Commentary (I)

Ethics and the Medical Uses of Radiation

During the twentieth century, man has created many desirable changes; for example, in health and medicine the average life span has been increased and the quality of life has been improved. A vast amount of current medical knowledge is a direct result of the use of ionizing radiations, particularly of the x- and gamma-radiations that were discovered at the turn of the century. Initially, physicians and scientists made use of this new diagnostic tool with no thought of harmful effects. Within a decade though, it was discovered that indeed great harm can be wrought as a result of exposure to ionizing radiations.

Our limited time span of 80 years of use and research with ionizing radiations has given us a data base upon which certain analyses can be made with respect to the negative effects of their use. Yet many unanswered questions remain. Our concerns are within two areas: somatic and genetic. The somatic effects that have been clinically identified include erythema, loss of hair, cataract formation, and induction of various types of cancers (leukemias and thyroid carcinomas in particular). Since many different tissue types are involved when an individual is exposed to radiation, it has not been possible to designate a single parameter as a "somatically significant dose." Our experience with somatic effects in man comes from either accidental exposure, wartime exposure, or from radiotherapy. No evidence has verified that low-level radiation, such as used for diagnostic purposes, has the potential to produce clinically significant somatic effects. On the other hand, there is no proof that exposure to low levels of radiation will not produce somatic effects. Much of the data collected from animal studies is invalid for somatic effect studies in man because of the differences in life span after exposure.

There is sufficient evidence that genetic effects can be a direct result of exposure to ionizing radiation; yet no levels of radiation exposure beyond which specific genetic effects may be manifested have been determined. Certain facts are known: (1) intra- and extra-uterine growth may be retarded; (2) embryonic, fetal, or neonatal death may occur; and (3) congenital or genetic effects may be present (*1*).

A 1970 study showed that during the course of a year, approximately 26,000 women in the U.S. in the 15-to-45 age range had medical x-rays; 30% of those procedures involved the lower abdomen or pelvic areas. The dose in mrads for a routine abdominal study (e.g., retrograde pyelogram, KUB, BE, IVP, renal arteriogram, lumbopelvic, or lumbosacral spine) varies from 200 to 800 mrads to the uterus (or embryo) per exam, assuming three projections per exam (*2*). A 1976 study by Fletcher showed that in some hospitals, as many as 30% of pregnant patients were receiving diagnostic x-rays of the abdominal and pelvic regions during the third trimester (*3*).

Nuclear imaging procedures may deliver up to 3 rads to the gonads and varying levels to a fetus, depending upon the procedure and the type and activity of radiopharmaceutical. Therapeutic procedures may deliver as much as 6,000 rads to a fetus over a six-week period of therapy under highly exceptional situations.

Radiation damage to the fetus has been characterized according to the three stages of fetal development, and levels of radiation damage have been extrapolated from data obtained from animal studies. The preimplantation stage in humans occurs from conception to ten days postconception. For exposures of 150 rads or more, the most likely radiation damage at this stage is prenatal death. Lower levels may allow the embryo to survive but if so, there is a possibility of some minor genetic abnormality. Major organogenesis occurs from implantation up to six weeks postconception, and this is the stage during which gross abnormalities may be effected. Prenatal or neonatal death for radiation levels of 25 rads or more may also occur at this stage. During the fetal stage, from six weeks on, fewer obvious abnormalities occur but mental retardation is possible in dose levels as low as 5 rads according to animal studies that have been done (*4*).

Ethical Decisions in Clinical Nuclear Medicine

There are several areas of clinical practice where ethical decisions come into play in the physician-patient or technologist-patient relationship, in order to keep a patient's exposure to radiation as low as possible. Many of the day-to-day problems that must be solved are on the technical level; however, it is the physician who must decide whether a diagnostic or therapeutic procedure is appropriate. The technologist must determine that the equipment is functioning within the standards of practice and that the study is done according to protocol.

