HUMAN RADIATION EXPERIMENTATION: A HEALTH PHYSICS PERSPECTIVE

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ABSTRACT: This paper observes ethical human experimentation can be considered in terms of two basic principles or tests: informed, willing and knowledgeable subjects; and expectation of benefits. A number of human experiments are evaluated in terms of these principles, including a sixteenth century toxicology experiment, the deliberate exposure by an x-ray pioneer, and the plutonium injection cases of the 1940's. The following rational ethic is proposed for the practice of health physics with respect to human radiation experimentation: ***At all levels, the health physicist has a professional as well as personal obligation to ensure that proper humanitarian requirements, including proper informed consent and willing subjects, are carried out with respect to human radiation experimentation, and must be convinced that the real or potential benefits to be derived from the experiment clearly exceed the potential detriment and risk.***

INTRODUCTION

Since the primary mission of the health physicist is protection of people and the environment from the harmful effects of radiation while at the same time permitting (and indeed promoting) its beneficial applications, human radiation experimentation is a topic of particular interest to the health physicist. However, the leading professional societies involved with radiation protection, including the International Radiation Protection Association and most national associations, provide little, if anything in the way of guidance. The Code of Ethics of both the oldest and by far the largest national organization, the American Health Physics Society, is published annually on the inside back cover of the Society Handbook, and provides nothing specific with respect to human radiation experimentation or public benefit. Indeed, this Code is, in a general way, patterned after the Code of Practice for professional engineers, minus the business aspects. Similarly the current Code of Ethics of the American Academy of Health Physics and its professional certification arm is vague and general, and refers only to obligations and responsibilities of the health physicist to the profession.

In developing a health physics perspective regarding human radiation experimentation, it is important to bear in mind what might be called the fundamental guiding principle of health physics. As elucidated in numerous publications, and in particular by the International Commission on Radiological Protection, this principle can be paraphrased thusly: *No person should be subjected to any additional radiation exposure unless the benefit to be derived clearly exceeds the risk to be incurred.* This is the fundamental underpinning of the concept of ALARA and the day to day practice of health physics. But, whose benefit and whose risk? Is it the individual, or the society, or somebody else who derives the benefit? And, is it the individual, or the society, or somebody else who incurs the risk? These are important questions that need to be considered by the health physicist in the overall context of human radiation experimentation.

TYPES OF HUMAN RADIATION EXPERIMENTATION

Human radiation experimentation can take many forms, and can be divided into two categories. Category I exposures are those in which the purpose is to direct administration of radioactivity or external radiation in order to study the radiation in relation to the individual. Perhaps the most common or obvious Category I exposures involve new and unproven radiological therapies or diagnostic procedures with significant exposure to radiation. A corollary, perhaps, to the preceding, are radiation effects studies in which a person or persons may be exposed to radiation to determine the effects on the healthy body. Category I exposures would also include biokinetics studies in which radioactive substances, albeit in small quantities, are administered for studies of uptake, distribution and excretion, and determination of various biokinetic parameters such as biological half-life for medical or health physics applications.

Category II exposures are those in which the radiation exposure is incidental to the primary purpose of the investigation or treatment. These include tracer studies of various kinds; additional diagnostic or evaluation procedures involving radiation exposure required by a nonradiological experimental treatment; and major exposure ancillary but essential to a particular treatment. Category II exposures might even be extended to include the exposures incurred by personnel involved in the preparation, handling, and administration of the radioactivity or external irradiation procedures. The radiation experimentation in the United States over the past half century has encompassed all types of Category I and Category II exposures.

POTENTIAL LEVELS OF INVOLVEMENT OF THE HEALTH PHYSICIST

The health physicist can become identified with human radiation experiments on many levels. He or she can be a member or even the leader of the experimental team carrying out the research. A somewhat lesser level of involvement would be to provide direct health physics support to the experimental team. More indirect but still at a higher level of involvement would be review and possible approval of the experimental protocols as a member of an Institutional Review Board, Human Subjects Committee or similar body, or review and approval of the experimental protocols from a professional health physics standpoint only. At a lower level is incidental involvement, which may arise out of and in the course of employment, such as when the colleagues of the health physicist seek advice or consultation on a specific aspect of the research, or when the health physicist is aware that the research is planned or being carried out by the institution. The lowest levels of potential involvement are incidental and not related to the employment or professional practice of health physics. For example, the health physicist may be aware that a human radiation experiment is planned or being carried out at another institution, or that waste shipped to his or her institution has been generated as a byproduct of a human radiation experiment.

ELEMENTS OF APPROPRIATE HUMAN EXPERIMENTATION

Although there are many points of view ranging from impermissibility of any type of human experimentation to the permissibility of extensive types experimentation on certain classes of people, it is the generally accepted viewpoint that human experimentation is permissible and even desirable under certain circumstances, and with certain assurances and controls. Much has been written with regard to ethics of human experimentation, and specific cases and scenarios present conundrums and paradoxes with ample basis for discussion and serious consideration, but in sum and substances, the basic principles are twofold. First, the subject(s) must be fully informed, knowledgable and understanding of the procedure and its attendant risks and discomforts and detriments, and must be unreservedly willing to participate. The second principle is that there must be some reasonable expectation of benefit.

