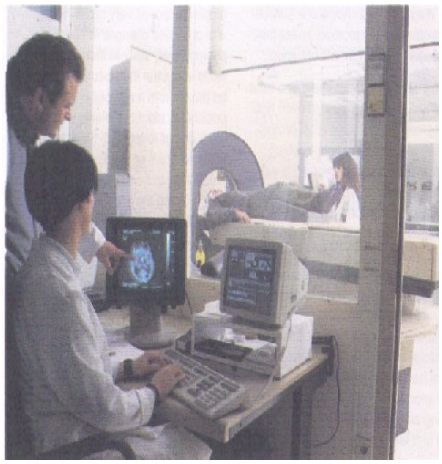
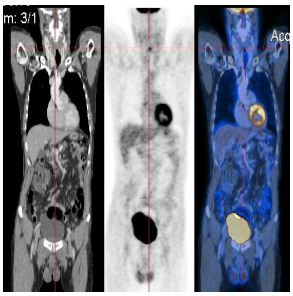
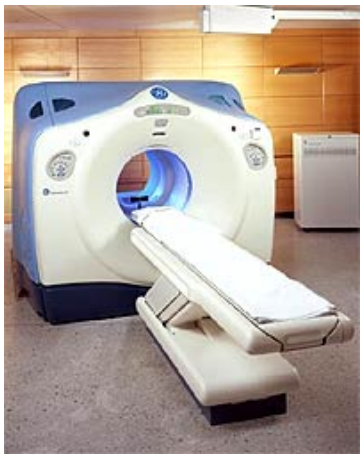


CANM
ACMN





CANM POSITION PAPER ON PET

Canadian Association of Nuclear Medicine Standards for Positron Emission Tomography

Policy Statement Approved: November 10, 2001
Amended: November 16, 2001

Canadian Association of Nuclear Medicine
Association canadienne de médecine nucléaire
774 promenade Echo Drive
Ottawa, ON K1S 5N8

INTRODUCTION

Positron emission tomography is a nuclear medicine imaging modality that utilizes radiopharmaceuticals labeled with positron emitting radionuclides to derive functional or molecular images of disease status.

The most commonly used radiopharmaceutical is ^{18}F-flurodeozyglucose (^{18}FDG) with indications confirmed in oncology, neurology and cardiology. Fluorine-18 is a short-lived radionuclide (T1/2 – 110 minutes) that is cyclotron produced. Fluroine-18 or ^{18}FDG may be shipped to sites up to 3-4 half lives from a central cyclotron and radiopharmacy.

Studies should be performed by qualified and knowledgeable physicians, scientists and technologists using appropriate equipment and technique. Examinations should be supervised and interpreted by appropriately trained nuclear medicine specialists.

QUALIFICATIONS OF PERSONNEL

Nuclear Medicine Physicians

Physicians involved in the performance, supervision and interpretation of PET images must be nuclear medicine physicians who have a fellowship in nuclear medicine with the Royal

College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec.

As PET is a new technology to the Canadian health care system, it is expected that individual physicians obtain additional training, under supervision and with appropriate documentation, before operating a PET facility or performing and interpreting such examinations or procedures independently.

The policy of the CANM is that this training should encompass all aspects of PET facility operation, radiopharmaceutical quality control, patient preparation and image acquisition and interpretation. At a minimum this training should include three months observational and didactic training with experience of a minimum of 250 cases. As with other imaging modalities it is expected that additional Fellowship training will become normal for individuals practicing in the field and that those physicians running PET centres have additional training commensurate with their responsibilities.

This training should meet pertinent provincial and federal regulations. Continuing professional development must meet with the expectations of the Royal College of Physicians and Surgeons of Canada.

Medical Physicists

A medical physicist shall have the responsibility for the initial acceptance testing of the PET scanner. If a cyclotron is part of the PET facility the medical physicist shall also be responsible for acceptance testing, commissioning, licensing and operational issues associated with cyclotron operations, in conjunction with the institutional RSO where appropriate to ensure compliance with CNSC regulations.

On an ongoing basis the medical physicist will be responsible for quality control and assurance of the scanner and of all quantification protocols. The medical physicist shall be certified by the Canadian College of Physicists in Medicine and shall have specific training and experience in nuclear medicine and PET.

Training and experience shall include detailed knowledge of the physics of PET imaging, cyclotron operations, system components and performance, safety issues, acceptance testing and scanner optimization and ongoing quality assurance.

PET Technologists

The medical radiation technologist must have the Canadian Association of Medical Radiation Technologists (CAMRT) certification in nuclear medicine (RTNM) or be certified by an equivalent licensing body recognized by the CAMRT. In addition he or she should have completed additional training in PET such as the added competency course offered by the British Columbia Institute of Technology.

Service Engineers

Expectations of the service engineer will vary according to whether or not the centre has a cyclotron. The service engineer shall have appropriate training in both scanner and cyclotron maintenance if a cyclotron is present and shall be responsible for service requirements and liaison with the manufacturer(s) as identified by institutional practice.

