Abstract. As our system of radiological protection evolves, several significant issues loom within radiation protection discussions and publications. These issues influence the nature of epidemiological and radiobiological research and the establishment of radiation protection recommendations, standards, and regulations. These issues are like the proverbial "elephants in the room". They are large, and it is unwise to ignore them. This paper discusses the impact of three young elephants as they make their presence increasingly obvious: increased cancer susceptibility from early-life exposure to radiation, terrorism and fear of radiation, and patient safety. Increased cancer susceptibility from early-life exposure to radiation is emerging as a discussion topic related to the safety of computed tomography (CT) and other medical modalities. Shortly after publication of CT dose data, manufacturers were helping to reduce doses to children by increasing flexibility for adjustment of technique factors. Also, radiation epidemiological data are being used in the development of guidance on exposure to chemical carcinogens during early life. Re-emergence of public fear of radiation has been fueled by threats of radiological dispersion devices and confusing messages about personal decontamination, emergency room acceptance or rejection of contaminated victims, and environmental clean-up. Finally, several professional publications have characterized risk of medical radiation exposure in terms of patient deaths even though epidemiological data do not support such conclusions. All three of these elephants require excellent science and sophisticated data analysis to coax them from the room. Anecdotal communications that confuse the public should be avoided. These are not the only elephants in the room, but these three are making their presence increasingly obvious. This paper discusses the need for radiation protection professionals to rely on good science in the evolution of the system of radiological protection.

1. Introduction

Since the discoveries of x rays and radioactivity, we have learned much about the biological effects of radiation. Our system of radiation protection has become more sophisticated, but considerable uncertainties about the effects of low doses of radiation still exist. These uncertainties are exacerbated by numerous variables that influence dose response including physical factors such as dose rate and linear energy transfer and biological factors such as the bystander effect and the role of tumor suppressor genes. At the same time that we are trying to understand or eliminate uncertainties associated with risk of stochastic effects, technology is allowing us to reduce doses to the population. Thus, it is becoming more feasible to consider additional reductions in recommended maximum permissible doses for various elements of the population. Dose reduction considerations must not ignore several significant issues that may affect our recommendations, i.e. the proverbial "elephants in the room." This paper briefly discusses three of these issues: increased cancer susceptibility from early-life exposure to radiation, terrorism and fear of radiation, and patient safety.

2. Increased Cancer Susceptibility from Early-Life Exposure to Radiation

Data on A-bomb survivors and medical radiation exposures show that exposure to ionizing radiation early in life results in higher cancer rates relative to adult exposure for certain tissues, e.g. thyroid, bone marrow, stomach, colon, lung, and breast [1,2]. There is also evidence of specific windows of susceptibility e.g., puberty may affect breast cancer risk from radiation treatment for Hodgkin's lymphoma [3]. Increased susceptibility to radiation early in life is also supported by the data on radiation treatment of infants and children for various conditions and young women show received repeat fluoroscopy for tuberculosis [4,5,6].
Even though increased cancer rates are usually associated with high radiation doses, a small increased risk has been demonstrated at relatively low doses. Data on A-bomb survivors published by Thompson et al. (1994) show a large increase in incidence rate for all cancers in the high-dose cohort (mean dose of 1.6 Sv) and a small increase in incidence rate in the low-dose cohort (mean dose of 0.16 Sv). Because the number of cases in each cohort is small, there is considerable uncertainty among the risk estimates. The authors provided incidence rates for six age groupings for various types of cancer. However, the number of cases within many of the cohorts is very small; several of them have zero cases. This is particularly problematic for the high dose (>1 Sv) cohorts. Thus, even though the data show increased risk, the uncertainties cannot be ignored. For example, the ERR for thyroid cancer in the 0-9 age group was 9.46 and for the 10-19 age group was 3.02, but the 95% confidence interval for all ages was 0.48 - 2.14. Based on data from studies of the A-bomb survivors, Hall [7] concluded that children are ten times more sensitive than adults to the induction of cancer. The U.S. Environmental Protection Agency [8] has used round figures of 10X and 3X, respectively, in these age groups in their estimates of the increased risk of cancer in children exposed to mutagenic chemicals.

