



AMERICAN COLLEGE OF GASTROENTEROLOGY

6400 Goldsboro Road, Suite 450, Bethesda, Maryland 20817-5846; P: 301-263-9000; F: 301-263-9025

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April 15, 2010

Division of Docket Management
Food and Drug Administration
U.S. Department of Health & Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging; Request for Comments (FDA-2010-N-0080)

The American College of Gastroenterology (ACG or the College) is pleased to provide comments to the FDA's recent public hearing entitled "*Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging*," held March 30-31 2010. The request for comments was published in the *Federal Register* on Wednesday, February 24, 2010.

INTRODUCTION

The College is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the ACG currently numbers more than 11,000 physicians among its membership of health care providers of gastroenterology specialty care. Although the vast majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists, and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, efforts directed at promoting and optimizing quality care including education.

Colorectal cancer (CRC) is a major public health issue. CRC is the third most common cancer in the U.S. with nearly 150,000 new cases of CRC diagnosed each year and remains the second leading cause of cancer death in the U.S. with close to 56,000 deaths each year. What's tragic is that CRC is a largely preventable disease. ACG advocates the use of complete colonoscopy as the preferred screening strategy because of the overwhelming evidence that complete colonoscopy is the most widely available and effective strategy for reducing the incidence of this disease. While ACG recognizes that computed tomography (CT) colonography, or "virtual colonoscopy," has a role in CRC screening and that this technology may very well increase the number of patients referred for a complete colonoscopy, we remain concerned that there is no demonstrable evidence that CT colonography prevents the development of CRC or reduces CRC mortality rates. Identical concerns have also been made by those federal agencies tasked with evaluating the use of virtual colonoscopy as a screening strategy, such as the Centers for Medicare and Medicaid Services (CMS) the U.S. Preventive Services Task Force.^{1 2} ACG is also concerned that the repeated CT exposures to a healthy patient when used for CRC screening, and when considered in the context of a patients' personal history of exposure to ionizing radiation, may also lead to an increase in radiation-induced cancers. Taken together the use of CT colonography in healthy asymptomatic patients may increase the public health burden and raise economic costs.

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RADIATION EXPOSURE FROM COMPUTED TOMOGRAPHY

ACG commends the Food and Drug Administration (FDA) for holding this public hearing on the risks of radiation exposure from CT. This is a major public health issue as CT scans and other imaging advancements have become increasingly more popular in treating patients. CT and other imaging services have revolutionized the practice of medicine and patient care. However, according to testimony provided during the hearing, CT also has the highest radiation dose of any imaging test.³ As the FDA notes on its website, “the risks of CT include an increased lifetime risk of cancer due to x-ray radiation exposure. This risk is greater for children as they are more sensitive to radiation and will likely be exposed to accumulated amounts of radiation exposure from imaging services over their lifetime.”

To limit radiation exposure over a patient’s lifetime, physicians and medical providers must weigh the clinical benefit of imaging services such as CT scans versus the potential harm in subjecting a patient to doses of radiation. FDA has noted on its website that “at this time, the FDA knows of no data demonstrating that any CT system is effective for screening (i.e., examining individuals without symptoms) for any disease or condition.”⁴ What is known, however, is that accumulated radiation dosage from CT scans increase the risk of cancer. Medical researchers, as well as FDA physicians and scientists⁵, have concluded that this risk of harmful radiation may not outweigh the clinical benefit for asymptomatic patients receiving routine screenings when there is an alternate method of screening available. This position is consistent with ACG’s long-held view on virtual colonoscopy. The College maintains that colonoscopy is the gold standard in colorectal cancer screenings for eligible patients. CT colonography has a place in CRC prevention, however, regulators and clinicians must be cognizant of the fact that these technologies, depending upon how they are used, may not increase the clinical benefit for certain patients and have shown to potentially do more harm than good. For screening tests that are supposed to detect or prevent cancer, it is troubling that the repeated virtual colonoscopy screening can actually increase the risk of developing cancer.

