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Joint project of the International Network of Agencies for Health Technology Assessment—Part 2: Managing the diffusion of positron emission tomography with health technology assessment

Elizabeth J. Adams
Veterans Administration Technology Assessment Program

Cari Almazán
Catalan Agency for Health Technology Assessment and Research

Berit Mørland
Norwegian Knowledge Centre for the Health Services

Ian Bradbury
University of Ulster

Richard King
Monash Medical Centre

Paul Rheinberger
National Association of Statutory Health Insurance Physicians

Objectives: Since 1997, members of the International Network of Agencies for Health Technology Assessment (INAHTA) have collaborated on a Joint Project to track the diffusion, evaluation, and clinical policy of positron emission tomography (PET). Part 2 of this updated Joint Project report summarizes HTA-based strategies for directing the clinical use of PET and a discussion on the value of HTA in managing the diffusion of high cost diagnostic technologies, which were presented at an INAHTA-sponsored workshop at the Health Technology Assessment International Annual Meeting in 2004 on strategies for managing high cost diagnostic technologies.
Methods: A summary of the workshop proceedings is presented.
Conclusions: Sharing assessment work, universal agreement in assessment conclusions, stakeholder input, and modeling techniques help manage the uncertainty in the evidence base while targeting clinical use of PET toward the most promising

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indications. Emphasis on HTA findings, linkage between financing of clinical PET and outcome evaluation, and targeted dissemination of scientific findings empower providers to reduce unnecessary utilization and contain costs within a quality improvement framework. Above all, a trustworthy source of HTA information and a process that is conducive to using scientific evidence as the basis for decision making are essential for managing the diffusion of complex and costly diagnostic technologies in patient care.

Keywords: Positron emission tomography, Tomography emission computed, Technology assessment, Health policy, Diffusion of innovation

The International Network of Agencies for Health Technology Assessment (INAHTA) established Joint Projects to encourage collaboration among members on subjects of common interest. In 1997, INAHTA initiated a Joint Project to track the diffusion, evaluation, and policy strategies of positron emission tomography (PET) in the healthcare systems of its members. The first report was produced in 1999 (2).

Recognizing the growth in the popularity of PET, in membership, and in the use of HTA to guide clinical policy on PET, INAHTA sought to update its first report with emphasis on policy implementation. Part 1 of this report update presents survey results of PET-related activities undertaken by INAHTA members since 1999 (unpublished data, 2005). Part 2 summarizes six case examples of evidence-based strategies for managing PET in clinical care and a discussion on the value of HTA in policy making presented at a workshop of Health Technology Assessment International scientific conference in June 2004 entitled: *Strategies for Managing the Diffusion of High Cost Diagnostic Technology—the Case of PET Scanning*.

CASE EXAMPLES: STRATEGIES FOR CLINICAL USE AND FINANCING OF PET

Catalonia

The Catalan Health Service (CHS) is responsible for planning and managing health services to approximately 6.5 million inhabitants. Public reimbursement for PET scanning is based on a list of indications established by the scientific evidence and expert consensus (3). To manage the demand for PET toward appropriate clinical indications, a systematic analysis and structure are needed that incorporate relevant health outcomes based on the scientific evidence within an appropriate socioeconomic context.

CHA and the Catalan Agency for Health Technology Assessment and Research (CAHTA) created a PET register in October 2002 to monitor the clinical demand for PET, describe current use of requested PET exams, and assess PET's impact on the clinical management of patients, with indications approved for public reimbursement. CAHTA collected data from January 2003 to December 2004 and defined reporting requirements for professionals requesting PET and centers performing PET.

The results of the register demonstrated how PET has been used in the Catalan region in routine clinical practice. Initially, interest from marketing pressures created an excess supply of PET scanners over the demand for PET. Approximately 24 percent of requested PET exams were not approved for public reimbursement. PET was used mainly as an add-on technique. The first results reporting the impact of PET on managing lung cancer and recurrent colorectal cancer showed a change in clinical management in 50 percent of patients, mainly redirecting patients away from futile surgery and toward medical therapy options. With evidence-based guidance and dissemination of registry findings to physicians, expansion of public reimbursement is expected to drive the supply and demand for PET, improving appropriate use and patient outcomes.

