

Benefit-cost analysis and decision-making under risk uncertainty: issues and illustrations

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Abstract In determining how to set regulatory standards or guidelines for contaminants found in drinking water supplies, decision-makers typically try to balance public health protection benefits against costs. This is a difficult task given the types and degrees of uncertainty (as well as variability) that underlie the assessment of the health risks posed by contaminants. This paper describes methods that use probabilistic approaches (such as Monte Carlo techniques) to describe the types and levels of uncertainties that exist at each stage of a public health-oriented benefit-cost analysis (BCA). This research focuses on how uncertainty and variability need to be characterized, and how propagation of uncertainties often leads to broad confidence intervals for benefit estimates. This information is then assessed within the decision-making context of public health officials and regulators, to reveal how complex probabilistic analysis of benefits and costs can be presented and interpreted in the face of extensive uncertainties.

BACKGROUND

The role of health risk reduction benefits in standard setting

Common sense suggests that the benefits and costs of various standard setting options be taken into consideration in some manner when making regulatory policy decisions. For drinking water regulations, this ideally would entail comparing the anticipated incremental health risk reduction benefits to the incremental costs of alternative possible stringencies at which one might set a standard. (In an ideal context with perfect information the standard would be most efficient, i.e. welfare maximizing, in its protection of public health at the stringency where marginal benefits equalled marginal costs. Note that nonhealth benefits, e.g. water aesthetic improvements, also may arise because of some drinking water standards. These nonhealth benefits need to be considered in a benefit-cost analysis along with the health risk reductions attained.)

In the United States, standard setting under the federal Safe Drinking Water Act, before it was amended in 1996, precluded any consideration of what the quantified health benefits of a regulation might be, or how these benefits compared to costs. Instead, the statute required that the US Environmental Protection Agency (EPA)

establish technology-based standards called Maximum Contaminant Levels (MCLs). Under the law before 1996, MCLs were to be set as close to the "risk free" levels (MCL goals) as feasible, where feasibility pertained to technologically achievable contaminant removal and the practical limits of quantification. Public health risk reduction benefits were rarely quantified in any meaningful or systematic manner, nor could they be taken into account in standard setting under the statute.

Under the 1996 Safe Drinking Water Act Amendments (SDWAA), the EPA Administrator is required to publish a report describing the public health risk reduction benefits and costs for every proposed or promulgated standard. The Administrator also is required to issue a formal "determination" that the benefits of each standard justify the costs. Further, the Administrator is authorized to set MCLs at levels other than what is technologically feasible if the benefits are found not to justify the costs; the Administrator is enabled to set the standard "that maximizes health risk reduction benefits at a cost that is justified by the benefits". Hence, statutory requirements in the United States now formally mandate that public health risk reduction benefits be systematically estimated, communicated to decision-makers and the public, and then evaluated *vis a vis* costs in making regulatory decisions.

The use of benefits information in the past

In environmental, health, and safety areas in particular, significant challenges to the application of benefit-cost analysis (BCA) include uncertainties, gaps in available data, controversies surrounding methods for quantifying physical effects or placing monetary values on nonmarket outcomes (such as change in risks to health), and issues of equity. These unresolved issues suggest that BCA should not be used as a strict decision rule for defining which policy options can be considered and which must be selected. Rather, better use of sound scientific and policy approaches to address uncertainties and other problems is required so that BCA can be used as a practical, objective, and valuable tool that contributes to a more informed decision-making process.

BCA has been applied successfully and constructively to several important public health, safety, and environmental issues. For example, EPA conducted an outstanding BCA of lead exposures from vehicle exhausts because of leaded fuels. This BCA was instrumental in accelerating the phased reduction of lead concentration in motor fuels (without the BCA, society would have continued to bear the cost of higher lead exposures). There also are examples of useful benefit-cost applications to drinking water programmes, including a study that demonstrated that some past EPA regulations cost over US\$ 1 billion for each cancer case avoided, whereas MCLs for other contaminants could achieve the same level of protection at less than US\$ 1 million per case avoided, such that close to 99% of the regulatory programmes carcinogenic risk reductions could be achieved at approximately 60% of the cost if there were greater flexibility in selecting which contaminants to regulate and how stringently to regulate them (Raucher, 1996).

These and other applications illustrate that when pursued with due care, BCA can serve as a viable, objective, and valuable tool for decision-makers. However, critical

challenges remain, especially in the area of addressing uncertainties. This paper, by examining the issue of uncertainty in BCA, is intended to help analysts improve the quality and value of benefits assessment for public policy purposes, especially as related to standard setting.

