

PET Scanning Moves Into Community Hospitals

Until last summer, doctors at Baylor University Medical Center, a tertiary care teaching community hospital in Dallas, Texas, had to plan a patient's road trip to the nearest university medical center if they wanted to order a Positron Emission Tomography (PET) scan. But not anymore. Since December 1998 BUMC has its very own scanner, and six to seven patients are assessed with the scanner every day. And BUMC isn't alone. A growing number of community hospitals have recently purchased or leased PET imaging equipment; or set up contracts with several new mobile PET companies, who, much as in the early days of MRI or CT scanning, haul around a scanner on a flatbed truck and park it at the hospital for a day every week or two.

Accelerated interest by community hospitals in having direct access to PET scanning is less than a year old but growing fast, says Ryan Goulding, a research analyst at Frost & Sullivan, a leading market research firm. Barbara Franciose, group vice president of the Nuclear Medicine Group at Siemens Medical Systems, Inc., which holds 60% of the U.S. PET market, says she expects the market for PET scanners to grow by 30% in the next five years, with much of that growth coming from use of the scanners in community hospitals.

PET, of course, has been a known imaging modality for decades but has remained mostly a research technology both because of the high cost of scanners—about \$1.2 million each—and the difficulty of obtaining the isotope F-18 fluorodeoxyglucose (FDG) needed for scanning. FDG must be made in a cyclotron and has a half-life of only 110 minutes.

The new rush to have an in-house PET scanner is the result of some recent changes, according to R. Edward Coleman, MD, professor of radiology and director of nuclear medicine at Duke University Medical Center. Coleman attributes the recent surge in interest to three factors: a recent vote of safety and effectiveness for FDG by the Food and Drug Administration, which now allows companies to make and market the agent; coincidence imagers mounted on dual-head gamma cameras allowing for PET applications at a much lower cost than dedicated PET scanners; and, most importantly, a decision by the Health Care Financing Administration to reimburse facilities for five PET applications.

The FDA has found FDG to be safe and effective for several applications. These include evaluation of malignancy in patients with known or suspected abnormalities already detected with other imaging modalities or in patients already diagnosed with cancer; detection of myocardial perfusion in patients with known or suspected coronary artery disease under rest or pharmacologic stress conditions; and for patients with coronary

artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, to identify myocardium with reversible loss of systolic function.

The agency is expected to review use of FDG for evaluating dementia and movement disorders later this year.

The FDA's decision opened up a new business almost overnight—the regional manufacture and distribution of FDG, which could finally make PET scanning a viable imaging option almost anywhere. At least two companies, Syncor International Corp. of Chatsworth, CA, and P.E.T.Net Pharmaceutical Services LLC, of Norcross, GA, have formed alliances with universities who have cyclotrons across the country for regional distribution of FDG.

Joan Washburn, director of national sales and marketing for P.E.T.Net, said her company, which started up three years ago in anticipation of the FDA decision, now has 15 distribution centers and will open eight more in the first half of 2000. The cost of the isotope is about \$600 to \$800 per patient. Hospitals ordering high levels of FDG are likely to pay lower prices. The cost of the isotope is part of the insurance reimbursement, which hovers between \$1,800 and \$2,000 in most of the country.

The price of the scanners has also been a deterrent, especially for cash-starved community hospitals. But several years ago companies including Siemens and GE began making what some call "poor man's PET"—coincidence imagers loaded onto dual-headed gamma cameras, which cost \$600,000 to \$700,000. Resolution is poorer than with a dedicated scanner, but large lesions, greater than that 1.5 centimeters, can be detected.

PET experts, though, are divided on whether hospitals should bother pursuing PET imaging with adapted gamma cameras, though HCFA reimburses whether a scan is done on a gamma camera or a dedicated scanner, according to Jennifer Kepler, executive director of the Institute for Clinical PET.

"If you get a coincidence imager, make sure you know what the limitations are and what the future developments will be," said Landis Griffeth, MD, director of nuclear medicine at Baylor. "I'm a bit of a PET purist," admitted Griffeth, who says he chose a dedicated scanner over a gamma camera because that would enable his practice to do more PET scanning rather than simply select those patients who could be well served by coincidence imaging. "We wanted to do the best imaging we could to maintain the credibility of PET among referring physicians," Griffeth said.

Coleman acknowledged the limitations of a gamma camera, but said that a dedicated PET scanner is hard to justify

financially without a guaranteed minimum number of patients one can expect to scan with the device. His threshold for purchasing a dedicated scanner is three scans a day.

