New Equipment in Nuclear Medicine, Part 2: Dual-Head FDG Coincidence Detection Cameras

With new gamma cameras that challenge the borderlines between positron emission tomography (PET) and single-photon emission computed tomography (SPECT), more nuclear medicine deparents can now provide metabolic studies based on glucose uptake. A number of dual-head SPECT systems on the market today can produce positron images with fluorine-18 fluorodeoxyglucose (FDG), which may provide a clinically validated substitute for FDG PET scans. These systems will make FDG studies available to many patients who don't live anywhere near a PET scanner or cyclotron.

Most major equipment manufacturers now have coincidence detection options for imaging positron tracers with their SPECT systems, either commercially available or in development. These include ADAC Laboratories (MCD, for molecular coincidence detection); Siemens Medical Systems, Inc. (E.CAM+); Picker International(PCD, positron coincidence detection; γ PET³, gamma PET); GE Medical Systems (CoDe, coincidence detection); Elscint (VCoDe, volumetric coincidence detection); Toshiba Medical Systems (E.CAM+); Hitachi Medical Corporation (CDR, coincidence detection reconstruction); and SMV (VR, volumetric coincidence reconstruction). In general, these systems use a dual-detector configuration. Recently, however, Picker introduced a triple-detector system, the IRIX, for its PET3 technology.

Reimbursement and Radiotracer Availability

According to P.E.T.Net Pharmaceutical Services, an FDG distribution network based in Norcross, GA, more than 500 private insurance carriers and managed care organizations now reimburse for certain FDG studies. P.E.T.Net manufactures FDG at 12 distribution sites in the United States, making the radiotracer available to institutions that don't own and operate their own cyclotrons.

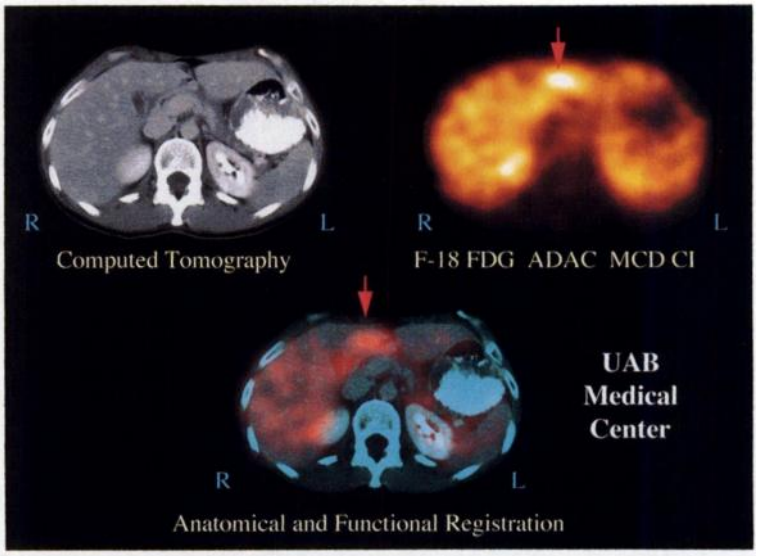

Figure 1. The CT (top left) and FDG (top right) studies were obtained from a patient with a solitary liver metastasis (arrow) from colon cancer. The fusion image (bottom) identifies the anatomic location of the liver metastasis. Courtesy of J.M. Mountz, University of Alabama at Birmingham Medical Center.

HCFA/Medicare Reimbursement Covers All Coincidence Imaging

In January 1998, a new Medicare policy took effect that provided reimbursement in the United States for FDG studies of lung cancer. According to HCFA guidelines, approved reimbursement covers any type of FDG coincidence imaging study, whether obtained with a dedicated PET system or a dual-head coincidence detection system. The average national payment in the United States is $1,980 for the technical component, including the FDG. The physician fee is billed separately and should be reimbursed at the same rate as a SPECT study.

"We have encouraged HCFA not to distinguish between the two types of scanners, dedicated PET or dual-head coincidence detection. It would be better for Medicare to look at the clinical value of FDG studies, period," explained Robert E. Henkin, MD, FACNP, FACR, professor of radiology at Loyola University Medical Center in Maywood, IL. Henkin has been active in government relations and reimbursement issues. Leaders in nuclear medicine are working to have Medicare coverage for FDG studies expanded to other cancers, brain disorders, and cardiac viability studies.

