Radiation Safety in the Era of Helical CT: A Patient-Based Protection Program Currently in Place in Two Community Hospitals in New Hampshire

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Purpose: To describe a patient-based radiation safety program currently in place in 2 community hospitals in southern New Hampshire and the patients identified and managed by this program.

Methods: The rationale, components, and early results of a patient-based radiation safety program are summarized and reviewed. The patient populations who may be affected by frequent exposure to helical CT scanning are identified both prospectively and retrospectively via a threshold approach using the number of studies the patient has had rather than attempting to directly measure radiation dose. This was arbitrarily defined as 5 studies of the neck, chest, abdomen, pelvis, or abdomen/pelvis in patients under 40 years of age with benign diagnoses, whose estimated exposure might approach 50 mSv. The mechanisms that can be put into place to prevent further exposure in these patients are discussed and outlined.

Results: Fifty-four patients were initially identified over a 3-year period who had over 5 helical CT studies of the neck, chest, abdomen, pelvis, or abdomen/pelvis for benign diagnoses. An additional 104 patients were identified over a 12-year period by retrospectively "data mining" our radiology information system. A detailed program is outlined for the management of these patients, the future identification of patients, and the education of patients and providers.

Conclusion: Frequent exposure to possibly carcinogenic levels of ionizing radiation from helical CT scanning is a potentially large public health issue for the medical community. The identification and management of potentially at-risk patients is feasible.

Key Words: Helical CT, radiation safety, community hospitals, radiation exposure

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INTRODUCTION

Helical computed tomography (CT) has revolutionized diagnostic imaging in the last 15 years with its ability to image with extraordinary speed and accuracy. An unprecedented increase in the use of these studies has resulted. Approximately 60 million CT studies were performed in 2005 in the United States, a rate of 1 study for every 5 US residents [1]. At Southern New Hampshire Medical Center in 1985, the radiology department performed approximately 2,500 CT studies. In 2006, more than 18,000 CT studies, a 7-fold increase, were performed (D. Dionne, RT, MBA, personal communication, 2007).

In 2005, I interpreted a renal stone CT scan on a 14-year-old adolescent with renal tubular acidosis and realized in reviewing his old records that he had undergone 14 of these studies. Our medical physicist was consulted for a dosimetry estimation, which I had previously done for patients in early pregnancy who had been inadvertently exposed to diagnostic irradiation. The results were horrifying. A subsequent event in August 2005 with my own 22-year-old daughter at a teaching hospital after major trauma moved me to action [2]. The radiation safety program reported in this article chronicles my data collection and efforts to curb frequent exposure to CT radiation. The aim of this program is to refocus radiation protection on patients who may receive potentially carcinogenic exposures, rather than radiation workers and equipment.

Epidemiologic evidence has clearly implicated radiation exposure with carcinogenesis. In the Japanese atom bomb survivors, carcinogenic effects with both solid and hematopoietic tumors have been demonstrated in excess

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Radiation Dosage and Effect

- **10,000 mSv-** Radiation sickness with immediate illness and death w/i several weeks
- **1,000 mSv-** Immediate radiation sickness, unlikely to cause death
- **100-1000 mSv** –Clear dose related increasing risk of carcinogenesis
- **50 mSv-** Clearly associated with increased cancer risk and the highest dose recommended yearly in occupational exposure (National Council on Radiation Protection and Measurements, 1993)
- **20 mSv/year averaged over 5 years-** Highest recommended allowable dose for radiation workers (International Commission on Radiation Protection, 1991)
- **3-5 mSv/year-** Typical dose rates of uranium miners in Australia and Canada

Fig 1. Radiation dosages and biologic effects (Adopted from Hall EJ, Giaccia AJ. *Radiobiology for the Radiologist.* Philadelphia: Lippincott Williams and Wilkins; 2006).

of dosage estimates of 50 mSv. These effects were seen at distances as close as 3 km from the hypocenter of the explosions. They were most apparent in patients aged less than 40 years, with children an order of magnitude more sensitive to these effects [3].

Dosage estimates from helical CT scanning are highly variable and depend on the body part scanned, manufacturer, scanner architecture, technique used, and patient body habitus. Given the variability of dose estimates for different studies, various scanners, and patient body habitus, the actual dosage any patient receives is difficult to calculate [1]. No causative relationship between CT radiation exposure and carcinogenesis has been made. Nevertheless, patients aged less than 40 years may receive radiation dose estimates that easily exceed the 50 mSv carcinogenic threshold estimate established with the atom bomb survivors [1]. To prevent this increased exposure to patients, I have established comprehensive radiation safety programs that are outlined below. These rely on radiation safety that is patient based, rather than focusing on devices and occupational exposure on which most efforts have been concentrated by regulatory agencies [1]. The outline of this program is included in Appendix 1, and the rationale for the program follows.

EDUCATION

Lee et al [4] have clearly documented the lack of awareness of providers, patients, and radiologists to radiation dose estimates and risks associated with CT scanning. Medical education must be developed to educate physicians and allied health providers in all specialties to the dangers potentially associated with unchecked ordering of CT studies [1]. Where I work, radiation safety officers (RSOs), health physicists, and radiologists are educating all health care personnel about radiation biology, radiation safety, and the issues surrounding cumulative doses that may occur in some patients.