A recurrent issue in radiology is the problem of equipment standardization and calibration so that the appropriate x-ray beam is used. Also, the field of exposure should be limited to that area under diagnostic inquiry, and in many cases gonad shields should be used. If all these criteria are met, and the patient is cooperative, the technologist should be able to obtain the desired films with a minimum of patient exposure. An ethical problem arises though, when the film does not turn out as desired and the study must be repeated.

In nuclear medicine a somewhat similar problem arises when a technologist injects the wrong radiopharmaceutical or more than the prescribed activity for the study being done. In either case, the patient is subjected to levels of radiation in excess of that necessary to obtain the diagnostic information.

A patient who is scheduled for a therapeutic procedure should be screened by the referring physician to assure that there are no contraindications to therapy. The technologist should double-check to make sure that this screening has been done. It is then the therapist's responsibility to obtain consent to therapy from the patient.

Another problem that arises is that of the radiation worker and the exposure he is allowed to receive as a function of his employment. For the sake of brevity, my remarks on this issue are simply that all precautions should be taken to limit personal exposure to the radiation worker. Guidelines for safe working conditions have been established by the National Council on Radiation Protection (NCRP) (*5,6*). If a female worker becomes pregnant it is generally her responsibility to assure self-protection for her fetus; however, hospital policies vary from no policy at all to a strict policy of no exposure for the pregnant worker.

Several guidelines on the safe use of ionizing radiation have been put forth. The

"as low as reasonably achievable" (ALARA) concept is the most recent. This concept grew out of the National Committee on Radiation Protection (now the NCRP), which in a 1949 report, introduced the philosophy that radiation exposure should be kept "as low as practicable." The principle of maintaining occupational radiation exposures ALARA is the basic philosophical stand of the U.S. Nuclear Regulatory Commission (*7*) and has been recommended by the National Academy of Sciences–National Research Council (*8*), and the National Council on Radiation Protection and Measurements (*9*). The ALARA concept has also been endorsed by several state regulatory agencies. The ALARA philosophy is based upon two major premises:

(1) "All exposure to radiation may be harmful; thus all doses must be minimized.

(2) Exposure of large numbers of people to small amounts of radiation can produce the same genetic effects in a population as the exposure of a small number of people to large doses of radiation. Under this approach, each exposure situation should be evaluated not in terms of how one might avoid exceeding maximum permissible exposure values, but rather in terms of how to achieve the lowest exposure commensurate with reasonable cost and effort" (*10*).

Weighing Benefits Versus Risks

In keeping with the ALARA philosophy, physicians are guided by the "benefit versus risk" principle. Each patient must be evaluated on an individual basis. The benefits that a diagnostic or therapeutic study may bring to the health and well-being of a patient must be weighed against the risks involved with the procedure. The radiation risks accompanying a single diagnostic procedure might be well within the limits of acceptability as we now understand radiation effects; however, the additive effects of multiple studies on an individual patient might well carry more risk of somatic effects than the benefits of diagnosis would warrant. Likewise, the risks that accompany radiation therapy may in some cases carry a potential medical problem of greater patient risk than the original problem for which the patient was treated.

For the woman of childbearing age, the rule that has been suggested by the NCRP is the "10-day rule"; it states that diagnostic nuclear medicine and x-ray examinations should be restricted to the first ten days after the onset of menses in fertile women at risk for pregnancy (*11*). Even further, in the event of unintentional radiation of a fetus, the "Danish rule" has been established as a guideline in reaching clinical decisions on the necessity of therapeutic abortions. According to the rule, an abortion is advised if the fetal dose is 10 rads or more but not if the dose is less than 1 rad, assuming the dose was received during the first six weeks in utero (*12*).

In order to facilitate reduction of medical irradiation of the patient who might be pregnant and implementation of the ALARA concept, the Bureau of Radiological Health (BRH) has conducted an extensive campaign to place the public on notice that the possibility of inadvertently irradiating a pregnant woman may supercede the need for diagnostic procedures, except in extreme cases. As a part of this campaign the BRH has developed a slide-tape series on radiation exposure, posters for placement in radiology waiting rooms, and an x-ray record card that helps a patient keep a concise history of x-ray exams taken in various health facilities.

