Guidelines for Professional Responsibilities for PET-CT Imaging

Academy of Medicine, Singapore
GUIDELINES FOR PROFESSIONAL RESPONSIBILITIES FOR PET-CT IMAGING

1.0 Introduction:

The clinical value of fusing functional PET images with anatomical CT images is well recognised. With the development of an integrated PET-CT scanner, clinical-quality functional images and clinical-quality anatomical images can now be acquired in a single scanning session, overcoming the technical and logistical difficulties associated with post-hoc software image fusion. The PET-CT scanner probably currently offers the most accurate superimposition of functional & anatomical data. The ability to perform CT-based attenuation correction is seen as an additional advantage.

With the introduction of combined PET-CT imaging into clinical practice, nuclear medicine specialists & diagnostic radiologists have the responsibility to ensure that imaging standards for both the PET & CT components are maintained. The purpose of this document is to provide a framework for professional responsibility in PET-CT. As the technology is still evolving, the guidelines should be viewed as providing current best practice, which will be updated as new information becomes available. These guidelines are recommended by the PET-CT Guidelines for Professional Responsibilities for PET-CT Imaging Subcommittee, Chapter of Radiologists, Academy of Medicine, Singapore, and Singapore Radiological Society.

2.0 Utility of the PET-CT scanner

The PET-CT scanner can be used:

2.1. As a hybrid imaging device for:

   2.1.1 attenuation correction of PET emission data using the CT X-ray beam

   2.1.2 co-registration of PET findings with CT images

2.2 As a PET-alone scanner

2.3 As a CT-alone scanner, able to produce clinical-quality images.

3.0 Licensing of the PET-CT Scanning Facility & Personnel

3.1 Site license

The PET-CT scanning facility must obtain the following Licensing Certificates under the Radiation Protection Act (Chapter 262) and the Radiation Protection (Ionising Radiation) Regulations 2000.
3.2 Personnel license
The operator must obtain the L5 license (to use an irradiating apparatus, other than sale) to use the PET-CT under the Radiation Protection Act (Chapter 262) and the Radiation Protection (Ionising Radiation) Regulations 2000.

Administration of PET tracers must be performed by a physician holding a license to handle, use and transport radioactive materials (L6) under the Radiation Protection Act (Chapter 262) and the Radiation Protection (Ionising Radiation) Regulations 2000 issued by the Centre for Radiation Protection, or by a physician acting on behalf of the license holder.

4.0 PET-CT Personnel

4.1 Qualifications

4.1.1 Physicians
All medical practitioners involved in performance, supervision, interpretation and reporting of PET examinations must be qualified nuclear medicine specialists, having received appropriate training in PET, and exit certified in nuclear medicine.

If the CT examination is to be of diagnostic quality, the medical practitioner involved in performance, supervision, interpretation and reporting of the CT must be a qualified diagnostic radiologist, exit certified in diagnostic radiology.

4.1.2 Radiographers/Technologists
Diagnostic radiographers and nuclear medicine radiographers may operate PET-CT equipment after obtaining appropriate additional training, and demonstrating competency.

All radiographers operating PET-CT scanners must possess a Diploma in Radiography or equivalent qualification recognised by the Singapore Society of Radiographers and the Ministry of Health.

4.1.3 Radiation/Medical Physicist
Minimum qualification for a radiation or medical physicist is a BSc (Hons) in physics with 3 years working experience in a Nuclear Medicine department.

4.1.4 Radiochemist
Basic degree in chemistry or pharmacy with an advanced degree in chemistry, preferably in organic chemistry, medicinal chemistry, inorganic chemistry, metallorganic chemistry, biochemistry. Proper training in nuclear medicine, handling of radioactive materials and radiation protection is required.

4.1.5 Radiopharmacist
Basic degree in pharmacy with additional training and experience in radiopharmaceuticals, handling of radioactive materials and radiation protection.

4.1.6 Medical laboratory technologist
Diploma or undergraduate level training in medical technology with additional training/experiences in working with radioactive materials and laboratory instruments.

4.2 Responsibilities

4.2.1 Physicians
It is the onus of the referring clinician to specify whether a diagnostic CT scan is required in addition to PET.

If only a PET examination is requested by the referring clinician, then the performance of the PET study must be done under the supervision of a qualified nuclear medicine specialist. This may require the incorporation of a ‘non-diagnostic’ CT for the purposes of attenuation correction and anatomical reference. The nuclear medicine specialist shall be responsible for all aspects of the PET study including reviewing indications for the study, handling of the radio-pharmaceutical, study protocol, interpreting images, generating written reports, and assuring the quality of the images and interpretations.

If a combined PET and diagnostic CT examination is required by the referring physician, then the performance of the PET aspect of the study must be done under the supervision of a qualified nuclear medicine specialist. The nuclear medicine specialist shall be responsible for all aspects of the PET study as
detailed in the preceding paragraph, and the diagnostic radiologist shall be responsible for all aspects of the CT examination. This includes reviewing the indications for the study, specifying the CT protocol, use of contrast agents, interpreting images, generating written reports, and assuring the quality of both the CT images and interpretations.

4.2.2 Radiographers
The radiographer is responsible for co-ordinating the daily workflow of PET-CT imaging, ensuring patient comfort and safety, preparing and positioning the patient for the examination, acquiring the PET-CT data and presenting the images in a manner suitable for interpretation by the physician. The radiographer is also expected to perform daily quality control testing of the PET-CT system.

4.2.3 Radiation/Medical Physicist
The physicist shall commission the PET-CT scanner and ensure that it is fit for operation. The physicist oversees the daily quality control of the PET-CT scanner and takes corrective action if necessary. He shall use a uniform and consistent method for measuring and reporting various performance parameters of a PET-CT scanner on a routine basis.

