CDRH Transparency Site

The U.S. Food and Drug Administration (FDA) launched the Center for Devices and Radiological Health (CDRH) Transparency Web site on April 19 as part of the agency's transparency initiative. The site will provide information about medical device and radiation-emitting product regulatory processes and decisions, as well as summaries of data that provide the rationale for agency actions. The new Web site is part of an ongoing effort within CDRH and across the FDA and Department of Health and Human Services to enhance public communication. CDRH's previous site provided information about approved products, industry guidance, medical device safety, and adverse event reports. On the new Web site, this and additional information is displayed in a more user-friendly format. "The CDRH Transparency Web site gives the public a window into our work," said CDRH Director Jeffrey Shuren, MD. "It provides a closer and clearer look at what we do and why we do it."

The site includes information related to: (1) premarket submissions for approved and cleared products: summaries of FDA's review of the documents and data that companies submit to FDA when requesting clearance or approval to market a new or improved device and the systems used to evaluate these submissions; (2) postmarket performance and safety: documents and data describing how well devices perform after they are on the market and information about how FDA monitors medical device safety; (3) compliance and enforcement: official actions FDA has taken in response to problems with devices or device companies; (4) science and research: research programs at CDRH or sponsored by CDRH; (5) educational resources: information to help industry and others understand CDRH requirements and processes; and (6) CDRH performance data: metrics about CDRH programs.

The site also features a searchable Total Product Life Cycle database, which integrates premarket and postmarket medical device information from multiple data sources into a single snapshot. FDA plans to expand the CDRH Transparency Web site to include premarket approval and clearance reviews. The site also includes a feedback mechanism through which the public can make suggestions for improvements. The Web site is available at: www.fda.gov/CDRHtransparency.

U.S. Food and Drug Administration

Medicare Cancer Imaging

From 1999 through 2006, the use of diagnostic imaging for Medicare patients with cancer increased, with PET increasing the most significantly, according to a study in the April 28 issue of the *Journal of the American Medical Association* (2010;303:1625–1631). Imaging costs for Medicare patients also increased, outpacing the growth rate for total costs among beneficiaries with cancer. Dinan et al. of the Duke Clinical Research Institute (Durham, NC) examined changes in the use and costs of imaging and the ways in which these changes have influenced the cost of cancer care. The study included an analysis of a nationally representative 5% sample of claims from the U.S. Centers for Medicare & Medicaid Services for new cases of breast cancer, colorectal cancer, leukemia, lung cancer, non-Hodgkin lymphoma, and prostate cancer. The researchers found that the numbers of PET scans per beneficiary increased at an average annual rate of 35.9% to 53.6%, depending on the type of cancer. Patients with lung cancer or lymphoma had the largest increases in PET use, accompanied by an overall reduction in conventional nuclear medicine imaging tests in both cancer types and stable CT rates in the lymphoma group. Increases also occurred in the use of bone density scans (6.3%−20.0%), echocardiograms (5.0%−7.8%), MR imaging (4.4%−11.5%), and ultrasound (0.7%−7.4%). Use of CT increased in all cancer subgroups (4.5%−7.6%) except lymphoma. Use of conventional radiographs decreased or stayed the same in each cancer subgroup but remained the most used imaging modality for all diagnoses, at an average of 4.3–12.2 procedures per patient.

The authors also found that for all cancer types, average 2-y imaging costs per beneficiary increased between 5.1%/y and 10.3%/y, at least double the rate of increase in overall costs (the cost of cancer care increased 1.8%/y−4.6%/y). Imaging costs for all cancers studied also accounted for a larger percentage of total costs in the 2006 group than in all previous years. "It is unclear whether the rapid increase in use of advanced imaging is a result of the novelty of the technologies, better outcomes, or a shift to new revenue sources after the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act," the authors concluded.

Journal of the American Medical Association

Quality and Disparities Report Issued

Improvements in patient safety continue to lag, according to the 2009 *National Healthcare Quality Report* and *National Healthcare Disparities Report,* issued on April 13 by the U.S. Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ).

