Funding of new cardiac technologies in Australia

A scarcity of funding resources is limiting patient access to major advances in medicine

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Health care spending represents a substantial and increasing proportion of national expenditure in most countries. Total annual health care spending in Australia now exceeds $120 billion, or 9.4% of gross domestic product.[1] The highest proportion of health care funding is spent on cardiovascular disease, which accounted for 11% of total expenditure in the 2008–09 financial year.[1] Rapid advances in pharmacotherapy and device technology are constantly pressuring funding sources. New cardiovascular technologies, including drug-eluting stents, implantable defibrillators, left ventricular assist devices, and devices for structural heart disease, are undoubtedly major advances, but access to the devices has often outpaced the availability of funding to pay for them.

Approval for commercial release of novel devices in Australia is dependent on a review of safety, quality and efficacy by the Therapeutic Goods Administration (TGA). Once approved, access to devices through the private health insurance scheme requires recommendation by the Medical Services Advisory Committee (MSAC), to generate a procedural item number and Medicare Benefits Scheme (MBS) fee, and the Prostheses and Devices Committee, which generates a prosthesis code and reimbursement. For patients not covered by private health insurance (currently 55% of the population),[2] TGA and MBS approval does not guarantee access to treatment in the public health system. Evaluation of new technologies for public hospital funding is coordinated through the Health Policy Advisory Committee on Technology (HealthPACT), which comprises representatives from all state and territory health departments, the Australian and New Zealand governments, the Department of Veterans' Affairs and MSAC. It has input from professional colleges and industry, and liaises with similar health technology assessment organisations internationally.

There are currently several avenues for public hospital funding of new technologies. Early-phase clinical trials of novel devices typically precede TGA approval and are largely funded by industry, providing not only prostheses for the patients involved, but also patient follow-up and intermediate-term device surveillance. On occasion, devices such as implantable aortic valve prostheses have been made available before TGA approval as part of an industry-supported registry. Under these circumstances, prosthesis costs have often been covered by limited, usually unsustainable, discretionary funds or charitable donations.

For devices that have been approved by the TGA, block funding for limited periods may be made available to selected public hospitals in some states through individual or regional HealthPACT submissions. Variations in availability of funds between states have recently led to differences in support for, and availability of, new technologies across the country. Technologies in established or emerging clinical practice that have a high cost and limited demand may also be considered under the Nationally Funded Centre (NFC) program, which is supervised federally but administered and funded by state jurisdictions.[3]

The current funding system has limitations. The approval process can be slow and inflexible. A recent review of health technology assessment processes[4] recommended measures to reduce delays by streamlining administrative systems and minimising duplication. However, such improvements will not necessarily increase access for public (Medicare-funded) patients. Cost-effectiveness is, and should be, a critical determinant of funding for new devices in the resource-limited, state-funded public system. Fundamental to cost-effectiveness analysis is the incremental clinical effectiveness of an intervention and its effect on quality of life.[5] Interventions that do not have a demonstrable incremental clinical benefit should not be funded simply because they are new. However, the true cost-effectiveness and net clinical benefit of new interventions can be difficult to calculate when only short-term data in selected populations are available.[5,6]

Some requirements for improving access are self-evident. Although bringing new devices to market is an undeniably expensive exercise for industry, with increasingly costly hurdles for regulatory approval, pressure must be kept on companies to minimise prices so as to make devices available to as many patients as possible. Other potential measures require greater debate. Under the National Health Reform Agreement, for example, public patients treated in a public hospital cannot be billed for surgically implanted prostheses.[7] A review of this philosophy may be warranted, to allow the uninsured who can afford to pay for certain interventions the opportunity to do so. Very expensive technologies need not necessarily be available at every public hospital or for all eligible patient subgroups.[6] In the first instance, public funding could be restricted to subgroups with the most compelling incremental cost-effectiveness ratios. When patients are transferred between hospital networks for these specialist procedures, a mechanism for transfer of appropriate funding between institutions should be available.

Ideally, the approval of complex new technologies should be accompanied by reliable special-purpose funding to allow selected sites across the country to develop expertise, obtain local cost-effectiveness data, and provide intermediate-term follow-up and device surveillance through locally sponsored multicentre registries. This could of course result in a conflict between institutional

demands for equitable access to new technology and adequate support for suitable sites. A coordinated national approach to advanced technology funding, perhaps as an extension of the NFC program, may be the most efficient and equitable, and provide the most timely access for patients to important medical advances in both the public and private health systems.

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1 Australian Institute of Health and Welfare. Australia's health 2012: in brief. Canberra: AIHW, 2012. (AIHW Cat. No. AUS 157.)
2 Paolucci F, Butler JRG, van de Ven WPMM. Removing duplication in public/private health insurance in Australia: opting out with risk-adjusted subsidies? *Agenda* 2011; 18 (2). http://epress.anu.edu.au/apps/bookworm/view/Agenda%2C+Volume+18%2C+Number+2%2C+2011/7401/Text/ch04-Paolucci%3AButler%3AVen.html#toc_marker-7 (accessed Jul 2012).
3 Australian Health Ministers' Advisory Council. Nationally Funded Centres: guidance for governance, management, funding, establishment, review. May 2007. http://www.health.vic.gov.au/newtech/documents/nfc_guide_07.pdf (accessed Jul 2012).
4 Australian Government Department of Health and Ageing. Review of health technology assessment in Australia. Canberra: DoHA, 2009. http://www.health.gov.au/internet/main/publishing.nsf/Content/hta-review-report (accessed Jul 2012).
5 Hlatky MA, Simons CT. Cost-effectiveness of transcatheter aortic valve replacement. *Circulation* 2012; 125: 1076-1077.
6 Neyt M, Van Brabandt H, Devriese S, Van de Sande S. A cost-utility analysis of transcatheter aortic valve implantation in Belgium: focusing on a well-defined and identifiable population. *BMJ Open* 2012; 2: e001032.
7 Council of Australian Governments. National Health Reform Agreement. Canberra: Australian Government Department of Health and Ageing, 2011: 56. http://www.coag.gov.au/docs/national_health_reform_agreement.pdf (accessed Jul 2012). ❑