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The history of health technology assessment in Australia

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Objectives: To describe the development and application of health technology assessment (HTA) in Australia.
Methods: Review of relevant literature and other documents related to HTA in Australia.
Results: Most HTA activity in Australia has been associated with provision of advice for the two national subsidy programs, Medicare, and the Pharmaceutical Benefits Scheme (PBS). National advisory bodies established by the federal government have had a prominent role. Assessments from the advisory bodies have had a major influence on decisions related to Medicare and the PBS, and in some other areas. Technologies without links to the national subsidy schemes, and those that are widely distributed, have been less well covered by HTA. To some extent these are addressed by evaluations supported by state governments, but details of approaches taken are not readily available.
Conclusions: HTA in Australia now has a long history and is well established as a source of advice to health decision makers. Challenges remain in extending the scope of assessments, developing more transparent approaches in some areas, and consistently applying appropriate standards.

Keywords: Australia, Health technology assessment, Health policy, History

THE AUSTRALIAN HEALTH SYSTEM

Australia's system of government includes a Commonwealth Parliament, and separate parliaments for each of the six states and the two major territories in the country. Coordination of public healthcare delivery is the responsibility of the health ministers of the Australian, state, and territory governments.[1] They are supported by the Australian Health Ministers' Advisory Council (AHMAC), a committee of the heads of health authorities in each jurisdiction.

Almost 70 percent of total health expenditure in Australia is funded by government, with the Australian Government contributing two-thirds of this. The Australian Government's contributions include the two national subsidy schemes, Medicare and the Pharmaceutical Benefits Scheme (PBS). Medicare subsidizes payments for services provided by doctors and allied health professionals, and the PBS subsidizes payments for a high proportion of prescription medications bought from pharmacies. The Australian, state, and territory governments jointly fund public hospital services.

State and territory governments are responsible for licensing or registering private hospitals, medical practitioners, and other health professionals. Each state and territory has legislation relevant to the operation of public hospitals. The Australian Government's regulatory roles include overseeing the safety and quality of pharmaceutical and therapeutic goods and appliances, managing quarantine arrangements, ensuring an adequate and safe supply of blood products, and regulating the private health insurance industry (6).

Regulatory Approval of Therapeutic Products

A comprehensive program for appraisal of safety and efficacy of pharmaceuticals was developed during the early 1970s, by the Commonwealth. Controls applied to imported pharmaceuticals and to products that were registered under the PBS. Detailed data were required from manufacturers to describe chemistry and quality control, and animal and human safety and efficacy for each product (13). Regulatory

[1]Titles of government organizations have changed several times over the period covered by this article. Recently "Australian Government" has replaced "Commonwealth" in the titles of federal government departments and authorities. Both forms of title have been used in the article. The current title of the federal health department is the Australian Department of Health and Ageing.

coverage was subsequently extended to medical devices and blood products.

The regulatory process is administered by the Therapeutic Goods Administration (TGA), a unit of the Australian Department of Health and Ageing (DOHA). Therapeutic goods must be entered on the Australian Register of Therapeutic Goods before they can be supplied in Australia. The TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard.

Insurance and Payment

Australia has had a universal health insurance scheme, Medicare, since 1984. It provides for free or subsidized treatment by medical practitioners and some other types of health professionals. Medicare has established a schedule of fees for medical services provided by private practitioners. Payments (Medicare benefits) that Medicare contributes for those services are based on the schedule fees. The patient is responsible for the gap between the benefit paid and the schedule fee, up to a maximum which is indexed annually, and for amounts charged above the schedule fee (6).

Another component of Medicare provides for public hospital care for Australian residents at no cost to the patient. Patients who choose to be treated in private hospitals, or as private patients in public hospitals, are liable for hospital accommodation and other charges, and for a portion of medical fees charged by private practitioners. In addition to their coverage by Medicare, Australians have a choice of a range of private health insurance schemes (6).