Little progress has been made on eliminating health care–associated infections (HAIs), according to a new section in the 2009 quality report. For example, in the 5 types of HAIs in adult patients tracked in the reports, rates of postoperative sepsis increased by 8%,

postoperative catheter-associated urinary tract infections increased by 3.6%, and rates of selected infections resulting from medical care increased by 1.6%. On a positive note, rates of postoperative pneumonia improved by 12%.

The study also noted continuing disparities in health care for minorities. Although rates are improving incrementally, blacks, Hispanics, Asians, and American Indians are less likely than whites to receive preventive antibiotics before surgery in a timely manner. "Despite promising improvements in a few areas of health care, we are not achieving the more substantial strides that are needed to address persistent gaps in quality and access," said AHRQ Director Carolyn M. Clancy, MD.

AHRQ's annual quality and disparities reports, which are mandated by Congress, were first published in 2003. The reports show trends by measuring health care quality for the nation using a group of "credible core" measures. Data are based on more than 200 health care measures categorized in 4 areas of quality: effectiveness, patient safety, timeliness, and patient-centeredness. The 2009 reports include a new section on lifestyle modifications.

The reports indicated that lack of health insurance slows improvement in health care quality and reduction of disparities. For many services, not having insurance was the single strongest predictor of poor quality care, exceeding the effects of race, ethnicity, income, or education. Americans with no insurance were much less likely than those with private insurance to obtain recommended care, especially preventive services and management for diabetes. The quality and disparities reports are available online at www.ahrq.gov/qual/qrdr09.htm.

Agency for Healthcare Research and Quality

FDA MDAC Process

The U.S. Food and Drug Administration (FDA) announced on April 26 that on May 1 it would change the way its expert panels review and discuss data and information during public hearings on medical devices under review for premarket approval. The changes were prompted by an increasing number of medical device advisory panel meetings in recent years. In 2008, 10 panel meetings were held, covering 14 major topics. In 2009, 17 meetings were held on 20 topics; and 2010 is on track to surpass those numbers, according to the FDA's Center for Devices and Radiological Health (CDRH). The changes address staffing issues, voting procedures, and other items related to information presentation and flow of discussion. "These changes are expected to empower the agency to make more effective decisions that are informed by more clear and focused discussion by panel experts," said CDRH Director Jeffrey Shuren, MD.

In the past, panel discussions have not always reflected a panel's final vote on approvability. Now, instead of voting on the approvability of premarket approval applications, including conditions of approval, the panel will vote on the safety and effectiveness of a device and the device's risk versus its benefit. "By making this change in voting procedure, panel members will address key scientific issues during their discussions, which will be reflected in their votes," Shuren said. "The change also will allow panel members to address issues related to their area of expertise instead of regulatory issues that may be unfamiliar to them."

Panels will vote by ballot instead of by a show of hands. Although votes will be publicly tallied so that panel members can be identified by their votes, the ballot process allows each panel member to cast his or her vote without immediate influence by other votes. Historically, FDA presentations to panels included comments on approvability of medical devices. With the changes, the FDA presentations will continue to include reviews of the agency's data analyses but will no longer include comments on approvability. Before the changes, the agency medical device reviewers presented a unified, consensus analysis of supporting data. Reviewers will now present the range of scientific opinion in the group, together with data and analysis. This move will allow more in-depth discussion on safety and effectiveness and risk versus benefit of the device under consideration. A description of changes to panel operations is available at: www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/ucm208485.htm.

U.S. Food and Drug Administration

New NRC Commissioners

Nuclear Regulatory Commission (NRC) Chair Gregory B. Jaczko, PhD, on April 1 administered the oath of office to 2 new commissioners, William D. Magwood, IV, and William C. Ostendorff, in a ceremony at NRC headquarters. A third new commissioner, George Apostolakis, PhD, was sworn in on April 23 to bring the agency to its full complement of 5 commissioners for the first time since 2007.

Magwood served 2 U.S. presidents and 5 Department of Energy secretaries from 1994 to 2005. Since that time, he has provided strategic advice to domestic and international clients through his consulting practice. Ostendorff, once the principal deputy administrator at the National Nuclear Security Administration, is a retired Navy Captain who most recently worked at the National Academies and also held a senior staff position at the House Armed Services Committee. Apostolakis is a former member and chair of the statutory Advisory Committee on Reactor Safeguards at the NRC. Before joining the NRC, he was the Korea Electric Power Corporation Professor of Nuclear Science and Engineering and a professor of engineering systems at the Massachusetts Institute of Technology.

