Limits to Science for Assessing and Managing Environmental and Health Risks

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I. CLAIMS AND EXPECTATIONS

Risk is a four letter word that is being used ever more frequently in discourse over regulation and public policy. Risk-based decision-making has been widely promoted as the preferred means for bringing rationality into the often fuzzy world of environmental and public health policy and decision-making.[1] Those advocating a risk-based approach, including U.S. Supreme Court Associate Justice Stephen Breyer,[2] have noted the inefficiency and waste that have been associated with public policies demanding enormous resources in futile attempts to reduce *de minimis* risks further towards zero. Yet, the exposition of countless examples of irrationality in past public policies cannot guarantee that a risk-basis can transform random or erratic decision-making by providing a rationale that claims to be armoured with the objective authority of science. To understand the dimensions of this problem and make better decisions, we must explore what science can and cannot provide as foundations to a risk-based decision-making rationale.

Because everyone has some notion of what risk means, using risk as a foundation for public policy provides a prime candidate for the first of Kaplan's two theorems of communication failure, namely:[3]

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1 A. Finkel & D. Golding, eds., 1994. *Worst Things First—The Debate Over Risk-Based National Environmental Priorities* (Washington, D.C.: Resources for the Future, 1994); K.R. Foster, D.E. Bernstein & P.W. Huber, eds., *Phantom Risk—Scientific Inference and the Law* (Cambridge, MA.: The MIT Press, 1993); E.M. Whelan, *Toxic Terror—The Truth Behind the Cancer Scares* (Buffalo: Prometheus Books, 1993); A. Wildavsky, *But Is It True? A Citizen's Guide to Environmental Health and Safety Issues* (Cambridge, MA.: Harvard University Press, 1995).

2 S. Breyer, *Breaking the Vicious Circle—Towards Effective Risk Regulation* (Cambridge, MA.: Harvard University Press, 1993).

3 S. Kaplan, "The words of risk analysis" (1997) 17 Risk Analysis 407.

> "Theorem 1: 50 % of the problems in the world result from people using the same words with different meanings.
>
> Theorem 2: The other 50 % comes from people using different words with the same meaning."

What is Risk?

Although advocates of risk-based decision-making seek to be rational, they often overlook the logical step of defining what they mean by risk in their communications promoting a risk-based approach. So, what do we mean by risk? Popular notions are as diverse as they are prevalent. The diversity of these popular notions can be illustrated by considering a reasonably comprehensive dictionary citation:[4]

> "**risk:** *noun* **1.** exposure to the chance of injury or loss; a hazardous or dangerous chance: It's not worth the risk. **2.** Insurance. **a.** the hazard or chance of loss. **b.** the degree of probability of such loss. **c.** the amount that the insurance company may lose. **d.** a person or thing with reference to the hazard involved in insuring him, her or it. **e.** the type of loss, as life, fire, marine disaster, or earthquake, against which an insurance policy can be drawn. **3. at risk, a.** in a dangerous situation or status; in jeopardy; families at risk in the area of the weakened dam. **b.** under financial or legal obligation, held responsible: Are individual investors at risk for the debt part of the real estate venture? **4. take** or **run a risk**, to expose oneself to the chance of injury or loss; put oneself in danger; hazard; venture. *transitive verb* **5.** to expose to the chance of injury or loss; hazard; to risk one's life. **6.** to venture upon take or run the chance of; to risk a fall in climbing; to risk a war. **Synonyms**. **1.** venture, peril, jeopardy. […] **5.** imperil, endanger, jeopardize. **6.** chance."

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4 *Dictionary of the English Language*, 2d ed., (New York: Random House Publishers, 1987).

Although the diverse range of meanings captured in the foregoing array of definitions might not readily offend our own personal concept of risk, a closer examination reveals that many of these meanings could invoke Kaplan's first theorem of miscommunication. Two illustrations will suffice to make my point about differing and even opposing meanings.

First, most of the meanings carry a negative connotation with notions of danger, peril or loss. Yet the notion of risk as venture relates to taking a chance for the prospect of gain. Among entrepreneurs, a strong propensity for risk-taking is an essential and inherently positive characteristic. This aspect is often overlooked in debates about risk issues where the opportunities that may be lost with regulation are not explicitly weighed against the risks to be averted by regulation.[5]

The other contrast relates to risk in relation to insurance. The insurance industry was the first to institutionalize concepts of risk and the longest standing group of professional risk managers are those business managers responsible for insurance or related means of covering financial risk. Consequently, the concepts of risk adopted by the insurance industry are prevalent and influential in practice. Yet, these concepts are often fundamentally different from the notions adopted by risk managers concerned with more recent issues about environmental and health risks.

