VARIABILITY AND UNCERTAINTY MEET RISK MANAGEMENT AND RISK COMMUNICATION

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ABSTRACT

In the past decade, the use of probabilistic risk analysis techniques to quantitatively address variability and uncertainty in risks increased in popularity as recommended by the 1994 National Research Council that wrote *Science and Judgment in Risk Assessment*. Under the 1996 Food Quality Protection Act, for example, the U.S. EPA supported the development of tools that produce distributions of risk demonstrating the variability and/or uncertainty in the results. This paradigm shift away from the use of point estimates creates new challenges for risk managers, who now struggle with decisions about how to use distributions in decision-making. The challenges for risk communication, however, have only been minimally explored. This presentation uses the case studies of variability in the risks of dying on the ground from a crashing airplane and from the deployment of motor vehicle airbags to demonstrate how better characterization of variability and uncertainty in the risk assessment lead to better risk communication. Analogies to food safety and environmental risks are also discussed. This presentation demonstrates that probabilistic risk assessment impacts both risk management and risk communication, and highlights remaining research issues associated with using improved sensitivity and uncertainty analyses in risk assessment.

Key Words: variability, uncertainty, risk communication, risk management, probabilistic risk assessment

1.0 INTRODUCTION

Risk analysis continues to evolve and mature as a field, with dramatic changes impacting the three elements of risk assessment, risk management, and risk communication. The Reactor Safety Study in the mid-1970s (1,2) and related studies in the late 1970s and early 1980s (3-5) began a shift toward improved treatment of variability and uncertainty in risk assessment as reviewed by Rechard (6). Since the late 1980s, calls for increased consideration of variability and uncertainty in risk assessments combined with significant advancements in computational speed and capability motivated a greater shift toward the use of probabilistic risk assessments (7-14). Sensitivity analysis is one type of uncertainty analysis that may be used to consider the impacts of uncertainty. Traditional sensitivity analysis is conducted by changing one uncertain input at a time and showing how the results of a model change over the range of possible values of that one input. However, two-way sensitivity analysis is also common (e.g., varying two inputs at the same time and plotting the results in a two-dimensional space), and as an analyst moves toward a larger number of inputs allowed to vary (and dimensions required to present the results), the sensitivity analysis essentially transitions into a probabilistic uncertainty analysis (typically using Monte Carlo simulation methods). Numerous references discuss sensitivity analysis and uncertainty analysis concepts (e.g., 15-23).

The importance of explicitly including consideration of variability and uncertainty in risk assessments arises directly from their ramifications in risk management (24,25). While the concepts of variability and uncertainty may be easily confused, they remain distinct concepts defined within a decision-making context (25). Variability refers to real and identifiable differences between individuals within a population addressed by the risk assessment. For example, variability might refer to differences between individual Americans or individual ships within a fleet or individual facilities that all produce the same commodity or individual crops or batches of a food. True variability does not disappear with better measurement. The existence of variability in the population implies that a single action or strategy may not emerge as optimal for each of the individuals, and consequently any decision made will go too far for some and not far enough for others.

Uncertainty differs significantly from variability. Uncertainty arises from our lack of perfect knowledge, and it may be related to the model used to characterize the risk, the parameters used to provide values for the model, or both. In some cases, we can reduce uncertainty by obtaining better information, but this may not always be possible. Uncertainty implies that we might make a non-optimal choice because we may expect one outcome but something quite different might actually occur.

In the past decade, the use of probabilistic risk analysis techniques to quantitatively address variability and uncertainty in risks increased in popularity as recommended by the 1994 National Research Council (NRC) that wrote *Science and Judgment in Risk Assessment* (24). The NRC emphasized the different ramifications of variability and uncertainty in risk by stating that: "Uncertainty forces decision makers to judge how *probable* it is that risks will be overestimated or underestimated for every member of the exposed population, whereas variability forces them to cope with the *certainty* that different individuals will be subjected to risks both above and below any reference point one chooses" (Ref. 24, p. 237). The NRC also challenged the U.S. EPA to "…develop the ability to conduct iterative risk assessments that would allow improvements to be made in the estimates until (1) the risk is below the applicable decision-making level, (2) further improvements in the scientific knowledge would not significantly change the risk estimate, or (3) … the stakes are not high enough to warrant further analysis" (Ref. 24, p. 14). The NRC report's emphasis on the importance of better uncertainty analyses emerged at a time when an increasing number of risk analysts discussed the use of Monte Carlo techniques to propagate uncertainties in risks and made distinctions between variability and uncertainty in risk. However, as noted by Finkel (26), who suggested that "…[practitioners of quantitative uncertainty analysis] have risked making ourselves akin to mousetrap salesmen who beleaguer the consumer with engineering details before he even understands that if the gadget works, the result will be a house free of mice," the analysts appeared to be primarily talking amongst themselves and failing to adequately communicate the benefits of better analyses to risk managers and the public.

