HTANALYSTS

ACCELERATING ACCESS TO INNOVATIVE MEDICAL TECHNOLOGIES IN AUSTRALIA

HEALTHCARE LEADERS SERIES

DECEMBER 2025

Edwards

FOREWORD BY **HT**ANALYSTS

HTANALYSTS has been providing boutique value and impact assessment services for over two decades. Originally founded in 2002, our organisation has grown to become a leader in social impact consulting, providing services to the healthcare industry. We exist to make a powerful impact on society by driving human-centric outcomes.

Our purpose is to have a powerful impact on the health of society by connecting people with the best treatments in the fastest time.

This report presents findings and recommendations derived from the Healthcare Leaders Series event, hosted by Edwards Lifesciences in November 2024. We are grateful to those who participated in the roundtable, especially the patient advocates who gave up their time and lived experience.

Our aim is for this report to provide tangible opportunities for reform, to improve speed to access for innovative medical technologies in Australia.

The Healthcare Leaders Series White Paper is a vital step towards the body of evidence to improve patient access to innovative medical technologies. As a patient advocate, I see firsthand how delays in reimbursement mean delayed care and compromised quality of life.

The current HTA review must take a holistic approach, not just focusing on the PBAC and PBS but considering the entire healthcare system. Medical devices and diagnostics are essential to modern care, and their reimbursement pathways should be as agile as those we advocate for pharmaceuticals.

By broadening the HTA review's scope, we can ensure patients have timely access to life-changing treatments. I strongly support the White Paper's call for a more patient-centred, streamlined approach to innovation.

Tanya Hall, Hearts4Heart

CONTENTS

3 Foreword by HTANALYSTS

6 Executive summary

11 Abbreviations

12 Introduction

12 Problem statement

13 Approach

14 Current reimbursement and funding process

17 Systemic barriers to device funding in Australia

17 Duplication of work

18 Funding models

20 Evidence generation

20 Narrow definition of value

22 Global examples

22 United States

23 Germany

26 Recommendations for reform

28 Streamline processes

29 Alternative funding mechanisms

30 Comprehensive value framework

31 Real-world evidence

31 Transparency

32 References

34 Appendix

EXECUTIVE SUMMARY

Significant advancements in health technologies, including novel medical devices, diagnostics and therapeutics, have led to dramatic improvements in patient health outcomes. However, Australia's healthcare reimbursement policies, processes and methods have not kept up with the pace of innovation, resulting in under-recognition of the true value of these new technologies. Our conservative approach to innovation means that major advancements in technology are not appropriately valued within existing assessment frameworks, causing patients to miss out.

To address this issue, Edwards Lifesciences convened a roundtable, including representatives from the medical device, diagnostic, and pharmaceutical industries, private hospital operators, clinicians and clinical societies, patient advocates, and other subject matter experts.

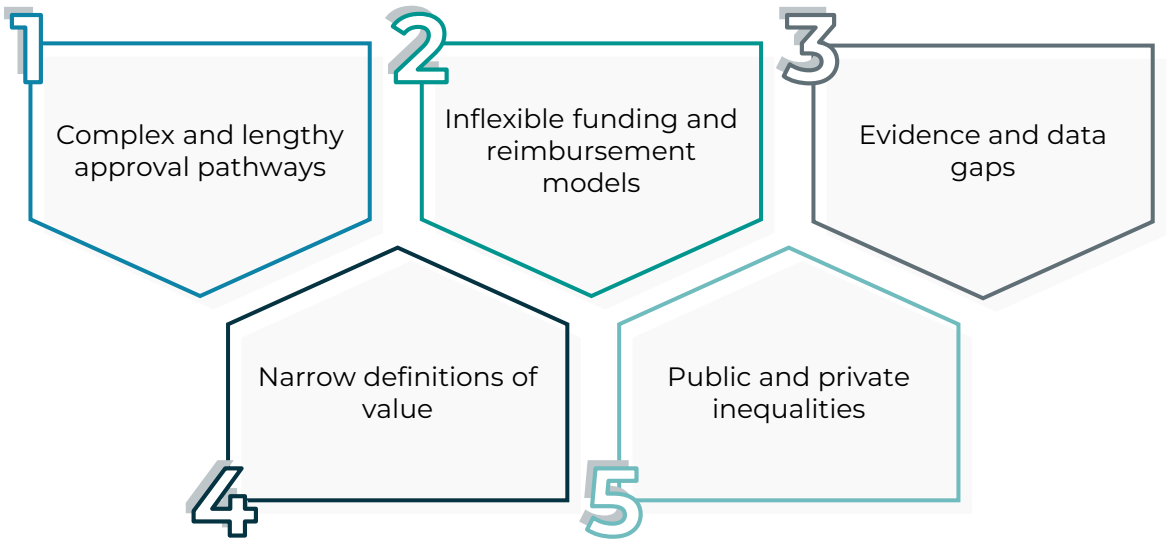
The roundtable was structured around one overarching question:

How can the health system be reimagined with speed to innovation as a core principle?

The discussion centred 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).

Australia's reimbursement and funding process for medical technologies is multi-layered and often slow, involving evaluation by the TGA for regulatory approval, and MSAC and, where applicable, MDHTAC for reimbursement (2-5). These processes often involve duplicate assessments of the same clinical evidence by multiple committees, causing inefficiencies in the reimbursement pathway and resulting in delayed patient access.

Despite Australia's commitment to providing best available healthcare and medical innovation, the current system for approving and funding new medical innovations remains overly complex, risk-averse and poorly aligned with the pace of technological advancement. These systemic inefficiencies create significant delays in patient access to potentially life-saving treatments, leading to broader consequences such as productivity loss and preventable disease progression. Five key barriers were identified, demonstrating the challenges faced by stakeholders within Australia's reimbursement and approval framework for medical innovations.



COMPLEX AND LENGTHY APPROVAL PATHWAYS

Reimbursement of innovative devices in Australia takes on average 4.7 years, as technologies must be assessed by the TGA, MSAC and MDHTAC. Multiple, overlapping evaluations of the same clinical data cause unnecessary delays. These inflexible and lengthy decision-making processes often result in missed opportunities for improving patient outcomes and healthcare system efficiency.

INFLEXIBLE FUNDING AND REIMBURSEMENT MODELS

Funding for medical devices in Australia is complex, involving contributions from the governments, private health insurance and patient out-of-pocket. Often, state governments are responsible for funding devices used in public hospitals. This fragmented approach can can create a misalignment of incentives that result in sub-optimal patient care.

EVIDENCE AND DATA GAPS

The current HTA process emphasises evidence from randomised controlled trials (RCTs) over real-world evidence (RWE). Yet, RWE is often more appropriate for evaluating improvements in devices, which can occur incrementally over time. This has implications for the cost-effectiveness evaluation of new medical devices, and ultimately their reimbursement.

NARROW DEFINITIONS OF VALUE

Australia's value frameworks focus almost exclusively on direct cost-effectiveness, neglecting factors important to patients, such as autonomy, independence and indirect societal benefits. This was recognised in the recent Health Technology Assessment Policy and Methods Review (the HTA Review), which recommended the development of an explicit qualitative values framework to capture value beyond cost-effectiveness, allowing more flexibility in the decision-making process.

INEQUALITIES BETWEEN PUBLIC AND PRIVATE SYSTEMS

The complex funding models for medical services and devices in Australia can create inequalities between the public and private systems. Patients in the public sector can sometimes get earlier access to innovative medical technologies than private patients, despite private patients paying a premium for their care. However, funding in the public sector can also be limited by artificially imposed caps to constrain total spending. These constraints are often applied at the hospital level, meaning access to treatment in the public system depends on where the patient lives. This can result in many patients missing out altogether.

GLOBAL BEST PRACTICE

Compared to countries like the United States and Germany, Australia's approach to funding innovative medical technologies is significantly slower and less flexible.

The Transitional Coverage for Emerging Technologies (TCET) in the United States and Germany's New Examination and Treatment Methods (NUB) pathway, offer faster, provisional access to new technologies while evidence is still being generated.

These pathways prioritise early patient access and real-world data collection, demonstrating that timely reimbursement and robust evaluation can coexist (15,16). Integrating provisional funding pathways and leveraging real-world evidence, can help to reduce delays, support innovation and ensure patients can access the latest, evidence-based medical technologies sooner.

RECOMMENDATIONS

Recommendations for reform were developed based on the priority areas identified by stakeholders at the roundtable. These were refined following consideration of health impact, feasibility, resource use, and acceptability.

	IMPORTANCE	TIMEFRAME
Recommendation 1: **Establish performance targets for reimbursement timelines** The Department of Health should establish measurable performance targets to monitor time to reimbursement following a positive MSAC recommendation.	★★★ Foundational	1 year
Recommendation 2: **Develop a priority review pathway through MSAC and MDHTAC that links to the TGA** The Department of Health should develop a priority review pathway, to enable devices that address a high clinical need to progress through the reimbursement process more rapidly.	★★★ Foundational	2+ years
Recommendation 3: **Develop a streamlined assessment pathway for MSAC and MDHTAC** The Department of Health should develop a streamlined assessment pathway for medical services and devices that must be assessed by MSAC and MDHTAC.	★★☆ Optimising	2+ years
Recommendation 4: **Develop a streamlined resubmission pathway to reduce time to recommendation** The Department of Health should develop more streamlined resubmission pathways for MSAC considerations, to enable submissions to more quickly and efficiently move forward to funding.	★★☆ Optimising	2+ years
Recommendation 5: **Develop a provisional funding mechanism for innovative medical technologies in the private sector** In collaboration with sponsors, private hospitals, and private health insurers, the Department of Health should develop a provisional funding mechanism for innovative medical technologies.	★★★ Foundational	1-2 years

	IMPORTANCE	TIMEFRAME
Recommendation 6: **Develop a provisional funding mechanism for innovative medical technologies in the public sector** Industry should collaborate to identify global best practice mechanisms for providing interim funding in the public sector, under the existing DRG mechanism.	★★★ Foundational	 1-2 years
Recommendation 7: **Prioritise consumer lived experience in decision making** MSAC guidelines should be updated to ensure that consumer lived experience is appropriately captured and valued in decision making.	★★★ Foundational	 1-2 years
Recommendation 8: **Develop a framework to improve clinical expert input into decision making** MDHTAC should update their guidelines to better allow for the inclusion of clinical expert opinion in decision making.	★★★ Foundational	 1-2 years
Recommendation 9: **Develop a comprehensive value framework** Industry, in collaboration with academia, patients and the broader community should develop a qualitative value framework including explicit guidelines and communications on the elements (beyond clinical effectiveness, cost-effectiveness and financial impact) considered in HTA.	★★☆ Optimising	 1-2 years
Recommendation 10: **Improve the use of real-world evidence in MSAC and MDHTAC decision making** Recommendations from the HTA Review regarding the use of real-world evidence in PBAC decision-making should be leveraged to improve the use of this evidence in MSAC and MDHTAC considerations.	★★★ Foundational	 1-2 years
Recommendation 11: **Monitor and publish progress towards MBS listing for recommended services** The Department of Health should establish a website which provides clear and transparent information on the status of new funding.	★★☆ Optimising	 <1 year

The Healthcare Leaders Series White Paper is an important contribution towards improving patient care. As a cardiologist, I see how delays in accessing innovative medical therapies can significantly impact patients' lives. We need a more streamlined, collaborative and patient-centred approach to reimbursement so that potentially life-saving treatments reach those who need them without unnecessary delays.

