



National Oncologic PET Registry Launch Delayed

During the first week of March, the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) notified the leadership of the National Oncologic PET Registry (NOPR) that it may require the NOPR to change its procedures related to Institutional Review Board (IRB) approval. Hopes for a quick launch of the registry had been high after the February 10 Centers for Medicare & Medicaid Services (CMS) announcement of an agreement with NOPR to collect data regarding PET scans. NOPR was given an exemption to the human protection regulations, with the understanding that the scans were acquired for medically necessary (not research) reasons and that the accumulation of associated patient data was the only risk to which patients were exposed. The OHRP reviewed the submitted materials and issued a position statement indicating that the NOPR does not qualify for exemption under the human protection regulations.

The immediate challenge posed by this restriction is that it threatens the broad representation of cases regarded as important in the registry. Many smaller imaging facilities do not have their own IRBs and, even after approval, the necessary consent procedures might be so cumbersome as to discourage participation by some practitioners. The NOPR is managed by the American College of Radiology (ACR) and the ACR Imaging Network in collaboration with the Academy of Molecular Imaging (AMI). The SNM and the American Society of Clinical Oncology have played key roles in guiding the project's development.

Speaking at the AMI annual meeting on March 26, Barry Siegel, MD, from the Mallinckrodt Institute of Radiology (St. Louis, MO) and cochair of the NOPR Working Group, pre-

sented an update on the status of the project to attendees. At present, all infrastructure and processes necessary for operation of the NOPR, in accordance with the original design of the registry, are in place. The NOPR is working to understand any new requirements under consideration and to plan support for NOPR participating sites should new requirements be confirmed. The NOPR is committed to activating the registry as soon as possible and to fulfilling its original objectives to "assess the effect of PET on referring physicians' plans of intended patient management across a wide spectrum of cancer indications that are currently not covered by the Medicare program, and in relation to cancer type, indication, performance status, physician's role in management, and type of PET," Siegel said. "The goal is to acquire data that can be used to evaluate PET in a manner that does not interfere with patient clinical care and minimizes the burden to the patient, PET center, and referring physician."

CMS and OHRP are working to resolve the question of whether individual IRB review and approval will be required for participation in the registry. When a final determination is reached, NOPR will post this information on its Web site and notify all registered facilities and those on its e-mail broadcast list. Until this issue is settled, the NOPR cannot accept patient registrations or finalize facility registrations. Meetings to resolve the IRB issues were scheduled for April, although no resolution had been announced at Newline press time.

American College of Radiology

Dynamic Bladder Software Tool Available

The Medical Internal Radiation Dose (MIRD) Committee of the SNM announced in March that an interactive, Windows-based computer program

written in Visual Basic 6.0 has been released as an educational and research tool for radiopharmaceutical dosimetry investigators. The program automates the model described in *A Dynamic Urinary Bladder Model for Radiation Dose Calculation* (MIRD Pamphlet No. 14 revised; 1999). The Dynamic Bladder Software Tool includes kinetic models for 20 standard radiopharmaceuticals and can accommodate user-entered data for new radiopharmaceuticals to produce graphs and tables of bladder wall surface doses for 7 initial bladder volumes, 9 initial void times, and 3 urine production rates.

The program allows comparison of the ways in which urinary bladder wall doses change as a function of the model variables for different radiopharmaceuticals. Data are displayed on the screen or may be sent to a printer or file, from which they can be exported into other programs for further analysis. Users may modify the kinetic models for the supplied standard radiopharmaceuticals should updates to the biologic parameters become available. The program provides convenient extension of the model for user-entered radiopharmaceuticals not included in the standard list, accommodating up to 4 separate components describing whole-body urinary elimination. The Dynamic Bladder Software Tool may be downloaded from: <http://interactive.snm.org/index.cfm?PageID=4309>.

SNM Medical Internal Radiation Dose Committee

Mallinckrodt Resumes ^{99m}Tc Generator Production

On April 5, Mallinckrodt, Inc./Tyco Healthcare resumed manufacture and shipment of its Ultra-TechneKow Technetium Generator. The move was announced in a March 23 letter to customers. The company voluntarily recalled the generator on November 19,

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2005, as a result of issues identified during a routine sterility assurance process revalidation.

"We have worked aggressively to implement highly effective quality assurance processes," said Steve Hanley, Mallinckrodt president, in the letter. "Improvements to our manufacturing processes and environmental monitoring systems support our confidence in bringing a high quality product back to market and should help to ensure a consistent supply into the future."