HCFA Town Hall Meeting

On January 20 and 21, 1999, HCFA's Cover-

This is the second article in a series . The first article appeared in the November 1998 *Newsline*

age and Analysis Group held a "PET Town Hall Meeting" in Baltimore to hear presentations from about 20 clinical investigators on the value of FDG studies in evaluating patients with colorectal cancer, lymphoma, head and neck cancer, melanoma and brain tumors. The data presented were primarily obtained with dedicated PET systems. However, several investigators brought clinical data obtained with FDG dual-head coincidence detection studies. (See "Impressions of the HCFA Town Hall Meeting," below.)

"There were quite a few referring physicians at this meeting, mainly surgeons and oncologists. The unanimous opinion was that the medical community wants to use FDG imaging in oncology for staging tumors," said James K. O'Donnell, jr., MD, director of the Division of Nuclear Medicine at the University Hospitals of Cleveland, who presented FDG data on colorectal cancer.

Impact of Dual-Head FDG Studies on Patient Management

James M. Mountz, MD, PhD, professor of radiology in the Division of Nuclear Medicine at the University of Alabama at Birmingham Medical Center, presented a case report in which a dual-head FDG study detected a focal hepatic mass at an early stage of metastatic disease when an x-ray computed tomography (CT) study showed no evidence of such metastasis (Figure 1). These postoperative evaluations were done 6 mo after the primary colon tumor was removed. Because of the FDG study, this patient was scheduled to undergo surgical resection of the solitary liver metastasis.

"The studies reported at the PET Town Hall Meeting emphasized changes in clinical management, both as a result of early detection of limited metastatic disease and identification on follow-up of disease recurrence after therapy," said Mountz.

Evaluating Head and Neck Cancer

Professor Jean-Noel Talbot, MD, ScD, of the nuclear medicine service at Hopital Tenon in Paris, presented results of dual-head FDG coincidence imaging in 63 patients with head and neck cancer. Talbot's group has used FDG stud-

Commentary: Impressions of the HCFA Town Hall Meeting

Ruth Tesar, CNMT

On January 20 and 21, 1999, a historic event took place in the quest for reimbursement for PET procedures. Physicians, patients, industry leaders, political advocates and bureaucratic representatives met together at the Health Care Financing Administration (HCFA) headquarters in Baltimore to discuss PET imaging–both in terms of clinical data and their own personal experiences. Although the meeting was initiated by HCFA, its form and content were the result of efforts on the part of several individuals who committed their time, energy and financial resources to bring PET advocates together to discuss their experiences with PET.

HCFA invited the PET community to present clinical data in support of five indications: colorectal cancer, melanoma, head and neck cancer, lymphoma and brain tumor. This was a public forum, and discussion on other indications and aspects of PET were also welcomed. HCFA representatives commented that they were impressed by the sheer number of PET supporters in attendance and the quality of data presented by the clinicians who perform PET scans as part of their daily practice. Of the more than 160 people who attended the conference, ten were cancer patients who described how PET was instrumental in the management of their disease.

A panel of experts from the payer community also attended. They listened as various clinicians–from both the U.S. and Europe–presented their papers demonstrating PET's effectiveness in the diagnosis and management of various cancers. The panel expressed a desire for more control groups in the study protocols and more data relating to "outcomes," a word that was oft-used by the panel. The different perspectives between payers and providers became apparent in the discussions that took place after data were presented.

I was personally pleased that a large number of PET supporters were given the chance to interact personally with HCFA representatives. These representatives indicated that they would take the information presented at the meeting and consider expanding coverage for PET. We are encouraging a timely response in the form of additional indications that would be covered for PET. Overall, the clinical data presented by PET practitioners was well-received and very clearly demonstrated the benefits of using PET.

This meeting is only the beginning of a new cohesive effort in the PET community to push forward for PET reimbursements by mobilizing patient advocacy groups, physicians, politicians and industry. It was a vivid demonstration of how the entire PET community can pull together and make a difference. An upcoming event to be held this month in Washington, DC, will educate members of Congress and their staffs about the benefits of PET imaging. We do not want to lose the momentum. We will continue to seek your involvement and help.