In step with the ALARA concept, the Food and Drug Administration has pro-

posed recommendations to minimize fetal exposure from medical x-rays. The three-step procedure recommends that: (1) the attending physician ascertain the likelihood of pregnancy, (2) consult forms should be used to call the attending physician's attention to the need to establish pregnancy status (in absence of physician's verification, the technologist must complete the consent form), and (3) based upon the individual patient needs if pregnant, establish a plan of action to cancel, modify, or continue with the study (*13*).

One further guideline for technologists is taken from the code of ethics of the American Society of Radiologic Technologists, which states in part, "technologists shall make every effort to protect all patients from unnecessary radiation" (*14*).

Radiation Guidelines and Clinical Realities

Generally speaking, guidelines have been set up to allow safe use of ionizing radiations based on present knowledge of the effects of these radiations. The agencies that have the responsibility of protecting the general public from a danger, which is to a certain extent unknown and unquantitated, have set exposure limits that are believed to be far below any levels of exposure that might cause damaging effects. If these strict guidelines can be policed and enforced, the general public is believed to be safe from harm.

Most physicians, however, adopt a utilitarian point of view. This stems from the philosophy that states a person ought to act so as to produce the greatest balance of good over evil, everything considered; an act is right if it is useful. They must operate under the premise that the need for a diagnostic procedure and the chances of obtaining an accurate diagnosis by x-ray or nuclear procedures give the patient greater benefits than any risks that might be involved in somatic effects to the individual or in genetic effects to the offspring. The physician should apply the benefits versus risk rule to each patient and it is the physician's responsibility to determine the usefulness of the diagnostic or therapeutic procedure and to counsel the patient accordingly. The patient has the right to take an active role in the decision whether to proceed with the examination. Note that many diagnostic x-ray procedures are invasive and carry a certain risk beyond the use of ionizing radiation and must be done only with the consent of the patient because of the invasiveness of the procedure.

After a study has been ordered and the patient agrees to proceed, the technologist enters the picture. Some technologists, whether they know it or not, are strictly Kantian in their daily operation of a diagnostic imaging room. Immanuel Kant was an eighteenth century German philosopher; he developed the premise that the moral rightness or wrongness of human actions is totally independent of the goodness or badness of the consequences; i.e., one is committed to adhere to rules and principles that have been established, regardless of the situation that may arise. These technologists maintain their equipment in proper operating modes or conditions with quality control being the primary concern to determine that the patient receives the recommended dose levels of radiation. No retakes are made unless absolutely necessary and all radiopharmaceutical doses are within the recommended levels. They are careful to maintain good procedural technique as their duty to the patient. The Kantian ethicist would not even think of using therapeutic levels of

radiation without proper assurance that the patient could not possibly be pregnant.

Other technologists act under a utilitarian code of ethics. For them the most important act is to get the study done, and if it is more useful on a busy day to skip quality control and get on with the patient study, this technologist rationalizes that since quality control was within limits yesterday, it ought to be the same today. If repeating a film might give a better image, an extra bit of irradiation probably will not harm the patient. If the patient is obviously going to be difficult to manage, it would be acceptable to increase the radiopharmaceutical dose in order to complete the study faster. After all, this technologist rationalizes, dose rates are simply guidelines—not hard and fast rules—and from what we know about the harmful effects of ionizing radiations, no harm could possibly come from an extra 5 mCi of radiopharmaceutical.

Somewhere between these two ethical points of view lies the philosophical stand that is most appropriate for the practicing technologist. Like the physician, the technologist must also apply the benefit versus risk tenet to the daily operation of the nuclear medicine department. Rules and regulations have been developed for the protection of the patient and the radiation worker, and the technologist should perform all tasks within those guidelines whenever possible. There are, however, exceptional cases in which it may benefit the patient to perform a lung scan when the camera is not operating with optimum resolution, or use a radiopharmaceutical when the tagging efficiency is somewhat less than desirable. Likewise, extravasation of a portion of a radiopharmaceutical dose might compromise the quality of a study, making the use of an additional quantity of radiopharmaceutical beneficial to the diagnostic outcome of the study. The technologist must be careful, though, to weigh all factors carefully before deciding to work outside the guidelines that have been established for the protection of patients and radiation workers.