Norway

In 1999, the Ministry of Health (MOH) requested the Norwegian Center for Health Technology Assessment (SMM), now the Norwegian Knowledge Centre for the Health Services, to assess whether public resources should be allocated to establish the first PET facility for clinical use in Norway. Because of the short time frame in which the information was needed, SMM relied on the findings of the INAHTA Joint Project Report on PET (2) supplemented with input from local hospital experts to critique the INAHTA report, identify additional relevant published studies, and produce cost data for establishing and operating a PET facility in Norway (18).

The experts concluded that there was a lack of documented clinical value of PET in the published evidence. As a result, the MOH did not support public funding of a PET facility in Norway.

In 2003, a growing interest in PET fostered by private industry investment led the MOH to request an update of the original SMM findings to prepare for the 2004 National Budget deliberations. To address the Minister's information needs within a short time frame, SMM conducted a rapid review and synthesis of INAHTA and non-INAHTA members' HTA reports published from 2001 to 2003 (14). From consistent agreement in the reports' findings, SMM concluded that the clinical use of PET had increased despite a continued paucity of evidence on clinical or health outcome effects. SMM identified clinical areas where evidence showed improved diagnostic accuracy with PET over other diagnostic

procedures and where PET could be considered for clinical use within the context of clinical trials.

As a result, the MOH allocated funding, along with contributions from industry and the Norwegian Research Council, to establish a PET facility at the National Cancer Hospital (15). SMM attributes the success of their strategy in influencing policy to international agreement within HTA reports, support from national experts, and meeting information needs in a time frame required for rapid policy making.

Scotland

The NHS Scotland is a tax-funded health system serving approximately 5.2 million Scottish citizens. The Health Technology Board for Scotland (HTBS), now NHS Quality Improvement Scotland, advises the NHS Scotland on the clinical and cost-effectiveness of new and emerging technologies using HTA. In 2000, an increasing demand for clinical PET exams prompted the Scottish Executive Health Department (SEHD) to request an assessment of PET to determine whether it should be adopted for clinical use in Scotland.

HTBS needed to address key concerns among stakeholders that PET was expensive, there was an expectation of "rubber-stamping" approval for PET use, there was an unwillingness to look beyond diagnostic accuracy to define PET's clinical utility, and PET was already in clinical use in England and Ireland. The HTBS HTA strategy (4) involved the following:

- Compiling evidence from a variety of national and international sources;
- Expert staff to undertake systematic reviews and economic modeling focusing on the impact of PET on patient outcome in cancer indications thought to have the strongest evidence base within a Scottish context—staging non-small cell lung cancer and restaging Hodgkin's lymphoma;
- A multidisciplinary expert Topic Specific Group to collect and critique evidence and analyses, and to determine the precise clinical pathways in the Scottish context;
- Quality assurance by the HTBS Governance Board, and;
- Wide-ranging open consultation and expert review.

HTBS concluded that PET should be adopted for limited clinical use but conditional on further evaluation (8). HTBS recommended establishing a PET imaging facility with a cyclotron dedicated to clinical use in cancer management, conducting health services research to inform future economic modeling in the two cancer areas, and functionally linking an existing cancer center to the Aberdeen facility. The SEHD formed a separate working group to implement the findings (17).

In retrospect, implementation processes can be hindered when enthusiasm for particular technologies exceeds the evidence supporting it. Experts or advocates who are reluctant to consider evidence beyond diagnostic efficacy can further hinder the research needed to inform questions about impact on clinical management and outcomes.

Limitations in the HTA process were identified that raise questions about the conduct of HTA for diagnostic tests and the best approaches to answer questions of PET's clinical and cost-effectiveness. Because diagnostic improvements may precede therapeutic improvements, the cost-effectiveness of PET identified through randomized clinical trials may not be realized for many years. The HTA process can rely on dubious gold standards, very long-term outcomes, and primarily published data that may not always reflect the current state of the technology or its clinical use.

