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GUIDELINE FOR REDUCING RADIATION RISK FROM COMPUTER TOMOGRAPHY FOR PEDIATRIC AND SMALL ADULT PATIENTS

This guideline is intended to serve as a resource for pediatric health care professionals and to improve understanding of pediatric CT radiation and its potential risk in the development of cancer. The report also includes suggestions for an informed discussion of this issue between those who provide and those who receive care.

The guideline was initially developed from the FDA Public Health Notification published 02 November 2001.

Document History

Final Version	Reason for Amendment	Effective Date
0	First issue and implementation	October 2009
1	– Content structured on the new SAHPRA Guideline Template – A unique document number SAHPGL-RDN-XR-06 allocated to this Guideline	August 2022

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Glossary

Abbreviation/ Term	Meaning
ACR	American College of Radiology
CT	Computed Tomography
IV	Intravenous
mA	milli-amperes
MRI	Magnetic Resonance Imaging
Axial Scanning	its where one or just a few slices are acquired during each gantry rotation
Biological Effects	Acute health effects arising from exposure to certain levels of radiation
Helical Scanning	the patient is moved through a rotating X-Ray beam and detector set
Ionizing Radiation	A type of high-energy radiation that has enough energy to remove an electron (negative particle) from an atom or molecule, causing it to become ionized
Sonography	An imaging method that uses sound waves to produce images of structures within your body also known as Diagnostic Ultrasound

1. INTRODUCTION

Computed tomography (CT) is a valuable and essential addition to the array of imaging modalities for children. CT uses X-Rays to provide rapid, consistent, and detailed information about virtually any organ system in infants and children. Because X-Rays are an integral component for image formation with CT, there is an obligatory radiation exposure during the CT examination. Ionizing radiation has been demonstrated to increase the risk of cancer in individuals exposed to high doses of radiation. Moreover, recent reports have discussed the potential risk of cancer that results from the lower radiation exposure from CT examinations. These publications have raised concerns on the part of pediatricians, patients, and families. A review of this literature, however, shows widely differing opinions concerning the cancer risk of diagnostic imaging studies. Although many different statements on ionizing-radiation risk exist in the literature, one principle has been supported consistently by the authors of articles to which this report refers: any estimated risk of a CT scan is far less than the likely benefit to the patient for indicated examinations.

1.1 Purpose

The purpose is to summarize current opinions about the risks of cancer from exposure to radiation from imaging studies and to provide pediatricians with information that will be helpful in discussions with patients and families/caregivers regarding the radiation risks of CT examinations and the important clinical advantages of these studies.

1.2 Scope

Measure we take to reduce radiation from CT scans include:

- Customizing the scanning based on the size and weight of the patient or the body part being scanned.
- Eliminating unnecessary exams.
- Investing in CT scanners with the latest hardware and software tools that minimize radiation exposure. We utilize the General Electric Discovery CT750 HD, which provides up to a 50% lower dose of radiation for our patients, along with high-definition image quality for any part of the body.
- Our Radiation Exposure Registry, currently in development, will provide benchmarks for determining the optimal level of radiation for each CT exam.
- In a Blue Cross Blue Shield quality improvement study of 40 hospitals and imaging practices,

called the Advanced Cardiovascular Imaging Consortium, our Cardiac Computed Tomography team reduced our average CT radiation exposure by 43 percent.

- Utilizing MRI or ultrasound, if either is considered an effective alternative.

2. LEGAL PROVISION

This guideline is implemented in promulgated the Hazardous Substances Act 15, 1973 and the Regulations R.1332.

3. BACKGROUND

3.2 The individual risk from the radiation associated with a CT scan is quite small compared to the benefits that accurate diagnosis and treatment can provide. Still, unnecessary radiation exposure during medical procedures should be avoided. This is particularly important when the patient is a child, since children exposed to radiation are at a relatively greater risk than adults.

3.3 The American College of Radiology has noted, "Because they have more rapidly dividing cells than adults and have longer life expectancy, the odds that children will develop cancers from X-Ray radiation may be significantly higher than adults".

3.4 It has been estimated by the National Research Council's Committee on the Biological Effects of Ionizing Radiation that children less than 10 years of age are several times more sensitive to radiation than middle-aged adults.

3.5 Unnecessary radiation maybe delivered when CT scanner parameters are not appropriately adjusted for patient size.

3.6 When a CT scan is performed on a child or small adult with the same technique factors that are used for a typically sized adult, the small patient receives a significantly larger effective dose than the full-sized patient. To compound the problem, the overexposure of children or small adults during CT procedures can easily go unrecognized. In conventional X-Ray procedures, medical personnel can tell if the patient has been overexposed because the resulting film is overexposed, producing a dark image.

3.7 But with CT, there is no obvious evidence that the patient has been overexposed because the quality of the image may not be compromised. Several recent articles stress that it is important to use the lowest radiation dose necessary to provide an image from which an accurate diagnosis can be made,

and that significant dose reductions can be achieved without compromising clinical efficacy (see references 2, 5, 6, 7, 8, 9, 10).

4. RECOMMENDATIONS

Here are the steps we are recommending. They are not new. Indeed, many facilities are already taking measures to protect children and other small patients from unnecessary exposure during CT procedures (see references 11, 12, 13).

