# Articles

# Risk Assessment and Comparisons: An Introduction

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Risk assessment is presented as a way of examining risks so that they may be better avoided, reduced, or otherwise managed. Risk implies uncertainty, so that risk assessment is largely concerned with uncertainty and hence with a concept of probability that is hard to grasp. The results of even the simplest risk assessments need to be compared with similar assessments of commonplace situations to give them some meaning. We compare and contrast some risk estimates to display their similarities and differences.

**D** VERY DAY WE TAKE RISKS AND AVOID OTHERS. IT STARTS AS soon as we wake up. One of us lives in an old house that had old wiring. Each time he turned on the light, there was a small risk of electrocution. Every year about 200 people are electrocuted in the United States in accidents involving home wiring or appliances, representing a risk of death of about  $10^{-6}$  per year, or  $7 \times 10^{-5}$  per lifetime. To reduce this risk, he got the wiring replaced. When we walk downstairs, we recall that 7000 people die each year in falls in U.S. homes. But most are over 65, so we pay little attention to this risk since both of us are younger than that.

How should we go to work? Walking is probably safer than using a bicycle, but would take five times as long and provide less healthful exercise. A car or, better, public transport would be both safer and faster. Expediency wins out, and the car comes out of the garage. Fortunately, the choice nowadays is not between horse or canoe both of which are much more dangerous. The day has just begun, and already we are aware of several risks, and have made decisions about them.

Most of us act semi-automatically to minimize our risks. We also expect society to minimize the risks suffered by its members, subject to overriding moral, economic, or other constraints. In some cases these constraints will dominate, in others there will be trade-offs between the values assigned to risks and the constraints. Risk assessments, except in the simplest of circumstances, are not designed for making judgments, but to illuminate them (1). To effectively illuminate, and then to minimize, risks requires knowing what they are and how big they are. This knowledge usually is gained through experience, and the essence of risk assessment is the application of this knowledge of past mistakes (and deliberate actions) in an attempt to prevent new mistakes in new situations.

The results of risk assessments will necessarily be in the form of an estimate of probabilities for various events, usually injurious. The goal in performing a risk assessment is to obtain such estimates, although we consider the major value in performing a risk assess-

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ment is the exercise itself, in which (ideally) all aspects of some action are explored. The results, goals, and values of performing the risk assessment must be sharply contrasted with the cultural values assigned to the results. Such cultural values will presumably be factors influencing societal decisions and may differ even for risk estimates that are identical in probability.

#### **Risk and Uncertainty**

The concept of risk and the notion of uncertainty are closely related. We may say that the lifetime risk of cancer is 25%, meaning that approximately 25% of all people develop cancer in their lifetimes. Once an individual develops cancer, we can no longer talk about the risk of cancer, for it is a certainty. Similarly if a man lies dying after a car accident, the risk of his dying of cancer drops to near zero. Thus estimates of risks, insofar as they are expressions of uncertainty, will change as knowledge improves.

Different uncertainties appear in risk estimation in different ways (2). There is clearly a risk that an individual will be killed by a car if that person walks blindfolded across a crowded street. One part of this risk is stochastic; it depends on whether the individual steps off the curb at the precise moment that a car arrives. Another part of the risk might be systematic; it will depend on the nature of the fenders and other features of the car. Similarly, if two people are both heavy cigarette smokers, one may die of cancer and the other not; we cannot tell in advance. However there is a systematic difference in this respect between being, for instance, a heavy smoker and a gluttonous eater of peanut butter, which contains aflatoxin. Although aflatoxin is known to cause cancer (quite likely even in humans), the risk of cancer from eating peanut butter is much lower than that from smoking cigarettes. Exactly how much lower is uncertain, but it is possible to make estimates of how much lower and also to make estimates of how uncertain we are about the difference.

