The Royal College of Radiologists

In collaboration with

The Royal College of Physicians

The Intercollegiate Standing Committee on Nuclear Medicine

The British Nuclear Medicine Society

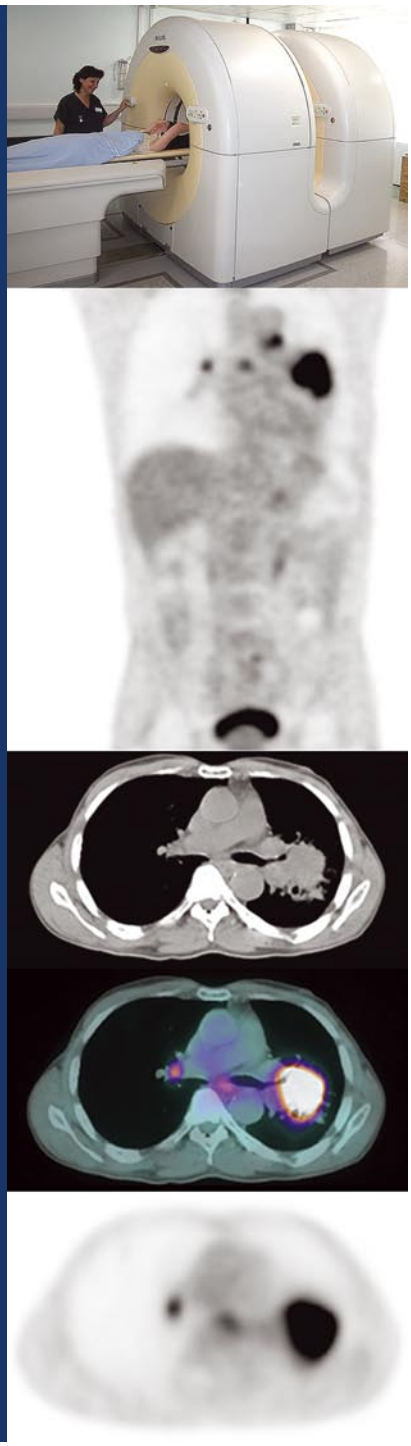
The Institute of Physics and Engineering in Medicine

and supported by

The Society and College of Radiographers

PET-CT in the UK

A strategy for development and integration of a leading edge technology within routine clinical practice



Contributors

Professor Janet Husband
Chair of Working Party
President of Royal College of Radiologists (RCR)
Professor of Diagnostic Radiology, Royal Marsden NHS Foundation Trust

Professor Isky Gordon
Lead Co-ordinator of Project
Lead on Working Party's Standards Sub-Group
Secretary, Intercollegiate Standing Committee
Professor of Paediatric Imaging, Great Ormond Street Hospital for Children

Mr Steve Ebdon-Jackson
Lead on Working Party's Contracts Sub-Group
Radiation Protection Division, Health Protection Agency

Professor Kenneth Miles
Joint lead on Working Party's Education & Research Sub-Group
Chairman Elect, Royal College of Physicians SAC for Nuclear Medicine
Professor of Imaging, Brighton & Sussex Medical School

Dr Gary Cook
Joint lead on Working Party's Education & Research Sub-Group
Consultant in Nuclear Medicine, Royal Marsden NHS Foundation Trust

Dr Paul Dubbins
Vice-President and Dean of the Faculty of Clinical Radiology, Royal College of Radiologists
Consultant Radiologist, Derriford Hospital Plymouth

Dr Rosemary Allan
Chair, RCR Radionuclide Radiology Sub-Committee
Consultant Radiologist, St. George's Hospital, London

Dr Nicholas Ashford
Consultant Radiologist, St. Richard's Hospital, Chichester

Dr Deborah Cunningham
Consultant Radiologist, St. Mary's Hospital, London

Miss Margaret Dakin
Clinical Manager, St. Thomas' Hospital Clinical PET Centre, London

Professor Adrian Dixon
Warden, RCR Faculty of Clinical Radiology
Professor of Radiology, Cambridge University

Dr Fergus Gleeson
Consultant Radiologist, Radcliffe Hospitals, Oxford

Dr Andrew Hilson
President, British Nuclear Medicine Society (BNMS)
Chairman, RCP Joint Standing Committee in Nuclear Medicine
Consultant in Nuclear Medicine, Royal Free Hospital, London

Dr Robin Hunter
Dean, RCR Faculty of Clinical Oncology
Consultant Oncologist, Christie Hospital, Manchester

Mr Andrew Jackson
Network Manager, Kent & Medway Cancer Network

Professor Michael Maisey
Chairman, Radiology Oncology Congresses

Dr Paul Marsden
Scientific Director, St. Thomas' Clinical PET Centre, London
Member, Institute of Physics and Engineering in Medicine (IPEM) Nuclear Medicine Special Interest Group

Dr Brian Neilly
Chairman, RCP SAC for Nuclear Medicine
Consultant Physician, Glasgow Royal Infirmary

Dr Thomas Nunan
Chairman, Administration of Radioactive Substances Advisory Committee
Consultant in Nuclear Medicine, St. Thomas' Hospital, London

Dr Mary Prescott
Chairman, Intercollegiate Committee on Nuclear Medicine
Consultant in Nuclear Medicine, Manchester Royal Infirmary

Dr Sheila Rankin
Consultant Radiologist, Guy's & St. Thomas' Hospital, London

Dr John Rees
Member, RCR Radionuclide Radiology Sub-Committee
Consultant Radiologist, University Hospital of Wales, Cardiff

Profesor Philip Robinson
Ex-chair, RCR Radionuclide Radiology Sub-Committee
Professor of Clinical Radiology, St. James' University Hospital, Leeds

Dr Wendy Tindale
Immediate Past Honorary Secretary, BNMS
Scientific Director, Medical Imaging & Medical Physics, Royal Hallamshire Hospital, Sheffield

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Preface

Positron emission tomography (PET) has become central in the management of patients with cancer and its role here and in other diseases continues to evolve. However, in the UK the development of PET services has been slow, compared with the United States and other European countries.
In 2003, the Intercollegiate Standing Committee on Nuclear Medicine (ICSCNM) issued a document *Positron emission tomography - A strategy for provision in the UK* [1] and in 2004 the Department of Health (DH) published a consultation document *A Framework for the Development of Positron Emission Tomography (PET) Services in England* [2] which identified the need for a comprehensive strategic approach for the delivery of PET services and sought views from the profession and many other key stakeholders. Whilst response to this document has been provided by many Royal Colleges and other major bodies, a more detailed plan for the provision of a PET service is now needed to address both practical and professional issues. Such a detailed plan will contribute to the way in which PET services are introduced nationally.

Recognising this opportunity, and building on the previous ICSCNM document, the Royal College of Radiologists (RCR), and with full support from the National Cancer Director, Professor Michael Richards, set up a short-lived Working Party in collaboration with the Royal College of Physicians (RCP), ICSCNM, The Institute of Physics and Engineering in Medicine (IPEM) and the British Nuclear Medicine Society (BNMS). Other important groups of healthcare professionals have also been recruited to the working group to develop a detailed strategy.

In this document, produced by the Working Party, we present a vision for the delivery of PET services within the UK which is aimed at providing a uniform, high quality service for patients irrespective of where they live or of what local services are currently available to them. This document will be presented in the first instance to the Department of Health in England, but has been prepared as a guide to development of PET-CT in all four countries in the UK. In so doing we have taken into account current PET installations and those at an advanced stage of preparation. The strategy is based on the need for an integrated diagnostic service for patients with cancer but also recognises the evolving applications for PET in cardiology, neurology and paediatrics. Nevertheless, it is recognised that PET is an expensive technology and not every hospital requires an installation. Thus, the service needs to be developed according to a logical plan.

Our plan proposes that all new PET services should be delivered through PET-CT scanners and that the service should be based on a Hub unit of a PET-CT scanner (the majority with a cyclotron) plus, where appropriate, a Satellite unit of a PET-CT scanning unit alone. The location of PET-CT scanners and the strategic placement of cyclotrons are addressed, as are contractual and service issues.
The Working Party has drawn on the expertise and previous work of the ICSCNM, and we have incorporated the document produced by this Committee, entitled *Standards for delivering a PET service within the UK*.[3] A proposal for staffing requirements is laid out within the document, which also incorporates a model for education and training. The objective of this model is to provide a fully staffed, comprehensive service for the NHS in the longer term.

The model for delivery has been presented as a two-phased approach. Although at present, we believe that there are sufficient physicians in the UK trained in PET to commence a service, major investment will be required to support all the staffing needs in the longer term, particularly with regard to radiopharmaceutical scientists and nuclear medicine technologists. In Phase I mobile PET-CT services will be essential, but in Phase II a greater number of static sites is envisaged. The pathway from Phase I to Phase II should be planned from the outset and be seamless and contiguous.

This proposal for a comprehensive plan to deliver PET-CT services provides a unique opportunity for the UK to conduct prospective research and audit studies within the NHS, which should be an integral part of the strategic plan.

Our focus has been on improvements in patient outcome that will be achieved by the planned development of PET-CT. PET-CT is likely to be at least as effective as PET alone and probably more so but, as yet, there is insufficient data available on PET-CT to make a substantive statement. PET-CT has already been shown to obviate the need for additional imaging investigations in certain cancers, and this may have important implications for economic and workforce issues. Equally important, appropriate deployment of PET-CT may make a valuable contribution to a reduction in the bottleneck of diagnostic services, thereby contributing to the achievement of cancer targets as defined in *The NHS Cancer Plan* [4] and to the 18-week target from GP referral to treatment for all patients, to be achieved by 2008.[5] Workload issues have been addressed in the document *Positron emission tomography - A strategy for provision in the UK*.[1]

The Working Party first met in April 2005, and I am extremely grateful to all its members who have worked tirelessly to produce this comprehensive document in a very short period of time. In particular, I would like to thank Professor Isky Gordon who has coordinated the project and the sub-groups within the Working Party. These sub-groups have been led by Mr. Steve Ebdon-Jackson (Contractual & Service Issues), and Professor Ken Miles and Dr. Gary Cook (Education & Research). Professor Isky Gordon has also led work on a model for provision of a PET-CT service and issues related to standards and protocols. Finally, I am most grateful to Dr. Paul Dubbins for his valuable comments and advice in the preparation of this document.

We are privileged to have this opportunity to help shape the future of this aspect of diagnostic imaging services in the UK. We have combined a strategic plan with guidelines for standards of practice to inform the quality of care for all patients having PET-CT examinations. We hope that all patients who need PET-CT now and in the future will benefit from a coordinated national programme of service delivery.