UNCERTAINTY AND VARIABILITY

Critical elements in estimating health risk reduction benefits

Regardless of one's normative arguments about the appropriate role of benefit-cost considerations in the public health policy arena, there are several practical problems that challenge analysts conducting BCA. The most fundamental of these challenges is that estimates of public health risk reduction benefits typically are subject to considerable uncertainties that impact the various components (individually and collectively) of the risk assessment and related benefits analysis. In order for BCA to serve as an objective and valuable tool to enlighten regulators and interested stakeholders, it is imperative that the uncertainties and variabilities inherent in benefit estimation be (a) addressed systematically, using good science, and (b) portrayed to decision-makers and interested parties in a manner that effectively, simply, and honestly communicates what is and is not known about the benefit estimates.

The proper research approach for BCA must embody a sound conceptual basis, clearly illustrate how the individual pieces of a health benefit analysis fit together, and explore the extent to which uncertainties may arise and dominate the analysis at each step. Analysts also must examine how these uncertainties can propagate through the steps when the pieces are integrated using various analytical techniques (such as Monte Carlo simulation models, in conjunction with second order random variables). The perspective of using scientific and statistical "best practice" must be balanced with the pragmatic needs of developing benefit estimates with limited data and resources (as typically is the case for many regulatory agencies and other stakeholder organizations). Further, the approach must facilitate communicating the findings of stochastic analyses to decision-makers, who must be able to interpret statistically complex outcomes in the context of their responsibilities as public health officials.

Defining uncertainty and variability

The terms "variability" and "uncertainty" have been broadly used to encompass a multiplicity of concepts, and the precise meaning of these terms varies across disciplines. Risk assessors view variability and uncertainty as very distinct concepts and issues that distinguish between inherent physical (or natural) characteristics and limitations of knowledge or understanding (as displayed by the risk assessor). The following definitions, following Bogen (1990) and EPA (1997), describe how risk assessors distinguish the differences between variability and uncertainty.

Variability is a fact of nature and refers to observed (or measurable) differences attributable to diversity in a population (e.g. members of a population exhibit

variability with respect to their weight). Variability is defined as the degree of variation in risk across an exposed population due to intersubject differences in exposure conditions, rates of intake (e.g. inhalation rates per unit body mass), uptake fractions, retention characteristics, biotransformation, and sensitivity.

Uncertainty in contrast, describes the state of knowledge of the analyst (not the population) and refers to the lack of understanding about specific factors, relationships, models, and model parameters.

Every risk assessment contains elements of both variability and uncertainty, as the following example illustrates. Suppose variability exists in a model parameter such as body weight. If one were to conduct a national survey on body weight, one could then estimate a distribution that explains the inherent variability of body weight, based on the survey results. If one were to conduct a second survey on body weight, the estimated distribution would in fact be different to the first estimated distribution. Two equally plausible distributions exist, and the difference between the two distributions reflects what is properly referred to as parameter uncertainty (e.g. measurement errors, sampling errors, systematic errors). Thus, even when one can characterize variability based on reliable data, uncertainty still applies to the knowledge about specific parameter values.

Uncertainty may also be introduced by model uncertainty (e.g. uncertainty due to the simplification of physical processes, model mis-specification, use of inappropriate surrogate variables) and scenario uncertainty (e.g. descriptive errors, aggregation errors, errors in professional judgement, incomplete analysis).

In general, variability cannot be reduced by further research and measurement. However, uncertainty, which refers to a lack of knowledge, can. The distinction between variability and uncertainty can have significant implications for decision-making, particularly with respect to whether or not probability information can be used to form meaningful averages (expectations).

THE COMPONENTS OF A BENEFITS ASSESSMENT

Evaluating the consequences of a regulatory policy is a process that involves integrating many types and sources of data and information, each of which is known only within certain limits of precision. Uncertainty and variability arise from many sources, some of which are the result of natural processes and inherent variation, while others are an artefact of our limited knowledge about many physical processes, behavioural responses, and interactions between the two. These relationships can be portrayed as a chain of events that link a regulatory action (e.g. setting an MCL), to its outcomes (public health risk reduction benefits).

