A Framework for the Development

of

Positron Emission Tomography (PET) Services in England

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Contents

Executive Summary/Key Recommendations

Objectives of the PET framework

1. This framework for the development of PET scanning services in England has been developed by the Department of Health at the request of Strategic Health Authorities and specialised commissioning groups. It is intended to guide commissioners and potential providers of services by providing advice on the current evidence of benefit from PET scanning; the current state of the technology; the number of scanners likely to be required; workforce and training issues; capital and revenue costs and further research and evaluation.

2. This framework was sent out for public consultation in July 2004. Since then, a Working Party has been established by 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 and the Institute of Physics and Engineering in Medicine. Their report can be found at http://www.rcr.ac.uk "PET-CT in the UK – A strategy for development and integration of a leading edge technology within routine clinical practice"; it has been produced to provide a multidisciplinary response to take forward and make a reality of this framework. The two documents have been launched together in order to provide a coordinated package of information to clinicians and managers in the development of PET-CT services.

Approach to development of the framework

3. The framework draws heavily on previous detailed work undertaken by expert groups including the Intercollegiate Standing Committee for Nuclear Medicine; Groups established by NICE to develop clinical guidelines on lung cancer and on improving outcomes in head and neck cancer and the Health Technology Board for Scotland.

4. The framework also takes account of the recommendation of the indications for the reimbursement of PET scanning in the USA provided by the Centre for Medicare and Medicaid Services (CMS). Comparisons of UK and European service provision are based on a recent paper by Bedford and Maisey (November 2003).

5. As this is a rapidly changing field it was considered important to obtain up to date advice from UK experts in the field. The National Cancer Director therefore convened an ad hoc meeting of experts from nuclear medicine and radiology in December 2003.

6. The framework does not make specific recommendations regarding sources of funding for PET. Plans for the implementation of a PET-CT service will have been announced alongside launch of this Framework, including the

procurement of a number of PET-CT scans from the Independent Sector as well as the availability of capital to support local schemes. Strategic Health Authorities working with PCTs, specialised commissioning groups, cancer networks and NHS Trusts will need to consider the relative merits of different public/private sector funding and management approaches.

Clinical applications of PET and evidence of benefit

7. The evidence of benefit from PET scanning is now sufficiently robust to support the establishment of facilities across the country, so that all appropriate patients can have access to this technology. Expert advice indicates that in the immediate future cancer will account for around 85 - 90% of PET scanning utilisation, with much smaller numbers of scans being required for neurological and cardiac conditions.

8. Within cancer the evidence of benefit from PET is strongest for patients with lung cancer, lymphoma and colorectal cancer. However, evidence is also accumulating of benefit from PET for head and neck cancer, oesophageal cancer, brain tumours and a range of less common cancers. The NICE guideline for the diagnosis and treatment of lung cancer published in February 2005 made a key recommendation that every cancer network must have rapid access to PET scanning for staging disease.

9. Within each of the cancers it is possible to identify specific indications for the use of PET. These can include initial diagnosis; determining the extent of spread of disease (including assessment of the suitability of patients for radical surgery); establishing response to therapy and the presence of residual disease after treatment and detection of recurrent disease.

Number of scans required per annum

10. Based on the current evidence and consensus among experts, **provision should be made for around 40,000 scans p.a. across England for cancer over the next 3 - 5 years (i.e. around 800 scans per million population)**. This figure is likely to rise further as the research evidence grows stronger and encompasses more cancer types and indications. The RCR working party report also anticipates increased indications.

Current provision of PET services in the UK and Europe

11. In August 2005 there were seven fixed-location full-ring PET- CT scanners routinely available for NHS patients in England and one PET scanner (Hammersmith), six of which are located in London and the South East. The scanner located at Mount Vernon in Middlesex is provided by charitable funds and the surplus earned from private scans is used to reduce costs of NHS scans, it is run by NHS staff. There are a further two fixed-location private scanners in London and three privately managed mobile scanners which provide some services for NHS patients across the UK. There

is also now a permanently sited mobile facility at Guildford. In addition to the above there are at present three institutions with PET facilities dedicated to research. These are in Cambridge, Manchester and Hammersmith.

12. The provision of PET facilities in the UK compares unfavourably with that of most other Western European countries, where PET is now an accepted technology for the management of patients with cancer. Five European countries already have at least one scanner per 2 million population, compared with around one per 5 million in the UK (including private scanners, but excluding research scanners). France with a similar population to that of the UK has recently committed to providing 75 PET scanners.

Advice on technology

13. PET-CT scanners combine the functional imaging advantages of PET with the anatomical detail shown by CT. PET-CT scanners also have higher patient throughputs than existing PET scanners. There is a clear consensus amongst experts that combined PET-CT scanners have considerable advantages over fused images from separate PET and CT scanning facilities. While gamma camera PET may have value, the technology is currently inferior to dedicated PET scanners and is unlikely to have the same versatility. **PET CT is therefore recommended for future installations where clinical applications are the agreed priority. This document is intended to address dedicated or full-ring PET.**

14. In the more immediate term as a potential interim solution we can envisage a role for mobile PET-CT scanners which could be run by private sector providers. Mobile PET-CT would not be able to provide the same capacity as fixed site scanners and there are particular health and regulatory requirements associated with this modality.

