Report of North American Workshop on Ethics

MEDICAL Discussion Group report:

The primary issues in medical applications of radiation are considerations of worker dose to the practitioner vs. patient care, risk communication to both workers and patients, and stakeholder engagement in Medicine.

The hospital area where radiation exposure is a primary concern is the fluoroscopy laboratory, i.e., interventional radiology, including interventional procedures, coronary angiography, and angioplasty. Except for some PET radiochemistry laboratories, nuclear medicine and radiation oncology practices do not result in high worker exposures.

Most people in the interventional radiology suite are not highly exposed, but those who are exposed can be highly exposed. The eyes are particularly difficult to protect; worker time in the laboratory can be 8 or more hours per day; photons can "wrap around" protective lenses due to scattering; and specialists in certain procedures are in high demand. Regulations do not allow worker exposure limits ever be deliberately exceeded. However, the group suggested that it would be ethical, if tissue reaction limits are not exceeded, that the stochastic limit be raised, but only if the worker (i.e., the interventional radiologist) signs an informed consent (or similar) document. The procedure may be related to a life saving treatment or extend the life of the patient, which justifies raising the stochastic limit of the radiologist if he/she is informed and willing. Could that also apply to others in the suite, such as nurses, technologists, and anesthesiologists? That is not so clear, as they could be under "coercion," i.e., trying to keep their jobs to agree to a raised exposure limit.

In general, a "fixed, defined limit is appropriate in any situation where the stakeholder cannot give informed consent" (e.g., public exposures, or subordinate workers.)

So how much of an increase could be ethical? Any new (raised) limit should still be protective of tissue reaction effects. The increased risk should remain comparable to risks in hazardous industries such as construction, mining, agriculture, but be less than risks in extremely hazardous occupations, such as space travel. The limit should also consider previous exposure and age. The dose limits for emergency responders based on activity (lifesaving, property protection, etc.) could be used as a model. Should we change the risk equation from risk of mortality to risk of injury? Hospital employees have a low mortality risk but a high injury risk, e.g. nurses have a high risk of needle sticks and back injuries. Can this exception through informed consent be applied to other occupations, e.g. industrial radiography? Could evacuation be voluntary in an emergency situation, i.e. could evacuees choose their own action level? What about early return to an evacuated area? Could people choose their own risk level for returning to their homes?

Is it ethical to have different limits for different professions? If so, can we allow professions to set their own limits (perhaps as long as an "upper bound" limit is not exceeded)?

How do we maximize autonomy and minimize coercion? Should a physician receive a financial incentive for treating more patients, which results in exceeding the regulatory radiation worker limit? Does the system of RP have the right to limit autonomy in order to limit coercion?

Can we ethically limit release of radioiodine therapy patients? Yes, because of public health concerns. Instructions are given to released patients on limiting exposure to members of the public (e.g. avoid public transport) but are not enforceable; should the hospital provide the service needed (e.g., transportation home) and fold the cost into the cost of the procedure? Government has the right to overrule individual autonomy to protect public health as in the quarantine of patients with infectious diseases. Some studies suggest that 95% of patients follow release instructions, but 5% do not. We can maximize the autonomy of the patient by using patient-specific dose rate calculations rather than the administered/retained activity; but we also need to look at cohabitants. What about the public? There is implied informed consent for all kinds of hazards, e.g. vehicle accidents, and the person seated next to you on the bus may have influenza. Second-hand tobacco smoke is not regulated everywhere. In general, restrictions placed on autonomy are commensurate with risk.

Both the treating physician and the patient have a duty to the public to minimize risk, by providing and following release instructions to minimize public exposure. In tort cases, there are three elements of neglect: actual harm (non-maleficence), duty owed (prudence), and proximal cause (patient not following instructions.)

Should limits protect the most vulnerable? Who is that? It is the elderly for tissue reaction effects, and children for stochastic effects. Ataxia-telangiectasia patients are the most sensitive to radiation effects, but comprise a very small number of people; some genotypes, e.g. BRCA1,-2 positive or other genetic indicators are similarly more sensitive. An annual exposure limit of 1 mSv, divided by the hours in year (8,766) and multiplied by the hours of exposure presents a negligible risk.

In the United States stakeholder engagement is built into the regulatory process, through the Advance Notice of Proposed Rulemaking (ANPR), public comments and hearings, stakeholder meetings, etc. Consumer groups also follow the process of rulemaking closely. Societal and cultural differences in other countries may limit this process elsewhere.

