*Cancer Imaging* (2002) **2,** 135–136
DOI: 10.1102/1470-7330.2002.0033

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# EDITORIAL

# Evidence-based medicine: clinical utility of PET in oncology

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## Introduction

The Australian Federal government has recently completed a two-year review into the safety, effectiveness and cost-effectiveness of positron emission tomography (PET). The review process, which included a thorough critique of the current literature as well as consultation with experts in the field, has led to extended public funding of PET within Australia. A further positive outcome is a freely available evidence-base for the clinical use of PET that provides a valuable resource for specialists with an interest in cancer imaging throughout the world (`www.health.gov.au/haf/pet`). This article summarises the review findings with respect to the level of service provision, suitable imaging technologies and clinical indications than can be justified on the basis of current evidence.

## Service provision and technology

The review has recommended funding of seven PET centres across Australia, approximately equivalent to one PET scanner per three million population. The centres were to be sited at facilities with comprehensive cancer care (major sub-specialty surgery, medical oncology, radiation oncology) and neuroscience (neurosurgery/neurology) services, located within a major teaching hospital. The review considered the performance of gamma camera based PET systems and partial ring dedicated PET systems to be inadequate, with funding to be limited to services performed on dedicated full-ring PET systems using as a detector material, bismuth germinate (BGO), sodium iodide (NaI) or newer crystal technologies. Although BGO systems were thought to have an advantage over NaI for *research* applications, the performance differences were judged to be small for *clinical* studies using fluorodeoxyglucose (FDG) that were to be funded following the review.

## Clinical indications

The available evidence for clinical effectiveness and cost-effectiveness was believed insufficient to allow unrestricted funding. Therefore funding (on a fee-for-service basis) was to be restricted to a limited range of specific clinical indications, including seven applications within oncology for lung cancer, malignant melanoma, cerebral glioma and recurrent colorectal cancer. All funded cases were to be included in an on-going data collection and analysis process to confirm clinical impact and cost-effectiveness so that long-term decisions about the role of PET in Australia could be made.

For lung cancer, PET was felt to have high accuracy and to provide sufficient clinical impact to justify its use for characterisation of solitary pulmonary nodules, but funding was recommended only if the nodule were unsuitable for fine-needle aspiration or if a prior attempt at pathological diagnosis had failed. Similarly, the accuracy and therapeutic impact of PET in staging non-small cell cancer was found to be sufficiently high as to allow funding prior to surgery or radiotherapy with curative intent. There was insufficient data to support funding of PET for re-staging or therapy monitoring.

For malignant melanoma, PET was judged to be more accurate than conventional imaging in the detection of metastatic sites but this improved accuracy was only likely to have therapeutic impact when PET was performed prior to resection of apparently limited metastatic disease.

The role of PET in cerebral glioma was considered to need confirmation by further long-term studies. However,



1470-7330/02/000135 + 02

interim funding was allowed for distinction of radiation necrosis from recurrence on the basis that current evidence suggests greater accuracy for PET over MRI. Interestingly, there was insufficient evidence to conclude that PET was superior to thallium single photon emission tomography (SPET) in this clinical situation. Funding was also approved for PET grading of glioma on grounds of greater accuracy than thallium SPET and the potential to guide biopsy to the most active tumour region.

For recurrent colorectal cancer, the evidence supported the use of PET in evaluating residual lesions after definitive therapy on account of the ability for PET to distinguish recurrence from fibrosis more reliably than CT. PET was also approved prior to planned resection of hepatic or pulmonary metastases due to the greater sensitivity of PET for detection of extra-hepatic tumour sites. Interestingly, the evidence did not demonstrate the accuracy for PET in diagnosis of intra-hepatic disease to be beyond existing modalities. The review also did not recommend funding for investigation of a raised serum carcinoembyonic antigen (CEA) level.

In addition, the review recommended a later evaluation of PET in lymphoma, head and neck cancer, gynaecological malignancy, sarcoma and upper gastrointestinal malignancy. Subsequently, interim funding has been approved for specific applications in these tumours on a similar basis to the indications outlined above.

## Discussion

Increasingly, governments and other health purchasers require an adequate evidence-base prior to agreeing to fund new medical interventions. It therefore behoves imaging specialists, and possibly equipment manufacturers, to conduct the research necessary to provide such evidence. However, the Australian PET review has raised important issues as to what an appropriate level of evidence should be for diagnostic imaging tests, as well as ethical concerns about how such information should be obtained. For instance, is it reasonable to ask for evidence of how a diagnostic imaging test impacts on ultimate outcomes, such as survival, when it is the treatment rather than the diagnostic methodology that primarily determines ultimate outcome? Is it ethical within a study to determine the effect of an imaging modality on ultimate outcomes, to randomise a patient towards investigation with previous methods when the new modality has already been shown to be more accurate? The danger of seeking an inappropriate level of evidence is the possibility of denying patients access to technology from which they would otherwise benefit. On the other hand, for those PET indications that have been approved by the Australian review, it is possible to make recommendations to our clinical colleagues and patients with a high degree of confidence.