In 1996, the Food Quality Protection Act (FQPA) led to sweeping changes in the assessment and management of food, microbial, and pesticide risks and to expectations that analysts would assess aggregate and cumulative risks that they did not know how to estimate, and which they are still trying to figure out how to estimate today, nearly five years later. Nonetheless, the FQPA opened the door for increased use of probabilistic risk assessment methods, and the U.S. EPA supported the development of tools that produce distributions of risk demonstrating the variability and/or uncertainty in pesticide-related risk assessment results and issued guidelines related to the use of these tools. While the effort remains far from complete, considerable analytical progress has been made, including the important recognition that time matters in the context of assessing risks and assuming lifetime average numbers for model inputs could lead to misleading results.

The production of probabilistic risk assessment results that represented a paradigm shift away from the use of point estimates created new challenges for risk managers. Instead of comparing single point estimates to "bright lines" of risk, risk managers must now struggle with decisions about how to use distributions in the decision-making process (25). Clearly recognizing variability in a population leads to questions about who to protect and how much, questions that look a lot different in nature than the question that they replaced: "Is this risk above the bright line or not?" While appreciation of the artificial nature of the "bright line" criterion and the dramatic oversimplification of the risk assessment required to derive a point estimate might provide some reassurance of the importance of using a probabilistic analysis to characterize the variability and uncertainty in the risks, it does not make the job of picking criteria to determine the "acceptability" of risk any easier. Following much debate, the U.S. EPA decided to make the 99.9th percentile individual its "threshold of regulatory concern" when assessing acute dietary exposure to a pesticide residue (with the expectation that a sensitivity analysis will be conducted, as appropriate, to properly gauge the "reasonableness of the upper-end percentile estimates"), but it did not select a percentile goal for chronic exposures due to limitations in the existing food consumption data (27).

While risk managers are now beginning to grapple with the challenge of dealing with probabilistic risk assessment results, the challenges for risk communication have only been minimally appreciated or explored. This paper extends two probabilistic risk assessment case studies to explore what happens when the results meet risk management and risk communication. The first case study explores the risks of dying on the ground from a crashing airplane, which Goldstein et al. (28) proposed as a good risk communication tool and Thompson et al. (29) recently reanalyzed using probabilistic methods. The second case study focuses on the deployment of motor vehicle airbags, which Graham et al. (30) assessed in the context of a cost-effectiveness analysis and which Thompson et al. (31) explored to identify the analytical errors that occurred in early estimate of the benefits of airbags and Thompson et al. (32) extended to consider the implications for cost-effectiveness analysis. These examples demonstrate how better characterization of variability and uncertainty in the risk assessment may lead not only to better risk management, but also to better risk communication. Following the case studies, the discussion explores some analogies to food safety and environmental risks and highlights remaining research issues associated with using improved sensitivity and uncertainty analyses in risk assessment for better risk management and risk communication.

2.0 LEARNING FROM THE PAST

2.1 The Risk to Groundlings from Crashing Airplanes

In 1992, Goldstein et al. (28) first estimated the risk of an American "groundling" dying due to crashing airplanes. Using a very simple model, they estimated the risk using a point estimate approach to find an average annual risk of 6×10^{-8}, and by multiplying this by 70 they estimated a lifetime risk of 4.2×10^{-6}. Goldstein et al. (28) emphasized that this risk might be very useful in the context of risk communication because: (i) it is a manmade risk (ii) arising from economic activities (iii) from which the victims derive no benefit and (iv) exposure to which the victims cannot control. While some of these criteria may be arguable (e.g., people living near airports can voluntarily move or they may derive some economic benefits from lower rents or housing prices or less car travel required to get to the airport if they fly frequently), these factors probably do make this risk generally one that is a good one for comparison to other technological risks with similar factors. Since this point estimate of lifetime risk exceeded the very commonly used "bright line" risk management threshold of 1×10^{-6}, Goldstein et al. (28) suggested it might be a useful risk communication tool, and in fact it has been used (33-35). Unfortunately, however, the analysis did not consider variability or uncertainty in the risk estimates or any sensitivity analysis.