When I first realized about ten years ago that there seemed to be a critical difference in perspective between these groups, I queried a colleague on the insurance side of risk management practice. He told me an anecdote that captured the distinction. Imagine that you had two skydivers jumping out of a plane, one with a parachute and one without, and you ask: "Who is the greater risk?" For most of us, we would judge the high level of peril facing the skydiver without the parachute and choose her or him as the higher risk. However, an insurance risk manager might logically choose the one with the parachute based on the rationale that the skydiver without a parachute is most certainly dead and accordingly is not an insurable risk. But, the skydiver with the parachute runs a substantial, but inherently uncertain chance of having the parachute fail. Consequently, the skydiver with the parachute could

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5 W. Leiss & C. Chocioloko, *Risk and Responsibility* (Montreal: McGill/Queens University Press, 1994).

be judged to be a greater risk because of the uncertainty in knowing what insurance premium to charge *versus* the certainty of denying coverage. While this anecdote is hypothetical and simplistic, it should make the point that risk can carry opposite meanings for different professionals coming at risk from different perspectives.

Imagine how diverse the understanding of risk can become when you move outside of professional practice and engage the public about risk and what it may mean to them. Covering the field of risk perception is beyond the scope of this presentation, but it is should be noted that various public perspectives on risk can and do differ dramatically from professional and scientific notions. In these cases, the potential is enormous for Kaplan's first theorem to cause communications chaos. An excellent collection of case studies of major risk communication failures is provided by Powell and Leiss.[6]

Whatever notion or notions of risk we may prefer, there is clearly an imperative to explain what meaning we assign to risk for the purposes of managing risk. In my experience, the most useful comprehensive notion of risk can be built upon the concepts first outlined by Kaplin and Garrick[7]. They proposed that risk is a multidimensional entity comprising the answers to three questions:

- What can go wrong?
- How likely is it?
- What are the consequences?

The answers to these questions, which effectively amount to an assessment of risk, combined with a need to specify a time frame and with consideration of some essential human issues that have been well described by Renn,[8] can lead to a functional notion of the kind of risk that we attempt to assess and to manage. This notion of risk is a prediction or expectation that involves:

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6 D. Powell & W. Leiss, *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication*, (Montreal: McGill/Queens University Press, 1997).

7 S. Kaplan & B.J. Garrick, "On the Quantitative Definition of Risk" (1981) 1 Risk Analysis 11.

8 O. Renn, "Concepts of Risk" in S. Krimsky & D. Golding, eds., *Social Theories of Risk* (Westport: CT Praeger, 1992) at 52.

- a hazard (the source of danger);
- uncertainty of occurrence and outcomes (expressed by the probability or chance of occurrence);
- adverse consequences (the possible outcomes);
- a time frame for evaluation;
- the perspectives of those affected about what is important to them.

These features of risk may be expressed for the purposes of risk assessment and risk management as:

> "Risk is the predicted or expected likelihood that a set of circumstances over some time frame will produce some harm that matters."[9]

Implications for Decision-Making

The foregoing notion of risk is practical and robust. But if we accept that assessed risk is always a prediction with attendant uncertainty and is comprised of at least the elements listed, we face some inevitable conclusions about risk-based decision-making and the underlying rationale for pursuing this approach. These conclusions include:

1. Risk cannot be represented objectively by a single number alone.
2. Risks cannot be ranked on strictly objective grounds.
3. Risk should not be labeled as "real."

The foregoing conclusions are generally not acknowledged in the claims made by advocates of risk-based decision-making. On the contrary, some advocates have promoted expectations that risk-based decision-making can be the rational panacea for resolving all irrational public policies for risk management.

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9 C.G. Jardine & S.E. Hrudey, "What is Risk? Chapter 17" in D.J. Briggs *et al.*, eds., Environmental Health For All (Dordrecht: Kluwer, 1999) at 205.

II. CAUTIONS AND REALITIES

Risk as a Single Number

One appeal of risk to rationality is the belief that it can be expressed numerically. Numbers are influential and whenever a decision-maker is faced with choosing between quantitative evidence and qualitative evidence, the quantitative evidence may be viewed as more scientific, rational and ultimately more persuasive. An appealing feature of assigning risk a single number is the utility this feature offers for ordering of priorities. The quantitative features of risk primarily include the magnitude of the consequences (*e.g.* number of lives lost per incident) and the probability of that magnitude occurring (*e.g.* 1 incident per 1000 exposure activities per year). This combination of numbers is often resolved arithmetically by taking the product of probability and consequences. However, such a simple product adopts an inherent equivalency between combinations such as a 1 in a 1000 possibility of 1000 deaths being treated as equivalent to the certainty of 1 death. Likewise, simple arithmetic approaches to expressing risk as a single number often adopt implied equivalencies in time frame such as 1 death every year for 10 years being treated as equivalent to 10 deaths at one time, once every 10 years.

