CT Cited as Among Top 10 Health Hazards

The ECRI Institute (Plymouth Meeting, PA) announced on November 8 its list of "Top 10 Health Technology Hazards for 2012." Dangers from clinical alarms, radiation exposure, and medication errors topped the list as published in the institute's *Health Devices* journal and available for download at www.ecri.org/2012_Top_10_Hazards. Now in its fifth year of publication, the annual hazard list is intended to "raise awareness of the potential dangers associated with the use of medical devices and systems" and includes recommendations on addressing these risks.

Number 2 on the list was "exposure hazards from radiation therapy and CT." Although the report stated that diagnostic imaging produces much lower radiation levels than radiation oncology procedures, the consumer was warned about "inappropriate use" and "inappropriate dose levels" with CT that could lead to unnecessary radiation exposure and potential cancers. Among the more familiar recommendations (such as maintaining ALARA practices) to address this and other potentials for radiation overexposure, ECRI pointed to the need to record and audit individual radiation doses.

The remaining hazards in the top 10 list included malfunctioning or misleading alarms, medication administration errors using infusion pumps, cross-contamination from flexible endoscopes, inattention to change management for medical device connectivity, enteral feeding misconnections, surgical fires, needlesticks and other sharps injuries, anesthesia hazards resulting from incomplete preprocedure inspection, and poor usability of home medical devices. Criteria for inclusion on the list included evidence that each hazard has resulted in injury or death, has occurred frequently, affects a large number of individuals, and has had a high profile or widespread news coverage.

ECRI Institute

Zevalin Scanning Requirement Changed

Spectrum Pharmaceuticals Inc. (Irvine, CA) announced on November 21 that U.S. Food and Drug Administration (FDA) regulators had altered the approval of its lymphoma drug, Zevalin, removing a requirement that patients undergo a ^{111}In-ibritumomab tiuxetan imaging dose followed by a gamma scan for biodistribution evaluation before the therapeutic dose. Prior to removal of the biodistribution scan, patients typically received an infusion of rituximab on d 1, followed by a diagnostic dose of ^{111}In-ibritumomab tiuxetan and a full-body scan at a nuclear imaging center within 10 min and again on d 3 or 4. Patients would then receive another infusion of rituximab and a 10-min injection of the therapeutic dose of Zevalin on d 7, 8, or 9. With the bioscan requirement removed, patients will receive the 2 infusions of rituximab followed by a 10-min injection of Zevalin. Spectrum will now refer to this simplified regimen as "RRZ"—rituximab, rituximab, Zevalin."

Zevalin, a CD20-directed radiotherapeutic antibody, is indicated for the treatment of B-cell non-Hodgkin lymphoma (NHL; relapsed or refractory, low-grade or follicular) and previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy. Zevalin was first approved in February 2002 for the treatment of follicular NHL patients in whom disease had recurred or progressed after other systemic therapies. "Despite Zevalin's excellent therapeutic profile, as recognized by inclusion in the NCCN guidelines for appropriate patients with follicular lymphoma, there has been a limited penetration of the potential market. With this approval, we believe that physicians, patients, and payers will find Zevalin to be an exceedingly more attractive treatment option," said Rajesh C. Shrotriya, MD, chair, chief executive officer, and president of Spectrum Pharmaceuticals. "Removal of the bioscan is an important step toward our fulfilling these objectives."

Spectrum Pharmaceuticals

Redefining "Oldest" Americans

A report from the U.S. Census Bureau commissioned by the National Institute on Aging (NIA) reported that by 2050 the ranks of individuals aged ≥90 y will be almost 5-fold larger than today. In 1980, there were 720,000 people aged 90 y and older in the United States. In 2010, 1.9 million people in the United States were aged 90 y and older. By 2050, these ranks may reach 9 million or more. The report, released on November 17, described this rapidly growing segment of the population and suggested that the designation of "oldest-old" should be changed from 85 to 90 y. The report, *90+ in the United States: 2006–2008*, detailed the demographic, health, and economic status of America's oldest adults. "With the aging boom it is critical to develop demographic data providing as detailed a picture as possible of our oldest population," said NIA Director Richard J. Hodes, MD. "The information on a variety of factors—income, health status, disabilities, and living arrangements—will be particularly useful to researchers, planners, and policymakers."