Some estimates of uncertainties are subjective, with differences of opinion arising because there is a disagreement among those assessing the risks. Suppose one wishes to assess the risk (to humans) of some new chemical being introduced into the environment, or of a new technology. Without any further information, all we can say about any measure of the risk is that it lies between zero and unity. Extreme opinions might be voiced; one person might say that we should initially assume a risk of unity, because we do not know that the chemical or technology is safe; another might take the opposite extreme, and argue that we should initially assume that there is zero risk, because nothing has been proven dangerous. Here and elsewhere, we argue that it is the task of the risk assessor to use whatever information is available to obtain a number between zero and one for a risk estimate, with as much precision as possible, together with an estimate of the imprecision. In this context, the statement "I do not know" can be viewed only as procrastination

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and not responsive to the request for a risk estimate (although this should not be read as condemning procrastination in all circumstances).

The second extreme mentioned, the assumption of zero risk, can arise because people and government agencies have a propensity to ignore anything that is not a proven hazard. We argue that this attitude is inconsistent if the objective is to improve the public health, may also lead to economic inefficiencies, and often leads to unnecessary contention between experts who disagree strongly. Fortunately, if risk assessors have been diligent in searching out hazards to assess, few hazards posing large risks will be missed in this way, so that there may be minor direct danger to human health from a continuation of the attitude.

#### **Risk Estimation Based on Historical Data**

The way in which risks are perceived is strongly correlated with the way in which they are calculated. Risks based on historical data are particularly easy to understand and are often perceived reliably. It is therefore easy to illustrate a risk calculated from historical data to understand some characteristics of risk estimation. There are plenty of data on automobile accidents (although never enough to make risk assessors happy). One thing that these data can tell us is the frequency of such accidents in the past and their trend through time. To make predictions, however, we must use a model. The simplest model is that there will be as many accidents next year as last, to within a statistical error of the square root of the number. A slightly more complicated, but perhaps more accurate, model might be to fit a mathematical function to numbers from previous years and to argue that next year's accidents will follow the trend given by this function. A possibly better and possibly more accurate model still might use all available information that might influence accident trends. For example, an oil embargo with a concomitant rise in oil price and reduction in automobile travel would be likely to reduce the risk of accident. In any event, it becomes clear that it is impossible to calculate any risk without a model of some sort, even the simple one that tomorrow will be like today.

#### **Risks of New Technologies**

We can only use the historical approach to estimating risks when the hazard (for example, technology, chemical, or simply some action) has been present for some time and the risk is large enough to be directly measured (although when it is not large enough to be

Table 1. Comparison of several common radiation risks.

Action	Dose (mrem/ year)	Cancers if all U.S. population exposed (assuming linearity)
Medical x-rays	40	1100
Radon gas (1.5 pCi/liter, equivalent dose)*	500	13,500
Potassium in own body	30	1000
Cosmic radiation at sea level	40	1100
Cosmic radiation at Denver	65	1800
Dose to average resident near Chernobyl first year	5000	Not relevant
One transcontinental round trip by air	5	135
Average within 20 miles of nuclear plant	0.02	>1

\*The radon exposure is to the lungs and cannot be directly compared to whole body external exposure. The comparison here is on the basis of the same magnitude of risk. The uncertainty of the radon number is at least a factor of 3.

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Table 2. Some commonplace risks (mean values with uncertainty).

Action	Annual risk	Uncertainty
Motor vehicle accident (total)	$2.4 \times 10^{-4}$	10%
Motor vehicle accident	$4.2  imes 10^{-5}$	10%
(pedestrian only)		
Home accidents	$1.1 \times 10^{-4}$	5%
Electrocution	$5.3  imes 10^{-6}$	5%
Air pollution, eastern United States	$2 \times 10^{-4}$	Factor of 20 downward only
Cigarette smoking, one pack per day	$3.6  imes 10^{-3}$	Factor of 3
Sea-level background radiation (except radon)	$2 \times 10^{-5}$	Factor of 3
All cancers	$2.8 imes10^{-3}$	10%
Four tablespoons peanut butter per day	$8 \times 10^{-6}$	Factor of 3
Drinking water with EPA limit of chloroform	$6 \times 10^{-7}$	Factor of 10
Drinking water with EPA limit of trichloroethylene	2 × $10^{-9}$	Factor of 10
Alcohol, light drinker	$2 \times 10^{-5}$	Factor of 10
Police killed in line of duty (total)	$2.2 imes10^{-4}$	20%
Police killed in line of duty (by felons)	$1.3 imes10^{-4}$	10%
Frequent flying professor	$5 \times 10^{-5}$	50%
Mountaineering (mountaineers)	$6 \times 10^{-4}$	50%