The foregoing assumptions of equivalency might be reasonable default assumptions, but they inevitably adopt an implied weighting of importance that may not be universally or even commonly held. For example, it may be more practical to prevent incidents involving large numbers of people than it is to avoid incidents involving individuals because our society maintains some value and respect for individual autonomy. The implied weighting that is commonly used cannot be held to be the only rational weighting that could be used in risk calculations. Matters become even more complex if qualitative issues are considered. Do we weight painless death from a lightning strike the same as we weight a lingering, chronic and painful death from ALS? Do we count the death of a 90 year old the same as a 10 year old? Do we count permanent, severe and painful disability as a greater or lesser negative than death?

The multidimensional character of risk can only be distilled into a single number by assigning implicit or explicit weighting factors to various numerical elements of the risk concept. Then, some algorithm must be adopted to combine them. Any such weighting of elements must involve value judgment. Despite the appeal that numerical estimates of risk offer to our search for rationality, such calculations, which inevitably depend upon underlying value judgments, should not be cloaked with the apparent authority of strict scientific objectivity.

Risk Ranking for Setting Priorities

A major appeal of risk as a rationale for environmental decision-making is the possibility of avoiding the seemingly random and irrational priority setting that has littered the environmental decision-making landscape. The expectation is that if we can introduce risk as the metric, then we can simply rank the risks in order of priority and deal first with the greatest risks.[10] But any strictly objective ranking scheme would be based upon numerical sorting from largest to smallest risk number. Such objective ranking can only be achieved, unambiguously, by expressing risk as a single number. According to the previous conclusion, we cannot assign risk a single number in an entirely value-neutral manner.

Another recurring theme with risk is the matter of uncertainty in our estimates of risk. If we focus on the probability element, we will see in the next section that we should have differing levels of confidence in our estimates of probability depending on the quality of the evidence relied upon. We can often express our level of confidence with numerical confidence intervals, much like we usually hear expressed for opinion polls. For example, we might hear that 58 %, plus or minus 5 %, of Canadians would favour Leslie Nielsen for Prime Minister, 19 times out of 20. This is an expression that the 95 % confidence interval (19 out of 20) on the response is between 53 % and 63 %. Greater uncertainty in our estimate will be reflected by a wider confidence interval. These confidence intervals reflect only the survey sampling error but they offer no insight about response bias (*i.e.* Does the question influence the answer? Are the answers meaningful for judging actual voting intentions?)

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[10] A. Finkel & D. Golding, eds., *supra* note 1.

The existence of uncertainty in probability estimates of risk is unavoidable, even if it is not commonly expressed. This creates an interesting dilemma for risk ranking as illustrated in Figure 1.

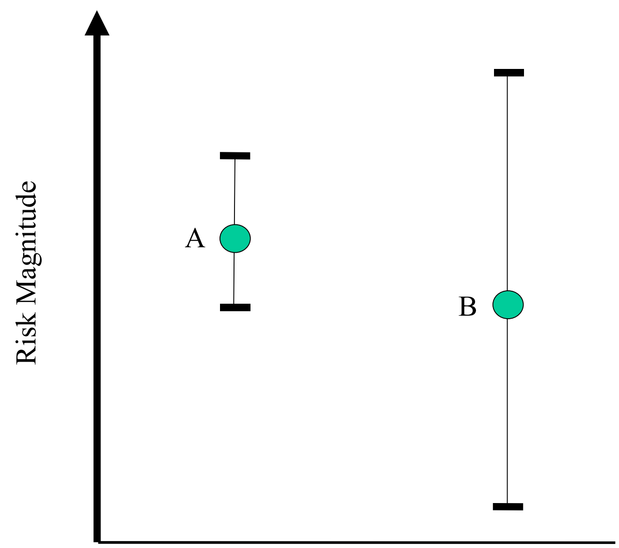

Figure 1: Risk Comparisons Considering Uncertainty (Confidence) Intervals

Which risk has a greater probability, risk A or risk B? The large size of the confidence intervals shown may seem pessimistic, but such wide confidence intervals are very common for estimated low level risks. This raises the challenge that we should really be ranking probability distributions rather than point estimates of probability. If we demand higher confidence (say 99 %), the size of the confidence interval and the potential for greater ambiguity created by overlapping confidence intervals will inevitably increase. In summary, ranking risk on strictly objective grounds is not possible given the true character of risk numbers.

