Researchers at Walter Reed Army Medical Center (WRAMC) in Washington, DC, have received Food and Drug Administration (FDA) approval to begin a clinical trial to assess the efficacy of LeuTech®, a 99mTc-labeled monoclonal antibody developed by Palatin Technologies, Inc. (Princeton, NJ), in imaging early-stage inhalation anthrax infection. In a rapidly unfolding series of events that were indicative of the nation's response to recent terrorist activities, Palatin was granted an Investigational New Drug (IND) approval in what well may be record time. Because of widespread agreement on the potential efficacy of LeuTech, patients with credible exposure to anthrax may now be imaged with this technique.

Background

Mathew Thakur, PhD, Professor of Diagnostic Radiology and Nuclear Medicine at Thomas Jefferson University (Philadelphia, PA), was the earliest nuclear medicine practitioner to work with the 99mTc-labeled antibody that would become LeuTech. Along with Carol Marcus, MD, Professor of Nuclear Medicine at the University of California at Los Angeles Harbor Medical Center (Los Angeles, CA), he imaged more than 70 patients in the early 1990s. “I have a long interest in imaging of infection, and this method provided great advantages over previous work with 111In-oxine and other agents,” says Thakur. “Not only is technetium less expensive than indium, but with this method you don’t have to draw the patient’s blood and perform white cell labeling in vitro prior to reinjection. The results of these early investigations were highly promising in terms of ease, speed, sensitivity, and specificity.”

Palatin, a development-stage biopharmaceutical company, began work with what would become LeuTech in 1996. LeuTech’s ability to bind with high affinity and specificity to a carbohydrate antigen, CD-15, on human polymorphonuclear leukocytes in vivo made it ideal for functional imaging in a range of infections, including appendicitis, osteomyelitis, bowel infections, and postsurgical infection. In consultations with clinicians, the need for a method to provide more reliable diagnosis of appendicitis was identified as an initial application of the LeuTech technology. “Because of the danger of rupture, common practice has been to recommend immediate surgery for a patient with an admission diagnosis of suspected appendicitis,” says Thakur. “The widely reported result is that 15%–40% of these surgeries turn out to be unnecessary.” Spiral CT, the current method of choice for diagnosing appendicitis, requires administration of contrast media, which is especially difficult in pediatric patients already in pain.

Earlier this year, the FDA Medical Imaging Drugs Advisory Committee (MIDAC) reviewed a Biologics License Application from Palatin for LeuTech for the diagnosis of equivocal appendicitis. “We received a unanimous vote from the FDA MIDAC that LeuTech is safe and effective,” says Perry Molinoff, MD, executive vice-president of research and development at Palatin Technologies. This decision was based on submitted studies spanning a 3-year period and culminating in a 10-site phase 3 trial including 203 patients. LeuTech detected appendicitis in 91% of patients shown to have the infection on review of a pathologic sample and correctly predicted the absence of appendicitis in 86% of patients without the infection. The negative predictive value of LeuTech was 96%. No significant adverse effects were noted. Palatin recently reported positive interim phase 2 clinical trial results for LeuTech in the diagnosis of osteomyelitis. “At the request of the FDA and to resolve manufacturing and process validation issues, we are working very closely with our manufacturer and Mallinckrodt, a subsidiary of Tyco Healthcare, to gain marketing approval of LeuTech as expeditiously as possible,” says Molinoff.

Anthrax as a Target

In October, inhalation anthrax suddenly went to number one on the list of infections for which early diagnostic tests were needed. “Once anthrax spores were discovered in the United States in 1977, the US government, working with the Armed Forces Institute of Pathology (AFIP), developed a highly sensitive test for anthrax spores called immunofluorescence [IF]. However, this test is tricky to perform and requires a special microscope to view the results,” says Thakur. “To expedite the diagnosis of inhalation anthrax, we are investigating the use of LeuTech for non-invasive diagnosis of this deadly disease.”
States, there was a real urgency to scour the various methods that currently exist to determine whether any offered promise in the early diagnosis of anthrax infection,” says Robert Bridwell, MD, associate professor of nuclear medicine and radiology at the Uniformed Services University of the Health Sciences (Bethesda, MD) and a member of the staff at WRAMC. “I was aware of the anti-CD15 antibody’s effectiveness in imaging infection, and we decided to pursue this.” Bridwell called Thakur and representatives of Palatin and confirmed the efficacy of the technique in appendicitis, osteomyelitis, and other infections. Working with staff from Palatin, Bridwell and others developed a protocol for early evaluation of asymptomatic patients who could be designated as having experienced “credible exposure” to anthrax spores. The imaging arm of the protocol was built into a much larger protocol.

“In addition to the ability to pinpoint infection before mediastinal widening would be visible on CT,” says Bridwell. “LeuTech offered a number of advantages in the clinical setting.” One of the most important, especially if the technique was to be applied in emergency medicine settings, was ease of administration and speed. In the “shake and bake” kit technique, the technetium solution is mixed with lyophilized monoclonal antibody, left to “label” for 30 minutes, and then injected into the patient. Imaging, either under a gamma camera or with SPECT, is rapid. In clinical trials of LeuTech in equivocal appendicitis, 37% of positives were identified in less than 5 minutes and 80% within 30 minutes.

“The challenge for us was to get FDA permission to begin a trial and to get it quickly,” says Bridwell. He credits “an astonishing level of cooperation among everyone involved” for speeding the process along. During late October, he says, “we worked on developing a protocol. We worked right through the night of October 25 to submit a proposal on the following day. The next week, preliminary approval was granted by the WRAMC Human Research Review Committee.” On November 5, Palatin announced that it had teamed with WRAMC under an agreement made through the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., to study patients exposed to anthrax. Later that week, the FDA issued IND approval for the submitted protocol.