Overall requirement for scanners and their location

15. A throughput of 2000 - 2500 scans per annum for individual scanners is considered reasonable as a basis for planning for PET-CT scanners, which are to be used predominantly to provide a clinical service based on ^{18}F - Fluorodeoxyglucose (^{18}F-FDG). This figure does not include scanning time for research into new applications of the technology (Phase I/translational research).

16. Development of clinical PET-CT services outside London should therefore be a high priority. **It is recommended that where individual facilities are established, they should serve populations of around 2.5m people.**

17. **Some further development is also likely to be needed in London and the South East**, given the fact that some of the existing facilities generally have lower throughput than current PET-CT scanners.

Cyclotrons (radiopharmacy production units)

18. A network of cyclotrons will need to be established across the country to produce the radio-pharmaceuticals required for PET scanning. One cyclotron can serve several facilities. For ^{18}F-FDG scanning, cyclotrons should normally be located no more than 2 hours travelling time from the scanning facility. A total of around 6 cyclotron facilities might be sufficient to cover the clinical requirements in England, if appropriately located. Scanners which are to be used for research into new technological developments (e.g. using radiolabels with half lives of less than 2 hours) should be co-located with a cyclotron. Consideration should be given to the establishment of cyclotron services functioning on commercial principles to supply several PET scanning facilities. **It is recommended that SHAs should work together with others (including/particularly specialised commissioning groups and cancer networks) to determine the optimal location for cyclotrons, based on the proposed location of scanning facilities, both for service purposes and for research.**

Workforce and training

19 Urgent consideration needs to be given to the workforce and training implications of expanding the provision of PET-CT in this country. Further work is being undertaken to take forward the recommendations from the RCR Working Party report. At a local level commissioners and providers should work closely with Workforce Development Confederations to ensure training requirements are met.

Research and Evaluation

20. Ongoing research and evaluation is needed to look into the benefits of PET scanning. The NHS Health Technology Assessment Programme is currently conducting a rapid review of the research evidence to establish a baseline for determining future research priorities. Research should be coordinated through the National Cancer Research Institute. **The NCRI has established a working party related to PET scanning.** It may be appropriate for NTRAC to take a lead on the translational aspects of research and for NCRN to take a lead on large scale Phase II/III trials. **It is strongly recommended that prospective audit of the impact of PET scanning on clinical management becomes a requirement on service providers.**

Capital Costs

21. The capital cost of installing a PET-CT scanner, including the associated building costs is likely to be around £2- 2.6m. A cyclotron facility is likely to cost around £3.5m. Planned procurement on a national basis is likely to yield some reductions on the overall cost. Private financing of PET-CT

scanning facilities and/or cyclotrons should also be considered. This would clearly reduce initial capital outlay, but would impact on revenue costs.

Revenue Costs

22. The annual revenue costs for an individual scanner is likely to be in the region of £1.5 - £2m. Assuming a total of around 40k scans in England the total revenue cost would be in the region of £33 - £44m p.a. The cost per scan is likely to be between £750 and £1,000. The revenue cost for a PCT with average usage would be between £100 and £150k p.a.

Queries on the Framework

23. Queries about this framework should be sent to Tracy Parker, Cancer Equipment Team, Area 402 Wellington House, 133-155 Waterloo Road, London SE1 8UG or to tracy.parker@dh.gsi.gov.uk .

1. Introduction

Aims and Objectives

1.1 Positron Emission Tomography (PET) is a rapidly evolving technology with a range of potential applications in the evaluation of patients with cancer, neurological conditions and cardiac disease. Formal evaluation of the cost-effectiveness of diagnostic techniques, particularly those which are developing rapidly, is notoriously difficult. The impact of diagnostic technologies on clinical outcomes may take several years to evaluate, by which time the technology may have moved on. Research findings may be difficult to interpret due to changes in approaches to treatment in the intervening years.

1.2 There has been a growing demand for the wider provision of PET services in England and increasing recognition that the UK is falling behind the USA and other European countries in relation to the establishment of PET services. Strategic Health Authorities (SHAs) and specialised commissioning groups have therefore asked the Department of Health to develop a framework to inform decision making regarding the commissioning and provision of PET services.

1.3 The aim of the framework is to provide SHAs, specialised commissioners, cancer networks, Primary Care Trusts and NHS Trusts with up to date advice on:

- The current evidence relating to the benefits of PET scanning for particular conditions;
- The number of scans that are likely to be needed each year for a given population over the next three to five years;
- The current state of the technology;
- Estimates of the number of scanners that are likely to be needed to meet demand and comments on their possible location;
- Workforce and training issues;
- A recommended approach to further evaluation of PET scanning through high quality research and audit;
- Indicative capital and revenue costs, both from the perspective of commissioners and providers.

Approach to the development of the framework

1.4 Development of the framework has involved collation and evaluation of several different strands of evidence and advice. These include

- The Health Technology Assessment (HTA) report 2, undertaken in 2002 for the Health Technology Board for Scotland (HTBS) and a subsequent report on implementation of PET scanning in Scotland (October 2003). The HTA focussed largely on the clinical and cost-effectiveness of PET in early stage non-small cell lung cancer (NSCLC) and in lymphoma. For NSCLC the HTA assessed clinical effectiveness by updating the literature presented by the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) in 2001, with literature published up to October 2001.

- Recommendations of the group established by the National Institute for Clinical Excellence (NICE) to develop clinical guidelines on lung cancer.

