rate per 100,000 in the unexposed*</i>	=	<i>Contribution to annual excess deaths per 100,000 among the exposed</i>
Colorectal	.6	×	(1.0 - 1.0)	×	22.3	=	0.0
Cancer	.3	×	(1.5 - 1.0)	×	22.3	=	3.4
	.1	×	(3.0 - 1.0)	×	22.3	=	+4.4
					Expected annual excess per 100,000 among the exposed:		7.8
Soft Tissue Sarcoma	1.0	×	(10.0 - 1.0)	×	.74	=	6.7

* for ages 0-74, both sexes, all races, weighted by national population age distribution from reference 3.

lives would be expected to be saved by regulating such an exposure than by regulating an exposure (affecting an equal number of persons) that is known with 100% certainty to increase by 10 times the risk of death from a rare cancer such as soft tissue sarcoma. An agency regulator holding these same personal probabilities should act to regulate the exposure associated with colorectal cancer before the exposure associated with soft tissue sarcoma, even if he or she believes there is a 60% chance that such a regulatory effort would have no health benefits. This is so because over time this regulator and the agency must consider regulating hundreds or thousands of chemicals; and thus, over the long run, the regulator will expect that more lives will be saved by using a Bayesian approach to regulation than by using an approach based on scientific consensus. The advantages of this Bayesian approach appear twofold: 1) it incorporates the attributable risk into decision making; 2) it requires the rationale for a regulatory decision to be stated explicitly.

PITFALLS OF THE BAYESIAN APPROACH

In principle the Bayesian approach to decision-making makes excellent public health sense. Nonetheless, advocating this approach may be quite dangerous in a society, such as ours, in which political and economic power is unevenly distributed. We provide examples of the possible dangers.

Using our Bayesian calculus, if economic costs are equal, it may be more beneficial in terms of total lives saved to control exposures associated with a small increase in risk to many individuals than to control exposures associated with quite a high risk for relatively few individuals. Clearly, however, this calculus is unfair to relatively small groups of workers performing dangerous jobs. The problem is that in advocating the Bayesian approach, we have acted as though the costs and benefits of regulation were applied to the same individuals. In fact, however, this is frequently not the case. Small groups of individuals are asked in our society to bear disproportionate risks. Attempts at resolution of this dilemma through offering incentives such as hazard pay for high-risk jobs is ethically and politically suspect, particularly when only the poor need consider such trade-offs. Thus, considerations of fairness must be integrated into any Bayesian approach. Explicit consideration of whose costs and whose benefits are at stake is a necessity.

Another potential pitfall of the Bayesian approach is its susceptibility to influence by the unstated prior beliefs of experts and regulators. For example, under the Toxic Substances Control Act, industrial epidemiolo-

gists are required to report to the EPA those chemicals found to be suspect in epidemiologic studies. If, however, industry selectively hires epidemiologists who have strong prior beliefs that most chemicals are not hazardous, such experts will, using a Bayesian approach, tend to discount observed relative risks of 2 to 3 as being due to bias or to confounding. As a consequence, they might be less likely to report a potentially dangerous chemical to EPA than would other members of the scientific community. Similarly, when the influence of the business lobby is strong in the Federal Government, individuals hired as regulators will tend to be persons who have demonstrated strong prior beliefs that most chemicals are safe. When these regulators combine uncertain positive evidence of hazard with their strong prior beliefs of safety, they may fail to regulate under circumstances in which other members of the scientific community would have taken action. Of course, the same considerations could apply in a reverse fashion to "pro-labor" epidemiologists or regulators with strong prior beliefs that many chemicals are hazardous. We expect that the distribution of political power among contending parties in the regulatory process will determine the relative influence of variously held prior beliefs.

CONCLUSIONS

Despite these potential pitfalls, we see two reasons for popularizing a Bayesian approach to regulatory decision-making. First, in the aftermath of the Supreme Court decision on benzene, there is a widespread feeling that the Federal Government should not and need not regulate exposures in the absence of scientific consensus. In this setting, relatively pro-industry experts will argue the position that the presently available data on a given substance are not sufficient to form any scientific consensus concerning causality; acceptance of this argument can effectively preclude regulation. Our argument, that the ability to reach scientific consensus should have little to do with regulatory decision-making, may help to counter such a position.

A second argument in favor of the adoption of a Bayesian approach is that it may persuade the scientific community to require that experts report explicitly the distribution of their subjective probabilities. Thus, experts would be put in the position of having to say explicitly whether or not they believe, for example, that there is a 5% chance that a particular chemical exposure will cause 500 excess deaths. Requiring experts to report explicitly their probability distributions will insure that their willingness to accept a substantial amount of risk to the public cannot be hidden behind

a cloak of apparent "scientific objectivity." The public may be much less willing than the expert to accept such a level of risk. Further, when the public has the opportunity to see the wide range of expert opinion as to the number of excess deaths to be expected from a particular exposure, it will become apparent that in many cases the available scientific data are open to quite conflicting interpretations. The Bayesian approach provides a means for rational decision making in the face of such uncertainty. Additionally, it provides a means for the systematic examination of the subjective beliefs of the experts and regulators chosen by those who hold political power.

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