“A key objective of our work is to define and validate a logical imaging protocol for the detection of early acute pulmonary anthrax infection in asymptomatic patients with a credible exposure to anthrax,” says Bridwell. “Our protocol offers a number of functional advantages to both patients and practitioners. Utilizing a functional radioisotope, it is hoped that we will be able to visualize the infection at its earliest stages, before any anatomical changes have taken place. In addition to the relative simplicity and what we believe from previous applications to be diagnostic accuracy, we built into our protocol a 7-day re-imaging with the technique, allowing us to identify patients who may have developed mediastinal or hilar inflammation after the initial imaging sequence.”

Ready with the protocol and encouraged by support from industry, nuclear medicine colleagues, and government regulatory and legislative bodies, Bridwell and the group at WRAMC were ready to image patients by the second week of November. Since that time and as of Newsline press time, only one additional patient in the United States has been diagnosed with inhalation anthrax, an elderly woman in Connecticut. No patients fitting the inclusion criteria of the protocol have been imaged with LeuTech. “Despite the fact that we have not produced any images of inhalation anthrax that can validate our protocol,” says Bridwell, “this has been a substantial and proactive step in getting a promising technique to a point where it is ready when circumstances call for it.”

Next Steps

A recent summary of medical findings in the first 10 patients treated for inhalation anthrax infection since September 11 provides evidence of the need for a sensitive early diagnostic method. In Emerging Infectious Diseases (2001;7:1–26), Jernigan et al. from the Centers for Disease Control and Prevention (Atlanta, GA) preface their remarks on radiologic examination by noting: “The nondistinctive nature of the initial phase of inhalational anthrax presents a diagnostic challenge.” None of the 10 patients had an initially normal chest X-ray, and among multiple abnormalities noted were mediastinal widening, para-tracheal fullness, hilar fullness, pleural effusions, and parynchymal infiltrates. However, these abnormalities varied widely and were subject to varied interpretations. Although chest CT was more sensitive than plain film in revealing mediastinal lymphadenopathy, several clinicians interviewed by Newsline noted that such involvement is characteristic of mid-stage involvement and cannot be said to qualify as “early” diagnosis. Nor did blood work prove a reliable early indicator of involvement. In those patients who sought medical care in the initial phase of illness, the total white blood cell count was normal or only slightly elevated.

For the group at WRAMC and for Palatin, the challenge is to gain timely access to patients who have experienced credible exposure to anthrax spores. In addition to the approved “credible exposure” protocol, Palatin is also developing a protocol for imaging of acute cases of inhalation anthrax. “For both these protocols, we’re hoping to get military and civilian authorities to agree to mechanisms that would allow for more rapid evaluation,” says Molinoff. “We’re convinced that LeuTech has the ability to identify the presence of infection regardless of the causative microorganism. Its ability to do so in anthrax is of vital importance, and we are grateful for the support we have received throughout the course of this project.” Should the initial results of this clinical trial demonstrate LeuTech’s utility in the diagnosis of inhalation anthrax, Palatin will initiate discussions with the FDA to provide LeuTech to other medical institutions caring for patients with a credible exposure to anthrax. “If the utility of LeuTech is validated, it will help not only in diagnosing patients early
Mid-Winter Meeting to Highlight Education

The Educational Symposium offered at this year’s Society of Nuclear Medicine (SNM) Mid-Winter Meeting will span 2 days and cover a wide range of practice and applications in nuclear medicine. Although the Mid-Winter Meeting, to be held in Scottsdale, AZ, February 9 and 10, includes governance and other planning sessions, the highlight for attendees is the Educational Symposium, which features noted clinicians and researchers. This year’s symposium will include a full-day session for nuclear medicine technologists, hosted by the SNM–Technologist Section.

You may preregister for the meeting on-line at www.snm.org, where a detailed outline of course offerings, continuing education credits, and additional information about travel are available.

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2002 SNM Mid-Winter Educational Symposium
February 9–10, 2002 • Scottsdale, Arizona

**Saturday, February 9**
8:00 am–5:30 pm  Nuclear Medicine for the Technologist
Hosted by the SNM–TS

8:00 am–5:30 pm  Image Fusion: Hardware and Software Solutions
Hosted by the SNM Computer and Instrumentation Council

8:00 am–12:00 noon  Update on Radiolabeled Antibody Therapy of Lymphoma
Hosted by the SNM Therapy Council

1:30–5:30 pm  The Role of Nuclear Medicine in Treatment Monitoring and Treatment Planning
Hosted by the SNM Correlative Imaging Council

**Sunday, February 10**
9:00 am–6:00 pm  PET: Instrumentation, Clinical Applications, and Case Presentation
Hosted by the Academy of Molecular Imaging/Institute for Clinical PET and the SNM

9:00 am–6:00 pm  The Socioeconomic Aspects of Nuclear Medicine: Affecting the Internal and External Factors that Impact Your Practice
Hosted by the American College of Nuclear Physicians

9:00 am–1:00 pm  Recent Advances in Pediatric Nuclear Medicine
Hosted by the SNM Pediatric Imaging Council

9:00 am–1:00 pm  Design Parameters for Radionuclide Therapy Clinical Trial Development
Hosted by the SNM Clinical Trials Council

2:00–6:00 pm  Cardiovascular Diagnosis in 2002
Hosted by the SNM Cardiovascular Council and the American Society of Nuclear Cardiology (ASN C)

2:00–6:00 pm  Clinical and Emerging Applications of Brain Imaging in Nuclear Medicine
Hosted by the SNM Brain Imaging Council
Medicare’s New Enrollment Procedures for Independent Diagnostic Testing Facilities

Beginning on October 1, the Centers for Medicare and Medicaid Services (CMS) implemented major revisions to Form 855 enrollment materials and to its enrollment requirements for Medicare providers and suppliers. Although most Medicare carriers will be accepting the old forms for a short transition period, the new forms are expected to be required by the end of the year. The new forms and enrollment policies will be available to all providers on the CMS Web site (www.cms.gov). Among the enrollment policy changes are significant changes to CMS treatment of independent diagnostic testing facilities (IDTFs).

