A BIOETHICAL PERSPECTIVE ON RADIATION PROTECTION AND "SAFETY"

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By way of developing the central theme of this Congress, I propose to review three problems of major concern to policy makers whose task it is to protect public health by setting criteria and standards for "safe" radiation management. The first problem is to decide if current conceptual tools for assessing potential biohazards--namely, basic harms to valued living systems--are ethically adequate. The second problem is how to set safety standards on the basis of informed consent to scientific evidence presented by experts who disagree in interpreting that evidence. The third problem is how to resolve value-conflicts underlying expert disagreement, namely conflicting philosophies about radiation protection.

A fundamental bioethical principle must be firmly established if we are to analyze and organize scientific evidence concerning radiation exposure, and to separate genuine from counterfeit claims to credibility. Social justice and equity require an equitable management of sources of basic harms, that is, potential hazards which might have adverse health effects and unjustifiable social consequences. By "equitable management" I mean that policy makers should first be comprehensively informed about the broad spectrum of both natural and ordinary man-made hazards that may have health effects for large segments of the population; then make comparisons of the actual risks as well as costs per capita to reduce these effects; and only then make policies and set safety standards that will get the most public health protection for the many out of a finite amount of money. Potential hazard management is ethically equitable only if it is proportional in relation to actual basic harm that can be identified and reduced by expenditures of human effort, time, and money.

CONCEPTUAL TOOLS

Contrary to a popular misconception, "hazards" have neither a bare facticity nor an intrinsic morality predetermining how human beings should behave in relation to them. Hazards are not baldly "there" in nature or in human transactions with it. What people regard as hazardous in any given era reflects what they have come to know about their environment, and what they value as essential or desirable on a scale of real possibilities. In short, human beings structure hazards; they are, in that sense, human artifacts. A hazard is not by definition "toxicity of substance" or "violence of event" or "magnitude of consequences" that can be known, classified, and predicted. A hazard exists only when, and to the degree that, harmful exposure of and assimilation by the human body or other valued living systems becomes a genuine and not merely an imaginable possibility. That possibility exists only when there is an inability or failure to devise and maintain controlling actions or safeguards.

Because there are vast uncertainties about "how the world works," it serves no human purpose to bewail our "legacy of risks to future generations," and then make the fraudulent claim that the goal of hazard management should be to assure centuries of control over toxic elements or prediction of future adverse events. Prof. William Clark states that hazard management is "the adaptive design of hazard structure," and that the primary goal of hazard management is "to increase our ability to tolerate error and to take productive risks."(1) His statement stands in sharp contrast to a popular yet unexamined notion, expressed as well as anyone by Wolf Häfele, that "we are locked in a world of untested hypotheses (of unimplemented trials) because we dare not let experience prove us wrong. The costs of failure have grown too great."(2) Not only does this notion reflect the New Pessimism spawning defeatism and pseudoscientific dire predictions which now pervade our cultural climate; but it also constitutes in itself the ultimate hazard -- the failure to design and maintain structures of social resiliency. It is the social ideal of resiliency that has been a major driving force behind the emergence of highly complex and technologically advanced societies. The social ideal of resiliency accounts for the burgeoning art of risk-analysis.

The hazy connection between hazards and risks gives rise to another common misconception. If popular literature on the subject is any indication, "risk" is steadily acquiring the moral opprobrium reserved for other four-letter words. I do not intend to add to that moralizing. Suffice it to say that many have adopted the uncritical assumption that risk is a normative concept for certifying consequences to human beings that are harmful, dangerous, or "bad." These contrast sharply with consequences that are beneficial, pleasurable, or good--hence by implication risk-free. This assumption is altogether understandable because it reflects a basic value-conflict about the nature of risk-taking.(3) For some persons, risk-taking is by definition hazardous, harmful, and perhaps the result of a demonic compulsion suppressing nobler human pursuits. For others, the word risk stands for the opportunity to undertake what is challenging and venturesome, innovative and fulfilling to the human spirit in its endeavor to live "the good life." This value-conflict has developed because risk-taking is not inherently good or bad -- neither in a psychological sense nor in a moral sense. The fact that the concept of risk is negatively overloaded in popular usage has no analytical justification.

Because of a facile identification of risks with hazards, a false antithesis has been set up between risks and benefits--as if there were a way to have one without the other. The trouble with the phrase, "risk-benefit analysis" is twofold: it fails to express a proper symmetry, and it tends to obscure the primary motivating force of human activity, i.e. the foreseen and intended benefit which can be gained or lost. In concrete decisions, what is actually "at risk" is the possibility that intended benfit may not materialize, and instead harm may occur. When harm results, it is clearly unwanted and unintended. Risks and benefits are inseparable, not antithetical.