Harmful effects of radiation during routine screening procedures should be avoided. (Johnson, Heft, and Rex, CT and radiation-related cancer risk- time for a paradigm shift?, *Nat. Rev Gastroenterol. Hepatol.* 6, 738-740 [2009]) As Johnson et al discussed, the FDA lists radiation derived from radiological sources as a known carcinogen, yet the U.S. Government has not established guidelines for acceptable indications and radiation doses for CT scans.

Conservative estimates are that more than 60 million CT examinations were done in 2002 in the U.S., representing an estimated 70% of all medical X-ray exposure. (OW Linton and FA Mettler Jr, National conference on dose reduction in CT, with an emphasis on pediatric patients, *AJR Am J Roentgenol* 181 (2003), pp. 321–329) Although it is a challenge to define precise risk estimates related to low doses of radiation exposure, the ionizing radiation exposure from a single abdominal or chest CT may be associated with elevated risk for DNA damage and cancer formation. (M Lobrich, N Rief and M Kuhne et al., In vivo formation and repair of DNA double-strand breaks after computed tomography examinations, *Proc Natl Acad Sci USA* 102 (2005), pp. 8984–8989) The seventh National Academy of Science report on Biological Effects of Ionizing Radiation (BEIR) is the most recent update from a respected organization. (Committee to Assess the Health Risks from Exposure to Low Levels of Ionizing Radiation, BEIR VII: health risks from exposure to low levels of ionizing radiation (<http://www.nap.edu/reportbrief/11340/11340rb.pdf>.) BEIR VII indicated that a single population dose of 10 mSv is associated with a lifetime attributable risk for developing a solid cancer or leukemia of 1 in 1000. The overall risk for developing a solid cancer or leukemia from all causes would be 42 in 100.

The radiosensitive tissues are predominantly within the field of view of common chest, abdominal, and pelvic CT scans as the typical abdominal examination dose is between 10 and 20 mSv. Unfortunately, many patients are exposed to multiple examinations that increase cumulative dosing. A recent report focused on the effects of multiple exposures to ionizing radiation during CT. Katz, et al found that a subset of patients with renal colic commonly had total exposure rates between 19.5 and 153.7 mSv. (SI Katz, S Saluja, JA Brink and HP Forman, Radiation dose associated with unenhanced CT for suspected renal colic: impact of repetitive studies, *AJR Am J Roentgenol* 186 (2006), pp. 1120–1124.) Radiation effects may not manifest until 5–20 years after the scan, and causal relations are unapparent on an individual basis.

Medical diagnostic procedures are the largest man-made source of radiation exposure to the population, contributing some 14% of the total annual exposure from all sources. Ionizing radiation from diagnostic procedures has been postulated to cause several hundred cases of cancer per year in the United Kingdom. In the U.S., adjusting for the prevalence of CT use, it is estimated that 1.5%-2.0% of all cancers at present are attributable to radiation exposure from CT scanning. (de Gonzales AB, Darby S. Risk of cancer from diagnostic x-rays: estimates for the UK and 14 other countries, *Lancet* 363 (2004), pp. 345–351)

Due to the cumulative nature of radiation exposure risk during a patient's lifetime, and the number of physicians a patient sees in his or her lifetime, it is reasonable to assume that many health professionals underestimate the potential hazard of ionizing radiation in common diagnostic procedures. There are also important implications of obesity on dosimetry requirements for these exams. Obesity (60 million US; 30% of population) increases the dosimetry for accurate CT imaging, approximately by a factor of two. Hence the impact of repeated higher dose exposures for these patients over time may be of even greater importance in a patient group that already has a higher associated risk for many intra-abdominal and colorectal cancers.

Various organizations and entities such as the International Atomic Energy Agency, the World Health Organization, the European Commission, and the International Commission on Radiological Protection (ICRP), are providing guidance and recommendations on radiation protection matters covering the whole range of applications of ionizing radiation. Most recommendations, including the ICRP recommendations, are based on reviews of updated knowledge on effects of radiation, concluding that stochastic effects may occur at even the lowest doses and that the relation between radiation dose and risk of unwanted effects is linear. (United Nations Scientific Committee on the Effects of Atomic Radiation, Sources and effects of ionizing radiation, United Nations, New York (2000)) Clinicians, as patient advocates, are obliged to understand and explain the risks associated with CT radiation, and to provide state-of-the-art dose-reduction techniques.