Exceeding a limit must be fully justified and demonstrated to be unavoidable. How could it be implemented in practice? Would it also require enforcement of dosimeter wearing to record the increased exposure? If an option exists to exceed the regulatory limit, motivation for not wearing the badge is decreased. Although a financial reward may exist for exceeding the limit, the motivation is often the ethical requirement of providing the best therapy to the patient. Recording and record maintenance of previous exposure is very important in the context of permission to exceed the limit.

Use of informed consent would add flexibility to the RP system: patient informed consent is needed for radiation exposure; emergency responders are under consideration for informed consent, but not considered for other occasions. The Fukushima Dai-ichi nuclear power plant accident showed that people could stay in contaminated areas with informed consent. We have to look very carefully at other situations to ensure that coercion by financial incentives does not interfere with informed consent.

Regulatory implementation could be extremely difficult; it is easier if there is a clear conflict between not exceeding the dose limit and saving (or prolonging?) life. A change to allowing limit exceedance via

informed consent would introduce variability and inconsistency; can it be extended to other areas where worker exposure is not so clearly linked to life-saving?

There is always a problem when comparing RP with other occupational safety issues: generally there is a very different level of risk involved than with electrical safety, working at height, etc. Conditions of urgency or unavailability of resources also change things. Standards for some occupational risks are actually mandated at a lower level than RP, so comparison with other industries may not be so bad.

We need to pay attention to total risk; higher risk limits in an emergency situation reflect an exceptional situation; is it really transferable to a non-extraordinary situation?

In the United States the old occupational exposure limit of 3 rem/quarter and the 5(N-18) system (where N is the worker's age in years) allowed this flexibility; current defined annual limits do not.

There has been no discussion in developing the RP system of differences between medical practice and other occupations; because of consideration of patient benefit and risk vs. practitioner benefit and risk, we need to take a look and revisit the situation. The medical ethic of patient care will always take precedence over the ethic of worker RP. We are trying to apply a system developed outside the medical system to it; the limits are so far below the level of demonstrable effects that they are not comparable to risks from not treating the patient.

In the United States, if it is absolutely necessary to exceed limit the public dose limit in the care of a hospitalized family member treated with radioiodine, the hospital can call NRC or state regulator for an exemption. An exemption request has probably never happened with patient release. However, it has been considered for certain caregivers/relatives of critically ill patients.

Communication Discussion Group report:

Preamble: believing that workers and the public have a right to know about rad risks and to understand radiation and the principles of radiation safety, the group recommends that:

1. Communication must be clear and understandable in the common language
2. Communication should facilitate informed decisions by institutions and individuals
3. Communications should include science, values (ethical, social, political and cultural) and experience
4. Communications should convey prudent and reasonable options for action
5. Communications should occur early and preferably before an incident
6. Communications should explain the benefits of options
7. Communicators should be a resource to help people make informed decisions
8. Communicators should hear and reflect concerns, fears and feelings
9. Communications should be truthful, accurate, open, impartial, and honest, and tell what we know and also what we don't know.
10. Communications should recognize and respect differences
11. Communications should foster rapport and help develop trust
12. Communications should convey the prevailing standards
13. Communicators should provide a service to different publics, groups and organizations
14. Communications should be low cost or free
15. Communications should bridge from cause to effect

Discussion:

In general, the RP expert is not the decider, but rather helps deciders to make informed decisions. Communications start with the prevailing current circumstances and reality of the situation.

The objectives of a communications effort cannot include building trust, because that can only be built over a long period; trusting does not necessarily include agreeing with us. However, the communications effort helps to develop trust, and if poorly done, can destroy trust.

Communications must assist people to make decisions; it is much more than just risk communication focused on data. One aim is to enhance the RP culture that focuses on safety; risk communications is only a part of the whole. We have put too much focus on the risk; we need to increase focus on protection methods, self-help, and empowerment. We must provide actionable information.

Who is the public? The public is anyone who is not an RP specialist. We must target communications to the target group and tailor messages to the audience's level of wealth, education, etc.

The ethical principles of dignity and autonomy apply to generate the public's "right-to-know"; communications should provide the public the skills to apply RP principles to self- and community protection.

Communicating probabilities usually doesn't help, especially very small probabilities; in fact, risk acceptance is usually independent of the probability. In Japan people want to know the risk probability

of 10-20 mSv exposures; RP experts may say the risks are too small to be of concern, but people do not understand. Some experts think a 20 mSv exposure is too risky for children, and dueling experts increase anxiety.

Do we understand cultural issues (including religion) well enough to incorporate them effectively in RP communications? Probably not, but efforts such as the recent environmental ethics conference in Budweis, Czech Republic are improving our understanding.