Special Report

Minimizing Medical Radiation Exposure by Incorporating a New Radiation "Vital Sign" into the Electronic Medical Record: Quality of Care and Patient Safety

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Perm J 2017;21:17-007

E-pub: 09/27/2017

https://doi.org/10.7812/TPP/17-007

ABSTRACT

There is a clearly perceived and imminent need to decrease unnecessary and detrimental exposure to medical ionizing radiation. We propose a new radiation "vital sign" that incorporates cumulative radiation exposure to create a risk score on the basis of an individualized assessment of potential harm from additional exposure to medical radiation. We propose to then tie the risk score to real-time, evidence-based, clinical decision support for procedures that use ionizing radiation. Additionally, we offer recommendations that minimize unnecessary or low-yield uses. Preference is given to approaches and modalities that use less or no ionizing radiation and that are medically appropriate, acceptable to, and safer for patients.

INTRODUCTION

The risks of radiation are substantial and varied.[1] It is generally accepted that any exposure to radiation carries some risk. The most commonly accepted paradigm is the linear no-threshold model, which assumes that the long-term, biological damage caused by ionizing radiation is directly proportional to the dose.[2] Still, some experts believe that there is insufficient evidence of any carcinogenic risk at low levels (< 50 mSv) of ionizing radiation exposure.[3] Even if their hypothesis is correct, there are medical procedures and combinations of multiple procedures that exceed these postulated thresholds for risk.[4] Also, each individual and organ has a variable threshold susceptibility based on many factors, which we discuss in this article. The physicians' precept to "first do no harm" must presume that all radiation has the potential for adverse effects.

Side effects of radiation include acute radiation sickness,[5] increased incidence of cancer,[1,2,6] ophthalmic damage,[7,8] chromosome aberrations,[9] birth defects,[5] immune system dysfunction, hematopoietic system disease,[1] gastrointestinal system disorders,[1] dermal injury,[10] nervous system damage,[1,5] growth retardation,[5] miscarriage,[5] organ and glandular injury,[11] premature menopause, stroke,[1] and cardiovascular disease.[1,12,13] (Irradiation induces a sustained vascular endothelial cell dysfunction. Such impairment is known to lead to occlusive artery disease and may be an important risk factor for cardiovascular diseases.[13]) The levels of radiation exposure that health care practitioners now order and administer can potentially induce any number of these adverse health effects.

Scope of the Problem

Sodickson and colleagues[14] studied a cohort of 31,462 patients at a tertiary medical center who underwent diagnostic computed tomography (CT) in 2007. They had undergone 190,712 CT examinations during the prior 22 years. One-third of patients underwent 5 or more CT studies during their lifetime, and 5% received 22 to 132 studies. Fifteen percent received an estimated cumulative effective dose (see Sidebar: Glossary of Radiation Terms) exceeding 100 mSv, with 4% of those receiving a cumulative effective dose between 250 and 1375 mSv. Doses in excess of 100 mSv are in the realm in which there is convincing epidemiologic evidence of increased cancer risk.

In 2010, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health launched an initiative to reduce unnecessary radiation exposure

Glossary of Radiation Terms

Air kerma: Air kerma (kinetic energy released per unit mass) is of importance in the practical calibration of fluoroscopy instruments. It is used for the traceable calibration of gamma instrument metrology facilities using a "free air" ion chamber to measure air kerma. Conversion coefficients from air kerma in gray (one joule of energy in the form of ionizing radiation per kilogram of matter) to equivalent dose in sieverts (see *Sievert*) are published in the International Commission on Radiologic Protection (ICRP) report 74 from 1996 (www.icrp.org/publication.asp?id=ICRP Publication 74).

Effective dose: The International Commission on Radiological Protection adopted the term effective dose (ED). The ED is based on the energy deposited in biologic tissue by ionizing radiation. It takes into account the type of radiation and the sensitivity of the tissue exposed. The ED is a measure of overall whole-body radiation risk, which enables comparison of doses received in different tissues and organs of the body. It is measured in sievert units (see *Sievert*). Acute ED radiation of 250 mSv is known to cause immediate harmful biological effects. An acute dose of 3000 mSv will cause death to 50% of a population exposed within 30 days, and 100 mSv is statistically associated with an increased risk of cancer. Besides medical radiation, humans are regularly exposed to "background radiation" from natural sources. On average, a person in the US receives an ED of about 3 mSv per year from naturally occurring radioactive materials and cosmic radiation from outer space.