The Reality of Risk

The premise that "perceived risks" must be distinguished from "real risks" has been an implicit, if not an explicit objective of risk-based decision-making. This premise has a long history. The theme of the inaugural meeting of the Society for Risk Analysis in 1981 was: "The Analysis of Actual versus Perceived Risks."[11] The merits of this debate can be addressed by considering the major elements of risk. Certainly, dangers are real. Likewise, consequences of those dangers can be real. However, when we consider risk, we are obliged to consider not only what could really happen, but also how likely is it; *i.e.* what is the probability? Reality must be judged by considering all of these elements.

A key aspect of the argument for risk being "real" is the quantitative character of risk, because we regard numbers as being more verifiable than qualitative characteristics. As noted above, a key element of the numerical character of risk is the probability estimate. We might expect that probability, being a mathematical concept, is free of debate about its meaning or interpretation. On the contrary, Bernstein[12] has documented the evolution of our modern concepts of probability including the debates that have raged about the meaning and interpretation of probability. Kleindorfer *et al.*[13] have described three different schools of probability as: classical, frequency and subjective.

The classical school is amenable to theoretical analysis because it defines probability as the number of specified outcomes divided by the total number of possible outcomes. This definition requires that both the numerator and denominator be known completely. Classical analysis is commonly applied to games of chance. The probability of an event (*e.g.* cards—1 in 13 chance of selecting any ace from a full deck) can be predicted strictly from a theoretical analysis of the circumstances. More complicated outcomes can then be calculated using the mathematical laws of permutations and combinations without actually performing the action. The conditions necessary to satisfy the requirements for classical

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11 V.T. Covello *et al.*, eds., *The Analysis of Actual versus Perceived Risk*: *Advances in Risk Analysis*, vol. 1 (New York: Plenum Press, 1983).

12 P.L. Bernstein, *Against the Gods—The Remarkable Story of Risk* (New York: J. Wiley, 1996).

13 P.R. Kleindorfer, H.C. Kunreuther & P.J.H. Schoemaker, *Decision Sciences—An Integrated Perspective* (Cambridge, U.K.: Cambridge University Press, 1993).

analysis are very specific and are generally too hypothetical to be applied to any meaningful health risk estimation. An artificial health risk example would be that the probability of drawing the bullet in Russian roulette, with a fair six-chamber revolver, would be 1 in 6.

The frequency school establishes probability estimates based on observations of repeated events or trials. This perspective is widely used in actuarial work (*e.g.* insurance—frequency evidence based on analysis of prior outcomes such as life tables). The difficulty with the frequency view is that it only applies well to stable and repetitive processes. The advantage of the frequency approach is that it can be applied to any situation that can be observed through many repetitions, including those cases amenable to classical analysis. Unfortunately, many events cannot be measured this way simply because they are rare or cannot be repeated a sufficient numbers of times to allow a meaningful determination of relative frequency. Accordingly, one can estimate future probability of motor vehicle fatalities in a given area based upon historical data for that area, provided that future causative conditions remain unchanged. In this example, the causal connection between the motor vehicle incidents and the resulting fatalities is usually clear enough so that the issue of causation is a minor source of uncertainty.

The subjective school holds that probability estimates for real events cannot be measured in a strictly objective sense. Rather, probability estimates reflect a degree of belief or confidence that a specified event will occur. The confidence of the estimator may be based upon classical analysis and/or substantial frequency evidence, so the subjective label should not imply emotion or irrationality. However, the nature of the prediction demands some elements of judgment and subjective belief of the individual who is making the prediction. As such, the subjective school holds that probability is not strictly objective, even if the supporting frequency evidence is substantial. Uncertainty will arise because experience is usually limited and the causal connection is often not clear. So, you can be very certain about the motor vehicle fatality risk estimates, but you can be much less certain that your probability of getting brain cancer from using cell phones is greater or less than 1 in 1,000,000.

We should recognize varying levels of confidence in subjective probability estimates, depending on the amount, quality, coherence and relevance of evidence upon which the belief, or inference is formed. However, we cannot escape the premise that risk probability predictions usually have most in common with the subjective school. For example, we may have a high level of confidence in predicting the probability of a random motor vehicle fatality in Canada next year based upon our access to substantial empirical evidence to support a frequency-based estimate. However, suppose we asked an expert team of physicists, automotive engineers and emergency room physicians to estimate the same risk, but restricted their evidence to a detailed road map of Canada, a list of motor vehicle registrations and any of their basic, discipline-specific knowledge. The experts could even perform experiments using rodents in miniature vehicles and robots in full size vehicles. Their prediction, regardless of its objectivity or expert pedigree, would be far less reliable than one derived primarily from an analysis of frequency statistics. Yet, the latter more uncertain scenario is usually much closer to most health and environmental risk assessments than the former. So, while the probability prediction may be based upon substantial relevant experience, the composite notion of risk for any real environmental health circumstance will always involve substantial inference and judgment such that assessed risk probabilities are inevitably statements of belief.