The PBS has a dominant place in influencing the use of pharmaceuticals in Australia. All Australian residents are eligible for PBS benefits, with those on low incomes having lower co-payments than general patients. Patients are protected from large overall expenses for PBS-listed medicines by safety net arrangements (6).

Policies to Control Use of Technologies and Services

The main avenues open to governments for controlling use of health technologies are financial, either through budgets for hospitals and clinic services (at state level), setting the rates of reimbursement under the Medicare and PBS programs, or in allocation of grants for specific technologies or services. These are imperfect ways of influencing the diffusion of technology, and control by regulation can only be partial (5). A joint approach has often been taken to the introduction of technologies that have high capital costs, with sharing of costs between the Commonwealth and one or more state governments. Such approaches tend to be interim arrangements before wider diffusion of the technology under Medicare funding, through grants from the Commonwealth or public hospital funding provided by the states.

Regulation of placement of services is the responsibility of state and territory governments and has typically been associated with a degree of financial control over public sector facilities.

INTRODUCTION AND DEVELOPMENT OF HTA: ORGANIZATIONS

Although HTA in Australia is undertaken by groups from universities, professional bodies, private consultants, and health authorities, a major direction has been set by national advisory bodies, established by governments. Support for these bodies has been provided from within health portfolios and by external evaluators. Most HTA activity has been in support of decisions related to Medicare and the PBS. A feature of Australian HTA to date is that assessment of pharmaceuticals has been organized separately to that for other types of technology.

Assessment of Pharmaceuticals

Applications for medicines to be subsidized by the PBS are assessed by a statutory body, the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC gives advice to the Minister about which drugs should be made available as pharmaceutical benefits. The committee is supported by DOHA.

The committee takes into account the conditions for which a medicine has been approved for use in Australia by the TGA, its clinical effectiveness, safety and cost effectiveness. Since 1993, it has been mandatory for sponsors to provide economic evaluation in submissions to PBAC. Guidelines for economic evaluations were introduced in 1990, and an update that drew on initial experience with their use was published in 1995 (8).

Economic evaluation is undertaken by or on behalf of manufacturing industry, and the evidence presented is then considered by PBAC. The overall HTA process therefore involves an externally prepared detailed application plus a review undertaken by staff at DOHA and their consultants. The review involves checking the literature search, verification of trial results, validation of key assumptions in models, and confirmation of resource costs (17).

Assessment of Nonpharmaceutical Technologies

HTA of nonpharmaceutical technologies developed following recommendations by a Committee on Applications and Costs of Modern Technology in Medical Practice (the Sax Committee) in the late 1970s. This was established by the Commonwealth in the light of the increasing costs of medical investigations and patient care. It considered effects of developments in technology on medical benefits and public hospital costs, with some emphasis on diagnostic methods (25).

The committee saw technology assessment as one of several long-term measures to improve the effectiveness of technological services in the healthcare system. It recommended that an expert national panel be established to advise on the scope, funding, and placement of new technology.

National committees. The National Health Technology Advisory Panel (NHTAP) was established by the Commonwealth in 1982. As envisaged by the Sax Committee, the membership comprised a balance of interests, including representatives of the medical profession, hospitals, the health insurance industry and manufacturing industry, and persons with technical expertise. The Panel was initially chaired and serviced by the Commonwealth health department, and later by the Australian Institute of Health and Welfare (AIHW).

The Panel got off to an uncertain start as vagaries within the health portfolio left it zero-funded in its first year and members paid their own way to its initial meeting. It went on to produce over forty reports on a range of technologies, with most of the research and drafting tasks being undertaken by its secretariat.

Health authorities, particularly the Commonwealth department, were major targets for NHTAP assessments. The Panel also made suggestions aimed at professional bodies concerning appropriate use of devices or procedures. The work of the Panel used a pattern followed by later Australian HTA programs of dialogue with health professional groups and industry during preparation of assessments. One of the achievements of the NHTAP was its involvement of the major medical colleges in its review of specific technologies (9).