Overview

Medicare payment for diagnostic tests is permitted only if the service is performed by a physician, a physician group, an approved supplier of portable x-ray services, or an IDTF. The IDTF, replacing the old independent physiological laboratory, is the principal vehicle by which free-standing imaging centers relate to Medicare. Physicians who assume “supervising physician” duties must be aware that their responsibilities for quality assurance of IDTFs are significant.

The rules for IDTFs are found at 42 Code of Federal Regulations §410.33 and prescribe requirements for the quality of the testing performed, the proper operation and calibration of equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. At least one supervising physician is responsible for quality control, such as equipment calibration, and other physicians are responsible for supervising diagnostic tests and assuring the qualifications of technologists who perform tests under their supervision.

Supervision Requirements

CMS has instructed carriers that supervising physician functions can be met separately at each IDTF location, regardless of the number of physicians involved. For example, a portable x-ray operation of a mobile ultrasound unit registered as an IDTF will be allowed to use different supervisory physicians at different locations. The IDTF must arrange for a specific physician to supervise the tests at each location. Many diagnostic tests can be performed under the general supervision of a physician, but some studies require direct or personal supervision.

Medicare rules define “general supervision” to mean that the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. For these studies, the training of the technologists who actually perform the diagnostic procedure and the maintenance of necessary equipment and supplies are the continuing responsibilities of the physician. Nevertheless, CMS does not impose a physical distance limit between the supervising physician and the location at which the test is performed. The only obligation is that the supervising physician be licensed in the state in which he or she is acting as a supervising physician. For procedures that require “direct supervision” at an IDTF, the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. The physician need not be present in the room during the procedure, however.

IDTF Enrollment

An attachment to the Form 855B enrollment application must identify each supervising physician. A group practice of physicians cannot be designated broadly. Each physician member of the group practice who actually provides supervision service must be listed separately. Every supervising physician is not required to be a member of the medical group; the group can make arrangements with independent contractor physicians to perform the supervising service. All modifications, additions, and updates to the list of supervising physicians must be communicated to the Medicare carrier by adding any new supervising physician to Form 855 within 30 days of the change. Medicare carriers can be expected to check to determine whether the supervision requirements for these facilities are being met. To substantiate this, the carrier can ask for written procedures from the IDTF describing how this is being accomplished.

Form 855 requires the applicant to supply a list of all procedure codes that the IDTF will perform. The applicant must also provide a list of the equipment it will use to perform those tests. The identity of all physicians for whom the IDTF entity will bill for interpretations of the diagnostic tests they perform (i.e., global billings) must be furnished. The interpreting physician(s) listed should be qualified to perform the interpretations of the types of test codes listed in the application. Each nonphysician technologist who performs the diagnostic tests must also be identified. If the nonphysician is state licensed or certified, the applicable license and/or certification must be attached for review by the carrier. Technologists do not have to be W-2 employees of the IDTF and may contract with the IDTF.

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Ordering Diagnostic Tests

A supervising physician at an IDTF, even for a mobile facility, is not authorized to order tests to be performed at the facility. Except for chiropractic studies and screening mammograms, the physician who orders the test must have a relationship with the beneficiary before the performance of the testing and must have been treating the beneficiary for a specific medical problem. The rule specifically requires that the test be ordered in writing.

Billing Issues

Although an IDTF is a provider of the technical component of diagnostic testing services, it is not restricted to billing the technical component only. IDTFs can bill “globally” for both the technical and professional components of the diagnostic test and interpretative services.

To allow the IDTF to bill for the professional component, each interpreting physician must make individual reassignment to the IDTF. Group reassignments are not permitted. Carriers have been instructed to retain on file all reassignment forms. If the interpreting practitioner is an employee of the IDTF, in accordance with Medicare Carriers Manual Section 3060.1, the IDTF must submit a reassignment of benefits form (Form 855R), which must be signed by the interpreting physician.

The most typical scenario that can be anticipated is for the interpreting physician to be a member of a group with an independent contractor agreement with the IDTF for performing the interpretation on the premises that the IDTF owns or leases. In this situation, under Medicare’s rules (Carriers Manual Section 3060.3C) the IDTF must submit to the carrier a reassignment of benefits form signed by each independent contractor.

If an IDTF wants to bill for a professional interpretation performed by an independent practitioner off the premises of the IDTF, the IDTF must meet the conditions shown in Carriers Manual Section 3060.5 for purchased interpretations. In this arrangement, Medicare would permit the IDTF to bill for diagnostic test interpretations when: (a) the tests are initiated by a physician or medical group that is independent of the IDTF and the physician or medical group providing the interpretations; (b) the IDTF submits either an assigned or unassigned claim for both the tests and the interpretations thereof; and (c) the physician or medical group providing the interpretations does not see the patient. For the application of the purchased interpretation rule, no formal reassignment of benefits is necessary, because the purchaser of the test—the IDTF—is considered the supplier of the test.

Physician Office Versus IDTF?

A major question for some carriers has been whether a physician office that performs diagnostic tests must enroll as an IDTF. This is a relevant question, because many enrolled provider types may perform and bill for diagnostic tests on the physician fee schedule without becoming an IDTF. Basically, a physician office or a part of a hospital may bill for the diagnostic tests without being enrolled as an IDTF. CMS has developed criteria to distinguish between a physician office and an IDTF. An applicant that is considered to be a physician office or a part of a hospital can bill for the diagnostic tests without being enrolled as an IDTF if: (a) it is a physician practice that is owned, directly or indirectly, by one or more physicians or by a hospital; (b) the entity primarily bills for physician services (e.g., evaluation and management [E & M] codes) and not for diagnostic tests; (c) it furnishes diagnostic tests primarily to patients whose medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice; and (d) the diagnostic tests are performed and interpreted at the same location where the practice physicians also treat patients for medical conditions. However, if a substantial portion of the entity’s business involves the performance of diagnostic tests, the diagnostic testing services may be a sufficiently separate business to require separate enrollment as an IDTF. In that case, the physician or group may continue to be enrolled as a physician or a group practice of physicians but must also enroll as an IDTF.