4.1 Optimize CT Settings. Based on patient weight or diameter and anatomic region of interest, evaluate whether your CT operating conditions are optimally balanced between image quality and radiation exposure. To reduce dose while maintaining diagnostic image quality:

- Reduce tube current. With all other factors held constant, patient radiation dose is directly proportional to X-Ray tube current. For example, a 50 percent reduction in tube current results in a 50 percent decrease in radiation dose (see reference 9).

- Develop and use a chart or table of tube-current settings based on patient weight or diameter and anatomical region of interest. See reference 9 for an example of tube current settings based on patient weight and anatomical region of interest (i.e., chest, pelvis or abdomen) for a single-detector helical-scanning CT unit. The diameter of the patient may be a better predictor of the tube-current required than body weight because patient diameter better correlates with the X-Ray beam attenuation in the patient. The scanner manufacturer can help in developing this chart or table.

- Increase table increment (axial scanning) or pitch (helical scanning). If the pitch is increased, the amount of radiation needed to cover the anatomical area of interest is decreased (see references 2 14). One study showed that increasing the pitch from 1:1 to 1.5:1 decreased the radiation dose by 33 percent without loss of diagnostic information (see reference 15). Consult your facility's medical physicist, who can advise you on optimal tube-current and pitch settings for diagnostic requirements. You can also contact the manufacturer of the CT scanner for recommendations specific to your model.

- Note that some newer CT scanners may automatically suggest or implement an increase in mA if pitch is increased. For these models, increasing the pitch may not result in a lower radiation dose. Contact the CT scanner's manufacturer for recommendations on your model's automatic current adjustment features.

4.2 Reduce the number of multiple scans with contrast material. Often, CT scans are done before, during, and after injection of IV contrast material. When medically appropriate, multiple exposures may be reduced by eliminating pre-contrast images (i.e., unchanged images) (see reference 9).

4.3 Eliminate inappropriate referrals for CT. In some cases, conventional radiography, sonography, or magnetic resonance imaging (MRI) can be just as effective as CT, and with lower radiation exposure. Most conventional X-Ray units deliver less ionizing radiation than CT systems, and sonography and MRI systems deliver no X-Ray radiation at all. It is important to triage these examinations to eliminate inappropriate referrals or to utilize procedures with less or no ionizing radiation (see reference 9).

5. REFERENCES

The following related documents are referenced:

5.1 David J. Brenner et al., "Estimated Risks of Radiation-Induced Fatal Cancer from Pediatric CT." AJR Vol. 176, pp. 289-296, Feb 2001.

5.2 "One Size Does Not Fit All: Reducing Risks from Pediatric CT." ACR Bulletin Vol. 57, Issue 2, pp.20-23, Feb 2001.

5.3 National Research Council, Committee on the Biological Effects of Ionizing Radiations. 1990. Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V). Washington, D.C.; National Academy Press.

5.4 Anne Paterson, Donald P. Frush, and Lane Donnelly, "Helical CT of the Body: Are Settings Adjusted for Pediatric Patients?" AJR Vol. 176, pp. 297-301, Feb 2001.

5.5 Lee F. Rogers, "From the Editor's Notebook. Taking Care of Children: Check Out the Parameters Used for Helical CT." AJR Vol. 176, p. 287, Feb 2001.

5.6 Lee F. Rogers, "From the Editors Notebook. Radiation Exposure in CT: Why So High?" AJR Vol. 177, p. 277, Aug 2001.

5.7 James G. Ravenel et al., "Radiation Exposure and Image Quality in Chest CT Examinations." AJR Vol. 177, pp. 279-284, Aug 2001.

5.8 Edward L. Nickoloff and Philip O. Alderson, "Commentary. Radiation Exposures to Patients from CT: Reality, Public Perceptions, and Policy."AJR Vol.177, pp. 285-287, Aug 2001.

5.9 Lane F. Donnelly et al., " Minimizing Radiation Dose for Pediatric Body Applications of Single-Detector

Helical CT: Strategies at a Large Children's Hospital." AJR Vol.176, pp. 303-306, Feb 2001.

5.10 John R. Haaga, "Commentary. Radiation Dose Management: Weighing Risk Versus Benefit." AJR Vol. 177, pp. 289-291, Aug 2001 and reference 1 cited therein.

5.11 A.E. Robinson, E.P. Hill, and M.D. Harpen, "Radiation Dose Reduction in Pediatric CT." Pediatr Radiol Vol. 16, pp. 53-54, 1986.

5.12 I.R. Kamel, et al., "Radiation Dose Reduction in CT of the Pediatric Pelvis." Radiology Vol. 190, pp. 683-687, 1994.

5.13 P. Rogalla, et al., "Low-Dose Spiral CT: Applicability to Paediatric Chest Imaging." Pediatr Radiol Vol. 28, pp. 565-569, 1998.

5.14 ACR Standard for the Performance of Pediatric and Adult Thoracic Computed Tomography. (American College of Radiology, 1995 Res. 1; Amended 1995 Res. 24, 53; Revised 1998 Res. 4; Effective 1/1/99).

5.15 A. Vade et al., "Evaluation of Image Quality Using 1:1 Pitch and 1.5:1 Pitch Helical CT in Children: A Comparative Study." Pediatr Radiol Vol. 26, pp. 891-893, 1996.

Getting more information:

If you have questions regarding this letter, please contact Marian Kroen, Office of Surveillance and Biometrics (HFZ- 510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov.

All the FDA medical device post market safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html

6. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients, revised October 2009. It will be reviewed on this timeframe or as and when required.