
Volume 11 - Issue 2, 2011 - Cover Story: A Primer on Radiation Protection: Patient & Personnel Safety in Focus

Communication, Consent and Patient Safety

In theory, good medical practice implies knowledge of the doses and long-term risks of radiological and nuclear medicine testing, since awareness of risk is essential for tailoring the risk-benefit balance in ascertaining test appropriateness. In practice, extensive recent data show substantial unawareness of radiological doses and risks - not only on the part of patients, but of prescribing and practising doctors as well. Both specialists and non-specialists may not understand the difficult jargon of radiation protection, in which doses are expressed in various, often esoteric units (megaBecquerel, milliCuries, kilovolts, etc.), and simple information on doses and risks is difficult to find and hard to interpret.

Ineffective communication currently poses significant ethical problems, with high litigation potential. Informed consent is necessary to establish a respectful, ethical relationship between doctors and patients. It should be managed by following a process model, in which the patient actively participates in medical decision-making. Hence, informed consent becomes a vital component of the physician-patient communication and - from a legal perspective - an integral part of the medical act, being based on a continuous dialogue between patient and physician, called mutual monitoring.

A transparent, informative, honest consent form should spell out the type of examination and the exposure in effective dose (mSv), derived from reference values in guidelines or - better - from actual values from the department. The dose equivalent should also be expressed in number of chest radiographs and the risk of cancer as the number of extra cases in the exposed population, derived from the most recent and authoritative guidelines (e.g. BEIR VII Committee, 2006). Complete radiological informed consent is an important step in the direction indicated by the American College of Radiology's (ACR) recent white paper, recommending that physicians "should work with patient advocacy organisations to more effectively communicate the potential radiation risks and health benefits of imaging procedures". Forced to explain to the patient what they currently disregard, doctors will gently and painlessly learn what they should already know.

Every radiological and nuclear medicine examination confers a low but definite long-term risk of cancer, but patients undergoing such exams often receive inaccurate or no information about these risks. Too-detailed information on dose and risk may result in undue anxiety, but information "economical with the truth" may violate basic patients' rights (see Oviedo convention 1997) and law (97/43 Euratom Directive 1997). In fact, one of the three fundamental principles of the charter of medical professionalism in the new millennium is the principle of patient autonomy: "Physicians must empower their patients to make informed decisions about their treatment".

Patient Awareness of Radiological Risk

Informed consent for radiological examinations is often not sought, and when it is, patients are often not fully informed, even when facing considerable levels of radiation exposure and long-term risk. The risk of a 64-slice computed tomography coronary angiography can be as high as 1 in 100 in a young woman or in a child. In theory, the majority of paediatricians from the Greater Toronto Area in Canada, practising in a wide variety of hospital and clinical settings believe that a risk of 1 in 10,000 or more should be discussed with the child's parents. In reality, patients are not given information about the risks, benefits, and radiation dose for a CT scan, even when a considerably higher risk is involved.

In another study performed in the emergency department of a U.S. academic medical centre, adult patients who underwent diagnostic CT scans were surveyed. Only seven percent of patients reported that they were told about the risks of their CT scan, and all patients were unable to estimate the dose for one CT scan compared with that for one chest radiograph. Only three percent of patients believed that their lifetime risk for cancer was increased as a result of the CT scan. In another study performed in the nuclear medicine department of a leading academic centre in Italy, 79 percent of surveyed patients thought that the cardiac stress scintigraphy they had performed gave a radiation dose of < 1 chest x-ray instead of the true dose of 500 chest x-rays, and 40 percent thought that no cancer risk at all was present. Ironically, 71 percent of patients thought they received good-to-excellent information on the risks and benefits of the cardiac stress scintigraphy from their physician.

Physician's Awareness of Radiological Risk

Extensive recent data show substantial unawareness of radiological doses and risks, not only of patients but of prescribing and practising doctors as well. In theory, good medical practice warrants knowledge of the doses and long-term risks of these tests - which can be judiciously employed when they are most appropriate. The results of surveys recently performed on British physicians, Israeli orthopaedists, Italian cardiologists, Canadian paediatricians, and U.S. academic radiologists, show that the majority of doctors grossly underestimate the radiation doses (usually by up to 500 times) and corresponding cancer risks, for most commonly requested tests.