During the period of recall, other companies, including Bristol-Myers Squibb Medical Imaging, cooperated to meet the demand for ^{99m}Tc generators in North America and related patient unit doses provided through radiopharmacy distributors.

Mallinckrodt, Inc.

NIH Provides \$24 Million to Support Research Network

The National Center for Research Resources (NCRR), a part of the National Institutes of Health (NIH), announced on March 17 that it will provide \$24.29 million over 5 years to the University of California, Irvine (UCI) for continued support to the Biomedical Informatics Research Network (BIRN). Currently a consortium of 28 universities and 37 research groups, BIRN is leveraging and sharing distributed tools, software applications, techniques, data, and expertise that extend beyond the boundaries of individual laboratories. This major NCRR initiative, involving both basic and clinical investigators, is initially concentrating on research involving neuroimaging, but the tools and technologies developed will ultimately be applicable to other disciplines.

UCI is leading the part of the project known as Function BIRN, which brings together researchers at 14 institutions for the common purpose of developing and testing interdisciplinary techniques for integrating efforts in functional magnetic resonance imaging (fMRI) across multiple sites. The award will allow the Function BIRN

team to improve calibration of imaging equipment across sites, develop robust protocols for cognitive assessment, formulate methods for analysis of resulting data, and develop a scalable technology toolkit to support such complex studies. A test project will interpret fMRI datasets from more than 200 subjects scanned at facilities across the country.

"Through this effort, we are creating new models for collaboration among researchers who study diseases at multiple sites with different equipment," said Elaine Collier, MD, Assistant Director of NCRR's Division of Clinical Research. "Function BIRN's utilization of emerging technology for collaborative research and sharing of knowledge gained will accelerate scientific discoveries by allowing researchers to tackle complex questions and large-scale research projects that were not previously possible."

In its initial phase, the Function BIRN focused on developing a shared data storage infrastructure and standard imaging methods for the multiple sites. The project entailed a set of 5 research participants who traveled to 9 sites around the country for brain scans using a common protocol. This formed the first calibration dataset of its kind in the world for systematically studying intersite variability. Software tools were developed to reduce such variability, to automatically correct image distortions, and to manage data for large and diverse neuroimaging research projects. The open-source data and tools are available at www.nbirn.net/Resources/Downloads/.

Function BIRN's director is Steven G. Potkin, MD, a professor of psychiatry and the Robert R. Sprague Director of Brain Imaging at UCI. "One of our most significant accomplishments is that through Function BIRN we have begun to create the sociology and culture for data sharing among researchers," Potkin said. "By working together with top researchers at many sites, we can simultaneously test a variety of approaches to a problem and compare results, which has greatly accelerated the progress we are able to make."

Another goal of Function BIRN is to encourage the research community

to make use of the tools, data, and lessons learned. Collaborations have already begun with other NIH-supported organizations such as the Neuroimaging Informatics Technology Initiative, the Treatment Unit on Research for Neurocognition in Schizophrenia, and NCRR-funded General Clinical Research Centers located around the country. In addition to Function BIRN, the overall BIRN initiative comprises: the BIRN Coordinating Center, the primary software development and computational hub; Morphometry BIRN, which is investigating whether structural differences in the brain correlate to symptoms of neuropsychiatric illnesses; and Mouse BIRN, which is studying animal models of diseases such as multiple sclerosis, schizophrenia, Parkinson's disease, and brain cancer.

With the infrastructure in place and the lessons learned from the neurology projects, NCRR plans to expand BIRN to support other types of large-scale, collaborative investigations, including the incorporation of other imaging modalities. BIRN is expected to eventually incorporate distributed computing resources, mechanisms for the integration of interoperable software tools, and linkage of data through the federation of databases.

For more information about BIRN, visit www.ncrr.nih.gov/biotech/btbiirn.asp.

*National Center for
Research Resources*

Berkeley Lab Dedicates Molecular Foundry

A new research center to be known as the Molecular Foundry was officially dedicated at the Lawrence Berkeley National Laboratory in Berkeley, CA, on March 24. The facility is the first of 5 proposed U.S. Department of Energy (DOE) Nanoscale Science Research Centers and is an \$85-million, 6-story, 94,500-square-foot, steel-and-glass building. As a DOE national research facility, the resources at the Molecular Foundry will be made available to qualified

scientists throughout the country. Already, more than 50 scientific projects to be conducted at the facility have been approved. “The Molecular Foundry has nanoscale research capabilities not found at any other facility,” said Foundry director Carolyn Bertozzi at the dedication ceremony. “It creates an environment in which scientists from different disciplines can work together under one roof to expand our knowledge of the nature of matter on a nanoscale.”

