

Health Technology Assessment Advice 2: Positron emission tomography (PET) in cancer management

Summary of recommendations

- It is recommended that a PET imaging facility including a cyclotron, dedicated to clinical use and specific health services research applications, should be set up in Scotland to allow Scottish patients and researchers to realise the potential benefits of FDG-PET imaging in cancer management as rapidly as possible. It should be linked to an existing cancer centre, with functional links to the existing PET facility in Aberdeen.
- It will take approximately two years to build such a facility, so interim solutions for the provision of PET imaging should be considered, particularly for the re-staging of patients with Hodgkin's disease. Possible options are the use of the John Mallard Scottish PET Centre in Aberdeen, other UK facilities, or the use of a mobile PET facility in a fixed location in Scotland.
- All patients who require re-staging of Hodgkin's disease should be sent for a fluorine-18 deoxyglucose (FDG)-PET scan. Extension to the re-staging of all patients with lymphoma should be investigated by further research.
- Appropriate research should be undertaken to inform economic modelling in order to produce a robust assessment of the value of FDG-PET imaging in the staging of patients with non-small cell lung cancer (NSCLC) who are computed tomography (CT)-negative in the regional lymph nodes.
- For other cancers, FDG-PET is likely to add most value where existing diagnostic/monitoring techniques have poor accuracy and information from PET imaging can substantially improve prognosis. This should be evaluated through health services research, taking account of the clinical-effectiveness results from other international Health Technology Assessments (HTAs). Research priorities should be agreed with multidisciplinary expert groups, Regional Cancer Advisory Groups, the Scottish Cancer Group, the NHS HTA programme and other international research organisations. All research should be coordinated with the Scottish Cancer Clinical Trials Network.
- All patients undergoing FDG-PET should have outcomes recorded, either through participation in a national or international trial to confirm and extend the current applications of FDG-PET imaging or through health services research designed to allow costs and patient outcomes to be recorded for economic modelling.

1. Introduction

- 1.1 This Advice from the Health Technology Board for Scotland (HTBS) is the outcome of a HTBS Health Technology Assessment (HTA) of positron emission tomography (PET) imaging in cancer management. The HTA had two objectives. The first objective was to determine the role of fluorine-18 deoxyglucose (FDG)-PET imaging in cancer management by evaluating the clinical and cost effectiveness in terms of impact on patient outcome (morbidity/mortality). The second objective was to consider the best configuration of PET facilities and cyclotrons to serve Scotland, if FDG-PET imaging was found to be clinically and cost effective. All HTAs address patients' needs and preferences and organisational issues. *HTA Report 2, Section 1*
- 1.2 The HTA provides a detailed evaluation of the clinical effectiveness of FDG-PET imaging in non-small cell lung cancer (NSCLC) and lymphoma and presents economic models determining the long-term impact of the imaging procedure. NSCLC was chosen because it is the most common cancer in Scotland and has the best supporting evidence base for assessing PET. Lymphoma was chosen, following discussion with the Scottish Cancer Group, because it is a cancer with a good prognosis following diagnostic work-up, allowing the impact of PET on clinical outcome to be measured. *HTA Report 2, Section 3.2*
- 1.3 This Advice is based on critical appraisal and analysis of evidence published in scientific literature. It also uses evidence submitted by experts, professional groups, patient groups, manufacturers and other interested parties. The assessment process, evidence base, methodology, results and recommendations are described in detail in *Health Technology Assessment Report 2: Positron emission tomography (PET) imaging in cancer management*. To help users of this Advice locate additional information provided in the HTA report, relevant sections are referenced in the right-hand margin of this document. *HTA Report 2, Section 3*
- 1.4 HTBS Advice represents the evidence-based view of HTBS. **Health professionals in NHSScotland should take account of advice and evidence from HTBS and ensure that recommended drugs or treatments are made available to meet clinical need.** However, this Advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patient, in consultation with the patient and/or guardian or carer.