Janet E. Husband, OBE FMedSci FRCP PRCR
Chairman of Working Party
President, Royal College of Radiologists

Executive summary

- Positron emission tomography (PET) is a complex imaging modality which utilises physiologically short-lived radioisotopes to distinguish biologically active from inactive tissue within pathological processes.
- PET-CT has major clinical advantages compared with stand-alone PET systems.
- PET-CT is of crucial importance in the management of patients with cancer.
- PET-CT provides more accurate diagnosis and staging in certain cancers and allows therapy to be instigated more rapidly.
- Planned implementation of PET-CT will contribute to improvement of waiting times for patients with cancer.
- PET-CT is an evolving technology, with potential application to many disease processes.
- Standards for the delivery of PET-CT should be uniform, regardless of service provider and should comply with those produced by the ICSCNM in *Standards for delivering a PET service within the UK*.[3]
- Standards are required for equipment and facilities, for staffing, and for operational matters. The vast majority of work should be protocol-driven and be subject to ongoing, robust audit.
- Currently the number of trained physicians is sufficient to provide a foundation for the introduction of PET-CT services, but major shortages exist in other disciplines which are essential for running a service.
- ^{18}F 2-Fluorodeoxyglucose (FDG) is the most common radiopharmaceutical currently used in PET. However, there is a clinical need to produce other short-lived radioisotopes.

Recommendations

Facilities and Equipment

- PET-CT is an expensive technology and not every hospital needs an installation. The service needs to be developed according to a logical plan.
- A Hub and Satellite service is recommended. This will assist in achieving the 18-week target set across all diagnoses and provide a service as close as possible to the patient's clinical management.
- Since over 90% of PET CT studies are performed to assess patients with cancer the Hub and Spoke design has been based on Cancer Networks.
- The Hub would comprise PET-CT, and the majority of sites would include a cyclotron. A Satellite PET-CT would rely on the Hub for technical and professional support; the Satelite's radiopharmaceuticals would come from the closest cyclotron.
- Initially, one PET-CT per 1.5 million population is planned to reflect the current role in cancer management.

- The requirement for cyclotrons may increase as the applications develop.
- PET-CT should be introduced in a phased approach. Twelve new Hubs each with a single, static or mobile Satellite are recommended in Phase I in the UK. A further eight to twelve Hubs plus Satellites are recommended in Phase II.
- At full implementation, each SHA (or equivalent body) should have direct access to one or more Hubs depending on population size and geography.
- Paediatric PET services should be provided by a specialist paediatric centre. To ensure patient safety, it is recommended that, at least, two supra-regional Hubs be designated paediatric referral centres.
- Mobile PET-CT scanners should be fully integrated into both the imaging services provided at the local hospitals and the Hub.

Staffing

- Sufficient staffing of PET-CT services is of critical importance for the sustained development of the service over time.
- Urgent recruitment and training of nuclear medicine technologists and radiopharmaceutical scientists and technologists are essential for PET to expand in the UK.
- If outsourcing is seen to be part of the solution, there will remain a requirement for PET-CT trained physicians to be available in Trusts to review and evaluate PET-CT studies.

Training

- Training and continued professional development for all staff involved in PET-CT delivery are essential.
- The e-learning model for multi-professional education proposed by the BNMS could make an important contribution to expansion of PET-CT expertise. This initiative requires funding for development.

Data handling

- PET-CT images should be available for multidisciplinary meetings (MDMs). These meetings are increasingly conducted electronically.
- Picture archiving and communication systems (PACS) do not at present allow the manipulation of PET-CT images. This issue requires urgent attention.

Audit and Research

- Audit and research should form an integral part of the PET-CT service.

Changing clinical indications and environment

- An advisory group should be formed to monitor the changing clinical indications for PET-CT and provide advice.

Introduction

PET is a complex imaging modality requiring the coordination of contributions from a range of different clinical and professional disciplines. It is vital that standards for the development and integration of this technology within routine clinical practice are met, maintained and continually refined, and that these are applied to all models of service delivery. PET-CT is a complex hybrid of two imaging modalities which has major clinical advantages over PET-only systems. Consequently, the implementation strategy focuses solely on the provision of combined PET-CT scanners. A brief, but more detailed description of PET-CT is given in Appendix 1.

The major clinical application of PET-CT is in oncology. Other evolving applications include cardiology and neurology. Oncology currently accounts for over 90% of its present usage.[6] In a large meta-analysis published by Gambhir, et al., in 2001 PET was shown to alter patient management in approximately 30% of patients (range 5% - 100%).[7] Examples include lung cancer in which PET-CT helps to define clinical management and to determine prognosis, and in lymphoma where the technique now has a well-defined, established role.[8-11] There is also considerable evidence that PET will be of value in the management of elderly patients with dementia. Similarly, it is anticipated that PET-CT will play an increasing role in cardiology, endocrinology, infection and inflammation but, as yet, these applications are not established in routine clinical practice.

The clinical importance of the full range of PET-CT applications must be taken into account when planning PET-CT services for the UK. Current indications for PET and PET-CT have been considered in *A Framework for the Development of Positron Emission Tomography (PET) Services in England*,[2] the definitive version of which will complement this document. Assessing the need for PET-CT services has also been addressed from a number of different sources, including the NHS *Cancer Plan*.[4] The development of Cancer Networks comprising Cancer Units and Cancer Centres is a central tenet of the NHS *Cancer Plan*. Each network typically serves a population of between 1-2 million people. Strategic placement of cyclotrons and PET-CT scanners within the Cancer Networks will be required to provide a uniform, high quality service to meet the needs of all patients.

In the past, investigations undertaken to reach a diagnosis have followed the dictum that the most expensive test should almost always come last. This approach is no longer appropriate. In certain clinical circumstances, early use of PET-CT will not only provide more accurate diagnosis and staging but will also allow therapy to be instigated more rapidly. This will contribute to achieving the ambitious cancer targets for the management of cancer set by the DH. Furthermore, greater efficiency of diagnosis may impact on health care costs and on the workforce by the avoidance, for example, of unnecessary exploratory surgery.

Provision for the costs of PET-CT services will need to be included in the funding allocation to Healthcare Resource Groups (HRGs) and these will need to be reviewed regularly to reflect current practice.

At present, access to PET and PET-CT services in the UK is very limited and geographically dependent (Appendix 2). There is an absolute requirement to develop equable access to PET-CT for all patients across the UK. This will require a coordinated approach to the planning of the service, to staffing and to training. Also important are the geographic and demographic considerations, issues relating

to communication, state of the technology now available, expected evolution in the field and the resources required. The complexity of the multi-professional team required to provide a comprehensive PET-CT service places pressure on ensuring adequate resources for training are available. Similarly, securing competitive national pricing for the radiopharmaceuticals produced would further help the provision of a high quality and fair service.

The proposal for service delivery is dependent upon a Hub and Satellite model which would combine the benefits of specialist expertise and procedures with the facility for more local delivery of common PET procedures.

The proposal for Hubs and Satellites is based on current PET-CT applications (predominantly in cancer care) but future development must acknowledge the development of applications across the medical specialties. On this basis, it is proposed that one PET-CT scanner should be provided for populations of 1-1.5 million people reflecting the distribution and location of cancer centres. It is recognised that in the longer term, as short-lived radiopharmaceuticals become more established, every SHA will need to have direct access to a Hub.

There is, however, a relative shortage of trained staff in certain critical areas. A phased development of the PET-CT service in the UK over the next few years will be required to allow for recruitment and training of the workforce to take place (see Appendices 3 & 4). Although there exists in the UK a critical mass of PET-trained physicians/radiologists and this will be sufficient to support the first phase of development, the early implementation of structured training for all professionals involved is vital to allow the establishment of a comprehensive PET-CT service. More crucial to the early and sustained development of the service is the major shortage of trained nuclear medicine technologists and radiopharmaceutical scientists. There is an urgent need to review recruitment, training, and career structure in these areas (see Appendix 5).

While mobile PET-CT scanning units may have a key role in enlarging access in the short-term, they are unlikely to provide a long-term solution for PET-CT provision within the NHS. However, the use of a mobile PET-CT scanning unit should be viewed as an integral part of a Hub, where the expertise and resources of the latter will provide sufficient and appropriate resources to support the former (see Appendix 3).

A number of technical and IT solutions will also need to be developed to overcome difficulties relating to image transfer and manipulation. This is an acknowledged problem for PET-CT because of the inability to manipulate PET-CT images in conventional PACS. This will impact on the review of images during MDMs.

Patient care is the abiding focus of this document, which therefore sets out the requirements needed to ensure that an unvarying standard of excellence and equality of access in PET-CT are available to all patients throughout the UK. The document asserts that all activities relating to PET-CT provision should comply with the standards set out by the ICSCNM in *Standards for delivering a PET service within the UK* (see Appendix 6).[3] As the provision of a PET-CT service is inherently complex, almost all activity should be protocol-driven (see Appendices 7a & 7b). Moreover, the quality of the entire service should be audited regularly (see Appendix 8).

Model for PET-CT provision in the UK

The model that has been developed is based on the growing importance of PET-CT in cancer care and, also, in recognition of its likely increasing significance to pathologies other than cancer over the longer term. There is a need to ensure the sustainability of the *Cancer Plan* targets where PET-CT will become an essential test. This model will assist in achieving the 18-week target that has been set across all diagnoses and provide a service as close as possible to the patient's clinical management.

For clinical services, every new PET camera should be a PET-CT scanner. In the long-term, every SHA (or equivalent body) and its associated cancer network should have a Hub, and every cancer unit should have full access to PET-CT services. This wide provision will ensure that areas such as cardiology and neurology are covered.

A key aspect of the proposed configuration of Hub with attendant Satellite is that the two components are fully integrated in terms of clinical and professional expertise and responsibility. In addition, the Hub and Satellite should be fully linked by PACS / radiology information systems (RIS). This will facilitate sharing and dissemination of expertise across the service locations and will additionally ensure that MDMs have rapid electronic access to all relevant radiological investigations from the participating cancer centres, cancer units and radiology departments. This model requires that the expertise be provided locally by experts employed by and working within the Trusts concerned (see Appendix 3).

A phased development with a limited number of Hubs, each associated with a Satellite, will make possible the maintenance of high standards of care and permit the efficient and timely training of relevant healthcare professions, currently in such short supply (see Appendices 3, 4 & 5). It is envisaged that, in addition to existing installations, twelve PET-CT installations will be required for Phase I; some of these will be Hubs and some Satellites (either static or mobile). Another eight to twelve Hubs plus Satellites will need to be established in Phase II.

The Hub

The Hub is the nucleus around which the PET-CT service in each area will develop and revolve. The Hub will consist of a PET-CT scanner; the majority of the Hubs will have a cyclotron, and will require staffing levels as outlined below. There is a statutory requirement that a Hub has at least one fully trained person with certification from Health Ministers through the Administration of Radioactive Substances Advisory Committee (ARSAC). The Hubs will be located at tertiary referral centres and, in the first instance, these are likely to be in or close to Cancer Centres. In the short-term, the Hub will have one PET-CT scanner, but in the longer term it may have two PET-CT scanners, as there are advantages to staff and patient throughput in centralising facilities (see Appendix 3).

Every Hub must have fast, reliable two-way electronic links to related radiology departments and to PACS systems of all the other cancer centres and cancer units that they serve. These image and data transfer arrangements must be available for MDMs.