“The dedication of the Molecular Foundry represents a milestone in the field of nanoscience,” said Paul Alivisatos, Berkeley Lab’s Associate Director for Physical Science, who will head the Foundry’s inorganic nanostructures research program. Research at the Molecular Foundry will encompass “hard” (inorganic) materials, including nanocrystals, nanotubes, and lithographically patterned structures, and “soft” (organic and biologic) materials, such as polymers, DNA, proteins, and components of living cells. Nanometer lengths-of-scale are where investigations into hard and soft materials meet, and to study this common ground, researchers at the Molecular Foundry will invoke the primary fabrication strategies of both the “top down” approach practiced by solid-state physicists and physical chemists (in which existing structures and objects, such as semiconductors, are made smaller) and the “bottom up” approach practiced by chemists and molecular biologists (in which atoms and molecules are connected together to make larger structures and objects). The Molecular Foundry will host its own research program and collaborative projects with visiting researchers and also will provide training for graduate and postdoctoral students.

In addition to its research programs and training component, the Molecular Foundry will also serve its collaborators as a “portal” into 3 other national user facilities at Berkeley Lab, each of which offers cutting-edge technical capabilities crucial to effective nanoscale research: the Advanced Light Source, the National Center for Electron Microscopy, and the National

Energy Research Scientific Computing Center. For more information about the foundry and its programs, visit <http://foundry.lbl.gov>.

*Lawrence Berkeley
National Laboratory*

Model Cancer Center at City of Hope to Include RIT

City of Hope Cancer Center (Duarte, CA) announced on March 9 the receipt of a \$20 million grant to establish the Arnold and Mabel Beckman Center for Cancer Immunotherapeutics and Tumor Immunology. The center will provide space and resources for scientists in City of Hope’s Division of Cancer Immunotherapeutics and Tumor Immunology (CITI). Within the center, scientists will research new treatment ideas, manufacture biologic agents on site, and conduct preclinical testing and clinical trials.

“We are pleased that the Arnold and Mabel Beckman Foundation is continuing its longstanding commitment to scientific discovery at City of Hope,” said Andrew Raubitschek, MD, CITI chair. “This new facility will strengthen our basic science efforts in areas such as tumor immunology, while speeding the outstanding work of our scientists directly to the hands of physicians to benefit patients more quickly than ever before.”

The wide array of disciplines represented at the center, from hematology to molecular biology, will promote collaboration and innovation. CITI researchers will bring together their expertise to focus on 4 key investigational areas: radioimmunotherapy, cellular immunotherapy, molecular immunotherapy, and vaccine immunotherapy.

City of Hope Cancer Center

CMS Opens New Pay-for-Quality Models

The Centers for Medicare & Medicaid Services (CMS) announced on March 22 that it is making available the shared savings payment model and quality measurement and reporting processes used in the Medicare Physician Group Practice (PGP) Demonstration

to Medicare Health Care Quality (MHCQ) Demonstration applicants. The PGP models give applicants a defined and industry-supported payment model and quality measurement and reporting process. “We are making the shared savings model and quality reporting tools available so physician groups and health care systems can focus their resources on system redesign to improve patient safety, enhance quality, increase efficiency, and reduce scientific uncertainty and unwarranted variation,” said CMS Administrator Mark B. McClellan, MD, PhD.

The PGP Demonstration shared savings model provides additional financial support for physicians to improve the quality and efficiency of health care services delivered to Medicare fee-for-service beneficiaries. Under the model, physician groups are eligible for performance payments derived from savings from better care management designed to anticipate patient needs, prevent chronic disease complications and avoidable hospitalizations, and improve quality of care. In turn, physicians can use these savings to invest in health information technology, care coordination, and other steps to improve care and reduce costs.

Physician groups, integrated delivery systems, and regional coalitions are eligible to use the PGP model. Newly formed regional coalitions of smaller physician groups could come together for demonstration purposes to participate in the MHCQ Demonstration using the PGP model. Applicants using the PGP model are required to meet all MHCQ goals and objectives (e.g., improve patient safety, enhance quality, increase efficiency, and reduce scientific uncertainty and unwarranted variation) and have 150 or more physicians. Industry analysts point out that although imaging groups may be reluctant to participate in such programs, the introduction of required pay-for-performance metrics across the board in medical practice are almost certainly on the CMS horizon within the next decade. Nuclear medicine, along with other imaging specialties, will be

challenged to develop metrics that adequately represent quality, patient-centered practice while at the same time not imposing unreasonable restrictions or record-keeping burdens on practitioners.