2. HTA conclusions

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| 2.1 | Clinical-effectiveness evidence demonstrates that for several cancers FDG-PET imaging is more <i>accurate</i> than alternative diagnostic/monitoring procedures, but evidence that this leads to changes in patient <i>outcomes</i> is weaker. | <i>HTA Report 2, Section 2.4</i> |
| 2.2 | HTBS evidence appraisal and economic evaluation have provided a robust case that FDG-PET imaging is cost effective compared with the use of computed tomography (CT) in the re-staging of Hodgkin’s disease at completion of induction chemotherapy. | <i>HTA Report 2, Section 7</i> |
| 2.3 | HTBS economic evaluation shows that FDG-PET is potentially cost effective in NSCLC if it is used before mediastinoscopy in CT-negative patients. These results are highly dependent on modelling assumptions and so further research is necessary to prove the value of FDG-PET in patients who are clinically eligible for surgery. | <i>HTA Report 2, Section 5</i> |
| 2.4 | Other HTA evidence suggests that FDG-PET is more accurate than conventional imaging and likely to improve clinical outcomes, particularly in single pulmonary nodule, malignant melanoma and recurrent head and neck cancer. However, there is a paucity of evidence on cost effectiveness so research to inform economic modelling of these cancers is encouraged. | <i>HTA Report 2, Section 10</i> |
| 2.5 | The justification for the Advice to provide a new PET facility in Scotland therefore comes from a requirement for increased capacity to accommodate the combination of proven need for re-staging in Hodgkin’s disease and the clear need for further targeted research in several promising, but unproven, indications. | <i>HTA Report 2, Section 10</i> |

3. Advice	3.1 Clinical applications of PET	
	3.1.1 Lymphoma	
	3.1.1.1 FDG-PET should be used to re-stage patients with Hodgkin’s disease at completion of first-line induction therapy, in order to select those for surveillance or radical radiotherapy.	<i>HTA Report 2, Section 7</i>
	3.1.1.2 The accuracy of FDG-PET demonstrated in re-staging after first-line induction therapy also applies to non-Hodgkin’s lymphoma (NHL). Expert opinion suggests that this accuracy may also translate into cost effectiveness in NHL. This should be further investigated by economic modelling and clinical research.	<i>HTA Report 2, Section 7.4.5</i>
	3.1.1.3 FDG-PET may also be beneficial in the early assessment of response to induction therapy and the early detection of recurrence. However, these should still be regarded as research topics.	<i>HTA Report 2, Sections 6.3.2 and 6.3.3</i>
	3.1.2 Non-small cell lung cancer (NSCLC) Appropriate research should be undertaken to inform economic modelling in order to produce a robust assessment of the value of FDG-PET imaging in the staging of patients with NSCLC. As CT-negative patients have a better prognosis, research should be undertaken in such patients. This research may be UK wide but should identify Scottish costs.	<i>HTA Report 2, Sections 5 and 10.4</i>
	3.1.3 Other cancers PET research is encouraged in single pulmonary nodule, malignant melanoma and recurrent head and neck cancer to inform economic modelling.	<i>HTA Report 2, Sections 10.4 and 10.5</i>
	3.1.4 Other therapeutic areas The evidence for benefit in cardiology, epilepsy and dementia is less clear and more research is required in these applications.	<i>HTA Report 2, Sections 2.4.1 and 10.1.5.2</i>

3.2 Data collection

3.2.1 All patients undergoing FDG-PET should have outcomes recorded, either through participation in a national or international trial to confirm and extend the current applications of FDG-PET imaging or through health services research designed to allow costs and patient outcomes to be recorded for economic modelling. Patients involved in research must give informed consent. *HTA Report 2, Section 10.4*

3.2.2 Data collected should include: reasons for imaging, the changes in therapy resulting from undergoing FDG-PET, the results of therapy and the reactions of patients who have undergone FDG-PET. *HTA Report 2, Section 10.4*

3.3 Patient information

3.3.1 Patients and their families or carers should be fully informed about all aspects of the PET procedure and the associated radiation risks. *HTA Report 2, Sections 8.3 and 8.5*

3.3.2 Clear comprehensive information in the form of patient information leaflets should be supplied sufficiently in advance of the procedure. *HTA Report 2, Section 8.3.2*

3.3.3 The written information about PET imaging provided to patients should be supported by discussion with health professionals, usually their consultant, to ensure that patients attending for PET examinations understand the information they have been given. Health professionals should be given training in communication to equip them for this role. *HTA Report 2, Section 8.3.1*