- Draft recommendations of the group currently developing 'Improving Outcomes Guidance for Head and Neck Cancers' on behalf of NICE.

- Recommendations on the indications for the reimbursement of PET scanning in the USA provided by the Centre for Medicare and Medicaid Services (CMS).

- "Positron emission tomography: A strategy for provision in the UK". This report of the Intercollegiate Standing Committee on Nuclear Medicine was published in January 2003.

- A comparison of UK and European PET service provision based on a recent paper by Bedford and Maisey (November 2003).

- The Department received over 50 responses to the consultation draft issued in July 2004 from Professional Bodies, Trusts, Cancer Networks, individual clinicians and providers.

1.5 As this is a rapidly changing field it was considered important to obtain up to date advice both on the evidence related to the benefits of PET and on current thinking related to developments in technology. The National Cancer Director therefore convened an ad hoc meeting of experts from Nuclear Medicine and Radiology in December 2003.

Background on PET

1.6 PET is a medical imaging technology that uses short lived radionuclides attached to biological molecules to produce images of metabolic processes in the body. PET can be used to visualise abnormalities of metabolism caused by disease processes such as cancer, coronary heart disease and neurological conditions. PET demonstrates biochemical or functional changes in the body, whereas other forms of imaging such as

magnetic resonance imaging (MRI), computed tomography (CT) and ultrasound primarily provide information on structural or anatomical changes.

1.7 The tracer most commonly used for PET imaging is ^{18}F-fluorodeoxyglucose (FDG). This can frequently highlight cancers because of their altered glucose metabolism. FDG can also demonstrate changes in other tissues, which use glucose as their main energy source (e.g. brain and cardiac muscle). FDG is also taken up by patients with other conditions like TB and infections. When patients are undergoing a PET scan using FDG it is important that they rest between the time of injection of the radionuclide and the scanning procedure in order that the radionuclide is not preferentially taken up by muscular tissues.

1.8 The radionuclides used for PET imaging are generated in cyclotrons and are then attached to the relevant biological molecule in a radiopharmacy. The half life of ^{18}F-FDG is around two hours, which means that cyclotrons have to be located within a relatively short travelling time from the PET scanner (typically within about 2 hours).

1.9 ^{18}F-FDG is the only tracer that currently has an established role in clinical practice in cancer. Other radionuclides (e.g. ^{15}O) which are the subject of ongoing research tend to have much shorter half lives. Facilities undertaking research based on radiolabels other than FDG normally need to have a cyclotron and a PET scanner co-located on the same site. Alternatives to FDG are also being developed using
^{18}F isotopes

2. Clinical applications and likely demand for PET

Potential utility of PET for cancer

2.1 PET scanning has a range of potential uses in the management of patients with cancer. These include:

- Initial diagnosis : Distinguishing between benign and malignant disease (e.g. in patients with solitary pulmonary nodules revealed by conventional imaging technologies);

- Staging: Assessing the extent of disease is important for the purposes of decision-making regarding different treatments. For example, in patients who appear to have early stage non-small cell lung cancer (NSCLC) on the basis of conventional imaging techniques, PET scanning may reveal spread of disease which would otherwise have been undetected. These patients can therefore be spared from radical surgery which would not be of benefit;

- Establishing the grade of malignancy (e.g. in brain tumours);

- Monitoring the effects of chemotherapy: Changes in the biological activity of a tumour may be apparent sooner than changes in the size of a tumour, which are detected by conventional imaging techniques such as CT scanning. This may help to determine whether a change from one chemotherapy regimen to another is indicated and/or whether a different treatment modality (e.g. radiotherapy) might be of greater benefit;

- Establishing whether there is residual/active disease at the completion of a planned course of chemotherapy or radiotherapy;

- Establishing whether disease has recurred and the site of recurrence (e.g. when tumour markers are rising);

- Identifying the primary site of a tumour (e.g. to enable a biopsy to be taken) when there are strong clinical indications of the presence of cancer, but the site is unknown;

- Treatment planning for radiotherapy.

Potential uses of PET for other diseases

2.2 PET scanning has potential applications in cardiology, neurology and neuropsychiatry. In cardiology PET may be used to assess poor ventricular function in patients being considered for revascularisation and to determine the extent to which myocardium is “hibernating”. In neurology, PET may be used to determine the focus of epilepsy in patients being considered for neurosurgery. However, the use of PET in cardiology and neurology is generally less well established than its use in oncology. It is generally agreed that around 85-90% of the use of PET scanning currently relates to cancer.

Applications related to individual cancers

2.3 A detailed assessment of the research evidence related to the clinical and cost-effectiveness of PET scanning for individual cancers is beyond the scope of this framework. It is now widely accepted that the evidence of benefit (based on sensitivity/specificity analysis of PET compared with other imaging modalities) is now sufficiently robust to support the establishment of PET facilities across the country, so that all appropriate patients can have access to the technology. The aim of this section of the framework is to summarise for service planners and commissioners those applications for which the current evidence of benefit is strongest and to highlight areas for which evidence of benefit is accumulating and for which services are likely to be needed within a very few years.

2.4 Within cancer the evidence of benefit is strongest for lung cancer, lymphoma and colorectal cancer. Evidence of benefit is accumulating for head and neck cancer and oesophageal cancer, and a range of less common cancers including brain tumours, melanoma, paediatric cancers, sarcoma, teratoma and thyroid cancer.