Radiotherapy planning:

Modern radiotherapy treatment planning benefits from multimodality imaging, particularly CT and MR. PET-CT offers a further improvement for some cancers, but to be realised it will have to be fully integrated into the planning process. Allowance has to be made for further scanning time, extra physician, technologist and physicist input, and some increased capital expenditure. This gain will be difficult to achieve if the Hub is not located near to the Cancer Centre.

Training

Every Hub should be a training centre, and the time for training must be incorporated into the job plan of the trainers. Attention must also be given to appropriate facilities, funding, and study leave for adequate training at all levels to take place. Satellites will also contribute to training (see Appendix 5).

Ultra short-lived radioisotopes will only be available within the Hub because of the availability of the cyclotron. These centres will then act as supra-regional centres where studies using these radiopharmaceuticals can be carried out. This is an essential requirement both for high quality patient care (including expansion in cardiology and neurology) and for fulfilling the needs of research as outlined in the *NHS Plan* (2000).[12] It is recognised that not every Hub will have its own cyclotron (see Appendix 3).

The Satellite

The Satellite is a PET-CT scanning unit (static or mobile) that is functionally integrated with and in many ways dependant on the Hub. The value of a Satellite lies in its ability to make PET-CT services available to patients as close as possible to where their clinical care is managed.

The Satellite PET-CT will initially be based essentially on the use of a fluorine ligand (initially, FDG) because the half-life of other short-lived radioisotopes make them impractical to use in facilities remote from the cyclotron. FDG PET, on which most of the current clinical information on the efficacy of PET is drawn, has important benefit for patients.[6-11] In the longer term, however, the full value of PET will only be realised if the Satellite is fully and appropriately supported for its workload.

Fast, reliable electronic communication between the Hub and the Satellite will be essential, and will include full PACS, RIS, and interactive links to MDMs. Currently, a Hub could only support one Satellite, if it is to maintain high standards of care. However, as expertise and resources expand, it is anticipated that a Hub may support more than one Satellite in certain locations where the needs of the population demand this. In the first instance, the additional Satellite could be a mobile PET-CT scanning unit. This would allow the workload to be evaluated and the necessity for a further static Satellite determined. The need for additional mobile PET-CT scanning units in the long-term can only be assessed at a later stage (see Appendix 3).

A Satellite PET-CT scanning unit will require staffing that includes the full range of healthcare professionals, with the exception of the radiochemistry and cyclotron staff.

Paediatric patients

The number of paediatric patients who require PET-CT scans is likely to be limited and, therefore, these studies will be best referred to a Hub where specialist paediatric skills are available. To ensure patient safety, at least two designated Hubs (that would act as supra-regional service providers) in the UK are recommended, both appropriately staffed for paediatric patients and particularly for those patients under 7 years of age and for all those with neurological deficits.

Multidisciplinary meetings (MDMs)

PET-CT images must be available for MDMs, which are increasingly run electronically. Sending only selected PET-CT images to an MDM is inappropriate, because another investigation may necessitate review of the entire PET-CT examination. Current PACS systems, without the purchase of additional equipment, do not allow full manipulation of PET-CT images. A PET-trained physician/radiologist should contribute to the MDM either by attendance or by interactive electronic links, whichever is most appropriate. It is anticipated in the medium-term that this expertise would be available locally within Hub and Satellite.

Radiopharmaceuticals

FDG is the most common radiopharmaceutical now used in PET. However, there is already a need to produce short-lived radiopharmaceuticals, e.g., ^{11}C-Methionine. Other ^{18}F ligands are being developed, and the need for other short-lived radioisotopes must be anticipated. The range of radiopharmaceuticals available at any site should reflect: (1) the particular clinical specialities, e.g., cardiac or neuropsychiatry, and/or (2) the research programme at that site, if the UK is to ensure that patient management is kept up-to-date and research is incorporated into the service, most especially at the Hub.

Research

The need to undertake PET-CT research will create a requirement for PET-CT capacity beyond clinical service provision. It is likely that the Hub will be on a site with a medical school and associated research programmes. There will, therefore, be great potential for academic / clinical partnerships at these sites. Funding for clinical research must be a consideration in developing the service.

Equipment

PET-CT scanner

Scanners should be full-ring PET-CT systems, incorporating a dedicated PET scanner and diagnostic-quality CT hardware. As this technology is evolving rapidly, expert technical advice must be sought for any procurement process. Gamma camera PET should not be performed once full-ring PET is available.[1] Current locations of clinical PET-CT scanners are shown in Appendix 2.

PET-CT mobile unit

In order to provide a high quality, safe service for patients, site-specific requirements for a mobile PET-CT scanning unit must be met. These may be summarised, as follows:

The mobile unit must:

- Be fully integrated into the imaging services provided at the local hospitals.
- Involve the local radiation protection adviser (RPA) and medical physics expert (MPE) in radiation protection, QA and patient dosimetry issues.
- Utilise NHS nuclear medicine / radiology medical staff who should receive all the referrals, justify and protocol the examination, and receive follow-up on these referrals (see section on Staff, and Appendices 5, 6 & 7a).
- Have adequate facilities for the administration of intravenous (IV) contrast media, and for dealing with any potential adverse reaction to it.
- Have appropriate waiting facilities, toilets, and waste disposal arrangements. Waste disposal arrangements are particularly problematic and require special consideration and funding.
- Have a high-speed electronic link to the hospital network, Hub, PACS, and RIS.

There are numerous areas of interface between the mobile unit and the hospital that need to be considered and, consequently, included in the business case / financial costing of a mobile service. These include:

1. The administrative time and resources required to operate and support a mobile unit as undertaken by the host provider and the mobile provider.

2. The need for local MPE / local scientific staff to be assured that the mobile scanner is operating at optimum performance each time it visits the site.

3. The NHS clinicians required to report the scans to ensure appropriate integration of PET-CT into patient management. This is of particular importance for PET-CT, as PET-CT studies will frequently need to be compared and interpreted in the light of results from other imaging modalities. These staff will require planned training opportunities to bring all reporting up to the required standards.

4. Staff and computing facilities required to be provided to allow studies to be read in local Trusts within the Network.

5. Staff time and other resources required for patient injections, pre-scan waiting, and other support services.

6. Electrical and telecommunication infrastructure required to be in place.

These full, indirect costs must be reflected in any tender for the mobile provision of PET-CT services (appendix 4). This will also help to ensure that appropriate funding is identified when static sites are developed.

Scanning facilities

Scanning facilities need to provide a high degree of patient comfort, but they also need to meet the required standard to comply with regulatory issues relating to health and safety, radiation protection and the environment. These standards will influence the design of the facilities and impact on patient throughput. The facilities should include:

- Reception area with appropriate refreshment facilities.
- Waiting room prior to injection of radiopharmaceutical (including bed / trolleys). This is often referred to as the 'cold waiting area.'
- Toilet.
- Injection area.
- Laboratory / drawing-up area for the radiopharmaceuticals.
- Separate waiting area for patients following injection of radiopharmaceutical (including bed / trolleys) - a 'hot waiting area.'
- Toilet for use by the patient after the injection of radiopharmaceutical or 'hot toilet.'
- Scanner room.
- Control room and reporting area.

Some areas may be shared with other departments, e.g., reception area, cold waiting area, hot toilet, and reporting area, depending on local arrangements. Regulatory issues will largely influence the ability to share resources, and careful planning must be undertaken to ensure compliance and good practice.

Cyclotron

The exact number of cyclotrons required in the UK is hard to predict at this time. With continuing improvements in target yield and FDG production, the country could be serviced by strategically placed cyclotrons and radiochemistry units able to deliver various ligands labelled with ^{18}F to a large number of sites. A cyclotron could, therefore, serve several PET-CT scanners, so careful placement could result in ready access for the planned model. This does not mean that a small number of Hubs require a cyclotron; on the contrary, a significant number should have one, in order that the maximum benefit is derived from the short-lived radiotracers that are available. This requirement is both for service provision and research and development, which require a patient population and a cyclotron production facility to be within the hospital.

Agreements will need to be established that will allow facilities to cover for one another in the event of production failure. Careful consideration, too, will need to be given to the location of new cyclotrons, taking into account the location of the established cyclotrons already operational and the location of those institutions about to become operational (see Appendix 2).

Staff

A diverse team of healthcare professionals is required to run a PET-CT Service. All staff involved should be appropriately trained and experienced in the PET-CT techniques (see Appendices 5 & 6). The professionals include:

- PET physicians
  - Nuclear medicine specialists
  - Radiologists
- Clinical scientists
  - Medical physics experts
  - Computer scientists
- Nuclear medicine technologists
  - Clinical technologists
  - Radiographers
- Radiopharmaceutical scientists
  - Radiopharmacists
  - Radiochemists
  - Radiopharmaceutical technologists
  - Cyclotron engineers
- Nurses
- Administrative staff

Training is a critical issue in building the service and, without a thoroughly orchestrated approach to it within the UK, there will be a continuing dire shortfall in almost all of the healthcare professions involved in the service (see Appendix 5). The standards required are set out in Appendix 6.

An e-based multi-professional educational model such as that in development by the BNMS may go a long way to remedy the current deficiencies, however, this proposed model requires resources to bring it to fruition.

In particular, the recruitment and training of two professional groups, nuclear medicine technologists and radiopharmaceutical scientists and technologists, require special, urgent attention. The duration of training of such individuals will depend on previous nuclear medicine experience; at least one year will be required for additional training in PET.

With concerted planning and appropriate funding, it is believed that current UK PET expertise can be expanded to meet the skill shortages in all PET disciplines and make possible the development of PET services in the UK.

PET physicians

The UK has medical expertise in PET-CT that exceeds current service provision. This spare capacity can be deployed to ensure that PET-CT services are properly integrated into existing imaging services. These PET-CT physicians will need to be released from current duties to enable them to devote appropriate time to assist in the development of the PET/CT service.

To expand the medical workforce further, beyond the initial provision, various types of training and education are needed.

- The first type is for fully trained staff who will run the Hub. This will include holding an ARSAC certificate. Ideally, each Hub will have two certificate holders. At the moment, all existing PET services have appropriately trained specialists. Fully trained physicians in PET already exist widely throughout the UK, some at locations where neither fixed nor mobile PET-CT services exist at present. All current nuclear medicine Specialist Registrars (SpRs) receive full training in PET. It is from this pool that future ARSAC certificate holders may be drawn. Plans are being developed to ensure that appropriate training in PET-CT is provided for all trainees.
- The second type of training is for radiologists working in Cancer Centres or Cancer Units who will need to be trained in the interpretation and evaluation of PET-CT. Taking into account the national shortage of radiologists and radionuclide radiologists, video-linked reading may provide a short-term solution for scan interpretation, but long-term requirements will be different.

  To maintain standards of expertise, the PET physician must have sufficient and continuing exposure to PET-CT to ensure sustained competence. This becomes most important at the Satellite, especially in the early years while the workload is still developing. By ensuring that the provision of service at the Satellite is integrated with its Hub, the minimum target workload as set out in Standard 2 of the ICSCNM document can be met (see Appendix 6). This standard is in keeping with the ARSAC *Notes for Guidance* that state: "…. those individuals who wish purely to provide clinical evaluations of PET images will not require an ARSAC certificate and will not require such extensive training. Training will still be required over and above that acquired as part of radionuclide radiology SpR training, as this does not currently include PET. It is recommended that medical practitioners acting in this capacity should have experience of reporting 300 scans, achieved as part of an interactive programme, rather than by reviewing a library of images and reports."