Sievert: The standard unit in the International System of Units (SI) of the equivalent dose of the biological effect of one joule of x-rays per kilogram of recipient mass.

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from medical imaging.[15] These efforts were in response to increasing exposure to ionizing radiation from medical imaging as highlighted in the National Council on Radiation Protection and Measurements Report No. 160[16] and safety concerns highlighted in the FDA's safety investigation on CT brain perfusion scans.[17] The FDA proposed the use of alternative diagnostic procedures, such as ultrasonography and magnetic resonance imaging (MRI), and reducing radiation exposure to medical imaging—limited examinations, dose optimization with adaptive statistical iterative reconstruction,[17] better collimation, protection of noninvolved or more highly susceptible anatomical areas, and medically acceptable delays (risks related to total dose exposure are time-interval dependent) including watchful waiting. Clearly, the medical community has been less than successful at implementing many of these concepts to achieve the goal of minimal but necessary medical radiation exposure.[14,18] For example:

1. Protocols are not always followed[19]
2. Not all equipment is state of the art or optimized[14,20]
3. Alternative investigative means may not be available or used[21]
4. Testing may simply be unnecessary in up to one-third of CT scans.[20]

Berrington de González et al[22] calculated that: "When we combined the age- and sex-specific annual frequencies with the estimated risk per 10,000 scans, it was estimated that, overall, approximately 29,000 (95% [upper limit], 15,000-45,000) future cancers could be related to the number of CT scans performed in the US in 2007."

The 29,000 future cancers were estimated using the specific distribution of CT scans done in the US in 2007. Because the number of diagnostic CT scans has been increasing at a rate of 6.5% per year (estimates are that 62 million CT scans were performed in 2006[6] and 85 million in 2011[23]), we could easily double those projections by now. According to the International Commission on Radiological Protection, an independent international organization with the mission to help prevent cancer and other diseases and the effects associated with exposure to ionizing radiation,[24] almost 1 in 4 persons have had a recent CT test or nuclear medicine procedure, and the use of CT now accounts for at least 50% of the collective dose from all imaging procedures. Prolonged fluoroscopic examinations (often those with other procedures) can expose patients to particularly high doses of radiation.

Efforts to Limit Radiation Exposure

Given these data and projections, it is critical that the medical community develop more effective methods to limit medical ionizing radiation procedures to medically indicated situations, and only when alternative, safer approaches will not suffice. Current concepts to achieve this include the following: Education for all stakeholders in the principles of radiation safety, appropriate utilization of imaging to minimize any associated radiation risk, standardization of radiation dose data to be archived during imaging for its ultimate use in benchmarking good practice, and the identification of alternative imaging of patients who may have reached or potentially will reach threshold levels of estimated exposure from diagnostic imaging. These concepts, important as they are, have been repeatedly recommended in scientific articles for many years, yet they have not been successfully implemented on a large scale.

In 2007, the American College of Radiology (ACR) created a white paper[25] stating: "There is increasing international and federal interest in, and scrutiny of, radiation dose from imaging procedures. Although there has been recent widespread interest in patient safety issues, the possible hazards associated with radiation exposure generally have not been brought into clear focus by the public or members of the medical community other than radiologists." They proposed accreditation programs, practice guidelines and technical standards, Appropriateness Criteria, a dose index registry, and educational programs. Routine reviews of patients were recommended, as were detailed imaging histories to alert radiologists that such alternatives should be considered. They charged technologists with the responsibility for determining the need for additional radiation safety actions before instituting radiation exposure. This included identification of high-risk patients and body parts, individualized shielding, more focused collimation, and lower-dose examinations. The ACR concluded that although the benefits of diagnostic imaging are immense, the rapid growth of CT and nuclear medicine studies since the early 1990s could result in an increased incidence of radiation-related cancer. The ACR went on to propose standardizing and archiving radiation dose data for use in benchmarking best practices, with the goals of identifying threshold levels of estimated exposure from diagnostic imaging and proposing alternative imaging for these patients. The College did not, however, create a method to actualize its proposals. We are proposing a method to take these proposals and implement them on a large scale.