Recognizing these differing concepts of probability is essential to understanding and communicating risk assessments. Classical probability carries the highest connotation of rigor and objectivity, yet it is largely irrelevant to risk assessment. Frequency probability is much more relevant to risk assessment if relevant empirical data are available and causal connections are clear. However, the predictions inherent in risk assessments which must deal with new situations, rather than exact replication of prior experience, inevitably require some recourse to inference and subjective probability.

When all the foregoing components of risk are combined, the prediction should not be labeled as “real.” However, we can and should focus on the reliability of the evidentiary basis and the quality of logical inference that has been used for generating any risk predictions. Most of us would place more reliance on a logically-derived prediction based upon extensive, relevant experiential evidence than one based strictly on the intuition or “gut” reaction of anyone, expert or otherwise. We may face some difficulty when social scientists argue that all risks are perceived. But, reasoned analysis of the concept of risk tells us that, in reality all risks are, at most, “inferred.” Arbitrary claims of reality for risk are only likely to distract us from a more important focus on how reliable is the basis for any risk prediction. Risk assessors and risk managers must not cloak their risk predictions and resulting management actions with more objective authority and confidence than their evidence and inferential procedures warrant.

Taxonomy of Health Risk Evidence and Uncertainty

There is a compelling need to consider the basis in evidence and inference that underlies any risk estimate. That evidentiary basis and the resulting inferential process used to reach judgments about health risks derives from the means we have at our disposal for studying environmental health risks.

Environmental and health risk assessment has been predicated on a simple model involving a chain of causation whereby a human receptor is exposed to an agent via one or more environmental media giving rise to a dose which may cause an adverse effect (Figure 2). This model must be recognized as an enormous oversimplification that does not realistically represent the Web of causal and contributory risk factors generally associated with any disease process.

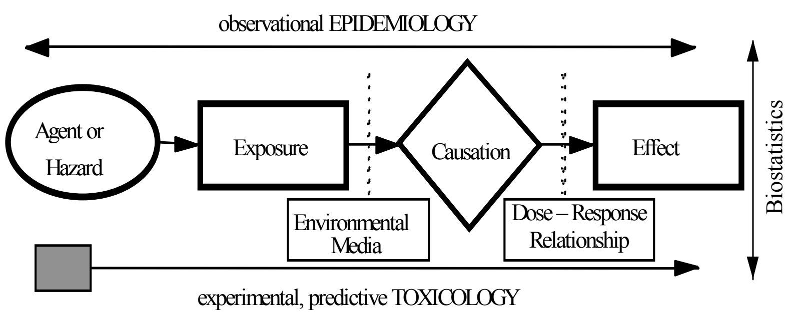

Figure 2: Causal chain model for environmental health risks[14]

14 S. Thomas & S.E. Hrudey, *Risk of Death in Canada—What We Know and How We Know It* (Edmonton: University of Alberta Press, 1997).

Our knowledge of the prevalence of various diseases in society is captured by our health care and vital statistics. These data may be collectively termed biostatistics in Figure 2. Evidence on causation relies upon epidemiology studies that seek to assign risk factors to various diseases based upon mostly observational studies of representative samples of human populations and upon experimental toxicology studies on animals.

Our knowledge about health risk can be better understood by considering uncertainty (Figure 3). The central core of this figure represents what is known, the remaining outer space is uncertain. If we look at what we know and how we know it, we find that the knowledge with the greatest certainty is the total number of deaths in a country in any given year. Of course, this is not particularly useful for risk management because it fails to inform us about cause, leaving us unable to focus our prevention. With every registered death in Canada, a death certificate is filed which must list an underlying cause of death. From this evidence, which is direct in the sense of being derived directly from individual fatalities, we obtain massive statistical data on reported causes of death. These involve considerable uncertainty because studies have shown that unless an autopsy is performed, the cause listed on the death certificate is often incorrect. This uncertainty is much higher for an elderly person dying while asleep than it is for a teenager killed in a motorcycle accident. Accordingly, there is a spectrum of uncertainty in statistics about cause of death that is a function of the nature of the cause (*i.e.* direct trauma vs. subtle disease) and the extent of medical diagnosis that may have preceded the fatality.

