

clinical trials that use measures of metabolic change to assess therapeutic response rather than conventional CT or MR imaging measurements of change in tumor size. PET assessment of changes in tumor uptake of  $^{18}\text{F}$ -FDG has been gaining acceptance as one such measure.

$^{18}\text{F}$ -FDG PET has now become a commonly used imaging modality in oncology, primarily because of the widespread availability of PET instruments, an accumulation of clinical data, and the gradual expansion of oncology indications for which Medicare will reimburse providers. With this increasing clinical experience, it is becoming clear that  $^{18}\text{F}$ -FDG PET may have an important role as both an effective clinical management tool and as a surrogate endpoint for assessing the clinical efficacy of novel oncologic therapies. Although  $^{18}\text{F}$ -FDG PET is increasingly used as a biomarker for predicting therapeutic response, we lack widely accepted and standardized protocols for using  $^{18}\text{F}$ -FDG PET as a tool for assessing response to therapy.

### The Development of Consensus Guidelines

It is increasingly clear that the potential of  $^{18}\text{F}$ -FDG PET as such a tool will not be achieved unless standard protocols are developed to facilitate the accumulation and comparison of data across multiple clinical sites. A review of scientific publications indicates that the methods currently used to acquire  $^{18}\text{F}$ -FDG PET images and to assess FDG metabolism and tracer uptake are varied.

To provide such guidance and to help standardize the acquisition and interpretation of  $^{18}\text{F}$ -FDG PET in clinical trials sponsored by NCI, the Cancer Imaging Program (CIP) of the NCI convened a workshop in 2005 in Washington, DC, to review the status of  $^{18}\text{F}$ -FDG PET technology and clinical experience in both diagnosis and monitoring response to therapeutic interventions. The assembled group of experts focused their review and recommendations on patient preparation, image acquisition, image reconstruction, quantitative and semiquantitative analysis of  $^{18}\text{F}$ -FDG PET images, quality assurance issues, reproducibility, and other parameters of importance to be used in PET studies before and after a therapeutic intervention. Their discussions were based on a review of the existing medical literature as well as on the expertise of those participating in the working group.

The workshop formed the basis for the development of guidelines that were honed over a series of discussions in

the working groups over the next several months. These consensus recommendations were published in *The Journal of Nuclear Medicine* (1). It is the NCI's intention that these guidelines will serve as the recommended set of procedures for the performance (i.e., acquisition and analysis) of  $^{18}\text{F}$ -FDG PET imaging of patients participating in NCI-sponsored diagnostic and therapeutic clinical trials.

In addition, the CIP has also engaged the MR imaging community in a similar process to develop consensus guidelines for the performance of dynamic, contrast-enhanced MR imaging as well as MR spectroscopy. These guidelines and additional information are available at the CIP Web site (<http://imaging.cancer.gov/>).

Among the questions that merit additional discussion are:

- (1) What is the appropriate process for implementation of the guidelines in NCI trials?
- (2) How will/should these guidelines be accepted and incorporated into other cancer trials?
- (3) How will data coming out of these trials be evaluated?
- (4) What constitutes a critical mass of trial data for defining test characteristics (i.e., variability, precision, accuracy, etc.)?
- (5) How will criteria/guidelines be developed for defining relevant clinical parameters (i.e., stratifying patients to higher or lower risk, defining partial or complete therapy response, etc.)?
- (6) How will the guidelines for acquisition, analysis, and interpretation be kept current and accurate in the face of constant change in the pertinent technologies and therapeutics?

### REFERENCE

1. Shankar LK, Hoffman JM, Bacharach S, et al. Consensus recommendations for the use of  $^{18}\text{F}$ -FDG PET as an indicator of therapeutic response in patients in National Cancer Institute trials. *J Nucl Med*. 2006;47:1059-1066.

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## Education and Training Activities at the NIBIB

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) supports training directly by providing individual and institutional training grants

and indirectly by providing research grants. More than 180 individuals are supported at the predoctoral or postdoctoral level through individual and institutional training grants.

The training grant is typically one support component of a training program. Students may receive 1–2 years of support on a training grant, followed by additional years of support through research grants. At the postdoctoral level, NIBIB supports individuals on training grants and also by direct support on research grants. In addition, NIBIB supports a 1-year research experience for medical residents by way of a special supplement program to regular research grants. These supplements are designed to give medical residents a productive research experience during their training.

NIBIB also supports graduate students and postdoctoral students by way of research grants. More than 600 grants are active. These research projects support more than 400 individuals in pre- and postdoctoral training. We also make use of mentored career development awards for providing a training/career development experience for new investigators.

In addition to graduate training, we also support summer programs for research experiences in bioengineering and bioinformatics at the intramural labs at NIH and in collaboration with the National Science Foundation at 10 universities. These programs support more than 100 students per year.

The NIBIB places a special emphasis on training in interdisciplinary research. Medical imaging science, which may require expertise and collaboration in clinical medicine, physics, engineering, chemistry, biology, informatics, or other fields of research, is particularly well suited to an

interdisciplinary approach. In collaboration with the Howard Hughes Medical Institute, we are developing new training programs in interdisciplinary research.

Several questions about continued training in medical and molecular imaging arise with regularity. Among these are:

- (1) What are the essential elements for a training environment in molecular imaging science? What is the appropriate mix of disciplines? Are co-mentors from different disciplines essential?
- (2) How should chemists and others from the physical sciences and engineering be trained clinically?
- (3) How can we best interest and recruit bright chemists to careers in molecular medicine?
- (4) How can we best interest and recruit bright clinicians to research in molecular medicine?
- (5) How should research and clinical responsibilities be balanced for a clinical researcher?
- (6) How should the training experience for clinicians be structured, and when should it occur in the overall clinical training?

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