If there are, at least, two trained nuclear medicine specialists, then double-reporting would ensure maintenance of skill and competence. Audit of PET-CT reports following MDMs will also ensure reporting skills are reviewed.

- Clinical medical specialists (e.g., oncologists and surgeons) will require education on an ongoing basis as the service and technology evolve.
- SHAs will need to be kept informed of developments, and the relevant healthcare professionals in that area will need to be educated on an ongoing basis.
- PCTs will need to be informed and educated.
- Healthcare Commissioners will also need to be informed of developments in PET-CT.

This process of education is essential if proper referral patterns, resourcing structures and appropriate service development are to take place.

Clinical scientists

The Hub should employ, or demonstrate ready access to, the services of a MPE, as set out in the *Ionising Radiation (Medical Exposure) Regulations 2000* (IR(ME)R). The MPE must be experienced in the application of physics to the diagnostic uses of ionising radiation and have specific expertise in PET and CT systems and procedures. The Hub must have a radiation protection supervisor and access to a radiation protection advisor (RPA). A MPE must be involved in the operation of both mobile systems and static sites; the requirements are the same for both. Where third parties are providing a scanning service, all lines of responsibility must be clearly established and agreed in such a way as to comply with all relevant regulations (notably, *The Ionising Radiations Regulations 1999* (IRR 99), The *Medicines (Administration of Radioactive Substances) Regulations 1978* (MARS) and IR(ME)R).

At least one dedicated, medical physicist is required for the operation, support and development of a basic, routine scanning service on a fixed site. This person may well be distinct from the MPE. Duties will include setting up equipment, defining system protocols, administering radiation protection, monitoring regulatory issues, image handling, exercising quality control, and general troubleshooting. Hubs performing non-standard or clinical research activities will require additional input from trained and experienced medical physicists and IT specialists in, for instance, agreeing complex protocols, and special image analysis, handling and transfer. If a PET-CT scanner is added to an existing nuclear medicine department the demand for medical physics resources will increase. For mobile services one, dedicated medical physicist can perform the duties, described above, for up to 4 mobile PET-CT scanners.

A computer scientist will be essential to set up and supervise secure and reliable image transfer procedures between PET-CT scanners, PACS systems, and remote reporting workstations. This group of professionals is crucial for the Hub and also the Satellite to function effectively and efficiently. In the early stages of development of the service while skills and experience are being developed, data acquired at a Satellite will need to be transferred to the Hub for reporting. Provision of this service will need to be an integral part of the *Connecting for Health* programme and will require appropriate funding.[13] In the longer term, this transfer may be required less frequently.

The model of a Hub supporting a Satellite will clearly permit the best use of the limited supply of medical physicists.

State registration of clinical scientists

Clinical governance considerations are likely to require that many of the scientific staff involved in patient care either are, or are supervised by, a state registered clinical scientist. A well-defined route to state registration via the Healthcare Professions Council (HPC) currently exists for medical physicists. Computer scientists will need to be registered, if they are involved in the care of individual patients.

Radiopharmacists who have undertaken an approved pharmacy training can be registered with the Royal Pharmaceutical Society of Great Britain (RPSGB). However, internationally recruited radiopharmacists may not be eligible for registration by the RPSGB. As the *grandparenting* route for HPC registration as a clinical scientist is closed, there is now no mechanism for state registering radiopharmacists, radiochemists or other radiopharmaceutical scientists via the HPC route.

Radiopharmaceutical technologists need to be recognised for state registration on the HPC Clinical Technologists Register. The RPSGB has a Pharmacy Technician Register, but it does not specifically recognise radiopharmacy and radiopharmacy technologists (i.e., chemistry graduates) who may not be eligible for registration via this route. This registration anomaly needs to be addressed urgently by the appropriate authorities.

Nuclear medicine technologists

Three whole-time equivalent nuclear medicine technologists are required for each scanner, whether static or mobile systems. This figure includes allowances for sickness cover, study leave and annual leave.

The radiation burden to staff becomes an increasingly important issue with the increased throughput of patients with PET-CT. Three staff for each scanner are required to reduce radiation doses to acceptable levels. As the radiation burden in PET investigations comes essentially from the patient, there is no simple, protective technique available to reduce this burden to the staff. The radiation burden to staff will also elevate when PET-CT is used for radiotherapy planning and for research projects. As the Satellite (mobile or static unit) will function as part of the Hub, staff rotation will be possible, and this alone has the potential to reduce the radiation burden.

Non-nuclear medicine trained radiographers will need both theoretical and practical, on-site training in the handling of unsealed radiation sources and other aspects of the service. Additional training in diagnostic CT will be required for nuclear medicine technologists, if PET-CT is to be used for diagnostic purposes rather than just for localisation or attenuation correction. The skill mix of radiographers and clinical technologists works well, but it needs to be developed further to broaden the recruitment base in this group of healthcare professionals. Appropriate training and qualifications need to be developed to ensure that opportunities are opened up for these individuals, because this is the area where a staffing shortfall may be experienced most acutely in the face of rapid service development. Therefore, the training needs of the group are probably the most pressing area for urgent, short-term funding.

Radiopharmaceutical scientists

Both the Hub and Satellite should have access to a named radiopharmaceutical scientist and technologist, either within the Trust or from a dispensing unit, to discuss radiopharmaceutical quality control procedures, radiolabelling techniques and related issues. If PET radiopharmaceuticals are prepared as Investigational Medicinal Products (IMPsl) then manufacturing authorisation is required and also a suitably trained qualified person (QP) for IMPs must be employed.

A radiopharmaceutical production facility providing only FDG will require at least two radiopharmaceutical scientists and technologists and two cyclotron engineers to provide adequate cover at all times. Duties of the radiopharmaceutical scientist and technologist include radiopharmaceutical production, quality assurance (QA), quality control (QC), dispensing, troubleshooting, and adherence to Good Manufacturing Practice (GMP). Duties of the cyclotron engineer include cyclotron operation, its maintenance, and troubleshooting. The roles of these staff may overlap and duties may vary depending on the degree of support provided by the cyclotron supplier. Additional support may be required to cope with the extensive paperwork and GMP documentation required by the Medicines and Healthcare Products Regulatory Agency (MHRA). Medical physics and radiation protection support will also be needed. Additional radiopharmaceutical scientists and technologists will be needed if a wider range of radiotracers is to be produced.

There is a serious shortage of trained radiopharmaceutical scientists and technologists, QPs and cyclotron engineers. The skill shortage in this area will be a serious impediment to the expansion of PET in both the short- and long-term unless the matter is addressed effectively and soon. Support should be established for trainers, and new training grades created in these specialist areas in order to provide an appropriate and adequate workforce for the future.

Nurses

The current nursing role and expertise in nuclear medicine should be expanded for the PET-CT service. An expanded role for the nursing staff would allow rotation between the nuclear medicine technologists and nursing staff. It must also be noted that for paediatric PET-CT scans, nurses are essential.

Administrative staff

Additional staff for both administrative and clerical duties will be required for this new service.

Standards for the delivery of a PET-CT service in the UK

The report of the ICSCNM details the standards required to provide a uniform, high quality service (see Appendix 6).

To maintain standards, as well as to ensure the same quality of service throughout the UK, the application of strict protocols and the robust use of service audit should be adhered to at both Hub and Satellite. The protocols and audit issues are set out in Appendices 7a, 7b & 8.

Nuclear medicine services offer greater logistical challenges than other imaging modalities in that an effective and efficient service depends on the availability of radiopharmaceuticals and the reliability of highly technical scanning equipment. PET-CT provides the greatest of all demands due to the short half-lives of the radioisotopes used and the complex methods and inherent expense of their production. In addition, once the difficulties of image acquisition are overcome, further issues must be addressed relating to the fusion of images from two separate imaging modalities and their subsequent use alongside images from other diagnostic procedures. These challenges become all the more apparent when all or some elements of the service are to be provided through external sources. Contracts for these elements must be carefully and precisely negotiated (see Appendix 4).

The proposal for PET-CT presents a real opportunity to establish a quality service with rigorous national monitoring, either through peer review or via healthcare commissioners.

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Appendix 1: Description of PET-CT

PET-CT

PET has been in use for over 25 years as a research tool and over the last 15 years in a clinical role. The major clinical applications of PET are in the areas of oncology, cardiology and neurology, with over 90% of the workload in oncology.

PET is a functional imaging technique that uses short-lived radioisotopes (with half-lives ranging from 2 to 110 minutes currently) attached to tracers to examine abnormal biochemical processes associated with disease. The biochemical processes that are altered by disease usually precede changes in size or structure of a particular organ or tissue.

PET is an inherently sensitive technique with the ability to detect disease, for example cancer, earlier than with anatomical imaging techniques. Biochemical and metabolic changes frequently precede changes in size with successful treatment, and so PET can also be used to monitor the effects of treatment earlier than is possible with conventional imaging methods. The most commonly used radiopharmaceutical in PET is ^{18}FDG. This compound acts as an analogue of glucose and can be used to trace tissues showing increased glucose transport and metabolism, such as cancer cells. There are potentially many more radiopharmaceuticals that can be used to investigate aspects of metabolism in the body, but currently ^{18}FDG is the only readily available tracer.

The functional images derived from PET lack fine, anatomical definition sometimes making it impossible to accurately localise the abnormality (in other words, to pinpoint the exact position of the cancer) or to tell what effect the abnormal function is having on neighbouring structures and organs.

CT

CT is a cross-sectional, X-ray technique that produces images of sections of the body. The resultant images are of high spatial resolution with the ability to define anatomy and different tissues in great detail. The major disadvantage of CT when used on its own is that it cannot necessarily indicate whether a tumour contains active cancer cells or only scar tissue following previous successful treatment. As CT predominantly relies on size for diagnosis, it may also be impossible to confidently detect cancer in small (< 1cm) lymph nodes or, alternatively, to tell the difference between enlarged cancerous nodes and enlarged benign reactive nodes.

Combined PET-CT

PET and CT are complimentary imaging techniques that, when combined, can maximise their individual advantages and minimise their respective disadvantages. Highly sensitive, functional PET images can be accurately superimposed on high spatial resolution CT images by obtaining both sets of information from a combined PET-CT scanner. The two sets of images can be displayed side-by-side or superimposed to allow improved interpretation. Another advantage of combining the scanning methods is that it is then possible to use the CT images to correct the PET images for attenuation errors, thus improving PET image quality and permitting increased scan speeds. With combined PET-CT patient throughput is increased by as much as 40% over acquisitions by PET alone. The appearances of an abnormality on the CT component can also aid in the interpretation of the PET findings.

Combined PET-CT scanners allow scans to be acquired within 20-40 minutes and can either be situated within a hospital department or on a mobile van to provide services to more than one hospital or clinic. There are a number of published research articles concerning diagnostic accuracy and changes to patient management that demonstrate the benefits of combined PET-CT over PET or CT alone.