MHCQ-PGP Model applications must be received on or before September 29, 2006. More information can be found on the MHCQ Demonstration webpage at www.cms.hhs.gov/DemoProjectsEvalRpts/.

Centers for Medicare & Medicaid Services

CMS Minority Outreach Demonstration Sites

The Centers for Medicare & Medicaid Services (CMS) announced on March 24 the selection of sites for 6 demonstration projects to improve the early detection and treatment of cancer and reduce health disparities among minority Medicare beneficiaries. "Medicare has the best coverage ever for preventing deaths through earlier detection and treatment, but we still have a big gap in using these treatments, especially for our minority beneficiaries," said CMS Administrator Mark McClellan, MD, PhD. "These new programs will support our key goal of better quality of care and reduced health disparities for people with Medicare."

Minority groups (and selected institutions) in the demonstration include American Indians (Huntsman Cancer Institute, Salt Lake City, UT); Asian Americans and Pacific Islanders (Molokai General Hospital, Hawaii); African Americans (Johns Hopkins University, Baltimore, MD; and Josephine Ford Cancer Center, Detroit, MI); and Hispanic Americans (University of Texas, Houston; and the New Jersey Medical School, Newark).

The demonstration projects will help more than 13,000 minority Medicare beneficiaries "navigate" the health care system in a more timely and informative manner. The services provided under this demonstration will help participants overcome barriers to 3 components of cancer care: screening, diagnosis, and treatment. Project sites

will provide services to help participants schedule timely appointments for cancer screening and, if needed, follow-up diagnostic testing. Other services that may be provided include assistance with transportation, translation or interpretation, and care coordination.

Centers for Medicare & Medicaid Services

Slight Slowdown in Health Care Spending Predicted

Health care spending in the United States is projected to grow 7.4% in 2005 and 7.3% in 2006, surpassing \$2 trillion, according to a report released on March 15 by the Centers for Medicare & Medicaid Services (CMS). Projections are updated each year based on the most recent available data (currently 2004 data). The 7.4% growth rate is 0.5 percentage points less than the 7.9% growth observed in 2004 and represents the third consecutive year of decelerating growth, a trend that is expected to continue in 2006.

Underlying the slowdown in national health spending in 2005 and 2006 is an expected drop in personal health care spending. Influenced by legislated Medicare payment adjustments that are to be implemented in 2007, growth in personal health care spending is projected to fall to 7.0% that year. In 2008, growth is expected to rebound to 7.5%, but then gradually slow over the remainder of the 10-year projection. Over the coming decade, however, with the aging of the population and changes in medical technology and utilization as the main contributing factors, national health expenditures are expected to double, growing an average rate of 7.2% per year. As a result, the health share of the Gross Domestic Product, 16% in 2004, is expected to reach 20% by 2015.

Hospital spending growth for 2005 is projected at 7.9%, marking the second consecutive year growth in this sector is expected to outpace growth in total personal health care. Private payer spending growth is expected to slow 1.1 percentage points to 8.5% in 2005

because of an expected slowdown in hospital price growth. In 2006, growth is expected to rebound to 9.0% and then moderate during the remainder of the period averaging 7.9%. Public payer spending growth is expected to slow to 7.5% in 2005 and to 5.5% by 2007, due to legislative adjustments to Medicare managed care payments and other factors. Growth is expected to subsequently accelerate to 6.8% by 2015.

The health care spending projection data can be found on the CMS Web site at www.cms.hhs.gov/National-HealthExpendData/03_NationalHealthAccountsProjected.asp.

Centers for Medicare & Medicaid Services

New Census Bureau/NIH Report Highlights Aging Trends

According to a new report issued by the U.S. Census Bureau on March 9 and commissioned by the National Institute on Aging (NIA), one of the National Institutes of Health, today's older Americans are different from their predecessors: They live longer, with lower disability rates and higher levels of education, and they are less likely to live in poverty. The report, "65+ in the United States: 2005," provides a picture of the health and socioeconomic status of the aging population at a critical time in the maturing of the nation. It highlights striking shifts in aging on a population scale and also describes changes at the local and even family level, examining, for example, important changes in family structure as a result of divorce.

Among the findings explored in the document are:

- The United States population aged 65 and over is expected to double in size within the next 25 years.
- Although the health of older Americans is improving, many are disabled and suffer from chronic conditions.
- The financial circumstances of older people have improved dramatically, although there are wide variations in income and wealth.