Sodickson et al[14] identified methods to reduce the dose of each examination, including technical developments (eg, automated tube current modulation, beam filtration, and adaptive collimation), imaging parameter selection (decreasing tube potential, tube current, or both), protocol modifications (reducing duplicate coverage regions and multiple-pass scanning), and utilization of standardized reference dose levels. Measures to reduce CT utilization include adoption of broadly applicable imaging algorithms and recommendations

Conservative Prescribing of Radiologic Procedures[26]

1. Think beyond studies that use ionizing radiation.
2. Practice more strategic ordering. Use evidence-based protocols/decision support/best practices. Order sets or forced functions can increase compliance. Built-in suggestions for alternative nonradiologic approaches can add to success. Involve radiologists in the decision tree. Ensure necessity of the imaging study.
3. Maintain heightened vigilance/concern regarding adverse effects.
4. Approach new indications for x-rays cautiously and skeptically.
5. Work with patients for a more deliberative shared agenda.
6. Consider longer-term broader effects (benefits vs risks), with ionizing radiation as a known adverse event.
7. Keep up to date by maintaining your continuing education and regularly updating your protocols with minimization of medical radiation exposure as a stated goal.

to use nonionizing imaging alternatives or no imaging at all. In addition, Sodickson et al[14] identified the requirement to include cumulative radiation exposure to accurately evaluate a patient's risk owing to further diagnostic radiation procedures. They also suggested using real-time clinical decision support. Their proposals presage our ideas recommending a radiation "vital sign" that is based on an individual's cumulative radiation exposure modified by his or her specific radiation-related risk factors and tied to real-time clinical decision support.

Schiff and coworkers[26] developed principles of conservative prescribing, which we have conceptually adapted to radiologic procedures, while adding a proposed seventh principle (see Sidebar: Conservative Prescribing of Radiologic Procedures).

Chassin et al[27] proposed relevant criteria for accountability measures in the process of medical care. Wachter[28] added accountability measures to those of Chassin and colleagues (see Sidebar: Accountability Measures) but noted that feedback leads only to modest change. Transparency ("disseminating the results of quality measures to key stakeholders") is the new norm. Chassin et al also discussed how to improve the quality of care.

We propose to systematically investigate ways to minimize exposure to ionizing radiation while maintaining high-quality medical care (see Sidebar: Minimization of Radiologic Imaging Exposure).

Each patient's full medical record and all medical procedures (completed and ordered) should be available digitally at any time on demand. The technologies available to process electronic medical records (EMRs), transmissions, and coding include: Health Level Seven (HL-7), the standardized protocols for clinical information and administrative data transfers; Digital Imaging and Communications in Medicine (DICOM), a document architecture for exchanging radiologic information and imaging; Current Procedural Terminology (CPT) and International Classification of Diseases (ICD) codes; and Systematized Nomenclature of Medicine (SNOMED), a subtype hierarchy of medical terms supported by defining relationships on the basis of description logic.

The DICOM-Structured Reporting (DICOM-SR)[29] standard is an approach that allows for structured medical imaging data to be electronically transmitted and integrated into HL-7 and thereby into EMRs. These digital standards enable advanced chart-based functions that search the record for patient exposure and the data for patient risk profiles, and allow for the insertion of advice. As Wachter[28] states in his pioneering book, *Understanding Patient Safety,* "innovative methods for screening caregiver notes, lab results and medication orders … will generate new and useful information. More and more of the work will involve real-time surveillance systems, with automatic 'just-in-time' feedback …" or, in other words, "real-time clinical decision support."

Our Proposal: A Method to Achieve Excellence in Radiation Ordering

We propose to harness the power of EMRs that use formats such as the DICOM-SR for radiation dose events and HL-7 so that we can create effective clinician and patient awareness of each patient's cumulative radiation dose, anticipate future exposures for patients with chronic diseases, and assess individualized risk from proposed exposure. Real-time clinical decision support will offer advice on alternative approaches. To accomplish this, we propose a new method: The radiation "vital sign" that is a risk score. The radiation vital sign will document all previous exposures to ionized radiation and create an individualized risk-specific assessment on the basis of the factors we discuss later in this article. Ideally, the radiation vital sign will be linked to clinical decision support that proposes medically appropriate and validated approaches based on evidence-based clinical practice guidelines[30] for each medical procedure that exposes a patient to ionizing radiation. Certain symptoms or diagnoses (especially chronic diseases) will trigger likelihood cascades to prevent accumulated radiation risks.