Professor Stephen Worthley,
Cardiologist

ABBREVIATIONS

ARTG
Australian Register of Therapeutic Goods

HTA
Health Technology Assessment

ICER
Incremental cost-effectiveness ratio

MBS
Medicare Benefits Schedule

MDHTAC
Medical Devices and Human Tissue Advisory Committee

MSAC
Medical Services Advisory Committee

NHRA
National Health Reform Agreement

PBAC
Pharmaceutical Benefits Advisory Committee

PBS
Pharmaceutical Benefits Scheme

RWE
Real-world evidence

PL
Prescribed List

TAVI
Transcatheter aortic valve implantation

SAVR
Surgical aortic valve replacement

TEER
Transcatheter edge-to-edge repair

TCET
Transitional Coverage for Emerging Technologies

TTVR
Transcatheter tricuspid valve replacement

TGA
Therapeutic Goods Administration

The Healthcare Leaders Series White Paper is a crucial initiative in rethinking how we approach the reimbursement of innovative medical technologies in Australia. As a cardiothoracic surgeon, I see firsthand how delayed access to cutting-edge treatments impacts patient care.

Our current reimbursement processes, while rigorous, often fail to keep pace with medical advancements, especially in structural heart disease. This White Paper highlights the need for a more dynamic and responsive HTA framework that recognises the unique challenges posed by medical devices compared to pharmaceuticals.

Importantly, we need a process that allows new innovations to be introduced with a 'coverage with evidence development' approach. This would enable access to promising technologies while simultaneously gathering real-world data to support long-term funding decisions. Integrating such a model into the HTA process would accelerate patient access to life-changing therapies while maintaining robust evaluation standards.

Professor Jayme Bennetts, Cardiothoracic surgeon

INTRODUCTION

PROBLEM STATEMENT

There is incredible advancement in technology leading to the production of new innovations in healthcare including novel medical devices, diagnostics and therapeutics. Yet healthcare reimbursement policies, processes and methods in Australia have not sufficiently recognised the full value of innovative medical technologies compared to the global best practices, limiting opportunities for faster patient access, improved patient outcomes and long-term cost savings. Currently, our conservative approach to innovation means that major advancements in technology often do not fit within existing assessment processes. As a result, healthcare systems are missing a significant opportunity to improve patients' lives by failing to fully realise the benefits of these innovations.

How can the health system be reimagined that has speed to innovation as a core principle?

A roundtable was held to foster a dialogue on how Australia's reimbursement system can be reimagined to prioritise speed in bringing medical innovations to market, enhancing patient outcomes and quality of life.

The roundtable aimed to improve access to medical devices and diagnostics, with a specific focus on medical devices used in the treatment of structural heart disease. 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).

The event brought together a diverse group of stakeholders, including representatives from the medical device, diagnostic, and pharmaceutical industries, private hospital operators, clinicians and clinical societies, patient advocates, and other subject matter experts. However, perspectives from payers, including private health insurers and government representatives, were not captured at this event.

There was strong consensus among participants on the importance of accelerating patient access to innovative medical technologies in Australia. Industry, patient, and clinical representatives emphasised the need to streamline access pathways while maintaining a strong focus on patient safety. Participants also acknowledged that the inclusion of payer perspectives may have introduced additional considerations, such as cost containment, budget sustainability, and management of clinical or economic uncertainty.

Participants were separated into breakout groups to discuss one of three key topics:

- Redefining values
- Innovative funding models
- Improving early patient access

Each roundtable group was tasked with identifying key barriers and enablers to access, and developing practical recommendations and a high-level roadmap aimed at accelerating access to innovative medical technologies in Australia (see Appendix).

In addition, desktop research was undertaken to explore international best practice reimbursement models for medical technologies.

Insights from both the roundtable discussions and secondary research have informed the development of this White Paper, which outlines a series of policy recommendations designed to enhance timely access to innovation and help shape future healthcare policy in Australia.

CURRENT REIMBURSEMENT AND FUNDING PROCESS

Australia's health system is a mix of public and private services and funding.

PUBLIC HEALTHCARE

Public healthcare in Australia includes **Medicare** and **public hospital services**. It is **jointly funded by the federal and state governments**, with the Commonwealth responsible for Medicare and contributing to public hospital funding, while states manage and fund the delivery of hospital care.

The National Health Reform Agreement (NHRA) outlines the shared funding responsibilities between state and territory governments. This system is designed to **ensure all Australians have access to free or low-cost medical services in the public hospital system**.

PRIVATE HEALTHCARE

Private healthcare refers to **services accessed as a private patient** in either public or private hospitals. It is **funded through a combination of Medicare rebates, private health insurance, and out-of-pocket payments** by patients. While Medicare covers a portion of the cost for medical services (typically 75% of the MBS fee for inpatient care), other expenses such as hospital accommodation and theatre fees are not covered and must be paid through insurance or directly by the patient. Private healthcare **enables choice** of doctor, **access to private facilities**, and often **faster treatment times**.

For a medical device or service to be reimbursed in Australia, it must go through several clinical and economic assessments, often involving substantial duplication in the information evaluated.

Firstly, medical devices must be approved by the Therapeutic Goods Administration (TGA) Australia's government authority on the **regulation of medicines, medical devices and biologicals.** The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are **safe and fit for their intended purpose,** focusing on the safety, quality and performance of medical technologies.

Once a product is listed on the Australian Register of Therapeutic Goods (ARTG) it can be legally supplied in Australia. For private patients to gain access to innovative medical technologies, further assessment by MSAC and MDHTAC is often required.

MSAC is an independent, expert, non-statutory committee that appraises medical services and technologies proposed for public funding and provides advice to the Government on whether a medical service or technology should be publicly funded via the Medicare Benefits Schedule (MBS). MSAC evaluates the **comparative efficacy, safety and cost-effectiveness of new medical devices or services.**

The Prescribed List (PL) is a list of implantable medical devices and technologies that are funded through private health insurance. It includes things like pacemakers, joint replacements, and heart valves. In order to be reimbursed by private health insurers, devices need to be added to the PL through a separate application. The PL specifies the **benefits private health insurers must pay for specific medical devices or human tissue products** and is updated through recommendations made on evaluation of applications by MDHTAC. This process can be completed simultaneously to MSAC evaluation and involves evaluation of similar evidence to establish the **cost-effectiveness of new medical devices.**

For patients treated in public hospitals, access to innovative medical technologies may be possible following the product being listed on the ARTG, as no consideration by MSAC or MDHTAC is required for funding. In some cases, this may mean that public patients gain access to innovative technologies sooner than private patients, despite private patients paying a premium for their medical care.

However, in some instances, new medical devices may still need to prove their cost-effectiveness and value at the individual hospital level in the public sector, to ensure they are adopted into a hospital's budget and procurement process. This can occur even if a new technology has been found to be cost-effective by MSAC, as no consistent national approach to public hospital procurement or funding is available. This results in additional duplication of effort and increased complexity in securing reimbursement.

Combined, the total process from initial application for registration in Australia to eventual subsidised availability to patients can take years. During this time, patients lose out on access to new and innovative technologies that improve quality of life and increase survival. In the interim, technology evolves, and newly reimbursed devices may become outdated, resulting in a continuous cycle of catch-up to provide best quality care to Australians.

Procurement and funding processes between state jurisdictions can vary greatly. As an example of the complexity of this process, information on the New South Wales (NSW) public health system can be found in the NSW Health "New Health Technologies and Specialised Services" guideline (1). **New technology may need to be assessed and approved at multiple levels**; locally, within a network, or at the state level. At each level, there are specific requirements, committees and timelines. These processes may lead to delays, an increased administrative burden, and variability in access to new technologies across public hospitals.

	TGA	MSAC	MDHTAC
Role	Ensuring that therapeutic goods available for supply are safe and fit for their intended purpose, and that the benefits to the patient outweigh the risks (4,5).	Advise whether a medical service or health technology should be publicly funded (3).	Advise on the suitability of medical devices and human tissues products for listing on the PL and their associated benefits (2).
Assess safety of medical devices	✓	✓	✓
Assess efficacy of medical devices	✓	✓	✓
Assess cost-effectiveness of medical devices	×	✓	✓
Type of evidence required	Non-comparative	Comparative	Comparative
Timelines for approval [a]	Statutory timeline of 255 'TGA business days' Actual average 131 'TGA business days'	Average 3.4 years (2016-2022)[a] (6)	24 weeks
Overall timeline for approval	When combining the processes from initial regulatory approval through to reimbursement and access, it can take over 1,700 calendar days (approximately 4.7 years)		

Note: a, Timelines reflect the average reported process length, which may be substantially greater for individual innovative devices. TGA business days is a defined term and may exclude 'stoppages' which would lengthen the process. Timelines for MSAC/MBS listing reflect timelines for in-vitro diagnostics only; timelines for therapeutic applications not available.