Another initiative in the early 1980s was the creation by the predecessor to AHMAC of a Superspecialty Services Subcommittee (SSS). This group developed guidelines on resources for highly specialized services involving costly or complex forms of treatment. The SSS relied on individual health departments to provide research support.

In 1990, NHTAP and the SSS were subsumed by a new body, the Australian Health Technology Advisory Committee (AHTAC), which reported to the Health Care Committee of the National Health and Medical Research Council (NHMRC). This change was in line with a move to involve NHMRC more closely in provision of advice to health authorities on health services and technology (13).

Project support for AHTAC was provided by the AIHW, maintaining the continuity established through earlier work with NHTAP. Much of AHTAC's work was concerned with references given to it by AHMAC under its Nationally Funded Centres (NFC) program, which provides highly specialized emerging technologies. Support is given on a short-term basis, with renewal of funding being subject to review of the technology and of the centers that are providing it. The AHTAC assessments included NFC applications for heart, liver, lung, and pancreas transplantation services (18).

In 1998, AHTAC was replaced by the Medicare Services Advisory Committee (MSAC) as part of an initiative aimed at strengthening arrangements for assessing new technologies and procedures before they were considered for reimbursement under the Medicare Benefits Schedule. This represented the start of a more systematic approach to linking HTA with this area of health policy.

MSAC has members with a range of clinical and evaluation expertise and is supported through DOHA. It provides advice to the Minister on the safety, clinical and cost-effectiveness of medical technologies and makes recommendations on whether they should be publicly funded. MSAC also undertakes HTA work on topics referred by AHMAC. External evaluators, often from university groups, are used to undertake the assessments. Use of external evaluators had the advantage of providing the committee with access to appropriate expertise, at a time when sources of quality technical advice from within the health department were unlikely to thrive. MSAC also has involvement with horizon scanning activities through a subcommittee.

Other HTA Programs. The AIHW undertook HTA in addition to supporting national committees, following directions recommended in a review of the NHTAP (26). This work included assessments requested by other agencies, collation of statistics on healthcare technologies, and participation in collaborative work with hospitals and other centers (13). In addition, the AIHW undertook a major assessment project, on behalf of AHMAC, on screening for breast and cervical cancer (3;4). There were also first steps in collaboration on HTA with agencies in other countries. Involvement of the AIHW with HTA ended in 1995, with responsibility returning to the Commonwealth department, giving a closer link with the bureaucratic machinery for Medicare.

The Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S) was set up in 1998 as a program of the Royal Australasian College of Surgeons (RACS). ASERNIP-S has a team of evaluators who carry out assessments of surgical and other interventional technologies, with a focus to date on systematic reviews. Each review is endorsed by the Council of the RACS, and disseminated to the surgical community, government, hospital credentialing committees, and consumers. ASERNIP-S undertakes some assessments on behalf of MSAC, as an external evaluator, and also manages surgical audits.

Adelaide Health Technology Assessment (AHTA) is located within the School of Population Health and Clinical Practice at the University of Adelaide. It was established in 2001 to conduct evidence based applied research that primarily informs policy makers in government and non-government organizations. AHTA conducts HTA on behalf of MSAC and PBAC, horizon scanning, and assists with the development of evidence-based clinical practice guidelines on behalf of the NHMRC.

HTA by State Organizations. HTA-related activities are undertaken at the state government level, usually in relation to the use of medical technologies within public

hospitals. Several states have established advisory committees to assess requests to use new medicines. These committees typically consider applications for formulary listing of high cost and specialized drugs, such as anticancer agents (1). States also have structures in place to obtain advice on nonpharmaceutical technologies. Assessments are typically undertaken by consultants or within health departments. Details of the approaches taken, and of most assessment products, are not readily available.

