



## Increasing Radiation from Medical Imaging

The amount of radiation the U.S. population receives from medical imaging has risen 750% in the last 25 years, according to preliminary results of a report of the medical subgroup of the National Council on Radiation Protection and Measurement (NCRP). A summary of these results was presented by subgroup member Fred A. Mettler, Jr., MD, on April 16 at the NCRP annual conference in Arlington, VA. Mettler reported that the collective annual dose of radiation from radiology and nuclear medicine sources will be estimated at 930,000 person-Sv in the full NCRP report, scheduled for release in 2008. The size of the increase was attributed to growth in the number of scans performed, with larger doses from multislice CT imaging accounting for the largest portion of the annual collective dose (440,000 person-Sv, with chest and abdominal/pelvic imaging making up the majority of the burden). Nuclear medicine procedures account for 220,000 person-Sv of the collective dose; of these, cardiac studies account for more than 85%.

Also in April, the American College of Radiology (ACR) Blue Ribbon Panel on Radiation Dose in Medicine published a white paper on radiation dose in medicine (*J Am Coll Radiol.* 2007;4:272-284; available at: [www.acr.org/s\\_acr/bin.asp?DID=26119](http://www.acr.org/s_acr/bin.asp?DID=26119)). The panel was headed by E. Stephen Amis, Jr., from the Albert Einstein College of Medicine/Montefiore Hospital (Bronx, NY). The panel concluded that information gleaned from studies dating as far back as World War II "suggests that the rapid growth of CT and certain nuclear medicine studies over the past quarter century may result in an increased incidence of radiation-related cancer in the not-too-distant future." The panel offered 33 specific

and practical suggestions, intended to guide ACR activities but instructive to all relevant organizations and practitioners, focusing on: enhanced efforts to educate all stakeholders in the principles of radiation safety, appropriate utilization of imaging to minimize any associated radiation risk, standardization of radiation dose data to be archived during imaging for its ultimate use in benchmarking good practice, and the identification and perhaps alternative imaging of patients who may have already reached threshold levels of estimated exposure from diagnostic imaging.

*National Council on Radiation Protection and Measurement  
American College of Radiology*

## New Focus on TBI

A public meeting of the President's Commission on Care for America's Returning Wounded Warriors (PCCWW) was held in San Antonio, TX, on May 4 and focused on traumatic brain injury (TBI) and patient rehabilitation. This was the third public meeting by the commission and first outside Washington, DC, since its creation in the wake of criticisms of medical care for returning soldiers and veterans. The meeting came only 2 weeks after an interagency task force, headed by Veterans Affairs Secretary Jim Nicholson, endorsed TBI screening for larger numbers of wounded military servicepersons. Previous meetings focused on an overview of the current health care system provided to servicemen and women and the issue of disability benefits.

Military health analysts have indicated that SPECT imaging will be an essential element in the stepped up TBI assessments. The increase in cases of TBI have already led to SPECT acquisitions in some military hospitals that did not previously incorporate this technology into routine screening. On

April 24, the Associated Press carried a story about a new SPECT unit to be installed at Evans Army Community Hospital (Fort Carson, CO). A recent study by physicians at Fort Carson found that 18% of troops returning from Iraq (2,392 of 13,400) suffered some degree of brain damage from the effects of explosive devices. Staff at the hospital will determine whether SPECT is a useful adjunct and/or replacement for the traditional assessment tool, a verbal questionnaire. Lt. Col. Reed Smith, head of nuclear medicine at the Evans hospital, said that initial studies will be conducted in soldiers who have already been diagnosed with TBI. Results will be reported to an Army review board that will consider integration of SPECT into routine TBI assessment protocols.