The Healthcare Leaders Series White Paper highlights a critical need to modernise how we approach the reimbursement of innovative medical technologies in Australia. As a representative of Catholic Health Australia and the private hospital sector, I see firsthand how outdated and fragmented reimbursement processes can delay access to life-saving treatments for patients.

Private hospitals are uniquely positioned to adopt new technologies, but current pathways slow down implementation and increase costs. Streamlining processes and reducing duplication between regulatory and reimbursement bodies would not only improve efficiency but also ensure that private patients benefit from the latest advancements as quickly as possible.

To truly make a difference, government policy must recognise the distinct challenges faced by private healthcare providers and work towards more coordinated, flexible, and timely approval processes. This will help ensure that private hospitals can continue to deliver cutting-edge care that meets the evolving needs of our communities.

Dr Katharine Bassett, Catholic Health Australia

SYSTEMIC BARRIERS TO DEVICE FUNDING IN AUSTRALIA

The adoption of innovative medical technologies is important for maintaining and improving healthcare delivery. It is essential for a health system to be efficient and responsive to the changing needs of its population. Research by the Productivity Commission has found that Australia's health system has experienced robust productivity growth in recent years, driven by quality improvements rather than cost reductions (7), demonstrating the importance of incorporating innovation into the health system rather than focusing on cost savings.

Australia's reimbursement processes for innovative technologies are seen by industry stakeholders as slow, rigid and too focused on short-term outcomes.

This creates systemic barriers that not only impact patients' access to new technologies but also undermine the potential to improve patient outcomes and long-term health system savings. Medical devices face unique challenges compared to pharmaceuticals, owing to different evidence requirements at a regulatory level, changes in device characteristics over time, variation in clinical practice and experience of the implanting physicians, and a complex funding system with multiple payers.

DUPLICATION OF WORK WITHIN THE ASSESSMENT PROCESS

The process for determining access and reimbursement for medical technologies in Australia involves several mechanisms including regulatory evaluation by TGA, reimbursement evaluation by MSAC and for some devices by MDHTAC. These processes can occur sequentially but may consider similar sources of clinical evidence, increasing time to reimbursement while replication of data evaluation occurs.

The evolution of medical devices, including in the structural heart disease space, often means that by the time the evaluation process is complete, **the technology has undergone design changes which complicate the reimbursement decision.** Such design advances are often the result of clinician feedback and may improve usability and safety of the device. However, these innovations are often overlooked by the reimbursement system as it tends to treat all products within a category as equivalent regardless of their clinical or technological progress.

Example: Surgical heart valves where **newer models are often reimbursed at the same rate as valves developed decades ago**. This issue is unique to the medical devices space as opposed to the pharmaceutical industry, discouraging innovation and failing to recognise the additional value of modern technologies for patients. Future reform initiatives need to consider the value of innovation for newer generation technologies.

These inflexible and lengthy decision-making processes often result in missed opportunities for improving patient outcomes and healthcare system efficiency. In delaying patient access to new technologies, the healthcare system overlooks long-term clinical value in favour of short-term financial goals.

FUNDING MODELS

Once a service has been added to the MBS and the corresponding device has been listed on the PL, the federal government and third parties such as private health insurers must fund the procedure, with no mechanism to limit utilisation. In contrast, funding in the public sector is determined on a case-by-case basis at a hospital or state level.

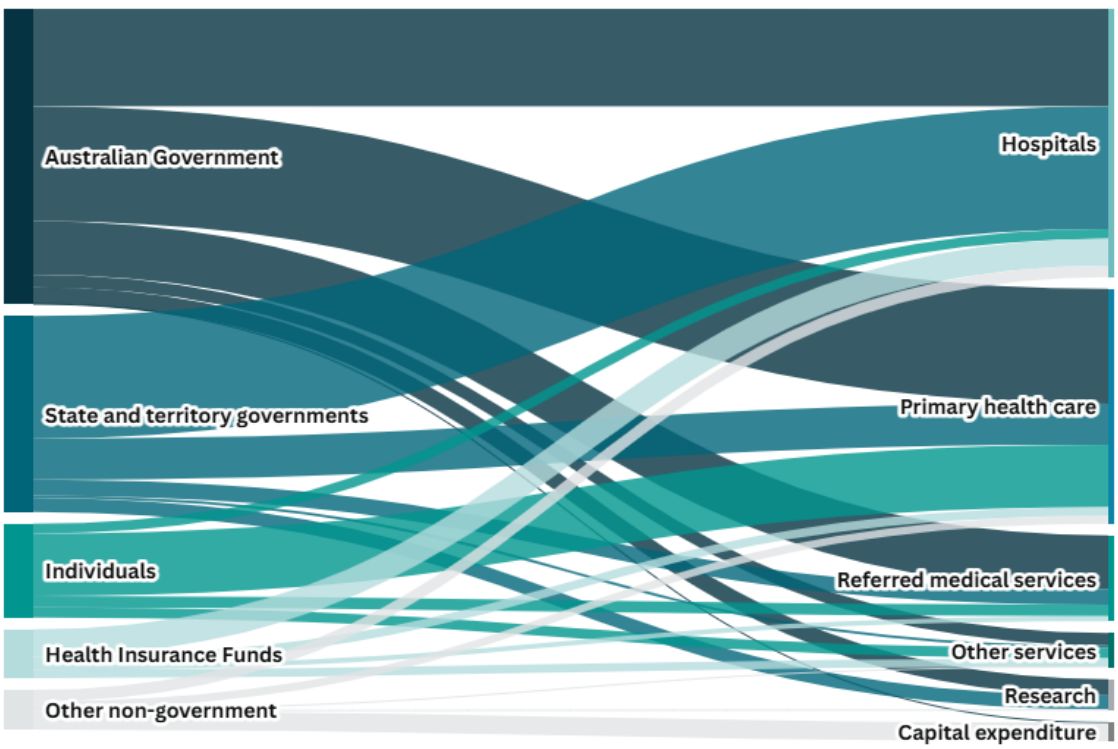
State governments can also limit utilisation of procedures by imposing specific caps. These caps may be based on budgets, workforce capacity or cost containment goals which can result in waitlists or delayed adoption of new technologies even after regulatory approval. This creates inequitable device funding as public patients may not be able to access clinically approved devices due to the caps imposed.

Differences in funding models between public and private patients create disparities in access, where public patients may get earlier access to a procedure despite premiums that private patients pay for care, or in contrast, private patients may have subsidised access with no similar support for public patients. This means that, depending on the funding model, one group may get access to a treatment sooner or at a lower cost, while the other may face delays or out-of-pocket expenses, and cost shifting between the systems may occur.

The Australian Government is the largest contributor to health expenditure, providing $105.8 billion (43.9%), followed by state and territory governments with $70.2 billion (29.1%). Individuals contribute $33.7 billion (14.0%), health insurance funds $17.5 billion (7.3%) and non-government sources $14.2 billion (5.87%) (8).

Notably, the consumer portion of health expenditure is increasing, reflecting a growing reliance on out-of-pocket contributions. This trend is likely to continue if funding does not keep pace with the speed of medical innovation, causing some patients to miss out and creating systemic equity issues.

Broad health spending flows, 2021-22



Note: adapted from AIHW Health Expenditure Australia 2021-22 (8)

CASE STUDY: TAVI UPTAKE IN AUSTRALIA

Transcatheter aortic valve implantation (TAVI) is a procedure used to treat aortic stenosis, the most common form of valvular heart disease. Historically, surgical aortic valve replacement (SAVR) was the only effective treatment however many patients are unable or unwilling to receive this treatment due to its invasive nature. TAVI is a less invasive treatment option, which has been shown to be safe, clinically effective and cost-effective. While TAVI valves are more expensive that SAVR valves, the overall cost associated with TAVI is lower due to the less invasive nature of the procedure and shorter hospital stays.

In the public sector, access to TAVI is often constrained by economic factors, as demand exceeds available funding for TAVI valves. This creates artificial barriers to access for this safe and effective therapy. While TAVI is expected to be cost saving due to the reduction in length of hospital stay, in the public sector these savings are often theoretical, as state governments continue to pay for the bed regardless of length of stay. Due to these limitations, it has been estimated that almost 1,500 patients per year are missing out on TAVI in the public sector (9), creating a significant equity issue.

Table 1: Time to reimbursement for medication innovations in Australia and other countries

Country	Regulatory approval	Reimbursement available	Time from approval to reimbursement
Australia	2013	2017	~ 4 years
Germany	2007	2007	< 1 year
United States	2011	2012	~1 years
United Kingdom	2007	2008-2009	1-2 years

The difference in timelines for reimbursed access to TAVI in Australia compared to other countries is significant (10-12). While TAVI received regulatory approval between 2007-2013, Australia stands out as the only country where it took approximately five years from regulatory approval to reimbursement.

This significant delay highlights a broader systemic issue in Australia's HTA and reimbursement pathway, particularly the extended timelines associated with MSAC processes. These prolonged assessments not only impact patient access to cost-effective technologies but also add more burden on clinicians and health services managing patients with limited treatment options.

Additionally, current funding models can create a misalignment of incentives that result in sub-optimal patient care. The current model of activity-based funding means that each episode of admitted patient care is funded at a set level (determined by the relevant DRG), regardless of the cost of administering care.

This can create a scenario where more expensive procedures are not performed if they are not reimbursed adequately under the DRG. Furthermore, there are limited incentives to deliver care that reduces long-term health resource utilisation such as hospitalisation, as each episode of care is funded separately.