The economic modeling undertaken in the HTA was valuable for assessing the role of PET in situations for which potential benefit is considerable but for which such outcome data may be difficult or impractical to collect (e.g., restaging Hodgkin's lymphoma). The greatest clinical value of PET appears to be when the accuracy of other diagnostic techniques is poor and where knowledge from FDG-PET imaging can lead to substantially improved patient prognosis. Modeling allows linking changes in diagnostic accuracy to patient management and long-term outcomes, which may be more practical for assisting immediate policy decisions. A detailed model that quantifies all associated uncertainties and uses a variety of data sources and sophisticated analyses can help determine the robustness of the model and the need for additional information.

Australia

In Australia before 1999, PET scanning was limited to two centers. Oncology comprised 50 percent of the indications, followed by neurology (40 percent) and cardiology (10 percent). Since then, interest in oncology has risen to 90 percent of the clinical activity. In 1999, two other providers applied for reimbursement benefits to offer clinical PET. The Minister of Health (MOH) asked the Medical Services Advisory Committee (MSAC) to make recommendations for clinical use of PET based on an evidence review of safety, efficacy, and cost-effectiveness.

MSAC assembled clinical specialists and PET imaging providers, chaired by an independent member from MSAC to identify the most promising clinical areas for PET use. The MSAC review consisted of three phases encompassing thirteen potential clinical applications of PET (12;13). MSAC concluded that PET was safe and effective, but evidence for the impact of PET on clinical management was lacking. MSAC recommended interim funding so that data on clinical impact could be collected.

The MOH formed a multidisciplinary advisory committee of independent experts to review the MSAC recommendations and develop an implementation strategy. The Australia New Zealand Society of Physicians in Nuclear Medicine was responsible for collecting data on patient demographics and

management change as a result of PET over a 3-year period using indication-specific protocols.

As of 2004, twelve protocols for clinical PET indications have been developed. Data collection will continue until 2006, at which time a full review of the local evidence and international literature will take place to determine whether PET will be placed on a more open-funding basis.

USA (Veterans Health Administration)

The Veterans Health Administration (VHA) is a publicly funded healthcare system that serves approximately seven million enrolled veterans of military service. VHA first purchased its eleven PET scanners in the late 1980s, distributed them geographically to ensure equitable access, and issued a moratorium on purchasing additional PET scanners until evidence of its clinical utility was established. The VA Technology Assessment Program (VATAP) monitors the clinical evidence on PET through HTA conducted in-house and by other agencies (1;7).

In response to requests from individual facilities and regional Veteran Integrated Service Networks to buy PET scanners, the Under Secretary for Health (USH) in 2003 requested an evidence review to reconsider the moratorium. VHA convened an Advisory Group of VHA clinical experts with guidance from the VATAP to review the evidence of the most promising and supported indications for use in the veteran population.

The Advisory Group recommended and the USH supported lifting the moratorium with evidence-based guidance for use, distribution, and associated cost options to avoid excess capacity and ensure equitable access and quality care. The guidance emphasized coordinating provision of PET services at the regional Network level either in-house or through contracting, placing in-house PET scanners at referral centers where a sufficient volume of clinical scans would be guaranteed, and defining clinical use initially on Centers for Medicare and Medicaid Services (CMS) Medicare-approved indications for use (19).

This guidance demonstrates a compromise between VHA's clinical needs and a capitated budget, taking into account the growing popularity of PET and VHA's need to maintain perceived comparable quality of care with the private sector. Identifying reliable data sources for determining indications for use and calculating accurate volume projections and associated costs for future budget decisions should help standardize provision of PET services across the system. Network managers will need to balance acquisition requests for PET scanners with other key budget priorities largely driven by under-funded Congressional mandates, increasing enrollment, and strained budgets.