Figure 3: Hierarchy of Health Risk Evidence and Uncertainty[15]

Although this "direct" evidence is better for characterizing risk to inform risk management than the total number of deaths, this evidence becomes increasingly difficult to interpret as the cause of death becomes more complex or subtle. So, knowing that about one out of three Canadians will die of cancer does not tell us what factors are causing those cases of cancer. As a result, we are left without the risk characterization insights needed to guide risk management. Accordingly, we must resort to epidemiolgical studies, which collect indirect evidence and apply considerable inference to identify risk factors that contribute to the documented causes of death. These approaches are indirect because they rely on samples of the population. They are preferably studied as groups of individuals to seek correlation between their exposure to risk factors and whether they experience a specified disease. The epidemiologic method is inherently limited to demonstrating correlation as opposed to causation.[16] The search for correlation is conducted in the presence of many confounding factors, and recourse must be made to considerable inference to propose a causal relationship between a risk factor and an adverse outcome. Likewise, because only samples of the population can be studied, with findings then generalized to the overall population, the underlying evidence is more indirect than the death certificate evidence, which covers all deaths. All of these factors contribute to greatly increase the uncertainty in knowing that any epidemiologic risk factor is responsible for any cause of death.

Epidemiologic evidence is limited for the majority of environmental health risks so that most are evaluated by risk assessment using evidence from toxicology experiments. In the toxicology approach the evidence is based on animal experiments and risk is estimated by a process of predictive inference. Application to humans relies upon extrapolation from high dose experiments to the low doses that occur in

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15 *Ibid.*

16 M. Angell, *Science on Trial—The Clash of Medical Evidence and the Law in the Breast Implant Case* (London: W.W. Norton).

the environment plus extrapolation from animals to humans. These processes introduce an enormous number of unknowns that greatly inflates the uncertainty inherent in the risk predictions. However, the primary advantage of this predictive inference is that, despite the enormous uncertainty that is introduced, it can be used to anticipate risks before substantial human exposures occur. This anticipatory factor is clearly advantageous for allowing risk management to be preventive in scope.

The foregoing taxonomy of health risk evidence and inference illustrates that our uncertainty grows enormously in relation to what we know as we progress from *direct evidence* up through *indirect evidence* to *predictive inference* (Figure 3). Yet the questions we typically face with environmental health risks often demand that we make use of the predictive inference from toxicological risk assessment. Those demands are valid, but we must understand that the objectivity and authority that may apply to the best direct evidence is not equally valid for inferential health risk predictions.

Realistic Perspectives on Causation

The model in Figure 2, which currently underlies our approaches to environmental health risk assessment, is grossly oversimplified. Even for infectious diseases that are caused by identifiable pathogens, we recognize that there are multiple factors that have a bearing on the disease causation process. Rather than a simple linear chain, we can often describe a complex Web of causal factors. However if we define a cause of a disease as an event, condition, characteristic or a combination of these factors which plays a role in producing the disease,[17] then we can consider three major classes of cause: *sufficient*, *necessary* and *contributory*.

A *sufficient cause* is one that is, of and by itself, sufficient to assure that a disease will arise. Given the complex Web of causation that is involved in most human diseases, this is a demanding premise that is not likely to be met by any environmentally mediated causes, at least not at the exposure levels normally likely to be encountered from the

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[17] R. Beaglehole, R. Bonita & T. Kjellstrom, *Basic Epidemiology* (Geneva: World Health Organization, 1993).

environment. A sufficient cause of death would be the example of our skydiver without a parachute.

A *necessary cause* refers to one that must be present for the disease to occur. Most infectious diseases are defined in terms of the pathogen that causes them (*i.e.* AIDS is caused by HIV, the human immunodeficiency virus). The same logic could be applied to any other disease that is defined specifically in terms of the causal agent. Even though other diseases may share similar symptoms, the specific diagnosis may be tied to the causal agent. Accordingly, pathogens or other agents can be seen as necessary causes for the diseases they define, but we can also recognize that even the most virulent pathogen is not a *sufficient cause* because exposure to the pathogen does not guarantee that the disease will follow. Among known infectious agents, perhaps HIV comes closest to being both necessary and sufficient for causing AIDS.

A *contributory cause* is simply an agent or risk factor that contributes to make a disease more likely to occur. Other than infectious diseases, environmental health risks mainly fall into this contributory class. So, although we can recognize benzene as being a human carcinogen because of evidence that benzene exposure is a risk factor for leukemia among occupationally exposed workers, benzene is neither *necessary* nor *sufficient* to cause leukemia in humans.

We need to be able to understand and evaluate the evidence of causation that we are relying upon, because uncertainty about health risks has different facets. Consider an analogy with a "positive" risk, the chances of winning a lottery. We know that our chances of winning the lottery will increase with the number of tickets that we buy, but unless we buy all of the tickets, there will always be some uncertainty about winning. In this sense, holding more tickets in search of the positive outcome might be seen as equivalent to having greater exposure (higher dose) giving rise to a greater chance of the disease. This situation is predictable, in a theoretical sense, as long as we are assured that there will be a draw and that someone will win the prize.