EVIDENCE GENERATION

In addition to issues around the timeliness and potential duplication of evaluation, the MSAC and MDHTAC are considered by stakeholders to be overly conservative in their evaluations, prioritising short-term costs and effects over longer-term benefits to patients and the health system. Generating clinical data on the long-term effectiveness of an innovative device is a lengthy process, and requirements for such evidence often mean that long-term benefits are excluded from consideration. The delay in gathering long-term data results in the undervaluation of innovative technologies and reduces the chance of timely reimbursement.

Evidence development for new technologies is often a challenge as it is expensive and time intensive, requiring clinicians to dedicate time and resources, often without financial compensation. Patients may also be reluctant to provide their data, especially when they perceive little immediate benefits.

Many devices involve incremental changes in design and function, as well as variability in clinical application. This results in difficulties in establishing standardised trial parameters, making it harder to conduct randomised controlled trials (RCTs) that would meet the approval criteria. This has implications for the cost-effectiveness evaluation of new medical devices, and ultimately their reimbursement. Additionally, when novel devices undergo changes throughout a clinical trial program, committees may require a minimum number of cases for each generation of the device to be funded. Clinicians felt that this delayed access to newer, safer and more effective devices. Placing a greater emphasis on expert clinical advice when considering new generations of proven medical devices was seen as an opportunity to improve speed to access for patients.

To supplement clinical trial data, real-world evidence (RWE) is becoming an increasingly important tool for evaluating the effectiveness of innovative technologies. RWE is particularly applicable to new medical devices where RCTs are difficult to conduct due to recruitment feasibility, cost, or ethical considerations regarding randomising patients to a surgical procedure. RWE provides valuable information on the utility of a device outside of a controlled setting and can help inform the evaluation on applicability to an Australian setting.

One approach to integrating RWE is to establish a framework that fully utilises RWE within the HTA processes. Instead of using RWE as supplementary information, the framework emphasises the true value of RWE allowing it to fast-track evaluation for technologies that are already in use in other countries or have proven evidence in the real-world setting. The framework should provide clear guidelines on data quality, sources and methodologies when utilising RWE. RWE could be integrated into early evaluations to assess the potential impact of a medical device in real-world scenarios, or serve as an ongoing, post-market monitoring tool for new technologies.

NARROW DEFINITION OF VALUE

Australia's HTA committees are required to consider cost-effectiveness when making recommendations for new medical services, devices or drugs to be reimbursed. While this process ensures value for money for the taxpayer, it can result in an overly narrow consideration of value, where only direct costs to the patient and health system are included in the analysis. This ignores elements of value that are important to patients and their families, such as autonomy in decision making, independence, and social impacts. This was recognised in the recent Health Technology Assessment Policy and Methods Review (the HTA Review), which recommended the development of an explicit qualitative values framework to capture value beyond cost-effectiveness, allowing more flexibility in the decision-making process.

CASE STUDY: TRANSCATHETER MITRAL VALVE REPAIR

Mitral regurgitation (MR) is prevalent in over 10% of people aged 75 and older. Transcatheter edge-to-edge repair (TEER) is one of the most common structural heart interventions worldwide and is recommended for the treatment of patients with primary MR at high risk for surgery or with secondary MR and persistent symptoms despite optimal medical management.

TEER is also used to treat mitral valve damage caused by rheumatic heart disease, which is more prevalent in First Nations people. Of the 7,192 people recorded with RHD in 2023, 79% were First Nations people (21). This highlights a significant health need.

MitraClip (a device used in TEER) was first recommended by MSAC in 2020, with the process from application to listing taking approximately 10 years.

Following the MBS listing of MitraClip, a new device called PASCAL was submitted for MSAC consideration.

PASCAL TEER required three submissions to MSAC to receive a positive recommendation in primary MR.

Direct RCT evidence demonstrating non-inferiority between PASCAL and MitraClip was presented to MSAC in November 2022, however this evidence was not considered sufficient for recommendation, despite the TEER procedure already having been shown to be cost-effective (13). A device-agnostic listing for TEER was recommended by MSAC in early 2024. The process to update the devices available on the PL took an additional 12 months. This severely limits access and choice for private patients with MR.

CASE STUDY: GENE EXPRESSION PROFILING IN EARLY BREAST CANCER

Breast cancer is the second most common cancer in Australia, with over 15,000 people diagnosed each year. Standard of care for early breast cancer includes surgery followed by adjuvant treatment to reduce risk of recurrence.

Gene expression profiling (GEP) can be used to estimate the likely future risk of recurrence, and in some cases predict which patients can safely avoid chemotherapy. In addition to supporting treatment decisions, GEP tests can provide information to patients which reduces their worry about disease progression or recurrence, a value which would not be captured in current considerations. The option to use GEP in early breast cancer appeared in National Comprehensive Cancer Network guidelines as early as 2008 (14).

Multiple GEP tests for early breast cancer have been developed. Collectively, these tests submitted over 12 MSAC applications over a period of 10 years before a positive MSAC recommendation and MBS listing was achieved in 2022-23, **more than 10 years after these tests were first included in international guidelines.**

In their considerations of these tests, MSAC noted that tests were being routinely used in practice to guide clinical care and that this created equity of access issues as patients were required to pay out of pocket.

Delays in access to GEP testing likely impacted thousands of patients, leading many to undergo avoidable chemotherapy, worry unnecessarily and pay high out of pocket costs for testing.

GLOBAL BEST PRACTICE

Australia frequently lags behind other jurisdictions in providing reimbursed access to innovative medical technologies. In cases such as TAVI and TEER this leads to patients experiencing unnecessary deterioration of health, worsening symptoms, and increased reliance on the health system. For access to genetic and genomic tests, this means patients may miss out on access to effective treatments or receive treatments that are not necessary or beneficial.

This leads to an increased burden on the health system, which could be alleviated with better and faster access to innovative technologies, which are often already available and in routine use overseas.

When comparing Australia's approach to the reimbursement and adoption of innovative medical technologies to global best practices, there are significant opportunities to streamline processes and enhance patients' access. Germany and the United States have established more flexible pathways for accessing new medical technologies.

UNITED STATES

The Transitional Coverage for Emerging Technologies (TCET) pathway in the United States offers a fast-track mechanism for FDA-designated Breakthrough Devices (15). This enables manufacturers to engage with the Centres for Medicare and Medicaid Services (CMS) early in the approval process, prior to FDA marketing authorisation. The CMS also works with manufacturers to identify evidence gaps and suggest study designs to address these gaps, which is then used to develop an evidence development plan (EDP).

The goal is to finalise a national coverage determination (NCD) for the device **within 6 months of FDA approval**. This process ensures faster Medicare coverage for innovative technologies, facilitating timely patient access while allowing for ongoing evidence collection.

The TCET pathway **facilitates faster access to innovative technologies**, ensuring that patients can benefit from new medical technologies without unnecessary delays. By offering temporary reimbursement, it alleviates the financial burden on healthcare providers and patients as technologies are often expensive and untested in real-world setting.

The pathway also acknowledges the time required to gather sufficient evidence to address any gaps identified in the evidence preview. Therefore, most coverage under a

TCET NCD can last for approximately five or more years to ensure the data collected is of high quality and provides a clearer and more accurate basis for long-term coverage decisions.

GERMANY

The New Examination and Treatment Methods (NUB) procedure in Germany allows the rapid adoption of new medical devices (16). This is designed to **allow hospitals to request additional reimbursement** for cost-intensive, innovative medical technologies that are used in addition to those covered under the DRG system.

Under the NUB procedure, hospitals can request for reimbursement of new technologies through temporary extrabudgetary payment. Once the payment has been approved, hospitals can enter negotiations with healthcare payers to secure temporary reimbursement until the technology gathers sufficient clinical evidence to justify the inclusion in the standard DRG system.

This procedure allows faster access to new technologies, **allowing hospitals to incorporate innovative devices into clinical practice** before they are fully included in the standard reimbursement system.

Temporary reimbursement support also **allows clinical evidence to be generated during real-world use**. This helps reduce financial barriers for hospitals and patients and enables gradual integration of these new technologies into the healthcare system without being burdened by high upfront costs. However, the approval rate for technologies under the NUB process remains relatively low, only 29% (288/981) of technologies receiving approval for funding negotiation in 2023 (16).

In addition to NUB, **the Digital Health Application (DiGA) programme** was introduced in Germany in 2019 to expedite the adoption of digital health solutions.

According to the DiGA guide, the programme allows manufacturers to apply for provisional listing of digital health applications based on preliminary evidence (17).

Once listed, manufacturers have a 12-month period to provide high quality evidence demonstrating clinical effectiveness and cost-effectiveness of the device. The programme ensures that products with strong clinical outcomes continue to receive reimbursement, supporting both the adoption of innovative solutions and the maintenance of high standards in clinical practice.

The Healthcare Leaders Series White Paper is a timely and important contribution to the policy conversation about improving access to innovative medical technologies in Australia as the Government considers the HTA Review recommendations. As someone engaged in health policy and market access, I see firsthand how our current reimbursement frameworks can be slow and overly complex, often hindering timely patient access to new treatments.

One of the key insights from this White Paper is the need to streamline processes across different regulatory and reimbursement bodies, such as the TGA, MSAC and MDHTAC. By reducing duplication and improving coordination between these bodies, we can significantly cut down the time it takes for new medical technologies to become available to patients.

Government policy must focus on creating a more integrated and efficient pathway for medical innovation, allowing patients to benefit from advancements sooner while maintaining robust evaluation standards. Addressing these systemic inefficiencies is essential for fostering a more dynamic and patient-centred healthcare system.

Brendan Shaw, Shawview Consulting

	AUSTRALIA	 UNITED STATES	 GERMANY
Key pathways for new medical technologies	Through submitting an MSAC and/or PL application	Transitional Coverage for Emerging Technologies for FDA Breakthrough Devices	NUB for temporary reimbursement until inclusion in G-DRG system
Timeframe for approval and/or reimbursement decision	On average **3.4 years** for MSAC to review and to be listed on MBS	**6 months** post-FDA approval	Around **4 months** (applications submitted in October, outcomes informed in January)
Temporary coverage	✘	✓	✓
Reimbursement flexibility	✘	✓	✓
Flexibility for evidence generation	✘	✓	✓
Post-market data collection	Often required for devices	Ongoing evidence generation	Extensive post-market data collection required

CASE STUDY: EVOQUE TRICUSPID VALVE REPLACEMENT SYSTEM

Tricuspid regurgitation (TR) is a common yet underdiagnosed condition, which can lead to significant morbidity. Traditionally, surgical intervention for TR has been challenging due to high surgical risk in many patients.