Special criteria have been developed to guide carriers to permit radiologists’ offices to maintain enrollment as physician groups rather than IDTFs. These include: (a) the practice is owned by radiologists, a hospital, or both; (b) the owner radiologists and any employed or contracted radiologists regularly perform physician services (e.g., test interpretations) at the location where the diagnostic tests are performed; (c) the billing patterns of the enrolled entity indicate that the entity is not primarily a testing facility and that it was organized to provide the professional services of radiologists (e.g., the enrolled entity should not bill for a significant number of purchased interpretations, it should rarely bill only for the technical component of a diagnostic test, and it should bill for a substantial percentage of all of the interpretations of the diagnostic tests performed by the practice); and (d) a substantial majority of the radiological interpretations are performed at the practice location where the diagnostic tests are performed.

Site Visits

An IDTF must receive a site visit before enrollment. The site visit should normally be accomplished within the 60-day processing time during which the carrier will verify that the information on Form 855 is correct, verifiable, and in accordance with IDTF requirements. To the maximum extent practical, site visits are performed on an announced basis. Additional follow-up site visits are performed based upon carrier judgment. For tests performed at the facility, inspectors conducting the site visit must obtain from nonphysician personnel: (a) the name of the physician(s) who are supervising the tests; (b) information on how such personnel can contact supervising physician(s) and their

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A Review of Trends and Demands for PET Imaging: One Community Hospital’s Experience

Although dedicated PET cameras were developed in the 1970s, only recently has PET been widely accepted in the clinical setting. One major reason is the cost of acquiring a PET camera and cyclotron, balanced against difficulties in reimbursement by third-party payers. Initially, most PET studies focused on neurologic and cardioligic conditions. However, the success of FDG PET in imaging human cancers (1,2) and a growing recognition of the technique’s cost-effectiveness (3) in cancer management have made oncology the focus for most clinical PET examinations.

The PET facility at William Beaumont Hospital (Royal Oak, MI) was planned by Howard Dworkin, MD, in 1989 and construction began in 1991. In the same year, Henry N. Wagner, Jr., MD, reported his long-range assessment, “Clinical PET: Its Time Has Come,” in the pages of The Journal of Nuclear Medicine (4). Despite its promise, the transition of PET into the clinic has been neither rapid nor smooth. Years of operational losses, nearly nonexistent reimbursement, and a general lack of awareness of clinical utility among referring physicians slowed the incorporation of PET into routine use. We are only beginning to explore the possibilities PET has to offer in the clinical setting.

Michigan has strict certificate-of-need (CON) criteria for PET camera approval. Michigan also has a unique way of calculating PET procedures for CONs. Instead of using the number of PET scans, a complex formula based on patient age, number of different chemical tracers, number of injections, acquisition mode, number of bed positions, scanning time, and the need for arterial sampling is used to calculate PET equivalents. As a result, only three hospital-based, dedicated PET cameras have been approved for clinical studies. According to data provided by the Academy of Molecular Imaging (Washington, DC), this is less than 2% of the nation’s total PET cameras. For the Michigan population of almost 10 million, this represents 0.3 PET cameras per million residents; the national average is 0.4 (5). It has been estimated that at least two PET cameras per 1–2 million people are needed for oncologic applications alone (6).

Wide variations in experience with PET have been reported by international researchers, including a number of groups in the United Kingdom (7) and Japan (8). Although such reports may be anecdotal, they contribute to a growing and useful body of knowledge on the transition of PET from a research modality to an integral part of clinical practice.

Our own study was initiated to analyze trends in and current demand for clinical PET imaging in our large (997-bed) community hospital, which offers comprehensive services in all major medical disciplines. As part of the study, we hoped to assess the financial impact of a PET and cyclotron center that is supported solely by clinical studies and to share various experiences in PET that might be useful and informative to colleagues in similar institutional settings. Part of the financial aspects of this investigation have been reported elsewhere (9).

Equipment and Method of Survey

PET clinical and report data, including both a dedicated ring-system PET camera and modified gamma camera positron coincidence imaging, are maintained in a DBASE III+-compatible database with a FoxPro CDX indexing scheme (Microsoft Corporation, Redmond, WA) and are stored on a Dell PowerEdge server, model 6300, with 1-Gb random access memory and a 45-Gb RAID Level-5 SCSI hard drive data storage system (Dell Computer Corporation, Houston, TX). The networking operating system is Novell 5 (Novell Corporation, Provo, UT). NUC-NET is an internally developed, Microsoft Windows 98/2000-based, Inprise/Borland Delphi Pascal 5.0 (Borland International, Inc., Scotts Valley, CA) data management program suite that interfaces with the main hospital computer, manages patient data, and generates patient histories and reports. PET data are extracted from the NUC-NET database using dtSearch 5.25 (dtSearch Corporation, Bethesda, MD). NUC-NET and dtSearch run on Dell OptiPlex GLI workstations using Microsoft Windows 98/2000.

Detailed clinical indications from 1991 to 2000 were analyzed to determine the trend of PET imaging and to reflect current demand of PET imaging. PET procedures were categorized as oncology, cardiology, and neurology studies.

Results

Because the first official operating year of PET in our institution was spent planning, building, and installing the PET camera (Siemens 951; Siemens Corporation, Chicago, IL) and cyclotron (CTI RDS 112; CTI, Knoxville, TN), patient data were not recorded for 1991. The demand for oncologic PET has increased exponentially from 1.3% of total procedures in 1992 to 84% in 2000 (Fig. 1), whereas applications in neurology and cardiology decreased gradually. The greatest growth occurred after 1998. The trend of PET procedures fluc-
Looking at the Trends

The greatest growth in demand for oncologic PET occurred after 1998, when the Health Care Financing Administration approved reimbursement for certain cancers (lung, colon, lymphoma, and melanoma). The low point in PET use in 1996 coincided with a period of poor reimbursement for procedures performed with the costly PET and cyclotron installation. The number of PET studies decreased drastically as the period of initial enthusiasm changed to one of realistic assessment of the cost of scans.