2.5 In the United States of America, the centre for Medicare and Medicaid Services (CMS) currently endorses reimbursement of PET scanning for a range of indications related to lung cancer, lymphoma, colorectal cancer, melanoma, oesophageal cancer and head and neck cancer. CMS also endorses reimbursement for the location of a seizure in pre-surgical patients with epilepsy and for the assessment of myocardial viability after an equivocal single photon emission computed tomography (SPECT) study.

2.6 The Health Technology Assessment undertaken in Scotland (based on research evidence to October 2001), concluded that the most compelling evidence of cost-effectiveness related to the restaging of patients with Hodgkin's Disease, a form of lymphoma. Although the cost-effectiveness model was restricted to Hodgkin's Disease the authors concluded that the significant benefits of PET are likely to be applicable to patients with non-Hodgkin's lymphoma.

2.7 In relation to lung cancer, the recommendations from the clinical guidelines development group established by NICE are that PET scanning should be made available for the following indications:

- An FDG-PET scan should be performed to investigate solitary pulmonary modules in cases where a biopsy is not possible or has failed.

- Patients who are staged as candidates for surgery on CT should have an FDG-PET scan to look for involved intrathoracic lymph nodes and distant metastases.

- Patients who are candidates for radical radiotherapy on CT should have an FDG-PET scan.

- Every cancer network must have a system of rapid access to FDG-PET scanning.

2.8 The recommendations from the NICE lung cancer guideline development group recognise that other indications for PET scanning within lung cancer may become common practice in the future. These include: monitoring for recurrence of disease; radiotherapy planning; staging of small cell lung cancer and hypoxia imaging.

2.9 The report of the Intercollegiate Standing Committee on Nuclear Medicine (ISCNM) published in January 2003, emphasised the fact that the largest influence of PET has been in the management of lung tumours, colorectal tumours and lymphoma. The report provides an extensive

bibliography related to each of these tumours and on the emerging research evidence relating to oropharyngeal (head and neck), oesophageal, breast and testicular malignancies.

2.10 The ISCNM report provides a table of clinical indications for PET scanning, with the strength of supporting evidence being classified as follows:

A : Randomised controlled trials, meta-analysis, systematic review

B : Robust experimental or observational studies

C : Other evidence where the advice relies on expert opinion and has the endorsement of respected authorities

2.11 A modified version of this table is shown at Annex A. This is confined to cancer related indications and excludes indications for which the evidence is at Level C.

Estimates of demand for PET in cancer

2.12 An ad hoc group was convened by the National Cancer Director in December 2003 to consider a range of issues in relation to future developments of nuclear medicine in England. This included experts from the Royal College of Physicians, the Royal College of Radiologists, the British Nuclear Medicine Society and the Institute of Physics and Engineering in Medicine.

2.13 The group, inter alia, considered the future development of PET services in England. The strength of evidence related to each potential cancer indication was briefly reviewed and an estimate of likely demand for each indication was made, based on the proportion of all patients with each of the relevant cancers who might be appropriate for one or more PET scan.

2.14 Estimates of demand for cancer related PET scans, based on the advice of the ad hoc group and on subsequent discussions with the developers of NICE guidance, are presented in Annex B. Figures for individual cancers are necessarily 'broad brush', but the composite figure of 40,000 scans p.a. across England is considered to provide a reasonable basis for service planning. As noted earlier, this figure is likely to increase as the evidence of benefit becomes stronger for some indications over coming years. The three cancer types for which the evidence is currently strongest (lung cancer, colorectal cancer and lymphoma) account for 30,000 of the estimated total requirement for 40,000 scans p.a.

2.15 Given the consensus amongst experts that cancer related indications are likely to account for 85 - 90% of the total requirement for PET scans, it may be reasonable to anticipate an additional requirement of around 4,000 – 6,000 scans p.a. for other conditions.

3 Current provision of PET services in UK and Europe

PET services in England

3.1 The current provision of PET scanning services and cyclotron facilities is shown in Annex C. Seven fixed-location scanners are routinely available for NHS patients. (6 PET CT, 1 PET). These scanners are mostly located in London and the South East. The facility in Birmingham has been scanning patients since July. The scanner located at Mount Vernon hospital in Middlesex is run using charitable funds, but is largely used for NHS patients.

3.2 In addition to the scanners mentioned above there are two private scanners in London, 1 private scanner in Guildford and three privately managed mobile scanners, which provide some services for NHS patients across the UK.

3.3 There are three PET institutions in England dedicated to research. These are located in Cambridge, Manchester and Hammersmith with one, two and two scanners respectively.

3.4 A further six NHS PET CT facilities are currently under development in England, these are planned for Preston, Nottingham, Bristol, London, Plymouth and a further charitable scanner at Cheltenham. Some plans are less well advanced, all are at differing stages of the contractual process. Outline plans for new PET-CT services are in preparation at other trusts in England. A further 25 thousand scans will be purchased per annum over the next five years as part of the Wave 2 Diagnostic Independent Sector procurement programme. These will be sited to assist local plans and strategies to achieve the estimated PET-CT requirement of 800 scans per million head of population.

3.5 There are six cyclotron facilities currently operating in England (two in London; one in Hertfordshire; one in Liverpool, one in Keele and one in Cambridge). Plans are also in place in support of PET-CT developments identified in 3.4, though these are yet to be finalised.

