

larger molecular imaging community. Specific strategies, many derived from points made in the formal presentations, were included for following through on each of the recommendations and appear here as bulleted items after each recommendation.

- (1) Increase education and marketing efforts directed to patients and advocacy groups.
  - Identify a well-known spokesperson.
  - Create a speakers bureau of imaging experts and physicians with expertise in PET/CT.
  - Identify key advocacy groups and provide information for inclusion in their Web sites.
  - Encourage interest in newsworthy stories, such as the negative impact of Centers for Medicare and Medicaid Services (CMS) decisions on the availability of health care.
  - Advertise and explore opportunities for product placement in the popular media.
  - Encourage production of programming on scientific networks, such as National Geographic and the Discovery Channel.
- (2) Increase awareness of practice and procedure guidelines among imaging experts and referring physicians.
  - Educate referring physicians about practice guidelines.
  - Educate imaging experts about procedure and reporting guidelines.
  - Participate in review and development of practice guidelines by other professional organizations.
  - Develop appropriateness criteria to encourage proper utilization of PET/CT.
  - Perform a needs assessment survey of referring physicians.
  - Engage other professional organizations in an intersocietal dialog on the value of molecular imaging, identify shared goals, and develop coordinated action plans.
- (3) Develop individually tailored PET/CT procedure guidelines to minimize radiation dose and improve image quality.
  - Provide education and cross training for physicians and technologists.
  - Educate referring physicians about the advantages of new paradigms.
- (4) Perform economic analyses of high-impact applications.
  - Example: Therapy monitoring in lymphoma.
- (5) Lobby CMS to provide appropriate reimbursement, including the following examples:
  - Radioimmunotherapy.
  - Unpackaging of PET tracers and technical reimbursement.
  - Reimbursement based on cost-to-charge ratio or average wholesale price + 5% + delivery.
- (6) Review and update information used to support PET/CT certificate of need applications.
  - The SNM Government Relations Committee should address individual state issues.
- (7) Identify potential high-impact areas of clinical and translational research.
  - Develop a prioritized list of important areas.
  - Identify National Institutes of Health funding opportunities and align research with programmatic goals.
  - Provide organizational support for research studies.
- (8) Educate medical students about the value of molecular imaging.
  - Invite local students to attend SNM Annual and Mid-Winter meetings.
  - Produce and distribute case-based educational DVDs.

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## A New Paradigm to Increase Utilization of PET/CT

**T**he fastest-growing clinical application of molecular imaging is the evaluation of tumor metabolism using <sup>18</sup>F-FDG. The National Comprehensive Cancer Network (NCCN) includes PET or PET/CT in 18 of its 31 practice guidelines. This reflects the large escalation we saw in the applications and capabilities of PET after the introduction of hybrid scanners in 2000 and 2001. Whereas the annual number

of CT procedures in the United States has risen to 60 million or more, only about 2 million PET/CT procedures are performed each year—significantly less than 5% of the total.

### Challenges to Increased Utilization

The first question is: why? One explanation is that the technology itself faces several challenges. We have little

available data on cost effectiveness, with surprising gaps in many areas. As a result, reimbursement is limited or absent in many areas. Moreover, we are challenged by limited availability of the technology outside large urban centers. Referring physicians who know that the technology is unavailable without substantial patient travel or is not reliably available 5 d/wk are understandably less likely to recommend PET/CT. Limited availability thus becomes an element in a vicious cycle of underutilization.

Interpreting physicians also face challenges in integrating PET/CT into their practices. Because it is a dual modality, additional education and training are required—regardless of whether one comes from a nuclear medicine or a radiology background. Outside of academic centers, the low rate of professional reimbursement for the amount of work required to interpret PET/CT images is perceived as a disincentive. The volume of studies may also initially be low in settings outside of urban academic centers. The result is another vicious cycle in which imaging specialists have insufficient incentive to take the first steps to begin to adopt PET/CT as a routine part of their practices.

The referring physician faces different challenges. Many referring physicians are still uncertain about the clinical value of PET/CT, especially when used as an adjunct to conventional CT imaging. We cannot underestimate the “hassle factor” for these physicians. Ordering a PET/CT as an adjunct to CT requires more paperwork. Even National Oncologic PET Registry paperwork, easy as it is, requires additional work and may constitute a significant barrier. Finally, referring physicians are sometimes confounded by contradictions and inconsistencies in the separate reports accompanying the diagnostic CT and subsequent PET/CT results.