measured, an upper limit may be calculated, if one assumes some sort of model). If there is no historical database for the hazard (a new power plant or industrial facility, for instance), one approach is to consider it in separate parts, calculating the risks from each part and adding them together to estimate a risk for the whole. For example, all possible chains of events from an initiator to a final accident are followed in an "event tree," with the probabilities of each event in the tree being estimated from historical data in different situations.

A particularly well-known example is the calculation of the probability of a severe accident at a nuclear power plant (3). That this procedure has at least a partial validity is due to the fact that the design of nuclear power plants proceeded in approximately this factorable way; attempts were made to imagine all major accident possibilities, "maximum credible accidents" or "design basis accidents," and then to add an independent device to prevent this accident from having severe consequences. To the extent that the added safety device is independent, the failure probability is independent, and the small overall accident probability is the product of individual failure probabilities which are larger.

#### **Risks by Analogy: Carcinogenic Risks**

Some carcinogenic risks may be estimated from historical data. But this is complicated by the time delay between the insult and the final cancer, one reason why causality is hard to prove if the risk is small. This is the difficult field of epidemiology.

Although some of the largest cancer risks have been identified through the use of epidemiology (4), preventive public health suggests that we endeavor to estimate risks even where no historical data exist and the risk is small. This is often done by analogy with the cancer risks to animals, usually rodents, which are deliberately exposed to large enough quantities of pollutant so that an effect is observed. To use these data to estimate the risk at low doses in people involves (to oversimplify matters) two difficult steps: the comparison of carcinogenic potency in animal and man (5-7) and the extrapolation from a high dose to a low dose. Because both steps require a certain amount of theory, they are controversial. Indeed, there are those who regard the uncertainty as so great that they prefer not to provide numerical estimates of risk (8, 9), although they may order materials in carcinogenic potency. The difference between this and providing a numerical estimate is important, but is one of presentation rather than substance.

If there are no animal data, or if in an animal experiment there is no statistically significant effect, it does not necessarily mean that there is no risk. If the experimenters have been diligent, the risk is probably small, although never zero, even though that may be the best estimate. Various attempts are made to use data even less direct than the animal bioassays to estimate risks in such cases. These include simple analogies based on chemical similarity (10), and comparison with outcomes other than cancer—for example, mutagenesis (11) and acute toxicity (12, 13). Not surprisingly, these more indirect procedures arouse even more controversy than the animal bioassays.

There have been few attempts to perform risk assessments for biological end points other than cancer. However, it is known that the pollutants in cigarette smoke cause at least as many deaths through heart problems as by cancer (14), and we should not be surprised if other carcinogens were to produce chronic effects other than cancer. For now, the cancer risk assessment has to act as surrogate for these other risks also.

#### **Risk Value Versus Certainty of Information**

After risks of a number of situations have been assessed, we often want to order them in order to decide which should command our attention. It is not always the order of increasing risk that is used for such purposes. There have been proposals to order potential carcinogens on other factors (8, 15), such as the certainty of information.

Vinyl chloride gas has been found to cause angiosarcomas both in people and in rats. Since an angiosarcoma is a rare tumor, the risk ratio (the ratio of the observed number of cancers in those exposed to the number expected by chance) is of order 100 or more in some cases. If an angiosarcoma is seen in a vinyl chloride worker, the attribution to vinyl chloride exposure is almost certain. On the other hand, the number of persons who have been heavily exposed to vinyl chloride is small, so that only about 125 angiosarcomas have been seen among vinyl chloride workers worldwide in the last 20 years. Now that exposures in the workplace have been greatly reduced, no angiosarcomas attributable to recent occupational exposure have been seen. We do not know the dose-response relation, but it is generally believed that the response falls at least linearly as the exposure is reduced, so that no more than one cancer is expected in several years.

