

Letter to the Editor

Regarding

Eur J Nucl Med Mol Imaging (2003) 30: 637-641

DOI 10.1007/s00259-003-1203-4

Copyright Springer-Verlag 2003

Dear Sir,

The International Network of Agencies for Health Technology Assessment (INAHTA) is grateful for the opportunity to respond to the criticisms made regarding Health Technology Assessment (HTA) of PET in oncology [1]. Højgaard makes strong accusations about the quality of HTA reports, surmises that reports from different members of INAHTA give a variety of conclusions and thus questions the value of HTA in determining the usefulness of PET and PET/CT. Here lies the crux of the issue. How does one determine the usefulness of a technology?

Third parties who directly fund or otherwise financially underwrite (eg via reimbursement) investment in health technologies are interested in evidence of improved health outcomes for health system consumers. In some cases HTA agencies have been established with this express purpose in mind. HTA Agencies consider that in the context of limited healthcare resources and focus on the patient, usefulness depends on the clinical and cost effectiveness of a technology. There is no evidence that HTA is inherently biased against new technologies. On the contrary, look at how often, e.g. technology appraisals from NICE, an INAHTA member, say "yes" on the basis of HTA reports [2].

We agree with Højgaard's deliberations about the scientific challenges of establishing the efficacy and effectiveness of a diagnostic modality. These challenges are common to all, PET scientists, clinicians responsible for patient management, and technology assessors. Different definitions of clinical effectiveness exist, but they all have the same basic concept; that it is to demonstrate benefit to the patient in routine clinical practice. The crucial question is how to demonstrate benefit to the patient. As an imaging technology will be just one part of a complex diagnostic workup for any cancer, diagnostic accuracy is not sufficient to demonstrate clinical effectiveness. Ideally, changes in patient outcome should be demonstrable, or at least changes in patient management. This is in line with the 'diagnostic efficacy' framework outlined over ten years ago by Fryback and Thornbury [3].

Despite an abundance of literature on the diagnostic accuracy of PET, there are relatively few papers on change in patient management or outcome and the former are generally case series of poor quality [4].

An HTA must put all such evidence together for assessment in light of the health service provision in the HTA province. This will often bring in social, organisational, economic and patient issues leading to value judgements to inform policy decisions. Given the variation in the way health services are organised and resourced, it is not surprising if HTA reports in different countries sometimes reach different conclusions. And one should also expect conclusions to alter as new evidence emerges over time. In fact, in the case of PET, all INAHTA HTA reports have reached very similar conclusions and the main differences in detail result from the evidence available at the time the report was prepared. The time span is more than four years. Indeed, the Norwegian HTA report has been recently updated to take account of new publications and HTA reports from other countries [5]. All these HTA reports conclude that there are problems with the quality of evidence available from PET studies. However, they go on to recommend that PET appears to be a promising technology and whilst clinical and cost effectiveness has not been demonstrated definitively, specific research should be undertaken in clinical practice to obtain more data to inform decision-making (ie changes in patient management and outcome). In order to obtain reliable clinical data concerning changes in patient management, quality of life and costs, several HTA-agencies, such as The Netherlands and Denmark, have commissioned clinical research projects that study the diagnostic accuracy and clinical and cost-effectiveness of PET in various indications.

Højgaard states that the Australian HTA report [6] ‘recommended the use of PET for 12 different indications’. This is incorrect; they recommended funding of these indications on an interim basis to enable further data collection. This does not necessarily mean RCTs, as Højgaard implies. Indeed following the Scottish HTA the cancer community has been encouraged to undertake economic modelling combined with targeted health services research, so that long-term benefits to patients can be estimated that cannot be observed in RCTs [7].

Højgaard refers to two Danish documents from 2001 and 2002. The first report (from the Danish HTA Agency, DACEHTA) [8] consisted of an internationally peer reviewed systematic literature review on FDG PET in oncology, cardiology, and neurology and a report on the provision of tracers and national scenarios based on PET/CT centres with and without gamma camera PET in a limited number of hospitals. The report did not claim to be a full HTA. The group of experts, who wrote the report, approved the literature review. The second report (from the Health Care Planning Division of the National Board of Health) [9] was written by a group of public servants and experts. The group built its work on the first report in order to further a coordinated diffusion of the technology including the production of FDG in the light of several potentially conflicting plans from local government. The report involved expert advice, and was not in conflict with the DACEHTA report.

