## COMMENTARY

# CLINICAL PET: A REALITY

PET HAS SUCCESSFULLY MADE THE TRANSITION from the research laboratory to the clinic. There are currently over 45 PET sites in the United States. A survey of manufacturers suggests that as many as 30 new clinical PET sites will become operational in the next 18 months. Over one-third of all PET facilities in the country are clinical sites and are being reimbursed on a regular basis. Current clinical PET procedures include the assessment of myocardial viability and myocardial perfusion, the presurgical evaluation of patients with epilepsy, the grading of malignancy in gliomas, the differentiation of radiation necrosis from glioma recurrence, and the differential diagnosis of patients with dementia. The vast majority of these scans are being reimbursed on a case-by-case basis at an 80% reimbursement level.

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PET has become an integral part of patient care at institutions with clinical centers. For example, at UCLA, brain tumor patients have PET studies prior to any operative procedure for tumor resection. The same is true of all patients being evaluated for surgical treatment of their epilepsy.

As recently as three years ago, PET was principally a research tool, today it is a proven clinical technology that provides unique diagnostic information that affects patient management. Unlike previous high technology advances, however, PET has a distinguished research record spanning more than a decade. This experience has proven to be both a curse and a blessing in the search for comprehensive reimbursement policies. The blessing is that the technology is proven; the results have been quantified in the research setting, are widely accepted, and have a long track record of safety. The curse is that insurers want to delay, as long as possible, the introduction of the technology to the clinical setting. An important element of this approach is the development of utilization protocols for the technology. More and more insurance carriers are relying upon these protocols to manage the widespread diffusion of new technologies—even when a technology, such as PET, is not "new."

In recognizing this fact, the Institute for Clinical PET (ICP) has responded to insurance carriers' desire for utilization by developing a scientifically based set of cardiac PET protocols. This approach is the first time that an industry is working closely with insurance carriers to develop a utilization protocol prior to an agreement on reimbursement policy.

These facts inevitably lead to the conclusion that PET will increasingly become the technology of choice within the protocols adopted by ICP. It is clear that PET is on the leading edge of technology assessment practices. While industry is supportive of ICP's approach, it should be recognized that this historical change has significant consequences for the future of all technology assessment and reimbursement decisions. In the future, multi-disciplinary technologies will be forced to develop organizations such as ICP to successfully manage regulatory and administrative hurdles.

In the past twelve months, ICP has taken a leadership position on education, regulation, and reimbursement—both public and private—of clinical PET. ICP has been actively engaged in working with the Health Insurance Association of America (HIAA), the largest insurance association in the country, on many issues relevant to clinical PET. During two conferences—one on cardiac PET in November 1990 and a second on clinical PET neuro-imaging in March 1991—individual insurance carriers were well informed about PET and heard its use debated. They are now ready to make policy decisions on reimbursement for clinical PET studies. In addition, ICP has begun a major effort with the national Blue Cross/Blue Shield organization on an agreement for their coverage policy decisions on PET.

In addition to ICP's efforts in the private sector, the organization has been coordinating the activities and submissions to the Health Care Financing Administration (HCFA) regarding Medicare reimbursement for PET scans. This process has been a long and involved one, but it is nearing its final phases. At present, the Office of Health Technology Assessment (OHTA) is completing its report to HCFA on PET. The report will contain recommendations on the parameters for Medicare reimbursement of PET scans. Traditionally, third-party insurers have waited until OHTA and HCFA have made their policy decisions for covered technologies. PET is demonstrating the new order of things by pursuing and achieving private sector coverage in advance of government approvals. Once OHTA completes its report—scheduled to be this summer—HCFA will make its decision in the following few months.

Although documented evidence demonstrating PET's effectiveness exists, nearly all of this information has been collected in the research setting. Indeed, the initial refusal of HCFA to consider PET for reimbursement was because so little "clinical" data existed in peer-reviewed journals. One of ICP's first priorities has been the collection and analysis of clinical data from a multi-center prospective study. The study has been ongo-

*(continued on page 54N)*

### *Mazziotta Commentary*

*(continued from page 46N)*

ing for nearly a year and was completed on March 15, 1991. The study involved six clinical sites and over 400 individual case studies. Physicians were surveyed pre-and post-scan to determine the effect of the PET results and to determine and quantify patient management decisions as a result of the unique PET information. ICP collected data on the reasons for obtaining PET studies, the pre-scan diagnosis, the ultimate diagnosis, the influence of PET data on diagnosis, other diagnostic testing, as well as any therapy plan and the ultimate outcome. ICP expects to extend this study to longer term evaluations. The four major categories of patients included: patients with dementia, with radiation/chemotherapy necrosis, or with complex partial epilepsy, and those in whom myocardial viability was assessed. The analyses and conclusions of this study will be submitted to a peer-reviewed journal for publication.

Another aspect of the continuing struggle for PET reimbursement has been the lack of independent quantitative data on the true costs of clinical PET. In order to solve this problem, ICP funded an independent assessment of the costs associated with clinical PET by the accounting firm of Coopers & Lybrand. This report which was issued to ICP members during February, represents one of the most comprehensive analyses of clinical PET costs. This report was distributed to numerous medical directors, congressional supporters, and staff personnel at HCFA, OHTA, and the Food and Drug Administration and has become the foundation upon which all discussions of clinical PET costs are based.

The many achievements of ICP have been possible through the efforts of individual physicians from The Society of Nuclear Medicine (SNM), the American College of Nuclear Physicians (ACNP), the American College of Cardiology (ACC), the American College of Radiology (ACR), and the American Academy of Neurology (AAN) as well as interested PET supporters from outside academia. By urging the federal government to begin the regulatory technology assessment process of PET, these individuals have brought PET to its current clinical state.

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### *Welch Commentary*

*(continued from page 44N)*

New Accelerators

| Company | Type of Accelerator | Particle(s) | Comment |
|---|---|---|---|
| Ion Beam Applications, Belgium | Cyclone (Cyclone-3) | 3 MeV deuterons | $^{15}O$-only accelerator; Size of a Coke® machine |
| Science Applications Int'l Corp., San Diego, CA | Radio-frequency quadruple accelerator | 8 MeV $^{3}He$ | With shielding 1/9 weight of cyclotron; $^{15}O$ and $^{11}C$ produced carrier added |
| ACCSYS Technology Pleasanton, CA | Ion linac | Several designs; 3 MeV deuterons 11 MeV protons | Lightweight high current machine |
| Science Research Lab, Inc. Somerville, MA | Electrostatic accelerator (TCA) | 3.7 MeV protons and deuterons | Very high current accelerator; theoretically can produce all PET nuclides at high yield |

**References**

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