Occurrence and exposure assessment

The basic foundation of risk reduction benefit quantification is understanding the levels of the risk-causing agent in drinking water systems. As these analyses typically pertain to national standards, national occurrence profiles are required to support both

the benefit and the cost analyses. This in turn requires deriving estimated probability distributions to reflect the likelihood that public water systems (PWS) will include the contaminant above a specific concentration level of concern. These probabilities typically are estimated from a sampling of PWS, with the findings then extrapolated to the universe of PWS.

The occurrence estimation process introduces several potentially significant uncertainties in the analysis (at utility-specific levels of analysis, where actual site-specific samples are taken, many but not all of the sources of uncertainty are bypassed). For example, the sample of PWS for which water quality data was extracted must be a stratified random sample of PWS nationwide (i.e. the sample must represent the universe). Even within a specific sampled PWS, attention must be paid to how representative the water quality samples are of the “true” levels (e.g. potential for measurement error, temporal variability, or bias introduced by the location of the sample point relative to levels more typical of human exposure points, like the tap).

Ultimately, there are numerous issues also associated with how the sample data (even if drawn from a stratified random sample and reliably measured) are statistically interpreted in order to develop the estimated national probability estimates. For example, EPA had traditionally used only system size (population served) as the basis for interpreting occurrence data, whereas other parameters are typically more important explanatory variables. For example, for radon as a naturally occurring compound, it was expected and then statistically supported that geological regions were among other important variables that needed to be taken into consideration when estimating occurrence levels, whereas land use patterns would be important variables in predicting occurrence for many synthetic compounds (Raucher *et al.*, 1995).

Exposure levels build on occurrence, but add several additional uncertainties. For example, “finished water” (post treatment, but typically measured at the point of entry to the distribution system) may be very different in quality from the “delivered water” obtained at the consumer’s tap. Even given concentrations at the tap, exposures may vary according to many factors, including the levels and timing of household water use (e.g. first draw versus flushed draws), the amount of water ingested (variability around the 2 l day⁻¹ typically assumed), exposures from sources other than tap water (foods, other beverages, etc.), multiple pathways of exposure as may be applicable to some agents (dermal and inhalation doses rather than ingestion alone), and activity patterns (e.g. time spent away from home).

Concentration-response and risk characterization assessment

A considerable literature has developed regarding risk assessment issues of dose-response relationships. There are numerous key issues for both microbial and chemical agents. As an entire research career could easily be devoted solely to dose-response issues, our approach here will be to provide readers with a basic understanding of the key issues.

Two broad trends recently have emerged to improve the scientific basis for risk analyses and resulting characterization. The first increases the use of biologically-based models in risk assessment, to better incorporate recent research advances in the

pharmacokinetic and pharmacodynamic basis of exposure-response relationships for environmental pollutants. These advances demonstrate that the simple use of calculations of risk based on average daily rate of intake and a nonthreshold slope factor can lead to significant inaccuracies in risk estimation for some carcinogens. Recent scientific research (e.g. Crawford-Brown, 1997) has identified a number of areas in which nonlinearity in exposure-response may be found, such as when:

- (a) transport processes across membranes, leading to uptake into target organs, can be saturated;
- (b) activation and/or inactivation of compounds through biotransformation may be saturated;
- (c) adaptive response mechanisms lead to stimulation of repair or antioxidative processes;
- (d) promoting agents, or agents acting by other nongenotoxic mechanisms, are considered;
- (e) a compound is simultaneously genotoxic (acting as an initiating agent) and cytotoxic;
- (f) mixtures of compounds, rather than isolated compounds, are considered.

The effect of these changes is that carcinogenicity risk assessments need no longer be based solely on linear exposure-response relationships, and non-cancer endpoints may require treatment through concepts other than No Observed Effects Levels (NOELs) and Lowest Observed Effects Levels (LOELs). The need to use one or the other of these in risk estimation was based on a previous dichotomy between either linear exposure-response or threshold models.

The second broad trend in the field of risk analysis is towards increasing the use of probabilistic methods. As summarized in the Policy for Use of Monte Carlo Analysis in Risk Assessment (EPA, 1997), EPA states that risk assessments should include analyses of variability and uncertainty for all risk estimates. With respect to variability, the regulatory goal generally is to ensure that the fraction of the population exceeding some allowed risk (e.g. a risk of 10^{-6}), is no more than some upper limit (e.g. no more than 5% of the exposed population can exceed the allowed risk). With respect to uncertainty, the regulatory goal generally is to ensure that there is adequate confidence that the fraction of the exposed population exceeding the allowed risk is acceptable. Combining uncertainty and variability results in a regulatory goal may be phrased generally as: For what source term into the environment may it be stated with at least $X\%$ confidence (e.g. 95% confidence) that no more than $Y\%$ of the population (e.g. 5%) will have a risk that exceeds Z (e.g. 10^{-6})? In addition, sensitivity analysis, in which the causes of residual uncertainty are identified, is valuable for directing research resources toward the largest contributors to uncertainty.