Germany

The health system of Germany encompasses approximately 80 million inhabitants. Regulation of ambulatory care and hospital care is handled separately. Whereas hospitals are allowed to use any intervention deemed necessary for patient care, diagnostic and treatment procedures used in the ambulatory care setting are only permitted and reimbursable with the approval of the Federal Standing Committee of Physicians and Sickness Funds ("The Committee"). PET has not been reimbursed either in ambulatory care or voucher-based hospital care. A rapid diffusion of PET in Germany from two scanners in 1985 to approximately ninety scanners in 2001 has created a demand for ambulatory care reimbursement and steady financing of PET services.

The Committee undertook a comprehensive evidence review of PET to decide about reimbursement of PET in ambulatory care (5). The review included written statements from key stakeholder groups, a systematic review of the international literature, and evaluation of national and international HTA reports, guidelines, and policies. The assessment considered the relative contribution of PET to the management and health outcomes of patients in several indications based on evidence from prospective and comparative studies.

The review concluded that the evidence was insufficient to show the benefit, medical necessity, or the cost-effectiveness of PET in comparison to methods already reimbursed by the statutory health insurance system. Patient benefit of the additive or substitutive diagnostic uses of PET was lacking. Therefore, reimbursement for PET within the statutory health insurance system was not recommended.

The German Ministry of Health confirmed the Committee's decision in 2002 not to approve the benefit, necessity, and cost-effectiveness of PET for ambulatory care. As of 2004, PET is not reimbursed in the ambulatory sector of the statutory healthcare system in Germany.

DISCUSSION ON THE VALUE OF HTA IN POLICY MAKING

Health technology has been identified as a major contributor to the growth of healthcare expenditures in industrialized nations. As part of an analysis of the impact of new and emerging health-related technologies (NEHRT) in health care, the Organisation for Economic Co-operation and Development (OECD) surveyed members on the management of health-related technological change in members' healthcare systems and the role of HTA in that process (16). They used five case examples, one of which was PET scanning.

Twelve countries participated in the survey; eight of those countries produced HTAs of PET. The HTAs were undertaken primarily at the request of a government payer or insurer at the national or state/provincial level in the late 1990s or early 2000s after the technology had been in use. The HTAs were designed to inform political decision makers and healthcare providers about reimbursement and other coverage decisions. They comprised evaluations of efficacy, effectiveness, quality and safety, and, to a lesser extent, cost-effectiveness, additional costs or savings, and burden of

disease in the population served. The primary modes of disseminating HTA results were Web sites, public databases, and direct links to decision makers.

The main conclusions from the NEHRT survey were as follows:

- HTA is of significant value to policy makers. Important challenges still exist in delivering timely and relevant HTA information that accurately reflects the dynamics of the technology and healthcare system.
- Healthcare decision making requires greater clarity and transparency and needs to be conducive to the incorporation of evidence.
- Greater stakeholder involvement can facilitate improved decision making and policy implementation and can help manage uncertainty while enabling access to safe technologies.

The Business and Industry Advisory Committee (BIAC) to the OECD, whose constituencies are the major business organizations in the OECD member countries, emphasized the importance of including a range of stakeholders in the HTA process to define the relative value of a new healthcare intervention with perspectives that extend beyond the health system setting (6).

An editorial cast doubt on the use of HTA to guide integration of new technologies such as PET into health care and challenged the integrity of the work of INAHTA and some of its members (9). Scientific challenges faced by stakeholders and assessors in determining the utility of diagnostic modalities have also been raised (20–22). INAHTA welcomed a public dialogue as an opportunity to address these concerns and improve the field of HTA (10;11).

Workshop participants recognized the importance of including stakeholders into the HTA process, particularly individuals with the authority to implement policy and the clinical experts responsible for patient care. Clinical experts can help identify the appropriate question(s) to be assessed and inform the best methods for the assessment in light of existing uncertainty, and they may be essential to implementing the recommendations.

Participants stressed linking data collection to funding of PET services to allow simultaneous access to potentially valuable imaging services and evaluation of their contribution to clinical care. Through this process, clinical and managerial stakeholders can receive the feedback needed to improve the quality of care within an evidence-based framework. The absence of either a funding or quality improvement incentive provides little impetus for busy clinicians and managers to participate in what could be perceived as a burdensome data collection process.