But suppose, instead of participating in a government lottery, that we hold a ticket in an underground lottery run by organized crime. Can we even be sure that there will be a draw? By analogy, for environmental health risks we must assess whether there will be anyone who will suffer the disease, as a result of environmental exposure to the hypothesized cause. In many cases, we know from high dose animal experiments or accidental, high level human exposures, that there will be adverse health effects if someone has an extreme exposure that was the equivalent of holding most or all the lottery tickets. But do we know that if many tickets are purchased, there will be a predictable (classical) probability of anyone winning, in direct proportion to the number of tickets they hold? We can expect proportional behaviour if we know the draw is fair and random. But suppose that anyone buying fewer than 100 tickets will have all their tickets excluded from the final draw. This would be like a threshold for an exposure to cause a disease. By analogy, the judgement we must make in resolving uncertainty in environmental health risks is to determine if there will be any draw at all (*i.e.* is the agent capable of causing the disease in humans at realistic exposure levels?). If there will be a draw, will it be random and fair? Or, will there be a threshold with holders of a small number of tickets excluded from any chance of winning (*i.e.* does an agent show a threshold of exposure, below which no disease causation occurs?). The regulatory policy that we choose to resolve these types of uncertainty will dictate the quantitative health guidelines that ultimately govern environmental risk management.

For administrative tribunals and the courts in civil matters, causation must usually be judged on the preponderance of the evidence. For any contributory cause to be judged to be responsible and liable to sanctions, its contribution to the causation should outweigh the contribution of all other contributory causes if the specified cause is to be judged as more likely than not to result in the specified disease.[18] In these circumstances we need to distinguish the question of how certain we can be that the cause under consideration is a contributory cause at all (*i.e.* will there be a lottery draw?) from how large a contribution this cause makes to the overall risk (*i.e.* what proportion of the lottery tickets do we hold?). We could believe with a high level of certainty that a contributory cause makes a definite, but very small contribution across the population. Likewise, we could believe with only a low level of certainty that a given contributory cause is the dominant cause of the disease. This distinction has been a major source of confusion at the interface between science and law because both matters involve uncertainty and both are commonly expressed in terms of probability.

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[18] *Supra* note 16.

The probability and risk issue is further complicated by the reality that we can only ever validate a risk prediction for populations or groups of individuals. We cannot validate a risk prediction for an individual. For example, a frequency-based risk estimate[19] predicts that a Canadian male in my age category stands about a 1 in 200 chance of death from any cause in the coming year. Whether I die or not in the next year will neither verify nor refute the validity of this individual risk estimate. A verification of this prediction could only be possible by having 200 clones of me, and following each while they are constrained to pursue identical activities for a year. If only one of those clones died in the year, that result would be consistent with the prediction. No real data that can be obtained on an individual could be interpreted as proving or disproving such an individual risk prediction.

III. USING RISK WISELY

Where does all of the foregoing leave us? Are we better off ignoring risk and seeking another basis for guiding our decisions. The short answer is a resounding no! Risk is an extremely useful concept for resolving many disputed issues in modern life. Provided that we take the trouble to explain carefully our meanings, risk offers a rich and valuable foundation for characterizing and resolving problems. Certainly, risk is a much better basis for setting priorities than any of its elements: hazard, probability or consequences considered alone.

In order to use risk wisely, we must recognize that it cannot be as determinative in our decisions as we might like it to be. Certainly, decisions would be much easier to render if risks could be known with absolute certainty to lie on one side or the other of an accepted risk standard. In such a case, the findings of the risk assessment would essentially make the decision for us. In reality, the best we can ask of risk assessment is to inform us about what little we do know with what level of certainty. Furthermore, risk assessment can and should reveal what we do not know that we ought to know. In our resulting informed state, our decisions will not be made more easily, but they should be better decisions. As we achieve better risk assessment in the future (more risk specific details about who, when, what, how much, etc.), the

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[19] *Supra* note 14.

challenge of making risk management decisions will become greater compared with the freedom of relying on our uninformed intuition.

At present, assessment of risk is only likely to provide us with the primary guidance for making decisions when we can be very confident that risks are either very high or very low. In the first case, we will see the need to take explicit actions even though the risk assessments will not be able to determine the best choices for managing those risks because of the range of inevitable individual and societal factors involved. In the second, we will be comfortable that explicit actions are not justified to reduce the risks below the low levels that are predicted. In reality, the middle ground is where most risk controversies ultimately fall. The risks are neither so large that action is demanded nor so small that action can be confidently dismissed. Challenges also arise for both high and low risks estimates that are accompanied by high uncertainty. In all of these more difficult cases, the risk estimate itself cannot determine the appropriate course of action and recourse to other guidance is needed to assure that a good decision is made. The following principles are offered for guiding societal risk management decision-making. The first four are adapted and modified from Hattis[20] while the last two are derived from my own experience.