Appendix 2: Existing PET-CT fixed scanning units in the UK installed predominantly for clinical use as of August 2005

Footnote: PET-CT installations that are primarily concerned with research have not been included (e.g. PET-CT at Manchester and Cambridge).

Appendix 3: Model for provision of PET-CT in the UK

The model for the development of the PET-CT service in the UK is based on maintaining the standards set out in the ICSCNM document, providing a high quality service to all patients in the UK and answering the clinical questions posed by the clinician. The model also recognises the need to expand existing clinical and professional expertise and the need to ensure an adequate body of fully trained staff to run the entire complex of the service.

The model that is proposed is based on a Hub with full PET-CT scanner with the majority of the Hubs having a cyclotron on site, and a Satellite that has a PET-CT scanning unit only and is well connected to and functions as part of the Hub. With the limitation on current staff and expertise, each Hub could support only one Satellite in the beginning stages of the service. In the longer term, the model is based on Hubs, static units (with highly developed PET-CT expertise) and mobile units. Thus, in the long-term, a static installation, whether a Hub or Satellite, could support one mobile PET-CT scanning unit.

As SHAs serve different sized populations and the geography of the UK can present special demands, such factors will need to be taken into account when choosing locations for the Hubs and Satellites.

Pre Phase I:

First measures need to take into account the current situation of PET and cyclotron provision in relation to the future distribution and commissioning of new cyclotrons and PET-CT scanning units. This includes taking note of institutions already fully operational and institutions at different stages of negotiation and delivery prior to commissioning.

Existing facilities (as well as the sites now under construction) will provide a minimal service to some cancer networks, either with a fixed or mobile PET-CT scanning unit. This is primarily the case in the South East of England; PET coverage elsewhere is generally poor. The quality of these services should nevertheless be expected to fulfil the criteria laid down in this document. These facilities will contribute to the build up of facilities which will provide the foundation for the development of a robust national service.

Phase I:

The establishment of an additional eight to twelve installations, some of which will be Hubs and some Satellites, either static or mobile, will need to take into account patient demographics across the UK (England, Scotland, Wales and Northern Ireland) to ensure adequate national coverage. This is achievable in the time scale outlined at the end of this appendix.

Each Hub will have one Satellite PET-CT scanning unit. This may be a mobile unit that will serve a number of sites around the Hub. This arrangement will allow maximum use of current expertise and resources. Every Hub will have an obligation to teach and train healthcare professionals to allow Phase II to be introduced.

Phase II:

The establishment of an additional eight to twelve Hubs in the UK will take place in Phase II. Each of these new installations will have one Satellite associated with it; this again could be a mobile unit. The new static installations will have an obligation to teach and train healthcare professionals.

At this stage the first wave of Hubs and their associated Satellites will be able to analyse the workload to

assess if an additional static Satellite is required, either in place of or in addition to the mobile Satellite. A fixed Satellite in a cancer centre could serve a number of additional cancer centres and cancer units. Mobile units may still be required in some areas that either cannot support a static site or where geography or transport links make patient movement difficult.

The placement of two PET-CT scanners at a Hub should also be seriously considered at this stage. While it might be ideal to have a PET-CT scanner at every cancer hospital, it would be more cost effective to have several scanners on one site with patients travelling to the PET-CT scanners (where the geography permits). This proposal would have the advantage of ensuring that adequate numbers of patients are seen in the Hub, so that the minimum number of scans to maintain clinical competence, as recommended by the ICSCNM, will be achieved. The overall requirement for professionally and technically trained personnel to run two PET-CT scanners on one site would then be less than it would be for two separated sites, but an increased number of PET physicians on that site would be needed to interpret scans and attend MDMs.

Conclusion:

In the long-term, the aim would be for every SHA (or equivalent body) to have a Hub with numerous Satellites. For those SHAs serving a population of greater than 1.5 million there might be a need for more than one Hub.

The pathway from Phase I to Phase II should be seamless and contiguous, but the planning of Phase II needs to start immediately with that of Phase I to ensure that the entire national NHS PET-CT service is developed strategically in collaboration with the independent and charities sectors. The facilities should be developed with the emphasis on patient care.

	2005-06	2006-07	2007-08
Current position	Working + Contracts	Partial Implementation	Full implementation
Phase I	Planning + Contracts	Partial Implementation	Full Implementation
Phase II	Planning	Contracts	Partial Implementation

Appendix 4: Contractual & service issues for PET-CT services

When considering the factors involved in providing a PET-CT service, it is essential that the process be considered as a whole, whatever way the service might be delivered. The roles of the Hub and Satellite have been discussed in the main document and in Appendix 3. This appendix highlights the major contractual and service issues to be considered when developing a PET-CT service. If any of the service elements are to be provided by suppliers that are not part of the hospital, they should be subject to precise contract negotiation and agreement.

Experience of PET-CT in the UK is largely limited to London and the South East of England and this, in itself, raises difficulties when considering how to establish a service. Because of this limited provision, it is not possible for all referring physicians and, indeed, those who offer clinical opinions as part of the imaging process to have a comprehensive knowledge of PET-CT. While some aspects of the service (e.g., radioisotope production) might be provided in isolation, others will need to be carefully merged into existing imaging services. The successful introduction of PET-CT into diagnostic imaging services cannot occur without involving and educating both those who will offer and those who will use the service. While it might be possible to consider *extra provision* for some diagnostic imaging services, for example MRI, while observing the principle of 'additionality', this is not the case with PET-CT, as the modality has no established user base. Any attempt to do so would be detrimental to the service and, ultimately, dangerous to the patient.

In considering the establishment of the NHS PET-CT service, a number of broad, but discrete service elements can be identified, each influencing the efficiency and viability of the service and each subject to conditions of a contract. These elements include the:

1. Production of radiopharmaceuticals and radioisotopes.
2. Availability of radiopharmaceuticals and radioisotopes.
3. Correct referral of patients including presentation of clinical images.
4. Justification of scans.
5. Scheduling and preparation of patients.
6. Reception, pre-scan preparation and post-scan care of patients.
7. Scanning of patients.
8. Processing, archiving, transfer and presentation of scan images.
9. Reporting of scans.
10. Presentation and discussion of results at MDMs, in the context of clinical management of patients.

Throughout these service elements, there are common requirements and issues, in relation to the patient, the equipment, the radiopharmaceuticals, and the images associated with the process. These include:

- For a number of elements, the primacy of patient care and safety.
- Quality control and assurance requirements around, for instance, the radiopharmaceuticals and equipment, and image integrity.
- The identification of timeframes, quality tolerances, and responsibilities for each element, particularly when within a contractual arrangement.
- The recognition and allocation of legal responsibility for each element.

- The embedding of audit as an integral element of the running of the service.
- Finally, costs of the service will be a major factor.
  - — Research should be encouraged and provision for the direct and indirect costs included in the budget for the PET-CT service.
  - — Teaching and training are essential in order for the service to expand. Staff time, facilities and other resources must be included in the indirect costs of running the service.
  - — It is essential that a fair and equitable cost is established throughout the UK. Provision of the radiopharmaceuticals used, as well as for the PET-CT scan itself must be accounted for and uniformly priced across the country. This is relevant whether the provision is from one NHS Trust to another or from outside the NHS to a NHS Trust.
  - — An equitable costing model should be developed that recognises that PET–CT + cyclotron facilities will bear the burden of more complex studies, provide more comprehensive training and undertake more research resulting in a higher unit cost than a PET–CT unit alone.

Production of radiopharmaceuticals and radioisotopes

Radioisotopes for PET-CT can be produced by generators, but this technology is largely in its development phase and, as such, is not available commercially. At present, the vast majority of radioisotopes used in PET-CT are dependent on cyclotrons for their production. Currently, PET-CT is used predominantly in oncology imaging and FDG is the most widely used radiopharmaceutical. However, Fluorothymidine (FLT) is already proving valuable in some clinical applications, and it is expected that a range of Fluorine-based ligands will be developed over the next five years. As such, the number of applications in oncology and other areas for other radioisotopes with much shorter half-lives will grow. The growth will be determined by research developments and radioisotope availability. This will influence the need for the co-location of cyclotrons and scanners and the number of Hubs and Satellites needed.

Issues raised in relation to radiopharmaceutical and radioisotope production include:

- *The radiopharmaceuticals and radioisotopes required must be identified and the level of demand determined*.*
- *The supply and the method of production must be agreed, particularly when the radioisotope and the required radiopharmaceutical are produced by different organisations.*
- *With a limited number of cyclotrons producing ^{18}F based ligands for the UK, downtime at any one cyclotron should not impinge upon services at the PET-CT scanners supplied by that cyclotron.*
- *A fair and equitable value for the ligands provided should be established nationwide ensuring an equality of cost throughout the UK.*
- *Adequately trained staff must be available to undertake production of radiopharmaceuticals and radioisotopes.*
- *Quality control and assurance requirements to ensure the integrity of the product must be undertaken (and responsibility allocated) and methods for validation must be agreed.*

* The initial level of demand for PET, both nationally or locally, will be based on the DH's consultative document on PET, although it is acknowledged that these estimates may be somewhat limited and reflect, at best, current rather than future expectations for the application of PET-CT, (i.e., the application of PET-CT in pathologies other than cancer is expected to grow with improved access to the modality just as applications within oncology will grow).

Availability of radiopharmaceuticals and radioisotopes

The short half-lives of some PET radioisotopes pose particular logistical problems in relation to their practicality in use at sites remote from Hub or isolated cyclotron installations. Having agreed the demand and types of radiopharmaceuticals needed, it will be necessary to ensure that these are available for injection into patients to ensure scanning facilities operate optimally. For this purpose:

- *Delivery schedules must be agreed.*
- *Alternative sources of radiopharmaceuticals and radioisotopes must be identified.*
- *Responsibilities for transport requirements (including training matters and legal issues) must be addressed.*
- *Delivery arrangements and receipt of products at the hospital should be agreed.*
- *Costs, availability of alternative supply sources, penalties for failure to supply, and related matters must be negotiated.*

Correct referral of patients, including presentation of clinical data

Because PET-CT is essentially new to most of the UK, the knowledge of its use among referrers is limited. Consequently, service issues relating to:

- *Training packages for referrers will need to be developed. These will include criteria for referral.*
- *Agreements on entitlement to refer, taking into account the need for integration of the PET-CT service into the established diagnostic services, will need to be set.*
- *Standard referral forms will need to be developed identifying specific details for oncology, cardiology and neurology.*
- *Minimum patient data sets, including imaging to support the referral, will need to be agreed.*
- *Intended alternative diagnostic procedures (in the absence of PET-CT availability) will need to be included with every referral.*

Justification of scans

The knowledge of PET-CT's appropriate use in the diagnostic process is limited. This is a direct contrast to situations when additional provision is made for established diagnostic services, such as for MRI. The knowledge amongst referrers and those who will determine the overall management of the patient is greater for modalities such as MRI than it is for PET-CT.

The number of nuclear medicine specialists with PET-CT training and experience is growing, and the use of this expertise should be maximised.