To make best use of the gamma camera for PET scans, say experts, physicians have to know what they will be scanning, since small lesions are not well resolved. "It's a little unrealistic to compare the two on a widespread basis," Coleman said, "[but] a camera-based scan is providing excellent information that you would otherwise not have access to."

Robert Hurwitz, MD, head of nuclear medicine at Hoag Memorial Hospital in Newport Beach, California, opted for the gamma camera system two years ago because of cost "but the idea of purchasing a dedicated system comes up at every staff meeting." The advantage of the camera, said Hurwitz, "is that with one touch of a button you can switch it from PET scanning to standard scanning such as gallium and bone scans." But Hurwitz admitted that even with his hospital's PET scanning ability, he had referred a few patients with very small lesions to a facility with a dedicated scanner.

Joseph Busch, MD, senior radiologist at the Hutcheson Medical Center in Chattanooga, Tennessee, says his six partners studied the market for a year and ultimately chose a dedicated scanner which went on line this summer, out of fear that the gamma camera might understage some cancers, "something we were already doing with CT," Busch said. His advice is to opt for a mobile scanner rather than a gamma camera.

Radiologists are going to have to make cost-benefit analyses to determine what to do. Coleman says PET applications are starting to show up frequently in non-nuclear medicine literature, especially among surgeons, which is increasing demand among all types of referring physicians. "We get referrals from general practitioners and ob-gyns, said Elizabeth Curren, marketing director of the Wendt-Bristol Diagnostic Imaging Center at Janesway, in Ohio, which has had a dedicated scanner for a year.

Over the next few years, said Coleman, the decision on what to purchase will be influenced by prices on dedicated scanners going down, technology on the coincidence imagers improving and the opportunity to lease scanners on a full-time or part-time basis. ADAC, which holds about 10% of the PET market, just announced the sale of five mobile scanners to P.E.T. Scans of America Corp, for use in mobile coaches.

Doug Holmberg, sales and marketing director of PET Imaging, LLC, transports a Siemens dedicated scanner around South Dakota. He needs only 1.2 scans per day to turn a profit. Holmberg noted, though, that while the scanner may belong to his company, the interpretation tends to remain squarely with radiologists. PET Imaging has access to physicians who can interpret the PET scans, but Holmberg says the doctors that they do business

with want to read and interpret the scans themselves—leaving the assessment to the radiologists and the business issues to his company.

But none of this would have been possible without HCFA's decision last March to begin reimbursing for five types of scans. The five approved Medicare reimbursements are evaluation of solitary pulmonary nodule (because CT or chest x-ray can't determine if the nodule is benign or malignant); staging lung cancer; staging recurrent melanoma; staging lymphoma; and staging recurrent colorectal cancer with a rising CEA. A spokesman for HCFA says that other uses will be evaluated over the next few months including staging of head and neck cancer and detecting recurrent head and neck cancer; grading degrees of malignancy in primary brain tumors and distinguishing brain tumor from treated brain tumor after therapy and staging of colorectal cancer after therapy without rising CEA.

A key imaging type under consideration with a PET scanner is for management and staging of breast cancer, though more research is likely necessary before HCFA considers reimbursement. "Once breast cancer is allowed by HCFA, sales of scanners will rocket," said Hurwitz.

Some cautions surround HCFA reimbursement, however, like the need to be sure that patients have been authorized or have signed waivers. Holmberg says that his company will not do a scan unless it first receives insurance authorization or a waiver from the patient. Other radiologists using PET scanners admit that their business requires a knowledgeable office person to deal with the insurance questions for payment.

While the entry cost may seem high, some radiologists look to the past to see the future, noting that it took eight to 10 years for MRI and CT to come down in price, and they expect the same to happen with PET. However, new technologies coupled to PET could keep some units fairly expensive. Recently Siemens coupled a CT scanner and a PET scanner to show its usefulness in early cancer detection. That system, however, is still in the research phase and is years away from a clinical application, says Steve Kuehn, head of public relations for Siemens.

But despite all the changes taking place, some experts liken failure to start PET scanning with a decision not to buy a personal computer because the technology keeps changing. Radiology department staff meetings that don't include discussion of PET at this point, though, may have to start changing their agendas. "I think that PET is bigger than the diagnostic community thinks it is at this time," said Hurwitz. "PET answers questions that CT and MR can't answer, so community hospitals had better start thinking about how they're going to get a unit."

—Francesca Lunzer Kriz