The physicist shall be responsible for the operation of the cyclotron, including acceptance testing, quality assurance, maintenance schedules, and safety.

He shall also be responsible for radiation safety and protection for staff and public in the scanning facility and laboratories.

4.2.4 Radiochemist
The radiochemist shall be responsible for the production of the radiopharmaceuticals, routine maintenance and quality assurance of equipment used for production of radiopharmaceuticals.

The radiochemist, in conjunction with the radiopharmacist, shall be responsible for setting up of protocols for production and quality control of radiopharmaceuticals as well as operation and quality assurance of clean room.

The radiochemist, in conjunction with the radiopharmacist and medical technologist, shall be responsible for the quality control of the radiopharmaceuticals.

4.2.5 Radiopharmacist
The radiopharmacist shall be responsible for the quality control of the radiopharmaceuticals and quality assurance of the raw materials and QC instruments.

The radiopharmacist, in conjunction with the radiochemist, shall be responsible for the production of radiopharmaceuticals.

The radiopharmacist, in conjunction with the radiochemist, shall be responsible for setting up of protocols for production and quality control of radiopharmaceuticals as well as operation and quality assurance of clean room.

The radiopharmacist, in conjunction with the cyclotron personnel shall be responsible for operation of the cyclotron and radiation protection.

4.2.6 Medical Technologist
The medical technologists, in conjunction with the radiopharmacist and radiochemist, shall be responsible for the quality control of the radiopharmaceuticals and quality assurance of the raw materials and QC instruments.

4.3 Continuing Professional Development and Skills Training
PET-CT practitioners must be aware of potential pitfalls in scanning technique, and the measures needed to avoid false results or image artifacts.

Professional education is a vital component for nuclear medicine specialists, diagnostic radiologists, radiographers and scientists involved in PET-CT. Scanning protocols are constantly being updated and it is imperative that all PET-CT staff keep abreast with new innovations.

5.0 Reporting of PET/CT Studies
5.1 All imaging studies involving the administration of a PET radiotracer shall be reported by a nuclear medicine specialist.

5.2 If the CT is used primarily for attenuation correction or anatomical reference for PET emission data, a non-enhanced CT scan is recommended. The CT images need not be of diagnostic quality. The referring clinician and the patient should be aware
that these CT images are sub-optimal. The scan will be reported and signed only by the nuclear medicine specialist, and the report may include an explanatory note on the limitations of the CT examination.

5.3 If the clinician requests for a diagnostic-quality CT scan in addition to the PET scan, the PET study will be only reported and signed by the nuclear medicine specialist, while the CT study will be only reported and signed by the diagnostic radiologist. The CT scan may involve the use of oral and intravenous contrast, and the CT scanning protocol will be decided by the diagnostic radiologist. Both the PET and CT scan reports should be issued separately, in accordance with the areas of professional responsibility. However, there should be cross-consultation between the nuclear physician and the radiologist, to avoid disparity between the scan reports.

6.0 Radiation Safety Guidelines

6.1 Guidelines for radiation safety are as stipulated in the Radiation Protection Act (Chapter 262) and the Radiation Protection (Ionising Radiation) Regulations 2000.

6.2 Any transport of radioactive materials into or out from the facility must be in compliance with the Radiation Protection (Transport of Radioactive Materials) Regulations 2000.

7.0 Quality Assurance

7.1 Cyclotron

Quality control, testing and inspection of the cyclotron and its subsystems are to be performed routinely based on the operation manual.

7.2 Radiochemistry and Radiopharmaceutical Production

The following quality assurance procedures are to be performed routinely as required by Current Good Manufacturing Practice (cGMP). The results shall be stored according to guidelines set by cGMP and Good Laboratory Practice (GLP).

Routine cleaning and servicing of the synthetic modules
Routine maintenance and servicing of the laminar flow hood
Routine cleaning and servicing of the dispensing modules
Routine calibration test of dose calibrator
Routine servicing of the clean room filters
Routine testing of the clean room air quality

7.2.1 Radiopharmaceutical products

The following quality control procedures are required to be performed routinely according to British Pharmacopeia. The results shall be stored according to guidelines set by cGMP and GLP:

- Routine radionuclidic purity test
- Routine radiochemical test
- Routine pH test
- Routine pyrogen test (digital readout)
- Routine residual solvent test
- Routine osmolarity test
- Routine dose calibrator test

7.3 PET-CT Scanner

A quality assurance programme must be maintained. Regular QA testing by PET-CT staff must be performed under the guidance of the medical physicist.

The QA programme should have written procedures and logs. QA testing should consist of:

(a) Acceptance testing at the time of scanner installation, to include the following tests:

PE1: Spatial resolution, scatter measurement, sensitivity measurement, count rate losses and random measurements, uniformity measurements, scatter correction and accuracy of attenuation correction.

CT: noise, modular transfer function, table position, constancy, lightmark (laser), homogeneity, kV & current check.

(b) Preventive maintenance and Servicing. This shall be scheduled, performed and documented by qualified service engineers on a regular program. Service records shall be maintained. The quality control tests to be performed during routine servicing are:

Blank scans, uniformity test and spatial resolution.

(c) Quality Control testing. This should be on-going to assess for any relative changes in system performance. Daily QC testing should include blank scans.
8.0 Research Studies

These guidelines applicable to clinical studies should also apply to research involving human subjects.

The research to be performed should be approved by the relevant ethics committee.

All safety guidelines should be adhered to.

Research protocols may differ from clinical protocols and may involve the administration of non-standard radiotracers. It is the responsibility of the physician in charge of the facility that research protocols do not compromise the safety of the subject or staff.

RESOURCE DOCUMENTS

2. Radiation Protection Act (Chapter 262).

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