The EVOQUE system is a transcatheter heart valve designed for patients with severe tricuspid regurgitation, offering a minimally invasive solution. The device is designed to be implanted using a catheter-based approach, avoiding the need for open surgery. The system is engineered for better durability and a lower risk of complications.

A formal request for the EVOQUE system was submitted in June 2024. In March 2025, the Centres for Medicare & Medicaid Services (CMS) agreed to cover transcatheter tricuspid valve replacement (TTVR) for the treatment of symptomatic tricuspid regurgitation (TR) under Coverage with Evidence Development (CED) (18).

CMS highlighted the potential of TTVR but there is limited evidence reporting reductions in mortality or hospitalisation versus best practice. There are also no clear outcomes from subgroup analysis and limited data on how facilities may affect outcomes. CED requires outcome monitoring and evidence generation to inform future National Coverage Determination (NCD) policies.

REFORMS TO ACCELERATE ACCESS

Delays in reimbursement can lead to missed opportunities for improving patient outcomes especially when treating structural heart diseases. Discussions at the roundtable highlighted key issues impacting faster access to medical innovation in Australia, including substantial duplication of work which lengthens the HTA process, inflexible funding models that do not incentivise optimal patient care, strict evidence generation requirements, and a narrow definition of value that limits what is considered by decision makers.

It is essential to reform the reimbursement processes to ensure patients benefit from the most appropriate and latest medical technologies.

Recommendations for reform were developed based on the priority areas identified by stakeholders at the roundtable. These were refined following consideration of health impact, feasibility, resource use, and acceptability.

	IMPORTANCE	TIMEFRAME
Recommendation 1: **Establish performance targets for reimbursement timelines**	★★★ Foundational	1 year
Recommendation 2: **Develop a priority review pathway through MSAC and MDHTAC that links to the TGA**	★★★ Foundational	2+ years
Recommendation 3: **Develop a streamlined assessment pathway for MSAC and MDHTAC**	★★☆ Optimising	2+ years
Recommendation 4: **Develop a streamlined resubmission pathway to reduce time to recommendation**	★★☆ Optimising	2+ years
Recommendation 5: **Develop a provisional funding mechanism for innovative medical technologies in the private sector**	★★★ Foundational	1-2 years

	IMPORTANCE	TIMEFRAME
Recommendation 6: Develop a provisional funding mechanism for innovative medical technologies in the public sector	★★★ Foundational	1-2 years
Recommendation 7: Prioritise consumer lived experience in decision making	★★★ Foundational	1-2 years
Recommendation 8: Develop a framework to improve clinical expert input into decision making	★★★ Foundational	1-2 years
Recommendation 9: Develop a comprehensive value framework	★★☆ Optimising	1-2 years
Recommendation 10: Improve the use of real-world evidence in MSAC and MDHTAC decision making	★★★ Foundational	1-2 years
Recommendation 11: Monitor and publish progress towards MBS listing for recommended services	★★☆ Optimising	<1 year

STREAMLINE PROCESSES FOR INNOVATIVE TECHNOLOGIES

Timely access to innovative medical technologies in Australia depends on navigating multiple layers of assessment, a process that must be streamlined to ensure all patients benefit from the latest advancements without unnecessary delay. Innovative devices face significant challenges to obtaining reimbursement, particularly when long-term follow up outcomes are required.

Recommendation 1: Establish performance targets for reimbursement timelines

The Department of Health should establish measurable performance targets to monitor time to reimbursement following TGA approval.

The HTA Review recommended that over 90% of drug products should be PBS listed within 6 months of ARTG listing, if the product has demonstrated superiority. A similar performance target should be established for MBS listing of new medical services, where the evidence demonstrates that the procedure has a significant health improvement.

To support this proposal, industry should collaborate to develop a robust policy and process proposal, covering proposed performance targets and potential mechanisms for achieving this goal.

Recommendation 2: Develop a priority review pathway through MSAC and MDHTAC

The Department of Health should develop a priority review pathway, to enable devices that address a high clinical need to progress through the reimbursement process more rapidly.

A priority review pathway was made available by the TGA in 2018 to expedite the assessment of certain medical devices giving applicants front-of-queue priority through the assessment process. Despite this recognition of importance from the TGA, there is no corresponding mechanism to support devices through the reimbursement process, meaning that the time taken for patients to have access to these innovative technologies is still substantial. The priority review pathway should also be linked to a priority funding pathway to accelerate time to MBS listing. This mechanism could include 'bridging funding' as proposed in the HTA Review.

Recommendation 3: Develop a streamlined assessment pathway for MSAC and MDHTAC

The Department of Health should develop a streamlined assessment pathway for medical services and devices that must be assessed by MSAC and MDHTAC.

The HTA Review has recommended the development of a unified pathway that would further integrate assessments across pharmaceuticals, medical devices or technologies. This would reduce duplication and improve efficiency throughout the HTA process. Given that the cost of innovative medical devices is already included in the cost-effectiveness evaluations considered by MSAC, a streamlined assessment pathway where only one evaluation is required should be developed.

Recommendation 4: Develop a streamlined resubmission pathway to reduce time to recommendation

The Department of Health should develop more streamlined resubmission pathways for MSAC considerations, to enable submissions to more quickly and efficiently move forward to funding.

When an application is not recommended by MSAC, applicants who wish to resubmit must wait for the release of the MSAC meeting minutes and prepare a new assessment report, which results in delays of at least 12 months before the application can be reconsidered by MSAC. Rapid resubmission pathways established for the PBAC (such as Early Resolution and Early Re-entry) allow companies with high value products to gain access to dedicated, streamlined pathways to address specific reimbursement-related issues, reducing the time to reconsideration to as little as 2 months.

CONSIDER ALTERNATIVE FUNDING MECHANISMS

Stakeholders considered that a key limitation of current funding models for medical devices is that they are not considered flexible enough and do not allow for ongoing collection of data over time. Medical devices have unique characteristics which make conducting such trials difficult. RCT evidence should be supplemented by additional real-world data collection, which can be ongoing as the device evolves over time. As additional data becomes available, the funding level for products can change to appropriately reflect the value of the innovation.

Recommendation 5: Develop a provisional funding mechanism for innovative medical technologies in the private sector

In collaboration with sponsors, private hospitals, and private health insurers, the Department of Health should develop a provisional funding mechanism for innovative medical technologies.

Industry should collaborate to conduct a comprehensive landscape review of global provisional funding mechanisms, to develop a policy proposal for how this could be translated to the Australian landscape.

Risk-sharing agreements and provisional funding mechanisms that allow coverage with evidence development would encourage innovation by allowing manufacturers and healthcare providers to share the financial risk associated with new technologies. If a new treatment does not deliver the expected outcomes, the manufacturer or provider may carry some of the financial risk; if the treatment is highly effective, the rewards would be shared. This creates a mutually beneficial relationship that supports the development and adoption of new technologies that offer substantial long-term benefits to patients. These mechanisms should be co-developed alongside industry, providers and funders to ensure that risks are appropriately shared between stakeholders.

Managed entry arrangements were formally introduced for the PBS in 2011. However, these have historically been underused due to perceptions of administrative burden and a lower starting price, which places significant risk on the Sponsor. The HTA Review recommended the existing MEA framework for medicines be revised to address these limitations. Ongoing work as part of the HTA Review implementation should be leveraged to develop a similar program for innovative medical devices.

Recommendation 6: Develop a provisional funding mechanism for innovative medical technologies in the public sector

Industry should collaborate to identify global best practice mechanisms for providing interim funding in the public sector, under the existing DRG mechanism.

A provisional, flexible funding mechanism is also needed for public hospital services. Under the current system, reimbursement for public hospitals is based on the relevant AR-DRG and the associated costs per admission from previous years. The cost of innovative medical devices can take years to 'flow through' the system, meaning that public hospitals are often under-funded when providing these newer medical services.

While TAVI devices were first approved by the TGA in 2013 and recommended for reimbursement by MSAC in 2017, a DRG accurately reflecting the cost for TAVI was not available for public hospital funding until 2023-24. This meant that for the decade after TAVI was first approved by the TGA, public hospitals were unable to access appropriate funding to conduct the procedure, severely restricting patient access. Processes such as the NUB procedure used in Germany would allow hospitals to request additional funding under the DRG system, while additional evidence is being generated.

INCORPORATE CLINICIAN AND PATIENT INPUT

Clinician stakeholders at the roundtable expressed that their expert input was often undervalued compared to the stringent evidence requirements specified in guidelines, particularly for listing of devices on the PL. Additionally, patients have unique and important perspectives on the value of medical innovations and the benefit that new technologies may bring to their lives. The recent HTA Review identified the importance of consumer feedback in HTA, however noted that stakeholders were unclear how their input was being used in the evaluation and decision-making process, and that consultation was not occurring early enough.

Recommendation 7: Prioritise consumer lived experience in decision making

MSAC guidelines should be updated to ensure that consumer lived experience is appropriately captured and valued in decision making.

The recent publication of 'Enhance HTA: An Enhanced Consumer Engagement Process in Australian Health Technology Assessment: A Report of Recommendations' supports this. In the report, the Co-design Working Group (CWG) for the Enhanced Consumer Engagement Process proposed more transparent communication and timely notifications to enhance clarity of HTA processes and enable timely consumer engagement (recommendation 1), elevate of consumer evidence and input in HTA deliberations and decision-making (recommendation 5), and establish guidance to enable early and continuous collaboration between stakeholders (recommendation 6). Although the report focuses on the PBAC process, the CWG developed its recommendations with potential adaptation to other HTA committees like MSAC (20).