In our institution, we initially offered free PET scans to promote awareness of the new technology among our clinical colleagues and the public. After announcement of significant charges for the procedure, the number of scans dropped significantly. Despite ongoing financial difficulties, however, a referral base for PET scans remained. From 1992 to 1998, this base was mainly in neurologic and cardiac applications. During this period, the use of PET in oncologic diagnosis and staging (with the exception of CNS tumors) was still relatively unknown in the larger medical community.

The trend in initial experience at our hospital was similar to those reported in PET centers in the United Kingdom (7) and Japan (8). Within the United States, of course, clinical applications of PET vary widely, depending on size of the institution, patient base, research and training activities, etc. Centers such as the Cleveland Clinic Foundation focused their initial work with PET predominately in cardiology (personal experience and communication with Drs. Raymundo Go and James MacIntyre). At Johns Hopkins University, the initial focus was on neurologic applications (personal experience and communication with Henry Wagner Jr., MD). At some academic centers, such as Duke University, oncologic applications emerged earlier (personal communication with Edward Coleman, MD).

Our own PET procedure volumes dipped slightly in 2000 because of the replacement of our dedicated PET camera and frequent repairs to the old camera. During periods of downtime, the use of gamma camera positron coincidence imaging was limited and highly selective because of diagnostic capabilities inferior to those of the dedicated PET system. It is interesting to note that an entire year was needed to bring our first PET scanner into operation. However, when it failed catastrophically in 2000, a CON was submitted and approved, capital funding was approved, a vendor was selected (GE Medical Systems, Waukesha, WI), a GE Advance PET camera was ordered and shipped, remodeling was accomplished, installation was performed, training was completed, quality acceptance and health department approval were received, and the first patient was scanned—all within 2 months. This accelerated replacement cycle was necessary to meet the continued demand for PET service.

Beginning in 1998 and 1999, oncologic PET began to experience exponential growth nationwide. We experienced a similar trend but were severely restricted by the limited field of view of the old PET camera, lengthy transmission scans, and a lack of postinjection transmission capability. Because of previous annual deficits with the PET camera, we were unable to convince our institution to purchase a new camera until the old camera was too costly to repair and until we had solid proof of reimbursement. To follow the strict guidelines set by Medicare and ensure adequate reimbursement, a compliance team for PET was set up. Team members include nuclear medicine physicians, registered nurses, billing personnel, and appointment clerks. The compliance team serves

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a vital role in the triage of patients for limited PET resources, follow-up of patients, and satisfying multiple random Medicare audits. The results of PET have been constantly correlated with pathological findings and integrated into mainstream management by presenting results in multidisciplinary tumor conferences and by positive interactions with referring services.

The revenue generated by PET imaging is now a substantial portion of the total nuclear medicine department income and is roughly equal to that of SPECT myocardial perfusion imaging. In 1998, PET-Net (Knoxville, TN) contracted the use of our cyclotron facility to share the expenses of the costly cyclotron operation and to benefit other PET centers. The demand for oncologic PET applications has increased because of the technology’s proven effect on clinical management and cost savings. It is worth noting that the projected total number of scans for 2001 does not exceed the 1999 number as much as one would anticipate from the accompanying increase in popularity of PET. This is because brief brain scans with calculated attenuation correction have now been replaced by whole-body attenuation corrected PET scans, which typically take about 50 minutes. (The whole-body PET takes about the same amount of time as in 1999 because of today’s addition of transmission scans in all patients and much wider coverage in the scan.) Oncologic applications now compete with neurologic and cardiac indications for PET imaging. This is further fueled by the implementation of hospital picture archiving and communication systems (PACS) in conjunction with mini-PACS within the nuclear medicine department.

With the announcement of expanded coverage of PET in oncology and cardiology by Medicare and wide awareness of the usefulness of PET imaging in the general medical community, the trend of clinical PET applications seems to be toward continued growth. However, the survival of fast-growing PET centers may be affected by the potential decrement in reimbursement and competition for patients among various nearby PET centers. The shortage of human resources within nuclear medicine may be another challenge in the future. A fight for reimbursement for tracers other than 18F FDG and 82Rb may be necessary for further growth in clinical PET. Internal usage studies like ours may be important for planning and scheduling of limited PET resources for various competing clinical indications.

Conclusion

In our community hospital, a high and accelerating demand for oncologic PET imaging has changed both the clinical and financial operation of the nuclear medicine department. Nearly half the total PET scans are for staging of lung cancer and evaluation of single pulmonary nodules. Similar reports and analyses from other community hospitals will be important in providing the experiential information necessary for newly established centers to address the changes that new imaging technologies may bring to their institutions. Because of the tremendous potential for future growth in PET imaging, the results of such analyses are also important in the reallocation of human and financial resources in nuclear medicine departments.

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NRC Update. The ongoing joint effort by the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) to prevent implementation of the Nuclear Regulatory Commission (NRC) revisions to 10 CFR Part 35 were rewarded with success in October. During that month, the joint effort focused on extensive lobbying and grassroots contacts to convince members of the House–Senate conference committee to work out differences in language between the two bills. ACNP and SNM members were urged to call conferees to ask that they support the Senate-passed language on Part 35. “This language is critical,” noted a letter to the conferees, “if we are to avoid spending $500 million to implement a poorly conceived program when health care dollars are increasingly scarce.”

On the evening of October 30, the House–Senate Conferees adopted this compromise which included the following language on Part 35:

...notwithstanding any other provision of law, no funds made available under this or any other Act may be expended by the Commission to implement or enforce any part of 10 CFR Part 35, as adopted by the Commission on October 23, 2000, with respect to diagnostic nuclear medicine, except those parts which establish training and experience requirements for persons seeking licensing as authorized users, until such time as the Commission has reexamined 10 CFR Part 35 and provided a report to Congress which explains why the burden imposed by 10 CFR Part 35 could not be further reduced.

The language was almost identical to that suggested by the SNM and ACNP. On Monday, November 12, President Bush signed HR 2311, the fiscal year 2002 Energy and Water Appropriation bill, into law. The bill included the suggested NRC Part 35 language. The bill contained language from the House–Senate Committee directing the NRC to submit its report no later than January 31, 2002, and noted that the language included in the bill is only an interim measure until a more permanent solution can be reached, either by the authorization committees or through a revised rulemaking.

