Risk Assessment: Implications for Biologic Education

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As science and technology have evolved, the power for humans to do good (or harm) has increased. Decision makers have begun to rely on better assessments of risk to reduce errors in judgment. Risk assessment techniques provide an increasingly reliable mechanism for relating empirical knowledge to social problems and identifying the implication of isolated data. Ironically, public trust in risk analysis and its management has declined as the procedures have matured (Morgan 1993). The public neither understands the elements of the risk analysis nor the assumptions inherent in the resulting models.

Risk Assessment as a Modeling Process

It is not only the public that is overwhelmed by statistical knowledge associated with assessing risk, but also policy makers and those responsible for finding solutions to social problems. Individuals do not always have complete information or fully understand the technical, but critical, facts. The public stance on issues tends to be more influenced by external factors such as values and perceived morality. Although the typical citizen is unskilled in technical decision making, sophisticated questions requiring "scientific" judgments are being put to a public vote. The results are unpredictable. For example, the public generally may support nuclear research if it relates to medicine, but nuclear research as an alternative source of energy is negatively viewed. Those in science realize that there is little difference in either context. It is essential that the public become familiar with risk assessment techniques.

Developments in mathematics and in computer science have made new analytical techniques available that have resulted in a revolution of modeling as part of both basic and applied research. These skills have contributed greatly to the development of assessment strategies. They generate sophisticated information for use in the decision-making process. But it is important to clearly differentiate between the model and the reality it depicts. The more a model is used, the more it is perceived as reality rather than as a means of *representing* reality. A classic example of the model *becoming* reality is the Watson-Crick model of DNA; the research paradigm for molecular biology for three decades. Students of introductory biology come to think of DNA as sticks-and-balls molecules or colored paper cut-outs of nucleotide bases. Although the model is but a tool, and modeling an intellectual process, they frequently take on characteristics beyond the context of their use.

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Models & Social Values

Personal and social values can conflict with empirical knowledge. It makes no difference if the decision is based on personal criteria or awareness of overpopulation, the responsibility for decision making is forced upon the individual. The model and the assessments drawn from it are neither true nor false! They are only approximations of what is being studied. To make rational choices requires access to empirical knowledge, an understanding of risk, skills to analyze data, and the ability to separate values from empirical knowledge. It is common for personal beliefs to conflict with empirically derived knowledge. An example can be drawn from population biology.

It is clear from studies in ecology that the human population will soon exceed the carrying capacity of the Earth. Further, the decades of scientific study of the human reproductive system have yielded an understanding of the processes of conception, development and birth. Sophisticated birth control technology resulted from that knowledge and can now be applied in a way to control the population growth rate. Individual *choice* based on value systems outside of science is not necessarily made in a rational or objective manner.

Although we have the scientific knowledge and technology to address problems (i.e. overpopulation), much of the world ignores the empirical knowledge that you can*not* maximize two variables simultaneously. We cannot increase the population of the planet without reducing individual freedoms. The options for choice will decrease as overpopulation continues.

Risk assessment, in general, is based on knowledge of past research and even on past mistakes. The simplest risk model is an extrapolation from unadorned empirical data. However, a more accurate prediction is drawn from a theoretical model that accounts for trend data, social transition and other information that might affect the risk calculation. A common use of this technique has been in the design of regulations in environmental policy making (Russell & Gruber 1987).

Models & Political Decision Making

Risk assessment models do *not* make judgments; they simply *illuminate options* (Lave 1987). Hence, risk assessment is one of the most viable methods of reviewing alternatives. There is increasing use of risk assessment to inform policy makers of the implications of various options they may have in setting priorities or in decision making.

Some might suggest that the available amount of information is overwhelming and causes decision makers to throw up their hands in dismay. The reality is that the decision-making process allows the decision maker the luxury of subjectively determining the information or data upon which to base a decision. Even with risk data a politically expedient decision is easily justified for the public good. What a researcher knows about the limitations of specific research, for example a flu vaccine, becomes merely raw data in the policy-making process used by a president. In these circumstances, empirical knowledge is of only passing concern to the decision-maker; such knowledge is merely another piece of data in the decision-making process and generally given less priority than undefined or non-clarified values. It is ironic that in an "information society" empirically derived knowledge is relegated to a less than honored state.