Leveraging the ongoing work to increase consumer engagement in HTA, industry should work with patient organisations and academia to develop a robust proposal for how patient lived experience can be considered by MSAC.

Recommendation 8: Develop a framework to improve clinical expert input into decision making

MDHTAC should update their guidelines to better allow for the inclusion of clinical expert opinion in decision making.

As medical devices undergo incremental change, newer generations of a device may be required to undergo comprehensive clinical and cost-effectiveness evaluations, even when the device has already been found to have a positive risk-benefit profile by the TGA, and MSAC have already considered the procedure to be cost-effective. Clinicians felt that the guidelines for MDHTAC focused too heavily on in-human clinical evidence and did not leave sufficient scope for their expertise when new devices become available. A framework should be developed to determine when iterative device changes are sufficient to require a full review of updated clinical evidence or when clinical expert opinion on the changes is acceptable, particularly in cases where no price premium is being proposed.

Recommendation 9: Develop a comprehensive value framework

Industry, in collaboration with academia, patients and the broader community should develop a qualitative value framework including explicit guidelines and communications on the elements (beyond clinical effectiveness, cost-effectiveness and financial impact) considered in HTA.

Patients and their advocates, as well as medical device and diagnostics manufacturers should be involved in the process of developing this framework, to ensure that multiple perspectives on value are considered. The value framework should be sufficiently broad to encompass the unique characteristics of medicines, medical devices and diagnostic technologies.

This process should leverage an ongoing proposal to develop a similar framework as part of the HTA Review.

DEVELOP METHODS FOR ANALYSING AND INCORPORATING REAL-WORLD EVIDENCE

Recommendation 10: Improve the use of real-world evidence in MSAC and MDHTAC decision making

The HTA Review considered the topic of real-world evidence, noting its increasing importance in the consideration of novel health technologies. The review made specific recommendations relating to the collection and governance of real-world data (recommendations 27-29). Additionally, the review recommended the development of methods for using real-world data, including identifying how real-world data can best resolve uncertainty in health technology assessment (recommendations 30 and 31). These recommendations should not be specific to PBAC considerations and would apply to both MSAC and MDHTAC as well. Internationally, both the FDA and NICE have guidance on the use of real-world evidence which could be leveraged to ensure alignment global best practices.

IMPROVE TRANSPARENCY

When new medical services are recommended by the MSAC, a policy team responsible for the relevant funding program then progresses the advice. The steps to develop a new MBS item include further stakeholder consultation, consideration of the financial impact, and implementation advice for the new service. Funding for new MBS items may also require a budget proposal which can be influenced by government policies and the budget cycle. According to the Commonwealth Budget Guideline, if the budget impact costs more than $20 million per year, it is required to undergo additional step of review via the Expenditure Review Committee for consideration (19).

Recommendation 11: Monitor and publish progress towards MBS listing for recommended services

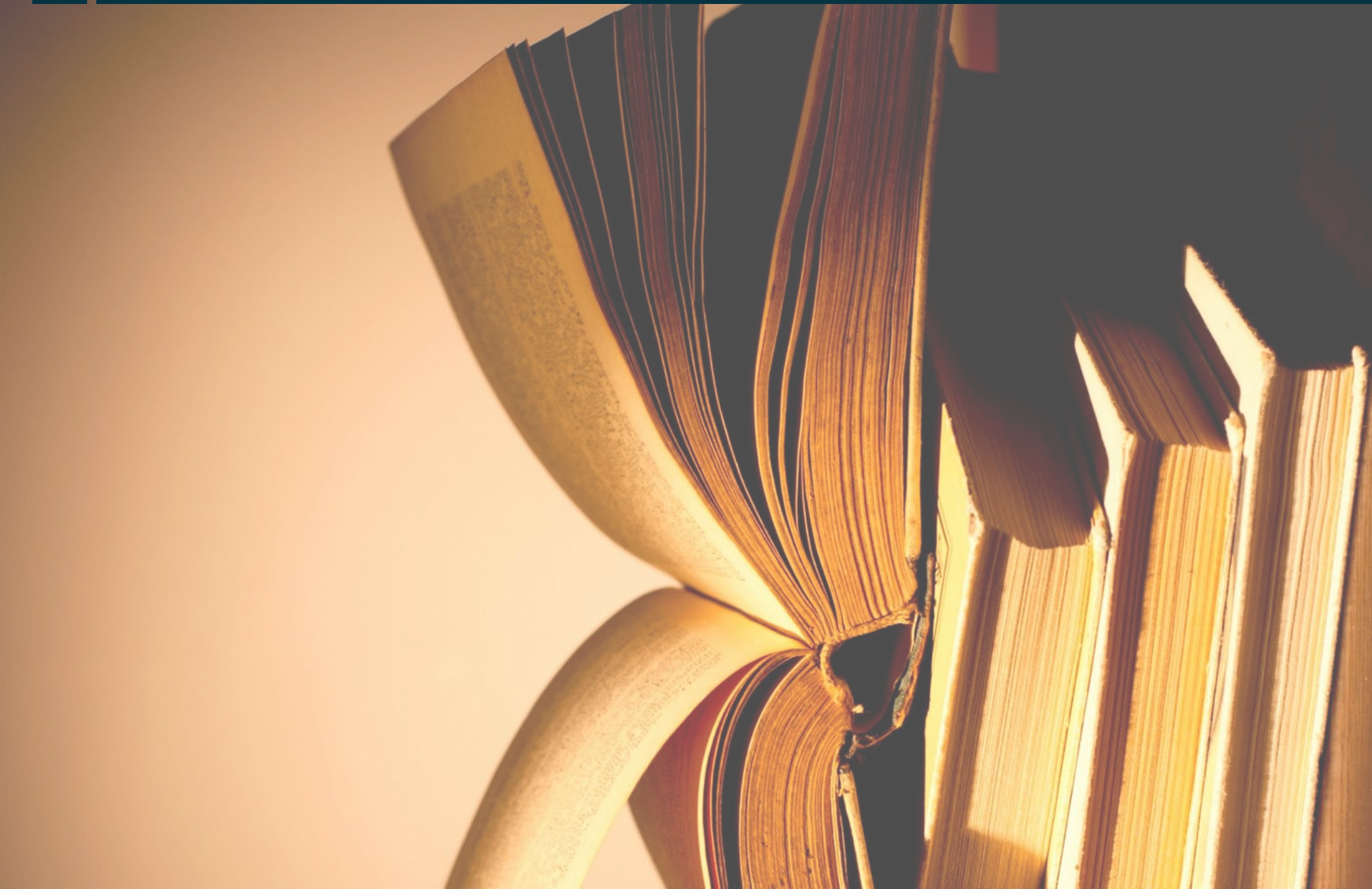
The Department of Health should establish a website which provides clear and transparent information on the status of new funding.

When an application is considered by the PBAC, the Medicine Status Website tracks the progress of the application through the submission, PBAC consideration, outcome and progress to listing. A similar website should be developed for medical services to allow stakeholders to track the progress of developing a new MBS item, through the relevant policy team, stakeholder consultation and budget process.

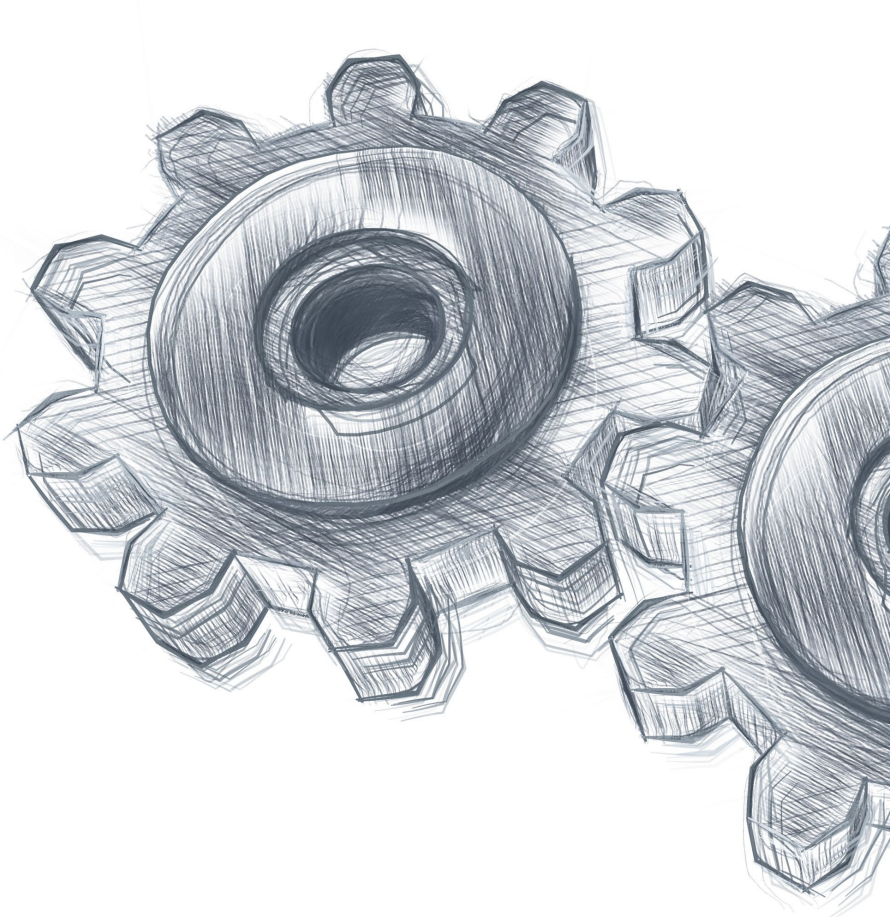
This transparent reporting process should track key milestones to reimbursement for innovative devices, including TGA timelines, time taken to submit to MSAC, time from MSAC submission to MBS listing, and time for MDHTAC consideration and PL listing. This would monitor the process for both regulatory and reimbursement bodies, as well as submission timelines for sponsors. This would help to identify delays and improve system efficiency.