Based on the American Community Survey, the 27-page report described in detail this rapidly growing population and stated that a majority of the 90-plus population are widowed white women who live alone or in a nursing home. Most of them are high school graduates. Social Security provides almost half of their personal

income, and almost all have health insurance coverage through Medicare and/or Medicaid. The vast majority report having 1 or more types of disability. Among other report findings were: (1) An average person who has lived to 90 y has a life expectancy today of 4.6 y more (versus 3.2 y in 1929–1931), whereas those who pass 100 y are projected to live another 2.3 y; (2) the majority (84.7%) of those ≥90 y reported having 1 or more limitations in physical function, with 66% having difficulty in mobility-related activities such as walking or climbing stairs; (3) About 1 % of the "young elderly" (65–69 y) live in nursing homes, with correlating percentages rising to 3% for those 75–79 y old, 11.2% for ages 85–89 y, 19.8% at ages 90–94 y, 31.0% at ages 95–99 y, and up to 38.2% among centenarians; (4) Women ≥90 y outnumber male counterparts nearly 3 to 1; (5) Whites represent 88.1% of the total ≥90-y population, with African Americans at 7.6%, Hispanics at 4%, and Asians at 2.2%; and (5) The annual median income for individuals ≥90 y is $14,760.

"Previous seminal work on demography designated age 85 as the cutoff for what we termed the oldest-old," said Richard Suzman, PhD, director of NIA's Division of Behavioral and Social Research, which supported the report. "With a rapidly growing percentage of the older population projected to be 90 and above in 2050, this report provides data for the consideration of moving that yardstick up to 90. Can 90 be the new 85?" Copies of the report are available at www.census.gov/prod/2011pubs/acs-17.pdf.

National Institute on Aging

SNM Patient Web Site

SNM announced on October 24 the launch of a new patient-focused Web site, discoverMI.org, to provide patients with information about nuclear medicine and molecular imaging and the ways in which these can play a critical role in the detection, treatment, and management of diseases. "Many times patients referred for nuclear medicine or molecular imaging studies are nervous about what to expect," said George Segall, MD, SNM president. "By providing information and explaining the benefits of the study in an easy-to-understand format, we can offer them both help and support."

The Web site focuses on 3 common disease areas—heart disease, cancer, and brain disease. For each area, specific types of disease are detailed along with the various nuclear and molecular imaging procedures associated with each. General information on molecular imaging, an extensive glossary, and a video library are also included on the site. In addition, patients can stay up to date on the latest in molecular imaging news through Facebook and Twitter pages designed to complement the site.

DiscoverMI.org is supported by several patient advocacy groups that are part of SNM's Patient Advocacy Advisory Board (PAAB), including the Alzheimer's Association, American Thyroid Association, Leukemia and Lymphoma Society, Ovarian Cancer Alliance of Arizona, Ovarian Cancer National Alliance, American Heart Association, Men's Health Network, and Thyroid Cancer Survivors' Association.

"I am thrilled that this comprehensive resource for patients is now available," said Betsy de Parry, a member of SNM's PAAB and author of *Adventures in Cancer Land*. Laurel Pracht, SNM PAAB member and patient advocate for the Ovarian Cancer National Alliance added, "As a patient, it is critical to have access to user-friendly information about what is available for someone with your disease. The Web site provides information about both what is currently available in molecular imaging and how it may affect you."

SNM

FDA FY 2011 New Drug Approvals

On November 3 the U.S. Food and Drug Administration (FDA) released a statement providing an overview of the 35 new medicines approved by the agency in the past 12 mo. This was among the highest number of approvals in the past decade, surpassed only by 2009, when 37 new drugs were approved. The most recent approvals include, among others, 2 new treatments for hepatitis C, a drug for late-stage prostate cancer, what the FDA termed "the first new drug for Hodgkin lymphoma in 30 y", and the first new drug for lupus in 50 y. In a summary report, *FY 2011 Innovative Drug Approvals*, the FDA provided details of success with expedited approval authorities, flexibility in clinical trial requirements, and resources collected under the Prescription Drug User Fee Act (PDUFA) to boost the number of innovative drug approvals during fiscal year 2011. The report also detailed faster approval times in the United States than in many of the agency's counterparts around the world. Twenty-four of the 35 new approvals occurred in the United States before any other country and also before the European Union.

"Thirty-five major drug approvals in 1 y represents a very strong performance, both by industry and by the FDA, and we continue to use every resource possible to get new treatments to patients," said Margaret Hamburg, MD, Commissioner of Food and Drugs. "We are committed to working with industry to promote the science and innovation it takes to produce breakthrough treatments and to ensure that our nation is fully equipped to address the public health challenges of the 21st century."