Radiologists must reacquaint themselves with radiation biology and physics so that they are aware of the issues of dose-related carcinogenesis. Radiologists must take the lead with CT technologists to ensure the highest levels of radiation safety are practiced on a daily basis. Each institution should identify a radiologist "champion" who takes primary responsibility for radiation safety. Numerous grand rounds and other educational forums in the hospitals are used to continually keep health care providers aware of this issue. An essay entitled "Radiation Safety for Clinicians" has been published in medical staff newsletters, handed out at staff meetings, and included in this publication in Appendix 2. A compilation of radiation dose estimates for various studies is available throughout our departments (Figures 1 and 2).

Appropriateness criteria are also an important component of any educational effort [1]. There are automated systems being developed and in early testing to assist a provider in ordering a study [1]. Clearly there are certain diseases for which the risk of frequent exposure is high and the clinical utility of repeated studies is marginal. Examples of this include repeated renal stone CT studies

Units of Radiation Measurement

1) Millisievert (Old term, millirem)-International Unit of Effective Dose Corrects for Organ Sensitivity and Absorption of the Particular Radiation. Example: Breast Tissue is more sensitive in young females, so the "fudge" factor increases absorbed dose in these patients when breast tissue is exposed. Similarly, neutron irradiation is much more readily absorbed by tissue thereby transferring its energy to the tissue more completely and increasing dose by a factor of 10. This is the important number to know.

2) Milligray (Old term, millirad)-International Unit of Absorbed Dose. Does not correct for organ sensitivity or photon/particle absorption. At diagnostic x-ray energies, i.e. 28-140 kVp, 1 mGy=1mSv, for the actual energy characteristics of the photons.

Procedure Dosage Estimate (Procedures performed at Cleveland Clinic)

Yearly Background in New England 3-5 mSv
Chest x-Ray 0.06 mSv
Limbs/Joints 0.06 mSv
Pelvis/Hip Plain Films 0.83 mSv
Cervical Spine Plain Film 0.30 mSv
Thoracic Spine, 2 view 1.40 mSv
Lumbar Spine, 2 view 2.10 mSv
Abdomen, 1 view 1.70 mSv
Barium Enema 8.7 mSv
UGI/Barium Swallow and SBFT 15.0 mSv
Screening Mammogram 0.13 mSv
Radionuclide Bone Scan 4.4 mSv
Ventilation/Perfusion Lung Scan 6.8 mSv
Whole-Body PET Scanning 14.0 mSv
Whole-Body PET/CT Fusion Imaging 30.0 mSv
CT of Pelvis 7.1 mSv
CT of Abdomen 7.6 mSv
CT of Chest 7.8 mSv
CT Angiography of Coronary Arteries 10.0 mSv
Whole-Body CT Screening 22.5 mSv
Three-Phase Hepatic CT 29.9 mSv
Three-Phase CT Pyelographic Study 44.1 mSv

Fig 2. Radiation dosages of common radiographic procedures (Adopted from Cleveland Clinic Journal of Medicine 2006;73:583-6).

in young patients with known renal stones and no complicating clinical factors, uncomplicated pancreatitis, Crohn's disease, chronic abdominal pain with repeated normal imaging, and repeated CT pulmonary arteriograms to assess for pulmonary emboli in young women with minimal risk factors and low clinical suspicion. Other populations subject to frequent imaging with chronic diseases may benefit from these criteria, such as patients with sickle cell anemia who may have multiple CT pulmonary arteriograms for sickle cell crisis (SR Baker, MD, personal communication, 2007).

TECHNICAL FACTORS

Radiologists and CT technologists are able to decrease estimated doses to patients for any individual study by doing the following:

1. Coning the study to the body part to be scanned. A chest CT study in our department does not include a large part of the upper abdomen or extend to the mandible.
2. Careful instruction by the technologists to the patients about respiration and motion to minimize repeat imaging.
3. Minimization of multiphase studies when appropriate. For example, magnetic resonance imaging (MRI) is the preferred modality for the evaluation of renal masses and hepatic masses in younger patients in our practice. A multiphasic study, such as a CT pyelogram or 3-phase hepatic CT, exposes patients to 2 or 3 studies, respectively.
4. Use of breast and thyroid shields. The use of thyroid and breast shields is estimated to decrease surface dose to the breast and thyroid by approximately 20% to 30%. These shields are used in all female patients regardless of their age. The shields are placed on the patient after the scout imaging in most manufacturers' scanners because automatic exposure control is based on scout image density in the majority of multidetector scanners. The premature placement of these shields will result in an increase in the technique based on the shield density. One major manufacturer uses an automatic exposure control algorithm that renders these shields less effective.
5. Use of automatic exposure control or manual dose modulation and a manual increase in noise index to decrease individual study dose. Image quality can usually be satisfactorily maintained with lower techniques without loss of diagnostic information. Every radiology practice should try different noise indices for various clinical indications in patients with variable body habitus to minimize the output of their particular scanner for any given study.
6. Centering of patients in the gantry. This simple technique results in diminished dosimetry to the patient as a result of even distribution of the x-ray beam and improved functioning of automatic exposure control [5].
7. Spot checking of dose estimates from your scanner. New 64-channel CT scanners produce a dose profile for each examination. By using the dose length product, a gross estimate of radiation exposure from a particular scan can be calculated with conversion factors generated by the European Guidelines on Quality Criteria for Computed Tomography [6]. Review of these values helps the radiologist monitor technologist adherence with radiation safety practice, although this is not considered a true dose estimate.