The NRC has 5-y terms, each staggered a year apart. Magwood was confirmed to a term that will end on June 30 and be reappointed for a term to expire June 30, 2015. Ostendorff's term will end June 30, 2011. Apostolakis's term will end on June 30, 2014. "I'm looking forward to the new commissioners joining our discussions about important policy issues facing the

agency and the nation," said Jaczko. "They bring exceptional backgrounds and talents to the NRC. Their insights and experience will strengthen our decision making and help us to continue to meet our critical mission to protect public health, safety, and the environment."

Nuclear Regulatory Commission

Joint Workshop on Imaging Standardization

The U.S. Food and Drug Administration (FDA), SNM, and the Radiological Society of North America (RSNA) hosted a joint 2-topic workshop on April 13 and 14 at the Natcher Conference Center of the National Institutes of Health (Bethesda, MD). The goal of the meeting was to generate discussion on the use of imaging for assessing endpoints in clinical trials. Participants came from academia, industry, and regulatory groups. The first day of the workshop focused on general issues of standardization to control variability and inconsistency in methods of acquisition, interpretation, and analysis of images in clinical trials. The second day included an interactive tutorial on ways to address FDA regulatory expectations for PET drugs, particularly with respect to recently issued regulations establishing Current Good Manufacturing Practice (CGMP).

"This workshop offers a unique opportunity to work with the imaging community to help optimize the role of imaging in public health," said Dwaine Rieves, MD, director of the Division of Medical Imaging Products in the FDA's Center for Drug Evaluation and Research.

"We are delighted to partner with the FDA and RSNA to bring the molecular imaging community together on the important transition to the new regulations," said Michael M. Graham, PhD, MD, president of SNM. "The PET community remains very focused on preparing to comply with these regulations and is committed to working together to ensure a smooth transition."

The FDA published a final regulation on CGMP for the production of PET drugs in December 2009. The new regulations (21 CFR Part 212) take effect on December 12, 2011. All PET drug manufacturers will be required to submit a new or abbreviated drug application for PET drugs in commercial/clinical use by that date. In the interim, U.S. facilities must continue to comply with USP General Chapter <823>, which sets standards for the production of PET drugs.

The agenda, supporting documentation, and many of the workshop PowerPoint presentations are available at: www.rsna.org/snm/index.htm.

Society of Nuclear Medicine
Radiological Society of North America

PET/CT H&N Cancer Staging Trial

The American College of Radiology Imaging Network (ACRIN) recently activated "A Multicenter Trial of FDG-PET/CT Staging of Head and Neck Cancer and its Impact on the N0 Neck Surgical Treatment in Head and Neck Cancer Patient" (ACRIN 6685). Led by Val Lowe, MD, professor of radiology, Division of Nuclear Medicine, at Mayo Clinic (Rochester, MN), the trial's primary aims are to determine the predictive value of PET/CT for staging the clinically defined negative neck based on pathologic sampling of the neck lymph nodes and to determine the potential of PET/CT to change patient management in this setting.

Participants with newly diagnosed head and neck squamous cell carcinoma will undergo a PET/CT scan before surgical resection. The surgeon will have access to the PET/CT results before the surgical procedure. Resulting data will demonstrate the effect of PET/CT on determination of extent of disease, disease characterization and prognosis, and changes in surgical plan from plans originally devised from clinical nodal assessment and CT or MR imaging. Quality of life assessments and cost effectiveness analyses will be included in the study to determine the impact of PET/CT in treatment of the N0 neck.

The study is expected to confirm that ^{18}F-FDG PET/CT imaging improves characterization of the N0 neck by accurately diagnosing disease, better defining extent of primary disease, discovering unappreciated distant metastases, reducing morbidity, and representing value to society. Up to 15 participating sites are expected to accrue 292 study participants in approximately 2 y. Additional details are available at: http://clinicaltrials.gov/ct2/show/NCT00983697 and by contacting the project manager at imahon@acr-arrs.org.

American College of Radiology Imaging Network

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 di-