Thompson et al. (29) recently reanalyzed the risks to groundlings from airplanes using more recent data from the National Transportation Safety Board and also explicitly characterized the variability and uncertainty in these risks using a geographical information system approach to modeling the population around airports. Following the approach used by Goldstein et al (28) and simply updating the data to reflect current information, the results suggest that the average annual risk is now 1.2×10^{-9}, which becomes 9×10^{-7} when multiplied by 70 and which falls below the risk management "bright line" threshold of 1×10^{-6}. While this result alone is interesting because it shifts the point estimate from above 1×10^{-6} to below that level, this average result still fails to consider the variability and uncertainty in the risks. In the analysis of the variability and uncertainty of this risk, Thompson et al. (29) find that the exposure to groundling fatality risk varies by about a factor of approximately 100 in the spatial dimension of distance to an airport, with the risk declining rapidly outside the first 2 miles around an airport. Figure 1 shows the estimates of the current annual risks as a function of distance away from the airport for the population. Figure 2 shows the upper tail of the cumulative distribution.

Several key implications of this analysis emerge. First, from a risk management perspective, the risks of planes killing people on the ground are very small, and for most of the population that lives greater than a mile or two from an airport, the annual risks are below 1×10^{-8}. Given these remarkably low levels for most people, the lack of public concern about the risks of planes falling out of the sky and killing people on the ground is not surprising. Second, even for this very small risk, approximately 3% of the U.S. population experiences an annual risk that exceeds 1.5×10^{-8} (which when multiplied by 70 leads to a lifetime risk estimate exceeding 1×10^{-6}).

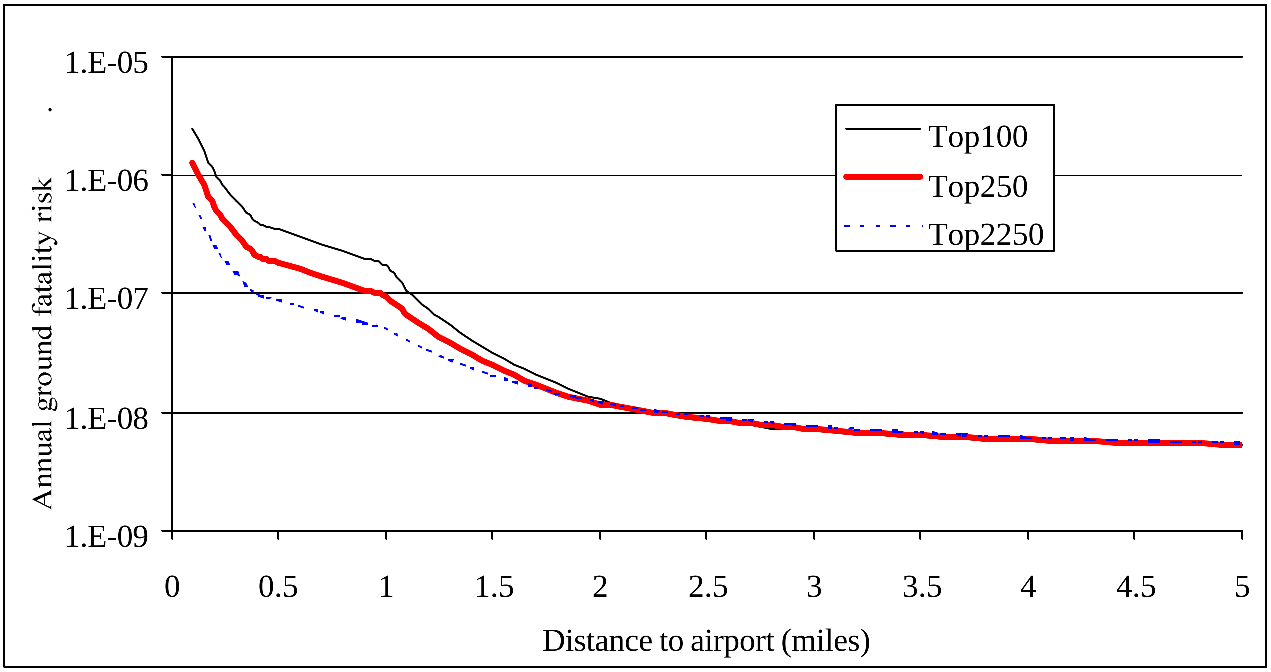

Figure 1. Variability of the risk of groundling fatalities in the dimension distance to an airport for the Top100, Top250, and Top2250 airports (*Source*: Ref. 29, Figure 7).

