

# Health technology assessment in Australia: challenges ahead

Terri J Jackson

*Australia is well placed to again lead the world in health technology assessment*

Australia led the world in 1993 when it introduced the so-called “fourth hurdle” of economic evaluation into the approvals process for drugs (in addition to the usual regulatory “hurdles” of quality, safety, and efficacy).<sup>1</sup> We are among the dozen or so developed countries that had invested in health technology assessment (HTA) since the early 1980s, but it was the requirement of a favourable economic evaluation that attracted international attention to HTA in Australia.<sup>2</sup> While economic evaluation had always been considered a component of HTA, a policy requiring evidence of cost-effectiveness was groundbreaking.<sup>3</sup>

In 1998, the federal Minister for Health created a parallel HTA process for new medical services. Evidence of sufficient safety, effectiveness and cost-effectiveness to be included in the Medicare-subsidised benefits package now forms the basis for coverage recommendations to the Minister by the Pharmaceutical Benefits Advisory Committee (PBAC) for drugs, and the Medical Services Advisory Committee (MSAC) for medical services and technologies (Box).<sup>5</sup>

In contrast to most other countries, HTA in Australia has been woven into the fabric of health services funding, giving it greater impact on the introduction of new treatments. Our approach is similar to that of the United Kingdom’s National Institute for Health and Clinical Excellence<sup>6</sup> but differs from Canada’s more “hands off” implementation approach,<sup>7</sup> both described in this issue of the Journal (*page 283* and *page 286*, respectively).

Most other countries have structured their HTA processes to be “advisory” to doctors and health care services. It is unclear whether this separation of advice from funding is more effective than the direct application of HTA to coverage decisions seen in Australia and the UK, but a common lament from academics and policy-makers in such systems is that HTA findings are not “taken up” by health care providers.<sup>8,9</sup> Separating HTA from coverage decision making may lead to less contention with professional groups and the biotechnology industries, but perhaps also reduces the impact of the HTA effort.

Because of their direct impact on government coverage decisions, and the still novel requirement for an acceptable incremental cost-effectiveness ratio, both the PBAC and MSAC have been subject to industry and political scrutiny. The most comprehensive inquiry was a 2005 Productivity Commission report on advances in medical technology in Australia.<sup>10</sup> The PBAC was a major focus of negotiation leading to the Australia–United States Free Trade Agreement,<sup>11</sup> and the MSAC has conducted an internal review and consultation process,<sup>12</sup> in part as a response to industry criticism of delays in the assessment process.<sup>4</sup> A third article in this issue of the Journal by Petherick and colleagues (*page 289*) examines the evolution and shortcomings of systematic reviews in published MSAC assessment reports since 1998.<sup>13</sup>

Although the Australian system is apparently fragmented (medicines versus services, federal versus states, public versus private systems), differing characteristics of each may justify separate approaches. It is clear that the longer history of drug safety regulation makes pharmaceutical evaluation more straightforward

## Requirements for Medicare subsidy of drugs and medical technologies in the Australian health care system

### Drugs

- Applicants are required to prepare detailed evidence-based submissions to the Pharmaceutical Benefits Advisory Committee (PBAC), once drug safety has been assessed by the Therapeutic Goods Administration (TGA).
- Applications are rigorously assessed by health technology assessment (HTA) organisations contracted to PBAC, which then provide confidential reports to PBAC.
- All documentation for PBAC recommendations is considered “commercial in confidence”, and only brief reports on decisions and deferrals are published.

### Medical services and technologies

- The Medical Services Advisory Committee (MSAC) undertakes its own assessments, also by contracted HTA organisations.
- MSAC reports are published once the Minister has made a determination about listing on the Medical Benefits Schedule.
- About a third of the work program of MSAC comes as referrals from the federal Department of Health and Ageing.<sup>4</sup> ♦

than evaluation of medical services.<sup>10,14</sup> Surgical interventions provide their own unique challenges to evaluation methods, and the Australian Government has funded ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures — Surgical) to conduct HTAs under the sponsorship of the Royal Australasian College of Surgeons.<sup>15</sup>

Funders at each level of the system (federal and state) have differing responsibilities and interests, probably best served by dedicated evaluation efforts, but there has been considerable synergy in the development of HTA among these stakeholders. The Productivity Commission report highlighted a number of recent developments that fill gaps and reduce friction between the needs of different HTA users.<sup>10</sup>

Through the Australian Health Ministers’ Advisory Committee (AHMAC), the states pool funds to sponsor HealthPACT (Health Policy Advisory Committee on Technology) which performs “horizon scanning” for state health departments,<sup>16</sup> and shares secretariat and other functions with MSAC. This mechanism alerts the funders of public hospitals to emerging medical technologies with potential to influence their health care systems. The states together determine HealthPACT’s budget and work program. In addition, AHMAC has delegated to MSAC a role in advising on Nationally Funded Centres (NFC). These are services where the volume of relevant cases is not sufficient to justify more than one or two units in the country — historically, these have been transplant units. The NFC designation ensures that all states contribute to funding of such units, thus guaranteeing access for residents of all states.