The strong pressure to ignore or exclude empirically derived knowledge from the decision-making process appears to be a result of four factors:

1. The need to base decisions on information that is politically correct
2. The drive to select data that are in support of predetermined decisions
3. An ignorance of, or insensitivity to, the implications of the empirical knowledge
4. A lack of confidence in or understanding of the empirical data.

It is not always clear how objective knowledge can or should interface with the subjective value-laden problems in society.

Since the purpose of risk assessment is to provide useful information about hazards and other negative aspects concerning different options, it is important that the model provide a perspective about magnitude of risk. To this end relative comparisons are used. For example, the risk of traveling in an automobile might be compared with that of riding a horse, flying or walking. The comparative data must be generated by the same procedure and in most cases based on similar historical data. It is this comparison that provides the decision maker and the public with an understanding of the statistic. In addition, the human and social factors must be identified to ensure the best possible estimate of effect. The framework criteria could be based on accidents or deaths per miles traveled as a function of daily use or of the cost of travel. In this example, accidents per mile traveled is the usual consideration.

Risk Assessment & the Public

Some elements of risk are related to other assessments of risk. An example is that we know that babies are safer in transportation when they are in an approved "car seat." The argument can be made that when traveling on airlines, babies must be strapped into car seats just as they would in an automobile. However, this would require that parents pay an increased fare since an additional seat would be used for holding the baby.

Air travel per mile is considerably more safe than travel by automobile. Nevertheless, given that the cost for travel would be increased, parents would be forced to make greater use of automobiles. The decision to require special seats for babies in airplanes would actually result in greater numbers of deaths and injuries as travel by auto increased. Reducing the risk in one mode of transportation forces the use of another, less safe, mode of transportation. Risk assessment must be made within the broader context of the broader issues and alternatives.

There are also times when a decision related to a problem is needed immediately—before benefits or hazards are clearly defined. Although only a portion of the risk can be projected, there can be no postponement of the decision. (A postponement might, for example, allow further study that would result in a better informed decision maker.) This can be illustrated by a case history concerning decision making and the formulation of public policy related to long-term effects.

In 1983, the Committee on Diet, Nutrition and Cancer (of the National Research Council) called for a deliberate effort to reduce the amount of fat in the diet of the American public. The effort was proposed as a step that *might* reduce the incidence of certain cancers 20 to 30 years in the future. The recommendation was based on three lines of empirical research data that predicted risk.

1. Several epidemiological studies show that the incidence of various cancers around the world varies with different dietary habits. The studies show a strong correlation of high-fat diets with cancers of the prostate, colon and breast.
2. The findings of the epidemiological studies were subsequently tested under laboratory conditions with various animals (used as living models of human reaction). The results suggested that the higher the fat intake, the less time before tumors develop, the more frequently the tumors develop, and the higher the death rate.
3. The third line of evidence came from molecular biology and a reasonable hypothesis as to the way that fats produce the cancerous effects.

What we eat today determines what we will be tomorrow. If the decision is made to delay informing the public and further research supports the hypothesis, it will be too late for many people.

It is essential that the reader realize that none of the data in the preliminary studies was conclusive. More research was necessary. For example, we now suspect that there is at least one gene that influences the effect of dietary fat. Since it is usually a long period of time between the beginning of a cancer and its final diagnosis, is it not the responsibility of the scientist to inform the public of the tentative relationship?

On the other hand, if the suspected relationship between dietary fat intake and cancer is not real and a warning given to the public is heeded, agricultural businesses may well likely be adversely affected. Further confusion would occur as the special interest groups mount research and distribute reports that downplay the laboratory animal research, emphasize the uncertainty, and provide alternative explanations of the data.

