New Guidance on ^{131}I Patient Release

The Nuclear Regulatory Commission (NRC) on February 14 announced that it had advised medical licensees who conduct outpatient ^{131}I treatment of thyroid patients that "recommending patients stay at hotels immediately after treatment is strongly discouraged." NRC also reminded doctors of their "responsibilities to consider a patient's intended destination and provide instructions on how to limit potential radiation exposures to the public following treatment."

In a related press release, the NRC indicated it was responding to continuing concerns that thyroid patients, who typically remain radioactive for a few days after administration of ^{131}I, sometimes check into hotels/motels instead of going home, raising the potential that other people (especially hotel workers and guests) may unknowingly be exposed to radiation. "The administration of radioactive iodine provides essential medical therapy to thousands of seriously ill patients, and outpatient procedures can increase access to this treatment without significant health or safety risk to the public," said Robert J. Lewis, director of the NRC Division of Materials Safety and State Agreements. "However, it is the NRC's goal to limit unnecessary radiation exposure to anyone to the greatest degree possible, and it is the doctor's responsibility to carefully evaluate patient release to other locations and communicate to the patient additional radiation safety precautions that may be appropriate for such locations."

NRC regulations allow patients to be released after ^{131}I treatment when the radiation dose to third parties is not likely to exceed 500 millirems. The regulations assume the dose would apply principally to the patient's family or other caregivers during the first few days at home after treatment. Doctors are thus required to consider the patient's living conditions and provide instructions for avoiding unnecessary exposure to others. NRC also reminded doctors to inquire about the patient's intended destination after treatment so that appropriate instructions may be given on how to manage exposure to others. If a patient is adamant about not being hospitalized or not going to a private residence and plans to go to an alternative location, such as a hotel, doctors must still provide adequate instructions on how the patient can keep radiation doses to others as low as possible.

The guidance is available on the NRC Web site at

www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2011/index.html.

Nuclear Regulatory Commission

Imaging Demonstration Participants Announced

The Centers for Medicare & Medicaid Services (CMS) announced on February 2 the selection of 5 participants in the Medicare Imaging Demonstration (MID), a project intended to "promote appropriate utilization of advanced imaging services." CMS solicited proposals from interested parties (referred to as conveners) who would recruit physician practices for participation in the demonstration. The conveners selected were the Brigham & Women's Hospital (Boston, MA), Henry Ford Health System (Detroit, MI), Maine Medical Center–Physician Hospital Organization (Portland), University of Wisconsin–Madison, and National Imaging Associates (Avon, CT). "The demonstration provides CMS an opportunity to work closely with individual conveners and physician practices in testing whether the use of decision support systems can improve quality of care by diminishing patient exposure to potentially harmful radiation caused by unnecessary overutilization of advanced imaging services," said CMS Administrator Donald Berwick, MD.

The 2-y demonstration will assess the impact that decision support systems used by physician practices have on the appropriateness and utilization of advanced medical imaging services ordered for beneficiaries in original fee-for-service Medicare. The demonstration focuses on MR imaging, CT, and SPECT. Eleven advanced imaging procedures—SPECT myocardial perfusion, MR lumbar spine, CT lumbar spine, MR brain, CT brain, CT sinus, CT thorax, CT abdomen, CT pelvis, MR knee, and MR shoulder—are included in the demonstration. The 11 tests were selected based on high spending and utilization in the beneficiary population covered by original Medicare and the availability of relevant medical specialty appropriateness guidelines developed or endorsed by medical specialty societies. The decision support systems provide immediate feedback to the physician about the appropriateness of the test ordered for the patient. Approaches that would require prior authorization are specifically excluded. The demonstration will have no impact on current Medicare coverage or payment policies, and demonstration participants will be paid for data. Additional information is available at: www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1222075.

Centers for Medicare & Medicaid Services

FDA Clears Mobile Dx Imaging App

A new mobile radiology application approved on February 4 by the U.S. Food and Drug Administration (FDA) will allow physicians to view medical images on the iPhone and iPad manufactured by Apple Inc. (Cupertino, CA). The application is the first cleared by the FDA for viewing images and making medical diagnoses based on CT, MR, and nuclear medicine technology, such as PET. According to an FDA press release,

the application "is not intended to replace full workstations and is indicated for use only when there is no access to a workstation." "This important mobile technology provides physicians with the ability to immediately view images and make diagnoses without having to be back at the workstation or wait for film," said William Maisel, MD, MPH, chief scientist and deputy director for science in the FDA Center for Devices and Radiological Health.