*President's Commission on Care for America's Returning Wounded*

*Associated Press*

## Medicare Proposes Revised Clinical Trial Policy

The Centers for Medicare & Medicaid Services (CMS) announced on April 10 proposed revisions to the Clinical Trial Policy national coverage determination (NCD). Under the Clinical Trial Policy, first developed in September 2000, Medicare pays for certain items and services for Medicare beneficiaries involved in clinical trials. "This new decision will signal our continued support to provide access to services for beneficiaries by facilitating participation in the full range of qualified, scientifically sound research projects," said CMS Acting Administrator Leslie V. Norwalk, Esq. In developing the revised policy, CMS convened the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) on December 13, 2006. The MedCAC proposed several recommendations, subsequently

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reviewed by a federal panel led by the Agency for Healthcare Research and Quality, CMS, the U.S. Food and Drug Administration (FDA), the Health Research Services Administration, and the National Institutes of Health (NIH). Among the highlights of the proposed policy changes are:

- Renaming the policy as the Clinical Research Policy;
- Adding FDA postapproval studies and coverage with evidence development (CED) to studies that would qualify under this policy;
- Requiring all studies to be registered on the NIH ClinicalTrials.gov Web site before enrollment begins;
- Requiring studies to publish their results;
- Paying for investigational clinical services if they are covered by Medicare outside the trial or required under a CED through the NCD process; and
- Expanding the “deeming” agencies to all Department of Health and Human Services agencies, the Veterans Affairs Administration, and the Department of Defense. Deeming agencies are agencies that can determine whether a trial has met the general standards outlined in the policy.

The proposed NCD opened a 30-day comment period that ended in May. CMS will review public comments and suggestions and incorporate these into a final NCD to be published no later than 60 days after the end of the comment period.

Details of the coverage policy are available at the CMS coverage Web site at: [www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186](http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186).

*Centers for Medicare  
& Medicaid Services*

## **Cancer Biomarkers Collaborative Formed**

The American Association for Cancer Research (AACR), the Food and Drug Administration (FDA), and the National Cancer Institute (NCI) announced on April 19 the formation of the AACR–FDA–NCI Cancer Bio-

markers Collaborative (CBC) to facilitate the use of validated biomarkers in clinical trials and ultimately in evidence-based oncology and cancer medicine. The collaborative brings together leaders from academia, government, industry, and patient advocacy groups to develop a set of guidelines for effectively integrating predictive biomarkers into clinical trials. “Major advances in cancer biology over the last quarter century have provided us with a better fundamental understanding of cancer in all of its forms, yet the translation of this knowledge into medical practice remains painstakingly slow,” said William N. Hait, MD, PhD, president of the AACR. “Therefore, we are joining forces with our partners to find new ways of exploring the use of biomarkers in cancer detection and treatment, without sacrificing high standards for safety and efficacy.”

The collaborative evolved from a think tank session of academic, industry, and government researchers and patient advocacy groups held in 2006. Think tank participants laid the groundwork for the new collaborative and identified 4 priority areas of research: biospecimens, bioinformatics, assay validation, and information sharing. This summer, the collaborative will meet to discuss various aspects of these areas as they relate to biomarker validation and to develop guidelines for integrating predictive biomarkers into clinical trials. These guidelines will inform policies that are a part of the Critical Path Initiative, the FDA effort to modernize the scientific process through which a potential human drug, biological product, or medical device is transformed from a discovery or “proof of concept” into a medical product.

*American Association  
for Cancer Research*

## **NIBIB Symposium Celebrates Fifth Anniversary**

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) celebrated its first 5 years on June 1 with a commemorative scientific symposium on technological innovation in medicine. The symposium, entitled

“Changing the World’s Healthcare through Biomedical Technologies,” was held in the Lister Hill Center Auditorium on the campus of the National Institutes of Health (NIH) in Bethesda, MD. The celebration opened with a dinner reception on the evening of May 31, where the opening address was given by former U.S. Surgeon General David Satcher, MD, and the keynote speaker was former Apollo astronaut and former U.S. Senator Harrison Schmitt. The first NIBIB Landmark Achievement Award was presented in honor of the late Nobel Laureate Paul C. Lauterbur, PhD, and accepted by his wife, M. Joan Dawson, PhD.