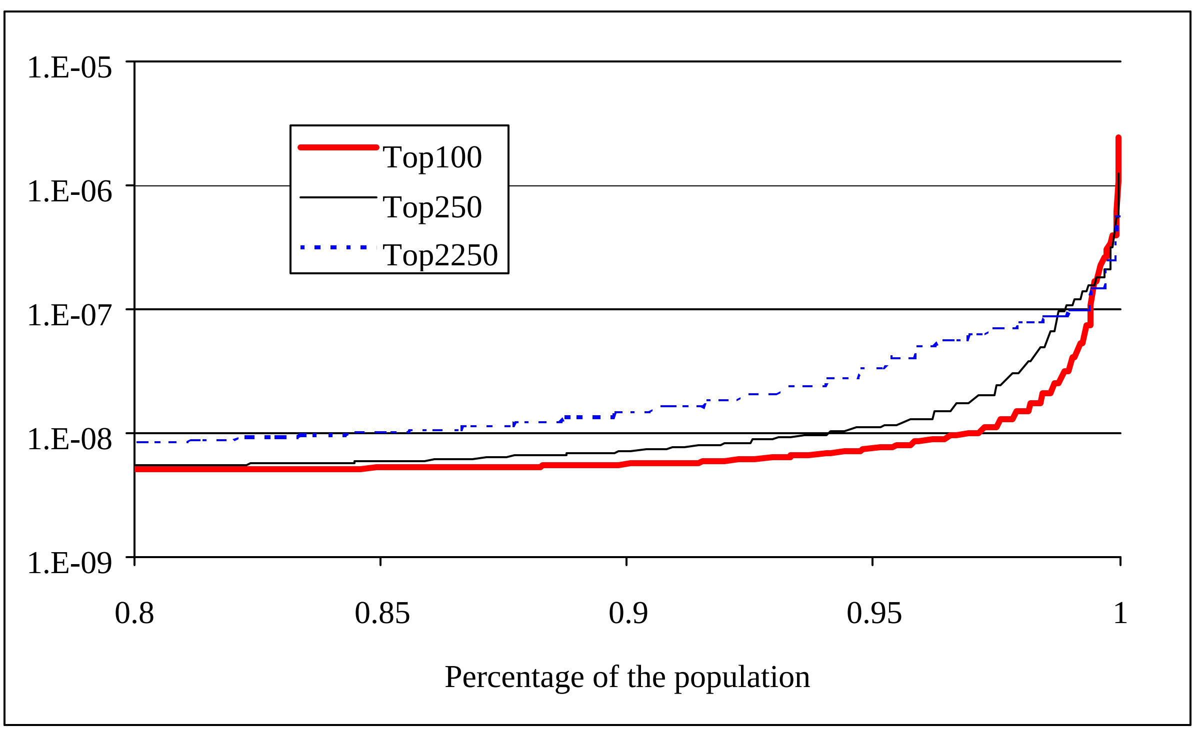

Figure 2. Upper percentiles of the estimated risks for the entire population

Hypothetically, if we were to apply a 99.9th percentile "threshold for regulatory concern" to this risk (recognizing that it is a "chronic" risk), then that might lead to some consideration of actions that could be taken to reduce this risk, at least for the people who live close to the airport. Airport authorities do benefit economically from their activities that appear to impose heightened risks to nearby residents and consequently remedial, and/or compensatory measures might not seem inappropriate based on that risk management criterion. However, several limitations in this analysis lead to uncertainty in the results. Specifically, Thompson et al. (29) assumed that characterizing the variability in risk as a function of distance to the airport would suffice; however, greater resolution of this variability could be obtained by considering the distance to runway flight paths, which would better incorporate the specific dynamics at each individual airport. Second, Thompson et al. (29) relied on the use of Census data to estimate the number of people living within a certain distance of the airports and ignored mobility in the population by using the resident population at that distance as the denominator in the risk assessment. Thus, the results give the hypothetical risk of someone remaining at distance d during an entire year, and any given individual will exhibit diurnal and seasonal displacements that may heighten or reduce the risk in Figure 2. Finally, considerable uncertainty arises in extrapolating the annual risks to lifetime risks. When we look at this particular case, we see that airplane travel risk reduction activities including better plane design and air traffic control continue to reduce the chances of collisions and make airplanes safer. However, the increasing size of the population, the number of people traveling by plane, and the trend toward urbanization may all lead to increases in the groundling risks. Airplane travel 70 years ago was very uncommon, and the groundling risk estimates for that period in American history would probably have been much lower than the estimate given by Thompson et al. (29). Similarly, we can only guess how airplane travel will change in the next 70 years, just as we can only guess that life expectancy in 70 years may be higher (e.g., it is now approximately 75 years). Further, we know that people are highly mobile and that the probability of living in one place for an entire lifetime is very small. Thus, extrapolating the current annual risk numbers to a lifetime of 70 years introduces a great deal of uncertainty into the analysis. In fact, the approach of multiplying the distribution obtained for the annual risk by 70 years implicitly assumes that the distribution will not change over time and ignores the fact that uncertainty about the current distribution being representative of future years increases with the number of years. This suggests that going from the distribution that shows variability in annual risks to the one that shows lifetime risks would require another dimension that would convey the uncertainty, which should be expected to get wider as the length of time included in the extrapolation increases.

From a risk communication perspective, these results provide an important insight that is completely lost in the average risk estimate. They show that while the risk for most people is very small, so small that many people would consider it to be negligible, the risk is not zero for anyone; and for the small percentage of the population that lives near airports, the risks appear to exceed the commonly used risk management criterion of one-in-a-million if extrapolated to a lifetime assuming that people stay in one place for their entire lives. Using the average result for the entire population as suggested by Goldstein et al. (28) in the context of risk communication is very misleading, because it suggests that the risks are larger for the entire population than they really are and it ignores the fact that some people are at what some might consider a significantly elevated risk. In this case, doing a proper uncertainty or sensitivity analysis is critical to accurately characterize the risks for individuals in the population.