Whether PET-CT services are provided within Hubs or Satellites (static or mobile scanners), local expertise should be available in conjunction, where appropriate, with the expertise at centres, to ensure that each scan is properly justified and each PET-CT investigation is appropriate within the context of the full range of diagnostic services available. If this expertise is not immediately available, it should be developed in conjunction with the Hub as part of the provision of the PET-CT service.

- *Justification of PET-CT scans should be made by a local PET physician holding an ARSAC certificate (including PET procedures) or a nominated deputy who is trained in PET CT.*

- *Where this is not possible initially, supporting external PET-CT expertise should be available from an associated Hub and responsibilities agreed.*
- *Where external expertise is used for justification, training programmes should be agreed and developed to enable a local PET physician to take on the justification responsibilities.*
- *Clinical governance issues must be robust.*
- *Scanning protocols should be developed and agreed.*

Scheduling and preparation of patients

If PET-CT services are to develop and grow, it is essential that they run efficiently and effectively. Two vital parts of this are the correct scheduling of patients and the provision of information to patients regarding their preparation and attendance. In contracting and service delivery, the following should be flagged:

- *Patient scheduling (i.e., time slots) should be agreed.*
- *Timeframes, mechanisms and responsibility for patient contact, appointment times, pre-scan preparation information, directions to the service, etc., should be agreed.*
- *Systems, conditions and responsibility for patient rescheduling (in the event of failure of supply of radiopharmaceutical or equipment breakdown), including maximum delays for alternative appointment, should be agreed.*

Reception, pre-scan preparation and post-scan care of patients

PET-CT procedures make particular demands relating to reception facilities, pre-scan preparation of patients, and pre-scan. Facilities must be in place for patients to be injected and to wait in a quiet and calm environment, all taking into account the activity and energy of PET radiopharmaceuticals. These may be provided, by agreement, as part of the main imaging facility, or as separate facilities, either provided by the hospital or an external provider of the PET-CT service. Adequate patient facilities following the scan (e.g., recovery area and waiting for transport) must likewise be included.

- *Adequate signage must be provided to facilitate timely arrival of patients.*
- *Car parking facilities and ambulance access should be considered.*
- *Access to patient records should be available.*
- *Reception areas and reception staff should be available and adequate for patients, accompanying staff, relatives,et al.*
- *Injection areas should be appropriate for the activities and energies of radiopharmaceuticals used.*
- *Patient toilet facilities (for radioactive discharge) should be designated.*
- *Patient changing facilities should be available.*
- *Adequate and safe transfer routes (from reception to injection to scanning facilities) should be identified and provided.*
- *Adequate and sufficient numbers of post-injection waiting areas should be available, consistent with the agreed scanning schedule and the need for patient privacy.*
- Adequately trained staff should be available to inject patients.

Scanning of patients

The scanner, scanner room, associated local services and adequately trained staff are essential elements of a PET-CT service if patients are to be scanned safely and effectively and images acquired. Responsibility for the provision of these elements must be agreed between all those parties involved in the provision of these aspects of the service. In addition:

- *All telephone, IT, electrical, water, heating, and waste services should be provided by the hospital.*
- *The scanner room (whether static or mobile) should be of adequate size to enable safe and efficient scanning of patients.*
- *Where a mobile scanner is used, adequate access and hard standing must be provided by the hospital.*
- *Dedicated full-ring PET-CT scanner (specify multi-detectors) is provided.*
- *Quality control and assurance requirements (including calibration) must be undertaken (and responsibility allocated) and methods for validation must be agreed.*
- *Appropriate resuscitation and patient safety equipment and resuscitation teams should be provided particularly where intravenous contrast is used.*
- *Clinical consumables should be provided.*
- *Dedicated staff trained to undertake PET-CT scans should be available.*

Processing, archiving, transfer and presentation of scan data

Following acquisition, image processing, archiving, presentation and ownership are essential elements of a PET-CT service. Responsibility should be allocated for:

- *Stewardship of images in accordance with the Data Protection Act 1998.*
- *Appropriate storage of images in agreed forms (raw, compressed, etc.).*
- *Secure transfer of images, as required for use in MDMs, etc.*
- *Processing of images according to agreed protocols (reconstructions, image fusion, etc.) and into agreed formats (digital, analogue) to facilitate image interpretation.*
- *Arrangements for importing and presentation of images from previous procedures that are relevant to a diagnosis.*

Reporting of scans

Image interpretation must be undertaken by appropriately trained staff. As with justification of procedures, local expertise should be available to ensure that each scan is properly interpreted within the context of the patient images available at referral and taking due account of other diagnostic information. If this expertise is not provided locally, it should be developed locally as part of the provision of the PET-CT service.

- *Image interpretation of PET-CT scans should be provided by a PET physician. Where this is not possible initially by local specialists, external expertise should be available and responsibilities agreed.*
- *Where external expertise is used to provide a medical interpretation, training programmes should be agreed and developed to enable local consultants to take on the reporting responsibilities.*
- *Report content and format should be agreed at least locally and developed nationally as necessary and all reports provided in this format.*

Presentation and discussion of results at MDMs in the context of clinical management of patients

As indicated previously, although PET is an established modality, its use in the UK is still relatively new and its value in patient management (sensitivity, specificity, negative and positive predictive values and accuracy) not widely understood within the clinical community. It is essential therefore that the value of the information from PET-CT scans is critically appraised in light of the overall management of individual patients and patient groups. This is best achieved in the setting of multidisciplinary meetings (MDMs). Therefore, the PET-CT service should be integrated into the hospital's imaging services.

- *Training programmes should be developed to ensure imaging and other staff are able to maximise the value of the PET-CT scan images and reports within the context of MDMs.*
- *Systems should be put in place to automatically allow the results of patient management to be fed back to those justifying PET-CT and reporting scans.*
- *Provision should be made for the collection of these images on a national basis to ensure the appropriate and cost effective use and development of PET-CT in the UK.*

Appendix 5: Staff training for PET-CT

Summary of training and educational issues

With coordinated planning and appropriate funding, current UK PET expertise can be expanded to meet the skill shortages in all PET disciplines that otherwise threaten the development of PET services in the UK, both in the short- and long-term. This appendix is a summary of the document that the BNMS is drawing up in connection with training for all relevant professionals involved in PET-CT. The following issues are required to achieve this expansion:

- Development and accreditation of training courses and other educational resources for all disciplines.
- Funding to set up new training courses and other educational resources (e.g., e-learning).
- Funding for training at Hubs and Satellites that have relevant expertise.
- Salary support to allow backfilling of posts to release trainers.
- Training of staff prior to commencement of a new PET-CT service and/or replacement of experienced staff moving from training centres to other NHS sites or the private sector.
- A multi-professional approach (where possible) to maximise cost-effectiveness of knowledge-based training programmes (e.g., the e-learning model for multi-professional education proposed by BNMS that requires development).
- Involvement of the NHS, academic institutions and independent sector providers of PET-CT services in PET-CT training, in view of the shortage of training opportunities.
- Clear identification of the costs of providing PET-CT education, to enable these overheads to be taken into account when comparing the costs of PET-CT service delivery between training and non-training centres.

Development of Training Resources

There is a need to establish specific PET-CT certificates of competence, Diplomas and/or MSc modules that are accredited by appropriate bodies, e.g., Society & College of Radiographers (SCoR), BNMS, Consortium for the Accreditation of Nuclear Medicine Education (CANME), and IPEM. A combined multi-professional course attended by any healthcare professional working in nuclear medicine is likely to be cost-effective and maximise the limited training resources available nationally, even though each professional group is likely to begin the course with different levels of essential skills / knowledge.

The skill base itself will be mainly delivered on site; every Hub will need to participate in the training of all healthcare professions providing the PET service. The knowledge base could be delivered electronically. A PET-CT e-learning module could be developed within the proposed BNMS multi-professional education project. Seed funding will be required to establish this resource. A partnership between the providers of the skill base and those providing the knowledge base will be essential.

Nuclear medicine technologists

There is a national shortage of nuclear medicine technologists, from both radiography and clinical technology backgrounds. Radiographers currently receive minimal theoretical training on PET within BSc courses and no practical PET experience is included in current training courses. For clinical technologists, current basic training includes minimal theoretical knowledge and no practical experience in PET or CT.

There is a need to address the issues of recruitment and retention. PET-CT offers the possibility of expanded roles and attractive packages of duties and responsibilities, which could be aids to recruitment and retention.

Nuclear medicine technologists form one of the crucial groups if a nationwide service is to be delivered in the very near future. One potential problem that could arise is the movement of the already limited supply of nuclear medicine technologists from routine nuclear medicine into PET-CT, thus limiting the nuclear medicine services that can currently be provided.

Cyclotron engineers & radiopharmaceutical scientists and technologists

There is a serious shortage of cyclotron engineers, radiopharmaceutical scientists and technologists. The skill shortage in this area will be a serious impediment to the expansion of PET in both the short- and long-term unless it is addressed effectively.

Cyclotron operators / engineers tend to be drawn from a range of backgrounds in engineering and radiation workshops. No formal training courses are available. Training courses for such engineers are required and a career structure needs to be established. No formal training courses are presently available for radiopharmaceutical scientists and technologists, but a new MSc programme in 'Radiopharmaceuticals and PET Radiochemistry' is being set up by King's College, London.

Physicists

There is an overall shortage of medical physics personnel coming into the field. This shortage may potentially result in pressure upon existing medical physicists to act as designated MPEs in PET-CT without adequate training or experience. Currently, training in medical physics is via the IPEM Diploma / MSc (as part of a 4-year programme) leading to state registration. It includes various placements. There is very limited postgraduate training specifically directed towards nuclear medicine (including PET).

Medical

PET: Training of established consultant radiologists is required, while many consultant nuclear medicine physicians are already trained. Training for specialist registrars (SpRs) in nuclear medicine is established.

CT: Training of nuclear medicine consultants (if reporting on their own without a radiologist) will be required. The training of nuclear medicine SpRs will be sufficient to allow independent reporting of PET-CT.

There is a need to educate physicians, especially oncologists, radiotherapists, neurologists,and cardiologists, as well as surgeons in PET-CT.

Appendix 6: Standards for delivering a PET service within the UK

A Report of the Intercollegiate Standing Committee on Nuclear Medicine

Representing

The Royal College of Physicians of London

The Royal College of Physicians and Surgeons of Glasgow

The Royal College of Physicians of Edinburgh

The Royal College of Pathologists

The Royal College of Radiologists

and the British Nuclear Medicine Society

http://www.rcr.ac.uk/docs/radiology/worddocs/StandardsPETcentre2.doc

INTRODUCTION

Positron emission tomography (PET) has been in use for over 25 years as a research tool and over the last fifteen years in a clinical role. The major clinical applications of PET are in the areas of oncology, cardiology and neurology, with over 85 - 90% of the workload in oncology there is no reason to suspect this distribution of workload will change dramatically in the next few years. There is a strong likelihood of expansion in cardiology and in the use in the evaluation of dementias in the medium to long term.