State health departments are developing their own HTA capabilities. For example, the Victorian Policy Advisory Committee on Clinical Practice and Technology<sup>17</sup> was set up in 2004 to under-

take a variety of HTA activities, including horizon scanning, assessment and monitoring for the Victorian Department of Human Services. State-based committees commonly consider applications for high-price and/or high-volume drugs, devices and procedures, and create a mechanism to approve funding for novel or statewide specialty services outside normal hospital funding arrangements.

Hospitals and regional health services in Queensland, Western Australia, South Australia and Victoria have established internal HTA committees to oversee the introduction of new drugs and medical procedures, with examples from Bayside Health and Southern Health in Victoria cited by the Productivity Commission in its report.<sup>10</sup> Public hospitals, with their role in medical education and research, may need to focus on different technologies at different stages of the product development cycle than do private hospitals and health insurers.

In contrast to Australia, the HTA efforts of Canada and the UK have a unified approach to drugs and other technologies. The UK National Institute for Health and Clinical Excellence has an advantage over MSAC and PBAC in setting its own agenda, the so-called “needs-led” prioritisation of HTA topics. Canadian HTA organisations seem to balance the needs of the system as a whole against those of particular interests, including those of funders,<sup>7</sup> but probably come closer to HealthPACT’s user-led prioritisation. All jurisdictions grapple with the politically charged problem of “disinvestment” — that is, ceasing to support therapies whose effectiveness (and/or cost-effectiveness) cannot be demonstrated. Both the UK and Canada have successfully pioneered “rapid response” methods for HTA users requiring timely answers to tightly framed clinical questions, an approach not yet common in Australia.

Clinical evidence for HTA is derived from systematic reviews, and these in turn rely on randomised controlled trials (RCTs). Evidence-based medicine has refined the tools available for evaluating evidence of clinical benefit; basic physiological evidence of efficacy can come from trials in any country. However, evidence of real-world effectiveness is dependent on the medical culture, workforce and referral patterns of a particular health system, and economic evaluation is even more dependent on the organisational forms of health care, including the skills mix and relative wages of different professional groups. Generally economic assessments use decision-analytic models, with key outcomes costed locally to determine the cost-effectiveness of an intervention in each health care system.

None of the national HTA processes described has the capacity to commission new clinical research, and there is little articulation with existing medical research priority-setting processes. This often results in rejecting new technologies because there is no RCT evidence of their efficacy or effectiveness, rather than evidence that they are ineffective.<sup>4</sup> Both the UK and the US are trialling “coverage with evidence” approaches to funding new medical technologies as a way of bridging current gaps in evidence.<sup>18</sup> These allow introduction of new services or biotechnologies on the condition that patients are entered into rigorous clinical trials, and with the understanding that continued funding will depend on the evidence from these trials.

The coming of molecular medicine with its individualised and gene-based therapies will exacerbate the lack of clinical evidence from RCTs.<sup>19</sup> The “demise of the blockbuster” drug will demand a new research-intensive paradigm for evaluation and regulation of

therapies in developed countries.<sup>20</sup> Monitoring drug safety<sup>21</sup> and funding the collection of randomised evidence<sup>22</sup> are possible in Australia, even with current evaluation tools. However, we will need focused effort to develop more “fine-grained” clinical epidemiology techniques to identify patient characteristics that mediate response to treatment and define *which* subgroups are likely to derive *how much* benefit from new treatments *at what cost*.

The phrase “rapid learning health system” has recently been coined to characterise the ways in which computerised medical information can be used to inform health care decision making from the bedside to national HTA efforts.<sup>23</sup> With Australia’s large health information technology investment, well established disease registries and systematic metadata specifications, we are in a position to pioneer rapid learning strategies that can be used earlier in the evaluation process, and at an acceptable research cost.

The challenges then are to manage the inevitable tensions that arise when HTA directly influences funding decisions, to tailor HTA methods to the needs of different stakeholders with differing timelines, to focus HTA strategically to meet national needs including the capacity to disinvest from ineffective treatments, and to supplement RCT efficacy evidence with real-world evidence of effectiveness and cost-effectiveness. Australia could once again claim leadership of international HTA by creating the evaluative and funding mechanisms to rise to these challenges.

### Acknowledgements

I am grateful to Judith Healy, Director of RegHealth Program, Regulatory Institutions Network (RegNet), Research School of Social Sciences, Australian National University, for comments and suggestions on a draft of this article.

### Competing interests

Terri Jackson has served as a member of the Medical Services Advisory Committee since 1998.