IDENTIFICATION OF AT-RISK PATIENTS

Radiology departments have been encouraged by the American College of Radiology to "... define a surveillance mechanism to identify patients with high cumulative radiation doses due to frequent imaging" [1]. A system to accomplish this goal has been established and uses existing information on radiation safety and biology to establish criteria for at-risk patients. The following criteria, which are admittedly somewhat arbitrary but based on currently available information and literature, are used:

1. Patient age: age less than 40 years. This is the age threshold most often cited as being at risk and takes into account the increased longevity of our patient population and data from the atom bomb survivors.
2. Diagnoses: benign diagnoses. No patients with cancer are included in this identification process at this time. Certainly, many young patients with cancer on various protocols do receive many follow-up studies, particularly positron emission tomography/CT fusion studies, that may result in high cumulative exposures.
3. Study types: Five studies of the neck, chest, abdomen, or abdomen/pelvis would expose the patient to a dose estimate of approximately 50 mSv. These are dose estimates, not calculations done by physicists, and we have therefore stayed away from using any sort of precise measurement. Rather, we prefer to use the number of studies in our thresholds. This is in keeping with the difficulties that physicists have in measuring exact dosages in patients, given the huge number of variables involved in this process [1].

Our CT technologists have been empowered in this process to actively research imaging histories in the radiology information system (RIS) and report any suspicious histories to the radiologist on duty at that time and then to the RSO. The imaging history and studies are then reviewed, and if the criteria are met, the patient is entered into our database of at-risk patients.

Once a patient is identified using the above system, the following events take place:

1. The patient's demographics are annotated in the RIS with the annotation of "RADIATION SAFETY ALERT," similar to contrast allergy.
2. Further studies on these patients are only performed with radiologist consultation to assess for clinical appropriateness and the suitability of nonionizing modalities for evaluation instead of CT, or because of overwhelming clinical indication.
3. When the patient activates the 5-study threshold, a certified letter is sent to the referring clinician and the primary care provider, if there is one. This letter discusses the radiation safety issues and the potential risks of further studies. The practitioner is also informed of the necessity of radiologic consultation if further CT studies are needed. (Sample letters are included as Appendix 3.)
4. If the patient has had more than 10 studies listed above, he or she is then placed in a higher risk category. In addition to the measures detailed above, a certified letter is sent to the patient (Appendix 2). We have become aware that many of our patients have received care at multiple institutions where they may have had many additional radiologic studies. Patients in this category should be informed of these issues in a calm manner, so that they can take charge of their medical care, record their imaging history, and have a say in any future imaging.
5. The RSO and our consulting physicist are made available for patient and provider consultation, as needed.

Anecdotally, this program has met with high acceptance by patients, clinicians, and radiologists. In the course of the last year, at least 30 patients have been switched from CT to either no imaging or alternative imaging. Only one patient was openly upset and complained about our policy. More than 150 letters to providers and 15 patient letters have been sent without negative feedback. All of our CT technologists and radiologists actively participate in the implementation of this program. Hospital administrators, hospital lawyers, and risk managers have vetted the letters to patients and providers.

The original patient, whom we identified 3 years ago, is now 17 years old. He has had no subsequent renal stone CT studies and has received 10 renal ultrasounds, 10 x-ray examinations of the kidneys, ureters, and bladder, and a single-shot intravenous pyelogram. There has been a substantial diminution in radiation dose, no significant changes in the clinical management of his continued episodes of renal colic, and no adverse impact on his health by limiting his CT studies. His urologist enthusiastically embraced this program and frequently calls for radiologic consultation. Currently, a study is under way at our institution to quantify and characterize the effects these interventions have had longitudinally and with a larger cohort of patients.

PATIENT DEMOGRAPHICS OF FREQUENT EXPOSURE TO CT IN THE COMMUNITY HOSPITAL SETTING

In the course of approximately 3 years, we have identified 54 patients who fulfill the above criteria. These patients were identified by the so-called prospective method, that is, our technologists and radiologists identify patients about to be scanned or who have been recently scanned. The most common diagnoses identified in this cohort of patients are the following: 1) 20 patients with multiple emergency department (ED) visits, episodic care, and no insurance; 2) 13 patients with renal and ureteral stones; 3) 9 patients with chronic abdominal pain and normal imaging studies; 4) 3 patients assessed for pulmonary embolism; 5) 3 patients with pancreatitis; 6) 2 patients with Crohn's disease; 7) 2 patients with diverticulitis; and 8) 2 patients with juvenile-onset diabetes mellitus and multiple medical problems.

