



R. Edward  
Coleman, MD



Ruth D. Tesar,  
CNMT

# Clinical PET: Are We Ready?

**P**ET imaging of fluorodeoxyglucose (FDG) is one of several metabolic imaging procedures being used to detect various diseases (1). FDG-PET imaging has been demonstrated to be useful clinically in evaluating neurological diseases such as brain tumors, complex partial seizure disorders and dementia, myocardial viability and malignant tumors throughout the body (2-6). Several factors are responsible for this increased utilization of FDG-PET imaging, but its use in the evaluation of malignant tumors has had the greatest effect on its growth. It is accurate and cost-effective for evaluating several non-central nervous system (CNS) tumors (4,5). The Health Care Financing Administration and CHAMPUS

commissioned the Technology Evaluation Center (TEC) of Blue Cross/Blue Shield to review FDG-PET imaging of non-CNS tumors. The TEC report concluded that the literature supported the use of FDG-PET for staging lung cancer and evaluating solitary pulmonary nodules (SPNs) that are indeterminate after routine imaging assessment (6). The Institute for Clinical PET (ICP) has filed a supplement to the FDA new drug application for FDG to expand its approved uses to include evaluation of lung cancer. Several third-party payers now have policies for paying for FDG-PET scans for staging lung cancer and evaluating indeterminate SPNs. It was announced in November 1997 that Medicare would begin paying for PET scans for the diagnosis and staging of lung cancer by the end of the year.

These recent developments will have a major effect on FDG utilization and FDG imaging in the U.S. Of the 150,000 new SPNs identified each year, 80,000 are considered to be indeterminate after review of previous radiographs and after CT scan (Gambhir SS, *personal communication*, 1997). These patients meet the TEC criteria for an FDG-PET scan. Approximately 170,000 people are diagnosed with lung cancer in the U.S. each year. Gambhir and his colleagues (4) have estimated that 85,000 of these patients undergo staging procedures that would include an FDG-PET scan. Thus, evaluation of indeterminate SPNs and staging of lung cancer could lead to an annual demand of 165,000 FDG-PET scans.

## Limiting Factors

In addition to the ability of PET facilities to meet such demand for FDG-PET scans, there are several other factors that will limit the number of requests for new FDG-PET studies in the next year or two: education of referring physicians, number and geographic location of PET scanners and availability of FDG. Referring physicians who are not familiar with PET imaging will need to be educated concerning the use of FDG-PET. Despite articles on FDG-PET imaging in clinical and imaging journals, ICP-sponsored educational sessions at national meetings of oncology pro-

fessional organizations such as the American Society of Clinical Oncology and continuing education sessions at the Radiological Society of North America meeting, spreading information about the role of FDG-PET scans in lung cancer to most physicians who care for lung cancer patients will take time.

Another limiting factor is the number and geographic location of PET scanners. In 1996 there were approximately 65-70 PET scanners used for imaging in the U.S. Approximately 50 of those were used for clinical PET studies. Several states and regions of the U.S. do not have access to PET scanners. A few centers were using gamma cameras and SPECT imaging of the 511 keV photons of FDG, but the limitations of SPECT imaging for detecting small tumors with FDG make it unlikely that this methodology will have a large effect on FDG tumor imaging (7). More recently, coincidence imaging of the annihilation radiation of  $^{18}\text{F}$  with dual-head gamma cameras became feasible (8). As of August 1997, there were approximately 60 camera-based PET systems installed in the U.S., and the number of installed systems is increasing rapidly. This technology is very promising for tumor imaging, and the prospective studies now being done need to be reported in the literature for the technology to be widely accepted by referring physicians and by payer organizations that have differentiated PET scanners from coincidence camera PET systems.

Can the nuclear medicine community provide the increased number of studies that will be needed? If the 25,000 FDG studies performed in 1996 were evenly distributed among the 50 clinical PET centers, each center would have performed an average of 500 FDG studies each year—2 patients per day. If the additional 165,000 lung cancer and SPN patients were to be distributed evenly throughout those 50 centers, each center would need to perform an additional 3300 studies each year (i.e., 13 patients per day). The present protocols used for whole-body imaging require a minimum of 1 hour and a maximum of 2 hours of scanner time. The 1-hour scanner time is based on emission scans performed at 10 bed positions and no transmission scans. The 2-hour scanner time is based on the whole-body emission scan plus transmission scans performed for regional and/or whole-body attenuation correction. SPN studies are also performed using attenuation-corrected scans. If only attenuation-correction images are obtained, SPN studies require a minimum of 45 minutes of scanner time. However, whole-body scans are frequently performed on patients being evaluated for SPNs.

If the 13 patient studies performed each day at each PET center included 7 staging studies and 6 SPN studies, the additional imaging time would be a minimum of 15 hours ( $7 \times 1.5 \text{ hours} = 10.5 \text{ hours} + 6 \times .75 \text{ hours} = 4.5 \text{ hours}$ ). PET centers would require major changes in hours of operation and staffing to meet this demand. If all patients were able to go to the available PET centers, two shifts (16 hours) would not be adequate to meet the additional demand. Because PET centers are already doing studies other than lung cancer staging and SPN evaluation, some centers will elect to obtain additional instrumentation for

(Continued on page 24N)

**Clinical PET***(Continued from page 16N)*

performing these studies. Coincidence camera systems may be demonstrated to be useful for many of these studies. Certainly, studies for lung cancer staging and SPN evaluation will need to be distributed over a larger number of instruments and PET centers. In addition, the utilization of FDG-PET imaging for other indications is also increasing and will cause even greater clinical demands.