We can compare this with the possible cancer incidence that was predicted by the Food and Drug Administration (FDA) in 1977 from use of saccharin (16). This was based on experiments with rats, leading to an additional uncertainty. More people ate saccharin than were exposed to vinyl chloride, and nearly 500 cancers per year were estimated for the United States alone. For vinyl chloride we therefore have the situation that the individual risk is now low, yet there is considerable certainty that there is a risk. For saccharin the risk is higher, but there is more uncertainty about the value of the risk. Some persons, in some situations, may demand that more attention be given to the risk from vinyl chloride than to the risk from saccharin; for other persons or situations the reverse may be the case.

#### **Comparison of Risks**

The purpose of risk assessment is to be useful in making decisions about the hazards causing risks, and so it is important to gain some

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perspective about the meaning of the magnitude of the risk. Comparisons can be useful. We are not born with an instinctive feeling for what a risk of one in a million per lifetime means, although we do learn that some risks are small and others large. It is particularly helpful to compare risks that are calculated in a similar way. For example, the risk of traveling by automobile can be compared to that of traveling by horse with the use of historical data.

Another common procedure is to compare exposures only. Table 1 shows a list of radiation exposures in typical situations (17). The dose-response relation for radiations with similar energy deposition per unit track length will be similar, although there may be some correction required for dose-rate effects, so that ordering by exposure should be similar to ordering by risk. In estimating the number of lethal cancers on a linear hypothesis, we have here assumed approximately 8000 man-rems per cancer (at low doses), in itself uncertain by 30% or more.

An example of comparison of risks that are similarly calculated is the comparison of risks of various chlorinated hydrocarbons in drinking water. The risks to humans are estimated from carcinogen bioassays in rodents (rats and mice). Since these are similar materials, we might expect that the dose-response relationships have the same shape. Chloroform, which is produced by interaction of chlorine with organic matter during the chlorination of surface waters to kill bacteria, produces cancer in animals 20 times as readily as does trichloroethylene, an industrial solvent that is occasionally found in well waters as a result of accidental pollution. Although neither is known to cause cancer in people, we might expect that chloroform would do so about 20 times as readily.

Table 2 shows a variety of risks calculated in various ways and our estimate of the uncertainty. They are deliberately jumbled to provoke thought by juxtaposition. [Risk estimates quoted by the Environmental Protection Agency (EPA) for carcinogens tend to be greater than those shown in Table 2 by a factor approximately equal to the uncertainty factor—this is not accidental (5, 18).]

#### **Contrasting Risks**

Objections have been raised to risk comparisons on the ground that they are misleading. This would be true if all risks of the same numerical magnitude were treated in the same way. But they are not. In some cases it is useful to contrast risks to indicate the different ways in which they are treated in society. In Table 3 we give an example by comparing and contrasting the carcinogenic effects of aflatoxin B1 and dioxin, both among the most carcinogenic chemicals known. The difference in treatment of these two materials is perhaps a reflection of different values assigned to various aspects of the problems caused by their presence.

Aflatoxin and dioxin have similar toxicities and carcinogenic potency (perhaps within a factor of 10, although both measures for both chemicals vary substantially with species tested). The certainty of information for aflatoxin is great. There is less information about carcinogenicity of dioxin. Dioxin may be a promoter and pose a minuscule risk at low doses, whereas aflatoxin is almost certainly an initiator also. Nonetheless such standards as there are appear to be more stringent for dioxin, possibly because dioxin is an artificial chemical and possibly because it was a trace component of a chemical mixture (Agent Orange) that was used in warfare.

The small risk of a large accident in a nuclear power plant can also be contrasted with the more numerous small accidents or events that occur every day in the mining, transport, and burning of coal. One feature that is brought out clearly here is that we do not always compare the risk averaged over time, but worry more about risks that are sharply peaked in time.

