Imaging and Radiation in Integrated Health Systems

In the June 13 issue of the *Journal of the American Medical Association* (2012;307:2400–2409), Smith-Bindman from the University of California, San Francisco and colleagues reported on a study estimating trends in diagnostic imaging utilization and associated radiation exposure among members of integrated health care systems over a 15-y study period. The study was based on retrospective analysis of medical records of 6 large integrated health systems in the United States, with between 1 million and 2 million patients enrolled each year from 1996 to 2010. Over the course of the study, enrolled members of these systems underwent a total of 30.9 million imaging examinations or 1.18 tests per person per year. Thirty-five percent of these studies were considered to be advanced imaging (CT, MR, PET or SPECT, and ultrasound), a percentage that increased annually over the study period. CT examinations increased from 52 to 149 per 1,000 enrollees from 1996 to 2010 (7.8% annual increase). MR imaging increased from 17 to 65 per 1,000 enrollees (10% annual growth), and ultrasound rates increased from 134 to 230 per 1,000 enrollees (3.9% annual growth). Nuclear medicine overall decreased from 32 to 21 per 1,000 enrollees (3% annual decline) over the study period, but PET imaging rates increased after 2004 from 0.24 to 3.6 per 1,000 enrollees (a 57% annual growth rate). The authors calculated that increased use of CT between 1996 and 2010 resulted in a doubling in the mean per capita effective radiation dose (from 1.2 to 2.3 mSv) as well as a doubling in the percentage of individuals who received high (>20–50 mSv; from 1.2% to 2.5%) exposure and very high (>50 mSv; from 0.6% to 1.4%) annual radiation exposure. By 2006, 6.8% of enrollees who underwent imaging received high annual radiation exposure and 3.9% received very high annual exposure.

Journal of the American Medical Association

CARE Bill in Senate

The Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act of 2012 bill was introduced in the U.S. Senate on June 26 by Senators Mike Enzi (R-WY) and Tom Harkin (D-IA). The CARE bill, S. 3338, would ensure that basic minimum education and certification standards are established as part of the Medicare program for all medical imaging and radiation therapy personnel. Basic educational standards for medical imaging and radiation therapy professionals currently are voluntary and vary among many states, allowing some individuals to perform radiologic procedures with little or no formal education. Six states, along with Washington, DC, have no regulations relating to qualifications of personnel performing medical imaging exams. The bill would require practitioners to meet education and certification standards determined by certification organizations designated by the Department of Health and Human Services and obtain state licensure where required. In June 2011, the House CARE bill, H.R. 2104, was introduced by Representative Ed Whitfield (R-KY) and now has more than 125 bipartisan cosponsors, including SNMMI and SNMMITS.

"Ensuring that the personnel who perform medical imaging or radiation therapy procedures have the proper training is critical to patient safety and avoiding the misdiagnoses and treatment delays that can result from poor quality images," said Senator Harkin. "The CARE Act is commonsense legislation that will protect patients, ensure quality care, and reduce the millions of dollars in medical costs each year caused by needless repeat examinations."

U.S. Senate

SNM Position Statement on Dose Optimization

On June 18 SNM (now SNMMI) issued a position statement on dose optimization for nuclear medicine and molecular imaging procedures. In part, the statement said that SNM and SNMTS "recognize that the use of low levels of radiation in [nuclear medicine] procedures entails some possible risk. Radiation dose for all nuclear medicine and molecular imaging procedures should be optimized so that the patient receives the smallest possible amount of radiopharmaceutical that will provide the appropriate diagnostic information. SNM and SNMTS also recognize that if an appropriate procedure—one that can provide the physician with clinical information essential to the patient's treatment—is *not* performed when necessary due to fear of radiation, it can be detrimental to the patient. The SNM and SNMTS believe that the right test with the right dose should be given to the right patient at the right time. When nuclear medicine and molecular imaging procedures are performed correctly on appropriate patients, the benefits of the procedure very far outweigh the potential risks. The procedure that provides the most useful clinical information is the one that should be performed. To ensure the appropriate use of these procedures, all nuclear medicine facilities should have comprehensive quality control measures in place, their nuclear medicine physicians should have up-to-date training, and their technologists should be appropriately trained and certified. SNM and SNMTS and their members continually strive to improve quality and standards to ensure patients receive the best, safest, and most appropriate care."