2.2 The Risks and Benefits of Airbags

The case of mandatory airbags in motor vehicles also provides an important example of where insights from the sensitivity analysis and framing of the issue can lead to very different outcomes. Early evaluations of airbags based primarily on experimental testing and engineering judgment made different predictions about the lifesaving benefits of this technology. The National Traffic Highway Safety Administration (NHTSA) estimates from 1977 to 1987 were that 9,000 lives could be saved each year if all passenger cars were equipped with airbags (31). Now, over a decade later, extensive real-world crash experience led to revision of lifesaving estimates downward and NHTSA currently assumes an annual lifesaving of approximately 3,000 lives each year when the fleet is fully equipped with frontal airbags (31). Thompson et al. (31) pinpointed four major errors in lifesaving forecasts: (1) a large optimistic bias in the estimate of airbag effectiveness for unbelted adult occupants; (2) a pessimistic bias in the estimate of the number of adult motorists who would wear lap/shoulder belts; (3) a generally pessimistic view of the number of occupants who would be at risk of fatal injury and potentially available for protection by airbags, and (4) poor appreciation of the unique hazards that airbags pose for children under the age of 12. Graham et al. (30) performed a cost-effectiveness analysis for airbags that showed large differences in the cost-effectiveness of the driver and passenger airbags, with the passenger airbags being less effective overall in large part because young children are more likely to sit in front of a passenger airbag and be killed by it. This analysis included both one-way and two-way sensitivity analyses that showed how the estimates of the cost-effectiveness ratios changes as a function of key model inputs. Recently, Thompson et al. (32) performed a retrospective analysis of the cost-effectiveness ratios using a one-way sensitivity analysis and quantified the inputs that had the most significant impact on the estimated cost-effectiveness of airbags based on the 1984 model inputs compared to the 1997 model inputs.

Remarkably, for a lifesaving technology, airbags can pose a significant risk, particularly for children and small-stature adults. Current estimates of airbag effectiveness suggest that on net airbags kill more children under the age of 10 than they save and that passenger airbags are bad for children. Graham et al. (30) estimated that passenger airbags save 5 to 10 adults for every child that they kill. If we put this in the context of the risk-only management criterion, the results clearly demonstrate a problem. Airbags put approximately 10% of the U.S. population at a greater risk of dying in a motor vehicle accident than those members of the population would experience in the absence of the airbag, and annual risks of dying in motor vehicle accidents already exceed 1×10^{-6}. Again, if we look at this result as a function of how the risks distribute in the population, airbags simply could not meet the risk management criterion that they protect a 99.9^{th} percentile individual given their harmful effect on children who comprise more than .1 percent of the population. Even without meeting this criterion, however, airbags may be good public policy because they save more lives overall than they take. One of the interesting ironies of airbags is that they were an engineering solution to a behavioral problem (i.e., the fact that people were not wearing their safety belts), but given their impact on kids, the engineering solution (i.e., airbags) has led to the need for a new behavioral solution (i.e., the need to have children ride in the back seat).