3.4 Organisation of PET facilities in Scotland

3.4.1 PET imaging should be coordinated with other diagnostic tests to minimise delays in treatment, the need for travel and the level of stress for patients undergoing imaging. *HTA Report 2, Section 8.2*

3.4.2 A PET facility should be designed to make the patient feel at ease. *HTA Report 2, Section 8.2*

3.4.3 PET facilities should be linked to specialist cancer centres. *HTA Report 2, Section 9.1.2*

- 3.4.4 PET facilities may be designed with or without a cyclotron on site, provided that FDG can be delivered to the facility from the production site within two hours. FDG could be provided from one cyclotron located in the Central Belt of Scotland or from the Aberdeen PET facility. Alternatively FDG may become available from a suitable commercial source. *HTA Report 2, Sections 9.4 and 9.9*
- 3.4.5 It will take approximately two years to build a PET facility, so interim solutions for the provision of PET imaging should be considered, particularly for the re-staging of patients with Hodgkin's disease and to allow participation in the research necessary to demonstrate the cost effectiveness of PET in other cancers. Possible options are the use of the John Mallard Scottish PET Centre in Aberdeen, other UK facilities or the establishment of a mobile PET facility in a fixed location in Scotland (i.e. situated in the grounds of an existing cancer centre). *HTA Report 2, Section 10.1.8*
- 3.4.6 The layout of the PET facility, and the production, handling and transportation of radiopharmaceuticals must comply with legal requirements. *HTA Report 2, Section 9.3*
- 3.4.7 Expert staff in the form of specialist nurses, clinicians, physicists, radiopharmacists, radiochemists and cyclotron engineers will need to be employed. For all categories of staff, training is required. Programmes for this should be considered on a UK basis. *HTA Report 2, Section 9.5*

4. Budget impact

- 4.1 The preferred PET facility is a fully equipped PET unit (imager, cyclotron, chemistry facility) integrated with nuclear medicine and radiology departments. It has the lowest annual running costs and cost per scan (£677) per 1500 patient throughput per annum. The initial capital outlay is approximately £4.2 million. The annual running costs will be approximately £1.02 million. *HTA Report 2, Section 9.6*
- 4.2 A PET imager (without a cyclotron and chemistry facility), where the FDG is bought from another source, will cost approximately £1.8 million in capital outlay and approximately £1.01 to £1.16 million in annual running costs. The cost of FDG will depend on the source and distance over which it must be delivered. Consequently, the cost per scan will be approximately £800 to £900 per 1300 patient throughput. *HTA Report 2, Section 9.6*
- 4.3 A commercially provided mobile PET facility is more expensive on a cost per scan basis (approximately £1130). It will cost approximately £141,000 in capital outlay and approximately £1.4 to £1.6 million in annual running costs, per 1300 patient throughput. *HTA Report 2, Section 9.6*

5. Review

As HTBS chooses broad topics for HTAs, it is likely that new evidence will emerge which bears on the specific recommendations on an ongoing basis. Rather than having a fixed review period, HTBS, in conjunction with experts, will determine the importance of new evidence and produce report addenda in which the evidence is analysed and any alteration to the recommendations is explained. If a major change is required, the HTA report, HTBS Advice, and Understanding Advice will be rewritten.

Further information

- *Health Technology Assessment Report 2: Positron emission tomography (PET) imaging in cancer management*
- *Understanding HTBS Advice: Use of PET imaging for cancer in Scotland*
- All HTBS documents are available in a variety of formats on request and from the HTBS website, www.htbs.co.uk

Health Technology Board For Scotland

HTBS works to improve Scotland's health by providing evidence-based advice to NHSScotland. It evaluates the value for money of new and existing health technologies such as medicines, devices, clinical procedures and healthcare settings.

HTBS:

- Conducts Health Technology Assessments, which are open and inclusive processes that take account of medical, ethical, social, and economic impacts of using health technologies.
- Provides Comments on NICE Guidance, identifying differences that affect the suitability of the English and Welsh Guidance for Scotland.
- Supports the Scottish Medicines Consortium which provides advice on new medicines at the time of market launch.

The Advice is available from the HTBS website or HTBS in the following formats:

- Disk
- Audio cassette
- Braille
- Large print
- Gaelic.

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