PET services in Scotland, Wales and Northern Ireland

3.6 There is currently one PET facility (scanner and cyclotron) in Scotland, located in Aberdeen. This is primarily intended for research.

3.7 Business cases are in preparation in the three regional cancer groups which will determine the pattern of medium term provision.

3.8 The Welsh Assembly Government is considering the development of PET services for Wales, taking into account both clinical and research

interests. A cyclotron facility in Cardiff has been proposed and is being considered.

3.9 A PET-CT scanner was installed at the Royal Victoria Hospital in Belfast in 2003. Isotopes are provided by a commercial supplier in Dublin.

PET services in Europe

3.10 Comparative figures related to the provision of PET services in the UK and Europe are shown at Annex D. These figures are based on a report by Bedford and Maisey (Nov 2003). The current provision of PET facilities in the UK compares unfavourably with that of most other Western European countries. Five European countries (Belgium, Germany, Austria, Sweden and Denmark) already have at least one scanner per two million population. This compares with around one per five million in the UK (including private scanners, but excluding research scanners). France, which has a similar population to that of the UK has recently committed to providing 75 PET scanners.

4 Current advice on technology

4.1 The technology related to PET scanning is advancing rapidly. Up to date advice was therefore sought from experts during the development of this framework in relation to the following issues:

- The relative merits of combined PET-CT scanners and standalone PET and CT facilities.
- The relative merits of fixed-location and mobile PET (or PET-CT) scanners.
- The requirements for cyclotrons and radiochemistry facilities.

4.2 There is a clear consensus amongst experts that combined PET-CT scanners have considerable advantages over fused images from separate PET and CT scanning facilities. PET-CT scanners combine the functional imaging advantages of PET with the anatomical detail shown by CT. In addition the throughput of the current generation of PET-CT scanners is considerably higher than that of existing PET scanners and throughput is set to increase further with the next generation of PET-CT scanners This will have an impact on facilities in terms of the requirement for patient change facilities, patient handling spaces and revenue costs. This means that fewer scanners would be needed to meet national requirements. Combined PET-CT is considered both to be the most cost-effective solution and to have advantages in relation to workforce and training requirements.

4.3 The advantages of mobile PET-CT scanners are that they can be commissioned relatively rapidly (either by the NHS or private sector) and they

can move from one location to another to meet local needs. However, the throughput of mobile scanners is likely to be considerably lower than that of fixed-location scanners. In part, this relates to the requirement for patients to remain immobile close to the scanner between injection of the radionuclide and scanning (and space is limited in mobile scanners).

4.4 The consensus view of experts is that new PET-CT developments should largely be based on fixed-location scanners. These should normally be co-located with a cancer centre. A case can, however, be made for providing services based on mobile scanners while fixed scanners are being commissioned and installed (see the RCR Working Party report).

4.5 For clinical PET-CT services based on FDG it is acceptable for radioisotopes to be provided by a cyclotron/radiochemistry facility located up to about two hours travelling time from the scanning facility.

4.6 It is anticipated that the clinical requirements for PET services in England could be met by the establishment of a network of around six cyclotron facilities across England.

5 Overall requirements for clinical PET services and their location

5.1 A throughput of around 2,000 - 2500 scans per annum from an individual machine is considered reasonable as a basis for planning for PET-CT scanners providing a clinical service based on ^{18}F-FDG. An additional 4,000 – 6,000 scans could probably be justified to take account of non-cancer related work.

5.2 The figure of 40,000 does not take account of scanning time for research into new applications of the technology (Phase I/translational research). It does, however, include some scanning time related to Phase II/III studies of relatively new indications for FDG-PET (Annex B). It is also anticipated that high quality prospective studies will also be undertaken on the impact on clinical management of all patients undergoing PET scanning (see Section 7).

5.3 The planning of new facilities will need to take account of the current location of PET facilities and the fact that most existing facilities are based on PET scanners with lower throughput than the current generation of PET-CT scanners.

5.4 Development of clinical PET-CT services outside London should therefore be given a high priority. It is recommended that facilities should serve populations of around 2.5 million.

5.5 Some further development is recommended in London and the South East.

5.6 It will be important to ensure broad geographical coverage across the country. SHAs, PCTs, specialised commissioning groups and cancer networks have been working together to ensure the appropriate location of facilities/ provision of scans. The Department of Health has been facilitating this process by providing advice, coordination of information and planning for that purpose.

5.7 It is anticipated that a total of around six cyclotron facilities (including radiopharmaceutical preparation) will be sufficient to cover the clinical requirements for PET in England, if appropriately located, taking account of geographical communication links. Consideration should be given to the establishment of services functioning on commercial principles to supply several scanning facilities.

5.8 It is recommended that SHAs should work together (and with the Department of Health) to determine the optimal location for cyclotron and radiochemistry facilities. Account will need to be taken of any proposals for the development of further research.

6 Workforce and Training

6.1 Effective implementation of this framework will require concerted efforts both at a national and at a local level to ensure that appropriately trained staff are available to deliver the service.

6.2 Interpretation of PET-CT images will require skills both in radionuclide imaging and in cross-sectional anatomical imaging. The RCR lead Working Party Report has addressed some of these issues and the DH will be working with them to further develop their recommendations.