PET is a technology that uses short-lived radioisotopes (half lives ranging from 2 to 110 minutes currently) attached to tracers to examine metabolic processes associated with health and disease. These functions are often altered by disease and precede changes that can be visualised by cross sectional imaging (e.g. CT, MRI). PET are produced in cyclotrons that are available in a variety of sizes and energies. The most common radioisotope produced is fluorine-18 (F-18), but others include nitrogen-13 (N-13), carbon-11 (C-11) and oxygen-15 (O-15). Fluorine-18 has the advantage of having a longer half-life (110 min) and can be attached to a molecule that mimics glucose metabolism, fluorodeoxyglucose, to produce 18F-FDG. Cancer cells have altered glucose metabolism and therefore FDG is a major tracer used in the assessment of cancer (ICSCNM report).

PET should only be carried out on dedicated full ring equipment, and a further expansion of coincidence PET on a gamma camera should be discouraged (ICSCNM document). PET in the UK has been severely restricted by the lack of availability of scanners and cyclotrons, this situation is likely to change over the next 5 - 10 years. To take advantage of this change and benefit the maximum number of patients requiring PET investigations, trained staff to run PET-CT scanner + Cyclotron Facility are required. The lack of trained medical staff has been addressed by the incorporation of PET training in the training programme for Nuclear Medicine. There is still a short fall in other staff groups including radiologists developing radionuclide radiology sub-speciality skills, medical physicists, radiographers and nuclear medicine technologists, Radiopharmaceutical Scientist and Technologists and cyclotron engineers.

Currently FDG is the most common radiopharmaceutical used in PET. Tracer development is proceeding at a pace and it is likely other tracers will be available routinely. The role of F-18 fluoride for bone scanning is emerging and offers a number of possible advantages over conventional bone scanning. There is already a requirement for C-11 methionine, in brain tumours, and the likelihood that other C-11 tracers will continue

to be needed for diagnosis and research. It is therefore necessary that at least some cyclotrons should be sited next to imaging departments. Clinicians and colleagues operating a PET facility need to have knowledge of all aspects of PET including tracer production, image processing as well as image interpretation. The other major development that continues at a pace is the combination scanners – PET-CT, where the PET imaging is available combined with Computed Tomography (CT) scanning to provide an attenuation map and improved anatomical definition to complement the functional images. The primary modality is still PET, and specialist knowledge of functional imaging using radiopharmaceuticals is essential to be aware of the wide use of tracers in imaging, tracer theory and importantly the radiation safety issues associated with unsealed sources. In some disease areas it is likely that diagnostic CT images will need to be obtained in combination with PET images. It is likely therefore that a combination of skills will be called on to report such images depending on their use. For instance radiotherapy planning may require the input from the nuclear medicine trained individual, a radiologist and an oncologist.

The Intercollegiate Standing Committee on Nuclear Medicine has already produced two documents related to the provision of Nuclear Medicine Service in the UK and a Strategy Document for PET. These documents have been endorsed by the Royal Colleges of Physicians (London, Edinburgh, Glasgow), the Royal College of Radiologists and the Royal College of Pathologists. The Royal College of Physicians and Royal College of Radiologists have also agreed a training programme for Nuclear Medicine Specialists and a training programme for Radionuclide Radiologists. These training programmes detail the training required for PET, as part of the training for Nuclear Medicine, and require the demonstration of both knowledge and competencies for this service delivery.

The purpose of this publication on Standards for PET Centres is to provide guidance for best practice. This guidance links with the previously published Strategy documents and the DoH publications related to cancer waiting times and the organisation of multidisciplinary meetings to discuss cancer care. This guidance is designed to encompass the range of methods of provision of a service including static and mobile sites as well as the changes in technology that may occur. A PET Centre is therefore a generic term for delivery of PET whether this uses combination technology e.g. PET-CT or a stand alone PET scanner. It is envisaged that the progression towards fixed sites in the UK based on the proposal by the Intercollegiate Standing Committee on Nuclear Medicine will take a number of years and mobile services will be a temporary solution. These mobile services should however require the presence of trained specialists within the cancer networks ensuring education of clinicians in the locality and allowing a local presence at multidisciplinary meetings. To ensure consistency of standards, these guidelines identify standards that should apply to PET services within and outside the NHS.

GENERAL GUIDELINES

1. A PET Centre must demonstrate that it has suitably trained staff, workload and facilities to provide a PET service. There are six general standards with various criteria listed relating to each standard. Each criterion should be reached to provide a service meeting best practice.

2. It is envisaged that there will be three types of Centre each must meet the standards given below. The centres will be:

    a) A full clinical imaging and tracer production Centre– one containing PET scanners and a cyclotron and radiochemistry facility. This centre will carry out clinical service work with a range of tracers, research and may also act as a distributor of tracers.

    b) An imaging and production Centre – for research. This may also provide a limited clinical service for a local population.

c) An imaging only Centre – a predominantly clinical service facility receiving tracer from a remote production facility

3. The standards will apply to both static and mobile PET centres.

4. The standards will also apply to private and managed service PET centres. Management pathways will need to be very clearly defined – between the provider company and the host Trust.

5. In general, a centre would be expected to provide a range of PET studies using available tracers appropriate for the disease being studied.

6. Each institution / facility undertaking PET examinations has the responsibility to ensure that training of health care professionals is an integral aspect of the work.

7. A Centre capable of providing most of the PET curriculum could provide part of the training but sufficient time at another Centre would need to be arranged for aspects not covered. In general only those Centres able to meet the generic guidelines for PET training of an SpR will be considered as training Centres. A clear job plan and a training agreement for the SpR must be produced, as identified in the Orange Guide. The Royal Colleges standards for a training department should be used in conjunction with this guideline.

8. Each clinical PET Centre must have, (i.e. employed by the host institution either with an honorary contract or a normal contract), at least one clinician holding an ARSAC certificate for the PET tracers used. They will need to demonstrate that they have met the competencies documented in the Nuclear Medicine and Radionuclide Radiology training programme.

9. Other suitably trained clinicians may report PET studies with the agreement of the ARSAC certificate holder. The individual must demonstrate sufficient training in PET reporting, and will normally be expected to have undertaken radionuclide radiology/nuclear medicine training and have the basic science knowledge for PET, tracer theory and knowledge of the limitations of the technique.

10. The advent of PET-CT has determined that the Nuclear Medicine curriculum will contain sufficient cross sectional imaging training to enable a nuclear medicine physician to use CT as both an anatomical reference as well as tissue characterisation. An alternative model is to use the expertise of the Nuclear Medicine Specialist and the Radiologist to provide joint reports.

STANDARD 1

The PET Centre shall provide appropriate supervision for the examination being carried out.

Criteria:

1. The Centre will have sufficient number of consultant programmed activities (PAs) and supporting PAs cover to comply with the time for reporting, vetting requests and general administration recommendations outlined in the Royal College of Physicians Working for Patients document 2005 and all subsequent updates

2. The provision of a full-time PET service is expected to require at least one whole time equivalent PET Specialist (either a Nuclear Medicine specialist or a radionuclide radiologist with PET training). For mobile services, if the ARSAC certificate holder, does not all hold a permanent post within the specific cancer network/ trust, they must hold an honorary contract with that Trust/employer.

3. For a static site, the lead clinician shall be based within the Hospital Trust/PET Centre 60% or greater of the time the PET facility is operating. For a mobile site the lead Nuclear Medicine Specialist should hold a permanent post within the Cancer Network and visit the mobile site to ensure the site is operating according to best practise.

4. The lead PET clinician or deputy should ensure that the requests for PET and other imaging are vetted according to set criteria and scans reviewed following their acquisition. During holiday and professional leave of the lead PET clinician there must be a named appropriate specialist to provide cover.

5. There should be written guidelines for the areas of responsibility of each clinician involved in the department

STANDARD 2

The PET Centre shall have sufficient workload of patients to maintain expertise for clinicians involved in reporting.

Criteria:

2.1 The target workload of a static PET Centre, in the start up period, should aim at 400 patients per annum. Individual clinicians should be actively involved in reporting 300 cases annually to maintain skills. If the Centre is performing only oncology examinations then this number should encompass a variety of different cancer types and sites.

2.2 The number of paediatric PET scans is likely to be limited and therefore these studies are best referred to a specialist paediatric centre to perform these.

2.3 A system of audit is required for any Centre. This is particularly important for a new centre; from its inception a system should be in place for audit, both local and national, and meetings for discrepancy between reporters instituted.

STANDARD 3

Every PET centre should have a teaching and training programme.

Criteria:

3.1 The PET Centre should provide training for SpR trainees, the centre must comply with the Standards set for Nuclear Medicine and Radionuclide Radiology training centres and be inspected by the SAC in nuclear medicine.

3.2 The PET Centre should have a training programme for all health care professionals involved. Mobile sites should be used to provide some elements of training, but there is recognition that mobile PET cannot offer the full range of facilities required.

STANDARD 4

The Centre shall have access to the necessary scientific staff and equipment to ensure the optimum use of equipment and the production of the highest quality examinations and patient safety.

Criteria:

4.1 The Centre shall employ, or demonstrate ready access to, the services of a Medical Physics Expert (MPE), as defined in the IR(ME)R regulations, who must also be a state-registered clinical scientist. The MPE must be experienced in the application of physics to the diagnostic uses of ionising radiation and specifically have expertise in nuclear medicine.

4.2 The Centre must also have access to a state-registered clinical scientist with up-to-date specialist knowledge of PET and CT systems and procedures (PET clinical scientist). In some cases this will be the same person as the MPE.

4.3 Quality control and quality assurance procedures must be carried out regularly and results recorded. QC and QA procedures must be appropriate to the studies being performed and be approved by the PET clinical scientist. Results of QC and QA procedures must be checked regularly by the MPE or PET clinical scientist, to ensure maintenance of image quality.

4.4 All routine preventative maintenance must be performed to a prearranged schedule, and all faults must be investigated and resolved in a timely manner.

4.5 The Centre shall have a Radiation Protection Supervisor and access to an RPA.

4.6 The Centre shall have access to a named radiopharmacist/radiochemist, either within the Trust or from the dispensing unit, to discuss problems in radiopharmaceutical quality control procedures, radiolabelling techniques and related issues.

4.7 The radiopharmaceutical production facility should meet the EANM guidelines for Radiopharmacy and any subsequent drafts (Eur J Nucl Med Mol Imag 2003; 30: BP63 – 72) and MHRA requirements.

4.8 When more than one group is involved in the operation of a centre (e.g. a hospital and a commercial partner) responsibilities and reporting structures for the above staff must be formally agreed.

STANDARD 5

The PET Centre will have suitably trained radiographers/nuclear medicine technologists and nursing staff operating the facility.

Criteria:

5.1 The Centre should only employ staff trained in use of the PET or PET-CT equipment or be able to offer supervised training of new radiographers/nuclear medicine technologists.

5.2 Depending on the case mix and numbers of patients suitably trained nursing staff may need to be employed to administer radiopharmaceuticals, and to carry out relevant nursing procedures and monitoring of patients undergoing PET.

STANDARD 6

The Centre shall have a mechanism for communicating results and providing advice to Multidisciplinary Team Meetings.