Economic valuation

Valuation of quantified changes in health risks raises numerous normative and positive issues. However, regardless of how one views the issue of assigning monetary values to changes in health status, sound policy development requires at least implicit valuation of changes in health risk (i.e. a notion of what cost per change in health risk

is reasonable). Our recommended approach is to make explicit valuations of health risk reductions, but these same values and concepts will also be applicable in cases where benchmarks are needed to interpret implicit valuation decision approaches (e.g. when is a cost per cancer case avoided too high?).

It also is important to understand the appropriate conceptual basis for valuing changes in risk. This includes key concepts such as the value of a statistical life (VSL), in which the key point is that we are not valuing an individual's life *per se*, but instead are using information regarding how individuals value changes in modest level risks of fatality. There is an extensive literature on health effects valuation. Issues to be addressed include how to reflect and embody uncertainty about the values to apply, issues associated with quality adjusted life years (QALYs) and similar indices to quantify changes in health outcomes, issues associated with discounting future risk reductions to account for latencies or other temporal aspects of risk reductions, and the interpretation of cost of illness type approaches vs results from research on willingness to pay/accept compensation for changes in health risk.

POLICY INTERPRETATION UNDER UNCERTAINTY

The final phase of the BCA entails two important facets. First, the various individual steps of the benefits quantification and valuation effort need to be assembled into a whole. The Monte Carlo approach is particularly useful in this regard, as it helps portray how much uncertainty is embedded in each step, how the uncertainties are propagated through the assembled analysis, and which uncertainties dominate the final outcome. Figure 1 provides a graphical representation of how this can be portrayed (in this example, the overall uncertainty is dominated by the dose-response relationship).

The second important facet addressed in this stage of the BCA pertains to how stochastic benefits estimates can and should be interpreted by policy-makers for comparison to costs. Policy interpretations based on central point estimates can be extremely misleading and inappropriate, but are often appealing because they tend to imply clear outcomes (e.g. a single point estimate of benefits is either unambiguously greater than, or less than, costs). Yet even where users of the BCA are prepared to view the world as uncertain and can understand the notion of probability density functions for portraying benefits, there is still limited experience or direction on how to interpret the results. For example, how does the EPA Administrator or any other decision-maker make a determination of whether the benefits justify the costs where the benefits are widely distributed (e.g. 90% confidence limits that are orders of magnitude apart) and must be compared to costs (which, although uncertain in their own right, are often subject to considerably less uncertainty than are health benefits, and such that at many times costs are portrayed as point estimates)?

In terms of interpreting the Monte Carlo results, there are no existing and objective measures that can be applied to determine whether it is prudent public policy to promulgate public health regulations in which the quantified benefits have a low probability of equalling or exceeding costs. Nonetheless, there are interesting benchmarks that can be considered in a policy interpretation. For example, policy interpretation can be based on how the expected value of benefits (the mean value