This is a major victory for ACNP and SNM and the diagnostic nuclear medicine community. The task ahead is to engage the NRC in a dialogue, so that nuclear medicine has a meaningful say in what happens next. ACNP and SNM discussions with the NRC will take place against the background of newly found Congressional influence. The January 31, 2002, deadline (which may be fairly flexible if progress is being made) provides some urgency to meeting and setting an agenda for change. On November 15, SNM and ACNP hosted a meeting of other specialties regulated by Part 35 to invite them to join in establishing which provisions of new 10 CFR Part 35 make sense and which are superfluous. After the nuclear medicine agenda is set, SNM and ACNP representative will contact NRC Chair Richard Meserve and offer to meet to discuss appropriate changes.

The success of the nuclear medicine community in this endeavor relied on the work of Al Lorman, who drafted the language included in the bill; Dave Leiter and the team from Mintz Levin; and SNM and ACNP members who made important legislative contacts.

The bill also contained the Department of Energy (DOE) isotope appropriation. Isotope support is set at $26,177,000. University reactor support is set at $17,500,000, with a directive to begin implementing the Nuclear Energy Research Advisory Committee (NERAC) report and to include the nuclear medicine community in the required peer review process. DOE must report back to Congress by May 31, 2002, on its progress in implementing the NERAC recommendations. Work is beginning on the FY 2003 budget.

CMS, HOPPS, and PET Reimbursement. In early October, as reported previously in these pages, SNM and the other members of the Nuclear Medicine Ambulatory Payment Classification (APC) Task Force submitted comments to CMS on the proposed Medicare Hospital Outpatient Prospective Payment System (HOPPS) reimbursement rates for 2002. The comments (available at www.snm.org) criticized the decision to move PET codes previously assigned to APC 981 (Level XII New Technology) to APC 976 (Level VII New Technology). The shift reduces the proposed 2002 payment rate for most PET procedures from $2,165.36 to $841.94. The proposed rates of reimbursement are so low that many HOPPS PET centers could be forced out of business. Uncertainty over reimbursement rates...
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may cause independent imaging centers to put orders on hold and force financing companies to withdraw from deals that were in the final stages of negotiation.

An e-mail action alert was sent to SNM members asking that they write CMS and describe their experiences with the costs of providing PET services. As hoped, many members responded and have provided useful information. The Task Force comments and action alert can be viewed at www.snm.org.

Concern about the new reimbursement rates extends beyond the nuclear medicine community. In a demand letter delivered on November 19 to Health and Human Services (HHS) Secretary Tommy Thompson, the American Hospital Association (AHA) litigation counsel warned HHS that the association would bring suit unless deficiencies were fixed in the rulemaking process for HOPPS. The Association of American Medical Colleges and the Federation of American Hospitals concurred with the AHA’s position. The letter described AHA’s “serious concern” that CMS failed to provide proper notice and comment period on the proposed pro rata reduction of pass-through payments and related changes under the Medicare HOPPS and said CMS should delay the effective date for the reduction until it has followed the proper rulemaking procedures. The letter explained that, without the necessary data, erroneous HOPPS rates “will impose unacceptable burdens on hospitals in these already trying times.” For more information, visit http://www.aha.org.

PET and Breast Cancer. Medicare reimbursement for the use of PET in breast cancer patients has crossed another hurdle. On October 17, the Medicare Coverage Advisory Committee (MCAC) met to consider ratification of the June action of the Diagnostic Imaging Committee recommending coverage of the use of PET in breast cancer patients in “detecting locoregional recurrence or distant metastases/recurrence when results from other tests are inconclusive.” Peter Conti, MD, appeared on behalf of SNM to reaffirm the Society’s support for coverage of PET and to bring to the MCAC’s attention the latest article in The Journal of Nuclear Medicine (2001;42:1334–1337) on the role of PET in managing breast cancer. After extensive discussion, the MCAC voted in favor of recommending coverage of PET for recurrent breast cancer. CMS staff was given a deadline of December 17 to release a coverage decision memorandum that, if positive, will trigger assignment of codes for covered indications. Under this timeline, new codes can be expected in spring 2002.


Approximately 7,500 codes represent services included in the Physician Fee Schedule effective January 1, 2002. CMS used actual specialty practice expense data from 1995 to 1998 to create six cost pools: administrative labor, clinical labor, medical supplies, medical equipment, office supplies, and other supplies. The 1999 Specialty Practice Expense data have been added for calendar year 2002. The final rule makes several changes affecting Medicare Part B payment: refinement of resource-based practice expense relative value units (RVUs); services and supplies incident to a physician’s professional service; anesthesia base-unit variations; recognition of CPT tracking codes; and nurse practitioners, physician assistants, and clinical nurse specialists performing screening sigmoidoscopies. The final rule updates the list of certain services subject to the physician self-referral prohibitions to reflect changes to CPT codes and Healthcare Common Procedure Coding System codes effective January 1, 2002.

The 2002 physician fee schedule update decreased by 4.8%, the initial estimate of the Sustainable Growth Rate (SGR) increased 5.6%, and the conversion factor for 2002 is $36.1992. CMS made an adjustment to the conversion factor to account for increases in work RVUs, volume, and intensity of services. Accordingly, nuclear medicine/radiology services will see an overall 1% decrease based on the final rule. As an example, the 78465 Heart Image (3D) multiple has a 2002 nonfacility rate of $74.93 compared with the 2001 nonfacility rate of $75.29, resulting in a 1% decrease. Wage rates for nuclear medicine technologists have been raised from $0.39 per minute (2001) to $0.49 per minute (2002). The rule can be viewed or downloaded from <www.hcfa.gov/regs/pfs/cms1169fc.htm> or www.snm.org.

