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Provision of Information to Individuals Regarding the Risks Related to Medical Radiation

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Abstract Despite the fact that the exact risk calculation for cancer is not possible on medical radiation, ionizing radiation clearly can do harm. The increased numbers of CT exams and also the relatively high radiation dose range of most CT exams have raised concern about the risk to develop cancer, triggering many actions of governmental agencies, medical societies, and equipment directed into reduction radiation dose strategies. Provision of information to patients regarding radiation risks is just another only logical action once radiation risks estimates are compared to other already regulated medical tests or procedures.

Keywords Ionizing radiation · Computed tomography · Informed consent

Introduction

For at least the last two decades, there has been considerable discussion, debate, and controversy on the subject of the risk of cancer development in patients undergoing X-ray examination [1–4]. This has only intensified within the last 5 years [5–7, 8••, 9]. The positive benefit of this discussion is that great strides have been made by equipment manufactures to deliver less X-rays per exam to patient, which has been especially evident for children. Strategies for CT have included reduced dose studies, modulation of the X-ray beam intensity as it encircles the subject, and new reconstruction techniques. These individually accomplished system improvements by manufacturers have been a lockstep with increasing involvement of government agencies. In fact, the latest major regulation, which has been mandated by the Joint Commission and has been set to come into effect on July 1, 2015, is the requirement by all centers to keep track of patient radiation exposure [10]. Major radiological societies, such as the RSNA, have taken part with other societies to develop safety programs, the first being the Image Gently campaign [11], designed for children, and the more recent Image Wisely campaign [12], designed for adults. All of these efforts are commendable, and have no doubt advanced greatly the concept of safety with medical radiation.

Nonetheless, the concept of informed consent has largely been skirted around [13]. There are two issues that have to be met in order to merit the use of some form of informed consent: (1) is there real risk and (2) is it sufficiently common that by describing the risk to patients, it merits the possibility that subjects may refuse to undergo a potentially important study to avoid this risk? This represents the risk/benefit analysis.

The explanation of the uncertainty among some stakeholders in medical imaging, reflects partly their concern of the existence or extent of risk of radiation, at the low levels of medical radiation, causing cancer. To address this subject, one should start with the biological effects of ionizing radiation (BEIR) VII report, formed as a subgroup of the National Academy of Sciences, the largest, and the most prestigious and respected scientific organization in the

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world, that unequivocally states that ionizing radiation causes cancer and endorses the no threshold theory (that there is no lower limit of dose, in which radiation is safe) [14]. This document is endorsed by the FDA [15], and is essentially identical to the statements and recommendations of all the major nonpartisan radiation societies, such as the International Commission on Radiological Protection (ICRP) [16] and The National Council on Radiation Protection (NCRP) [17]. Up until recently, skeptics also claimed that although medical radiation had resulted in cancer in past years, where radiation dose was largely uncontrolled and unmeasured, this has not been shown with CT. This claim has also been refuted by large population-based studies from Australia [18••] and the UK [19••]. In fact, the primary difficulty, in being able to demonstrate this association, is that radiation-induced cancer lags radiation exposure by at least 2 years and often by 10–20 years following the exposure; and since even at 1 in 1,000 increased cancers, it is sufficiently uncommon that the combined effect of the lag time and infrequency of the event requires that large population-based studies, are required with follow-up for at least two decades. Studies like this are lengthy and expensive to perform, and are furthermore severely hampered if there is a disinterested will to show the potential harmful effects of a profitable industry. Nevertheless, Australian researchers took on this challenge. Their findings were largely in accord with the estimates provided by BEIR VII, with a dose-response relation and an incidence rate ratio (IRR) increased by 0.16 (0.13–0.19) for each additional CT scan [18••]. Also, their results had shown that the IRR was greater after exposure at younger ages and that increased risk was manifested for many types of solid cancer (digestive organs, melanoma, soft tissue, female genital, urinary tract, brain, and thyroid), leukemia, myelodysplasia, and some other lymphoid cancers. There was an excess of 608 cancers in people exposed to CT scans (147 brain, 356 other solid, 48 leukemia or myelodysplasia, and 57 other lymphoid). The absolute excess incidence rate for all the cancers combined was 9.38 per 100,000 person-years at risk.

The other general uncertainty is how likely does a severe adverse event have to be for information that to be required to be provided. Both the National Academy of Science and the Federal Drug Administration recognize the potential for cancer development in 1 in 1,000 subjects, 40 years of age, who undergo 10 mSv of radiation (approximately, the dose of one abdominal CT). Perhaps the most authoritative evaluation of what level of risk should be present for information to be provided to recipients of that risk was undertaken by the Veterans Administration. They assembled a group of health care providers and medical ethicists, and this council arrived at the figure that if the risk is greater than 1 in 40,000, then individuals should be informed [20]. Although this investigation was not performed to assess the risk from medical radiation in specific, but broadly for all medical misadventures, this in fact is the strength of using this risk figure, as it is unsullied by stakeholders with vested interest. In that regard, it may be ideal to use this as the basis of level of risk to necessitate patient information in medical imaging.