Images are compressed for secure network transfer then sent to the appropriate portable wireless device via software called Mobile MIM (MIM Software Inc., Cleveland, OH), which allows the physician to measure distance on the image and image intensity values and to display measurement lines, annotations, and regions of interest.

In its evaluation, the FDA reviewed performance test results on various portable devices, assessing luminance, image quality (resolution), and noise against international standards and guidelines. The FDA also reviewed results from demonstration studies with qualified radiologists under different lighting conditions. All participants agreed that the device was sufficient for diagnostic image interpretation under the recommended lighting conditions. The display performance of mobile devices can experience significant variations in luminance levels even between devices of the same model. The Mobile MIM application includes sufficient labeling and safety features to mitigate the risk of poor image display resulting from improper screen luminance or lighting conditions. The device includes an interactive contrast test in which a small part of the screen is a slightly different shade from the rest of the screen. If the physician can identify and tap this portion of the screen, then the lighting conditions are not interfering with the physician's ability to discern subtle differences in contrast. In addition, a safety guide is included within the application.

U.S. Food and Drug Administration

CMS Corrects NCCI Errors

On February 18 SNM released a statement indicating that a number of members had reported sudden rejections of Medicare claims for nuclear medicine therapy and diagnostic procedures with dates of service beginning January 1, 2011. On February 17, Centers for Medicare & Medicaid Services (CMS) officials confirmed that the recent National Correct Coding Initiative (NCCI) edit file version 17.0, submitted to Medicare administrative contractors and carriers, was incorrect for 40 code pair change errors (89 nuclear code pair edits were correct). The contractor that manages these files was quick in assuring SNM that this error would be rectified with the next implementation of the NCCI edit version 17.1 on April 1. SNM recommended that providers defer submitting certain code pair claims until that time and resubmit, reopen, or appeal any previously denied claims after April 1. Medicare contractors would not be able to make any corrections prior to April 1. An update and tables listing both the incorrect and correct code pair edits are available at: www.snm.org/index.cfm?PageID=10415.

SNM

Sodium Fluoride-^{18}F Approved for Bone Scans

The U.S. Food and Drug Administration (FDA) on February 3 announced the approval of a New Drug Application from the National Cancer Institute (NCI) for a new strength of a previously approved drug, sodium fluoride-^{18}F, for use in bone scans. In contrast to ^{99m}Tc, which has been the only approved radioactive tracer for bone scans, sodium fluoride-^{18}F is not subject to the supply problems that have led to recent nationwide shortages of ^{99m}Tc.

Sodium fluoride-^{18}F was approved in 1972 but withdrawn in 1975, when the less-expensive ^{99m}Tc became available. Although sodium fluoride-^{18}F is more expensive than ^{99m}Tc, it can be produced in medical cyclotrons available at many academic universities and through commercial suppliers in the United States. The associated NCI press release also noted that the "drug also provides better images because it uses PET instead of SPECT imaging, allowing for improved, earlier detection."

The previous strength of sodium fluoride-^{18}F was discontinued for market reasons, not for reasons of safety or efficacy. NCI indicted its expectation that multiple companies and institutions will submit abbreviated new drug applications so that generic versions of the drug can be produced, allowing for a reduction in cost. A decision by the Centers for Medicare & Medicaid Services regarding coverage for sodium fluoride PET scans was posted on February 26, 2010, and allowed coverage with evidence development. A formal registry is being established by the National Oncologic PET Registry to help facilitate this coverage.

National Cancer Institute

NRC Announces External Blog

On January 31, the Nuclear Regulatory Commission (NRC) announced the launch of its first-ever external blog through the third-party site WordPress. The blog features posts from staff members throughout the agency writing about various topics of interest to the public, as well as moderated public comments. "We are excited about using this new communications tool and hope it will increase our collaboration and interaction with the public," said NRC Chair Gregory Jaczko, PhD. "The blog is intended to build upon our extensive efforts to explain and clarify the actions, roles, and responsibilities of the NRC, raise awareness about our agency and its mission, and... give us an opportunity to hear from the public." The blog can be reached directly at http://public-blog.nrc-gateway.gov or by clicking on the blog icon on the NRC Web site at www.nrc.gov. The new blog does not replace formal communications, such as *Federal Register* notices or

meeting notices, and will not accept allegations or comments on rulemakings. Complete comment guidelines are available on the blog.