—Ruth Tesar, CNMT

Ruth Tesar, CNMT, is the president of the Institute of Clinical PET and the vice president of P.E.T.Net Pharmaceutical Services, an FDG distribution network based in Norcross, GA.

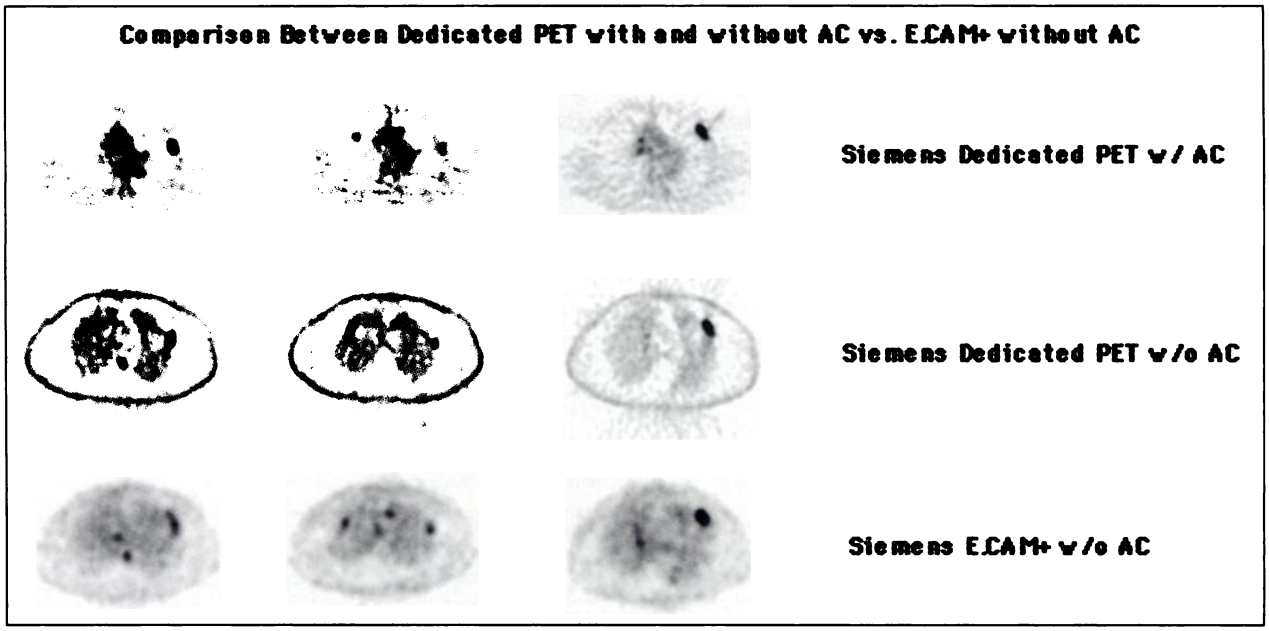

Figure 2. Comparison of ECAT dedicated PET image with attenuation correction (left) and without attenuation correction (middle). The image on the right was acquired from the E.CAM+ system without attenuation correction. Courtesy of J.K. O'Donnell, University Hospitals of Cleveland.

ies to evaluate more than 600 cancer patients. In this study, there were four main indications for FDG imaging: (1) staging tumors found malignant by oral panendoscopy biopsy; (2) evaluating the efficacy of preoperative chemotherapy; (3) searching for unknown primary tumors with known lymph node metastases; and (4) detecting recurrent disease, particularly in residual masses visible on CT.

In the 53 patients with known malignant tumors, the dual-head FDG study detected 50, for a sensitivity of 94% compared with a 72% sensitivity for conventional imaging tests. One false-negative result was due to hyperglycemia and two false-negatives were in patients whose tumors were less than 5 mm. In six patients referred for clinical suspicion of recurrence, the FDG test yielded three true-positive results, one false-positive, based on a normal panendoscopy, and two true-negative results (defined as still negative on a 15 mo follow-up).