Cyclotron Operator

Those facilities that operate a cyclotron should have a qualified cyclotron operator responsible for routine operations. Whilst this individual need not be a medical physicist his or her training should commensurate with the safe operation of the facility, with the need to trouble shoot and identify operational failings and to comply with all CNSC requirements and regulations.

Radiopharmacist/Radiochemist

This clinical scientist shall be responsible for ensuring that all Health Canada regulatory and Investigational Review Board requirements have been met in preparing PET radiopharmaceuticals for clinical use. In particular, for those centres involved in distributing FDG, this individual shall be responsible for ensuring compliance with all regulatory requirements in the production, packaging and shipping of the radiopharmaceutical.

DOCUMENTATION OF PET PROCEDURES

Federal and provincial regulations require that all imaging investigations be appropriately documented. For PET imaging this documentation includes:

1. Indication for examination and record of consultation
2. Plasma glucose at time of examination
3. Sedation if given
4. Diuretic if administered
5. Catheterization if performed
6. Scanning technique including transmission scanning, number of bed positions and scan parameters. These will vary from site to site depending on available equipment.
7. Interpretation
8. Archival images shall be kept for a period that is consistent with clinical need and with legal requirements.

EQUIPMENT AND QUALITY CONTROL

Each imaging facility shall have documented policies and procedures with respect to equipment maintenance and quality control. These should be established with respect to clinical care, patient and public safety and compliance with regulatory and legal requirements including those of the CNSC.

CHOICE OF EQUIPMENT

There are currently on the market three types of PET scanner:

1. Full ring PET scanners
2. Partial ring PET scanners
3. Coincidence gamma cameras

At present there are no regulations in Canada governing the clinical use of these scanners. In the United States the centres for Medicare and Medicaid services only recognize full funding for full ring PET scanners. Limited approval for hybrid systems was granted in June 2001. Purchasers of PET scanners should be aware of the relative limitations of each of the scanner configurations and should arrange their purchase according to expected clinical requirements.

Provincial health ministries should, in consultation with the nuclear medicine community establish the necessary framework for approval of PET scanners for specified clinical indications.

CONDUCT OF EXAMINATIONS

Established standards for the conduct of PET examinations have been published by the Society of Nuclear Medicine (1).

1. Oncology

In summary the minimum acceptable standards for the performance of a PET examination for oncology indications include:

a. Fasting - Patients should fast for 6-8 hours prior to the examination. Blood sugar should be measured prior to the examination; a high blood sugar (>7 mmol/L) will degrade the quality of the image. An appropriate protocol should be developed, if necessary with the support of the endocrinology service, to be used if needed to lower blood glucose levels with insulin within the PET imaging facility.
b. Patient Preparation - Increased muscle tone will artifactually increase FDG uptake. This is of particular diagnostic importance in the head and neck and thorax. Lorazepam may be used as a sedative and patients should rest quietly for one hour after injection of the radiopharmaceutical.
c. Waiting period - A minimum period of one hour is required after injection and prior to imaging.

2. Brain Imaging

Preparation for brain imaging should include a quiet dark environment after injection.

3. Cardiac Imaging

For cardiac applications, patients who are non-diabetic receive an oral glucose load with scanning one hour after FDG administration.

Reporting Parameters

The report should include all pertinent information, including name of patient, date of birth, hospital or office identification number; name of the referring physician(s); name or type of examination; dates of examination and the transcription; time of the examination, if relevant; radiopharmaceutical, including administered activity and route of administration; and patient history, including reason for requesting the study.

1) Body of the Report

a. Procedures and Materials
Include in the report a description of the PET imaging acquisition (i.e. transmission and emission imaging), procedure performed such as sedation, hydration, insertion of Foley catheter, administration of lasix (amount and time), and the area imaged.

b. Findings

Describe location and intensity of abnormal FDG uptake in relation to normal comparable tissues. State quantitative or semiquantitative measures of lesion FDG uptake, if performed.

c. Limitations

Where appropriate, identify factors that can limit the sensitivity and specificity of the examination (i.e. small lesions, inflammatory process).

d. Clinical Issues

The report should address or answer any relevant clinical issues raised in the request for imaging examination.

e. Comparative Data

Comparisons with previous examinations and reports if appropriate, are a part of the nuclear medicine consultation and report.

2) Impression (Conclusion or Diagnosis)

a. A precise diagnosis should be given whenever possible.
b. A differential diagnosis should be given when appropriate.
c. When appropriate, recommend follow-up and additional diagnostic studies to clarify or confirm the impression.

REFERENCES

1. Schelbert, Heinrich R., Hoh, Carl K., Royal, Henry D. et al. Society of Nuclear Medicine Procedure Guideline for Tumor Imaging Using F-18 FDG.
2. Institute for Clinical Evaluating Sciences (Chair Dr. Andreas Laupacis). Health Technology Assessment of Positron Emission Tomography. Prepared for the Committee on Technical Fees of the Ontario Ministry of Health and Long-Term Care. May 31, 2001.

APPENDIX 1

PROTOCOL DEVELOPMENT

Specific protocols should be developed for imaging the brain, head and neck, abdomen and pelvis. In particular abdominal and pelvic protocols should be cognizant of the likelihood of artifact from renal, bladder and bowel activity and techniques that are available to ameliorate these problems.