Not all known risks of radiation are well quantified or even identified. This field of study has the potential to advance with artificial intelligence (AI) or machine learning. Newer designs for "deep" learning (eg, the IBM Watson computing system AI combined with sophisticated analytic software and brute force computing power,[31] and Google's probabilistic neural networks,[32] in which AI grows from the data rather than from the rules) look promising to advance personalized medicine. Describing Google's networks, Lewis-Krauss[32] writes: "The simplest description of a neural network is that it's a machine that makes classifications or predictions based on its ability to discover

Accountability Measures[27,28]

1. There is strong evidence that the care process improves outcomes.
2. Documentation exists that the evidence-based care process has been provided.
3. The measurement is fairly direct.
4. There are no unintended consequences.
5. Improvement in medical care is promoted and supported.

Minimization of Radiologic Imaging Exposure

1. Ordered radiologic examinations are justified by evidence-based medicine, and nonradiologic alternatives are considered and strongly encouraged. The Agency for Heathcare Research and Quality's national guideline clearinghouse is a public resource for summaries of evidence-based clinical practice guidelines that would be an excellent starting point.[27]
2. Radiation exposures are minimized by well-accepted radiologic standards for exposure during each specific examination, and preference is given for nonradiologic approaches.
3. Radiation exposure from each ordered examination is clearly documented during the ordering process and considered in light of the documented cumulative radiation exposure. This is presented to the clinician as a new radiation "vital sign."
4. Each patient is uniquely considered for his/her risk of exposure to radiation, accounting for his/her age; medical, genetic, and family history (precision medicine); and previous cumulative radiation exposure.
5. A risk profile is developed to assess the individual risk for each level of new exposure, which is clearly documented with each examination ordered. Alternative strategies are increasingly forcefully recommended as the risk level or potential risks are increased.

patterns in data. With one layer, you could find only simple patterns; with more than one, you could look for patterns of patterns."

Automated repetitive systems such as what we propose have been shown to be far more effective than other measures to induce and maintain change.[33] Existing strategies to decrease medical radiation exposure have fallen short on a national level. Adding a radiation vital sign to the EMR—a personal risk assessment tied to evidence-based, patient-specific advice—will be far more likely to create an effective routine[34,35] that will decrease exposure to ionizing radiation. It can be time-consuming and problematic for clinicians to deal with warnings and computer-generated alternatives. However, incorporation of accepted medical imaging protocols based on patient history, symptoms, and/or diagnoses, or based on tests ordered (appropriate indications/risk-benefit analysis) would ensure that clinicians have the latest guidelines at their fingertips and that they evaluate patient safety whenever ordering medical ionizing radiation exposure. This would require a major effort to create buy-in because it causes delays, but clinical decision support provided contemporaneously with clinical decision making is achievable and often becomes invaluable.[33-37]

The National Research Council's Biological Effects of Ionizing Radiation VII (BEIR VII) *Health Risks from Exposure to Low Levels of Ionizing Radiation*[1] report in 2006 planned to do the following:

> 1) [D]evelop appropriate risk models for all cancer sites and other outcomes for which there are adequate data to support a quantitative estimate of risk, including benign disease and genetic effects; 2) provide examples of specific risk calculations based on the models and explain the appropriate use of the risk models; 3) describe and define the limitations and uncertainties of the risk models and their results; 4) discuss the role and effect of modifying factors, including host (such as individual susceptibility and variability, age, and sex), environment (such as altitude and ultraviolet radiation), and lifestyle (such as smoking history and alcohol consumption) factors; and 5) identify critical gaps in knowledge that should be filled by future research.

Thus, medical exposure to ionizing radiation should be tracked and monitored.