"The accuracy of N-staging [nodal disease] in these patients was 90% for FDG versus 81% for CT. The primary tumor was localized in three fourths of cases of malignant lymph nodes of unknown primary," reported Talbot. In addition, the dual-head FDG study caused a "direct modification of patient management" in 16 of the 63 patients, he said. "The cost of primary staging has been reduced by indicating chest and abdominal CT only in those patients with distant FDG foci," he added.

Since July 1997, the Paris group has used a Picker Prism 2000 system equipped with PCD and 19mm crystals "instead of the 9.5mm crystals used in ordinary gamma cameras," Talbot noted. "This gamma camera is still able to perform high-quality standard examinations in nuclear medicine, including those with isotopes emitting low-energy photons, such as technetium-99m and thallium-201. To detect fluorine-18, the collimators are removed and replaced by septa, which limit the accepted incidence angle of the photons. Switching to coincidence-detection mode is completely automated. An energy spectrum is displayed, and we choose to accept only those photons at 511 keV."

Cost Minimization Analysis for Colon Cancer Evaluation

The HCFA Town Hall Meeting included discussion on the cost-effectiveness of FDG imaging. Frank J. Papatheofanis, MD, PhD, director of the Advanced Medical Technology Assessment and Policy program at the University of California, San Diego, reported the results of a work-in-progress cost-minimization analysis for colon cancer evaluation. Based on studies with the ADAC MCDACPET, Papatheofanis and his group analyzed diagnostic evaluation costs for patients at three stages of disease: Dukes colon classification A (stage I), B (stage II), and C (stage III). In all three stages, dual-head FDG studies resulted in statistically significant cost savings in diagnostic evaluation (Table 1). The savings with FDG studies ranged from about $5,000 to more than $10,000 per patient.

Heart Transplant vs Bypass Surgery

At Loyola University Henkin also uses the ADAC-MCD coincidence detection system with

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Table 1
Diagnostic Costs for Colon Cancer Evaluation*

Stage of Disease	With FDG Study	Without FDG Study	Significance
I (Dukes A)	$9,680	$15,386	P<03
II (Dukes B)	$10,722	$17,301	P<017
III (Dukes C)	$11,905	$22,518	P<003

** Cost in 1998 $U.S. per patient*
Source: Papatheofanis et al, University of California, San Diego

attenuation correction, which was installed in December 1997. The department gets about 3 to 7 referrals per week for FDG studies, primarily for cardiac, neurosurgical, and general oncology cases. "We have a heavy cardiac load because of the active heart transplant program at this institution," said Henkin. "The referring physicians are very attuned to the use of FDG in this area. We do a lot of FDG decision-making on transplant versus bypass surgery," he explained.

In Henkin's opinion, dual-head coincidence detection is a viable alternative to dedicated PET at institutions that cannot economically justify a PET scanner or where the volume of FDG studies is relatively low. On the other hand, he noted, "when the demand for FDG studies reaches 5 to 8 patients per day, a dedicated PET system might be the better choice from a management point of view."

Cancer Diagnosis and Staging

O'Donnell's department uses the Siemens E.CAM+ dual-head coincidence imaging system and the Siemens ECAT dedicated PET scanner. The E.CAM+ mainly handles two applications: diagnosis and staging lung cancer in patients with solitary pulmonary nodules on x-ray computed tomography (CT), and myocardial viability studies. All patients imaged with dual-head coincidence detection also undergo dedicated PET scanning so that images can be compared in a prospective study.

"We've done about 50 patients with lung cancer, and the correlations with PET are excellent. I'm at the point where I'd feel comfortable using just the E.CAM+ with these patients when there's a backlog for the dedicated PET scanner," said O'Donnell. Most physicians are convinced that an FDG study is far superior to CT for staging tumors, he added.

At the VA Hospital of Palo Alto, California, the nuclear medicine group uses the Elscint VariCam for coincidence imaging and the Siemens ECAT for dedicated PET. "We've used coincidence detection for one year, primarily for the diagnosis and staging of cancer," said George M. Segall, MD, chief of the nuclear medicine service and professor of radiology and medicine at Stanford University. "We're still in the investigative stage. All of our patients are being studied on both machines because we want to validate coincidence imaging. We are one of the few sites with state-of-the-art PET as well as dual-head coincidence detection, so we feel a responsibility to validate the technique," said Segall.