A major problem about the growing dispute over radiation protection and radioactive waste management is the inadequacy, not of risk analysis, but of harm-benefit analysis. Some refinement in the notion of benefit is essential. Okrent and Whipple suggest three qualitative distinctions in benefits, namely those goods essential to society (e.g. food, water, energy) or basic goods; advantageous to society (e.g. most manufacturing); and of peripheral if any value to society (e.g. aerosal deodorants having substitutes at lower cost and likelihood of harm.) Each qualitative benefit has corresponding levels of harm. (4) Basic harms may result from being deprived of good essential to subsistence and material well-being. Justice and equity require a society to provide access to basic goods and avoid basic harms. As for second-level benefits, the total outcomes of any social policy toward such improvements will have an unclear mix of benefits and harms. Auto and airplane manufacture afford major economic benefits to employees, capital investors, travelers, and the general health of international economies. Yet each time someone drives a car or enables an airplane to take off, the benefits pursued may entail the possibility of unintentionally causing the death or serious impairment of a fellow human being. Any society must, at some point, deliberately decide how we ought to balance economic benefits and costs against possible harm or loss of life.

According to critics of such balancing, a human life is of infinite value, and its loss or impairment cannot be put in a class with other "negative consequences," much less be given a finite monetary value. To do so indicates the moral bankruptcy of our materialistic, consumerized, decadent society. Cost/risk/benefit quantifications, say its critics, manifest a loss of respect for the sacredness of human life. Those who defend this conceptual tool have often used simple observations, such as "There are necessary tradeoffs in any public policy decision," or "Everyone puts a finite, monetary value on one's life when buying life insurance, installing safety mechanisms in a home or auto, taking hazardous jobs because they pay higher wages." Although true, such analogies are not sufficient. The public must be confronted with the fact that any society has but a finite amount of money to spend on health protection and safety, and that the ethical problem is to get the most protection for the most people from this finite amount.

As a conceptual tool which attempts to enhance informed consent, cost/risk/benefit quantifications are simply one tool among many others whereby policy makers endeavor to allocate finite amounts of money in a just and equitable manner. They are not tools for putting some callous dollar value on human life or injury as a moral judgment of individual worth, much less of using economic losses to society as a measure of personal expendability. We are in fact maximizing the value we place on human life when we endeavor to allocate limited amounts of money in such a way as to reduce widespread hazards, thereby preventing as much loss of life and protection from injury as possible.

The fact that our tools for balancing economic costs against risk to human life are not morally or ethically objectionable does not amount to saying that they are easy and acceptable to the public. Far from it. The task of public education in this matter is monumental. Moreover, as my colleague in social ethics, George Pickering, observes: "We are going to have to do more than find some level of 'acceptable risk;' we are going to have to come to terms with the question of 'justifiable harm.' There are, after all, some kinds of harm which cannot be avoided; but there are other kinds of harm which any society should not allow and against which it should adopt protective or remedial measures to the best of its ability."(5) Which is which?

We must face up to the disconcerting task of developing a more enlightened concept of--and method of informed consent to--unavoidable hence justifiable harm, and not divert attention away from it by focusing exclusively on "acceptable risk" criteria. Our failure to take up this task lies at the root of the second problem noted above: the frustrating dilemma of a policy-maker who wishes to set safety standards on the basis of informed consent, yet when he turns to scientists upon whom he relies for "expert testimony," he finds they have basic disagreements about what data should count, how it should be interpreted, and what level of health protection is "safe enough to be safe."

EXPERTS, REGULATORS, AND STANDARDS FOR "SAFETY"

Aaron Wildavsky has recently observed, "Experts are used to disagreeing, but they are not so used to failing to understand why they disagree." (6) At the heart of the matter lies a misconception about safety, especially as it relates to risk acceptability.

A case in point is the unending controversy over whether or not there is a threshold for radiation below which no harmful effect occurs. For most toxic elements, a threshold concept has been accepted. It carries the implication that below a threshold dose any exposure is "absolutely safe." But over the twenty years of evolution in radiation protection philosophy, the ICRP and NCRP came to adopt a conservative assumption, namely that it would be more prudent to assume some harmful effect from any radiation dose, however small, than to assume a threshold dose and then discover data proving it to be false. This conservative assumption carries the implication that there is no absolutely safe radiation dose except zero, and every dose greater than zero entails a corresponding possibility of genetic or somatic harm. In the ensuing process of applying a linear no-threshold hypothesis to the development of standards, regulatory institutions and some of their expert advisers seem to have forgotten that their quest for radiation limits rests only on a hypothesis, a conservative assumption, and not on a scientifically established fact. According to G. Hoyt Whipple, "The data on the biological effects of radiation can be interpreted in terms of a threshold dose, but even the vast amount of radiobiological data cannot conclusively prove the existence, or absence, of a threshold."(7)

Given this state of affairs, the dilemma of a policy-maker could be mitigated if two factors were clarified: (1) the meaning of "safe" and (2) the ambiguity of a threshold concept.