Tracking the radiation dose delivered to patients for medical purposes is gathering increasing attention from professional societies and regulatory groups. Publications include European directive Euratom 97/43,[38] the ACR dose white paper,[25] and Japanese regulations.[39] Ideally, we will be able to accomplish the patient-specific and quality of care measures of radiation exposure elucidated in the Sidebar: Radiation Exposure Tracking Guidelines.[40]

Although standards exist, such dose tracking has not been widely deployed because of the following:

- difficulty coordinating the roles of the different equipment involved (which actors should do what)
- difficulty coordinating tracking across multiple departments and multiple institutions
- the need to converge on one of the available standard approaches.

In our review of the literature, we found that many approaches have seen some success at decreasing medical ionizing radiation exposure. We have used these in the formulation of our proposal with the hope that their ideas and localized efforts can be broadened to the entire medical community. Patients with chronic medical conditions are at increased risk of radiation overexposure.[41] Lin[3] reviewed the risks of medical imaging and encouraged clinicians to play a role in prevention by referring their patients only to facilities that used reduced exposure methods as well as by ordering fewer tests, noting that "all imaging tests, particularly those with potential patient harm, be performed only when indicated." He also reviewed methods and equipment by which radiologists could decrease radiation doses.

Some authors have focused on radiation exposure in patients with specific medical conditions. Smookler et al[42] wrote: "Clinicians should recognize that increased radiation exposure puts patients with spina bifida and hydrocephalus at higher risk for cancer. The population of children and adults with spina bifida and hydrocephalus should be surveyed for incidence of cancer." Smookler has, since 2009, been involved in a successful program to decrease medical radiation exposure in patients with spina bifida by increasing awareness of the substantial imaging radiation exposure by head CT at his institution and in his subspecialty, and by including the radiation dose as part of the radiologist's report while encouraging a switch to First post-contrast Acquisition SubTracted (FAST) MRI (Gregory L Smookler, MD; personal communication, 2016 Aug 22).[a] However, some studies have found that evidence-based change is less effective in the long run than clinical decision support.[43]

Massachusetts General Hospital[44] achieved significantly decreased exposure, reducing its dose levels for CT examinations by 30% to 95% over National Council on Radiation Protection reference levels. The hospital customized its CT examinations for each patient on the basis of multiple factors, including weight, age, and history. Techniques to minimize radiation exposure included employing radiation-free alternatives such as ultrasonography and MRI. Massachusetts General Hospital actively maintains its equipment to ensure patient safety and takes advantage of technology advances by upgrading and replacing equipment expeditiously. Minimizing radiation exposure for all patients is a key guideline, especially for children. Multiple safeguards were put in place to prevent accidental exposure, and hospital personnel committed to continually strive to improve the protocols that govern each type of scan, with the goal of exposing patients to less radiation while obtaining not the best images but, rather, those of sufficient quality for accurate diagnoses.

Radiation Exposure Tracking Guidelines[40]

1. View a patient's history of cumulative radiation exposure.
2. View the organ-specific dose that a patient received from each previous examination.
3. Determine whether a given patient dose exceeds the maximum guidelines or is otherwise an outlier requiring investigation and action.
4. Compute the population "dose profile" for a certain hospital or region.
5. Compute the population dose profile for a certain disease.
6. Compare dose profiles against other sites/regions, local policy targets, or standards of practice.

Table 1. Risk ranking of radiation vital sign

Rank	Risk
1	very low significance
2	low significance
3	significant
4	high significance
5	very high significance[a]

[a] Patients with elevated likelihood of excessive exposure because of chronic medical conditions may be preventively given a high score.

Fetterly et al[45] introduced a philosophy of radiation safety that they successfully implemented through a collection of sustained practice and x-ray system changes for invasive cardiovascular procedures. These led to a significant 40% decrease in the radiation dose administered to patients. These practices included the following: "intra procedure radiation dose announcements; reporting of procedures for which the air-kerma exceeded 6000 mGy, including procedure air-kerma in the clinical report; and establishing compulsory radiation safety training for fellows. Technical changes included establishing standard x-ray imaging protocols, increased use of x-ray beam spectral filters, reducing the detector target dose for fluoroscopy and acquisition imaging, and reducing the fluoroscopy frame rate to 7.5 per sec."[45] (For an explanation of air kerma, see Sidebar: Glossary of Radiation Terms.)