SNMMI

Discovering New Uses for Existing Molecules

On June 12 the National Institutes of Health (NIH) announced that 5 additional pharmaceutical companies had joined an effort to help scientists

research promising new treatments for patients. Funding and molecular compound information is available now for the initial phase of the recently launched Discovering New Therapeutic Uses for Existing Molecules program. This NIH/industry collaboration will match researchers with 58 compounds to test ideas for new therapeutic uses. Since the start of the program in May the total number of compounds the companies are making available has more than doubled. Abbott, Bristol–Myers Squibb Company, GlaxoSmithKline, Janssen Pharmaceutical Research & Development, and Sanofi have joined Pfizer, AstraZeneca, and Eli Lilly and Company in this innovative approach to research.

The NIH's new National Center for Advancing Translational Sciences (NCATS) created the Therapeutics Discovery program to help re-engineer the research pipeline. By crowdsourcing compounds that already have cleared several key steps in the development process, including safety testing in humans, scientists nationwide have the opportunity to contribute their expertise to advancing these resources for new disease therapies. The 8 participating companies will provide their compounds and related data, which were determined by the NIH to meet specific eligibility criteria. For example, each compound must have advanced to clinical studies but been unsuccessful in its original therapeutic indication or not pursued for business reasons. Preliminary information about the compounds, including mechanism of action, route of administration, and any limitations in use based on safety and tolerability, are available at http://ncats.nih.gov/therapeutics-directory.html.

"Each company participating in this innovative collaboration has made substantial research and development investments to advance these compounds to the point where they can be used in clinical studies," said Kathy L. Hudson, PhD, NCATS acting deputy director. "If researchers funded through this effort can demonstrate new uses for the compounds, they could significantly reduce the amount of time it takes to get a treatment to patients in need." For the pilot phase of the program in fiscal year 2013, NCATS will provide up to $20 million to fund 2- to 3-y staged, cooperative agreement research grants. If specific milestones are met, funded researchers will conduct preclinical validation and clinical feasibility studies in the first stage and proof-of-concept clinical trials in the second stage, to test whether one of the compounds may be effective against a previously unexplored disease target. The pilot phase also is intended to test the utility of the newly created template agreements by reducing the negotiation time that otherwise could delay the research.

Researchers interested in the NCATS Therapeutics Discovery funding must submit a preapplication in response to the NIH Funding Opportunity Announcement at http://grants.nih.gov/grants/guide/pa-files/PAR-12-203.html by August 14. For more information, visit ncats.nih.gov/therapeutics.html.

National Institutes of Health

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. 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.

PET/CT and Melanoma Treatment

Beasley and colleagues from Duke University (Durham, NC) and the Moffitt Cancer Center (Tampa, FL) reported on June 11 ahead of print in *Annals of Surgery* on the clinical utility of ^{18}F-FDG PET/CT in evaluating response to treatment or to monitor after treatment in patients with stages IIIB/IIIC extremity melanoma. The prospective study included 97 such patients undergoing isolated limb infusion who underwent whole-body PET/CT before and every 3 mo after treatment. Response Evaluation Criteria in Solid Tumors were used to determine clinical response at 3 mo. Thirty-two patients (33%) had complete responses on histology at 3 mo after therapy. PET/CT correctly identified 59% (19) of these but found residual metabolic activity in the extremity in the remaining 41% (13). For patients who were classified as complete responders by both PET/CT and histology, the 3-y disease-free rate was 62.2%, whereas this percentage was only 29.4% for those histologic complete responders who had been found to have residual metabolic activity on PET/CT. When used for surveillance of recurrence outside the field of treatment, PET/CT correctly identified the 52% (51 patients) of all participants who developed distant disease, at a median time of 212 d after pretreatment imaging, leading to early resection in almost half of such patients. The authors noted that although PET/CT is not accurate in identifying all patients who have histologic complete responses after isolated limb infusion, it appears to "identify a subgroup of patients whose regional progression-free survival is markedly worse." In addition, they concluded that "PET/CT appears to be an excellent method for surveillance in stage IIIB/IIIC patients after isolated limb infustion with ability to identify surgically re-