The above principles are generic, much like the Biblical injunction "Thou shall not kill". And, like the injunction, detailed examination of each of the basic principles poses a host of further questions -- e.g. What is 'reasonable'? What constitutes 'knowledgeable'? Or 'understanding'? Whose benefit? Is it acceptable to experiment on a comatose patient if there is reasonable hope of achieving an otherwise impossible cure? -- are might best be left to detailed discussion and consideration by ethicists, scientists, semantisicists, clergy and laity and as such outside of the scope of this paper. More instructive would be an examination of past practices in the light of these two principles or tests, with an eye towards developing a rational ethic for health physicists with respect to human radiation experimentation.

PAST EXPERIMENTS IN THE LIGHT OF THE TWO GUIDING PRINCIPLES

In his diary *Journals Into Diverse Places*, the great French barber surgeon, Ambrose Paré (1510-1590) describes a visit to another country in which a test was made of the efficacy of the bezoar stone at preventing poisoning. It had long been believed that the bezoar stone, the hairball of a calf, would prevent the action of certain poisons. A cook, condemned to death the next day for stealing, was offered the opportunity to test the bezoar stone, with the understanding that if it worked, he would be set free. If, of course, it did not work, the cook would still die, although much less pleasantly and humanely. The cook cheerfully and willingly chose to participate in the experiment. He was administered a caustic poison, but the bezoar stone had no effect. Despite the ministrations of Paré and the attempts to ease his suffering, the cook died an agonizing and horrible death.

Did this experiment, carried out nearly five centuries ago, meet the two tests? The answer is clearly affirmative. The cook was willing and informed, and understood the potential consequences of his participation. Thus the first test was met. There was also expectation of direct benefit to the subject, who would be set free and not executed if the experiment worked, as well as to the greater community from the knowledge gained vis-a-vis the effectiveness of this potential treatment.

The second experiment involved a group of men in the U.S. suffering from syphilis in the 1930's who were denied treatment so that physicians could observe the end stages of that disease. This experiment met neither of the tests; the subjects were completely and deliberately uninformed and presumably would have unwilling to forgo treatment. There was no expectation of benefit either to the subjects or to anyone else, for the end stages of tertiary syphilis were already well known, and had been for many years.

The third example is that of the first known human radiation experiment. On November 18, 1896, less than a year after the discovery of x-rays, American physicist Professor Elihu Thompson reported the results of deliberately exposing the little finger of his hand to x-rays, describing the physical damage, pain and suffering that he had incurred. Thompson's classic experiment met both tests: he was both willing and knowledgeable (although he did not anticipate such serious consequences, he knew as much about potential biological effects of x-rays as virtually anyone) and there was a clear expectation of benefit in the form of better understanding of the possible biological effects of x-rays, and of protection of people from excessive exposure.

Another example of radiation experiments, this one with a more equivocal answer to whether the two tests are met, relates to the plutonium injection cases. In the 1940's, 18 individuals thought to be suffering from incurable diseases that would result in death within ten years were injected with plutonium so that the biokinetics of this new manmade element could be studied and documented. Whether this experiment met the test of willing, informed, and understanding subjects is open to question; there was no documentation, and it is impossible to reconstruct what may or may not have been told to the subjects as they and the scientists carrying out the experiments are largely deceased. that there was an expectation -- indeed almost a guarantee -- of benefit in the form of new knowledge potentially useful for establishment of safety standards is unequivocal. But whether this benefit would have overridden the potential detriment, even if the subjects had been fully informed and willing is also open to question.

One final human radiation experiment bears consideration. In the 1960's, a group of mentally impaired children at the Fernald School in the northeastern United States was administered tracer doses of iron in a nutrition study. The fact that these were children, with serious mental deficiencies, raises the ethical question of the acceptability experimentation on groups or individuals whose ability to evaluate the merits of their participation is lacking or minimal. Even though the consent of the parents (who were likely not informed that a radionuclide was to be used in the study) was obtained, the ethical question remains. Permitting such a practice would seem to open the door to justification of the grotesque medical experiments carried out by the Nazis on groups they considered inferior and hence incompetent to judge whether they should participate as individuals.

TOWARD A RATIONAL ETHIC FOR HEALTH PHYSICISTS

The above lead to a simple rational ethic for health physicists with regard to human radiation experimentation: ***At all levels, the health physicist has a professional as well as personal obligation to ensure that proper humanitarian requirements, including proper informed consent and willing subjects, are carried out with respect to human radiation experimentation, and must be convinced that the real or potential benefits to be derived from the experiment clearly exceed the potential detriment and risk.*** In practice, this means that the health physicist should not participate in or provide support to experiments that do not meet the two basic criteria for human experimentation. Moreover, the health physicist has a professional and societal obligation to attempt to prevent any such studies with human subjects that do not meet humanitarian considerations. This is a fundamental responsibility of the professional practice of health physics, which after all, is devoted to the betterment of mankind.

In conclusion, it perhaps bears mention that the term ***humanitarian requirements*** as used in the above proposed ethic is of necessity dynamic and not static. What is acceptable today may not be so tomorrow. Consider, for example, the bezoar experiment described by Paré, which met both of the tests or criteria for human experimentation. By the standards of today, such an experiment would be unthinkable for manyethically based reasons. But we can and must learn from the past, so that as Santayana has pointed out, we are not condemned to repear our mistakes.