Report on Radiology Medication Errors Provokes Alarms, Responses, and Recommendations

The United States Pharmacopeia (USP) announced on January 18 that medication errors occurring in radiologic services produced “the highest percentage of harm—7 times higher than all medication errors studied in the 2000–2004 reporting period,” according to the USP’s 6th annual MEDMARX Data Report. The report, A Chartbook of 2000–2004 Findings from Intensive Care Units and Radiological Services, analyzed 40,403 records collected from hospitals and health care institutions across the country over a 5-year period. From 2000 to 2004, 12% of the 2,032 medication errors reported in radiological services included in the study resulted in patient harm. Radiologic services were also more likely to result in the need for additional care and consumption of resources.

“These errors signal hidden risks for patients—hidden because most people view radiological procedures as routine and may not be aware that high risk medications are being used before, during, and after a radiological procedure,” said John P. Santell, RPh, primary author of the report and director of Educational Program Initiatives for the Center for the Advancement of Patient Safety at USP. “Based on our data, we believe that this is a serious issue and must be addressed for patient safety and quality of care.” The study defined radiologic error as that occurring in, or as a result of, imaging performed in inpatient and outpatient services including the radiology department, cardiac catheterization laboratory, and nuclear medicine.

Responses from Radiology and Nuclear Medicine

The report, which received broad coverage by major news outlets and prompted widespread concern among patients, met with immediate responses from organized radiology and nuclear medicine. Later on January 18, the American College of Radiology (ACR) issued a statement characterizing the USP study as containing “incomplete, inaccurate information” that was “without careful and logical analysis.” The ACR statement pointed to the possibility that the report “may unnecessarily alarm patients and may cause many patients who require imaging care to mistakenly avoid getting it.”

“The ACR works for the day when all medical errors are eliminated. However, this report is deeply flawed and fails to relate the extremely low frequency of such errors in relation to the more than 570 million medical imaging procedures performed in the United States each year. This incredibly vague report does not provide evidence that imaging facilities operated by trained, certified physicians and certified nonphysician personnel present a significantly increased risk over other medical facilities in regard to medication usage,” said James P. Borgstede, MD, chair of the ACR Board of Chancellors.

The ACR pointed out that the USP report did not make clear how representative the voluntarily reported data were or how the number of errors reported compares with the total number of procedures performed safely. Moreover, the USP report failed to delineate which medical specialists actually perform exams and incorrectly attributed to radiology nearly half of the 2,030 errors cited. Cardiac catheterization labs were listed as the areas in which the highest percentage (40%) of medication errors cited in the report occurred. The report attributed all 823 errors incurred in these labs to radiology. The ACR release noted that although “interventional radiology is a growing subspecialty of radiology and the number of these procedures performed by radiologists is increasing, radiologists currently perform less than 1% of cardiac catheterization procedures nationwide.”

The signal failure in the report noted by the ACR and numerous other groups was the fact that the USP attributed to radiology events that may have been unrelated to the performance of imaging procedures but which occurred in or on the way to or from the radiology department. Pharmaceutical errors in patients who arrive in the radiology department with scheduled medications, injections ordered by other physicians, or who are medicated on their clinicians’ advice after experiencing medical emergencies unrelated to imaging were all counted as radiology errors.

“The massive flaws in the report’s methodology and its failure to provide context as to the scope of any errors reported seriously undermine the study’s conclusions. To take this report as evidence of systemic failures in radiology facilities which represent an increased risk to patients is not only inaccurate, but irresponsible and potentially dangerous,” said Borgstede.

Taking a somewhat different approach, the SNM responded on January 18 by issuing a press release pointing to the relatively low number of errors reported by the USP for nuclear medicine procedures. “The number of errors voluntarily reported for nuclear medicine in this comprehensive analysis—resulting from environmental, situational or organizations factors—is exceptionally low,” said President Peter S. Conti, MD, PhD.

Robert E. Henkin, MD, chair of the SNM Committee on Health Care Policy and Practice, said, “We agree with the USP findings and are pleased that nuclear medicine
procedures—such as PET scans to diagnose and monitor treatment in cancer, cardiac stress tests to analyze heart function, bone scans for orthopedic injuries, and lung scans for blood clots—continue to be safely prescribed, transcribed, dispensed, and administered. The report indicated that 4 nuclear medicine patients in the study were affected by dispensing errors and that no patient suffered permanent injury. Given the participant information provided in the report, “the results would indicate that approximately 40 errors might be made in 20 million nuclear medicine procedures,” said Henkin. “SNM would like to work with the USP in the future and further define any issues that affect patients.”

**USP Responds**

The USP responded to criticism of the study later on January 18 with a statement from Roger L. Williams, MD, executive vice president and chief executive officer, who said, “We are disappointed with the response from the ACR regarding the USP report issued today on medication errors in radiological services. The ACR response is inaccurate and mischaracterizes the report and the 5-year compilation of data behind it. USP stands by the validity of its report, which was reviewed by USP’s Safe Medication Use Expert Committee, made up of independent healthcare experts, prior to publication. We also applaud the dedication of more than 850 hospitals who have reported medication errors to USP since 1998.”

On January 25 the USP followed up by issuing a list of “safety tips to help consumers prevent medication errors from occurring during their trip to radiological services.” Imaging service providers should be aware that patients may ask for cooperation from staff based on the following list provided by the USP:

1. Keep an up-to-date list of medications in your wallet or purse at all times.
2. Always inform the radiological services staff, as well as your health care providers, of all your allergies.
3. If you are transported to another area in the hospital, always ask where you are going and why.
4. When you are transported to radiological services, make sure your chart goes with you.
5. Whenever possible, have a family member or close friend with you to serve as your advocate for quality care.
6. For outpatients, make sure you fully understand the home preparation instructions for your scheduled procedure.

**MEDMARX**, which issued the report and is operated by USP, is an anonymous, Internet-accessible program used by hospitals and related institutions nationwide to report, track, and analyze medication errors. The report on radiology error is available for a fee from MEDMARX at www.usp.org/products/medMarx/.
Two important studies reported at the end of 2005 and the beginning of 2006 provide valuable information for nuclear medicine specialists who diagnose and treat patients with thyroid carcinomas.

