



Positron Emission Tomography: The VHA PET Experience

What is positron emission tomography?

Positron emission tomography (PET) is a form of nuclear medicine imaging. Using radioactively labelled compounds (radiopharmaceuticals), PET produces images that display the *functioning* of human organs. PET may complement information obtained from anatomic imaging methods, such as CT or MRI.

Why is PET important to VHA?

VHA has made a substantial resource commitment to PET. Since 1979, VHA has approved 12 PET centers, 10 of which are operational. PET is recognized as a valuable basic research tool. The potential clinical diagnostic applications of PET were the focus of an assessment by the Management Decision and Research Center (MDRC).

Why was an assessment of PET conducted?

The MDRC Technology Assessment Program was charged with conducting a rigorous assessment of PET to assist the Under Secretary in planning VHA policy on PET. The MDRC was asked to provide information on VHA's current uses of, and experience with PET, and to consider whether VHA should establish additional PET centers.

Methods

The MDRC convened an Advisory Committee to focus the assessment and to recommend policy decisions based on the assessment findings.

The Committee identified several clinical conditions of importance to veterans for which PET has potential diagnostic applications:

- solitary pulmonary nodules;
- lung cancer;
- head and neck cancers;
- breast cancer;
- colorectal cancer; and
- Alzheimer's disease.

The Committee restricted the scope of the assessment to studies that used the most common radiopharmaceutical,

fluorodeoxyglucose (FDG), with PET as a diagnostic test in the clinical management of these conditions.

Using explicit criteria and an analytic framework developed from principles of evidence-based medicine, the MDRC conducted systematic reviews of research articles published in peer-reviewed medical journals.

The MDRC also conducted surveys and site visits of VHA PET centers to collect information on PET imaging utilization, center operations, and research activities.

Highlights of the PET assessment

The MDRC found that research into the clinical utility of PET for the selected conditions is in its preliminary stages. Methodologic weaknesses in the published studies seriously limit the validity and generalizability of the available evidence on the accuracy of PET as a diagnostic test. Few studies addressed changes in treatment decisions based on PET findings. None of the studies identified by the MDRC reported changes in the outcomes of care or the cost of care that could be associated with the use of PET.

Based on these findings, the assessment team believes that the literature, as of September, 1996, does not support widespread incorporation of PET into routine diagnostic strategies for the applications addressed in this assessment.

Alzheimer's disease

Published studies using PET to diagnose Alzheimer's disease have been relatively well constructed. Diagnoses of dementias of the Alzheimer's type using PET correspond closely to those made with widely used clinical criteria. Studies in Europe are underway to define the agreement of PET with the gold standard for diagnosis of Alzheimer's disease (examination of brain tissue on autopsy). However, several compelling reasons argue for continued use of PET primarily as a research tool. These reasons include:

- lack of valid estimates of the positive predictive value of PET,
- parallel developments in other tests, and
- the limited treatment options for Alzheimer's disease.

Selected cancers

The published evidence for the accuracy of PET in diagnosing cancer is less convincing. Many studies did not adhere to established principles of study design and tended to overestimate the accuracy and clinical value of PET. The lack of epidemiologic information in these studies is a critical obstacle in VHA's efforts to rationalize service provision on a regional or system-wide basis. This short-coming makes extrapolation of study results to defined populations, and subsequent planning for these populations, difficult.

FDA compliance

The FDA has approved two PET radiopharmaceuticals for limited use in PET scanning. FDA regulations state that PET centers which manufacture radiopharmaceuticals and clinical investigators who wish to conduct clinical trials with an unapproved PET radiopharmaceutical must proceed under the aegis of federal (not state) regulations. The FDA has offered to work with the PET community to help sponsors and investigators interpret and follow the appropriate regulations.

Site visits

The site visits and surveys confirm that VHA has made a substantial resource commitment to its PET imaging facilities. VHA researchers who were interviewed for this assessment widely credited PET as an important basic research tool. Several suggestions were offered to improve the efficiency of basic research activities and PET center operations. Site investigators identified a wide range of research and clinical activities in VHA PET centers, but noted that these activities remain largely uncoordinated.

Recommendations

The Advisory Committee concurred with the results of the assessment and supported the conclusion that VHA should not invest in additional PET centers at the present time. Rather, VHA should maximize the value of its existing commitment, which could include:

- Implementing a VHA PET registry for collecting systematic, standardized data and for tracking the utility of PET in selected conditions.
- Coordinating efforts by VHA PET centers and their academic affiliates to comply with FDA regulations to identify clinical research areas of interest to VHA, and to design multi-center studies of high methodologic quality.
- Supporting rigorous, prospectively designed clinical research that expands the body of PET literature in a manner that is methodologically sound.
- Submitting currently unpublished data from studies of high methodologic quality for peer review.

Implementation of recommendations

The recommendations in the VHA PET assessment were reviewed and approved by the Under Secretary, and will be implemented through the Office of Patient Care

Services. Dr. John Booss, the field-based Director of Neurology, has been appointed to facilitate the process. The "PET Action Plan Group," which includes VHA PET Center Directors, will coordinate the activities of PET facilities throughout the VHA system, with some central oversight and assistance. Initially, the Group's primary focus will be to establish a PET registry and to coordinate relations with the FDA. The Group will meet on July 1 at Headquarters to finalize plans for the registry and to discuss clinical topics for which multi-center studies could be conducted.

The VHA PET community has a unique opportunity to improve the quality and content of its scientific base, and to provide sound, valid evidence on which to base future decisions regarding the role of PET in improving health care to veterans and to the general population.

How to get the PET report

- Request a copy through your local VAMC library.
- Download an electronic copy in PDF format on the VA intranet (<http://152.128.2.7/mdrc>) or from the VA home page (<http://www.va.gov/mdrc>).
- Order a copy from the NTIS by calling 800-553-6847 and asking for publication # PB97-143614 (paper copies, code A14) \$49.00, (microfiche copies, code A03), \$19.50.

REFERENCE

Management Decision and Research Center Technology Assessment Program. *Positron emission tomography: descriptive analysis of experience with PET in VA and systematic reviews: FDG-PET as a diagnostic test for cancer and Alzheimer's disease.* October, 1996. Veterans Health Administration. Department of Veterans Affairs: Washington, D.C.

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A N N O U N C I N G

The MDRC Technology Assessment Program of the Health Services Research and Development Service, Office of Research and Development, Veterans Health Administration, is pleased to announce the release of the following technology assessment report:

Positron Emission Tomography:

- descriptive analysis of experience with PET in VA
- systematic reviews: FDG-PET as a diagnostic test for cancer and Alzheimer's disease

How to get the report:

Within VA:

- Download an electronic version (PDF) from the VA intranet at <http://152.128.2.7/mdrc> or from the VA home page at <http://www.va.gov/mdrc>.
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