### A New Paradigm: PET-Optimized CT

I propose a new paradigm for PET/CT imaging that addresses many of these challenges. In short, adoption of this paradigm would replace the 1-size-fits-all approach with the 1-stop shop: replacing the conventional eyes-to-thighs PET/CT scan with PET-optimized CT. The practice standards in most types of cancers do not include imaging of the neck, chest, abdomen, and pelvis. All the cancer algorithms include focused imaging of 1 and possibly 2 body regions. If we take these practice guidelines and apply them to PET/CT, then PET-optimized CT can be an effective single diagnostic procedure in those patients for whom imaging is a part of the diagnostic or evaluation algorithm.

More specifically, in dealing with patients with: (1) head and neck cancer, we would scan only from the skull base to the aortopulmonary window; (2) chest (lung) cancers, we would scan only from the clavicles to the kidneys; and (3) colon cancer, where abdomen and pelvis imaging is indicated, we would scan from the lung base to the pubic symphysis. When indicated we would do this with intravenous or oral contrast, either negative or positive, using the same CT protocols as those in standalone CT imaging.

### Advantages

This new paradigm, single-step PET-optimized CT, offers significant advantages over dual-step diagnostic CT followed by eyes-to-thighs PET/CT. First and most important, patients benefit from higher-quality diagnostic data and lower radiation exposure. The interpreting physician benefits by performing less work for about the same reimbursement, with more time to adequately interpret the studies. Referring physicians benefit with a lower hassle factor, ordering only a single procedure for which results will be returned more quickly in a single integrated report without contradictory findings.

A closer look at each of these areas of advantage reinforces the potential of this paradigm to increase utilization and acceptance of PET/CT. Most individuals in the imaging community are familiar with the 2007 article by Brenner and Hall on CT as a source of significant radiation exposure (*N Engl J Med.* 2007;357:2277–2284). This provocative and widely publicized article suggested that because of the high rate of CT utilization, “1.5%–2% of all cancers in the United States may be attributable to the radiation from CT scans.” Logic dictates that if everyone who undergoes CT proceeds to PET/CT imaging, the rate would double. One advantage of moving from the eyes-to-thighs to a more focused PET/CT approach is that we can cut down on the amount of <sup>18</sup>F-FDG we use from 15 to 7 mCi or less. This would constitute a significant gain over and above that achieved by eliminating the initial CT. If we acquire the CT scan from the skull base to the thighs using 100 mA as the tube current (not an unreasonable setting and 1 used by many practices), the whole-body effective dose equivalent is quite high at 2.5 rem. Moreover, using this approach we are including breasts, ovaries, and testes, often unnecessarily. If, for example, all we want to do is acquire a PET/CT in a patient with a lung nodule and we stop scanning at the kidneys, the ovaries and testes receive virtually no radiation exposure. If we perform PET-optimized CT in colorectal cancer, the breast would receive almost no exposure.

A case study will serve as an example of the benefits of this new paradigm for the interpreting physician. A sample eyes-to-thighs scan from a 62-y-old man with a lung nodule includes 256 axial slices alone, not including the multiplier for the multiple windows we may need to review in the diagnostic process. By the time lung, bone, and soft tissue windows are added in, this single scan produces upward of 700 images. We know that image interpretation time varies with complexity. Although uncomplicated cases may require as little as 10 min, more difficult cases may take 30 min or more. This is not economically viable and, in fact, is a disservice to patients, because the result is that we are rushed in other cases and unable to spend sufficient time where it is most needed. In the same patient with a lung nodule, I would propose scanning only the thorax/upper abdomen and abdomen/pelvis, for a total of only 179 slices and a review time of 5 min. In addition to reducing radiation exposure to the patient as well as to ourselves, this approach

would decrease by half the number of images to be reviewed. The result would be that we could spend half as much time on the case *or* spend the same amount of time and look at it more carefully.