Iterative Reconstruction: A Major Advance

For dual-head coincidence detection systems, iterative reconstruction has replaced filtered back-projection, resulting in significantly improved image quality. Nearly all manufacturers have adopted a known algorithm, ordered-subsets expectation-maximization (OSEM), for iterative reconstruction. "With filtered back-projection, because it projects along a ray, we get ray artifacts that degrade the image. But with OSEM, which is a reconstruction of pixel subsets, we have a cleaner image," said R. Lin Sinclair, product manager of nuclear medicine at Toshiba.

OSEM is very computer-intensive and only became practical for nuclear medicine once workstations could provide ultrafast processing capabilities. In the mid-1990s, noted Sinclair, it could take up to 4 hours to process a study with OSEM, but now "it takes about 1 second per slice with the Ultra SPARC," the Sun Microsystems UNIX-based workstation that Toshiba offers with the Siemens E.CAM camera. With the ICON, the Macintosh-based workstation that Siemens provides with its E.CAM, OSEM processing time has been reduced to less than 1 minute. "The acquisition of coincidence-detection data is identical with both E.CAM systems, but Siemens and Toshiba have developed different reconstruction algorithms for their respective workstations," explained Sinclair.

"Iterative reconstruction allows the patient to be handled in a more accurate way, mathematically, at each angle," explained Hines. "It allows the anterior sum of the data to be different from the lateral sum of the data. Filtered back-projection, on the other hand, assumes that those data sums are the same at each angle, which is not the case because of attenuation."

"We have an iterative reconstruction that is unique to our design, and is optimized to the way we do coincidence imaging with our slip-ring gantry," said Raffi Kayayan, PhD, product marketing manager at GE Medical Systems. Whereas most other systems acquire data from one tomographic revolution, the VariCam/CoDe5 system, formerly marketed by Elscint and now by GE (which acquired Elscint's nuclear medicine business last year), does multiple revolutions around the patient.

Because there is significant decay with FDG by the end of an imaging session, the multiple revolutions were designed so that averaging the decay would yield a more accurate data set. For example, "instead of doing one revolution for 30 minutes, we would do 10 revolutions of 3 minutes each. This way, at the end of each tomographic session, the tracer has decayed for 3 minutes instead of 30 minutes," explained Kayayan. "and instead of doing iterative reconstruction on the entire coincidence session, the iteration is performed using each revolution data as a subset with OSEM."

Impact of Attenuation Correction

Nuclear medicine physicians experienced with dual-head coincidence detection have divergent views on attenuation correction. Currently, only ADAC provides an attenuation-correction option for its coincidence detection system. "Attenuation has more of an effect on coincidence detection than on single-photon studies. This is because in positron imaging, two gamma rays are emitted from the body in opposite directions, and both photons have to make it out of the body," said Horace H. Hines, PhD, chief technical officer at ADAC Laboratories. "If you were to rate image quality, filtered back-projection would be the lowest, iterative reconstruction would be intermediate, and iterative reconstruction with attenuation correction would be the best," he added.

In a series of 44 patients, the Loyola group has evaluated dual-head FDG studies with ADAC's MCD system that were reconstructed twice, once without attenuation correction and again with attenuation correction. When graded on a scale of 0 to 5, physician confidence in interpretation improved from a mean of 2.7 on noncorrected studies to 4.0 when attenuation correction was used. In 18 patients, attenuation correction resulted in either more clearly identified lesions or additional lesions compared with noncorrected studies. In addition, attenuation-corrected images had fewer artifacts.

Investigators who have evaluated coincidence detection systems note that the benefit from a separate attenuation-correction package may apply primarily to the ADAC system. According to some physicists, the elimination of extensive background noise with an attenuation-correction option may actually result from additional corrections for randoms and/or scatter.

Segall's group compared non-attenuation-corrected coincidence detection images acquired on the Elscint VariCam with attenuation-corrected images acquired on the Siemens ECAT dedicated PET scanner. "We studied 73 patients prospectively, and results showed that the non-attenuation-corrected coincidence images detected 83% of all lesions seen with attenuation-corrected PET. More importantly, perhaps, we found that the same clinical decisions would have been made in 93% of patients studied with both techniques," said Segall.