6.3 In addition to medical staff, PET-CT facilities will need radiographers and/or nuclear medicine technicians, medial physicists, together with nursing, administrative, secretarial and portering support. At a local level commissioners and providers will need to work with workforce development confederations and appropriate professional bodies to ensure that staffing and training requirements are met.

6.4 Cyclotron and radiochemistry facilities will need the following expertise: medical physicist(s), medical physics technician(s), radiochemist(s) and radiopharmacy technician(s).

7 Research and Evaluation

7.1 Research associated with PET scanning can be considered at several different levels, each of which would bring benefits to NHS patients:

- Phase I/ translational research into new applications of radiopharmaceuticals. Because of the short half-lives of some potential radiolabels, this type of research generally requires cyclotron and scanning facilities to be co-located on a single site.

- Early Phase (I/II) studies of existing technologies (e.g. ^{18}F-FDG) applied to cancer types and indications which have not previously been evaluated.

- Phase III randomised controlled trials of the clinical and cost-effectiveness of FDG PET-CT. It should be noted that these types of study are extremely difficult to conduct for new imaging technologies.

- Large scale prospective audits of the impact of FDG-PET scanning on clinical management and outcomes in areas where existing Phase II/III studies suggest benefit.

7.2 The Department of Health has asked the NHS Health Technology Assessment Programme to undertake a rapid review of the current evidence-base related to FDG-PET for cancer. The aim of this review is to inform the commissioning of research/audit studies.

7.3 It is recommended that future research into PET scanning for cancer should be coordinated through the National Cancer Research Institute (NCRI). The NCRI has established a working group related to PET scanning. It may be appropriate for NTRAC to take a lead in coordinating the translational aspects of research and for NCRN to take a lead on large scale Phase II/III trials and prospective audits. It is strongly recommended that prospective audit of the impact of PET scanning on clinical management becomes a requirement for all service providers.

8 Costs

Capital Costs

8.1 The capital cost of installing a PET-CT scanner, including the associated building costs is likely to be around £2 – 2.6m. A cyclotron facility is likely to cost around £3.5m. Central procurement on a national basis is likely to yield reductions on the overall cost. Private financing of PET-CT scanning facilities and/or radiopharmaceutical provision should also be considered. This would clearly reduce initial capital outlay, but would impact on revenue costs.

Revenue Costs

8.2 The annual revenue costs for individual scanners are likely to be in the region of £1.5 - £2m. To provide a total of 46k scans the total revenue cost

would be in the region of £33 - £44m p.a. The cost per scan is likely to be between £750 and £1,000. The revenue cost for a PCT with average usage would be between £100 and £150k p.a.

8.3 The additional revenue cost of PET scanning is likely to be offset to some degree as unnecessary surgery (e.g. thoractomy, oesophagectomy) is no longer carried out following a PET scan. Such patients are likely to be offered alternative therapies including chemotherapy and radiotherapy.

Annex A

Clinical indications in oncology for positron emission tomography

[Derived from the Intercollegiate Standing Committee on Nuclear Medicine report published in January 2003.]

Cancer type	Indication and level of evidence
Lung	Differentiation of benign versus malignant lesions where anatomical imaging or biopsy are inconclusive or there is a relative contraindication to biopsy (A)
	Pre-operative staging of non small cell primary lung tumours (A)
Colon and rectum	Assessment of recurrent disease (A)
Lymphoma	Staging of Hodgkin's lymphoma (B)
	Staging of non-Hodgkin's lymphoma (B)
	Assessment of residual masses for active disease (B)
Brain and spinal cord	Suspected tumour recurrence when anatomical imaging is difficult or equivocal and management will be effective (B)
	Benign versus malignant lesions, where there is uncertainty on anatomical imaging and a relative contraindication to biopsy (B)
Thyroid	Assessment of patients with elevated thyroglobulin and negative iodide scans for recurrent disease (B)
Oesophagus	Staging of primary cancer (B)
Testicle	Assessment of recurrent disease from : seminomas and teratomas (B)
	Assessment of residual masses (B)
Musculosketal	Soft tissue primary mass assessment to distinguish high grade malignancy from low or benign disease (B)
	Staging of primary soft tissue malignancy to assess non skeletal metastases (B)
	Assessment of recurrent abnormalities in operative sites

Melanoma	Malignant melanoma with known dissemination to assess extent of disease (B)

Note:

1 (A) Denotes indications supported by randomised controlled trials, meta-analyses and/or systematic reviews.

2 (B) Denotes indications supported by robust experimental or observational studies

3 Indications for which there is only a lower level of evidence (C) have been omitted from this list.

Annex B

Estimated demand for cancer-related PET scans in England

Tumour Group		Indications/basis for estimate	Likely No of scans
Lung Cancer	*	Assessment of suitability for radical therapy (surgery or radiotherapy) (33% of patients with NSCLC)	]]]] 10,000
	*	Assessment of solitary pulmonary module	]]]
	*	Monitoring for recurrence/other	]
Lymphoma	*	2-3 scans per new patient with HD or NHL, for staging, monitoring treatment response and assessing recurrence	15,000
Colorectal Cancer	*	Assessment of recurrent disease including suitability for resection of liver metastases (33% of patients with advanced colorectal disease)	5,000
Oesophageal Cancer	*	Assessment of suitability for radical surgery (33% of new cases p.a.)	2,000
Other cancers with level 'B' evidence	*	Brain and spinal cord	5,000
	*	Thyroid	
	*	Testical	
	*	Sarcoma	
	*	Melanoma	
Cancers with level 'C' evidence only	*	Head and Neck	3,000
	*	Breast cancer	
	*	Unknown primary	
		Total	**40,000**

1. * A strong case can be made for further high quality research related to these indications.