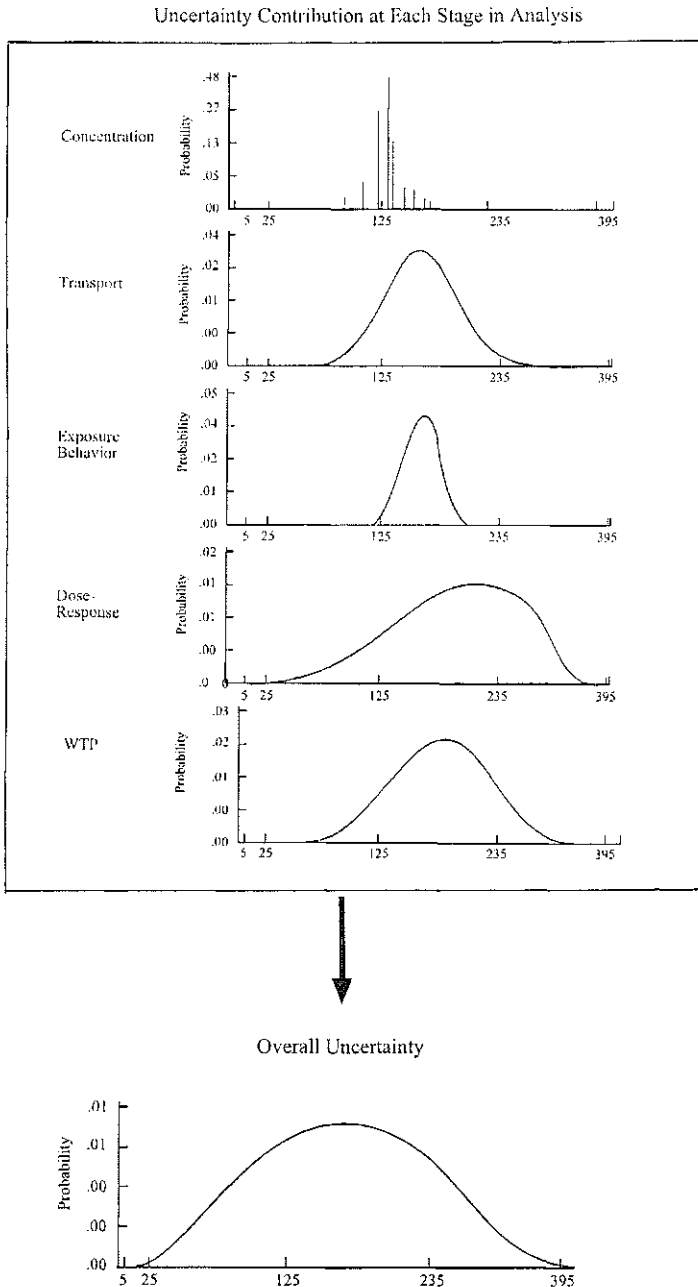


Fig. 1 Sources and relative contribution to overall net benefits uncertainty (net benefits in millions US\$).

from the probability distribution) compares to costs. In one Monte Carlo analysis we conducted for a proposed rule, the expected benefits were appreciably less than costs, with the expected value benefits roughly one-third the value of costs. Since the mean benefits were less than costs, does this imply that the benefits do not justify the costs?

Since using only the mean value of benefits in a BCA can be misleading, one may also wish to consider the broader range of potential benefit values. For example, to provide an extra measure of conservatism in dealing with uncertainty in matters of public health, the upper end of the benefits distribution might be used in benefit-cost comparisons. By analogy to the standard practice in health risk assessment of using the upper 95% confidence limit for deriving the slope of the dose-response function for carcinogens, one could consider programmes for which benefits have a better than 5% chance of exceeding costs (i.e. costs are less than 95% likely to exceed benefits) as being justified. Using this benchmark, the Monte Carlo analysis suggests that the regulation in question would pass the criterion, as it had an estimated 6% probability that benefits exceeded estimated compliance costs.

Finally, one might simply wish to determine if benefits and costs are commensurate, which is often interpreted as meaning that they are of approximately the same order of magnitude. In the case of this illustration, there was an estimated probability of greater than 40% that the benefits were less than an order of magnitude of the costs (i.e. there is a better than 40% chance that costs are at least 10 times greater than the cancer risk reduction benefits). Do the benefits justify the costs in this instance?

These illustrations reveal that there is no set decision-criterion that is readily available to assist decision-makers in the policy interpretation of probabilistic BCAs. Instead, a range of measures and criteria will need to be explored and considered.

REFERENCES

- Bogen, K. T. (1990) *Uncertainty in Environmental Risk Assessment*. Garland Publishing, New York, USA.
- Crawford-Brown, D. (1997) *Theoretical and Mathematical Foundations of Human Health Risk Analysis*. Kluwer Academic Publishers, Amsterdam, The Netherlands.
- EPA (1997) Policy for use of Monte Carlo analysis in risk assessment. *US Environmental Protection Agency, Washington, DC, USA*.
- Raucher, R. S. (1996) Public health and regulatory considerations of the Safe Drinking Water Act. *Annual Review of Public Health* 17, 179–202.
- Raucher, R. S., Castillo, E. T., Dixon, A., Breffle, W., Waldman, D. & Drago, J. A. (1995) *Estimating the Cost of Compliance with Drinking Water Standards: A User's Guide*. American Water Works Association Research Foundation, Denver, Colorado, USA.