**rhTSH in Euthyroid Patients**

In an article e-published ahead of print on December 29 in the *Journal of Clinical Endocrinology and Metabolism*, an international team of researchers reported on a randomized, controlled study of radioiodine ablation of thyroid remnants and recombinant human thyrotropin in patients with differentiated thyroid carcinoma. Led by Furio Pacini, MD, of the University of Pisa (Italy), the study included participant authors and researchers from multiple sites in the United States, France, Canada, and Germany. The aim of the study was to compare the efficacy and safety of recombinant thyroid-stimulating hormone (rhTSH) to prepare euthyroid patients on L-thyroxine therapy for $^{131}$I remnant tissue ablation (3.7 GBq) with the efficacy and safety of conventional remnant ablation preformed in the hypothyroid state. Among the comparative variables measured were quality of life at separate time points and rate of radiation clearing from blood, thyroid, and whole body.

The authors found that in 100% of patients in both groups, the techniques fulfilled the primary criterion for successful ablation: “no visible uptake in the thyroid bed, or if visible, fractional uptake less than 0.1%” on neck scans performed 8 months after therapy. A secondary criterion for successful ablation (rhTSH-stimulated serum thyroglobulin concentration $<$2 ng/mL) was achieved by 23 of 24 (96%) euthyroid patients and 18 of 21 (86%) hypothyroid patients. Assessment scales for hypothyroid signs and symptoms and general health indicated that quality of life was significantly better preserved in the euthyroid group than in the hypothyroid group. Of great interest was the finding that patients in the euthyroid group had a statistically significant one-third lower radiation dose to blood compared with those in the hypothyroid group. Of great interest was the finding that patients in the euthyroid group had a statistically significant one-third lower radiation dose to blood compared with those in the hypothyroid group.

The authors concluded that, “This study demonstrates comparable remnant ablation rates in patients prepared for $^{131}$I remnant ablation with 3.7 GBq by either administering rhTSH or withholding thyroid hormone.” However, the finding that rhTSH-prepared patients maintained a higher quality of life and received less radiation exposure to the blood should be taken into account. These findings, one nuclear medicine expert told Newsline, “have the potential to change the way that remnant thyroid tissue ablation is currently being performed.”

**Revised ATA Management Guidelines**

On January 20 the American Thyroid Association (ATA) released updated guidelines for the management of patients with thyroid nodules and thyroid cancer, reflecting a decade of improved strategies for identifying, evaluating, and treating thyroid disorders. The new guidelines were prepublished online and appeared in the February issue of *Thyroid*. The 34-page document was prepared by a task force of experts in nuclear medicine, endocrinology, and surgery from leading academic and research institutions across the United States. It provides recommendations on several currently controversial treatment issues, including the most cost-effective approach for diagnostic evaluation of thyroid nodules, the extent of surgery needed for small thyroid cancers, the appropriate use of thyroxine suppression therapy, the role of recombinant human thyrotropin, and the use of radioactive iodine to ablate remnant tissue after thyroidectomy.

Led by task force chair David S. Cooper, MD, director of the division of endocrinology at Sinai Hospital of Baltimore (Maryland) and professor of medicine at Johns Hopkins University School of Medicine (Baltimore), the authors focused on the importance of timely and accurate diagnostic evaluation of thyroid nodules to rule out thyroid cancer and on therapeutic strategies for differentiated thyroid cancer, which represents approximately 90% of the estimated 26,000 cases of thyroid cancer diagnosed each year in the United States. “I am gratified that the ATA had the foresight to develop evidence-based guidelines that will enable physicians who care for patients with thyroid disease to do so rationally, judiciously, and cost effectively,” said Cooper.

The guidelines also include hands-on information on the follow-up and treatment of thyroid nodules, including the role of medical therapy. They outline the goals of therapy for differentiated thyroid cancer, strategies for staging thyroid tumors, the role of adjunctive external beam radiation and chemotherapy, and long-term management issues. With a comprehensive 300-item reference list, the document also provides an excellent review of current practice and research.

Several other groups that release practice guidelines relative to thyroid carcinoma diagnosis and treatment, (Continued on page 26N)
SNM 2006 Scientific Program Explores Expanding Imaging Technologies

The rapid multiplication of imaging technologies is driving much of the educational content of the 53rd Annual Meeting of the SNM, June 3–7 in San Diego, CA. The continuing advances in therapy and molecular imaging that have resulted from the expanded molecular targets available in both the clinical and research settings along with fusion imaging and CT training will be recurring themes.

Recently named one of the top 10 imaging-related educational events by the readers of Medical Imaging magazine, the SNM Annual Meeting will again include the popular educational exhibits that were added last year. These exhibits are designed to teach or review common nuclear medicine techniques, problem solving skills, pattern recognition, imaging skills, or use of correlative imaging. New computerized “Case of the Day” posters will allow attendees to test their nuclear medicine acumen and earn continuing education credits by reading and interpreting actual cases. Correct diagnoses will be entered into a lottery for complimentary registration at the 2007 Annual Meeting in Washington, DC.

Even before the meeting officially gets underway, full-day categorical seminars on Saturday, June 3, will offer physicians, scientists, and technologists in-depth instruction on single topics. Organized by the SNM councils, the PET Center of Excellence, and the Technologist Section, the courses cover:

- Diagnosis and Management of Breast Cancer: Current Practice and New Frontiers
- Biomarkers in CNS
- Molecular Imaging and Therapy and the NIH Roadmap: Perspectives and Potential
- PET/CT in Oncology: Focus on the Referring Physician: What Does Your Referring Physician Want from PET/CT?
- PET/CT Scanners: What’s Available and How They Work
- Expanding the Use of Nuclear Cardiology: Advances in Radionuclide Imaging and Integration with Other Developing Image Modalities
- Pediatric Oncology: From Bench to Bedside and Beyond
- New Horizons in Oncology and Neurology
- Opportunities and Challenges in Modern Medicine
- Technology
- PET/CT: An Atlas in Application in Technology
- Cardiology: A Comprehensive Look at Nuclear Medicine Today

Technologists and physicians planning to sit for professional exams may take advantage of weekend exam review workshops. Two-day workshops on Saturday and Sunday will cover topics of interest for those currently studying for the Nuclear Medicine Board Exam and the Nuclear Medicine Technology Certification Board exam. A 3-day workshop designed to help prepare nuclear medicine technologists for the CT certification exam will be offered Saturday through Monday.

The heart of every scientific meeting is the presentation of original research. Scientific sessions will run Sunday afternoon through Wednesday morning, with basic science summary sessions highlighting the most important research presented in the radiopharmaceutical sciences and computer and instrumentation tracks on Monday and Tuesday afternoons.

SNM is implementing a new CE credit reporting process at this annual meeting. Credit reporting forms are being eliminated. Instead, all registered attendees will receive a CE session tracking card that can be scanned as they enter and exit each CE session. Attendance will be tracked and, for SNM members, credit will be automatically entered into their CE transcript.