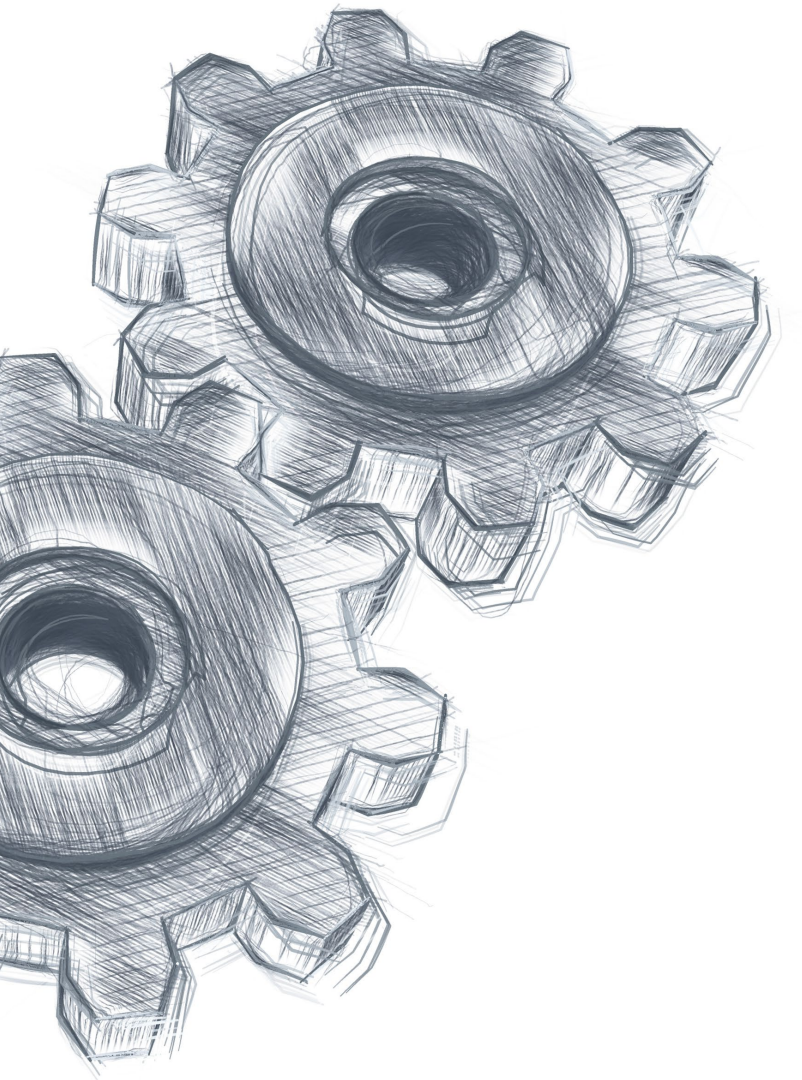
REFERENCES

1. New South Wales Health. New Health Technologies and Specialised Services 2024 [Available from: https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2024_008.pdf.
2. Australian Government Department of Health and Aged Care. Medical Devices and Human Tissue Advisory Committee - Member Guidelines 2023 [Available from: https://www.health.gov.au/committees-and-groups/medical-devices-and-human-tissue-advisory-committee-mdhtac.
3. Medical Services Advisory Committee. Medical Services Advisory Committee (MSAC) terms of reference: Australian Government Department of Health and Aged Care; 2024 [Available from: https://www.msac.gov.au/about-us/what-we-do/terms-reference.
4. Therapeutic Goods Administration. What the TGA regulates: Australian Government Department of Health and Aged Care; [Available from: https://www.tga.gov.au/what-tga-regulates.
5. Therapeutic Goods Administration. Report on TGA processes and timelines for the regulation of medical devices and access to market. International benchmarking. Australian Government Department of Health and Aged Care; 2019.
6. Peacock A, Taylor C, Jan S. Pathways to MBS funding for in-vitro diagnostics: Timelines and success rates in Australia. ISPOR 2025; Montreal, Canada2025.
7. Productivity Commission. Advances in measuring healthcare productivity. Canberra2024.
8. Australian Institute of Health and Welfare. Health expenditure Australia 2021-22 2023 [Available from: https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia-2021-22/contents/main-visualisations/broad-flows.
9. Ryan JB. Who should get the last TAVI valve? Public versus private access to disruptive technologies in the Australian health care system. Medical Journal of Australia. 2024;220(5):231-3.
10. Oettinger V, Hilgendorf I, Wolf D, Stachon P, Heidenreich A, Zehender M, et al. Transcatheter aortic valve replacement in Germany with need for a surgical bailout. J Cardiol. 2024;84(2):99-104.
11. Mahmaljy H, Tawney, A. Young, M., . Transcatheter Aortic Valve Replacement 2023 [Available from: https://www.ncbi.nlm.nih.gov/books/NBK431075/#article-37354.s15.
12. Mylotte D, Osnabrugge RLJ, Windecker S, Lefevre T, de Jaegere P, Jeger R, et al. Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. J Am Coll Cardiol. 2013;62(3):210-9.
13. Medical Services Advisory Committee. Public Summary Document Application No. 1662.1 – The reduction of mitral regurgitation through tissue approximation using transvenous/transeptal techniques 2022 [Available from: https://www.msac.gov.au/sites/default/files/documents/1662.1%2520Final%2520PSD-Nov2022_redacted.pdf.
14. Benowitz S. Revised Guidelines Signal That Gene Expression Profiles Are Coming of Age. JNCI: Journal of the National Cancer Institute. 2008;100(13):916-7.
15. Centers for Medicare & Medicaid Services. Transitional Coverage for Emerging Technologies (CMS-3421-NC) 2023 [Available from: https://www.cms.gov/newsroom/fact-sheets/notice-comment-transitional-coverage-emerging-technologies-cms-3421-nc.
16. Institute for the Hospital Remuneration System. Aufstellung der Informationen nach § 6 Abs. 2 KHEntgG für 2024: ; 2024 [Available from: https://www.g-drg.de/content/download/13863/file/Erl%C3%A4uterung%20zur%20Aufstellung%20NUB_DRG_2024_aktualisiert_240627.pdf.
17. Federal Institute for Drugs and Medical Devices. The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V. A Guide for Manufacturers, Service Providers and Users. 2022.
18. Centers for Medicare & Medicaid Services. Decision Memorandum: Transcatheter Tricuspid Valve Replacement (TTVR) 2025 [Available from: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=314.
19. Department of Finance. Budget Process Operational Rules. 2023.
20. Australian Government Department of Health and Aged Care. Enhance HTA: An Enhanced Consumer Engagement Process in Australian Health Technology Assessment - A Report of Recommendations health.gov.au; 2024 June 2024.
21. Australian Institute of Health and Welfare. Acute rheumatic fever and rheumatic heart disease in Australia 2024 [Available from: https://www.aihw.gov.au/reports/indigenous-australians/arf-rhd/contents/rhd/rhd-in-qld-wa.



APPENDIX





BREAKOUT GROUP DISCUSSIONS

REDEFINING VALUE

OBJECTIVES

- Recognise the HTA should consider a more holistic definition of benefit that goes beyond traditional clinical trial evidence and includes outcomes relevant to patients.
- Identify barriers and enablers to improve how Australia's HTA system can better evaluate the value of innovative technologies including diagnostics and therapeutics.

OUTCOMES

- Move beyond quantitative measures to include a qualitative values framework that considers value beyond cost-effectiveness.
- Involve external experts such as clinicians, patient representatives to define what constitutes value for specific disease.
- Align values across stakeholders by organising cross-functional meetings.

Australia's healthcare system is slow to incorporate new technologies due to extensive time for approval and uncertainty around funding. This leads to delays in patient access and can push valuable technologies out of the Australian market. There are multiple perspectives and stakeholders which make it difficult to define what constitutes value in healthcare. There is a lack of alignment on value both across and within government departments. A well-defined and systematic value framework would facilitate a more objective and transparent process for evaluating new technologies. This would facilitate better decision-making and alignment across departments. Using a holistic approach to measure value by incorporating both economic factors i.e. cost-effectiveness and social factors i.e. equity, patient outcomes would better reflect the broader value and impact of medical innovations.

BARRIERS

- Stakeholders may have differing opinions about what is considered value in healthcare.
- Insufficient real-world data to support the value of new technologies, particularly with limiting human data which creates challenges in justifying new technologies for approval.
- Lack of alignment between government priorities e.g. prevention vs. immediate health issues and healthcare funding decision creates inefficiencies within the system.
- There is tension between cost-effectiveness and the long-term value of technologies. The budget impact and incremental cost-effectiveness ratio (ICER) of new technologies often complicate decision-making due to its uncertainty.
- A lack of feedback loops from the MSAC process, making it difficult for stakeholders to understand the true value of new technologies over time and after initial assessments.

ENABLERS

- A consistent and structured value framework would enable a more objective and transparent approach to evaluate new technologies.
- Greater coordination between government departments would help establish a shared understanding of value and improve decision-making.
- A shift from focusing only on short term costs to incorporating long term functional outcomes in evaluations would better align the healthcare system with patients' needs.
- Incorporating patients' perspective in defining value could better capture what is prioritised in healthcare decisions. This could be valuable in disease specific contexts which patient needs vary widely.

INNOVATIVE FUNDING MODELS

OBJECTIVES

- Identify potential funding mechanisms for medical devices, such as coverage with evidence development, which are used internationally and for pharmaceutical products.
- Ensure that funding aligns more closely with the evolving needs of patients and healthcare systems.

OUTCOMES

- Funding models should be flexible enough to recognise the value of innovation, allowing for ongoing evaluation of new technologies.
- Financial incentives need to align with clinical care pathways, ensuring high value patient care.
- Funding should cover the continuum of care, rather than focusing on hospital-based care.

Innovative funding models are needed to expedite patient access to novel health technologies and meet the evolving needs of patients and the healthcare system. Current funding models were seen by stakeholders as being inflexible and favouring in-hospital care, which may not always lead to optimal patient outcomes.