Facts singled out by the FDA as noteworthy were: (1) Two drugs—one for melanoma and one for lung cancer—are "breakthroughs in personalized medicine," each with a genetic test that helps identify patients for whom the drug is most likely to bring benefits; (2) Seven drugs provide major advances in cancer treatment; (3) Almost half the drugs were judged to be significant therapeutic advances over existing therapies for heart attack, stroke, and/or kidney transplant rejection; (4) Ten of the drugs are for rare

or "orphan" diseases, such as a treatment for hereditary angioedema; (5) Almost half were approved under "priority review," in which the FDA has a 6-mo goal to complete safety and effectiveness reviews; (6) Two-thirds of the new approvals were completed in a single review cycle; (7) Three were approved using "accelerated approval"; and (8) All except 1 were approved on or before the review time targets agreed to with industry under PDUFA.

In October 2011, the FDA released a new plan, Driving Biomedical Innovation: Initiatives to Improve Products for Patients, to assist companies engaged in new product development, particularly smaller, entrepreneurial companies. In a separate action, the agency also released a report in early November on drug shortages, expanded its current actions to address the problem, and broadened early notification of drug shortages. The new drug approval report can be accessed at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm276385.htm.

U.S. Food and Drug Administration

FDA and Investigational Devices

The U.S. Food and Drug Administration (FDA) on November 10 issued a draft guidance aimed at fostering early-stage development of medical devices within the United States. The guidance document contains new approaches toward early feasibility studies, which are conducted in a small number of patients early in device development, while providing appropriate human subject protections. Such studies are necessary to resolve final design issues before the device is ready for large clinical trials typically required for product approval. FDA is seeking a small number of companies to pilot the new approaches in the guidance. The results of the pilot will help to inform the final guidance.

On the same day, FDA issued guidance regarding clinical trials and medical devices. It described the FDA's process for approving applications from companies that want to conduct clinical trials involving medical devices. "Approaches to regulation that facilitate early clinical experience with investigational medical devices can result in safe and effective devices that reach patients sooner and create incentives to innovate in the United States," said Jeffrey Shuren, MD, director of the FDA Center for Devices and Radiological Health. "Today's guidance documents give sponsors and FDA device reviewers more flexibility to start investigational studies sooner while maintaining appropriate human subject protections, and they propose efficient ways to support product or study design changes once the study begins."

Before investigators can proceed with a clinical study involving a medical device that poses significant risks to human subjects, the FDA must approve an Investigational Device Exemption (IDE). IDE approval allows a medical device to be studied on subjects who consent to being part of the investigation. The draft guidance "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations" clarifies the FDA's process for approving clinical trials of medical devices and includes information on: (1) when the FDA might allow patients to enroll in a study while issues are resolved, an approach called "approval with conditions"; and (2) when the FDA might allow studies to begin with a smaller group of subjects while companies gather additional data, prior to the larger general enrollment, an approach called "staged approval."

The draft guidance "Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, including First in Human Studies" applies to medical devices in the early stages of development to better inform the final design of the device. It would allow studies to start earlier in the device development process than previously allowed and would permit select device modifications to be made without FDA approval.

Participation in the pilot will be limited to 9 sponsors. To qualify they should focus on innovative, early-stage development technologies that are most likely to benefit from the efficiencies of the program. Enrollment began on December 12 and will continue until early February or until a final guidance is published, whichever occurs first. For more information see: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/Default.htm.

U.S. Food and Drug Administration

Gamma Camera Market to Grow

Global Industry Analysts, Inc. (San Jose, CA), a publisher of off-the-shelf market research, announced on November 18 the publication of a report on the gamma/scintillation camera market, predicting that worldwide sales will top $842.6 million U.S. by 2017. According to the report, market growth will be significantly influenced by aging populations, increasing scientific understanding of and effective therapeutics for cardiac and neurologic disorders as well as all types of cancer, and consumer awareness of advanced medical technologies. The United State remains the world's largest market, with Europe second and the Asia–Pacific sector emerging as the fastest growing region. Economic resurgence, improving health care scenarios, and rising personal disposable incomes are presenting opportunities for medical technology companies to capitalize in emerging and underpenetrated markets.