Studies also have shown an increased risk of cancer when humans are exposed to medical radiation. Elevated risks of a variety of radiation-related second cancers have been observed subsequent to high-dose radiotherapy for malignant diseases. Risks have been particularly high following treatment for childhood cancer [6]. The carcinogenic effect of therapeutic or accidental radiation is highest when exposure occurs during childhood [4].

Second cancer is the leading cause of death in long-term survivors of Hodgkin's disease (HD), with exceptionally high risks of breast cancer among women treated at a young age. Risk increased 8-fold (95% CI, 2.6-26.4) with a dose of more than 40 Gy (P<.001 for trend) [9]. The relative risk (RR) of solid tumors including breast cancer increased inversely with age at the first treatment for Hodgkin's disease, with RRs of 4.9, 6.9, and 12.7 for patients first treated at ages 31 to 39 years, 21 to 30 years, and less than 21 years, respectively [10]. Risk of breast cancer among young women treated with radiotherapy for Hodgkin's disease was 34.0% for women younger than 20 years at the time of treatment (RR 56), 22.3% for those who were 20 to 29 years (RR 7.0), and 3.5% for those who were 30 years or older (RR 0.9) [11].

Puberty may present a particular window of increased susceptibility. Bhatia et al. [3] showed that children 10 to 16 years of age at the time of radiation treatment for Hodgkin's disease had a significantly increased risk of breast cancer compared to those less than 10 years of ages (relative risk of 1.9).

In recent years interest has increased in risks associated with doses to children who receive computed tomography (CT). Brenner et al. [12] estimated that lifetime cancer mortality risks attributable to the radiation exposure from a CT in a 1-year-old are 0.18% (abdominal) and 0.07% (head). These risks are an order of magnitude higher than for adults; however, they still represent a small increase in cancer mortality over the background rate. In the United States, approximately 600,000 abdominal and head CT examinations are performed annually in children under the age of 15 years. Brenner et al. [12] estimated that 500 of these individuals might ultimately die from cancer attributable to the CT radiation. The risk-benefit balance still strongly
favors benefit, but the frequency of pediatric CT examinations is rapidly increasing. Since risk estimates for children undergoing CT are not negligible efforts should be made to more actively reduce CT exposure settings for pediatric patients [12,13].

The introduction of helical CT has transformed diagnostic radiology, especially in pediatric patients. The benefits are clear, but helical CT has potentially higher doses, and in children, even higher effective doses. Hall [7] estimated that an abdominal helical CT scan in a young girl results in a risk of fatal cancer later in life that amounts to about one in a thousand. The risk to the individual patient is small, and the medical benefits clearly outweigh the risk. However, the public health issue becomes significant when the small individual risk is multiplied by 2.7 million procedures per year. Hall [7] emphasized that every effort is needed to minimize doses by an appropriate choice of peak kilovoltage (kVp) and milliampere-seconds (mAs). At the same time he urged a more selective use of pediatric CT.

Use of beta radiation, x rays, or gamma rays to treat cutaneous haemangioma before age 18 months during 1930-59 has been demonstrated to reduce cognitive abilities in adulthood. The proportion of treated boys who attended high school decreased with increasing doses of radiation to both the frontal and the posterior parts of the brain from about 32% among those not exposed to around 17% in those who received more than 250 mGy. A negative dose-response relation was also evident for the three cognitive tests for learning ability and logical reasoning but not for the test of spatial recognition [14].

Several issues are in need of clarification as we attempt to further understand the risk of low doses of radiation. One is the uncertainty associated with the extension of risks of cancer in the A-bomb survivors to diagnostic x rays and the cumulative impact of multiple scans. Another is the significance of dose rate in radiology exams, e.g. the comparative risks of conventional x rays with CT. Third is the impact of technique on the benefit/risk equation as it relates to penetration, relative organ dose, and organ risk. Finally, unless we can clearly demonstrate no risk below a threshold level of radiation, we must continue to optimize medical radiation protocols to minimize the dose to the patient without losing essential diagnostic information and restrict such examinations to those cases where there is a clear clinical indication.