The 2006 SNM Annual Meeting will offer up to 31.75 hours of category 1 credit toward the AMA Physician’s Recognition Award and 30.25 hours of Verification of Involvement in Continuing Education credit for technologists. Continuing education credit for designated sessions will also be available for pharmacists from the Accreditation Council for Pharmacy Education and for medical physicists from the Committee on Accreditation of Medical Physicists Education Programs.
Converting Activity into Visibility

The society has initiated an effort to increase its visibility—along with that of molecular and nuclear imaging—through activities described in its new 3-year public relations (PR) plan. Implementation of the new plan, approved by members of the society’s PR Committee, began this past spring. Since then, the society has had numerous successes: in the amount of media coverage achieved; in the number of reporter queries to headquarters; in the diversity of press release content; and in attracting attention from trade publications, general interest (consumer/patient) publications, professional and specialty Web sites, consumer Web sites, and broadcast stations.

As chair of the PR Committee, I can tell you that public relations is integral to the society’s strategic goals of increasing public recognition and familiarity with molecular/nuclear imaging, contributing to the profession’s significant growth in science and utilization, and continuing as an essential center of knowledge for members and professionals. Success on the public relations front can be far reaching—for example, as educated consumers investigate the potential of molecular and nuclear imaging, as research-funding opportunities are opened, and as insurance coverage of related procedures is increased. Ultimately, the society seeks to ensure that whenever a referring physician, patient, consumer, government legislator or regulator, media representative, educator, medical student, career service officer, industry representative, health insurance official, or non-member needs reliable, accurate information about molecular and nuclear imaging, he or she looks to SNM.

One way to bring attention to the profession and the society is to get our news—about research, government relations activities, and society actions—reported in the profession-specific and general press. For the first time, SNM is closely monitoring media impressions/press hits—the estimated number of people who may have read, seen, or heard about SNM and its members in a printed news story or an online story or radio/television broadcast. This allows us to better understand how, where, and how often the society is mentioned, as well as establishing a baseline for comparison to help us measure the results of our new initiatives.

For the period from October 2004 through October 2005, more than 76 million individuals have read, heard, or seen news about the society and its members. In this same period, the number of society press releases—focusing on government relations and research presented in The Journal of Nuclear Medicine or at the Annual Meeting—has doubled.

Significant press mentions—resulting from press releases distributed to the society’s comprehensive media list—were routed through Reuters and Associated Press news agencies; other major press hits included MSNBC and Consumer Reports. Articles appeared in all kinds of publications—from trade publications such as Medical Imaging and FDA News to big city newspapers such as the Los Angeles Times, New York Times, and Wall Street Journal to business outlets such as Forbes magazine.

The top SNM news stories in the consumer press, based on our coverage summary, focused on nuclear medicine procedures setting off radiation alarms, imaging Alzheimer’s, the effects of having coffee before a CT scan, and the society’s efforts to include basic nuclear medicine research in the federal budget. In the trade press, research published in JNM or released at the Annual Meeting was reported widely.

SNM continues to build the foundation for its PR program. Fact sheets are being developed to send to reporters and government representatives. Key audiences have been pinpointed, and officers have worked on key messages. Internet metatags have been developed to ensure SNM’s site gets top placement in Internet search results for nuclear medicine keywords. The number of calls from reporters is constant, demonstrating our success in positioning SNM as an expert source of molecular imaging and nuclear medicine–related information for the media.

PR Committee members are recommending possible resources/interviewees for incoming press requests; they have also identified SNM/SNMTS members for inclusion in an online experts listing. At SNM’s Annual Meeting in June, SNM officers who deal frequently with media were professionally trained in media communications. Other efforts in the current plan include developing an online press room, initiating a Members in the News section, and possibly exploring a branding event—an annual event connected to SNM that attracts media attention.

SNM’s PR plan is an ambitious undertaking, and the initiatives in this first 3-year plan are just a start on a goal that may take many years to achieve.

Martin P. Sandler, MD
President-Elect, SNM

Martin P. Sandler, MD
President-Elect, SNM
From the SNM

SNM Commends FDA Efforts

On January 12, the SNM issued a statement commending the Food and Drug Administration (FDA) Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Office of Regulatory Affairs for their commitment to facilitating safe and effective research with the release of 2 important documents on investigational new drugs. “Guidance for Industry and Reviewers: Exploratory Investigational New Drugs (EIND) Studies” provides new protections for patients as well as a pathway for investigators to more efficiently conduct life-saving studies. “Guidance for Industry: Approaches to Complying with Current Good Manufacturing Practice (CGMP) During Phase 1 Studies” will facilitate the production of investigational drugs for use in phase 1 studies, with the primary focus again on human safety. “These guidance documents took a significant amount of the FDA’s time and dedication to ensure a secure process for researchers and developers of drugs and biological products,” said SNM President Peter S. Conti, MD, PhD, professor of radiology, clinical pharmacy, and biomedical engineering at the University of Southern California, Los Angeles. “The nuclear medicine and molecular imaging community appreciates their hard work.” An SNM task force compiled and submitted comments on EIND when the draft version was released to the public in spring 2005. Both documents can be accessed through the FDA Web site at www.fda.gov, where the CGMP guidance language remains available for public comment.

Society of Nuclear Medicine

Changes to Hospital Radiopharmaceutical Reimbursement

On January 1, the Centers for Medicare & Medicaid Services (CMS) implemented a temporary, 1-year policy for payment of radiopharmaceuticals in CY 2006. During this year, CMS will pay hospitals for outpatient radiopharmaceuticals with status indicator “H,” based on the charge on the claim, times the overall hospital specific cost-to-charge ratio (CCR). CMS stated on New Year’s Day in the Federal Register that “hospitals have the ability to set charges for items properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs.” Specifically, it is appropriate for hospitals to set charges for these agents in CY 2006 based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients.

This new radiopharmaceutical payment policy was implemented by CMS in an effort to maintain consistency between the payment rates for these agents from CY 2005 to CY 2006. CMS also stated that the temporary policy was needed because there was insufficient data for radiopharmaceuticals and because CY 2004 mean and median costs from the hospital claims data were substantially lower than CY 2005 radiopharmaceutical payment rates.