The financial impact of implementing this paradigm in this example is surprisingly small. The latest Centers for Medicare and Medicaid Services Physician Fee Schedule reimbursement rate for skull base-to-thigh CT imaging (78815) is \$113.22. Reimbursement for the more limited area scan is \$102.09. This small negative impact would be more than offset by the decreased time needed to interpret the study, as well as the advantages to patients and practitioners.

Another advantage of imaging only a limited area is suggested in data in a 2003 article by Leonard Berlin, MD, on the potential legal ramifications of performing whole-body CT as surveillance (*Am J Roentgenol.* 2003;180:317–322). When we acquire CT scans from the eyes to the thighs, we are, in fact, performing CT as surveillance in areas where the likelihood of metastatic disease is quite low. How many of us, for example, have seen metastases in the pelvis when scanning a patient with head and neck cancer? The answer is almost never. But the CT scan we are reading and for which we are legally responsible is, in effect, a broadly focused surveillance scan.

Berlin's statistics point to the problematic aspects of these scans. Missed diagnoses are not uncommon among experienced radiologists, with estimates ranging from 15% to 30%. He cited as an example a study of thoracic radiologists asked to review chest CTs in patients with known pulmonary nodules. Thirty percent of small pulmonary nodules were missed by experienced radiologists who knew their assigned task was to look for them. Overdiagnosis is a second problem area. FDG is not 100% specific for tumors, and we have many false positives as a result of focal physiologic and benign uptake. Berlin estimated the rate of overdiagnosis based on CT alone to be 22%. If we add in overdiagnosis of inconsequential findings from the PET part of the examination, the percentage could be as high as 50%. Berlin also addressed the subject of radiation exposure. His rough estimate was that every rem effective dose equivalent increases the incidence of fatal cancer by 1 in 2,000. Most of us are performing at least that number of PET/CTs per year and some of us many more. Finally, Berlin discussed the pitfalls associated with our duty to communicate unexpected findings. Almost by definition, anything we see in the head and neck of a colon cancer patient, for example, is going to be an unexpected finding. If we fail to communicate these findings, we may be in legal jeopardy. Adopting the new paradigm would significantly reduce the jeopardy attached to the surveillance aspects of broader-field CT imaging.

What prevents us from adopting this new paradigm? The answer is: almost nothing. If we look at the 2007 NCCN practice guidelines for imaging 5 common types of tumors (in head and neck, non-small cell lung, breast, and colon cancer and lymphoma), based on decades of experience with these cancers, nowhere is there a statement

that we *must* scan the neck, chest, abdomen, and pelvis. By changing the paradigm to PET-optimized CT of a limited area, we would be fitting in exactly with established practice guidelines that have served us well for decades.

Evidence in the literature also suggests that we do not need to perform eyes-to-thighs PET/CT. Aquino and Fischman (*Chest.* 2004;126:755–760) looked at more than 1,000 patients with either lung nodules or newly diagnosed lung cancer. They read the scans looking only from clavicles to midkidney instead of reviewing the entire dataset. They found that the additional data would have resulted in treatment management changes in only 1 patient.

In a more recent study by Wartski et al. (*Nucl Med Commun.* 2007;28:365–371), contrasting focused with conventional PET/CT in patients with head and neck cancers that presented as unknown primaries, distant disease was found in about 7% of patients. In this case, all of the additional findings were found in the thorax, indicating that an eyes-to-thighs scan including the abdomen and pelvis would have been unnecessary.

At my institution, Iagaru et al. performed a study on which we reported at the 2007 SNM Annual Meeting. In 175 PET/CT scans of patients with head and neck cancer, we found disease below the diaphragm in only 4 patients. I should note that those pickups were balanced negatively by 3 false-positive diagnoses below the diaphragm resulting from benign etiologies.

What about incidental findings? We have examples from our lab in which a regional approach would still identify most incidental findings. But certainly there are cases in which this would not be so. As an example, we had a patient with known lung cancer referred for staging. The clavicle-to-midkidneys data showed no incidental findings, but the patient actually had stage 4 disease with a metastasis behind the psoas muscle. Another example was in a patient evaluated for a new lung cancer in which the more focused scan would have missed a focal lesion in the abdomen. Do these examples mean that PET-optimized CT is too problematic for routine use? I would suggest an easy solution: we should perform a non-attenuation-corrected PET scan over the wide field of view. We would not have missed either of these incidental lesions on the noncorrected images, which can be read quite quickly. After spotting incidental findings on a non-attenuation-corrected study, we would always have the option to go back and perform PET-optimized CT over the area in question.