One of these patients with renal stone disease had 24 renal stone CT studies and 73 x-ray examinations of the kidneys, ureters, and bladder during a 7-year interval on review of her imaging history. Another 31-year-old patient had 14 renal stone CT studies in one of our hospitals, and when she was in the process of being transferred for an ultrasound to evaluate her stones, she reported a history of at least another 20 stone CT scans that were performed at a tertiary care center in the course of her care during the last 5 years.

In addition, our information technology staff has done "data mining" at the Southern New Hampshire Medical Center using Crystal Reports. An additional 104 patients have been identified since the installation of our RIS and our first single-detector helical CT scanner in 1998 who fulfill the requirement for frequent exposure to CT as defined above. The data from this group were exported to Microsoft Excel (Microsoft Corp, Redmond, Washington), in which a pivot table was created (M. Guilfoyle, MS, personal communication, 2007). The average age of these patients was 32.0 ± 5.4 years; 62.7% of the patients were women and 37.3% were men. The most common diagnoses identified with this method were as follows: 1) 32 patients with chronic abdominal pain and multiple ED visits; 2) 26 patients with renal and ureteral stones; 3) 8 patients with pancreatitis; 4) 7 patients with Crohn's disease; and 5) 3 patients each with follow-up for lung nodules and assessment for pulmonary embolus diagnoses. None of these patients had cancer.

STATE AND REGIONAL EFFORTS

Anthem New Hampshire Blue Cross/Blue Shield was looking for ideas from the imaging community on how to better serve patients and providers, as well as how to implement their business plans. This radiation safety program was brought to a diagnostic imaging committee on which I served. Elizabeth Malko, MD, and Richard LaFleur, MD, medical directors of Anthem in New Hampshire, became strong advocates for radiation safety through the tracking of insurance data in their plan. Tom Dehn, MD, then-chief medical officer of National Imaging Associates, a leading imaging benefits management firm, used similar thresholds as we had advocated and is monitoring patients through the preauthorization process. The aim of these programs is not to deny CT studies but instead to inform patients and providers of the potential risks and act as an educational tool in this process. Anthem has put together a radiation safety toolkit that is available to all providers either in hard copy or on the Web [7]. This program is available in New Hampshire, Maine, and Connecticut and may soon be offered nationally (E. Malko, MD, personal communication, 2007). National Imaging Associates has obtained national data from many patients and has even found a patient, without cancer, who has had 341 CT studies (T. Dehn, MD, personal communication, 2006). In addition, a pay-for-performance initiative has been proposed by Anthem in New Hampshire as a way to induce practices and hospitals to monitor patient exposure through the establishment of programs similar to ours. On first glance, most physicians will insist that these policies are simply ways to avoid paying for and denying services. Yet the number of patients that would be affected by these thresholds is relatively small compared with the number of insured lives that these companies carry. The cost of the information technology infrastructure needed to perform this monitoring and notification far exceed the cost savings involved.

The state board of radiation protection has no legislative mandate to pursue patient-based radiation protection of this sort and cannot involve itself in these efforts at this time (D. O'Dowd, MS, personal communication, 2006). This is a common state of affairs across the United States [1].

CONCLUSIONS AND RECOMMENDATIONS FOR THE FUTURE

Patient-based radiation safety programs to protect patients from frequent and potentially injurious exposure to ionizing radiation can be accomplished in the community hospital setting. Our program has met with excellent clinical acceptance, and through our department's educational efforts, our radiologists have seen a distinct change in culture.

No longer do clinicians rather blindly order renal stone CT studies in our hospitals. Instead they often think about it first. Will the study change management? What will I do with the information? Are we still doing too many CT scans that could be considered unnecessary? Yes. Have I had to read a CT pulmonary angiogram on a 12-year-old girl without a predisposing thrombotic disorder, ordered by an ED physician without seeking radiologic consultation, performed in the middle of the night, and read by a nighttime coverage service without question? Yes. Have I had an ED physician insist on the 12th CT study for a young patient with Crohn's disease for abdominal pain without other complicating factors of Crohn's disease? Yes. We have a long way to go, and we are nowhere near the as low as reasonably achievable (radiation exposure) goal that should be on the mind of every radiologist as these studies are interpreted.

When radiologists do fluoroscopy or interventional procedures, we are present and aware of the exposure to the patient, as well as to our staff. All efforts are made to cone the beam, properly position the imaging intensifier, and use appropriate shielding. CT studies are almost always done without a radiologist present, and the images are then transferred electronically to our desks. The demand has become so great and burdensome that a lucrative industry has burgeoned to read CT cases at night so we can sleep. I do appreciate our nighttime coverage, and it has made my middle-aged life bearable again when faced with on-call responsibility. The radiology community, faced with increasing demands of clinicians and having the incredible technology we have at our disposal to make rapid, accurate diagnoses, has ignored one major focus from our training that separates us from virtually all other specialties. That unique attribute is our knowledge of radiation physics and biology and the deleterious effects of our tools when used injudiciously. Radiologists must take charge of this issue, educate our clinical colleagues, and insist that patient care and safety again become a primary goal of what we do. Given the data that virtually any radiologist can find in their practice if they elect to look, one has to wonder whether CT radiation exposure is the medical equivalent of climate change and global warming for which decisions made or not made today may be catastrophic 10 or 20 years from now.