The nuclear medicine community expressed concerns to CMS that hospitals might not have consistently and uniformly accounted for all acquisition, transportation, preparation, handling, and overhead costs of radiopharmaceuticals in their previous pricing on hospital charge masters. The preparation, distribution, administration, and safe disposal of radiopharmaceuticals, along with labor costs and necessary patient and hospital staff protection costs, were not uniformly and accurately reflected in hospital charges. An analysis using 2004 hospital claims data provided by the Council on Radiation and Radiopharmaceuticals estimated that 33% of hospitals might be underreporting the cost for at least 1 radiopharmaceutical product using the hospital overall CCR and that 13% might be overcharging. In response, the SNM created the “Hospital Analysis of Radiopharmaceutical Cost and Charge Spreadsheet.” The spreadsheet includes formulas and data from 3 sample hospitals showing the new 2006 radiopharmaceutical payment methodology and potential impact on hospitals. Users can apply their own hospitals CCRs, charges, and costs to perform analyses and keep their facilities’ 2006 radiopharmaceutical charges up-to-date.

SNM also presented 2 Coding Road Shows in January and February to “take the mystery out of HCPCS Level II coding and billing.” For more information or to download a copy of the spreadsheet visit the SNM Web site at www.snm.org and click on Practice Management.

Society of Nuclear Medicine

Additional Newsbriefs

NRC Recognizes ABSNM Certification

The Nuclear Regulatory Commission (NRC) announced in early 2006 that it would recognize American Board of Science in Nuclear Medicine (ABSNM) certification in 2 new categories: nuclear medicine physics and instrumentation, and radiation protection for radiation safety. Beginning in June 2006, ABSNM diplomates with these specialties can be approved as radiation safety officers by NRC.

(Continued on page 23N)
Study Assesses U.S. Market for Radiopharmaceuticals

A report issued on January 19 by Bio-Tech Systems, Inc., a market research and analysis firm based in Las Vegas, NV, points to the strength and diversity of radiopharmaceuticals in the United States market. The report notes that U.S. sales of diagnostic radiopharmaceuticals reached $1.53 billion in 2004 and are expected to rise to $3.20 billion by 2010. Radiopharmaceutical sales grew by 14.3% in 2004 and should continue growth in the range of 13%–16% through 2008. This growth will be based on the introduction of new products, strong demand for cardiology procedures, and increased sales of oncology products, particularly 18F-FDG. Sales of nuclear cardiology products will continue to drive the radiopharmaceutical market, with high utilization of nuclear perfusion studies coupled with advanced pharmacologic stress agents. Nuclear cardiology sales of $1.06 billion in 2004 will increase to $1.89 billion by 2010. 18F-FDG sales will increase from $249 million in 2004 to $522 million by 2010. 18F-FDG distribution will continue to improve, allowing more widespread use of PET in community hospitals. With reimbursement stabilizing and procedure volume increasing, PET should become more profitable for providers as well as suppliers of 18F-FDG. In addition, new PET radiopharmaceuticals in the pipeline for specialized applications should add to these sales estimates. Market growth should also benefit from higher prices for many of the new products. More biopharmaceutical products for SPECT imaging will incorporate monoclonal antibody- and peptide-based targeted agents, expanding the range of nuclear procedures.

In a press release summarizing the report, Bio-Tech Systems noted that recent approval of 2 therapeutic radiopharmaceuticals has overlapped into the diagnostic market, creating a stronger link between targeted imaging and complementary therapeutic products. This has helped nuclear medicine, which is required in all cases to assess biodistribution and dosing of therapeutic radiopharmaceuticals as well as evaluate patient response to therapy. The report has a strong focus on new products and technology and emerging market opportunities. Many of the new diagnostic agents have a therapeutic counterpart. The prospects for growth of PET and PET/CT procedures are also covered, as well as SPECT/CT. The report can be ordered through www.bio-tech.com.

Savri Receives KFAS Prize
In a ceremony held on December 5, the prime minister of Kuwait presented Dr. Osama Savri with the Kuwait Foundation for the Advancement of Science (KFAS) award for applied sciences. The award is one of 5 annual prizes that are widely known as the “Nobel prizes of the Arab world.” The award went to Savri for his scientific achievements in evaluating the role of...
for this year’s award. A brochure describing the award and nomination process, with contact information, is available at www.science.doe.gov/lawrence/lawrence_brocure(oc2005).pdf.

U.S. Department of Energy

Blaufox Laboratory for Molecular Imaging Dedicated

A dedication ceremony for a new imaging laboratory at the Albert Einstein College of Medicine of Yeshiva University (New York, NY) was held on January 10. The new facility, the M. Donald Blaufox Laboratory for Molecular Imaging, will house state-of-the-art microPET imaging equipment for the study of animal models. The laboratory was established with a major gift from Ronald Lissak, president and chief executive officer of Integral PET Systems, and his wife, Marcia, chief operating officer of the company. The company named the facility in honor of Blaufox, university chair and professor of nuclear medicine at Einstein and its affiliated university hospital, Montefiore Medical Center. “This is a wonderful gift. It will play a key role in our investigations of a wide range of diseases, from cancer to epilepsy, from rheumatoid arthritis to diabetes,” said Dr. Dominick P. Purpura, the Marilyn and Stanley M. Katz Dean of the Albert Einstein College of Medicine. “Marcia and I are very pleased to make this gift in honor of our good friend, Don Blaufox,” said Ron Lissak. “I met Don almost 11 years ago when we began planning for the installation of the first PET scanner at Einstein/Montefiore. One of the leading nuclear medicine physicians in the nation, Don has been, and has remained through the years, a wonderful friend and mentor.” Blaufox has served as editor of numerous professional publications and has published more than 260 articles and book chapters. A collector of antique medical instruments and artifacts, he is the author of several books, including An Ear to the Chest: An Illustrated History of the Evolution of the Stethoscope, published in 2002. “MicroPET has the potential to revolutionize animal studies of disease models by providing more efficient and accurate data on growth, response to therapy, and systemic effects in all types of animal models,” said Blaufox.