1. Do More Good than Harm (Adaptation of the Hippocratic Oath, do no Harm)

The Hippocratic Oath which guides physicians in their management of health risk for their patients states: "*I will prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone.*" Because zero risk is unattainable for environmental and health risks it is not wise to promise "no harm." The ultimate goal of risk management should be to prevent or minimize risk. All risk management decisions will involve trade-offs—so the exercise is to balance the quantity and quality of "good" against any potential "harm."

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20 D. Hattis, "Drawing the Line: Quantitative Criteria for risk Management" (1996) 38 Environment 6 at 11-15, 35-39.

2. Provide a Fair Process of Decision-Making (Natural Justice)

In a democratic society, we hold the requirements for natural justice high among our behavioural expectations for public institutions. Parties who are potentially affected are often ignored in decisions that can affect their valid interests. Perceived lack of fairness underlies most public risk controversies. If parties carefully adhere to a fair process there will be a greater opportunity to keep the focus of discussion or debate on the quality of evidence and inference about risk, and thereby, on constructive solutions.

3. Insure an Equitable Distribution of Risk (Equity)

In a democratic society we hold the concept of equality of treatment as a basic ideal. Yet a lack of equity often underlies public risk controversies. Equity is very difficult to achieve because of qualitative differences among the elements of risk. An absolute equivalency of risk among all affected parties will not be achievable, but the nature of the distribution must be explicitly considered. The target of equity also requires consideration and balancing of who benefits and who is harmed by any risk.

4. Seek Optimal Use of Limited Risk Management Resources (Utility)

Inevitably, our resources (intellectual, tangible and financial) for achieving effective risk management are limited. This reality means that effective choices of risk management actions must be made. Optimal risk management demands using limited resources where they will achieve the most risk reduction or overall benefit. Pursuing this requirement will likely create challenging tradeoffs between individual risk and population risk.

5. Promise no More Risk Management than Can be Delivered (Honesty)

Creating expectations for risk management that cannot be satisfied will generate conflict that could be avoided. Failure to understand the limitations to our knowledge impairs our ability to make difficult decisions under uncertainty. The problem of misguided confidence in what the process of risk assessment, even with its scientific foundations, can deliver currently may be the largest single problem for risk management and risk communication

6. Impose no More Risk than You Would Tolerate Yourself (the Golden Rule)

The Golden Rule has served society extremely well as a beacon for guiding civilized human behaviour. The Golden Rule forces risk managers to abandon complete detachment from their decisions so they may understand the perspectives of those affected. Honouring this principle may be the most difficult of all, a reality that does not detract from its value as a guiding principle for risk management.

CONCLUSION

Risk-based decision-making has been widely promoted over the past decade as the cure for avoiding a number of costly policy decisions aimed at reducing uncertain, low level and *de minimis* environmental and health risks further toward zero. The appeal to rationality that has accompanied some of the promotion of risk-based decision-making has itself not been entirely rational. First, there is a need to clearly and comprehensively define what notion of risk will be used for the decision-making process. Given a viable and robust definition, we find that some of the appeal that risk-based decision-making has apparently offered to decision-makers is not justified. When we face the realities associated with the quantitative character of risk estimates, we are left with a much more cautious perspective about the claims of objectivity for risk-based decision-making.

A key element of risk is the notion of probability. Understanding that risk predictions must inevitably rely on subjective probability reveals that claims for strict objective authority for risk assessments are not justified. Our basis for developing evidence on health risk is fundamentally constrained, forcing us to rely on substantial inference to make health risk predictions. Likewise, realistic notions of causation further restrict our ability to make authoritative judgments about cause and effect.

Ultimately we find that risk predictions cannot prescribe the need for risk management unless they fall at the extremes of very certain high or low levels of risk. Even when we find a need for risk management actions, the choices of the best actions cannot be prescribed by the risk assessment predictions because of the value-laden choices that will need to be made in society. Accordingly, we must base our risk management decision-making on a sensible set of principles that can provide guidance for making those difficult, value-laden choices.

Health risk assessment plays a critical role in organizing our knowledge in a manner that can be used to anticipate and predict health risks. This predictive capability is essential to provide the preventive approach that is fundamental to risk management. However, we must acknowledge the evidentiary basis of predictions that health risk assessment can produce. We must avoid mistakenly assigning risk assessment predictions with the scientific authority that we should normally reserve for knowledge that the scientific method has been able to validate rigorously and directly.