#### **Expression of Risks**

Just as a comparison of risks is an aid in understanding them, so is a careful selection of the methods of expression. It is hard to comprehend the statistical (stochastic) nature of risk. There are ways to mitigate this difficulty in comprehension. We are almost all used to one such statistical concept-the expectation of life. When we talk about the expectation of life being 79 years (for a nonsmoking male in the United States) we all know that some die young and that many live to be over 80. Thus the expression of a risk as the reduction of life expectancy caused by the risky action conveys some of the statistical concept essential to its understanding. One particular calculation of this type can be used as an anchor for many people, because it is easy to remember. The reduction of life expectancy by smoking cigarettes can be calculated from the risk, one in 2 million, of smoking one cigarette, multiplied by the difference of the average life-span of a nonsmoker and a lung cancer victim. This turns out to be 5 minutes, or the time it takes to smoke the one cigarette.

It is important to realize that risks appear to be very different when expressed in different ways (19). One example of this can be seen if we consider the cancer risk to those persons exposed to radionuclides after the Chernobyl disaster. According to the Soviets (20), the 24,000 persons between 3 and 15 kilometers from the plant, but excluding the town of Pripyat, received and are expected to receive 1.05 million man-rems total integrated dose, or about 44 rems average. Even if we assume a linear dose-response relation, with 8000 man-rems per cancer, the risk may be expressed in different ways. Dividing 1.05 million man-rems by 8000 gives 131 cancers expected in the lifetimes of that population. This is larger than, and for some people more alarming than, the 31 people within the power plant itself who died within 60 days of acute radiation sickness combined with burns. Dividing the 131 again by the approximately 5000 cancer deaths expected from other causes, the accident caused "only" a 2.6% increase in cancer. This seems small compared to the 30% of cancers attributable to cigarette smoking. The difference is even more striking if we consider the 75 million people in Byelorussia and the Ukraine who received, and will receive, 29 million man-rems over their lifetimes. On the linear doseresponse relation this leads to 3500 "extra cancers," surely a large number for one accident. But dividing by the 15 million cancers expected in this population leads to an "insignificant" increase of 0.0047%. Of course, none of the methods of expressing the risk can be considered "right" in an absolute sense. Indeed, it is our belief that a full understanding of the risk involves expressing it in as many different ways as possible.

#### Cost of Reducing a Risk

Another interesting and instructive way of comparing risks is by comparing the amount people have paid in the past to reduce them. It might be thought that people would try to adjust their activities until the amount spent is roughly the same. Cohen (21) has shown that the amounts spent vary by a factor of more than a million. He shows that it would be possible even for an American to save lives in Indonesia by aiding in immunization at \$100 per life saved. Society is willing to spend more on environmental protection to prevent cancer (over \$1 million per life) than on cures (about \$50,000 per life with the high value of \$200,000 for kidney dialysis raising some objections). This ratio is in rough accord with the maxim "an ounce of protection is better than a pound of cure." People are willing to spend still more on radiation protection at nuclear power plants and

Table 3. Comparison of two very toxic chemicals, aflatoxin B1 (22) and dioxin (23); CDC, Centers for Disease Control.

Measure	Aflatoxin B1	Dioxin
Acute toxicity	High	Equal
Carcinogenic potency to people	~500	Unknown
[(kg · day)/mg]		
Carcinogenic potency to rats	$\sim 5000$	$\sim 5000$
[(kg · day)/mg]		
Mutagenic	Yes	No
Certainty of information on human carcinogenicity	High	Low
Activity (initiator or promoter)	Initiator	Promoter (?)
Possibility of threshold dose response	Low	High
Source	Natural	Artificial
Common knowledge	Little known	Agent Orange
FDA action level in peanuts (ppb)	20	-
CDC level of concern in soil (ppb)		1

on waste disposal. Economists and others often argue that efficiency depends on adjusting society until the amounts spent to save lives in different situations are equalized. It seems to us that society does not work that way. People are aware of the order of magnitude of these differences, and approve of them. Nonetheless, we believe that providing this information to a decision-maker is essential for an informed decision.

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