A critical component of this type of risk assessment lies in the level of certainty (or uncertainty) of the knowledge. What level of certainty must exist before establishing a policy to encourage the average American to reduce his/her intake of fats by 25%? Perhaps more importantly, how is the public informed of the levels of uncertainty without causing doubt, mistrust or even panic. Perception of risk is an important variable in policy making. The public must make its own decisions, but the policy maker must determine what, when and how to communicate the information to the public.

This example of risk assessment illustrates a significant dilemma for the decision maker; he/she does not normally have all the information or data to insure making the correct choice since a decision must generally be made before all the data are in. The tentative data generally present only two options, to warn or not to warn or, to alert or not to alert. Yet, to make no decision is to make a decision. Postponement merely means that the decision has been negative for the period of the delay. The notion of optimization, that is, making the *best* decision based on the data that are available is not well accepted. It is for this very reason that risk assessment models can play an important role in the development and implementation of policy and decisions.

Between 1977 and 1983 the Environmental Protection Agency (EPA) established that the pesticide ethylene dibromide (EDB) was a potent carcinogen in laboratory animals. It was also believed that people were exposed to EDB through fruits and some grain products. Until this time, the model used for determining risk did not account for differential levels of risks for different groups. When in 1983 studies showed that groundwater was being contaminated, risk assessment data were used to establish regulations to suspend further use of EDB as a soil fumigant. However, the data were not sufficient to ban total use of EDB until further analysis was completed.

When it was learned that EDB residue on foods was higher than first estimated, reconsideration of the regulations became a priority. At about the same time the public became concerned and demanded action. The risk assessment model was modified using different safety standards. The challenge was to design a policy that:

1. Reflected an awareness of the carcinogenic potential
2. Responded to public concern
3. Did not disrupt the national food distribution causing major economic divestiture.

We see in the case histories that risk assessment can be used to adjust policy in response to the severity of different aspects of the problem. While empirical data are used, the analysis must be done in consideration of the public need. Furthermore, the use of the model requires that policy be dynamic and responsive to change. Clearly, different people holding to different values might elect different actions at different times. However, the risk assessment allows policy making to reflect the empirical knowledge as well as social conditions.

Public perceptions cannot be treated lightly. Results from studies of the perceptions of risk (Slovic et al. 1981) suggest that the public has no real understanding of risks if risk assessment is not provided. In the case of nuclear power, the deep anxieties and fears of the public formed through unfavorable media coverage prevent acceptance of empirical demonstrations of safety. It will take experience and time for the acceptance of risk data. Meanwhile the decision makers must not overstate or understate risk.

Communicating risk and uncertainty to the public is a major challenge (Morgan et al. 1992). Rhetoric will do little to reduce fear. Table 1 illustrates the

Table 1. Perceived risk for selected activities & technologies (Slovic 1987, p. 281).

Activity/Technology	*League of Women Voters*	*College Students*	*Experts*
Motor vehicles	2	5	1
Smoking	4	3	2
Alcoholic beverages	6	7	3
Hand guns	3	2	4
Surgery	10	11	5
Motorcycles	5	6	6
X-rays	22	17	7
Pesticides	9	4	8
Electrical power	18	19	9
Swimming	19	30	10
Oral contraceptives	20	22	11
Private aviation	7	15	12
Heavy construction	12	14	13
Food preservatives	25	12	14
Bicycles	16	14	15
Aviation (commercial)	17	18	16
Police work	8	8	17
Fire fighting	11	10	18
Railroads	24	23	19
Nuclear power	I	1	20
Food coloring	26	20	21
Home appliances	29	27	22
Hunting	13	18	23
Antibiotics	28	21	24
Vaccinations	30	29	25
Spray cans	14	13	26
High school football	23	21	27
Power mowers	27	25	28
Mountain climbing	15	22	29
Skiing	21	25	30

differences in perception of risk by three different groups. Individuals were asked to rank order selected activities and technologies as to the risk of each. The experts, of course, had the advantage of accessing accident and injury data as well as other information. Note, for example, that both groups representing segments of the public ranked nuclear power as the greatest risk. The experts rated it as 20. A vote on the issue would certainly be based more on perception than on facts.