Information disclosed during the recent public hearings hosted by the Agency suggests the FDA ignored repeated warnings over the risks of radiation exposure during routine screenings.⁶ FDA physicians and scientists raised serious safety and effectiveness concerns at various times in 2009 concerning asymptomatic patients and radiation from CT devices. These recommendations were based on not only on the FDA-gastroenterologist's review of the current medical literature but also that of the FDA's expert radiologist. What's more troubling are the allegations of the FDA suppressing its own physician and scientists' scientific recommendations on this issue.⁷

PATIENT IMAGING SERVICES HISTORY

The hearing evoked various recommendations to reduce patient exposure to unnecessary radiation. The College would like to take this opportunity to support the suggestion that a patient's medical record include a history of x-ray procedures such as CT and fluoroscopy. A tracking system or log of imaging history will assist providers in selecting the best course of action when treating patients. It could also provide a central database to keep track of the various settings in which the imaging services took place. Data show that over a 2 year period roughly 70% of adults (age 18-64) in the U.S. undergo at least one imaging procedure associated with ionizing radiation exposure, with CT scans accounting for roughly 50% of these services. (Johnson, Heft, and Rex. Nat. Rev Gastroenterol. Hepatol. 6, 738-740 [2009]) Many patients over age 50 are exposed to multiple examinations and screenings in 5-10 year intervals, leading to cumulative radiation exposure 5-6 times that of a single CT scan. (Johnson, Heft, and Rex. Nat. Rev Gastroenterol. Hepatol. 6, 738-740 [2009]) As radiation exposure is cumulative, Johnson et al note, history of radiation use should be considered for all patients to maximize benefit and long-term health outcomes. While more studies need to be conducted to better quantify the dosage level of radiation one should avoid, it is well established that accumulated radiation exposure via imaging services increases the risk of cancer.^{8 9 10} It is important to monitor just how many imaging procedures a patient has over his/her lifetime as well as the specific level of dosage they are exposed to. This history will not only reduce exposure unnecessary radiation it will also provide medical researchers and scientists the data to study and better determine the range of radiation a patient should avoid.

In furtherance of this goal, the College also supports incorporating in any health information technology (IT) software and in any measure on "meaningful use" of health IT as the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONCHIT) begins to publish regulations to promote electronic health records.

The College appreciates this opportunity to provide comment and welcomes any opportunity to further discuss this major public health issue with the FDA. Please contact us or Brad Conway, Vice President, Public Policy at 301.263.9000 or bconway@acg.gi.org.

Sincerely,



Philip O. Katz, M.D., FACP
President
American College of Gastroenterology



Costas H. Kefalas, M.D., FACP
Chair, FDA Committee
American College of Gastroenterology

1. Centers for Medicare and Medicaid Services. Decision memo for screening computed tomography colonography (CTC) for colorectal cancer (CAG-00396N) (<https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=220>).
2. U.S. Preventive Services Task Force Recommendation on Colorectal Cancer Screening: (<http://www.ahrq.gov/clinic/uspstf/uspscolo.htm>)
3. Robert C. Smith, M.D., J.D., “*Reducing Unnecessary Radiation Exposure from CT Devices*,” FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
4. Robert C. Smith, FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
5. Robert C. Smith, FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010; Julian J. Nicholas, M.D., PhD, MRCP, “*Device Improvements: Reducing Unnecessary Radiation Exposure from CT Imaging: FDA’s Responsibility to the Public*,” FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
6. Julian J. Nicholas, FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
7. Julian J. Nicholas, FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
8. Robert C. Smith, FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
9. Julian J. Nicholas, FDA Public Hearing: Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging. March 30, 2010.
10. Johnson, Heft, and Rex, CT and radiation-related cancer risk- time for a paradigm shift?, *Nat. Rev Gastroenterol. Hepatol.* 6, 738-740 (2009).