Among the featured symposium speakers was 1964 Nobel Laureate in Physics, Charles H. Townes, PhD, who offered “Reflections on the Discovery of the Laser.” MR imaging pioneer, Waldo S. Hinshaw, PhD, a colleague of Lauterbur, delivered the commemorative lecture, “Reflections on the Development of MRI.” Others appearing on the symposium program were Harvey Fineberg, MD, PhD, president of the Institute of Medicine; The Honorable Shirley A. Jackson, PhD, president of Rensselaer Polytechnic Institute and past president of the American Association for the Advancement of Science; Anthony Atala, MD, director of the Institute for Regenerative Medicine, Wake Forest University; Ralph Weissleder, MD, PhD, director of Molecular Imaging Research, Harvard University; Dennis Spencer, chair of the Department of Neurosurgery, Yale University, and a member of the first team to receive a NIBIB grant; and Elias Zerhouni, MD, NIH Director. “The symposium celebrates our 5 years of remarkable accomplishments in leading technology development and innovation to address the challenges facing health care in the 21st century,” said NIBIB Director Roderic I. Pettigrew, MD, PhD.

*National Institute of Biomedical  
Imaging and Bioengineering*

## **Large-Scale Cancer Study Announced**

The American Cancer Society (ACS) announced on April 25 the

launch of a major cancer research study described as possibly the “last best chance” for large-scale, long-term population research in the United States to discover the genetic and environmental factors that cause and prevent cancer. The Cancer Prevention Study 3 (CPS-3) is designed to enroll a geographically and ethnically diverse group of half a million adults across the United States to provide direction for the next generation of ACS research. “There are no U.S. studies on the horizon positioned to take advantage of rapidly developing new knowledge and technologies over the coming decades, except CPS-3,” said Eugenia E. Calle, PhD, managing director of analytic epidemiology at the ACS and study lead. Large studies of up to 1 million participants are being conducted in Europe, the United Kingdom, China, and Taiwan. Such efforts are somewhat easier to implement in countries in which a national health system and unique patient identifiers link and document all health care data.

The ACS indicated that it will enroll CPS-3 participants at 64 of the 4,800 Relay For Life cancer survivor fundraising events taking place across the country in 2007 and continue at select relay events through 2011. CPS-3 will enroll men and women between the ages of 30 and 65 who have never been diagnosed with cancer and who are willing to make a long-term commitment to the study. Enrollment takes 20–30 minutes and includes the completion of a questionnaire, waist measurement, and a blood draw. During the coming decades, ACS researchers will track CPS-3 participants through questionnaires mailed every few years, identifying and studying factors associated with cancer occurrence or prevention in the study cohort.

“It is not an exaggeration to say the ACS is the only organization likely to be able to successfully recruit and retain such a large-scale population for cancer research,” said Calle. “We have an excellent record dating back to the 1950s of conducting these types of studies; we can bring together a world-class research department with a unique

community-based volunteer structure like Relay For Life; we can reach diverse populations nationwide who have a shared commitment to cancer research and to eliminating this disease; and because we are a nonprofit organization with the ability to partner with volunteers, we can conduct the study for much less than would be possible for the government or a private corporation.”

For more information visit [www.cancer.org/cps3](http://www.cancer.org/cps3).

*American Cancer Society*

## CMS Inpatient Service Reforms

The Centers for Medicare & Medicaid Services (CMS) on April 13 issued a proposed rule designed to “improve the accuracy of Medicare’s payment under the acute care hospital inpatient prospective payment system, while providing additional incentives for hospitals to engage in quality improvement efforts.” The payment reforms include a proposal to restructure the inpatient diagnosis-related groups (DRGs) to account more fully for the severity of patient condition. The proposed rule also includes provisions to ensure that Medicare no longer pays hospitals for their additional costs of hospital-acquired conditions (including infections) and includes an expanded list of publicly reported quality measures. The proposed rule would also reduce payment for a DRG involving the implantation of a device, when a hospital replaces a device and the replacement is supplied to the hospital at no or reduced cost. The proposed rule also is estimated to increase payments to more than 3,500 acute care hospitals by \$3.3 billion.