Albert Einstein College of Medicine

NRC Looks at New Regulations

The Nuclear Regulatory Commission (NRC) announced on January 4 its plans to consider amending regulations to improve, update, and clarify requirements for the possession and use of products containing radioactive material. The NRC has authority to issue general and specific licenses for the use of byproduct material and to grant exemptions from licensing for beneficial uses of licensed material where the exemption will not constitute an unreasonable risk. Commission regulations currently have 15 exemptions from licensing for byproduct material. Examples include watches and smoke detectors containing certain amounts and types of radioactive material. The proposed improvements and updates to the exemptions include the following changes: (1) Transfers of products and materials to persons exempt from licensing would have to be reported by the next January 31 date. Currently, such reports are required only once every 5 years. (2) Exempt amounts of radioactive material could not be bundled together into a single product if it would create a radiation level above what was anticipated in authorizing the exempt use. (3) Extraneous provisions of the regulations would be removed by deleting exemptions for products that are no longer being distributed. (4) A specific exemption from licensing requirements would be granted to smoke detectors containing only specified small amounts of $^{241}$Am. In addition, the NRC proposes to clarify the steps general licensees must take if they wish to transfer a product to a specifically licensed status. The proposed rule was published January 4 in the Federal Register, and comments will be accepted until March 20.
should be submitted through the NRC rulemaking Web site at: http://ruleforum.llnl.gov/

The NRC also announced on January 12 the opening of a narrow window during which it sought public comment on several issues concerning the protection and security of radiation sources, as part of requirements under the Energy Policy Act of 2005. This legislation established the Radiation Source Protection and Security Task Force, with the NRC as its chair, to evaluate and provide recommendations relating to the security of radiation sources in the United States from potential criminal or terrorist threats, including acts of sabotage, theft, or use of a radiation source in a radiation dispersal device. The task force is comprised of representatives from more than a dozen federal agencies and departments. The task force’s efforts have focused for the most part on category 1 and 2 sources as defined by the International Atomic Energy Agency’s Code of Conduct on the Safety and Security of Radioactive Sources.

The topics on which the NRC sought comment included: (1) the list of sources requiring security because of their public health risk or potential attractiveness to terrorists; (2) the national system for recovery of lost or stolen radiation sources; (3) safe and secure storage of radiation sources when not in use; (4) the national source tracking system for radiation sources; (5) a national system for proper disposal of radiation sources; (6) import and export controls; (7) procedures for improving security and control for use and storage of radiation sources; (8) procedures for improving the security of transportation of sources; (9) background checks for individuals with access to sources; and (10) alternative technologies that could perform all or some of the functions that use radiation sources. The comment period closed on February 10, but the topics addressed are informative in that they suggest areas in which changes to current rules may be considered.

Nuclear Regulatory Commission

Michigan Physician Receives iBOT System

Ben Dwamena, MD, a nuclear medicine physician at the Ann Arbor (MI) Veterans Affairs (VA) Hospital and clinical assistant professor of radiology at the University of Michigan, made national news in November when he received an Independence iBOT 4000 mobility system. Dean Kamen, inventor of the Segway transporter, designed the iBOT in partnership with Johnson & Johnson. It uses a combination of electronics, sensors, and software components to provide new levels of freedom and accessibility for individuals with disabilities. A 1998 traffic accident left Dwamena with a quad-3 disability and some remaining upper mobility. He learned about the iBOT system from a report on the ABC newsmagazine “20/20.” With the push of a button, the chair elevates users to move at eye level and to reach high places independently. The front wheels rotate up and over the back wheels while users remain seated at an elevated position. Stair functions and 4-wheel functions enable users to safely climb up and down stairs, climb curbs, and travel over uneven terrain, such as grass, gravel, and sand. “The iBOT will provide me with greater freedom and accessibility, both on the job and at home,” said Dwamena. Interviewed by Ann Arbor reporters in late December after more than a month’s experience with the new device, he noted that his range of personal mobility, both in and outside the workplace, had increased significantly. Face-to-face conversations, once impossible without asking colleagues and patients to be seated, are now possible as well. “The eye-to-eye contact is very nice,” said Dwamena.

Mary Free Bed Hospital
Grand Rapids, MI

(Continued from page 15N)

including the SNM, are expected to respond to the ATA document in the coming months. In addition, increasing numbers of innovative studies, such as the remnant ablation research by Pacini et al. and reports of highly accurate predictive nuclear medicine imaging techniques, may spur frequent revisions by the ATA and other groups.

The complete guidelines are available online from the ATA at www.thyroid.org/professionals/publications/guidelines.html. ©
Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Many selections come from outside the standard canon of nuclear medicine and radiology journals. Note that although we have divided the articles into diagnostic and therapeutic categories, these lines are increasingly blurred as nuclear medicine capabilities rapidly expand. Many diagnostic capabilities are now enlisted in direct support of and, often, in real-time conjunction with therapies. 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.

DIAGNOSIS

FROM THE LITERATURE

Prognostic Value of Normal MPI in CAD

In an article published in the January 1 issue of the American Journal of Cardiology (2006;97:1–6), Schinkel et al. from the Erasmus Medical Center (Rotterdam, The Netherlands) reported on the long-term prognostic and predictive capabilities of stress 99mTc-tetrofosmin SPECT in patients with coronary artery disease (CAD). The study involved identification and follow-up of 147 consecutive patients with previous myocardial infarction and/or myocardial revascularization, who underwent exercise bicycle or high-dose dobutamine-atroline stress 99mTc-tetrofosmin myocardial perfusion imaging and had normal results both during stress and at rest. In the follow-up period of 4–8 years, 20 patients (14%) died, 10 (7%) of whom died as a result of cardiac causes. Twelve patients (8%) experienced nonfatal myocardial infarction. Annual cardiac death rates were 0.5% during the years 1–3 and 1.3% in years 4–6. Rate-pressure products at rest and rate-pressure products at peak stress were independent predictors. The authors concluded that regardless of the degree of viability on PET imaging, early intervention may be associated with improved survival in patients with heart failure.

American Journal of Cardiology

PET and Myocardial Viability Testing

Tarakji et al. from the Cleveland Clinic Foundation (OH) reported in the January 17 issue of Circulation (2006;113:230–237) on the use of 18F-FDG PET to identify patients with advanced left ventricular systolic dysfunction for whom revascularization might lead to improved survival. The retrospective analysis included survival data on “early intervention” in 765 patients with advanced left ventricular systolic dysfunction (ejection fraction ≤35%) and with no significant valvular heart disease who underwent 18F-FDG PET imaging. Early intervention was defined as any cardiac intervention (surgical or percutaneous) within the first 6 months after the imaging study. Almost one-third of patients (230 patients, 30%) underwent early intervention. Of these, 25% underwent open heart surgery, 5% underwent percutaneous revascularization, and 70% were treated medically. The authors used 39 demographic, clinical, and imaging variables to propensity-match 153 of the 230 patients undergoing early intervention with 153 of the patients who were treated medically. The early intervention group experienced a markedly lower 3-year mortality rate than the group that did not undergo early intervention (15% and 35%, respectively). The authors concluded that regardless of the degree of viability on PET imaging, early intervention may be associated with improved survival in patients with heart failure.

Circulation

Challenge for Exercise or Pharmacologic PET?