## Conclusion

I would recommend, then, that optimized PET/CT of a single anatomic region should replace our conventional approach, as long this is consistent with standard clinical practice. I am not proposing that we perform PET/CT on every patient. Instead, I am proposing that when CT and PET are both indicated in the workup, we replace the conventional sequence with a single optimized PET/CT. This would be readily accepted by referring physicians, because it is

consistent with their practice standards, is less hassle, and results in less uncertainty about the value of the study. For interpreting physicians, economies of time can be achieved by limiting the scan to a single body region, which is consistent with practice guidelines. Decreased patient radiation exposure will also increase acceptance of the technology.

Nuclear medicine physicians and radiologists must educate referring physicians about the utilization of PET/

diagnostic CT. Adoption of this approach could have a profound, positive impact on clinical utilization of molecular imaging with PET.

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# Engaging and Nurturing Referring Physician Relationships

In the years since we received Centers for Medicare and Medicaid Services (CMS) approval for the first covered clinical indications for PET, we have overcome many of the barriers that prohibited widespread adoption of this modality. Today, the availability of unit-dose PET tracers; technical equipment advances in PET/CT; cost-effective entry options, including turnkey management solutions; mobile PET/CT access providing weekly service into rural communities throughout the United States; and broadened coverage by CMS have combined to make PET/CT more feasible and more readily adopted and utilized. Yet PET/CT procedures represent only 2.5% of the total oncologic CTs performed annually in the United States. Outside of academia, referring physician adoption of PET/CT as a routine clinical tool for patient management remains the final hurdle. My own perspective on the current state of referring physician adoption and utilization of PET/CT in the community setting, as well as experience-based strategies for nurturing and developing key referring physician relationships, will be the focus here. The role of the interpreting physician as a PET/CT consultant and champion will be reviewed, and case studies demonstrating successful techniques for broadening the referral base and increasing utilization will be discussed.

## Identifying and Crossing Barriers to Adoption

One of the greatest early barriers to clinical adoption of PET and PET/CT was limited access to technology, a problem that no longer is so daunting. We now have cost-effective mobile entry points for rural communities. In the western part of the country, where I work, PET/CT is available within 100–120 miles of every patient. In almost every community in which an oncologist practices, PET is available at least once each week. A broad network of commercial cyclotrons provides reliable supplies of unit-dose <sup>18</sup>F-FDG. Turnkey management solutions are now available, and all vendors

offer support for program implementation to help individuals surmount the barriers to getting started in PET and PET/CT imaging.

Another initial barrier to widespread adoption that remains challenging is limited coverage by CMS and private payers. On the positive side, we now have wider CMS coverage for diagnosis, staging, and restaging of 6 major cancers as well as conditional coverage for breast, cervical, and thyroid cancer. Moreover, access to any and all oncology applications through the National Oncologic PET Registry (NOPR) has been available for more than 2 y. As a result we have seen an 18%–20% increase in referrals from the same referral market. The NOPR mechanism has expanded the ability of referring physicians to use this beneficial technology to solve problems in a wide range of patients. Many if not most commercial payers are covering uses of PET and PET/CT beyond the CMS restrictions when medical necessity is demonstrated.

But the reimbursement news is not all good. The proposed Deficit Reduction Act changes in imaging reimbursement threaten to impact molecular imaging and, in fact, to have the most significant adverse effects on patients for whom access to these technologies has been difficult in the past. If services are provided by a mobile provider, for example, and the cost per scan exceeds reimbursement, the service cannot continue. If the cost for the pharmaceutical includes a \$600–\$1,600 charter air flight into rural areas and the FDG cost is bundled into the hospital reimbursement cost, there is no way to make up the difference. The biggest risk in widespread adoption of PET/CT as a clinically viable tool in the community environment is that it cannot be supported if adequate reimbursement is not available for the cost of distributing the radioisotope in those communities.

Another barrier in the past was the widespread view of PET as “unclear” medicine. PET provided limited anatomic correlation, a fact that sometimes made it difficult to