REFERENCES

1. Amis ES Jr, Butler PF, Applegate KE, et al. American College of Radiology white paper on radiation dose in medicine. J Am Coll Radiol 2007;4:272-84.
2. Birnbaum S. Helical CT: too much of a good thing. Br Med J 2007;334:1006.
3. Pierce DA, Preston DL. Radiation-induced cancer risks at low doses among atomic bomb survivors. Radiat Res 2000;154:178-86.
4. Lee CI, Haims AH, Monico EP, Brink JA, Forman HP. Diagnostic CT scans: assessment of patients, physicians, and radiologist awareness of radiation dose and possible risks. Radiology 2004;231:393-8. Epub 2004 Mar 18.
5. Li J, Udayasankar U, et al. Automatic patient centering for MDCT: effect on radiation dose. Am J Radiol 2007;188:547-52.
6. European Commission. European Guidelines on Quality Criteria for Computed Tomography. EUR 16262EN. Office for Official Publications of the European Communities; 2000:74.
7. Anthem.com. Available at: http://www.anthem.com/wps/portal/ahpprovider?content_path=provider/noapplication/f5/s2/t0/pw_ad85140.htm&state=nh&rootLevel=0&label=Radiation%20Safety%20Toolkit. Accessed December 12, 2007.

APPENDIX 1: SOUTHERN NEW HAMPSHIRE MEDICAL CENTER COMPREHENSIVE PATIENT RADIATION SAFETY PROGRAM

I. Reasons for a new patient-based policy
  A. Marked increased use of helical computed tomography (CT) scanning and cardiac nuclear medicine during the last 10 years
  B. Lack of patient-based safety programs at the state and national level
  C. Lack of monitoring of patient radiation exposure for benign conditions in young adult and pediatric patients
  D. Prevention of further exposure in frequently exposed patients
  E. Minimize exposure to all patients undergoing helical CT scans
  F. Improve radiation safety education for all health care providers who order studies
  G. Credential all physicians who use ionizing radiation in diagnosis and treatment as Joint Commission on Accreditation of Healthcare Organizations requirement

II. Components of the Southern New Hampshire Medical Center patient-based radiation safety program
  A. Education
    i. Providers on the benefits and risks of ionizing radiation in diagnosis
    ii. Radiologists
    iii. CT technologists with periodic in-service on at least a yearly basis
    iv. Credentialing of all physicians who use fluoroscopy in diagnosis and treatment with recredentialing at time of clinical privilege recredentialing
    v. Use of alternative nonionizing modalities depending on clinical indications
    vi. Minimization of multiphasic CT studies when possible
  B. Technical modifications
    i. Cone CT imaging to smallest possible field by technologists
    ii. Use minimal radiation technique for studies based on clinical indications, age, and patient body habitus
      1. Automatic dose modulation
      2. Noise index
      3. Centering of patient in gantry
    iii. Minimize repeat and re-do imaging through patient instruction at time of study
    iv. Use of bismuth breast and thyroid shields in patients of appropriate age and sex
  C. Monitoring activities
    i. Prospective identification of frequently exposed patients
      1. Patients aged less than 40 years with benign diagnoses *and* with 5 or more helical CT studies of the neck, chest, abdomen, abdomen/pelvis, or pelvis.
      2. Other patients who may be deemed to have frequent exposure based on clinical history, age, and study numbers after review by the radiation safety officer (RSO)
    ii. Patients identified prospectively at time of scans by CT technologists, radiologists, or referring physicians
    iii. Flagging of patients in the radiology information system (RIS) with field denoting "radiation safety alert"
    iv. Requirement of radiologic consultation for further performance of studies on identified patients
    v. Retrospective identification of frequently exposed patients
      1. Use of database querying of RIS to identify patients previously treated at Southern New Hampshire Medical Center with frequent exposure to CT irradiation
      2. Handling of patients similar to above
    vi. Handling of identified patients
      1. Patients with cumulative history of 5 to 10 studies as identified above with gross estimate of exposure of approximately 50 to 100 mSv
        a. Notification of provider by certified letter
        b. Flagging of patient in RIS
        c. Necessity of radiologic consultation before additional CT imaging
      2. Patients with cumulative history of more than 10 studies identified above with gross estimate of exposure greater than approximately 100 mSv
        a. Notification of provider by certified letter
        b. Notification of patient by certified letter
        c. Availability of RSO for patient counseling
        d. Necessity of radiologic consultation before additional CT imaging
    vii. Monitoring of fluoroscopy use
      1. Monitoring of fluoroscopy times in radiology, cardiac catheterization laboratory, and operating room
      2. Review of fluoroscopy times by RSO with investigation of any outlying results