CONCLUSIONS

INAHTA members have demonstrated that HTA can be an effective tool for managing the diffusion of complex and costly diagnostic technologies such as PET, taking into account local needs and patient focus. However, criticisms of HTA as an instrument for policy making need to be taken seriously by the HTA community if HTA is to continue to influence policy making effectively. To that end, several themes emerged at the workshop that can strengthen HTA as an integral component of the policy-making process:

- ***Use the body of work in HTA to strengthen local policy.*** Sharing assessment work is an important means of supplying timely and relevant information to policy makers within a short time frame. Universal agreement in the conclusions regarding the state of the evidence combined with input from local experts can help direct local evidence-based policy recommendations.
- ***Recognize the limitations of HTA.*** The HTA process may be imperfect in its reliance on published data, uncertain gold standards, or very long-term outcomes, which are not always practical for more immediate policy decisions. Improvements in therapy and associated outcomes may influence the cost-effectiveness of a diagnostic test in the future. Clinical experts and decision modeling can focus assessment of a diagnostic test on applications for which the potential benefit is considerable but for which such outcome data may be difficult or impractical to collect.
- ***Educate and involve key stakeholders in HTA.*** Stakeholders from multiple perspectives are important for reducing the misunderstandings about HTA and for improving the quality of HTA and decision-making based on HTA findings. In particular, drawing healthcare providers into the HTA process may help integrate HTA more effectively into medical practice. Clinical experts may be called upon to implement clinical policies, so their cooperation early in the assessment process is essential. Care must be taken to balance the enthusiasm of technology advocates with the scientific integrity of the process.
- ***Link the financing of high cost diagnostic tests to the delivery of clinical care in a high quality, cost-effective manner.*** The diffusion of diagnostic imaging technologies such as PET can be managed within traditional clinical trial research models as well as fee-for-service and capitation payment models. Systematic observational and experimental data collection, augmented with decision modeling, can be used to monitor utilization, define clinical performance in select indications, and examine the impact on patient management and health outcomes, all of which are important determinants of high quality clinical care.
- ***Strive to manage the uncertainty in the available evidence base through continuous quality improvement.*** Systematic data collection efforts and regular dissemination of the scientific findings to providers may help increase appropriate use of diagnostic technologies like PET. Such approaches may empower providers to reduce unnecessary utilization and costs while improving quality care and patient and provider satisfaction.
- ***Finally, make the entire policy-making process amenable to using scientific evidence as the basis for decision making.*** For decision makers to make use of HTA, the information must come from a trustworthy source. A transparent, rigorous, and inclusive HTA process is as critical to the successful creation of evidence-based policy making as the existence of funding or performance management systems.

CONTACT INFORMATION

Elizabeth J. Adams, MPH (Elizabeth.adams@med.va.gov), Research Analyst, Veterans Administration Technology Assessment Program, VA Boston Healthcare System (11T), Boston, Massachusetts 02130
Cari Almazán, MD (calmazan@aatrm.catsalut.net), Staff, Health Services Assessment, Catalan Agency for Health Technology Assessment and Research, Esteve Terrades, 30, Edifici Mestrsl 1a planta, 08023 Barcelona, Spain
Berit Mørland, DDS, PhD (berit.morland@nokc.no), Deputy Director General, Norwegian Knowledge Centre for the Health Services, P.O. Box 7004, St. Olavs Plass, N-0030 Oslo, Norway
Ian Bradbury, PhD (i.bradbury@ulster.ac.uk), Lecturer in Epidemiology and Statistics, Biomedical Sciences, University of Ulster, Cromore Road, Coleraine, Co. Derry BT62 1SA, Ireland
Richard King, MD (rking@vegas.com.au), Medical Director, Medicine Program, Monash Medical Centre, Southern Health Victoria, 873 Centre Road, East Bentleigh 3165, Australia
Paul Rheinberger, MD (PRheinberger@kbv.de), Chief, Department of Health Technology Assessment, National Association of Statutory Health Insurance Physicians, Herbert-Lewin-Platz 2, 10623 Berlin, Germany

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