A profound misconception of "safety" dominates the controversy over radiation protection. The working assumption has been that safety is an intrinsic, measurable, absolute property that a given system or product or activity can and should possess. Our society has institutionalized and appointed the regulator to measure approximations to that elusive property. The mandate of the regulator is to make ever more stringent regulations, presumably to come ever closer to that property by reducing risks. But the only risks he is expected to monitor and minimize are a small percentage of the total spectrum of risks tolerated by members of society as a whole. Intent on making a set of risks publicly "acceptable" as an index of "safety," the professional regulator must continue to propose risk-reduction without regard to economic costs or social impacts of ever-changing regulations.

Presumably he is "only giving the public what it wants," namely safety. This spiral is likely to continue unless or until the public comprehends the fact that safety is not an intrinsic property measured by approaching zero-risk. Safety is an evolving, relational value judgment derived from current personal or social priorities. Whereas risks can be measured, quantified, and predicted, safety cannot be measured, much less predetermined by the presence or absence of risks.

Judgments of safety are judgments about the justifiability or unjustifiability of harm. The process of reasoning for ethical safety-policy decisions should be dictated--not by risk avoidance, an impossible ideal--but by comprehensive risk/risk assessments and cost/risk/benefit ratios. When these comparisons make it clear that a point of diminishing returns on allocations of money, time, and effort has been reached by comparison with other potential hazards in a society, then the product or process under scrutiny is "safe enough." If indeed unintended and unwanted harm should occur, then such harm can be judged justifiable because unavoidable or negligible by comparison with other harms and essential benefits.

Greater clarity about the process of making safety judgments would help to clarify the ambiguity of a threshold concept. As noted above, regulatory standards have been predicated--not on a scientifically established fact--but only on a hypothesis, an assumption that there is no threshold below which harmful effects will not occur. As a result, reduction in radiation exposure levels has been required to become "as low as reasonably achievable," (ALARA). J. J. Cohen has this to say about ALARA: "Philosophically, this is based on the premise that, since we do not know the effects of low-level radiation exposures, the conservative standard will effectively minimize them. Supposedly any degree of reduction in radiation exposures will do some good. However, some evidence indicates that there might in fact be a net beneficial effect of radiation at low levels. Since we do not in fact have a complete understanding of low-level exposure phenomenologically, perhaps we should recognize the possibility of beneficial as well as harmful effects. If the net effects are in fact beneficial, then by insisting upon the application of ALARA--rather than being conservative--we may actually be causing harm."(8) Speaking from an ethical perspective, I must ask what scientific evidence justifies marginal reductions if "conservative" actually means "doing the least harm?" Since net beneficial effects of low-level exposures can be proven with other toxic materials (e.g. copper, selenium, fluoride), why not look at radiobiological data through the lens of that assumption?

The assumption of a zero-threshold for "safe" radiation exposures may be justifiable for some radiobiologists. But for the policy maker there can and must be a practical threshold below which the possibility of unintended and unwanted harm is ethically justifiable because it is either unavoidable or negligible by comparison with other potential hazards against which citizens ought to be protected.

The dissensus amongst health physicists and biostatisticians may mean that what we need is not more stringent regulations; but rather we need to devise innovative institutional methods for dealing fairly with complaints without undermining still further public confidence in experts, in safety-policy decisions, and in regulatory actions. Whatever these institutional innovations may be, they must somehow take account of the possible origin of basic disagreements over safety judgments, namely conflicting philosophies.

PHILOSOPHICAL ORIGINS OF VALUE CONFLICTS

The mounting controversy over radiation protection and radioactive waste management has revealed basic value conflicts, compelling us to probe more deeply into the philosophical and ethical principles from which values derive their justification.

For some time now, representatives of environmental protection organizations, together with special interest groups purporting to protect the public's health and best interests, have espoused as a fundamental philosophical principle "non-degradation of the environment"--defining a "degraded environment" as any place that human actions have affected or changed.(9) Some representatives adopt the "pre-existing natural state" of any given environment as an appropriate standard for human transactions with nature because "it emphasizes the role of a trustee as one who maintains the non-renewable environment as it was originally, to pass on to the next trustee." This fundamental goal is a key consideration, "because if any degradation is allowed (in the name of 'allowable radiation exposure'), there is no clear bound at which degradation becomes, by anyone's standard, too much." On behalf of the public,these representatives are of the opinion that the ethical principles of equity and participation require criteria for radiation protection against energy technologies and waste disposal to be neutral to future generations, stating that "the least unfair way of managing intertemporal relationships is for each generation to try to leave the earth as it was when they arrived. As a goal, the only acceptable distribution of hazards and benefits is the neutral allocation, where no pattern of benefits and hazards is imposed."