OPERATION AND INFLUENCE OF AUSTRALIAN HTA

Organization and Scope of HTA Programs

In a 2005 report, the Australian Productivity Commission considered that "the fragmented HTA effort in Australia has cost and time implications for sponsors, patients and government." The Commission suggested that this can increase regulatory compliance costs, and delay the introduction of new treatments, with adverse impacts on patient outcomes and company revenues (1). No attempt was made to quantify the extent of such adverse effects. The Commission concluded that "overall, the evidence points to the opportunity for an overarching framework for coordinating HTA activities at a national level."

A contrary view put to the Commission was that centralized approaches may seek to impose mandatory requirements that would limit the flexibility of jurisdictions. It has also been suggested that the characteristics of different systems related to HTA may justify separate approaches (19).

The scope of the Australian HTA programs has varied. A review of the NHTAP endorsed the concept of an independent panel with a broad mandate including HTA and collection of primary data on health technologies (26). The concept of an independent HTA organization shifted somewhat with the creation of AHTAC, and its support by a secretariat that had more a focus on committee servicing than any depth of expertise in the appraisal process (12). The scope of activities changed again on the replacement of AHTAC by MSAC with its main responsibility being the provision of advice for a particular government program. The development of HTA activities at ASERNIP-S gave an alternative approach with a broader mandate in evaluation of surgical technologies, a group of in-house evaluators, and strong links to surgeons and other health professionals.

International collaboration in HTA has included a close association with the development and operation of the International Network of Agencies for Health Technology Assessment (INAHTA). The AIHW participated in the discussions leading up to the formation of INAHTA, was a founding member of the network, and a participant in its first collaborative project. AIHW also developed contacts with Canadian HTA groups, which included a joint project on laparoscopic cholecystectomy. MSAC, ASERNIP-S, and AHTA are all current members of INAHTA and have contributed to its activities through participation in its working groups. A member of the New Zealand Department of Health became a corresponding member of NHTAP and there has continued to be New Zealand representation on the national advisory bodies.

Methodology and Procedures

The PBAC economic guidelines call for a societal perspective, comparison with the treatment most likely to be replaced, evidence of effectiveness, and incremental and sensitivity analysis. Only direct costs are required, and there is a strong preference for effectiveness to be demonstrated through results of randomized trials, preferably "head to head" studies. Cost–benefit analysis and changes in productive capacity as an outcome of therapy are not encouraged in submissions to the PBAC (11).

There were few submissions that included cost-utility analysis in the first few years of application of the guidelines. A recent major revision of the guidelines includes a more explicit preference for cost-utility analysis and also a structured presentation of premodeling studies (23).

Approaches to assessment of nonpharmaceutical technologies have followed similar trends to those in other countries' HTA programs, with increasing emphasis on use of systematic reviews and economic analysis. The review of NHTAP recommended the Panel add economic assessments to its evaluations and economic evaluation was included in several reports produced at AIHW. Economic information considered by MSAC includes capital, direct treatment, and indirect costs. A societal perspective is taken regarding indirect costs, so that MSAC appears to take a broader perspective than PBAC (1).

Increasing detail in assessments, and sometimes further consultation processes, have tended to lead to more elaborate reports. The time taken to produce assessments has been the subject of criticism, for example regarding delays in the introduction of new technology (1). However, such comments tend to come from parties with strong interests in the technologies concerned, are often based on anecdotal information, and do not consider the possible costs and hazards of premature introduction. From 1998 to 2006, the average time taken to complete MSAC evaluations varied between 11 and 18 months (1;22).

A possible approach to improving timeliness of HTA is increasing the use of rapid HTAs, which are not yet common in Australia. The nature and use of rapid HTAs was explored in a study by ASERNIP-S, which includes accelerated systematic reviews in its own work program (7). MSAC is currently considering the use of streamlined assessments for some of its work.