- Higher levels of education, which are linked to better health, higher income, more wealth, and a higher standard of living in retirement, will continue to increase among people 65 and older.
- As the United States as a whole grows more diverse, so does the population aged 65 and older.
- Changes in the American family have significant implications for future aging.

The 65+ report is a project of the NIA's Behavioral and Social Research Program, which supports the collection and analysis of data in several national and international studies on health, retirement, and aging. The program's director, Richard M. Suzman, PhD, suggested that, with 5 years to go before the baby boom begins to turn 65, "Many people have an image of aging that may be 20 years out of date. The very current portrait presented here shows how much has changed and where trends may be headed in the future."

The 243-page compendium examines in detail 5 key areas: growth of the older population (changes in age and racial/ethnic composition); longevity and health (life expectancy and causes of death); economic characteristics (income and household wealth); geographic distribution (by population and race); and social and other characteristics (marital status, living arrangements, and voting patterns).

The public can view and also download the report at www.census.gov. To view an appendix of selected highlights from "65+ in the United States: 2005," see www.nia.nih.gov/NewsAndEvents/PressReleases/PR2006030965PlusReport.htm.

U.S. Census Bureau

UNSCEAR at 50

The first full session of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) opened on March 14, 1956, and the committee recently celebrated its golden anniversary as the UN scientific body responsible for documenting our

radiation legacy. UNSCEAR's first 2 substantive reports, submitted to the UN General Assembly in 1958 and 1962, provided initial international consensus summaries on the state of scientific knowledge on human radiation exposure. Together the reports laid the scientific grounds on which the Partial Test Ban Treaty on the prohibition of nuclear weapon testing in the atmosphere was negotiated and signed in 1963. Over the decades, UNSCEAR became the official international authority on the levels and effects of radiation used for peaceful as well as military purposes and derived from natural and artificial sources.

According to a press release marking the anniversary, UNSCEAR's findings and influence include: the recognition that medical diagnostic and therapeutic exposures were a major component of artificial radiation exposure globally; periodic published reports that have influenced the programs of international bodies, such as the International Atomic Energy Agency (IAEA), International Labor Organization, World Health Organization, and the International Commission on Radiological Protection; regular evaluations of the evidence for radiation-induced health effects from studies of the survivors of the atomic bombings in Japan in 1945 and other exposed groups; and assessment and updates of the radiologic consequences from the 1986 Chernobyl accident. The Committee also participates in the Chernobyl Forum, which the IAEA and partner organizations launched to document the accident's health and environmental effects.

UNSCEAR's work today is taking on added dimensions, noted its secretary, Malcolm Crick. "Countries are confronting important decisions that involve radiation effects," he says. "They include new medical uses of radiation, environmental restoration, waste disposal, and the nuclear power option—all areas in which UNSCEAR is called upon to provide authoritative scientific information." Over the coming year, the committee plans reviews of the risks from radon, epidemiolog-

ical studies of radiation and its cancer and noncancer effects, and cellular responses to radiation exposure. UNSCEAR, with a membership that includes 21 countries, will hold its annual meeting later this month in Vienna.

*United Nations Scientific Committee
on the Effects of Atomic Radiation*

When Patients Know About Physician Compensation

In a study published in the March 27 edition of the *Archives of Internal Medicine* (2006;166:623–628), Pearson et al. from Harvard Medical School and Harvard Pilgrim Health Care (Boston, MA) investigated the effects of disclosure of physicians' financial incentives to patients. The randomized trial was conducted among 8,000 adult patients at 2 multispecialty group practices in Boston and Los Angeles, CA. These patients received a compensation disclosure letter written by the chief medical officer of their physician group and then responded 3 months later to a survey. The authors found that patients who had received the disclosure letter were significantly more capable of correctly identifying the compensation models of their primary care physicians and also had more confidence in their ability to judge the possible influence of incentives on their own health care than were patients who received no disclosure. Although the "disclosure intervention" did not change the perceived level of trust in primary care physicians overall, almost one-fourth of patients who remembered receiving the disclosure indicated that it had increased their trust either greatly or somewhat. Less than 5% of patients responded that the information decreased trust. Patient loyalty to physicians was found to be higher among disclosure patients. The authors concluded that, "This study suggests that regulators, policy makers, and physician groups themselves should renew their consideration of disclosure as an instrument to advance the best interests of patients and physicians."

Archives of Internal Medicine