Another major issue is the availability of FDG. In 1996, FDG was available for 25,000 studies. The majority of PET centers have a cyclotron and produce the FDG they use. Several centers have recently formed partnerships with industry sources to provide FDG for use at the local PET center and distribute FDG on a regional basis. The commercial partner generally provides the staffing and obtains regulatory approval for distribution (e.g., obtaining an FDA abbreviated new drug application). There are currently 12 regional distribution centers that are distributing FDG doses to the local PET center, to other PET centers and to nuclear medicine departments using SPECT imaging and coincidence camera imaging. Because of the regulations related to distributing FDG, most PET centers with a cyclotron do not distribute FDG without an agreement with a commercial partner.

To meet future needs for FDG for lung cancer staging and SPN evaluation, the 38 centers that are producing their own FDG will need to produce an additional 13 FDG doses each day. This will require major changes in production techniques and personnel. The distribution centers will need to produce daily the 13 doses used locally and the doses distributed regionally. Because of the 110-minute half-life of  $^{18}\text{F}$  and the absence of proven methods for rapid distribution, the amount of FDG production necessary for distribution within 2 hours of the production facility is approximately 3 or 4 times that needed for local use. This demand will require more distribution centers, more efficient production of FDG and more efficient transportation methods.

**Addressing the Challenges**

These challenges of meeting the potential demands for clinical FDG-PET studies will be addressed by instrumentation manufacturers, nuclear medicine facilities and FDG suppliers. These new challenges facing the nuclear medicine community are better than the challenges of not having enough demand for clinical

FDG-PET studies. Clinical PET is no longer on the brink of extinction; it is an important part of the present and future practice of nuclear medicine. PET centers that have so long struggled with how to address a low procedure volume will now have to contend with the problems of high procedure volume and increased clinical demands. Not only will PET centers need to change, but instrumentation manufacturers will need to provide dedicated imaging instrumentation that will produce excellent clinical studies in less than 1 hour, and FDG suppliers will need to provide the radiopharmaceutical in the amounts and at the times necessary to perform these clinical studies. The nuclear medicine community needs to prepare for the number of PET studies that will be needed. Rapid growth can result in problems that may be more challenging than those we faced before if it is not managed correctly. Are we ready?

**REFERENCES**

1. Coleman RE. Revealing biochemistry in a single image. *J Nucl Med* 1995; 36(9):32N-33N.
2. Kuhl DE, Wagner HN, Alavi A, et al. Positron emission tomography (PET): clinical status in the United States in 1987. *J Nucl Med* 1988;29:1136-1143.
3. Al-Aish M, Coleman RE, Larson SM, et al. Advances in clinical images using positron emission tomography. National Cancer Institute Workshop Statement. *Arch Int Med* 1990;150:735-739.
4. Gambhir SS, Hoh CK, Phelps ME, Madar I, Maddahi J. Decision tree sensitivity analysis for cost-effectiveness of FDG-PET in the staging and management of non-small-cell lung carcinoma. *J Nucl Med* 1996;37:1428-1436.
5. Valk PE, Pounds TR, Tesar RD, et al. Cost effectiveness of PET imaging in clinical oncology. *Nucl Med Biol* 1996;23:737-743.
6. *FDG positron emission tomography for non-CNS cancers*. Chicago: Blue Cross/Blue Shield TEC Assessment Program; 1997;12:5.
7. Martin WH, Delbeke D, Patton JA, et al. FDG-SPECT: correlation with FDG-PET. *J Nucl Med* 1995;36:985-995.
8. Coleman RE. Camera-based PET: the best is yet to come. *J Nucl Med* 1997;38:1796-1797.

—R. Edward Coleman, MD  
Department of Radiology,

Duke University Medical Center, Durham, North Carolina

—Ruth D. Tesar, CNMT  
P.E.T.Net™ Pharmaceutical Services,  
Sacramento, California

For correspondence contact: R. Edward Coleman, MD, Box 3949, Duke University Medical Center, Durham, NC 27710.

**Lines from the President***(Continued from page 21N)*

demic institutions and private practices worldwide. Once gathered, the data will be expanded to include indications for studies. The final data set, not expected to be collected until some time in the future, will be the outcome for patients undergoing procedures.

**Communications**

While continuing to publish our well-regarded journals, the SNM Department of Communication Services is wit-

nessing a revitalized book-publishing program and launching an innovative nuclear medicine self-assessment series.

In the past six months, the SNM Communication Services Department has released two important new books: *MIRD Cellular S Values* (a long-awaited and much-needed reference text by the SNM MIRD Committee) and *Radionuclides in Nephrourology* (published in partnership with the Group on Radionuclides in Nephrology and containing major consensus reports). Over the next nine months, two more notable books will be added to the SNM list—*Diagnostic Differentials*, by

*(Continued on page 25N)*