Horizon scanning (HS) for health technologies was first undertaken in Australia by AIHW, which prepared a series of briefs on new devices and procedures that seemed likely

to have a significant impact on the healthcare system. Their greatest impact was in stimulating further HTA (including AHTAC activities) (13). At that stage, policy decision makers often lacked effective mechanisms to make use of HS information.

In 1999, ASERNIP-S started a New and Emerging Techniques—Surgical (NET-S) project which by September 2008 had prepared 176 HS publications on surgical/interventional procedures. In 2003, the Australia and New Zealand Horizon Scanning Network (ANZHSN) was established as an initiative of MSAC, DOHA, and AHMAC to provide HS advice to health departments in Australia and New Zealand (1). ANZHSN is the responsibility of a subcommittee of MSAC and is supported the National Horizon Scanning Unit (a component of AHTA) and by NET-S. ANZHSN is a member of EuroScan, giving it close contact with HS work by agencies in other countries.

Following the review of NHTAP, modest funding was made available for commissioned research on HTA. This approach was not continued, and it has been noted that none of the national HTA processes has the capacity to commission new clinical research (19).

Transparency

There have been ongoing concerns about the transparency and accountability of HTA mechanisms for pharmaceuticals. The level of disclosure by the PBAC relating to recommendations for listing on the PBS was considered to be poor compared with the requirements of other regulatory processes in Australia and overseas (1).

For many years, little was available on the details of evaluations or the reasoning behind the decisions on listing. Provisions of the National Health Act required that the data submitted to the PBAC and the deliberations of the committee remained confidential (20). It may be that such restrictions were not unwelcome to either side of the evaluation process. In 2002, DOHA began to publish summaries of PBAC's positive recommendations on its Web site and Public Summary Documents (PSDs) on PBAC decisions are now available. Each PSD includes information on the economic analysis presented by the sponsor company and on PBAC's evaluation of the cost-effectiveness claims. Their availability is the result of initiatives coming out of the Australian-United States Free Trade Agreement (1;2). They still fall short of providing full details of the assessment process.

HTA of nonpharmaceutical technologies by national bodies has been more transparent. The approach taken in the assessments by NHTAP and AIHW was that evaluation should make data and analysis explicit, being itself open to challenge and subject to change. This was not a view of the world that proved popular with some policy areas (11).

The Productivity Commission noted that MSAC is more transparent than PBAC in terms of the public release of information. MSAC undertook a review on its procedures to identify opportunities to improve the ways it provided advice on new medical technologies (21). Action taken included obtaining applicant feedback on evaluation protocols and draft reports, inviting comment from industry and medical associations on evaluation protocols and assessment reports, and inclusion of minutes of its meetings on its Web site. Reports prepared by MSAC, ASERNIP-S, and AHTA are widely available and included in the HTA database.

Impact of HTA Programs

A review of forty-five of the earlier Australian HTAs (from NHTAP, AIHW, and AHTAC) noted that their impact had been greatest in cases where there was local primary data collection, or when the technology was not available or had just been introduced (15). Twenty-six of thirty-five detailed assessments had influenced policy on the technologies covered.

An example of assessment with primary data collection was a study of MRI, coordinated by NHTAP, at five public hospitals. Clinical and cost data were obtained, with major contributions from representatives of the Royal Australasian College of Radiologists (RACR). The study informed policy on reimbursement of MRI exams and on funding of additional scanners in public hospitals. The experience from the assessment led to a consensus statement on the place of MRI in Australian health care, which formed the basis for the RACR's position on use of the technology for some years (13;14).

The AIHW evaluations of breast cancer and cervical cancer screening, which included detailed economic assessment, were influential in the establishment of national screening programs after their acceptance by AHMAC (11).

The assessment process for drugs being considered for listing under the PBS has been highly influential in informing decisions by PBAC. It has been possible to build routine appraisal of cost-effectiveness onto a closely regulated area of healthcare technology, supported by legislative provisions, with a focus on a particular government program (11). A review of major submissions to the PBAC between 1994 and 2004 found that probability of recommending coverage was influenced by clinical significance, cost-effectiveness, cost to government, and severity of disease (16).