By explicitly considering the variability in the population, risk management efforts can be developed to target reducing the risks for children and small-stature adults, and had this been the expectation from the beginning, airbags may have been designed differently in a way that avoided the tragic risk trade-offs that have been observed. For example, campaigns to require children to sit in the back seats of motor vehicles could have been implemented sooner, reducing the exposure of children to passenger airbags. Also, airbags could have been "depowered" initially, instead of "over designed" as required by the original standard (31). Recognition of variability in the population with respect to how people interact with airbags led the NHTSA to change its motor vehicle compliance standards for airbags such that the tests now use different sizes of crash dummies instead of simply the large adult male-sized dummy.

Appreciating the variability in the population also clearly impacts risk communication. Clearly simply saying that airbags save approximately 3,000 lives each year fails to capture the significant threat that airbags pose to children and small-stature adults. Once this variability is acknowledged, however, opportunities for reducing the risks to those groups may be recognized and implemented.

3.0 DISCUSSION

These two cases represent examples of risks that are familiar and relatively well characterized. The implications of applying a simple, seemingly objective bright-line risk management criterion like protecting the 99.9^{th} percentile individual to these cases would appear to be a potentially bad idea and should lead to questions about whether the application of such a criterion in any context might make sense, particularly based on highly uncertain lifetime risk estimates.

Appreciating the variability in risk should lead to better understanding of the distribution of the risks and should increase the opportunities to make changes that can target and reduce risks for those people at the highest risk. Appreciating uncertainties, including uncertainty about variability in the population, can lead to appropriate consideration of the option of seeking better information, using a value-of-information approach as suggested by the National Research Council report *Understanding Risk: Informing Decisions in a Democratic Society* (Ref. 36, see p. 110).

While these examples may be categorically different than examples that could be found in the context of other risks including pesticide and food-related risks, at a basic level these cases would suggest that variability and uncertainty in risks should be explicitly considered and addressed to ensure that ignoring them does not mislead either the risk manager or the public. Recently the FDA has performed probabilistic risk analyses for a number of pathogens (e.g., Foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods, *Vibrio parahaemolyticus* in raw molluscan shellfish, Fluoroquinlone resistant *Campylobacter* attributed to the consumption of chicken), as has the USDA (e.g., for *E. coli* O157:H7 in beef in the U.S., *Salmonella Enteritidis*-infected shell eggs and egg products). Probabilistic risk assessments are also playing a role in the deliberations of the World Trade Organization, and we can expect that the number of risk management decisions based on the results of probabilistic analyses will continue to grow. In these cases, the risk managers are now grappling with making decisions and issues that we can expect to see arise include discussion of how to deal with the implications of variability in the context of managing risks, particularly as a function of the underlying source of the variability (e.g., differences in genetic susceptibility, voluntary and involuntary behaviors, etc.). Clearly more research is needed to improve our ability to effectively implement the analytic-deliberative process (36) and to make risk management more iterative.

We have a long way to go in developing effective ways to present the results of probabilistic risk assessments and sensitivity analyses to risk managers and to the public and in ensuring that these results do ultimately lead to improved risk management decisions. At a minimum, we must shift away from the past practices of using point estimates of risks and benefits and begin to teach people that any point estimate probably represents a gross simplification that may ignore important underlying dynamics. Indeed, we will have to find an effective way to get past the legacy of the point estimate approach that has left the public believing that we can estimate risks exactly with incredible precision (which has sometimes been expressed with far more significant figures than justified), and which leads to the perception that when we come back to the public with the results of an uncertainty analysis we are now *more* uncertain than we were when we presented the point estimate (even though from an analytical perspective we are typically more confident that we understand things better having gone through the probabilistic analysis). This means that we must arm risk communicators with better information about variability and uncertainty in the risks that they use for risk comparisons, test different strategies for communicating about variability and uncertainty in risk using both qualitative and quantitative information, and strive to develop appropriate risk management criterion for risks assessed probabilistically.

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