3. Terrorism and Fear of Radiation

Terrorism has many faces, but public anxiety has increased in recent years over the potential use by terrorists of biological, chemical, or radiological agents to expose a population. A "dirty bomb," a conventional explosive packed with radioactive material, kills or injures through the initial blast. However, airborne radioactivity generated by the blast will cause significant fear and require considerable funding for decontamination. Most people probably fear a radiological event more than a conventional explosion. This fear may be directly related to their inability to perceive the presence of radiation with the ordinary human senses and to their concerns about perceived long-lasting radiation effects. Studies of radiological accidents have found that for every contaminated casualty, there may be as many as 500 people who are concerned, eager to be screened for contamination, sometimes panicked, and showing psychosomatic reactions mimicking actual radiation effects [15]. A case in point is the Goiania radiation accident. A 50.9-TBq 137Cs source was removed from a radiation therapy facility causing a radiological accident.
in September 1987. People who lived adjacent to the known contaminated areas and who had some kind of contact with contaminated victims were instructed to report to the Olympic Stadium for monitoring. In addition to the expected few hundred people, 112,000 anxious individuals showed up to determine whether they were contaminated [16]. Such responses would likely be common in any radiological event. As professional communities prepare for the response to terrorism, health physicists and other safety professionals may be called upon to deal with terror in their own communities. These professionals are well trained technically to respond to a dirty bomb, but they may not be well prepared to deal with the public fear of terrorism [17]. Safety professionals should receive training on how to deal with terror and how to interact with other elements of the emergency response community who can offer professional social and psychological expertise.

Since the terrorist attack of September 11, 2001 in New York, governmental agencies, military organizations, local emergency responders, and the health care system have prepared for an act of terrorism. Scenarios for terrorist acts involving radioactive material (dirty bomb) have been identified. Emergency response plans have been developed based on past experience from atomic weapons detonations and radiation accidents. Medical specialists, e.g. emergency physicians and hematologists will be asked to play a significant role in evaluating and treating victims of mass accidental or deliberate exposure to radiation. Appropriate response requires physicians and health care personnel to have a basic understanding of how radiation levels are quantified and how radiation alters the function of cells, tissues and organs. Emergency response personnel must know how victims who receive a significant radiation dose can be identified and managed. Clinical signs and symptoms associated with the acute radiation syndrome must be understood and not confused with other medical conditions that could manifest similar symptoms. Clinical and laboratory personnel must understand methods to assess radiation doses, including time to onset and severity of vomiting, rate of decline in absolute blood lymphocyte count and the appearance of chromosome aberrations such as dicentrics and ring forms. Numerous educational efforts have attempted to educate these emergency response and medical communities [18,19,20]. Local communities should conduct emergency exercises involving potential scenarios of a radiation terrorist event. These drills should test the ability of various agencies to provide a coordinated response. Drills in the United States should incorporate the supportive care that has been developed by the Strategic National Pharmaceutical Stockpile Working Group, a mechanism to provide emergency supplies to the community. Emergency plans should include decision trees on when and how potassium iodide or other radiation treatment agents should be used after exposure to radioiodines, other radionuclides, or direct radiation.

4. Patient Safety

The report of the Institute of Medicine (IOM) To Err is Human [21] stressed the importance of automating repetitive, time-consuming, and error-prone tasks through the use of technology. While automation holds substantial promise for improved safety, error experts caution that all technology introduces the potential for new and different errors [22]. Field-based research is essential in the emerging field of patient safety to create the evidence as to which technologies
actually improve patient safety and those that may well increase the potential for harm. While this recommendation to use technology was not aimed at equipment used in radiation medicine, it is clear that avoidance of errors in radiation medicine must be given a high priority. Likewise, recommendations aimed at elimination of medication errors impact the use of radiopharmaceuticals used in the diagnosis and treatment of disease.