Assessments published by MSAC have been influential in guiding decisions on government funding for technologies through Medicare. The process for MSAC followed that for the PBAC in linking assessment results and recommendations to decisions on funding.

Coverage of Technologies by HTA Programs

The assessment process for the PBAC provides coverage for new pharmaceuticals that are being considered for PBS listing. However, many drugs used in public hospitals are not considered by the PBAC, and any assessment of these is carried out by state government organizations (1).

An earlier review of HTA in Australia suggested that there were "islands" of assessment and fully informed policy, with the mainstream of health technology deployment evolving through less formal mechanisms (15). Numbers of nonpharmaceutical technologies covered by full HTAs remain relatively limited. According to the 2003–05 program assessment report for MSAC, the committee had received 129 submissions applications or references for review since its establishment in 1998 and had completed 75 reviews or 70 percent of all submissions that were eligible for review. There still appear to be islands of assessment, albeit some important ones. There is good coverage of emerging technologies at the horizon scanning stage with the preliminary reports prepared through ANZHSN.

Some types of technology without immediate links to the national subsidy schemes are less well covered. For example, there is limited work on rehabilitation technologies or on issues relating to organization and operation of health services (10). Nor have e-health and telemedicine received much consideration since early assessments by AIHW.

The emphasis of the main HTA programs has, understandably, been on new technologies. Follow-up of assessments to provide further information on clinical effectiveness and economic aspects is sporadic. Drugs currently approved by the PBAC are only evaluated in terms of cost-effectiveness in initial controlled trials, with no follow-up to ensure they continue to provide value for money after their addition to the PBS (1). All the nonpharmaceutical HTA programs have undertaken some follow-up assessments, but have been constrained by limited resources and other priorities.

DISCUSSION

The emphasis on use of HTA in Australia has been in informing decisions on government support for health technologies through the PBS and Medicare. There has been an important and sustained link to policy on coverage for drugs, devices, and procedures under these national subsidy schemes. There have also been successes for Australian HTA in informing decisions on support for introduction of certain high cost technologies, including organ transplant and diagnostic imaging services (11). The establishment of an HTA program by the RACS has enhanced the evaluation of surgical and interventional technologies, and the dissemination of advice on these to the medical profession.

The focus on the requirements of the national reimbursement schemes has meant there has been less consideration by the current programs of other directions in HTA such as workforce impacts of health technologies and wider social aspects, which were suggested in a review of an earlier program (26). It has been noted that HTA programs in some other countries consider a broader range of topics, including issues relating to organization and operation of health services (10).

The status of HTA in support of other areas, such as procurement and use of technologies in public hospitals, is less certain. Useful assessment has occurred at the state level on an ad hoc basis, but establishment of HTA programs could provide continuity of evaluation expertise to deal with local issues (10). As things stand, the scope and standards of HTA at the state level are unclear.

Although there have been many successes with HTA informing decisions on new technologies, the situation is less impressive for those that are already established and distributed. There may be consequences for the control and appropriate use of technologies. For example, HTAs of shockwave lithotripsy successfully influenced policy and helped set conditions for the initial use of the technology, but subsequent decisions on procurement led to substantial overcapacity (11).

It is also of interest to consider the growth of computed tomography (CT) scanning in Australia, as a technology that was raising concerns for government at the time of the Sax committee. A 1988 report by NHTAP noted that Australia had 10.8 scanners per million population, more than any European country. By early 1994, numbers were approaching 20.3 per million (13) and had reached 45.3 per million by 2005 (24). Decisions on this growth have not been informed by HTA, and there is probably limited information on how many CT services are being used and to what effect.

HTA in Australia now has a long history and is well established as a source of advice to health decision makers. Challenges remain in extending the scope of assessments, developing more transparent approaches in some areas, and consistently applying appropriate standards.

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