The FDA recommends that criteria be developed and implemented to use radiologic procedures appropriately.[14] The FDA recommendations include advising the health care professional community to develop and adopt criteria for appropriate use of CT, fluoroscopy, nuclear medicine, and other procedures that use these techniques. Building on the efforts of various professional organizations, including the ACR and the American College of Cardiology, the FDA recommends that the health care professional community continue to develop and adopt appropriate use criteria for CT, fluoroscopy, and nuclear medicine procedures. In addition, the FDA encourages incorporation of electronic decision support tools for ordering imaging procedures to improve quality and consistency in clinical decision making.

From the professional experience of one of the authors (JL), some examples come to mind. The diagnosis of pneumonia rarely needs a CT scan; a plain film will do.[46] Few neonates need a routine daily chest x-ray film. Not every patient receiving high-frequency ventilation needs a chest x-ray to be obtained every four hours as is often the standard of care. Not every patient seeing an orthopedic surgeon needs a radiograph before his or her clinical examination. These routines, and many more, must be reexamined and reimagined.

Vital signs are measures of the status of the body's life-sustaining functions. There are four main vital signs: body temperature, blood pressure, pulse (heart rate), and breathing rate.[47] Additional vital signs have been proposed and used. A "fifth" vital sign may refer to a few different parameters. Pain is considered a standard fifth vital sign in some organizations such as the US Department of Veterans Affairs.[48] Other suggested fifth vital signs include menstrual cycle,[49] Glasgow Coma Scale,[50] pulse oximetry,[51] and others. Tysinger[52] identified that increased patient complexity in health care has led to greater efforts to identify early deterioration and adverse events. Key components of these efforts include timely vital sign collection and review as an early warning system. Tysinger notes that vital signs are intended to anticipate and prevent adverse outcomes.[52]

Radiation Vital Sign Risk Factors

1. patient's age
2. gestation of pregnancy
3. genetics
4. patient's sex
5. body mass index
6. smoking status and history
7. medical history, especially chronic disorders, with prematurity and malignancy included, creating an at-risk category (renal and cardiovascular disorders may also put patients at risk of excessive exposure)

8a. cumulative exposure
8b. time intervals between exposures (time intervals decrease at least some risks of exposure)

9. proposed imaging exposure
10. occupational and dwelling (radon) exposure[14]
11. specific organ exposure[21]
12. alcohol consumption

On the basis of that premise, it is our opinion that the traditional measures of a person's vital signs can be expanded to include a radiation "vital sign" that measures the risk from a patient's past and potential radiation exposure.

PROPOSED RADIATION VITAL SIGN

Our proposal for a new and universal radiation vital sign is intended to create clinician awareness of each patient's risk (an early warning system) owing to one's cumulative radiation exposure assessed relative to one's known sensitivity factors for harm from additional radiation exposure and, in conjunction with clinical decision support, offer medically appropriate alternatives. Each person's cumulative radiation exposure and known medical history will be combined to create the radiation vital sign.

The factors that are currently known to affect risk caused by radiation exposure are listed in the Sidebar: Radiation Vital Sign Risk Factors. Incorporation of these 12 radiation vital sign risk factors, and other risk factors as they may be identified, will require an extensive method involving acquisition and analysis of an ample patient radiation exposure and outcomes database, as well as use of sophisticated statistical analysis techniques. However, the initial scoring system could be based on the few well-studied risk parameters, including cumulative radiation exposure, patient age and pregnancy status, and the anticipatory medical history of chronic disorders that are known to engender repeated studies.

The radiation vital sign will be individualized and developed to dovetail with real-time clinical decision support to minimize radiation to "as low as reasonably achievable consistent with obtaining the required diagnostic information."[38]

We propose that the overall risk score for the radiation vital sign be ranked according to the categories listed in Table 1. The incorporation of the radiation vital sign's risk factors into an overall risk score will present several challenges. Most factors that contribute to the malignancy risks of radiation exposure have been identified, but nonmalignant side effects have not been well monitored or quantified. Although the risk of cancer is better studied, it still needs more in-depth study.

RADIATION VITAL SIGN RISK FACTORS

Several risk factors that are included in the radiation vital sign are discussed here as they pertain to the risk of cancer.

