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Tracking Radiation Exposure From Diagnostic Imaging Devices at the NIH

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The potential risk of exposure to low doses of ionizing radiation derived from diagnostic medical imaging tests is actively debated in the popular press [1-3]. These news stories followed from publications in prominent scientific journals asserting that an increasing number of cancer deaths are to be expected in the United States because of the frequent use of CT for diagnostic purposes [4-6]. One widely publicized appraisal of medical radiation exposure suggested that about 1.5% to 2% of all cancers in the United States might be caused by the clinical use of CT alone [4]. Because there are no epidemiologic data directly relating CT to cancer deaths, scientific assessment must instead rely on the relationship between radiation exposure and death rates from Japanese atomic bomb survivors. Atomic bomb survivor data are extrapolated to lower dose radiation exposure resulting from cumulative CT scans to estimate cancer death rates [7,8]. Although the legitimacy of this approach remains debated [9,10], radiologists as well as clinicians may rightfully be confused by the ongoing controversy. Patients seeking medical help may legitimately question the rationale of, and risks from, diagnostic radiology tests.

Although radiation biologists agree that high doses of ionizing radiation can result in neoplasms a decade or more after irradiation [11], controversy remains around lower dose (<150 mSv) diagnostic medical radiation exposure. The linear-no-threshold hypothesis of health physics implies that any amount of ionizing radiation, however small, has a finite probability of inducing cancer. This approach forms the basis of current radiation protection regulations and guidelines. Such regulations were initially suggested by the Manhattan Project managers and later expanded by the International Commission on Radiological Protection, for the purpose of ensuring that no workers were likely to suffer any harm from being exposed to ionizing radiation [12].

In contrast to the linear-no-threshold hypothesis, some scientists argue that biochemical and physiologic defenses operate at multiple levels in the body by scavenging toxic, radiation-induced molecules; repairing damage, especially in deoxyribonucleic acid; removing permanently damaged cells; and even replacing “lost” cells to ensure the structural and functional integrity of the organism necessary for survival. In support of this theory, epidemiologic studies in areas of the world with high natural background radiation exposures have failed to show an increase in observed cancer incidence compared with control groups [13,14].

The failure of epidemiologic studies to detect cancer increases from diagnostic test–derived low-dose radiation exposures could simply be related to the lack of lifelong data on

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cumulative medical radiation doses to individuals. Because the incidence of other, non–radiation-induced cancer in humans is relatively high, data on hundreds of thousands of patients may be required, with all exposures recorded, to conclusively show an excess risk from medical test radiation. Low-dose ionizing radiation may be a relatively weak carcinogen compared with many other “cancer inducers” to which humans are exposed. There may also be a genetic subset of humans who are more sensitive to radiation damage and more likely to develop subsequent cancers, hidden in the larger numbers of less sensitive individuals in a population. Very little is known about the genetic mutations that might change an individual's “radiation sensitivity.”

The National Council on Radiation Protection and Measurements reported recently that Americans received 7 times more medical test radiation exposure in 2006 than was the case in the 1980s [15]. CT and cardiac nuclear medicine studies accounted for much of this increased medical radiation exposure. Whereas all other medications or treatments given to a patient in a hospital or clinic are routinely accessible in the patient's medical record, radiation doses from diagnostic imaging tests stand in stark contrast as being unavailable or inaccessible. Current radiology information systems in hospitals-generally do not collect or report radiation exposures; the medical imaging devices that communicate with radiology information systems do not currently forward data on the radiation dose received by a patient from each such test, despite recommendations to the contrary from the ACR [16].

To begin to address these questions, Radiology and Imaging Sciences at the National Institutes of Health (NIH) Clinical Center (http://www.cc.nih.gov/drd/) will be taking steps to incorporate radiation dose exposure reports into the electronic medical record (EMR). Radiology and nuclear medicine at the NIH have developed a radiation reporting policy that will be instituted in cooperation with major equipment vendors, beginning with exposures from CT and PET/CT. All vendors who sell imaging equipment to Radiology and Imaging Sciences at the NIH will be required to provide a routine means for radiation dose exposure to be recorded in the EMR. This requirement will allow the cataloging of radiation exposures from these medical tests. In many cases, radiation dose is already recorded but is not entered into the Digital Imaging and Communications in Medicine header for CT and PET/CT. Assistance from manufacturers in standardizing reporting algorithms will allow these data to be entered and subsequently extracted from the Digital Imaging and Communications in Medicine header for storage either in the radiology information system or, preferably, in the hospital-based EMR.

Although these steps by themselves are not sufficient to allow the population-based assessment of cancer risk from lose-dose radiation, they are nonetheless necessary to begin a data set for this determination. The accumulation of medical testing doses from hundreds of thousands of individuals in the United States over many years will ultimately be necessary. The means to collect such a vast amount of data are beyond the scope of the current proposal. However, the Obama administration's proposals to implement and standardize elements of EMRs could eventually provide for a large population data set for subsequent epidemiologic studies to assess radiation risk from lifelong medical testing.

Besides such population-based risk assessment data sets, radiology at the NIH will require that vendors ensure that radiation dose exposure can be tracked by patients in their own personal health records. We are now in an era when patients have increasing electronic access to their own medical records. Web sites such as Google Health and Microsoft HealthVault allow patients to catalog their own medical records from multiple care providers. In view of these opportunities, patients should be able to store data regarding their radiation dose exposures directly into the personal medical records of their own choosing. Presently, patients can easily receive the records of their diagnostic imaging studies on CD-

ROMs. Simple software tools can and will be developed with vendors to extract the examination type and date, along with the radiation dose exposure, for uploading to a personal health record. This approach is consistent with the ACR's and Radiological Society of North America's stated recommendation that “patients should keep a record of their x-ray history” [17].

In summary, the cancer risk from low-dose medical radiation tests is largely unknown. Yet it is clear that the US population is increasingly being exposed to more diagnostic test–derived ionizing radiation than in the past. Radiology at the NIH Clinical Center has mandated that equipment vendors provide for electronic reporting of patients' radiation exposures from their equipment. This radiation dose reporting will be both to hospital EMRs as well to the patients' own personal electronic health records. In our discussions with vendors, these goals are thought to be easily achievable. We encourage all medical imaging facilities to include similar requirements for radiation dose reporting outputs from the manufacturers of radiation-producing medical equipment. Although this step by itself is insufficient to provide needed answers regarding low-dose radiation exposure and increased cancer risk, it is nonetheless a necessary first step toward achieving that goal.

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