Annex C

PET Services in England, August 2005

Table 1(a) : Current Clinical PET Scanning Facilities		
PET Scanning Facilities		**Comments**
London		
Guy's and St Thomas' NHST and Kings College London.		2 PET CT jointly owned and managed (clinical 75% and research 25%).
Hammersmith Hospitals NHST		1 clinical PET due to be replaced with PET CT.
University College London Hospitals NHST		1 PET CT
The Royal Marsden NHST, (Sutton)		1 PET CT
West Hertfordshire Hospitals NHST, Paul Strickland Scanner Centre		1 PET CT (charitably funded)
Private		
The London PET Centre, Lister InHealth, Harley Street		1 PET (PET CT from Oct 2005)
The Alliance Imaging Centre, near Harley Street		1 PET CT
Outside London		
Midlands		
University Hospital Birmingham NHST		1 PET CT – NHS/IS partnership.
North		
Christie Hospital NHST, ManPET, University of Manchester		1 PET CT (Clinical /Research) Clinical services provided 2 days per week.
South		
The Royal Surrey County Hospital, Guilford – Lodestone		1 PET CT (private)
The Royal Surrey County Hospital NHS Trust		1 PET CT mobile - permanently docked
Mobiles		
Mobile scanners provide services across UK.		1 PET (private, Alliance) 1 PET (private, Lister Healthcare) 1 PET CT (private, Alliance)
Totals		
London	NHS	5
	NHS/IS	0
	CHARITABLE	1
London Total		**6**
Outside London	NHS	2
	NHS/IS	1
	CHARITABLE	0
Outside London Total		**3**
Private		**3**
Mobile		**3**
Grand Total		**15**

NB: Tables assumes if no provider /partnership specified it is NHS provision. Where academic involvement is stated this has been counted as NHS provision.

Table 1b Current Research (only) PET Scanning facilities		
London		
Hammersmith Hospitals NHST		2 MRC research PET scanners
Outside London		
East		
Addenbrookes - Wolfson Brain Imaging Centre		1 PET Research only - plans to upgrade to a PET CT scanner for clinical use
North		
Christie Hospital NHST, Wolfson Molecular Imaging Centre:		1 research PET and 1 research PET CT –
Totals		
London	NHS	*2*
	NHS/IS	0
	CHARITY	0
London Total		**2**
Outside London	NHS	3
	NHS/IS	
	CHARITY	
Outside London Total		**3**
Private		**0**
Mobile		**0**
Grand Total		**5**

NB: Tables assumes if no provider /partnership specified it is NHS provision. Where academic involvement is stated this has been counted as NHS provision.

Table 2 Clinical PET Scanning Facilities in planning stage & to be confirmed		
London		
University College London Hospitals NHST		1 PET CT - due on line from Nov 2005 (the two UCLH scanners will be used for clinical and research scanning from March 2006)
Barts & the London NHS Trust		1 PET CT (clinical 80% Research 20%) - operational by Feb 2006.
Outside London		
Midlands		
Nottingham City Hospital NHST		1 PET CT – NHS/IS partnership, due to be operational from April 2006
North		
Lancashire Teaching Hospitals NHST (Preston)		1 PET CT NHS/IS partnership, (due to be operational from June 2006)
South		
Cheltenham – Linton Clinic, Colbalt Appeal Fund		1 PET CT (charitably funded) due to be operational April 2006.
Plymouth Hospitals NHST		1 PET CT – due to be operational 2006/7
United Bristol Hospitals NHST		1 PET CT – University/IS Partnership (Clinical 60%/Research 40%) Due to be operational in Autumn 2006.
Mobiles		
Mobile Scanners - Lister Healthcare		1 PET CT scanner due to be operational Oct 2005
Totals		
London	NHS	2
	NHS/IS	
	CHARITY	
London Total		**2**
Outside London	NHS	1
	NHS/IS	3
	CHARITY	1
Outside London Total		**5**
Private		**0**
Mobile		**1**
Grand Total		**8**

NB: Tables assumes if no provider /partnership specified it is NHS provision. Where academic involvement is stated this has been counted as NHS provision.

Table 3(a) Current Cyclotron Facilities – Clinical & Research	
London	
Guy's and St Thomas' NHST and King's College London	NHS owned and managed cyclotron and radiochemistry facility. Jointly owned and managed with radiotracer production for both clinical and research studies in addition to the development of novel tracers.
West Hertfordshire NHST, Paul Strickland Scanner Centre	"PETnet" commercial provider of FDG to several centres on named patient basis
Outside London	
North	
Clatterbridge Hospital	Provides isotope to ManPET facility and PET Gamma-camera in Liverpool
Keele University Science Park	Erigal - commercial provider expected to go on-line end of Aug 2005.
Grand Total	**4**

Table 3(b) Current Cyclotron Facilities - Research Only	
London	
Hammersmith Hospitals NHST	"Hammersmith-Imanet" private supplier, serves research PET scanners on-site
Outside London	
East	
Addenbrookes NHST Wolfson Institute	Provides isotopes for its own research PET scanners
North	
Christie Hospital NHST, Wolfson Molecular Imaging Centre	1 research cyclotron.
Grand Total	**3**