Cumulative Radiation Exposure

Wiest et al[53] reported that 30% of their patients in 2001 had more than 3 CT examinations mentioned in their medical histories, 7% had more than 5 examinations, and 4% had more than 9. They found that cumulative radiation exposure was sufficient to add, incrementally, to baseline cancer risk in their cohort. Although most patients accrue low radiation-induced cancer risks, a subgroup is at higher risk because of recurrent CT imaging. Although CT represents only 15% of imaging procedures, it accounts for approximately half of the collective medical radiation dose owing to the relatively high dose per examination and its frequent use.[3] This was corroborated by Sodickson et al.[14]

Patient's Age and Sex

Statkiewicz Sherer and colleagues,[54] using BEIR VII,[1] calculated that the same radiation dose in the first year of life for boys produces 3 or 4 times the cancer risk as radiation exposure between the ages of 20 and 50 years. They reported: "For girls the difference is six to eight times. For children in general, the risk is approximately three times." Studies of cancer in children after exposure in utero or in early life indicate that radiation-induced cancers can occur at low doses.[1] For example, the Oxford Survey of Childhood Cancer[55] found a 40% increase in the cancer rate among children up to age 15 years. This increase was detected at radiation doses ranging from 10 to 20 mSv.

Authors of a 2009 study performed in adults reported the following:[20p2083]

> *The corresponding [lifetime attributable risks] of cancer were also higher than typically reported and markedly variable by study type, patient, and hospital. For example, it is commonly reported that a CT scan may be associated with an increase in the risk of cancer of approximately 1 in 2000. Based on the highest effective dose we observed, a 20-year-old women [sic] who underwent a CT for [evaluation of] suspected pulmonary embolism, a CT coronary angiography or a multiphase abdomen and pelvis CT scan could have an associated increased risk of developing cancer of as high as 1 in 80. The risks declined substantially with age and were lower for men, so radiation-associated cancer risks are of particular concern for younger, female patients.*

Dwelling (Radon) Exposure and Smoking History

Approximately 157,400 people died of lung cancer (from all causes, including smoking and radon exposure) in the US in 1995.[56] Of the 95,400 men who died of lung cancer, about 95% were probably smokers at some point ("ever-smokers"); of the 62,000 women, approximately 90% were probably ever-smokers.[55] On the basis of 2 models, the BEIR VI committee[56] estimated that

> *… about 1 in 10 or 1 in 7 of all lung-cancer deaths—amounting to central estimates of about 15,400 or 21,800 per year in the United States—can be attributed to radon among ever-smokers and never smokers together. The number of radon-related lung-cancer deaths resulting from that analysis could be as low as 3,000 or as high as 33,000 each year. Most of the radon-related lungcancers occur among ever-smokers, and, because of synergism between smoking and radon, many of the cancers in ever-smokers could be prevented by either tobacco control or reduction of radon exposure. The committee's best estimate is that among the 11,000 lung-cancer deaths each year in never-smokers, 2,100 or 2,900, depending on the model used, are radon-related lung cancers.*

Clearly, if exposure to radon is synergistic with smoking in causing cancer, medical radiation exposure should be as well.

IMPLEMENTATION OF A RADIATION VITAL SIGN

We propose that this new life-sustaining radiation vital sign be viewed alongside all other vital signs documented in the medical chart. To increase visibility and awareness, the radiation vital sign could be color coded, highlighted, or scripted differently and could demarcate certain predetermined patient-appropriate limits. We propose that this new vital sign be tied in with automated warnings whenever additional radiologic studies are being ordered; evidence-based alternate strategies with the lowest medically appropriate radiation exposure possible will be proposed. A focus on high-dose procedures or frequently repeated procedures would be the traditional and most targeted approach. However, with this functionality built into the EMR, the radiation vital sign could easily encompass all patients and all ionizing radiation exposures.

CREATION OF A RADIATION VITAL SIGN RISK SCORE

Our proposed universal radiation vital sign uses the power of standards for EMRs to potentially allow us to enhance clinician awareness of radiation exposure and risk and to offer safer alternatives. The American Society of Radiologic Technologists created an online x-ray risk calculator (http://xrayrisk.com). This risk calculator is a progenitor to our concept, but it is limited to evaluating only the risk incurred for a proposed radiation study. The only risk factors it takes into account are the patient's age and sex. The calculator is therefore severely limited because it does not include the dose accumulated by a patient from previous tests or other known risk factors. However, it does offer a stepping-stone to actualizing our concept.