Emergency room physicians and radiologists alike are unable to provide accurate estimates of CT doses regardless of their experience level. In particular, among radiologists, five percent of respondents thought that a CT scan dose was less than one chest radiograph, and 56 percent estimated the CT scan dose between one and ten chest radiographs, with dramatic underestimation of the true dose (about 500 chest radiographs). Forty percent of paediatricians underestimate the dose of a pre- and post-contrast head CT by up to 100 times. A minority of doctors also suffer from what we might call imaging daltonism, i.e. the inability to separate green (non-ionising) from red (ionising) techniques. Five percent of British doctors do not realise that ultrasound does not use ionising radiation, and 10 percent do not realise that MRI does not use ionising radiation. Among Canadian paediatricians, four percent believed that ultrasound involves ionising radiation and 12 percent were not

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aware that scintigraphy scans do. Faced with this diffuse background level of radiological unawareness, inappropriate examinations may proliferate, to the profound detriment of society and patients.

Informed Consent: How it is

There are three possible ways to look at radiologic risk communication in medicine – no mention of risk, understatement of risks, and specific detailing of risk.

Strategy 1: "Don't Say a Word"

One philosophy is not to mention radiological risk. Even for procedures with high radiation dose, such as interventions under fluoroscopic control, there is no explicit or implicit mention of long-term risks. The risk exists and may be substantial, but it remains unheard (by the patient) and unspoken (by the doctor). The basic argument is that radiologists are too busy to spend time obtaining informed consent and anyway are too wise to undertake inappropriate examinations. Patients' legal right to information is eclipsed by the two forces of efficiency and a paternalistic, "expert knows best" vision of individual autonomy. The long-term nature of the risk, not its absolute amount, seems to be the excuse for disregarding informed consent.

Strategy 2: Understatement

In other aspects of radiological practice, obtaining written informed consent is part of standard practice. In this case, the issue of efficiency bias is not raised: a patient must give informed consent before contrast is injected. But what is the quality of the information given to patients? On the websites of scientific societies, in the information section for patients and in the informed consent forms to be signed by patients, we read statements such as "A nuclear medicine examination is safe, with an irradiation corresponding to a simple radiograph" or "almost always less than a common radiological examination". Both patients and clinicians might believe that a common radiological examination or a simple radiograph would be a chest x-ray, which is by far the simplest and most common radiological examination. In reality, however, the dose exposure in cardiology ranges from 500 chest x-rays for a sestamibi to 1,500 chest x-rays for a dual isotope cardiac stress scintigraphy. Such imprecise statements are probably intended to reassure patients, to avoid useless concern about an unavoidable risk. However, this attitude of one consent fits all for radiological examinations may mislead clinicians to underestimate the associated risks.

Strategy 3: Full Disclosure

Some organisations, such as the U.S. National Institutes of Health (NIH), describe radiological risk in more straightforward terms, at least when the test is performed within a research project and with a radiation dose greater than 15 milliSieverts (corresponding to the average dose of 64-slice computed tomography coronary angiography): "Your scan involves exposure to radiation. Although it can vary from person to person, your whole body radiation exposure during each scan will be about 15 milliSieverts. This is about five times the average annual radiation exposure a person in the United States receives from natural background radiation. Although no harmful effects are expected, your long-term risks of harm from this degree of radiation exposure might be as high as one in 1,000. Harmful effects could include the development of cancer and genetic changes".

Informed Consent: How it Should Be

Non-specialists (and sometimes specialists) often do not understand the difficult jargon of radiation protection. The pressures of an old-fashioned paternalistic view of medicine as well as a more modern efficientism act against the creation of a truly informed consent. The well-known permeability of medical opinion-leaders and media to industry and corporate interests can further modulate communication towards underestimating and obscuring risks. In an ideal consent process, the standard of risk communication already adopted for irradiation in research might be fruitfully followed for irradiation in clinical practice. The form - as a functional yet not exhaustive tool for the legal compliance to the correct implementation of a valid consent - should at least spell out the type of examination, the exposure in effective dose (mSv), the dose equivalent in number of chest radiographs, and the risk of cancer as number of extra cases in the exposed population. This minimal information constitutes the legal fundament to develop a wider dialogue, which is not only worthwhile but also beneficial within a process of informed consent both in the radiological area as well as in nuclear medicine.

