Why Australian patients are waiting years for innovative medical devices & what can be done

New report highlighting urgent reforms to accelerate access to life-saving technologies

The new report, *Accelerating Access to Innovative Medical Technologies in Australia*, reveals patients are missing out on faster, more effective treatments due to outdated and slow reimbursement systems, delaying access to proven medical innovations by nearly five years on average.

Developed by HTAnalysts in collaboration with Edwards Lifesciences, the report captures insights from the 'Healthcare Leaders Series' roundtable held in November 2024. The event united experts from across the medical device, pharmaceutical, hospital, clinical, and patient advocacy sectors.

The discussion focused on the Health Technology Assessment (HTA) processes used by the Medical Services Advisory Committee (MSAC) and the Medical Devices and Human Tissue Advisory Committee (MDHTAC), previously known as the Prostheses List Advisory Committee (PLAC), with particular focus on medical devices used in the treatment of structural heart disease. At the centre of the discussion was one overarching question:

How can Australia's health system be reimagined with speed to innovation, without compromising safety or value?

The report aims to highlight tangible opportunities for reform to improve the speed in which patients can access innovative medical technologies in Australia.

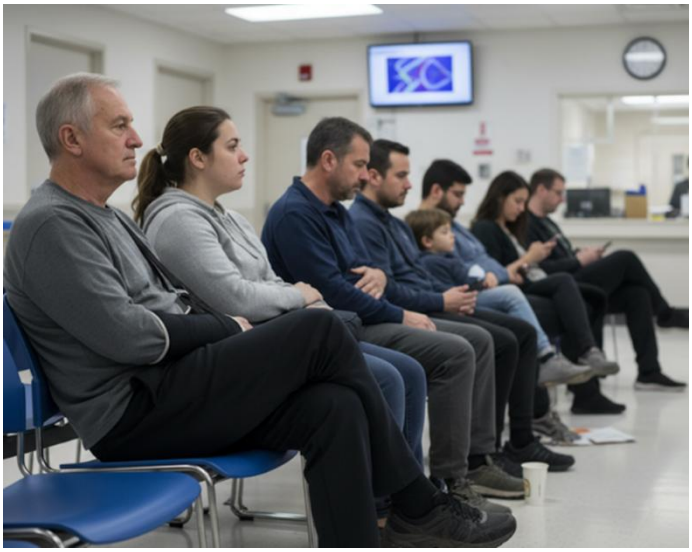
Innovation delayed, care denied: the human cost of inaction

Despite major advances in medical technologies that improve patient outcomes, Australia's outdated and conservative reimbursement policies fail to properly value innovation, leaving patients without access to cutting-edge care.

The report identifies five key barriers, demonstrating the challenges faced by stakeholders within Australia's reimbursement and approval framework for medical innovations.

1. **Complex and lengthy approval pathways** – on average, it takes **4.7 years for innovative devices to receive reimbursement due to overlapping, slow decision-making.**
2. **Inflexible funding and reimbursement models** – fragmented public/private systems and funding caps misalign incentives and creative inequities.
3. **Outdated evidence and data gaps** – current Health Technology Assessment (HTA) process relies heavily on randomised controlled trials, under-utilising **real-world evidence (RWE) more suited to device evaluation.**
4. **Narrow definitions of 'value'** – value frameworks focus almost exclusively on cost-effectiveness, overlooking what truly matters to patients – independence, autonomy, and societal benefits. The HTA Policy and Methods Review (the HTA Review) recommended the development of a qualitative values framework to provide more flexibility in the decision-making process.
5. **Public and private inequity** – depending on where they live, and how they're insured, patients may face very different access outcomes e.g. public patients may sometimes access new technologies earlier than private patients, despite paying costly premiums for private care.

Case in point: aortic valve delays cost lives



- The report highlights the case of **Transcatheter aortic valve implantation (TAVI)** – a minimally invasive heart procedure for aortic stenosis, offering a safe and cost-effective alternative to open-heart surgery with shorter hospital stays, despite higher valve costs.
- While TAVI is widely available in countries like the **US, UK, and Germany** within 1–2 years of approval, Australian patients waited **five years** from approval, to reimbursement.[1,2]
- This delay highlights inefficiencies in Australia's HTA and reimbursement processes, particularly prolonged Medical Services Advisory Committee (MSAC) reviews.
- An estimated **1,500 Australians miss out** on TAVI each year due to system bottlenecks,[3] resulting in unnecessary deterioration of health, worsening symptoms, and increased reliance on the health system.
- Public hospitals often cannot offer the procedure due to funding shortfalls, despite evidence that TAVI can reduce hospital stays and long-term costs.

Australia is falling behind other comparable countries

- Globally, countries are finding smarter ways to balance innovation with safety.
- Australia is frequently falling behind other comparable countries in providing reimbursed access to innovative medical technologies.[6]
- Delayed access to genetic and genomic testing means patients may miss out on effective treatments, or receive tests unnecessarily, creating an increased burden on the health system. This burden could be alleviated through faster access to innovative technologies that are already available and in routine use overseas.[7]
- The United States' *Transitional Coverage for Emerging Technologies (TCET)* and Germany's *New Examination and Treatment Methods (NUB)* pathway **provide faster, provisional access to emerging technologies while evidence is still being generated**, allowing early patient access while data is being gathered. These pathways show speed and rigour can co-exist, and that **Australia is falling behind**.[4,5]

Cost & funding snapshot

- In the private sector, government and insurers must fund approved procedures without utilisation limits, unlike the public sector, where spending caps may restrict access.
- The Australian Government covers 43.9% (AUD 105.8 billion) of total health spending (43.9%), with State and Territory governments covering 29.1% (AUD 70.2 billion).[8]
- Individuals contribute 14.0% (AUD 33.7 billion), health insurers 7.3% (AUD 17.5 billion), and other non-government sources 5.9% (AUD 14.2 billion) per annum.[8]
- **Discrepancies in how public and private patients are funded can lead to treatment delays, unexpected out-of-pocket costs, and systemic inefficiencies.**

What needs to change: key recommendations

* *Medical Devices and Human Tissue Advisory Committee (MDHTAC)*

Recommendation	Importance	Timeline
Establish performance targets for reimbursement timelines	Foundational	1 year
Develop a priority review pathway through MSAC and MDHTAC* linked to the TGA	Foundational	2+ years
Develop a streamlined assessment pathway for MSAC and MDHTAC	Optimising	2+ years
Develop a streamlined resubmission pathway to reduce time to recommendation	Optimising	2+ years
Develop a provisional funding mechanism for innovative medical technologies in the private sector	Foundational	1-2 years
Develop a provisional funding mechanism for innovative medical technologies in the public sector	Foundational	1-2 years
Prioritise consumer lived experience in decision making	Foundational	1-2 years
Develop a framework to improve clinical expert input into decision making	Foundational	1-2 years
Develop a comprehensive value framework that includes patient impact	Optimising	1-2 years
Improve use of real-world evidence in MSAC and MDHTAC decision making	Foundational	1-2 years
Monitor and publish progress towards MBS listing	Optimising	<1 year

To access the *Accelerating Access to Innovative Medical Technologies in Australia* report, head here: htanalysts.com.au/accelerating-access-to-innovative-medical-technologies-in-australia

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