Although we have identified the known important factors necessary to perform an accurate risk evaluation, the design and implementation of a vital sign risk score is beyond the scope of this article. Creation of a radiation vital sign risk score will entail a major effort involving statistical quantification of the known contributing factors, programming to allow retrieval of necessary information from the EMR, and population of the EMR with the score. Real-time clinical decision support will require a similar effort.

All medical procedures (and treatments) must be "appropriate."[57]

The risk of ionizing radiation must be balanced against the benefits of any examination ordered. There are many clear and undisputed benefits to modern radiologic examinations, and there has been an explosion in the use of these tests.[58] Many authors have argued that they are now frequently overused.[19,59] According to Brenner et al,[6] "if it is true that about one third of all CT scans are not justified by medical need, and it appears to be likely, perhaps 20 million adults and, crucially, more than 1 million children per year in the United States are being irradiated unnecessarily."

Our goal is to create an implementable method that maximizes appropriate use of procedures that expose patients to ionizing radiation by informing patients and clinicians of their individualized risk profile. We aim to accomplish this via a radiation vital sign tied into clinical decision support that attempts to provide optimal medical care with the minimal additional risk clinically acceptable. This can be accomplished through minimizing unnecessary or low-yield exposures to ionizing radiation by looking to all other modalities and approaches that would utilize less or no ionizing radiation as long as the results are medically acceptable and patient approved.

DISCUSSION

We have documented that radiation exposure is known to cause cancer and a variety of other medical maladies. We also documented that current medical diagnostic testing exposes patients to sufficient quantities of radiation to be of concern for iatrogenic side effects. We reviewed the literature that shows our concerns have been extensively documented and that recommendations to decrease use of medical ionizing radiation have been promulgated, with limited local successes but little effect nationally, while documenting the unrelenting increased use of radiologic testing. Yet, we also argue that alternative, safer, and medically useful approaches are available and would result in a 20% to 50% decrease in medical radiologic testing. This could potentially avert 20,000 to 50,000 induced cancers per year as well as other radiation-induced side effects.

We therefore have proposed a new method to implement the accepted advice to decrease use of medical ionizing radiation exposure, especially to CT, positron emission tomography, and fluoroscopy. Our proposed new radiation vital sign could be an effective safety measure to reduce medical ionizing radiation usage. It will document each patient's individual risk-adjusted score for potential radiation damage on the basis of previous cumulative exposure to ionizing radiation and likely additional exposure, modified by an individualized risk assessment based on our current understanding of quantifiable risks.

We propose anticipatory guidance for patients who are identified as high risk (pregnant, premature) or likely to require repeated examinations because of their medical diagnoses (hydrocephalus, spina bifida, cancer, renal disorders, etc). This information will then be factored against any proposed new exposure to medical ionizing radiation in the context of state-of-the-art computerized medical decision making and advanced AI. Alternative approaches to testing include watchful waiting, repeated clinical examinations, MRI, ultrasound, elastography, reduced-exposure radiologic examinations, and even exploratory surgery.

All tests should potentially improve patient care more than they create risks for the individual. We propose that there be a new paradigm that values exposing patients to less ionizing radiation and commits to 24-hour availability of FAST MRIs (with anesthesia as needed) and high-resolution ultrasound. Our old paradigm rationed imaging technologies that are non-radiologic more than CT scans because of cost, time, and detail without regard to necessity of that detail or risk of exposure to ionizing radiation.

CONCLUSION

To accomplish our goals, it will be necessary to improve our measurements of patients' radiation exposure from radiologic procedures; we need accurate standardized measurements to assess and communicate risk. We must then integrate those measurements and relevant patient data into a risk assessment that can be used to generate our new radiation vital sign. That radiation vital sign will then initiate a computer-generated, patient-specific, best practice/minimalist exposure set of recommendations to present to clinicians and patients. ❖

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Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgment

We thank Neal Lonky, MD, MPH, for editorial review.

Kathleen Louden, ELS, Louden Health Communications provided editorial assistance.

How to Cite this Article

Lukoff J, Olmos J. Minimizing medical radiation exposure by incorporating a new radiation "vital sign" into the electronic medical record: Quality of care and patient safety. Perm J 2017;21:17-007. DOI: https://doi.org/10.7812/TPP/17-007.

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