In an article that received international media attention as individuals headed back to the gym in early January, Namdar et al. from University Hospital (Zurich, Switzerland) reported in the January 17 issue of the Journal of the American College of Cardiology (2006;47:405–410) on a PET study indicating that caffeine intake decreases exercise-induced myocardial flow reserve. The study included 10 healthy volunteers in whom 15O-H2O PET was used to quantify regional myocardial blood flow (MBF) at rest and immediately after supine bicycle exercise in both normoxia and inhalation-simulated hypoxia conditions. Imaging was repeated 50 minutes after oral ingestion of caffeine (200 mg). The authors found that although resting MBF was not affected by caffeine at normoxia, it was significantly increased at hypoxia. Exercise-induced hyperemic MBF, however, decreased significantly after caffeine at both normoxia (by 22%) and hypoxia (by 39%). The surprising conclusion was that in healthy individuals, “a caffeine dose corresponding to 2 cups of coffee significantly decreased exercise-induced MFR at normoxia and was even more pronounced during [simulated] exposure to altitude.”

Journal of the American College of Cardiology
of the Journal of the American College of Cardiology (2006;47:411–416) on a study comparing uptake and retention of $^{13}$N-ammonia after treadmill exercise and dipyridamole stress. The study included 26 patients who underwent treadmill exercise and dipyridamole stress $^{13}$N-ammonia PET imaging. After analysis of results, treadmill exercise was found to yield larger summed stress scores, larger summed difference scores, and larger left ventricular defect sizes. The authors concluded that in patients able to achieve adequate exercise, treadmill $^{13}$N-ammonia PET might more accurately reflect the true myocardial ischemic burden and so “might be the preferred method of stress for routine $^{13}$N-ammonia PET myocardial perfusion imaging.”

Journal of the American College of Cardiology

PET Validation of Microdialysis Efficacy

In the December issue of the Journal of Neuroradiology (2005;32:348–351), Sarrafzadeh et al. from the Humboldt University (Berlin, Germany) reported on the use of $^{15}$O-H$_2$O and $^{18}$F-FDG PET to assess the efficacy of microdialysis in the detection of ischemia in patients who had experienced subarachnoid aneurysmal hemorrhage. The study included 15 such patients in whom a microdialysis catheter was inserted immediately after aneurysm clipping into the brain parenchyma most likely to be affected by vasospasm. Dialysates were collected hourly and analyzed. $^{15}$O-H$_2$O and $^{18}$F-FDG PET scans were performed between 2 and 17 days after hemorrhage. $^{15}$O-H$_2$O PET data were coregistered with data from CT scans to provide quantification of regional cerebral blood flow within the microdialysis regions of interest. $^{15}$F-FDG PET data were evaluated by visual analysis, and regions of glucose hypometabolism were observed in 10 patients with symptoms of ischemia, who also had lower regional cerebral blood flow measures than asymptomatic patients. The measured dialysates were significantly higher in symptomatic than asymptomatic patients, with glutamate showing the closest correlation with regional cerebral blood flow. The microdialysis parameters were well correlated with glucose hypometabolism as measured by PET and with symptoms of ischemia. The authors concluded that “microdialysis is a useful tool to monitor ischemia, especially in patients with high-grade subarachnoid aneurysmal hemorrhage” and that PET provides both validation of the technique and a useful adjunct.

Journal of Neuroradiology

PET in Aging and Parkinson’s Disease

In an article e-published ahead of print on January 18 in the Journal of Cerebral Blood Flow and Metabolism, Bohnen et al. from the University of Michigan School of Medicine (Ann Arbor) reported on PET imaging of $^{11}$C-dihydroxytetrabenazine (DTBZ) and PET imaging to estimate striatal binding of type-2 vesicular monoamine transporter. Patients with PD were also evaluated in the clinically defined “off” state using 3 assessment scales. Imaging results indicated an age-related decline in striatal DTBZ binding in normal participants of approximately 0.5% per year. In individuals with PD, specific DTBZ binding was reduced in the caudate nucleus (by 44%), anterior putamen (by 68%), and posterior putamen (by 77%). DTBZ binding was also reduced by 50% in the substantia nigra of patients with PD and striatal and midbrain DTBZ binding was asymmetric in these patients, with greatest reductions contralateral to the most affected limbs. The authors concluded that “$^{11}$C-DTBZ PET imaging displays many properties necessary for a PD biomarker.”

Journal of Cerebral Blood Flow and Metabolism

PET and Congenital Hyperinsulinism

The utility of $^{18}$F-DOPA PET imaging in congenital hyperinsulinism (CHI) was reported by 2 groups in January. Both reports noted that until quite recently, preoperative differentiation between the focal and diffuse forms of the disease (which require different treatment approaches) have relied on technically demanding and invasive catheterization techniques. Otonkoski et al. from the University of Helsinki (Finland) reported in the January issue of Diabetes (2006;55:13–18) on a study designed to evaluate the ability of $^{18}$F-DOPA PET to provide noninvasive diagnoses. The study included 14 patients with CHI (ages, 1–42 months). In 5 patients, focal uptake of the tracer was easily visualized, and the standard uptake value (SUV) in the focal areas was more than 50% higher than that in the rest of the pancreas. Subsequent successful resections of the areas of focus were performed, and these matched the focal areas indicated on PET. Diffuse uptake of $^{18}$F-DOPA was seen throughout the pancreas in the remaining 9 patients, consistent with diffuse pathology. The authors concluded that “$^{18}$F-DOPA PET is a promising noninvasive method for the identification and localization of the focal form of CHI.”

In a study e-published ahead of print on January 10 in the Journal of Clinical Endocrinology and Metabolism, researchers from France, Belgium, and the United States reported on an immunohistochemical validation study of this technique for preoperative differentiation between focal and diffuse CHI. de Lonlay et al. studied 4 focal and 3 diffuse CHI pancreatic surgical specimens using anti-DOPA decarboxylase and proinsulin antibodies. Immunohistochemical detection of DOPA decarboxylase showed diffuse staining of Langerhans islets in the entire pancreas in all diffuse cases but showed dense focal staining in all focal cases. Additional immunohistochemical comparisons confirmed this differentiation of results. The
authors also noted that diffuse 18F-DOPA uptake observed clinically on PET in 1 child with diffuse CHI before treatment disappeared completely after carbidopa administration, suggesting that pancreatic cells can take up amine precursors and contain DOPA decarboxylase. They concluded that these results validated 18F-DOPA PET as a consistent test to differentiate between diffuse and focal CHI.