As it is irrefutable for the nonbiased scientist/physician that medical radiation can cause cancer, and that risk may be in the range of 1 in 1,000–1 in 10,000 for most CT exams, so well within the range of the report by the Veterans Administration, the next challenge is how is that information conveyed. Critics observe that informing all individuals of risk of cancer may result in some individuals refusing to undergo an examination that may be important for their welfare, and that the risk is far more insignificant than the benefit [9, 21, 22]. The reality is that this is true of all other medical procedures that involve patient consent, some will refuse the procedure even though the benefit vastly outweighs the risk. Berlin describes the distinction between 'real risk', documented with numbers from that procedure and 'presumed risk', derived from a theoretical basis [23]. Medical radiation has been considered as presumed risk, however following the large population-based studies from Australia [18••], the UK [19••], and Canada [8••], that have shown risk from modern imaging procedures including CT and cardiac procedures, would support the transition of medical imaging from presumed to real. Somewhat tangentially, the risk descriptions of many procedures in medicine are often derived from single large studies, that may not be generalizable to widespread or modern medical practice, so the assertion of their 'realness' could also be considered uncertain. The possibility that individuals may refuse studies that may be beneficial to them, comes with living in a free society, individuals have the personal freedom to manage their affairs in a fashion that may not seem reasonable to an expert. It is also not clear that when this claim of refusing a life-saving study is brought to attention, whether consideration has been made that alternate nonionizing studies may be equally life-saving, and should also be described to patients in the risk–benefit discussion.

The most recent term used to describe patient information delivery is shared decision-making [23]. With something as complex as health care, there is no doubt that there is tremendous value to an informed health care provider who discuss with patients about the various options that the individual may have for their care, in terms that they can comprehend. When having this discussion with patients, often our best approach is to inform them what we would do ourselves in their situation, keeping the discussion basic and not too technical. Otherwise to explain in a comprehensive fashion the complexity of considerations in

modern health care may be the equivalent of providing the individual with knowledge from a full decade and longer of medical training compressed into a 10-min dialog.

It may be immaterial whether the information delivered to patients is described as informed consent or shared decision-making. What is important though is that, that information should be standardized across the nation and that serious risk elements should be described. One recent survey questioned parents who brought in their children into emergency departments following head trauma, and 90 % of them described that they would want to know if there was malignancy risk for their children before proceeding with a CT study [23].

The problem with informed decision-making, as it is currently conceived, is that there is no requirement for standardized information that must be conveyed—specifically about the risk of cancer. So what Dr Semelka or Elias may inform a subject, as part of a shared decision-making encounter, is likely different from what a more CT-enthused radiologist may describe, and who may be dismissive or unaware of BEIR VII, the FDA medical radiation reports, and those of all major radiation protection societies [24]. Our position in brief includes the following: CT is great and perhaps essential for MAJOR trauma (capitalization is deliberate), interstitial lung disease (but not with frequent repeating of studies), for renal stone disease (but not with frequent repeats) and for assessing tubes and catheters, and those considerations with possible abscesses in an ICU-type patient with major chest or abdominal complications. In these above settings, the benefit almost always greatly outweighs the risk. In the great majority of other settings, appropriate imaging can also be achieved with MRI, and in more limited indications, with ultrasound. That may not be the physician information of shared decision-making models that most radiologists would ascribe to.

In the end, it should be mandated that when there is greater than 1 mSv radiation exposure, some form of patient consent should be obtained [13]. It must come down to a mandate from a major governmental agency such as Health and Human Services, or the Joint Commission, that all patients be informed about the risks of medical radiation. Much of the discussion that we have undertaken over the years has been focused on CT, and in fact much of the literature has also focused on CT. It should be recognized that nuclear medicine studies often exhibit even higher radiation doses, that also effect outside individuals second-hand. Experts from the nuclear medicine field have largely been silent on this subject. Relatively, more reports exist in the cardiology literature, regarding the potential risks from various cardiology ionizing imaging procedures [25, 26]. Clearly, the next important step is to develop a template of information that must be mandated to be provided to all patients who undergo higher dose medical imaging; we recommend the 1 mSv threshold, using an approach as laid out by the FDA [27].

In conclusion, to excerpt from Dr Berlin [24]:

> Notwithstanding the controversy and debate surrounding the quantification and nature of adverse effects from radiation exposure, can anyone honestly claim that exposure to radiation is absolutely free of such effects?

Conclusions

Ionizing radiation can do harm, with estimate risks for 10 mSv of 1:1,000–1:2,000 to cause cancer. Provide information to patients, for exams that reach 1 mSv or above is the only logical thing to do. Standardization of what and how to provide this information to patients throughout the nation should be pursued.

Compliance with Ethics Guidelines

Conflict of Interest Dr. Richard C. Semelka is a Section Editor for Current Radiology Reports. Dr. Jorge Elias Jr. declares no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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