Criteria:

6.1 The Centre should have a PET clinician attending appropriate Multi disciplinary team meetings (MDM). (The attendance could be by remote video-conferencing). This commitment has to be included in consultant job plans and adequately resourced.

6.2 Where MDM attendance of the PET clinician is not possible routinely, a detailed report and relevant images should be provided for a local expert clinician to attend the MDM.

6.3 In the case of mobile services, MDM attendance would best be provided by the lead PET Specialist who holds the ARSAC certificate for the mobile van or a deputy within the Cancer Network where the mobile site is provided. Electronic communication should be explored (as above) depending on local circumstances.

This will enable training and education for local clinicians and ensure that the local expert is available to advise on appropriate referrals and discuss further queries and problems.

REFERENCES:

Positron emission tomography - A strategy for provision in the UK. RCP January 2003

Nuclear medicine and radionuclide imaging - A strategy for provision in the UK. RCP January 2003

A guide to specialist registrar training. DHSS February 1998

Eur J Nucl Med Mol Imag 2003; 30: BP63 – 72

BNMS Nuclear medicine generic quality guidelines

BNMS Organisational audit standards

Appendix 7a: Protocols for PET-CT

Protocols should be established in compliance with the relevant regulations. All operational standards apply equally to all sites whether in the public or independent sector and to both static and mobile sites. Audit of these protocols should occur on a regular basis.

The protocols include:

- *Cyclotron operation*
  All activities must be carried out in accordance with established operating procedures to enable operation in a safe and efficient manner. All activities must comply with the relevant legislation, in particular those relating to health & safety, radiation protection and storage, and accumulation and disposal of radioactive substances. There must be an appropriate preventative maintenance program.

- *Quality Control of PET-CT scanner*
  PET-CT quality control and quality assurance procedures must be carried out regularly and results recorded. QC and QA procedures must be appropriate to the studies being performed and be approved by the MPE or clinical scientist. Results of QC and QA procedures must be checked regularly by the MPE or clinical scientist.All routine preventative maintenance must be performed to a prearranged schedule, and all faults must be investigated and resolved in a timely manner

- *Quality Control (QC) radiopharmaceuticals*
  All radiopharmaceuticals must be prepared under GMP.

  Every radiopharmaceutical dispensed must be accompanied by specific patient identification that includes full name, unique identifier plus one additional identifier, e.g., date of birth or address. A record must be kept of the radiopharmaceutical injected, the dose and time given. This record must be signed by the injector (although the record could be electronic). Any drug administered to the patient, relevant to the examination, must be similarly recorded.

- *Acquisition protocol*
  Acquisition protocols should adhere strictly to the IR(ME)R requirements. System protocols should be approved by the MPE. Common scans, or those as part of multi-centre trials, should be performed under nationally agreed protocols to ensure that images are consistent, comparable and reproducible.

- *Justification protocol*
  The accepted indications for clinical PET-CT studies are currently available. These indications should be constantly updated and be maintained nationally. It is accepted that individual cases that may benefit from PET-CT to change (or enable) management will still be able to be performed providing adequate justification can be shown.

- *Reporting protocol*
  There should be standardised reports. The report should be structured and include indications, current relevant drug / therapeutic regime, full radiopharmaceutical details of what was administered, description of what was undertaken, description of the views reviewed and analysed, description of the findings, and conclusion / interpretation of the results of the examination (see Appendix 7b).

  Ideally, double-reporting should be instigated. With the introduction of Satellites, this will be possible

as the Satellite will be established as an integral part of the Hub. Thus the expertise at the Hub will be available to those at the Satellite. This relationship will ensure adequate training, as well.

- *Data transfer protocol*
  Two-way image transfer between the Hub and Satellite (mobile and/or static units) could be achieved via appropriate connection to the NHSnet with adherence to NHS Information Authority guidelines. Removable image media could also be used to facilitate image transfer.

- *PACS integration protocol*
  All PET-CT data should be analysed and processed on the specialised PET-CT workstation. Ideally, it should be possible to reliably archive all acquired data to the hospital's PACS system, which should be fully compliant with national integration requirements for *Connecting with Health*. As a minimum, cross-sectional PET and CT images and maximum intensity projection data sets (MIPs) should be archived in such a way that they can be retrieved for display (including image fusion) and reviewed on the specialised workstation, PACS workstation and web clients. The PACS system must enable diagnostic quality image display of all cross-sectional data and support rapid display of MIPs and high resolution, colour display for PET-CT image fusion.

  The PACS systems should allow full functionality (including colour display) of the PET-CT images without the purchase of additional equipment (currently not possible).

- *Feedback from surgery*
  Details of any surgical procedure which follows PET-CT should be fed back automatically to the Hub and/or Satellite. (The precedent has been set up with the NHS Breast Screening Programme.)

- *Feedback from MDMs and long-term patient outcome*
  All those patients who have had PET-CT should have the clinical outcome fed back to the PET physician at the Hub and/or Satellite. This is a form of double-reporting that may inform the ongoing assessment process.

- Automatic feedback should occur from the clinical audit in Cancer Units and Cancer Centres in association with Cancer Registries that monitor the development of the cancer service network and its function. (*A Policy Framework For Commissioning Cancer Services*, DoH, April 1995)

Appendix 7b: Model FDG PET-CT oncology report

A model diagnostic report should include the following:

1. A separate descriptive and interpretative section of the report should be included.

2. A description of all abnormal FDG accumulation with comments on intensity of uptake and anatomical position.

3. A description of anatomical abnormalities corresponding to abnormal FDG accumulation, including shape, relationship to neighbouring organs / structures, presence of invasion when assessable, size and enhancement (if IV contrast used).

4. A description of physiological variants and artefacts only if they may be mistaken for neoplastic pathology.

5. A description of all clinically relevant CT abnormalities that are FDG-negative, e.g., enlarged FDG-negative lymph nodes, and lung nodules not resolved by FDG PET.

6. A description of incidental but clinically relevant CT abnormalities, e.g., abdominal aortic aneurysm.

7. A comparison to previous non-PET-CT imaging (including CT) when available.

8. A comparison of uptake and size of tumour foci and presence or absence of new lesions when assessing response to treatment and a conclusion on the response, including an answer to the clinical question, if possible.

9. An overall conclusion. For example a statement as to whether FDG abnormalities are likely to be benign or malignant or whether there has been a response to therapy. In follow-up studies, points 8 and 9, above, may be combined in a final conclusion.

Appendix 8: Audit of PET-CT

All Hubs and Satellites must undertake regular audits. This should be done on a quarterly or 6-monthly basis.

Every protocol (as listed in Appendix 7a) should have auditable criteria.

Other areas of audit should include:

- Staff numbers.
- Training of all groups of staff with 360 degree assessment.
- Clinical audit.
- Patient audit.
- Feedback from the clinical audit in Cancer Units and Cancer Centres in association with Cancer Registries.

Glossary

BNMS	British Nuclear Medicine Society
^{11}C	11Carbon - a short-lived radioisotope labelled to different chemical compounds, produced by the cyclotron
CANME	Consortium for the Accreditation of Nuclear Medicine Education
Central Unit	This is a Hub (PET-CT scanner + Cyclotron)
CT	Computed Tomography
Cyclotron	Equipment required to produce short-lived radioisotope
DH	Department of Health
^{18}F	^{18}Fluorine - a short-lived radioisotope, used on its own or labelled to different chemical compounds, produced by the cyclotron
FDG	Fluorine deoxyglucose is the commonest ligand currently in use
FLT	Fluorothymidine
Gamma camera PET	A gamma camera adapted to acquire images at high energy
GMP	Good Manufacturing Practice
Healthcare Professional	In the context of PET-CT this refers to the following professional groups: Radiographer; clinical technologist; clinical scientists including the following: physicist; computer scientist; radiopharmaceutical scientist and technologist; cyclotron engineer. Also included in this group are the administrator, nurse and medical doctor, including nuclear medicine specialist, radiologist, oncologist, surgeon and trainees in any of the above groups.
HRG	Healthcare Resource Group
Hub	This is the nucleus of the PET-CT service. It will consist of a PET-CT scanner and have the expertise to support a Satellite (in the long-term possibly a number of Satellites). It would serve as a centre for research and audit. A significant proportion of these will have cyclotrons attached.
ICSCNM	Intercollegiate Standing Committee on Nuclear Medicine
IPEM	Institute of Physics & Engineering in Medicine
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations 2000
IRR	Ionising Radiations Regulations 1999
IV	Intravenous
Ligands	A chemical compound that is attached to one of the short-lived radioisotopes that provides the unique functional image
MDM	Multidisciplinary meeting of relevant health care professionals
MARS	Medicines (Administration of Radioactive Substances) Regulations 1978

MHRA	Medicines and Healthcare Products Regulatory Agency
MIPS	Maximum intensity projection settings
MPE	Medical physics expert
^{13}N	^{13}Nitrogen - a short-lived radioisotope produced by the cyclotron
Adequately trained PET physician	Medical doctor suitably trained in Positron Emission Tomography
Nuclear medicine technologist	Includes both radiographers and clinical technologists working in nuclear medicine
^{15}O	^{15}Oxygen - a short-lived radioisotope produced by the cyclotron
PACS	Picture archiving and communication system
PCT	Primary Care Trust
PET	Positron Emission Tomography
PET camera	Full-ring camera dedicated to acquiring images at high energy
PET-CT scanner	A combined scanner capable of providing images of both PET and CT
PET-CT scanning unit	Refers to a PET-CT camera with no cyclotron on that site. This could either be in a fixed location or a mobile unit
QP	Qualified Person – for radiopharmacy
Radioisotope	A radioactive element that changes into a stable state by releasing energy by emitting a form of radiation. This energy is detected by the PET camera and converted into an image.
Radiopharmaceutical	A chemical that is attached to a radioactive element that changes into a stable state by releasing energy by emitting a form of radiation.
Radiopharmaceutical scientist & technologist	Radiopharmacist, radiochemist or other scientist specialising in radiopharmacy
RIS	Radiology information system
RPA	Radiation protection advisor
RCP	Royal College of Physicians
RCR	Royal College of Radiologists
Satellite	A PET-CT scanning unit functionally integrated with the Hub
SHA	Strategic Health Authority

The Royal College of Radiologists 38 Portland Place London W1B 1JQ

Telephone +44 (0)20 7636 4432 | Fax +44 (0)20 7323 3100 | Email enquiries@rcr.ac.uk |

Citation Details

Board of the Faculty of Clinical Radiology
The Royal College of Radiologists (2005)
PET-CT in the UK: A Strategy for development and integration of a leading edge technology within routine clinical practice
Royal College of Radiologists, London.

On publication this document will be made available on the College's web site: http://www.rcr.ac.uk

ISBN 1 905034 05 9

RCR Ref No. BRCR (05)5

Acknowledgement: pictures of the CT scanner, IMRT image and workstation are reproduced by kind permision of Dr Gary Cook and Miss Bernadette Cronin, Nuclear Medecine Department of The Royal Marsden NHS Foundation Trust.

Design by Tin Dog: email info@tindog.co.uk