*Cerebral Oxygen Metabolism in Stroke*

In an article e-published ahead of print on December 29 in Stroke, Kuroda et al. from the Hokkaido University Graduate School of Medicine and the Sapporo Medical University (Japan) reported on the use of SPECT to clarify whether oxygen extraction fraction (OEF) is elevated in all patients with reduced cerebral blood flow (CBF) and impaired cerebral reactivity (CVR; type 3) on SPECT and, if not, to characterize the underlying pathology when OEF is normal but CVR is impaired. The study included 46 patients with decreased CBF and CVR on N-isopropyl-p-123I-iodoamphetamine SPECT in the ipsilateral middle cerebral artery territory attributable to occlusive carotid diseases. Additional functional parameters were assessed in all patients by 15O-gas PET, and neuronal integrity was evaluated in 19 patients with 11C-flumazenil (11C-FMZ) PET. The authors found that OEF was significantly elevated in 20 (43.5%) of 46 patients classified as CVR type 3. The remaining 26 CVR type 3 patients had normal OEF. OEF was significantly correlated with cerebral metabolic rate for oxygen and 11C-FMZ binding potential but not with other parameters. These results suggest that type 3 patients with reduced CBF and CVR “may be divided into 2 pathophysiologically different subgroups: misery perfusion attributable to hemodynamic compromise and matched hypometabolism attributable to incomplete infarction.” Thus, the authors concluded, patients who are “type 3 but normal OEF may represent a transition stage from misery perfusion to matched hypometabolism.”

**SPECT Analysis of Recovery from Aphasia**

Jodzio et al. from the University of Gdansk (Poland) reported in the December issue of Neuropsychological Rehabilitation (2005;15:588–604) on a study of the relationship between poststroke recovery from aphasia and changes in cerebral blood flow (CBF) and used SPECT to assess right hemisphere (RH) involvement in restitution of language. The study included 24 right-handed patients with acute aphasia after left hemisphere (LH) ischemic stroke who were examined 2 times with a 6-month interval. 99mTc-ECD SPECT imaging and language assessment tasks were performed at each examination. The authors found that overall initial CBF was not a predictor for future language recovery. Increased perfusion of the RH during the 6-month interval paralleled recovery from aphasia, with a correlation between changes in the right parietal CBF (but not the left) and changes in several language abilities. However, only CBF values in the LH predicted performance on the language tests at both initial and follow-up examinations. The authors concluded that “the cerebral mechanism associated with early recovery from aphasia is a dynamic and complex process that may involve both hemispheres” and suggested that this mechanism involves functional reorganization in the speech-dominant (damaged) hemisphere and regression of hemodynamic disturbances in the non-dominant (structurally intact) hemisphere.

**Neuropsychological Rehabilitation PET Imaging of Pulmonary Endotoxin Inflammation**

In an article e-published ahead of print on January 19 in the Journal of Applied Physiology, Chen et al. from the Washington University School of Medicine (St. Louis, MO) reported on a study of 18F-FDG PET imaging of pulmonary endotoxin-caused inflammation. The study included 18 healthy volunteers divided into 3 groups of 6 for a dose escalation study of endotoxin instillation (at 1, 2, and 4 ng/kg). Each volunteer received a baseline PET scan. Endotoxin was delivered by bronchoscopy into a segment of the right middle lobe, and each volunteer underwent PET imaging approximately 24 hours later, followed by bronchoalveolar lavage (BAL). BAL neutrophil counts were significantly higher in the highest dose group. Autoradiography performed on cells harvested by BAL showed specific deoxyglucose uptake limited to neutrophils. The rate of 18F-FDG uptake was greatest in the highest dose group, with a consistent increase in the rate of uptake after endotoxin instillation compared with baseline. The authors concluded that “the inflammatory response to low-dose endotoxin in a single lung segment can be visualized and quantified by imaging with 18F-FDG PET.”

Journal of Applied Physiology

PET/CT and NSCLC in High TB Areas

Low et al. from the Singapore General Hospital reported in the January issue of Respirology (2006;11:84–89) on a study of the utility of PET/CT in the evaluation of non–small cell lung cancer (NSCLC) in Singapore, where tuberculosis (TB) rates are moderately high compared with those in Europe and North America. This retrospective study included a large group of patients who underwent PET/CT imaging for suspected NSCLC. Seven patients were found to have a solitary pulmonary nodule, for which PET/CT yielded a sensitivity of 100% and specificity of 75%. One patient’s PET/CT was false-positive as a result of active tuberculosis. The authors identified 41 patients from the larger group who underwent PET/CT for staging of NSCLC, with 1 false-positive (active tuberculous lymphadenitis) and 1 false-negative. This yielded a sensitivity of 92.3% and a specificity
of 95%. The authors concluded from these and histologic confirmation data that PET/CT for the evaluation and follow-up of solitary pulmonary nodules and NSCLC can provide “additional useful information to conventional radiology for treatment planning and a non-invasive determination of prognosis” but cautioned that “physicians need to be aware of the limitations of this imaging modality, particularly when tuberculosis has a high prevalence in the population.”

**11C-mHED and 18F-FDG PET in Pheochromocytoma**

In an article e-published ahead of print on January 19 in the *Annals of Surgical Oncology*, Mann et al. from the University of Washington (Seattle, WA) reported on the utility of a combination of 18F-FDG and norepinephrine analogue 11C-metahydroxyephedrine (11C-mHED) PET in the diagnosis and localization of pheochromocytomas. The study included 14 patients with suspected pheochromocytoma who underwent either CT or MR imaging and 131I-metaiodobenzylguanidine (131I-MIBG) planar imaging. PET imaging was performed using 11C-mHED as a tracer for dynamic adrenal imaging and a torso survey and 18F-FDG for a torso survey. Pheochromocytoma was confirmed by pathology in 8 patients. 131I-MIBG planar imaging failed to detect 1 or more confirmed sites of disease in 4 of these patients. 11C-mHED PET correctly identified all sites of confirmed disease. 18F-FDG-PET detected all sites of adrenal and abdominal disease in all 8 patients but did not identify bone metastases in 1 patient. 131I-MIBG and 18F-FDG PET were each negative in the 6 patients without pheochromocytoma, but 1 such patient with adrenal medullary hyperplasia had a positive 11C-mHED PET scan. The authors noted that PET scanning for pheochromocytoma offered both improved quality and resolution over current diagnostic approaches and concluded that “PET may significantly influence the clinical management of patients with a suspicion of these tumors and warrants further investigation.”