Formulas such as these obscure two questionable assumptions: first that an untouched "natural environment" by definition manifests a superior, if not sacred order which human interventions or changes violate to some degree; and secondly, that a trustee of a so-called "natural environment" can do nothing more nor less than pass it along in its original pristine state; to do otherwise is to be guilty of a moral wrong.

The philosophy of non-degradation has a long history, as is clear to anyone who has read Book I of Georgius Agricola's De Re Metallica, published in 1556. This sixteenth century inventory of objections to disturbing a pre-existing natural state of the environment make it abundantly clear that the arguments advanced in the name of protection of public well-being are specious.(10)

The philosophy of non-degradation uncritically assumes the idea that a benign environment is rapidly being ruined by human beings. However the historical record attests that an untamed environment has repeatedly wrought massive human degradation through catastrophic effects of famines, plagues, floods, earthquakes, and so forth. The basic problem, therefore, is not a question of pursuing an ideal of "non-degradation" of the environment, but rather represents a highly complex challenge of both protecting life-sustaining and aesthetic qualities of the biosphere and developing technologies that provide basic human goods as a necessary condition for maintaining a preferable environmental quality. As a fundamental, meaningful principle for securing that environmental protection, non-degradation is vacuous.

From a bioethical perspective, it is justifiable for policy makers to establish criteria and standards for health protection by reference to naturally occurring radiation sources from which man-made applications are derived. But it is not justifiable on the basis of a philosophy of non-degradation or trusteeship over some pre-existing natural state.

Those responsible for providing access to basic goods, methods of informed consent, and an equitable management of biohazards have an ethical obligation to derive value judgments of safety, acceptable risk and justifiable harm from a philosophy of congruence with a pattern of benefits and harms already established by naturally occurring radiation sources with which human beings have lived and evolved throughout recorded history. The philosophy of congruence and of logical consistency require a policy maker to form value judgments on the relative benefits of providing protection against radiation by first taking account of wide variations in personal exposures and population exposure from naturally occurring background sources. (These include external sources from cosmic rays, together with the radionuclides they produce and primordial radionuclides in the earth; and internal exposure from natural radionuclides inhaled or ingested via food and drinking water.) Large segments of the population in the U.S.A. receive natural external radiation doses varying from 40 to 105 mrem per year simply because of geographic location. Variations in natural exposure to thorium in monazite sands along the southeastern coast of India range from 130 to 2,800 mrem; while on the coast of Brazil, exposure ranges from 90 to 2,800 mrem with an average of 550 mrem per year. There is no scientifically established evidence that there are basic harms to those so exposed.

Human tolerance for, indeed dependence upon, such wide variations in natural radiation sources for several millenia demonstrate that increments from man-made applications of those natural sources can be kept well within the range of those variations without inflicting either unjustifiable harm or deprivation of basic goods to members of a society.

The philosophy of congruence and corresponding ethical principles set forth here are in contrast to what has been assumed by regulatory agencies when they have set excessively conservative standards in the past. However, with increasing knowledge of a pattern of benefits and harms from natural radiation, there is ethical justification for their gradual revision. It is a matter of fact that the largest increment from man-made radiation exposure comes from medical and dental health practices. These exposures are 10 to 100 times greater than other man-made sources which by contrast are stringently regulated.

From the perspective of bioethics, the inequitable management of biohazards in general--and of radiation protection in particular--ought to be reviewed and remedied. There is clearly a category of negligible risk and negligible harm which in practice ought to be ignored. This category coincides with the ethical principle of justifiable harm.

The perceptual problem of managing radioactive waste could benefit greatly from a philosophy of congruence applied to performance criteria for radioactive waste disposal. As they are proposed, these criteria require that ultimate waste disposal shall be conducted in such a way that there is no net increase in risk of harm by comparison with the typical ore body of natural uranium which yields the energy from which the wastes are derived. In other words, the wastes would be disposed of in a way that returns them to the same (if not better) level of risk which natural uranium ore in the earth's crust poses. The waste form would be required to have the same stability as the original ore body; the medium containing the wastes would be required to retain the same integrity as the medium containing the ore; and the geological media surrounding and isolating the wastes would be required to retain the same integrity of isolation from the biosphere as that isolating the original ore bodies. If technologies exist to meet these requirements, then the public and professional critics cannot logically demand greater "safety."

CONCLUSION

In view of the above reflections, I suggest that the following principle might serve as guidance in the formulation of social policies for radiation health protection:

Any involuntary risks imposed by social policies for radiation protection must be congruent with, must not be in excess of, and may be reasonably less than, those involuntary risks imposed by the wide variations in naturally occurring toxic elements and harmful effects from our natural environment.

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