With the E.CAM+ system, using no attenuation correction, O'Donnell believes that he obtains images of comparable quality to dedicated PET images (Figure 2). "Physicists will tell you that attenuation correction may improve the target-to-background ratio in one lesion, but at the price of introducing noise and potential artifacts," he explained.

"In the dedicated PET community, people use attenuation correction primarily to achieve standard uptake values (SUVs) for quantitative studies," noted Paul Ottoson, marketing manager at Siemens. "I'm not sure whether anyone's trying to achieve SUVs with current dual-head coincidence detection systems because of the sensitivity and efficiency limitations of sodium-iodide (NaI) detectors," he explained.

According to Ottoson, "contrast resolution, as opposed to spatial resolution, is the single most important factor in improving lesion detectability with NaI-based detectors. Contrast resolution is really the heart and soul of our development efforts with E.CAM+." The Siemens 20-year experience with PET, noted Ottoson, enabled the company "to leverage technologies and expertise toward maximizing contrast resolution in our dual-head coincidence imaging system."

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CHCPP NEWS

COMMISSION ON
HEALTH CARE POLICY AND PRACTICE

SNM Submits Comments on Practice Expense

The SNM and the ACNP recently submitted joint comments regarding HCFA's final rule on the 1999 Physician Fee Schedule and Practice Expense. The comments commended HCFA on many of the adjustments to the top-down methodology that increased the technical component practice expense relative value units (RVU) for nuclear medicine procedures. The SNM/ACNP stated that they remain concerned about the validity of the CPEP, SMS, and physician time data, but realize that the majority of these issues will be addressed during the four-year refinement period. Major recommendations to HCFA are summarized below.

- HCFA made several methodological changes in the final rule. One consequence of these was a greater reduction in the professional component reimbursement for nuclear medicine services. SNM/ACNP believe that reductions to the professional component of this magnitude are unacceptable and should be corrected during the refinement period.
- SNM/ACNP recommended that HCFA increase the 1999 physician work value of CPT code 78020 (Thyroid carcinoma metastases) from 0.60 to the AMA RUC-recommended level of 0.67.
- SNM/ACNP urged HCFA to correct several errors in the 1998 and 1999 Physician Fee Schedule regarding the technical component practice expense RVUs.
- SNM/ACNP recommended different crosswalks (reference codes) for two renal procedures new in 1998.

The recommendations that were provided, if implemented, would make relevant adjustments to the resource-based process and would make it more likely that the practice expense RVUs reflect the true cost of providing nuclear medicine procedures to older citizens.

To obtain a copy of the comments, check the SNM web site (click on Policy & Practice, Government Relations, Reimbursement, SNM Comments on HCFA's 1999 Physician Fee Schedule and Practice Expense Final Rule) or contact Wendy Smith, Director of Health Care Policy at (703) 708-9000 ext. 242 or by e-mail, wsmith@snm.org.

1999 HCPCS CODES

With the New Year it is time to review revisions to the 1999 HCPCS coding manual. What follows is a summary of the changes effective January 1, 1999.

NEW CODES

A9507, Supply of radiopharmaceutical diagnostic imaging agent, indium-111 capromab pendetide, per dose (trade name ProstaScint).

A9605, Supply of therapeutic radiopharmaceutical, samarium-153 lexidronamm, 50 mCi (trade name Quadramet).

G0125, PET lung imaging of solitary pulmonary nodules, using 2(flourine-18)- fluoro2deoxy-glucose (FDG), following CT (71250/71260 or 71270).

G0126, PET lung imaging of solitary pulmonary nodules, using 2(flourine-18) fluoro2deoxyglucose (FDG), following CT (71250/71260 or 71270); initial staging of pathologically diagnosed non-small cell lung cancer.

G0130, Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral, e.g., radius, wrist, heel).

G0131, Computerized tomography bone mineral density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine).

G0132, Computerized tomography bone mineral density study, one or more sites; appendicular skeleton (peripheral, e.g., radius, wrist, heel).