The market study, titled *Gamma/Scintillation Cameras: A Global Strategic Business Report*, provides a review of trends, issues, strategic industry activities, and profiles of major companies worldwide. Key product segments analyzed include gamma cameras, collimators, gantries, nuclear medicine patient tables, computerized video display consoles, and computer workstations. The proprietary report is available for purchase at: www.strategyr.com/Gamma_Scintillation_Cameras_Market_Report.asp.

Global Industry Analysts, Inc.

British Imaging Spending Criticized

On October 12 the United Kingdom House of Commons issued a report outlining multiple concerns

with National Health Service (NHS) oversight of MR, CT, and linear accelerator purchasing and operations. The NHS has spent £50 million ($80.5 million U.S.) on these technologies in the last 3 y but has delegated responsibilities for purchasing and operating them to individual trusts. "We continue to question whether the system provides value for money when foundation trusts act independently with no explicit incentive to adopt best practices nor to work together to achieve economies of scale," the report stated. Currently, NHS has no mechanism to compare imaging system performance, cost, and capacity value across trusts.

The report concluded: "The NHS needs to make high quality, comparable data available on machine use and cost. We welcome the department's plan to require all trusts to produce data on MRI and CT scan use. A standardized, national dataset would help trusts to compare unit costs and benchmark their performance. It would also enable commissioners to identify the large variations in utilization across trusts and take appropriate action." The report included 6 recommendations covering accounting and value documentation, improved data collection, more well-defined purchasing processes, consideration of bulk purchasing, and streamlined supply chains.

Health Imaging

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 articles outside of radionuclide-based procedures, in recognition of the extraordinary activity and promise of diagnostic and therapeutic progress across the spectrum of molecular imaging. 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

SPECT/CT and ^{131}I Therapy

Blum et al. from the New York University Langone Medical Center (NY) reported in the November issue of *Thyroid* (2011;21:1235–1247) on an investigation of ^{131}I SPECT and noncontrast CT to resolve cryptic findings on ^{131}I whole-body scans after thyroidectomy for thyroid cancer. The study included 184 whole-body scans from 38 patients after thyroidectomy. From a group of 184 whole-body scans, the authors identified a total of 49 "cryptic" findings in 40 scans (22%) in thyroidectomized thyroid cancer patients. Each was followed up with ^{131}I SPECT/CT imaging after either a tracer dose of ^{131}I ($n = 15$) or a week after an ablative or therapeutic dose of ^{131}I ($n = 25$). In 35 of these patients the whole-body scans were negative for evidence of metastatic disease, except for the cryptic findings; 5 patients' scans showed evidence of thyroid cancer. SPECT/CT indicated that 10 of the cryptic findings were of thyroid origin. In the 15 patients who received tracer ^{131}I doses, SPECT/CT analysis of the original scans provided significant information for the decision on administering ablative ^{131}I. In the 25 patients in whom SPECT/CT was performed after ablative or therapeutic doses of radioiodine, information from SPECT/CT was useful in identifying the presence of thyroid remnants or metastases. The authors concluded that "by identifying activity in some possible cancer sites as not thyroid cancer, SPECT/CT can reduce inappropriate treatment with ^{131}I" and that SPECT/CT of whole-body scans performed after ablative doses of ^{131}I is "useful in determining the nature of cryptic findings" and therefore likely to provide prognostic information."

Thyroid

Comparing MR and PET in AD

In an article e-published on November 16 ahead of print in *Neurology*, Chen et al. from the University of Pennsylvania (Philadelphia), Northwestern University (Chicago, IL), and AstraZeneca R&D (Sodertalje, Sweden) compared the abilities of arterial spin labeling with MR imaging and those of ^{18}F-FDG PET to differentiate patients with Alzheimer disease (AD) from age-matched controls without dementia. Arterial spin labeling MR imaging assesses cerebral blood flow. The study included 15 patients with AD and 19 controls, each of whom underwent MR imaging followed by PET. Statistical parametric mapping and region of interest analyses, including a voxel-by-voxel comparison, were used to compare the ability to identify patients and controls. Results from the 2 modalities were also compared against neuropsychological test scores. The authors found good agreement between the 2 imaging approaches, including similar hypoperfusion and hypometabolism patterns and overlaps in region of interest analyses. Both MR and PET were successful in differentiating patients from controls, with good correlations with neuropsychological test results. They concluded that these results suggest that arterial spin labeling MR imaging "provides largely overlapping information with FDG PET," with both