3. Notification of RSO of any cases with >30 minutes of fluoroscopy time for possibility of acute radiation effects
4. Notification of operating physician at 5-minute intervals when fluoroscopy time exceeds 30 minutes

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APPENDIX 2: RADIATION SAFETY HANDOUT FOR CLINICIANS

Radiation Safety for Clinicians

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Helical (aka slip ring or multidetector) computerized axial tomography has revolutionized diagnostic cross-sectional imaging by enabling the scanning of a volume of tissue instead of scanning the patient one slice at a time. This technology, combined with further advances in data handling, has allowed an unprecedented ability to image the body and reconstruct the data in multiple planes in ever shorter times with little loss of resolution. New applications of this technology have become common in daily use. Renal and ureteral stone studies, computed tomography (CT) pulmonary angiography, and acute abdomen imaging are here today and of proven diagnostic utility. Soon to come at the community hospital level is CT angiography of virtually any body part in 1 or 2 breath holds, including noninvasive coronary arteriography.

It is important to realize that as with anything in medicine or life, this incredible technology comes with a price. That price is increased radiation exposure. In the individual elderly patient undergoing 1 or several CT studies, this is of no concern given the dosages and lag time of low dose radiation-induced carcinogenesis.

The data concerning low-dose radiation effects come from several data sources. One is the atom bomb survivors whose dosage was estimated from their distance from the blast hypocenter. This is somewhat difficult to extrapolate to medical irradiation given it was a one-time exposure of mostly gamma and neutron irradiation. Nevertheless, there is a clear dose-related increase in carcinogenesis seemingly without threshold for these individuals. The second major data set is more akin to medical exposure. This occurred in 2 groups of female patients in a tuberculosis sanatorium in Nova Scotia and Massachusetts who were subjected to weekly/monthly fluoroscopy to monitor their disease, which was treated in the pre-antibiotic era with therapeutic pneumothorax. There was a clear dose-related carcinogenic effect in these patients of thyroid and breast cancer, again dose related over a large range of dosages.

Back to helical CT scanning. What is the risk? We do not know. We do know that the skin entry and equivalent dosages of helical abdominal CT may approximate those of the lower exposure end of the atom bomb survivors at some distance from the hypocenter of both Hiroshima and Nagasaki. An abdominal helical CT is approximately the exposure equivalent of 250 chest x-rays or 15 x-ray examinations of the kidneys, ureters, and bladder. We also know that with multiple helical CT studies, particularly of the abdomen and pelvis, including renal stone studies, that dosages will clearly approach those of the atom bomb survivors of Hiroshima and Nagasaki. We also know that chest CT scans, pulmonary CT arteriograms, and neck CT scans result in significant radiation exposure of the female breast and thyroid gland (Am J Radiol 2005;185:1228-33). Because pulmonary CT arteriograms are often ordered in female patients of reproductive age, radiation to the breast and thyroid gland may pose a significant lifetime risk of carcinogenesis (S. R. Baker, MD, personal communication, 2006). Intravenous contrast may increase thyroid radiation absorption through increased attenuation from iodine concentration. In fact, a CT pulmonary arteriogram results in breast irradiation equivalent to 10 to 25 two-view mammogram studies (Am J Radiol 2005;185:1228-33). Moreover, we know that the risk of radiation carcinogenesis is 10 to 15 times greater for children than for adults. At Southern New Hampshire Medical Center and Parkland Medical Center, we have for the last several years minimized the pediatric radiation dosage for CT by minimizing the technique necessary to obtain diagnostic imaging quality as recommended by the Food and Drug Administration.

What has also become clear is the lack of awareness of both clinicians and radiologists of these issues. A recent study from Yale (Radiology 2004;231:393-8) documents this from a busy teaching hospital. Only 7% of patients were informed of radiation risk before helical CT. Only 22% of emergency department (ED) physicians reported they had provided risk/benefit information to patients about helical CT. Forty-seven percent of radiologists in this study believed helical CT did result in an increase risk of carcinogenesis, but only 9% of ED physicians and 3% of patients were aware there may be an increased risk. None of the patients and few of the radiologists or ED physicians could give an accurate exposure estimate of an abdominal helical CT. Several examples from our hospitals follow:

1. A 14-year-old boy with metabolic abnormalities that cause him to make renal and ureteral stones. We became aware that he had undergone 14 renal stone CT scans during 4 years. After consultation with our radiation physicist, it was recommended he and his family seek genetic counseling because of an increased risk of carcinogenesis and the possibility of reproductive mutations. He is now managed with renal ultrasound and single-shot intravenous pyelograms when further imaging is necessary.
2. Young adults with Crohn's disease who will have a lifetime of this disease and who often have an abdominal CT ordered with every exacerbation. We have several patients aged less than 35 years who have had 8 to 12 abdominal/pelvic CT studies.
3. Management of nonspecific acute abdominal pain in the younger patient. We have a 49-year-old patient in our practice who made frequent visits to the ED with abdominal pain. This patient had had 8 abdominal CT scans in a 14-month interval, of all which showed normal results.
4. An 18-year-old woman with 8 abdomen-pelvic CT scans, 1 head CT scan, 1 CT pulmonary arteriogram, and 1 lower-extremity CT scan ordered through an ED during a 6-year period, all of which showed normal results. To quote our radiation physicist on consultation: ". . . current literature would suggest that the level of radiation exposure received by J. will increase her risk of getting cancer. An approximation of risk estimate from the dose received is 1/200."
5. A 38-year-old man with a seizure disorder has received 16 head CT scans during the last 6 years, through the ED, all of which showed normal results.