Above all, the technologist must be careful to maintain good working habits when using radioactive materials and to be constantly aware of the need for quality assurance in every study.

It is not enough to perform quality control checks on the gamma camera to assure it is performing properly. The camera must also be used properly: the appropriate window widths set; the right collimator used; and the proper patient-to-collimator distance maintained. Radiopharmaceutical quality control should be performed before injection of activity—not after a poor tag is evidenced in the patient image. Whenever possible, the quality of the study must be such that the physician can make the appropriate diagnostic decision without needing to repeat studies or recommend additional studies.

The Basics of Ethical Practice

The basis for ethical practice can be outlined in a few simple steps:

(1) Be informed of current guidelines for safe work practices and procedures.
(2) Establish and maintain a quality assurance program that includes all equipment and radiopharmaceuticals.
(3) Develop proper work habits, incorporating the ALARA concept.
(4) Establish protocols for routine procedures and use them routinely.
(5) Be able to make exceptions to established practice according to the benefit

versus risk philosophy, whenever exceptions are warranted.

(6) Make periodic audits to determine whether ethical standards are being applied as outlined in steps 1 through 5.

Surely, ethical practice in the use of ionizing radiations is the standard, now that training, certification, and continuing education have been stressed for several years. Also, the general public has come to demand accountability in medical practice in recent years and this has dispensed an awareness of ethical standards throughout the medical profession.

In summary, the medical community has an obligation to the patient to act according to certain rules and guidelines that have been established for the general protection of the patient from any somatic effects that might possibly arise from the use of ionizing radiations. We are also morally bound to protect future generations from the genetic effects of ionizing radiations. At times we must operate under rules that appear to have no significance to the individual patient or that keep us from obtaining immediate answers to current problems. However, professional ethics demand that the maximum benefits to the patient lie in minimizing the levels of radiation at all times.

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References

1. Witcofski RL. Nuclear medicine—Hazards in pregnancy. In *Continuing Education Lectures*, Society of Nuclear Medicine, Southeastern Chapter, Atlanta, 1976.

2. U.S. Department of H.E.W. *Population Exposure to X-Rays*, U.S. 1970. PHS No. 73-8047, November 1973;27–52.

3. Fletcher EWL. Is fetal radiography really necessary? *Lancet* 1978;8066:600–01.

4. Jeck S. The hazards of radiation in pregnancy. *J Am Osteopathic Assn* 1979;78:435–40.

5. National Council on Radiation Protection and Measurements: *Radiation Protection for Medical and Allied Health Personnel*, Report No. 48, Washington, CS, 1976;1–35.

6. National Council on Radiation Protection and Measurements: *Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally-Exposed Women*, Report No. 53, Washington, DC, 1977;1–7.

7. U.S. Nuclear Regulatory Commission: *Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Reasonably Achievable*, Regulatory Guide 8:10, Washington, DC, 1977;1–5.

8. National Academy of Sciences. *The Effects on Population of Exposure to Low Levels of Ionizing Radiation*, Washington, DC, 1972.

9. National Council on Radiation Protection and Measurements: *Review of the Current State of Radiation Protection Philosophy*, Report No. 43, Washington, DC, 1975;2–5.

10. Aamodt R. Radiation Safety, in *Textbook of Nuclear Medicine: Basic Science*, Philadelphia, Lea and Febiger, Rocha AF, Harbert JC, eds, 1978;146–62.

11. Travis EL. Clinical Radiation Biology I: Diagnostic Radiology, in *Primer of Medical Radiobiology*, Chicago, Yearbook Medical Publishers, 1975;151–70.

12. Parker HM, Taylor LS. *Basic Radiation Protection Criteria*, National Council on Radiation Protection and Measurements, Report #39, Washington, DC, 1971.

13. Brent RL, Gorson RO. Radiation Exposure in Pregnancy, In *Current Problems in Radiology*, 1972;11:3–48.

14. American Society of Radiologic Technologists. *Code of Ethics*. Chicago, ASRT, 1975.