BARRIERS

- Challenges associated with coverage with evidence development/managed access, as data collection can be expensive and intensive for clinicians who are not funded, patients can be reluctant to provide their data for free.
- Structural barriers exist between state and federal government funding models, with current funding favouring in-hospital care which is more expensive and may not result in better outcomes.
- Compared to pharmaceuticals, there is likely to be more variability in medical devices due to incremental change in device characteristics, learning curve for clinicians and procedural variability.
- Real-world evidence is not always accepted by decision making committees. When RWE is collected, access to registries can be limited and some organisations do not publish their data.
- There is a lack of trust between stakeholders which does not incentivise building better funding models.

ENABLERS

- Financial incentives should align with optimal clinical care pathways to improve patient care.
- Flexible funding models are needed to promote community-based or out of hospital care where appropriate.
- Availability of population-level big data to group patients with similar characteristics and identify who will benefit most and optimal interventional approaches.
- A bigger picture of health spending across the whole system, which includes identifying where benefits accrue, including outside of health.
- Understanding what patients want and promoting transparency in communication.

IMPROVING EARLY PATIENT ACCESS

OBJECTIVES

- Reduce the timeframe between regulatory approval and patient access.
- Promote collaboration between Government, industry and healthcare professionals to drive faster innovation adaptation.
- Link HTA recommendations to transparent and timely funding and reimbursement decisions.

OUTCOMES

- Develop a consumer engagement framework which to ensure that lived experience is appropriately captured and valued in health technology assessment.
- Develop a streamlined assessment pathway for innovative technologies which provides facilitated support for early market access.
- Commit to listing all recommendations made by MSAC within a specified timeframe, with monitoring and performance metrics to ensure transparency.
- Utilise real-world evidence, including local registries and international data, to demonstrate clinical effectiveness and value in the Australian healthcare setting.

A rapid pathway for interim funding could create upfront access for patients to new and innovative medical devices and procedures as they become available. Using current PL and MSAC pathways which have expert committees already in place minimises complexity. Ensuring that this rapid access funding benefits both public and private patients will prevent inequities in access and increased burden on one system. RWE could play a key role in reducing time to patient access through the acceptance of international data and data collected by local registries.

BARRIERS

- Geographic location (metro vs regional and rural, state), size of hospital, specific health fund all affects access.
- Data collection is critical, but barriers exist in the use of this data to generate RWE such as cost and ability to access.
- An insufficient level of trust in physicians – physicians have expertise in the potential benefit and value of a new medical device often before the currently required level of data is available for evaluation.
- Influence of politics around the PL process and a lack of secondary review to determine continued benefit and costs.
- The duplication of value assessment for new devices, in particular the evaluation of safety and efficacy, delays access and deters sponsors from bringing a device to market.

ENABLERS

- The consolidation of services, use of private capacity to relieve pressures on the public sector and transparency with patients in terms of services available will enable a faster access to new devices for patients.
- The use of clinical or administrative datasets to generate RWE is the key step in streamlining process. Currently registries are captured at a hospital level and are often owned by individual societies with a pay for access. There is opportunity for industry and academic partnership to utilise these datasets to generate RWE.
- Using examples from overseas e.g. Germany who are early adopters and use real time data to help inform decision-making. Minimise the number of assessments new devices need to go through to demonstrate safety & efficacy.
- Tighten policy across the PL to reduce flexibility and political influence. Secondary review to update costs and value associated with the device.

HTA REVIEW RECOMMENDATIONS

The HTA Review was a key commitment of the 2022-2027 *Strategic Agreement between the Commonwealth and Medicines Australia*. The review considered the HTA process for medicines and vaccines in Australia, and made recommendation aimed to:

- Address inequities in access
- Improve timely access to medicines
- Improve engagement
- Invest in HTA capability

While some of the recommendations focused on issues specific to medicines, a number of recommendations are applicable to innovative medical devices and diagnostic technologies. The implementation of these recommendations should be observed and impacts for medical devices measured. A summary of the key HTA Review recommendations that specifically relate to medical devices is included below:

Recommendation Number	Recommendation	Details and implication for medical devices
Streamlined pathways for more timely access		
3	Overarching recommendations for all HTA funding and assessment processes and pathways	Reform HTA pathways to align with the following principles: • Streamlined and simple • Proportionate and fit-for-purpose • Unified and consistent
4	Unified HTA pathway and committee approach for all Australian Government funding of health technologies	A single unified committee would likely encompass the role of both PBAC and MSAC. Unclear implication for MDHTAC.
7	Streamlined pathway for submissions using cost-minimisation analysis	A similar pathway could be developed for medical services and devices seeking listing on a cost-minimisation basis.
8 & 9	Improve the pathways and processes for listing therapies with high added therapeutic value in areas of unmet clinical need on the Pharmaceutical Benefits Scheme Extend the mechanisms above to all therapies claiming clinical benefit	Provide additional support for the submissions of therapies with high added therapeutic value in areas of unmet clinical need. Similar pathways could be developed for medical services and devices.
10	Alternative modelling and analysis types for disease areas	Investigate the feasibility and a potential place for alternative types of analysis and modelling for disease areas. Similar modelling flexibility could be considered for medical services and devices.

Recommendation Number	Recommendation	Details and implication for medical devices
13	Improved processes, accountability and timeliness for highly specialised therapies and other therapies co-funded between the Australian and state and territory governments	Encourage and provide support for expediting the development of a national HTA framework, including processes for HTA to inform advice on implementation, investment and disinvestment opportunities at Commonwealth and state and territory levels. May be particularly important for medical services and devices, to support improved equity of access between private and public patients.
15	Jointly owned performance targets	The Review recommends that the Australian Government and industry reaffirm their commitment to good faith negotiations aimed at minimising the time to completing HTAs and commercial agreements for products claimed to be superior to existing care. Similar performance targets should be established for MBS and PL listing processed.
Policies, methods and process supporting the translation of HTA recommendations into patient access		
17	Pricing offer framework	Publish a regularly updated post-HTA pricing, negotiation and listing policy framework that provides stakeholders with clarity and visibility about matters relevant to translating a positive HTA recommendation into subsidised access for patients. Particularly important for MSAC and MDHTAC considerations, given the current perception by stakeholders that this process lacks transparency.
19 & 20	Managed entry agreements Bridging funding program	Revise the policy and guidance framework of managed entry agreements, to provide more flexibility for sponsors and the Commonwealth to address identified uncertainties while better supporting timely access to health technologies for patients. Establish a bridging fund to facilitate earlier, temporary subsidised access to eligible therapies of high added therapeutic value that address high unmet clinical need for patients. No managed entry system or provisional funding currently exists for medical services and devices. Such a system should be developed to support coverage with evidence development.

Recommendation Number	Recommendation	Details and implication for medical devices
Transparency and stakeholder engagement *Applicable to both medicines and medical devices*		
24	Developing an engagement framework	Co-design a stakeholder engagement framework to describe how and why engagement with stakeholders is used across all HTA processes, from horizon scanning to post-market reviews.
25	Improving involvement of consumers in HTAs	Actively engage consumers across the HTA continuum, including by offering support and training. Request information from sponsors about how they engaged with consumers during the pre-HTA processes, including trial design.
26	Developing an explicit qualitative values framework	Support HTA committees to develop, in consultation with stakeholders, explicit guidelines and communications on the elements (beyond clinical effectiveness, cost-effectiveness and financial impact) they consider.
Enhancing real-world data and real-world evidence for HTA *Applicable to both medicines and medical devices*		
27	Governance and strategic oversight of real-world data to support HTAs	Develop an Australian framework to optimise timely access to relevant real-world data for HTA, covering enabling systems, pathways and evaluations, and research the collection and use of real-world data for HTA.
28	Data infrastructure to support HTAs	Develop a dynamic, enduring whole-of-government data infrastructure that evolves over time and is internationally harmonised.
29	Intergovernmental collaboration in standardised collection and sharing of health technology–related data	Promote state and territory government collaboration and participation in cross-jurisdictional data sharing to support nationally cohesive HTA.
30	Real-world data and real-world evidence methods development	Establish a multi-stakeholder coordinated approach to developing transparent evidence for HTA using best-practice methods that span data standardisation, standardised analytics and reporting.
31	Collecting and using real-world data to resolve uncertainty	Ensure early identification and/or configuration of data collections that could help resolve uncertainties when it is expected that an application is likely to result in a managed entry agreement.

Recommendation Number	Recommendation	Details and implication for medical devices
Methods for confident decisions *Applicable to both medicines and medical devices*		
33	Methods for assessing consumer evidence	Support the development of updates to MSAC guidelines about how to integrate consumer evidence and consumer inputs arising from engagement processes.
34	Overarching principles for adopting methods in Australian HTAs	Support the adoption of overarching principles for the methods used in Australian HTAs to ensure that decision-makers have the best possible evidence available, and sponsors and evaluators understand preferred methods and approaches.
35	Methods for assessing non-randomised and observational evidence	Support the development of updates to methods for using non-randomised and observational evidence that are in line with the overarching principles for adopting methods in Australian HTAs.
36	Methods for assessing surrogate end points	Support the development of additional methods for using surrogate end points in HTAs that align with the overarching principles.
37	Methods preferred by decision-makers	Support the generation of a curated list of methodologies preferred by decisionmakers.
39	Discount rate	Support reduction of the base case discount rate to no lower than 3.5% for health technologies that have upfront costs and benefits that are claimed to accrue over a long period (such as gene therapies and some vaccines).
41	Cost-minimisation submissions	Investigate mechanisms to differentiate cost-minimisation submissions based on the proportionate benefit and relative cost.
42	Valuing and pricing	Conduct research to understand if and where it may be reasonable for HTA committees to accept higher prices for health technologies than are currently accepted.
43	Environmental impact reporting	Investigate options, in consultation with industry and stakeholders, for reporting environmental impacts in the assessment of health technologies.
Supporting architecture for HTA (recommendations 44-50) *Applicable to both medicines and medical devices*		

Prepared by

Roxanne Maurin
Senior Manager

Adele Yau
Consultant

Colman Taylor
Chief Vision Officer

HTANALYSTS