### Author details

**Terri J Jackson**, PhD, Principal Research Fellow and Associate Professor Australian Centre for Economic Research on Health, University of Queensland, Brisbane, QLD.

**Correspondence:** t.jackson@uq.edu.au

### References

- 1 Taylor RS, Drummond MF, Salkeld G, Sullivan SD. Inclusion of cost effectiveness in licensing requirements of new drugs: the fourth hurdle. *BMJ* 2004; 329: 972-975.
- 2 Organisation for Economic Cooperation and Development. Survey of pharmaco-economic assessment activity in 11 countries. Health working paper 4. Paris: OECD, 2003.
- 3 Birkett DJ, Mitchell AS, McManus P. A cost-effectiveness approach to drug subsidy and pricing in Australia. *Health Aff (Millwood)* 2001; 20: 104-114.
- 4 O’Malley SP. The Australian experiment: the use of evidence based medicine for the reimbursement of surgical and diagnostic procedures (1998–2004). *Aust New Zealand Health Policy* [Internet] 2006; 3: 3.
- 5 Harris A, Bulfone L. Getting value for money: the Australian experience. In: Jost TS, editor. Health care coverage determinations: an international comparative study. Maidenhead, UK: Open University Press, 2005: 25-56.
- 6 Walley T. Health technology assessment in England: assessment and appraisal. *Med J Aust* 2007; 187: 283-285.
- 7 Hailey DM. Health technology assessment in Canada: diversity and evolution. *Med J Aust* 2007; 187: 286-288.

## EDITORIALS

- 8 Oliver A, Mossialos E, Robinson R. Health technology assessment and its influence on health-care priority setting. *Int J Technol Assess Health Care* 2004; 20: 1-10.
- 9 Harris A, Buxton M, O'Brien B, et al. Using economic evidence in reimbursement decisions for health technologies: experience of 4 countries. *Expert Rev Pharmacoeconomics Outcomes Res* 2001; 1: 7-12.
- 10 Productivity Commission. Impacts of advances in medical technology in Australia. Melbourne: Productivity Commission, 2005.
- 11 Harvey KJ, Faunce TA, Lokuge B, Drahos P. Will the Australia–United States free trade agreement undermine the Pharmaceutical Benefits Scheme? *Med J Aust* 2004; 181: 256-259.
- 12 Australian Government Department of Health and Ageing. Medical Services Advisory Committee (MSAC). <http://www.health.gov.au/internet/msac/publishing.nsf/Content/review-1> (accessed Aug 2007).
- 13 Petherick ES, Villanueva EV, Dumville J, et al. An evaluation of methods used in health technology assessments produced for the Medical Services Advisory Committee. *Med J Aust* 2007; 187: 289-292.
- 14 Henry DA, Hill SR. Assessing new health technologies: lessons to be learned from drugs. *Med J Aust* 1999; 171: 554-556.
- 15 Royal Australasian College of Surgeons. ASERNIP-S (Australian Register of Safety and Efficacy — Surgical). <http://www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/default.htm> (accessed Aug 2007).
- 16 Australian Government Department of Health and Ageing. Australia and New Zealand Horizon Scanning Network — about horizon scanning. The Health Policy Advisory Committee on Technology (HealthPACT). <http://www.health.gov.au/internet/horizon/publishing.nsf/Content/healthpact-2> (accessed Aug 2007).
- 17 State Government of Victoria, Australia, Department of Human Services. Victorian Government Health Information. New Technology/Clinical Practice program 2005–06. Victorian Policy Advisory Committee on Clinical Practice and Technology. <http://www.health.vic.gov.au/newtech/committee.htm> (accessed Aug 2007).
- 18 US Department of Health and Human Services. CMS (Centres for Medicare and Medicaid). Medicare coverage database. National coverage determinations with data collection as a condition of coverage: coverage with evidence development. 7 December 2006. [http://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=8](http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8) (accessed Aug 2007).
- 19 Hall WD, Ward R, Liauw WS, et al. Tailoring access to high cost, genetically targeted drugs. Assessment of real cost effectiveness, with data linked to individual health outcomes while protecting patient privacy, is an essential challenge we need to meet. *Med J Aust* 2005; 182: 607-608.
- 20 Cutler DM. The demise of the blockbuster? *N Engl J Med* 2007; 356: 1292-1293.
- 21 Kelman CW, Pearson SA, O'Day R, et al. Evaluating medicines: let's use all the evidence. *Med J Aust* 2007; 186: 249-252.
- 22 Glasziou P. Support for trials of promising medications through the Pharmaceutical Benefits Scheme. A proposal for a new authority category. *Med J Aust* 1995; 162: 33-36.
- 23 Etheredge LM. A rapid-learning health system. *Health Aff (Millwood)* 2007; 26: w107-w118.

(Received 25 Apr 2007, accepted 23 Jul 2007)

□