Nuclear Regulatory Commission

Health Care Quality Improving, Gaps Persist

Improvements in health care quality continue to progress at a slow rate (about 2.3%/y), but disparities based on race and ethnicity, socioeconomic status, and other factors persist at unacceptably high levels, according to the 2010 *National Healthcare Quality Report* and *National Healthcare Disparities Report* issued on February 28 by the Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ). The reports, which are mandated by Congress, show trends using data based on more than 200 health care measures categorized in several areas of quality: effectiveness, patient safety, timeliness, patient centeredness, care coordination, efficiency, health system infrastructure, and access.

Gains in health care quality were seen in a number of areas, with the highest rates of improvement in measures related to treatment of acute illnesses or injuries. For example, the proportion of heart attack patients who underwent procedures to unblock heart arteries within 90 min improved from 42% in 2005 to 81% in 2008. Other very modest gains were seen in rates of screening for preventive services and child and adult immunization. Measures of lifestyle modifications, such as preventing or reducing obesity, smoking cessation, and substance abuse, saw no improvement.

The reports indicated that few disparities in quality of care are being reduced, and almost no disparities in access to care are getting smaller. Overall, blacks, American Indians, and Alaska Natives received worse care than whites for about 40% of core measures. Asians received worse care than whites for about 20% of core measures, and Hispanics received worse care than whites for about 60% of core measures. Poor people received worse care than high-income individuals for about 80% of core measures. On average, Americans report barriers to care one-fifth of the time, ranging from 3% of people saying they were unable to secure or had to delay obtaining prescription medications to 60% of people saying their usual providers did not have office hours on weekends or nights.

The quality and disparities reports are available online at www.ahrq.gov/qual/qrdr10.htm.

Agency for Healthcare Research and Quality

Manufacturers and New Imaging Technologies

In the February issue of the *Journal of the American College of Radiology* (2011;8:124–131), authors from GE, Siemens, and Philips Healthcare offered an outline that imaging manufacturers could use in weighing the benefits of new medical imaging technologies and dealing with the increasingly complex regulatory and reimbursement environment. In "Evidence Requirements for Innovative Imaging Devices: From Concept to Adoption," Frank et al. identified 5 phases of an imaging procedure's lifecycle and described distinct clinical evidence needs for: design, regulatory clearance and approval, early adoption, reimbursement, and full clinical adoption.

Journal of the American College of Radiology

FROM THE LITERATURE

Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Most selections come from outside the standard canon of nuclear medicine and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role. We have added a special section on molecular imaging, including both radionuclide-based and other molecular imaging efforts, in recognition of the extraordinary activity and promise of diagnostic and therapeutic progress in this area. The lines between diagnosis and therapy are sometimes blurred, as radiolabels are increasingly used as adjuncts to therapy and/or as active agents in therapeutic regimens, and these shifting lines are reflected in the briefs presented here. We have also added a small section on noteworthy reviews of the literature.

DIAGNOSIS

Cell Phones and Glucose Metabolism

In an article that received substantial media and scientific attention after its publication in the February 23 issue of *The Journal of the American Medical Association* (2011;305:808–813), Volkow and colleagues from the National Institute on Drug Abuse (Bethesda, MD), the National Institute on Alcohol Abuse and Alcoholism (Bethesda, MD), and the Brookhaven National Laboratory (Upton, NY) reported on an experiment using PET to investigate the effect of cell phone use on brain glucose metabolism. The study included 47 healthy participants. Each participant underwent 2 ^{18}F-FDG PET scans on separate days. Before both scans, cell phones were placed on participants' right and left ears. On 1 of the days, both phones were deactivated (off) and worn for 50 min before removal for scanning. On the other day, the right phone was on (activated and receiving a call but muted with no sound emitting) and the left phone was off. For the "on" studies, activation of the right phone was begun 20 min before tracer injection and maintained