Injected Dose

The injected dose should be governed by the noise equivalent count (NEC) rate of the scanner to be utilized. Individual centers are responsible for determining the NEC of their particular system.

Scanning Parameters

Acquisition parameters for FDG imaging with dedicated PET scanners:

a. Intravenous injection of the radiopharmaceutical at a site contralateral to the site of concern is followed by the acquisition of the emission images beginning about 30 – 60 min later. For dynamic imaging, a sequence of serial images is initiated exactly at the time of radiopharmaceutical injection (see Dynamic image acquisition below).

b. Whole body imaging can be obtained with correction for photon attenuation which requires acquisitions of transmission images. Individual scanner protocols define how whole body transmission images are acquired.

c. Emission image acquisition typically ranges from 6 to 15 min and aims at collecting 5 to 15 million total counts depending on the body site.

d. Semiquantitative estimate of tumor metabolism (SUV, DUR, DAR, etc.) is based on relative lesion radioactivity normalized to injected dose and body weight. This requires a static emission image acquired typically at 30 min (images obtained after FDG reaches plateau concentration). In addition, it requires the total dose of FDG administered, the patient's weight or the patient's height for measurement of lean body mass or both for measurement of body surface area. A calibration factor is needed (see below in quantitative estimates of tumor metabolism). This measurement can be corrected for blood glucose concentration.

e. Quantitative or semiquantitative estimates of tumor metabolism may require measurements of the arterial input function, determinations of the plasma FDG and glucose concentrations, the total dose of the administered FDG and the patient's height and body weight so that the body surface area can be estimated. In addition, a

calibration factor is needed between scanner events in terms of (counts/pixel/sec) and in vitro measured activity concentrations in (counts/ml/sec). This can be accomplished by imaging a cylindrical phantom with a known concentration of a positron emitter and by measuring the activity of an aliquot of the cylinder solution in a well counter.

f. Limited Field Tomographic Images are used to most clearly delineate metabolic activity in lesions detected on physical examination and/or with other imaging modalities such as radiographs, CT or MRI. The addition of a dynamic acquisition may allow quantification of metabolic rates of tumors. Since the field of view is limited, accurate and careful patient positioning is critical for adequately including the suspected lesions in the tomography's field of view. Transmission images are acquired. Acquisition times and total counts collected may vary between PET systems. Some institutions acquire transmission images of about 125 million counts over 15 to 20 min.

APPENDIX 2

CLINICAL INDICATIONS

No Canadian guidelines for the clinical use of PET have been established. However, provincial recommendations in a number of provinces are being discussed and a recent Institute for Clinical Evaluative Sciences (ICES) report (2) has reviewed published criteria for use. A review of the literature suggests that the following are indications for which clinical use can be justified. Individual indications to answer specific clinical questions are well supported in the literature and the following indications will require ongoing modifications as new clinical data are developed to support them. They will be subject to annual review.

Directed Problem Solving

In addition to the indications discussed below, there will be occasions, primarily in oncological practice, where specific clinical problems require the power of PET imaging to plan ongoing management and these indications should be considered on an individual basis according to clinical need.

Oncology

Lymphoma

1. Staging completion for low stage aggressive small bulk disease
2. Advanced disease: Post therapy to establish need for RT
3. Aid evaluation at follow-up
4. If there is a possibility of RT cure
5. To replace gallium
6. To differentiate recurrent tumor from scar

Esophagus

1. At presentation to confirm radical surgery and chemoradiation
2. Evaluation at relapse
3. Evaluation after chemoradiation if radical surgery is a consideration
4. Pre-surgical evaluation

Colorectal

1. Suspected recurrence to evaluate a rising CEA
2. Suspected recurrence to evaluate with symptoms suggesting a recurrence and unhelpful standard investigations
3. Staging of equivocal or unhelpful standard investigations

Head and Neck

1. Staging at presentation of advanced disease
2. Recurrence – suspected or symptomatic
3. Evaluation of CT abnormality
4. To differentiate recurrence from scar

Unknown Primary

1. Establish primary site
2. Staging work up
3. Determining whether aggressive surgery is appropriate

Melanoma

1. Primary staging in high risk patients (1.5 mm)
2. Restaging at recurrence
3. Restaging for consideration of surgery

Thyroid

1. Evaluation of disease status in anaplastic cancer
2. Evaluation of rising thyroglobulin with negative radioiodine examination

Solitary Pulmonary Nodule

1. Evaluation of malignancy in indeterminate SPN

Non-Small Cell Lung Cancer (NSCLC)

1. Staging at presentation
    - N staging
    - M staging (not brain mets)
2. Diagnosis of recurrence
3. Diagnosis of progression
4. (RT planning)

Breast

1. Directed problem solving (brachial plexus)
2. Evaluation of high risk patient with dense breasts
3. Restaging at recurrence

1° Brain

1. To differentiate recurrence from scar
2. Biopsy guidance within a defined mass

Neurology

1. Evaluation of patients prior to surgery for epilepsy

Cardiology

1. Myocardial viability assessment