CT examinations now account for greater than one-half of the radiation dose due to medical procedures in the population of North America [23]. Multidetector CT (MDCT) has become widely used valuable tool in diagnostic radiology. Despite its benefits, this new modality has the potential for higher radiation exposure compared to single-slice CT or other imaging modalities. However, MDCT also offers options to save radiation exposure, such as choosing optimized exposure parameters. For example, low-dose spiral CT can detect lung cancers at a smaller size and earlier stage than chest radiography. Dose is minimized by using low-dose CT parameters including a technique of approximately 120 kVp and 40-50 mA [24,25]. Using the various options available, radiation exposure can even be lower than conventional single-slice helical CT [26]. Patient safety can be increased by taking advantage of advances in technology to increase the benefit/risk ratio. Additional research into the complex relationship between radiation exposure, image quality, and diagnostic accuracy should be encouraged to establish the minimum radiation dose necessary to provide adequate diagnostic information [23].

Since the development of interventional radiology, the number and complexity of procedures continues to increase. Interventional radiology procedures offer substantial health care benefits, but a lack of quality control can result in the occurrence of deterministic effects in patients. There is a growing literature of case reports describing deterministic effects [27]. For example, Rosenthal et al. [28] describe a woman with refractory paroxysmal supraventricular tachycardia who underwent radiofrequency catheter ablation of the slow pathway involved in atrioventricular nodal reentrant tachycardia. The patient subsequently returned 4 weeks later with acute radiation dermatitis that was attributed to a malfunction in the fluoroscopy unit. Recently, several cases of skin injuries were reported in patients undergoing cardiac radiofrequency catheter ablation. The radiation lesions were mainly erythematous lesions and chronic radiodermatitis. Poor image quality could have influenced the length of the procedures. Dose rate at the image intensifier entrance was within usual reported values in literature, but focus-to-skin distance for the horizontal X-ray beam was too short, resulting in a high skin dose rate. The authors suggested practical radiation protection considerations to avoid further incidents [29]. McFadden et al. [30] measured dose to patients from radiofrequency catheter ablation procedures. From a mean effective dose of 17 mSv, they calculated an excess risk of 0.1% of developing fatal cancer. Even though six patients (12%) received a skin dose above the threshold dose for radiation skin injury (2 Gy), no skin injuries were observed. Patient skin dose and dose-area product (DAP) were closely correlated, which allows DAP to be used to monitor patient skin dose in real-time. DAP levels were locally adopted as diagnostic reference levels (DRLs) that provide an indication during a procedure that a patient is at risk of suffering deterministic skin injury. Neofotistou et al. [31] describe the European DIMOND approach to defining reference levels (RLs) for radiation doses delivered to patients during two types of invasive cardiology procedures, namely coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA). A DAP trigger level to alert the operator to possible skin injury during cardiac studies was set to 300 Gycm².
The proposed RLs for CA and PTCA were for DAP 45 Gy cm$^2$ and 75 Gy cm$^2$, for fluoroscopy time 7.5 min and 17 min and for number of frames 1250 and 1300, respectively. The RLs were proposed as a first approach to help in optimization of these procedures thus increasing patient safety.

A number of authors have published estimates of the risk of fatal cancer from diagnostic x rays. One of the more recent estimates that 0.6-3.2% of patients will develop cancer as a result of their exposure to diagnostic x rays [32]. Such estimates are based on the assumption that the risk of cancer from diagnostic x rays delivered over the lifetime of the patient is equal to the risk of cancer among the A-bomb survivors. The extension of risks from the A-bomb scenario to the diagnostic x-ray suite is a huge leap in statistical inference space. Conclusions that diagnostic x rays are causing patients to die of cancer are difficult to defend. Even so, the medical community continues their efforts to reduce diagnostic x-ray doses to the lowest possible while still providing high quality diagnostic information.

5. Conclusions

This paper discusses three issues that affect our risk estimates and efforts to improve radiation protection: increased cancer susceptibility from early-life exposure to radiation, terrorism and fear of radiation, and patient safety. Research strongly suggests that children may be as much as ten times more sensitive to radiation carcinogenesis than adults. Even though uncertainties are high, medical radiation protocols should be optimized to minimize this risk. Most people probably fear a radiological event more than a conventional explosive because of their fear of the radioactivity. Safety professionals should obtain training on how to deal with this fear and how to interact with other elements of the emergency response community who can offer professional social and psychological support. Patient safety can be increased through continued efforts to reduce diagnostic x-ray doses to the lowest possible while providing high quality diagnostic information.

6. References