CMS Publishes Interim Final Rule on Payment for Pass-Through Categories. This interim final rule sets forth the criteria the Secretary of Health and Human Services will use to establish new categories of medical devices eligible for transitional pass-through payments under Medicare’s HOPPS. The new regulations became effective on December 3, 2001. To view the entire text or to send your comments to CMS on this rule, go to http://frwebgate5.access.gpo.gov/cgi-bin/ waisgate.cgi?W AISd0docID=22851625519+0+0+0&W AIS action=retrieve.

CARE Act Action Delayed. As a result of national events and after September 11, the Senate has delayed consideration of the Consumer Assurance of Radiologic Excellence (CARE) Act until after the start of the new year. Interest in the Act in Congress remains high, and Newsline will keep readers updated on important dates and information on grassroots lobbying. Despite inaction at the federal level, legislators and regulators in Montana, Arizona, Missouri, and New York continue to explore state regulation of nuclear medicine technologists.

—William Uffelman
Director, SNM Public Affairs
SNM General Counsel
NOTIFICATION OF PROPOSED BYLAW CHANGE

At its meeting in Toronto in June of this year, the Society of Nuclear Medicine (SNM; the Society) House of Delegates directed that language be developed designating the Board of Directors as the governing body of the Society. In accord with that directive, the following amendments to the Bylaws of the Society are proposed. (The current version of each affected section of the Bylaws is included below in its entirety; unaffected sections are not included. Proposed deletions are struck through. Proposed additions are underlined. Some minor housekeeping revisions to the Sections, such as relettering, are also included.)

ARTICLE VII
HOUSE OF DELEGATES

Section 1: DESCRIPTION
The House of Delegates is the legislative and policy-determining representative component of the Society.

Section 2: RESPONSIBILITIES OF THE HOUSE OF DELEGATES
A. To determine the goals of the Society in accord with the Mission and the Objectives.
B. To determine, develop and recommend to the Board Society policy policies and programs regarding professional issues affecting Nuclear Medicine.
C. To elect seven (7) Directors-At-Large, the majority of the voting members of the Board of Directors.
D. To approve amendments and revisions to the Bylaws in accord with the Bylaws and Procedures.
E. To approve establishment and dissolution of Chapters and Councils.
F. To review actions of the Board of Directors.

ARTICLE X
BOARD OF DIRECTORS

Section 1: DESCRIPTION
The Board of Directors is a component of the House of Delegates, representing it in between its meetings. The governing body of the Society.

Section 2: RESPONSIBILITIES
A. To perform fiduciary duties traditionally entrusted to Directors of a not-for-profit corporation, to include strategic planning, retention and oversight of the Executive Director, and related responsibilities.
B. To develop, approve, and implement the policies and procedures of the Society (see Article XIV, Section 2).
C. To determine other policy between meetings of the House of Delegates, as necessary.
D. To manage the business and financial affairs of the Society, to include the development and implementation of the annual budget for the Society, in accord with the policies approved by the House of Delegates, in a manner consistent with the strategic and operational interests of the Society and its membership.
E. To develop, monitor, and evaluate programs which implement Society policies established by the Bylaws and the House of Delegates.
F. To identify relevant professional issues for presentation to and action by the House of Delegates, either directly or by appropriate Councils or Committees.
G. To coordinate and monitor the activities of all the organizational components within the Society.
“Nanogenerator” Bombs Tumor Cells with $^{225}$Ac

In a report published in *Science* (2001;294:1537–1540) on November 16 and picked up by media outlets around the world, researchers at Memorial Sloan-Kettering Cancer Center (MSKCC; New York, NY) announced the development of a molecular “nanogenerator” that releases a cascade of $\alpha$ particles inside cancer cells. According to the article and a press release from MSKCC, each nanogenerator consists of a single atom of $^{225}$Ac inside a microscopic carbon and nitrogen “cage” made by Dow Chemical Co. (Freeport, TX). “We have found an effective way of containing and then delivering this highly potent element directly into cancer cells,” said study senior author David A. Scheinberg, MD, PhD, chief of MSKCC’s Leukemia Service and head of the Laboratory of Hematopoietic Cancer Immunochemistry at the Sloan-Kettering Institute.

The nanogenerators were tested in a variety of cell cultures, including human leukemia, lymphoma, neuroblastoma, and breast, ovarian, and prostate cancers. Two mouse models, one for prostate cancer and one for disseminated lymphoma, were treated with the technique, and promising results were noted.

The advantages to internal treatment of cancerous cells with radioactive atoms—more precision and improved tissue sparing—were noted by the MSKCC team. “If the atom is sitting on the outside of the cell, the $\alpha$ particle can travel in any direction, and it kills the cell only a fraction of the time,” said Michael McDevitt, PhD, the study’s first author and a senior researcher in Scheinberg’s group. “If the generator is inside the cell, every particle will be effective.”

Another distinct advantage is that the long half-life of $^{225}$Ac means that the nanogenerators could be manufactured at a central location for distribution to users. At the same time, injected doses are likely to be quite small, so that treatments may be administered on an outpatient basis.

The MSKCC group plans to file applications with the Food and Drug Administration to begin clinical trials in 2002.

NEMA Releases Scintillation Camera Standard

The National Electrical Manufacturers Association (NEMA; Rosslyn, VA) published updated standards for scintillation cameras in early October. *Performance Measurements of Scintillation Cameras*, NEMA publication NU 1-2001, provides uniform criteria for measurement and reporting of scintillation camera performance parameters. The publication also includes new tests to verify the alignment of multidetector systems. These include system planar sensitivity and penetration, system alignment, and detector-to-detector sensitivity variation. The detector shielding test has been modified to be more representative of clinical practice. The publication costs $57 and can be purchased by contacting Global Engineering documents at: www.globalhils.com.