Risk Assessment Techniques in the Biology Classroom

An introduction to risk or uncertainty calculations drawn from probabilistic models is a natural part of decision making. The decision maker must learn that the predictive value as well as the selection of options is a direct function of the quality of the data put into the model. As the individual develops the appropriate skills, expertise and understanding, the importance of sensitivity analysis to validate models will become clear and the implication of risk assessment will take on new meaning. The individual trained in the use of these kinds of models will develop an understanding of their limitations. The individual who receives *no* such training will be overwhelmed by statistical models in whatever specialty he/she functions.

The formulation of hypotheses, the design of investigations, and related analyses are each determined by the available methodologies. As biology went through a transition caused by the development of the microscope, the student of biology developed new skills and techniques associated with microscopy. These skills and techniques are part of biology. Biology has incorporated some aspects of modeling as seen in quantitative population and genetic models. We can expect risk assessment techniques to be similarly integrated into a range of different disciplines. As the skills become part of the knowledge base of that discipline, the level of sophistication in decision making will increase. Lack of skills in the new methodologies will limit full understanding of the impact of decisions and thus limit human options in the future.

Most scientific and technologic results have no immediate secondary effects; what occurs in the laboratories may eventually change society but it is usually a long-term result of other decisions. The decision to develop a pesticide is technologic; to use it is a political choice. (Similarly, the research in education may show the value of curricula or a particular class size on learning; it is a political or economic decision to decide whether or not to run a school in that fashion.) The effects will appear only if most of the political decisions immediately cause reactions among the people, with few decisions ever having complete support. The dilemma of the public decision maker is not to elect choices that are either good or bad but to decide between choices of equal benefit (or equal hazard) using different sets of criteria.

Each time the application of technology changes the environment—whether the ecology or social/political environment—an ethical decision was made by someone. How do ethics and values enter the political decision-making process? Is it ethically correct to prolong life at all costs using technologies such as dialysis machines, psychosurgery, respirators and the like? Clearly, the application of prenatal diagnosis forces an ethical issue that would not otherwise occur.

There are moral issues and ethical considerations that must take into account hazards, long-term effects, and costs to humanity. Just as the technology of management has not maintained pace with the hardware of nuclear power plants, apparently the technology associated with modifying human behavior has far exceeded the management of the people using the technology. Intelligent decision making must be based within a system that allows one to determine which potential hazards to ignore and how much risk reduction to seek.

Scientists and technologists have begun to recognize the importance of assuming responsibility for the knowledge that is generated and the method of inquiry used. For example, the American Fertility Society (1986) has developed a set of guidelines for the ethical use and experimentation of reproductive technologies. Policy makers, ethicists and researchers have been debating aspects of human gene therapy for years and the resulting regulations are specific and adhered to. The National Institutes of Health has been asked on several occasions to prohibit various kinds of experiments related to human gene therapy. Debates, such as those that surrounded the Strategic Defense Initiative research, range from the feasibility of the technology to the moral responsibility of the researchers. In all cases, the dilemma is that *all* the facts and data are not available.

Social and economic values are increasingly more important in directing research in science and technical fields. Although there is still a hard-line position taken by some scientists that science is amoral, the scientific ritual of inquiry is gradually being modified to consider the context and implications of the problem being studied.[1]

As society evolves, new ideas are generated and environments change. Public attitudes shift and needs change; such events provide direction but do not control the decision-making processes. The responsibility lies with the decision maker. As the rate of advancement of technology and science has increased in recent years, the pace of societal change has quickened dramatically. The interactive effects will cause social change at a rate never before seen. It will take powerful human intervention and sophisticated decision-making skills to insure that the post-industrial, civilized-identity society maintains what Glasser (1972) describes as a quality of humanness and concern for the human condition.

[1] As an aside, it is of interest to note that there are no guidelines or policies concerning risk to direct educational research. There are no standards to insure that the educational researcher be accountable for the data derived from studies. Surely the mistakes made in educational decision making have had ramifications that negatively affected students for their lifetime. The implementation of a curriculum in education should be planned with no less rigor than the development of policies and regulations of pesticides in agriculture.

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