J0151, Injection, adenosine, 90 mg (not to be used to report any adenosine phosphate compounds; instead use A9270).

REVISED CODES

J0150, Injection, adenosine, 6 mg (not to be used to report any adenosine phosphate compounds; instead use A9270).

DELETED CODES

Q0159 Adenoscan, 90 mg (now J0151).

—Wendy J.M. Smith, M.P.H. is the SNM director of health care policy

Detection Cameras

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Factors to Consider Before Acquiring Coincidence Detection Systems

When deciding whether to purchase a dual-head coincidence detection system, Henkin believes that "attenuation correction is very important." Attenuation correction provides more benefit when iterative reconstruction is employed, he added. "If filtered back-projection is used for reconstruction, then attenuation correction may degrade image quality," he explained.

In addition, "make sure that the detectors have very high count-rate abilities. Standard clinical operating counts are about 1.3 million counts per second, but you'd want to have about twice that capacity for FDG studies, at least 2.5 million," he said. Planning where to locate the FDG scanner, "where it

won't interfere with other equipment," is also a consideration. And lastly, "watch out for vaporware. There are lots of people selling software that doesn't yet exist."

The first step is to consider the need for FDG studies among the referral base, said O'Donnell. "The greatest need will be in oncology, so dual-head coincidence detection could be useful in hospitals with strong oncology programs. Right now, FDG plays a fairly minor role in cardiology." O'Donnell believes that most departments will plan to use the coincidence detection system for SPECT as well as FDG studies. "Those planning to use a dual-head coincidence system mainly for FDG studies might consider a dedicate PET system instead," he noted.

Growing Demand for FDG Studies

Dual-head coincidence FDG imaging has entered the realm of clinical practice, but it's still early. "Some of our installed sites are just getting up to speed in generating referrals, learning about the technology, and gaining access to FDG," said one vendor. As this procedure continues to undergo evaluation, as reconstruction algorithms improve, and as clinical investigators collect more data in prospective trials, the use of dual-head coincidence imaging with FDG will be more clearly defined as it expands into various clinical applications. With a growing base of referring physicians who want FDG studies, nuclear medicine facilities are preparing to meet some of that demand with dual-head coincidence imaging.

—Linda E. Ketchum

U.S. Senator Champions PET

Continued from page 23N)

Mike Phelps's staff, which informs women about the benefits of PET in terms of diagnosis and staging of diseases like breast cancer. The booklet, and other efforts initiated by Mike and his staff, are resulting in new relationships with patient advocacy groups and their representatives, like Fran Visco and the National Breast Cancer Coalition, Mike Milken and CaP CURE, Nancy Brinker and the Susan G. Komen Foundation and Horace Deets and the American Association of Retired Persons. These alliances are critical next steps in future efforts we must undertake to develop a coordinated strategy to involve a broad range of interest groups and other members of Congress in advocating recognition and reimbursement for PET.

Senator Stevens needs your help. As effective as he is, he needs to have more of his colleagues informed about the benefits of PET and advocating its use. I urge all of you who operate PET centers, who are involved in medical societies, or who are leaders in industry to contact your House and Senate representatives and tell them about PET. Tell them how it can benefit them and their constituents, and tell them about the problems we are having in getting Medicare reimbursement.

The best thing you can do is to invite them to visit your PET centers and your companies to see this extraordinary technology for themselves, to see the magic of PET and the value it provides in improving the healthcare of the people they serve. The PET community also needs to educate patient advocacy groups about the benefits that PET can bring to those they represent. I'm glad to see that this process has begun, and I encourage you to expand it.

Now is the time when we need to have the PET industry—those who manufacture and sell PET equipment—commit financial and other resources to help realize broad-based reimbursement from Medicare for PET. As I noted before, we've come a long way on a shoestring, but now we need to have a real campaign to carry us the rest of the way. Finally, the broad PET community MUST WORK TOGETHER. Coordinated efforts are needed to make this effort successful. "Lone Ranger" tactics only serve to allow those who oppose PET to succeed.

I know that with your continued and coordinated efforts and enthusiasm, we will succeed in our goal of bringing the widespread use of PET to the American people. It is a great pleasure for me to be part of this effort.

—Elizabeth J. Connell