Thakur Receives NY Berson–Yalow Award

The 13th annual Berson–Yalow Award of the Greater New York Chapter of the SNM was presented to Mathew L. Thakur, PhD (Philadelphia, PA), at the 15th annual northeast regional meeting of the Greater New York and New England chapters of the SNM in Stamford, CT, on October 27. John McAfee, MD, lauded Thakur for his extraordinary contributions to nuclear medicine and highlighted the major impact of his original work in the preparation of cyclotron-produced radionuclides, such as $^{43}$K, $^{52}$Fe, $^{67}$Ga, $^{81}$mKr, $^{76}$Br, $^{97}$Ru, $^{111}$In, $^{123}$I, $^{166}$Dy, and $^{203}$Pb, and in the preparation and evaluation of $^{123}$I steroids, $^{111}$In bleomycin, $^{111}$In leukocytes, $^{111}$In platelets, $^{111}$In lymphocytes, $^{99m}$Tc VIP, and other related peptides, and $^{99m}$Tc anti-CD15 antibody that specifically binds human neutrophils in vivo. Hussein Abdel-Dayam, MD, the president of the Greater New York chapter, presented a plaque, which read, in part: “An outstanding scientist and superb educator who has trained and unselfishly shared his vast knowledge with many grateful nuclear medicine physicians, scientists, and technologists.”

In accepting, Thakur described the importance of Solomon A. Berson and Roslyn Yalow, for whom the award was named. He added, “Honors like this do not come to anybody working with one head and a single pair of hands. It needs supportive superiors and creative colleagues. It needs a family which is loving, caring, and willing to sacrifice, and, above all, it needs peers who appreciate one’s contribution.”

Demand for PET Continues to Grow

According to a study released in October by the Medical Information Division of IMV (Des Plaines, IL), more than 40,000 PET procedures were performed in the second quarter of 2001, compared with 37,400 reported for the last quarter of 2000. IMV performs quarterly marketing surveys in medical imaging and other fields. The group reported that more than 500 facilities in the United States were equipped to provide PET diagnoses. A small but significant drop in the number of procedures performed with coincidence detection cameras was attributed to changes in Centers for Medicare and Medicaid Services reimbursement rates.

For more information on the study, see the IMV Web site at: www.imvlimited.com/mid or call 1-847-297-1404.

$^{90}$Y Microspheres Show Promise in Liver Cancer

Two separate groups at the European Cancer Conference in Lisbon, Spain, October 21–25, presented encouraging results on the direct infusion of $^{90}$Y
patients, five experienced decreased response was observed in three of these could be evaluated in nine. A partial susceptiod to radiation-induced dam-
tolered, even in whose livers are highly pheres appears to be safe and well primary hepatomas using 90Y micros-
cer program, University of Pittsburgh Carr, professor and chief of the liver can-
months.
At a median follow-up of 11 months, the survival for the group was 10 months.

In the second presentation, Dr. Brian Carr, professor and chief of the liver can-
cancer program, University of Pittsburgh Medical Center (Pittsburgh, PA) led a group that concluded that treatment of primary hepatomas using 90Y microspheres appears to be safe and well tolerated, even in whose livers are highly susceptible to radiation-induced damage. Of 14 such patients treated, response could be evaluated in nine. A partial response was observed in three of these patients, five experienced decreased tumor vascularity, disease stabilized in two, and one patient developed lung metastases.

Reuters Health reported that Dr. Carr said, “This appears to be a novel therapy whose primary attraction is its safety profile.” In addition to being very economical, he said, the treatment is advantageous, because “patients stay out of hospital so their quality of life is extremely good, and if patients come into treatment working, they are able to con-
tinue to work after this treatment and lead a normal life for many months after.”

FDG PET in the Diagnosis of Paraneoplastic Neurologic Disorders

I
n the November issue of Brain (2001;124:2223–2231), a group of researchers from several London medical centers reported a retrospective review of case notes on 43 patients with suspected paraneoplastic neurological disorder (PND). These patients had been referred for PET evaluation, and all had undergone standard radiological investigations and bronchoscopy (where appropriate) before PET scanning. The purpose of the retrospective review was to determine the utility of PET in changing diagnosis and management when conventional imaging was negative.

In 16 patients (37%), discrete areas of hypermetabolism were suggestive of malignancy (positive). A tissue diagnosis of cancer was subsequently made in seven patients (two post mortem), additional radiological studies were suggestive of cancer in one patient, one patient subsequently presented with a metastatic deposit (which was biopsied), and four patients died shortly afterward with no post mortem evaluation. In three patients, subsequent investigations were negative for cancer. Serum anti-
n neuronal antibodies were present in 43% and cerebrospinal fluid oligoclonal bands were present in 46% of patients with positive PET scans compared with 16% and 26%, respectively, in PET-negative patients, but this was not significant. Only one patient with a negative scan was diagnosed as having malignancy on prolonged follow-up. The authors of the study concluded that FDG PET is a useful technique in the detection of small tumors in patients with suspected PND. Although false-positives and false-negatives were noted, these occur at a sufficiently low fre-
quency to justify the clinical usefulness of the technique.

Medicare’s New Enrollment Procedures

(Continued from page 16N)
knowledge of procedures to follow if they have a problem with diagnostic tests they are performing; and (c) any procedures related to how the general supervision requirement is being met. However, written procedures are not specifically required, and these can be furnished sepa-
ately from the site visit. If no written procedures exist, a satisfactory written response to carrier questions is required. If an IDTF has more than 10 practice locations but is not a mobile unit, the carrier does not have to perform a site visit to each location, and a sampling of prac-
tice locations can be performed.

—Thomas W. Greeson, Esquire
Reed Smith Hazel & Thomas, LLP
Falls Church, Virginia

Early Detection of Inhaled Anthrax Infection

(Continued from page 12N)
in the course of the disease but in reduc-
ing unnecessary antibiotic administra-
tion to other individuals who are concerned about the possibility of expo-
Sure,” says Molinoff.

“With its high specificity and

affinity—and a number of other advan-
tages—this technique provides a logical and promising approach to early diagnosis, which assumes critical impor-
tance in an entity as life-threatening as anthrax and where criminal activity may be involved,” says Thakur. Bridwell agrees, noting that “this technique also reinforces nuclear medicine’s growing importance in providing fast and reliable functional information at the cellular diagnostic level.”