**Annals of Surgical Oncology**

**11C-MTO PET in Adrenocortical Tumors**

Hennings et al. from the Uppsala University Hospital and Uppsala Imanet AB (Sweden) reported on January 10 ahead of print in the *Journal of Clinical Endocrinology and Metabolism* on a study correlating 11C-metomidate (11C-MTO) PET in adrenocortical tumors with histopathologic findings. The retrospective study included a large pool of 11C-MTO PET studies that were matched to 75 histopathologic examinations from 73 individuals. These patients had been operated on or biopsied for adrenal tumors, with the following histopathologic diagnoses: adrenocortical adenoma (26), adrenocortical cancer (ACC; 13), adrenocortical hyperplasia (8), pheochromocytoma (6), metastasis (3), and tumors of nonadrenal origin (19). 11C-MTO PET showed a sensitivity of 89% and specificity of 96% in identifying adrenocortical origin of the lesions. Pheochromocytomas, metastases to the adrenal gland, and nonadrenal masses were tracer negative. PET was able to differentiate lesions >1–1.5 cm in diameter from normal adrenocortical tissue. Standard uptake values (SUVs) were higher in aldosterone hypersecreting adenomas, and the SUV ratio between tumor and the contralateral gland was significantly higher in all hormonally hypersecreting adenomas and in ACC. The authors concluded that 11C-MTO PET is a specific and sensitive method for diagnosing adrenocortical tumors, with special promise in the imaging work-up of adrenal incidentalomas, primary aldosteronism, or ACC.

*Journal of Clinical Endocrinology and Metabolism*

**PET/CT in Head and Neck Carcinoma**

In an article published in the January issue of the *Archives of Otolaryngology—Head and Neck Surgery* (2006;132;12–16), Ha et al. from the Johns Hopkins University School of Medicine (Baltimore, MD) reported on the role of PET/CT in the management of early- and advanced-stage primary head and neck squamous cell cancer. The study included 36 patients with previously untreated disease who underwent staging CT or MR imaging of the neck before undergoing PET/CT as part of initial diagnostic evaluations. PET/CT was found to provide additional information that confirmed existing treatment plans in 25 patients (69%) and altered management in 11 patients (31%). In the latter group, 6 patients’ tumors were upstaged. Treatment plans were altered in 4 of 8 patients with early-stage disease and 7 of 28 patients with advanced-stage disease. Eighteen of the patients progressed to surgery, and PET/CT correctly identified the primary tumor in

*Journal of Neurosurgery*

**PET and the “Wearing Off” Phenomenon in PD**

Nimura et al. from the Miyagi National Hospital (Japan) reported in the December issue of the *Journal of Neurosurgery* (2005;103:968–973) on the use of PET to elucidate the mechanisms behind the often observed “wearing-off” phenomenon that accompanies levodopa treatment for Parkinson’s disease (PD). The study included 3 patients who were experiencing the phenomenon. Each patient underwent 11C-raclopride PET imaging (once before and once 1 hour after levodopa administration) both before and after deep brain stimulation of the subthalamic nucleus (STN). Clinical features at all study periods were analyzed by 2 scales, and all scores on these scales were improved “dramatically” after deep brain stimulation. Before surgery, the administration of levodopa significantly reduced tracer uptake in the putamen. After surgery, the change in tracer uptake was almost unaffected by administration of levodopa. The authors concluded that “deep brain stimulation of the STN induces the stabilization of synaptic dopamine concentrations in the striatum and may attribute to the alleviation of levodopa-related motor fluctuations.”

*Journal of Neurosurgery*

**continued on page 32N**
(Continued from page 30N)

THERAPY

Radiolabeled Lym-1 with RIT in NHL

In an article published in the December issue of Cancer Biotherapy and Radiopharmaceuticals (2005;20: 662–670), Shen, from the University of Alabama (Birmingham), and collaborators from other institutions reported on splenic volume change and nodal tumor response in non-Hodgkin’s lymphoma (NHL) after radioimmunotherapy (RIT) using a radiolabeled Lym-1 antibody. The study included 29 patients with NHL who were treated with radiolabeled-Lym-1 and 9 breast cancer patients treated with radiolabeled ChL6, BrE-3, or m170. Each patient underwent CT splenic imaging before and after RIT. The authors found that in 13 of the 29 NHL patients, little or no change in splenic volume was noted after RIT, despite splenic radiation doses as high as 23.1 Gy. In the reference group of breast cancer patients, little or no change was noted in splenic volume after RIT, despite doses as high as 14.4 Gy. Splenic volumes decreased in 10 of the NHL patients and increased in the remaining 3 patients after RIT. The results also suggested that therapeutic remission was more likely when splenic volume decreased after RIT. Of the 10 NHL patients with a >15% decrease in splenic volumes after RIT, there were 5 complete responses and 7 partial responses. The authors concluded that RIT with radiolabeled-Lym-1 may benefit NHL patients with splenomegaly, “with reduction in splenic volume likely owing to a therapeutic effect on malignant lymphocytes.”

Cancer Biotherapy and Radiopharmaceuticals

Salvage 131I-Labeled mAb Therapy in Recurrent Brain Tumors

Reardon et al. from Duke University Medical Center (Durham, NC) reported in the January 1 issue of the Journal of Clinical Oncology (2006;24: 115–122) on the results of a study designed to assess the efficacy and toxicity of intraresection cavity 131I-labeled murine antitenascin monoclonal antibody 81C6 (131I-m81C6) in patients with recurrent malignant brain tumors. The study included 43 such patients with recurrent glioblastoma multiforme (33), anaplastic astrocytoma (6), anaplastic oligodendroglioma (2), gliosarcoma (1), and metastatic adenocarcinoma (1). Each patient was injected with 100 mCi of 131I-m81C6 directly into the surgically created resection cavity, followed by chemotherapy. Patients were followed for a median of 172 weeks. At the end of 1 year, 63% of the group of patients with glioblastoma multiforme or anaplastic astrocytoma were alive, and 59% of the patients with anaplastic astrocytoma or anaplastic oligodendroglioma were alive. Median overall survival for these 2 groups was 64 and 99 weeks, respectively. These survival rates are greater than those identified in retrospective studies of patients treated with surgery and 125I brachytherapy. Toxicity was termed “acceptable.” Administration of a fixed millicurie dose resulted in a wide range of absorbed radiation doses to the resection cavity. The authors noted that they are now conducting a phase II trial using patient-specific 131I-m81C6 dosing to deliver 44 Gy to the resection cavity followed by standardized chemotherapy.

Journal of Clinical Oncology