Table 3 (c) Cyclotron Facilities in Development which may include provision for full GMP commercial cyclotron on site.	
London	
University College London Hospitals NHST	Due July 2006
The Royal Marsden NHST, (Sutton)	Due 2006/7
Outside London	
Midlands	
Nottingham City Hospital NHST	Due April 2006
North	
Lancashire Teaching Hospitals NHST (Preston)	Due 2008
South	
Plymouth Hospitals NHST	Due 2008/9
United Bristol Hospitals NHST	Due Dec 2006
Grand Total	**6**

NB: Tables assumes if no provider /partnership specified it is NHS provision. Where academic involvement is stated this has been counted as NHS provision.

Annex D

PET Scanning Facilities: Europe

[Derived from Bedford and Maisey, Eur.J.Nuc.Med; Nov 2003]

Country	Population	PET facilities	Pop^{n} served per PET scanner
Belgium	10.3m	19	0.54m
Germany	82.2m	80	1.02m
Austria	8.1m	7	1.15m
Sweden	8.9m	7	1.27m
Denmark	5.4m	4	1.35m
Finland	5.2m	2	2.6m
Spain	39.8m	14	2.84m
Ireland	3.8m	1	3.8m
Netherlands	16m	4	4.0m
Italy	57.8m	11	5.25m
UK	60m	7	8.6m
France *	59.2	4	14.8m
Switzerland	7.2m	2	3.6m
Greece	10.9m	1	10.9m

* The French Government has committed to providing 75 PET scanners as part of the 'Plan Cancer'.

The following Western European countries with populations of more than 2 million had no PET facilities in 2003:

Annex E

Key References

Information in this Framework has been drawn from the following publications and reports on PET scanning

1. Health Technology Board for Scotland – Health Technology Assessment Advice 2: Positron emission tomography (PET) in cancer management, October 2002
   http://www.htbs.co.uk/docs/pdf/ASSESSMENT%20REPORT%202.pdf

2. Implementation of HTBS' Health Technology Assessment of Positron Emission Tomography in Scotland – Report and Recommendations, HDL (2003) 63 Scotland, October 2003
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3. Positron Emission Tomography – a Strategy for the UK, Report of the Intercollegiate Standing Committee on Nuclear Medicine, Royal College of Physicians et al, 2003
   http://www.rcplondon.ac.uk/pubs/wp_pet.pdf

4. Ad-hoc group of Specialists in Nuclear Medicine and Radiology convened by National Cancer Director 18/12/03.

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   http://springerlink.metapress.com/app/home/contribution.asp?wasp=9h0lyluqyhcyc9j3kg0v&referrer=parent&backto=searcharticlesresults,1,1;journal,1,1;linkingpublicationresults,1:100414,1

   Current Indications for PET scanning reimbursement by Centres for Medicare and Medicaid Services (CMS) available at:
http://www.cms.hhs.gov/manuals/pm_trans/R171CIM.pdf

6. Recommendations from NICE lung cancer guidelines

7. Draft Recommendations from NICE on IOG for Head and Neck cancers

Annex F

Glossary of PET Terms used in the Framework

Positron.	A positive electron. An elementary particle with electron mass and positive charge equal to that of an electron. The anti-particle of an electron.
18F-FDG	Abbreviation for 2-fluoro-2-deoxy-D-glucose. This is the main radioactive pharmaceutical used in PET scanning.
Cyclotron	An accelerator which uses an oscillating magnetic field to accelerate particles to produce radioactive isotopes, such as 18F
Radiopharmaceutical	A radioactive drug or medicine
Radio-active tracer	A low volume, high specific activity quantity of radio-isotope introduced into a biological system to allow measurement without influencing the physiological processes of the biological system/tissue/organ.
Radiochemistry	The study and application of chemical techniques to the purification of radioactive materials and the formation of compounds containing radioactive elements.
Radionuclide	A radioactive nuclide. An isotope of an element which undergoes radioactive disintegration.
Half-life	The time in which the amount of a radioactive nuclide decays to half the original value.
NCRI	National Cancer Research Institute. Partnership of the major cancer funding bodies. Takes a strategic oversight of cancer research in the UK, identifying gaps and opportunities in current research and facilitating collaboration between funding bodies.
NTRAC	National Translational Cancer Research Network**.** A national network of cancer research centres, embedded in the NHS, that integrates scientific and clinical expertise, and shares knowledge and resources for the benefit of cancer patients.
NCRN	National Cancer Research Network. Provides the NHS with an infrastructure to support research into cancer treatments and support research undertaken by cancer charities.
Isotope	Nuclides which have the same atomic number
SPECT	Single Photon Emission Computed Tomography. A nuclear medicine procedure in which the gamma camera rotates around the patient and takes pictures from many angles,

which a computer then uses to form a tomographic (cross-sectional) image.

Annex G

Consultation List

SHA Chief Executives
NHS Trust Chief Executives
NHS Foundation Trust Chief Executives
PCT Chief Executives
Workforce Development Confederation Chief Executives
PCT Professional Executive Committee Chief Executives
SHA Cancer Leads
Cancer Network Lead Clinicians
Cancer Network Lead Managers
Specialised Commissioning Groups
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