Of great concern is a previous example that befell the radiologic community in the midportion of the 20th century, early in the history of diagnostic imaging (S. R. Baker, MD, personal communication, 2006). Thorotrast (Heyden Chemical Corp, New York) was a suspension of thorium dioxide that was used as a contrast agent from approximately 1930 to 1950. It was a superb intravenous contrast agent with a low incidence of immediate side effects, but it was radioactive, emitting alpha irradiation. It was concentrated in the reticuloendothelial system.

Thorium dioxide has a biologic half-life of 400 years, and within approximately 20 years of its introduction as a contrast agent, it became clear that patients who had been exposed to this agent had approximately a 100-fold increased incidence of hepatic and splenic tumors and a 20-fold increase in leukemia incidence. At the time of Thorotrast's introduction, the only known radiation effects were seen in those individuals with very high occupational exposures, such as the original radiation physicists (eg, Madame Curie) and the infamous radium dial painters who painted the watch dials of time pieces with radium and then dipped the brushes in their mouths. Although Thorotrast exposed patients to high radiation doses at its sites of accumulation and was clearly more risky than the current use of helical CT, the parallels with CT scanning are real and should serve as a wake-up call to all of us who read and order CT studies.

What can we do?

1. Be aware of these issues when ordering studies, particularly in young patients or patients with chronic conditions, such as Crohn's disease.
2. Try to assess real risk-benefit from the study, for example, will the renal stone CT study resulting in relatively high radiation exposure really change management in the setting of acute renal colic, particularly in the young patient who may have multiple episodes over a lifetime and who has a known history of renal and ureteral stones?
3. Try to obtain imaging histories from old charts and patients.
4. Discuss cases with the radiologists when confronting these issues.
5. The radiation safety officer (RSO) is informed of all radiation issues that may arise in the hospital. Currently, we have an immediate notification of the RSO for more than 30-minute fluoroscopy times in the cardiac catheterization, operating rooms, and angiography laboratories. These patients, even the elderly, may be subject to skin burns and other local effects from concentrated local fluoroscopic exposure and may need to be evaluated 24 to 72 hours after any procedure with excessive exposure. This issue is a real one, and we have seen such patients in our practice.
6. The RSO is also informed of excessive CT exposure. We have set an arbitrary threshold of 5 abdominal/pelvic, chest, or neck CT scans in anyone less than 40 years of age with benign diagnoses. We are also monitoring on a case-by-case basis those patients who may have had excessive exposure via CT pulmonary arteriograms, head CT scans in childhood/infancy, and neck CT studies. The CT technologists or radiologists bring these cases to the RSO's attention. The RSO will then review the case, the imaging, and the clinical indications and decide whether a letter to the ordering clinician(s) is appropriate, as well as to the patient in the case of more frequent exposure. In addition, these patients' hospital records will be annotated in a fashion similar to contrast allergy such that radiologic consultation will be required for further CT imaging. Further management on a case-by-

case basis may become necessary if continued exposure is ongoing.

I hope this has been of help. Please call me with any questions or problems that may arise. I can be reached at Southern New Hampshire Medical Center at 577-2820, Parkland Medical Center through Ray Wilburn at 421-2020, or pager 771-4258.

APPENDIX 3: SAMPLE LETTERS

Letter 1. To patients who have had more than 10 helical CT studies

Department of Radiology
Southern New Hampshire Medical Center
8 Prospect Street
Nashua, New Hampshire 03060

Date

Dear {Patient Name}:

I am writing to you in my role as the radiation safety officer at Southern New Hampshire Medical Center. Part of my responsibility is to make sure that patients and employees are exposed to radiation only when necessary as part of their treatment or their jobs, because radiation from any source may lead to future health problems. As the medical literature surrounding exposure to medical radiation evolves, we have begun to track the doses of radiation received by patients undergoing diagnostic testing at the medical center.

Please understand that computed tomography (CT) scanning is valuable technology that has the ability to see into the body without an incision, stitches, or anesthesia. It has saved many lives. However, as with many things in life, it is important that we take steps to minimize risks, and that is what we are doing here at the Southern New Hampshire Medical Center. It has come to my attention that you have had a large number of CT scans in the course of your evaluation and treatment at our hospital. Although the risk to you is thought to be small, it is not fully known. Therefore, we are taking steps to work closely with your health care team to limit your future exposure, as appropriate.