The proposed rule would create 745 new severity-adjusted DRGs (Medicare Severity DRGs or MS-DRGs) to replace the current 538 DRGs. Payments would increase for hospitals serving more severely ill patients and decrease for those serving patients who are less severely ill. One purpose of this move, according to a CMS press release, is to “further reduce incentives for hospitals to ‘cherry pick,’ the practice of treating only the healthiest

and most profitable patients” and to “address concerns that specialty hospitals—hospitals that provide a limited range of services and typically are owned in whole or in significant part by physicians who serve as referral sources—may selectively provide such profitable services.” New disclosure requirements will also be mandated for specialty hospitals.

Comments on the proposed rule will be accepted until June 12 and a final rule, to be effective for discharges on or after October 1, 2007, will be published later in the summer. For more information, see: [www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp#TopOfPage).

*Centers for Medicare & Medicaid Services*

## Malpractice Juries Favor Physicians

In a study published in the May issue of the *Michigan Law Review* (2007;106:1–42), Philip G. Peters, Jr., from the University of Missouri at Columbia School of Law, reported on the results of a study collecting and synthesizing 3 decades of research on jury decision making in medical malpractice cases. He found that, contrary to widely held opinion in the medical community, juries treat doctors favorably, “perhaps unfairly so,” and that most malpractice suits (approximately 70%) end in defense verdicts. This is explained, in part, by the fact that those cases that reach trial are usually the weakest, because strong evidence of malpractice is a spur to settlement before trial.

Among the key findings from the data compiled for the study were: (1) Plaintiffs rarely win in weak cases; strong evidence of medical negligence is a significant factor in most plaintiff wins. (2) Juries agree with legal experts who later review cases 80%–90% of the time; that is, juries can recognize weak arguments. (3) The poor success of malpractice plaintiffs “strongly suggests the presence of factors that systematically favor medical defendants in the courtroom.” The author

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identified these factors as the defendant's superior resources, the social standing of physicians, social norms against "profiting" from injury, and the jury's willingness to give physicians the benefit of the doubt in disputed facts.

The study is timely because legislation is pending in Congress to transfer medical malpractice cases from civil juries to administrative health courts. In addition, the Institute of Medicine has recommended transferring such cases away from jury trials to a system of binding early settlement offers. Peters cautioned against such moves: "Both piecemeal reforms and more fundamental alternatives to malpractice litigation should not be driven by the mistaken assumption that juries treat physicians unfairly. Although the current system of resolving malpractice claims has many shortcomings, neither randomness nor favoritism toward injured patients is among them."

*Michigan Law Review*

## HHS Establishes BARDA Office

On April 26, U.S. Department of Health and Human Services (HHS) Secretary Mike Leavitt announced the establishment of an office that will manage the Biomedical Advanced Research and Development Authority (BARDA). The office will be created under the HHS Assistant Secretary for Preparedness and Response. The BARDA office will manage Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biologic, radiologic, and nuclear agents as well as the advanced development and procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield. "The creation of BARDA enhances the opportunity for innovation in our efforts to develop effective medical countermeasures against a host of

public health threats, either natural or manmade," Leavitt said. "I am pleased that Congress recognized the importance of advanced development in the establishment of BARDA, and the President's FY 2008 budget request of \$189 million for this purpose will help further the department's efforts to bridge the gap between the National Institutes of Health's research and development programs and Project BioShield."

The central BARDA mission is to provide an integrated, systematic approach to the development and purchase of necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. BARDA will incorporate all the programs, mission responsibilities, and organizational functions previously housed in the HHS Office of Public Health Emergency Medical Countermeasures, which will be subsumed in the reorganization process.

*U.S. Department of Health  
and Human Services*