Figure 1 underlines the linear relation between dose and risk and might be useful for passing information from doctors to patients and between doctors because the figure format complements the traditional table format (see table, p. 12) and the colour coding helps readers to understand risk levels. This simple evidence-based communication strategy, if used when obtaining informed consent, will raise the currently suboptimal level of radiological awareness among doctors and patients. Better knowledge of risks will help us to avoid the small individual risks that translate into substantial population risks. Consent forms would also help reduce pressure from patients for redundant and often useless examinations.

Common sense, deontological code, patients' rights, medical imaging guidelines, Euratom law - all coherently and concordantly suggest a responsible and informed use of ionising testing. Current practice clashes with these guidelines and laws. It will become more and more difficult to defend physicians ignoring doses and risks of exams with high radiation load, especially in the case of inappropriate examinations, which plague the current practice of medicine in every field. By law, there are strict limits for the general population (1 mSv per year) and for professionally exposed workers (20 mSv per year). Paradoxically a citizen, upon becoming a patient, loses his/her radiological rights and can receive literally hundreds of mSv of exposure without receiving any information and, in the case of inappropriate examinations, without any commensurate benefit. Perhaps it is time to change, and informed consent can help in this long-overdue turnaround from a culture of paternalism and over-diagnosis to a new culture of safety, prudence and appropriateness.

International Atomic Agency Endorses 2010 Approach

This approach has been now formally endorsed by the International Atomic Energy Agency, that in 2010 outlined how a truly informed consent is a fundamental requirement for all radiological procedures, and a key player of the three 'A's strategy (Awareness, Audit and Appropriateness) necessary to facilitate the justification process in radiological procedures. Along the same line, the recent landmark recommendations of Food and Drug Administration are aimed at optimising patient exposure to radiation from medical imaging exams, and thereby reducing related risks while maximising the benefits of these studies: "Each patient should get the right imaging exam, at the right time, with the right radiation dose".

A necessary step within this initiative is the need to increase patient awareness. The FDA "recognises the importance of empowering patients with information and tools to help them and their physicians manage their exposure to radiation from medical imaging". There is little doubt that the informed consent form is an essential tool to reach this still elusive target. It should be managed/implemented by means of following a "process" model, in which the patient actively participates in medical decision-making, alongside the diagnostic- therapeutic pathway. Hence, informed consent becomes a vital component of the physician-patient communication and - in a legal perspective - an integral part of the medical act, being based on a continuous dialogue among patient and physician, which is called mutual monitoring.

In our opinion, an effective radiological risk communication strategy should include:

- Sharing information with patients in a balanced way, listening to their concerns, encouraging them to ask questions, supporting their ability to make an informed decision;
- For exams involving high ionising radiation load (cancer risk 1/1,000-1/10,000): good documentation of the information process offering patient leaflets written in lay terms in suitable format, enriched with visual aids, with a consent form to be signed by the patient and informing physician;
- For exams involving low ionising radiation (cancer risk > 1/100,000): patient information posters in waiting rooms and public areas or other aids to enable informed decision-making without written consent.

Conclusion

Correct informed consent plays an essential role in the physician- patient relationship. A proper, complete, updated and comprehensive informed consent form should find a full implementation as part of a holistic process, in which the acceptance of the diagnostic and/or therapeutic act is the resultant outcome of three qualifying moments, logically and chronologically interlinked, as it follows:

- The correct and full communication about diagnostic and/or therapeutic information which - with regard to radiology and nuclear medicine - should focus on the dose equivalent in number of chest x-rays and the estimated risk of cancer as well;
- The act of ensuring that the patient has fully understood, the meanings and sense involved in that communication. This understanding could be increased by means of implementing tools and techniques such as video-registered feedback and teach back, as important components of a legally relevant process, and
- The final decision regarding the proposed diagnostic and/or therapeutic act.

Nobody is able to specifically endorse something if he/she does not achieve an adequate level of information and if he/she is not involved in both a communication and decision- making processes. Without the presence of these crucial components, whatever module of subscribed consent cannot be considered as valid within the juridical profile. This simple informed consent process and form policy will gently force the doctor to be more aware of what he/she does and the patient more aware of what he/she undergoes, and enabling both to make more responsible choices.

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