Our team will be tracking the number of CT scans you have had in the records we keep at the Medical Center. If you should need any further studies at our hospital, we will work closely with your physicians and other health care providers to identify alternate ways to diagnose your problem. For example, when appropriate, we will recommend alternatives to CT scanning, such as ultrasound and magnetic resonance imaging, which carry virtually no risk when deemed appropriate alternatives to CT scanning. In addition, if there is no good alternative to performing a CT scan, we will continue to take all possible steps to minimize radiation exposure to you.

In the meantime, it is important for you as a patient to take responsibility for your medical care. Please discuss any concerns you have about your specific risk with your health care provider. When you go to other institutions, it is important that you inform them of your history, including radiology studies performed, so that they too can take appropriate steps to safeguard your health. I am also available for consultation and can be reached at 577-2820.

Sincerely yours,

____

Steven Birnbaum, MD
Radiation Safety Officer
Southern New Hampshire Medical Center

Letter 2. Provider letter to providers of patients who have had more than 10 helical CT studies

Date

Dear Health Care Provider:

As part of Southern New Hampshire Medical Center's Radiation Safety Quality Assurance Program, we have begun to track patients less than 40 years of age who have had multiple helical computed tomography (CT) scans at Southern New Hampshire Medical Center and who are booked for additional tests to assess their exposure to radiation. This radiation exposure was received because helical CT scanning of the neck, chest, abdomen, and pelvis involves a relatively high rate of radiation exposure compared with most other imaging procedures.

We have recently become aware that one of your patients, ____________, was noted to have had 10 or more helical CT scans of the neck, chest, abdomen, and pelvis, exposing the patient to radiation, placing the patient in a higher risk category of radiation exposure. Although the amount received is not immediately dangerous, continued exposure could result in long-term health risks, particularly the risk of radiation-induced cancer. Although studies at present are not conclusive, these risks are thought to be additive over the lifetime of the patient. Ideally, this patient should not be exposed to any further radiation; therefore, it is extremely important that thoughtful consideration be given to the risks vs benefits of any imaging study that involves ionizing radiation. If additional x-ray procedures are necessary for this patient, please use the following precautions:

1. Consult a radiologist before ordering any further radiographic examinations.
2. Order a CT scan only when the benefits far outweigh the risks.

3. Substitute clinical evaluation for radiation-based imaging when possible.
4. Order alternative imaging with ultrasound or magnetic resonance imaging when appropriate, feasible, and indicated.
5. Perform shielding of any body parts not pertinent to the imaging study.
6. Optimize radiation safety when using fluoroscopy.

The Radiology Department at Southern New Hampshire Medical Center stands ready to assist your practice in determining the optimal imaging approach for this patient and to offer educational material to help reduce exposure to other patients. The radiologists are always available for consultation on these matters.

In the interim, because of the high number of CT scan exposures we have recorded for this patient, we have also notified the patient directly. A copy of the letter is attached.

Thank you for your partnership in working to keep our patients safe. Should you have any questions please feel free to contact one of us.

Sincerely,

____

Steven Birnbaum, MD, Radiation Safety Officer

Letter 3. Letter to providers who have patients who have had between 5 and 10 helical CT studies

Date

Dear Health Care Provider:

As part of Southern New Hampshire Medical Center's Radiation Safety Quality Assurance Program, we have begun to track patients less than 40 years of age who have had multiple helical computed tomography (CT) scans at the Southern New Hampshire Medical Center and who are booked for additional tests to assess their exposure to radiation. This radiation exposure was received because the helical CT scanning of the neck, chest, abdomen, and pelvis involves a relatively high rate of radiation exposure compared with most other imaging procedures.

We have recently become aware that one of your patients, ____________, was noted to have had between 5 and 9 helical CT scans of the neck, chest, abdomen, and pelvis, exposing him/her to radiation that may place him/her in a higher risk category of radiation exposure. Although the amount received is not immediately dangerous, continued exposure could result in long-term health risks, particularly the risk of radiation-induced cancer. Although studies at present are not conclusive, these risks are thought to be additive over the lifetime of the patient. Ideally, this patient should not be exposed to any further radiation; therefore, it is extremely important that thoughtful consideration be given to the risks vs benefits of any imaging study that involves ionizing radiation. If additional x-ray procedures are necessary for this patient, please use the following precautions:

1. Consult a radiologist before ordering any further radiographic examinations.
2. Order a CT scan only when the benefits far outweigh the risks.
3. Substitute clinical evaluation for radiation-based imaging when possible.
4. Order alternative imaging with ultrasound or magnetic resonance imaging when appropriate, feasible, and indicated.
5. Perform shielding of any body parts not pertinent to the imaging study.
6. Optimize radiation safety when using fluoroscopy.

The Radiology Department at Southern New Hampshire Medical Center stands ready to assist your practice in determining the optimal imaging approach for this patient and to offer educational material to help reduce exposure to other patients. The radiologists are always available for consultation on these matters. Thank you for your partnership in working to keep our patients safe. Should you have any questions, please feel free to contact one of us.

Sincerely,

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Steven Birnbaum, MD, Radiation Safety Officer