The same group that produced the CONSORT statement referred to by Højgaard have also published the STARD initiative (STAndards for Reporting of Diagnostic Accuracy) [10]. This indicates:

“The world of diagnostic tests is highly dynamic. New tests are developed at a fast rate and the technology of existing tests is continuously being improved. Exaggerated and biased results from poorly designed and reported diagnostic studies can trigger their premature dissemination and lead physicians into making incorrect treatment decisions. A rigorous evaluation process of diagnostic tests before introduction into clinical practice could not only reduce the number of unwanted clinical consequences related to misleading estimates of test accuracy, but also limit health care costs by preventing unnecessary testing.”

All HTAs on PET have been trying to balance the lack of evidence regarding patient benefits with the potential of this technology and so the HTA recommendations all have the same goal, that is the managed introduction of this technology into the service, with use focussed on cancers where the impact will be greatest.

Health Technology Assessment is a multidisciplinary field of policy analysis that evaluates the medical, social, ethical and economic implications of the introduction, development and diffusion of a technology. It is this policy analysis that includes the rigorous evaluation required by STARD that can help demonstrate the value of new technologies. Therefore device enthusiasts should be prepared to take up the research challenge in this new paradigm and recognise that in the world of limited healthcare resources, it is proving real benefit for the patient that counts. We believe that HTA is a complex task based on science and INAHTA Agencies continue to improve their methodology, individually and collectively. INAHTA has developed a common HTA checklist for assessing the quality of HTA reports which is available at the INAHTA website [11]. However, although HTAs are principally based on systematic reviews, it is important to stress the difference between the scientific validity of a systematic review and the recommendations of an HTA report targeted at a specific health system. The review should be reproducible, but the recommendations may not be.

Finn Børllum Kristensen, Chairman, International Network of Agencies for Health Technology Assessment (INAHTA)

Elizabeth Adams, Veteran Administration's Technology Assessment Program (VATAP), USA

Eduardo Briones, Andalusian Agency for Health Technology Assessment (AETSA), Spain

Damian Coburn, Australian Ministry of Health and Ageing

Karen Facey, Health Technology Assessment, NHS Quality Improvement Scotland, UK

Niels Würigler Hansen, Danish Centre for Evaluation and Health Technology Assessment (DACEHTA), Denmark

Jetty Hoeksema, The Netherlands Organisation for Health Research and Development (ZonMw)

Berit Mørland, The Norwegian Center for Health Technology Assessment (SMM)

References

1. Højgaard L. Are Health Technology Assessments a reliable tool in the analysis of the clinical value of PET in oncology? Who audits the auditors? *Eur J Nucl Med Mol Imaging* 2003; 30: 637-64.
2. <http://www.nice.org.uk/catta1.asp?c=153>
3. Fryback DG and Thornbury JR. The efficacy of diagnostic imaging. *Med Decis Making* 1991; 11(2): 88-94.
4. Bradbury I, Bonnell E, Boynton J, *et al.*, *Positron emission tomography (PET) imaging in cancer management*. Health Technology Assessment Report 2, Glasgow: Health Technology Board for Scotland, 2002.
<http://www.htbs.co.uk/docs/pdf/ASSESSMENT%20REPORT%202.pdf>
5. Formidling av internasjonale metodevurderinger 2001-2003. Positronemisjonstomografi (PET) -diagnostisk og klinisk nytteverdi. SMM Report 6/2003. Oslo: Senter for Medisinsk Metodevurdering, 2003.
<http://www.sintef.no/smm/Publikasjoner/FramesetPublikasjoner.htm>
6. *Positron emission tomography, part 2i*. Medical Services Advisory Committee. Canberra: Medical Services Advisory Committee, 2001.
<http://www.msac.gov.au/pdfs/msacref10i.pdf>
7. Bradbury I, Facey K, Laking G, Sharp P. Investing in new technology: the PET experience. *British Journal of Cancer* 2003; 89: 224-227.
8. Redegørelse vedrørende PET-skanning med FDG – med særlig henblik på kræftdiagnostik. Copenhagen: Danish National Board of Health, Centre for Evaluation and Health Technology Assessment, 2001.
<http://www.cemtv.dk/publikationer/docs/PET/Redegoerelse.pdf>
9. PET (positron emissions tomografi), anbefalinger for udbygning af PET og FDG produktion. Copenhagen: Danish National Board of Health, 2002.
<http://www.sst.dk/publ/Publ2002/KMO-PETskanningsrapport.pdf>
10. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwing LM, Lijmer JG, Moher D, Rennie D, de Vet HCW for the STARD group. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *The Lancet* 2003; 361:1-4 and <http://www.consort-statement.org>.
11. Hailey D. Toward transparency in health technology assessment. 7Hailey D. Toward transparency in health technology assessment. A checklist for HTA

reports. Int J Technol Assess Health Care. 2003; 19 (1): 1- 7 and
<http://www.inahta.org>