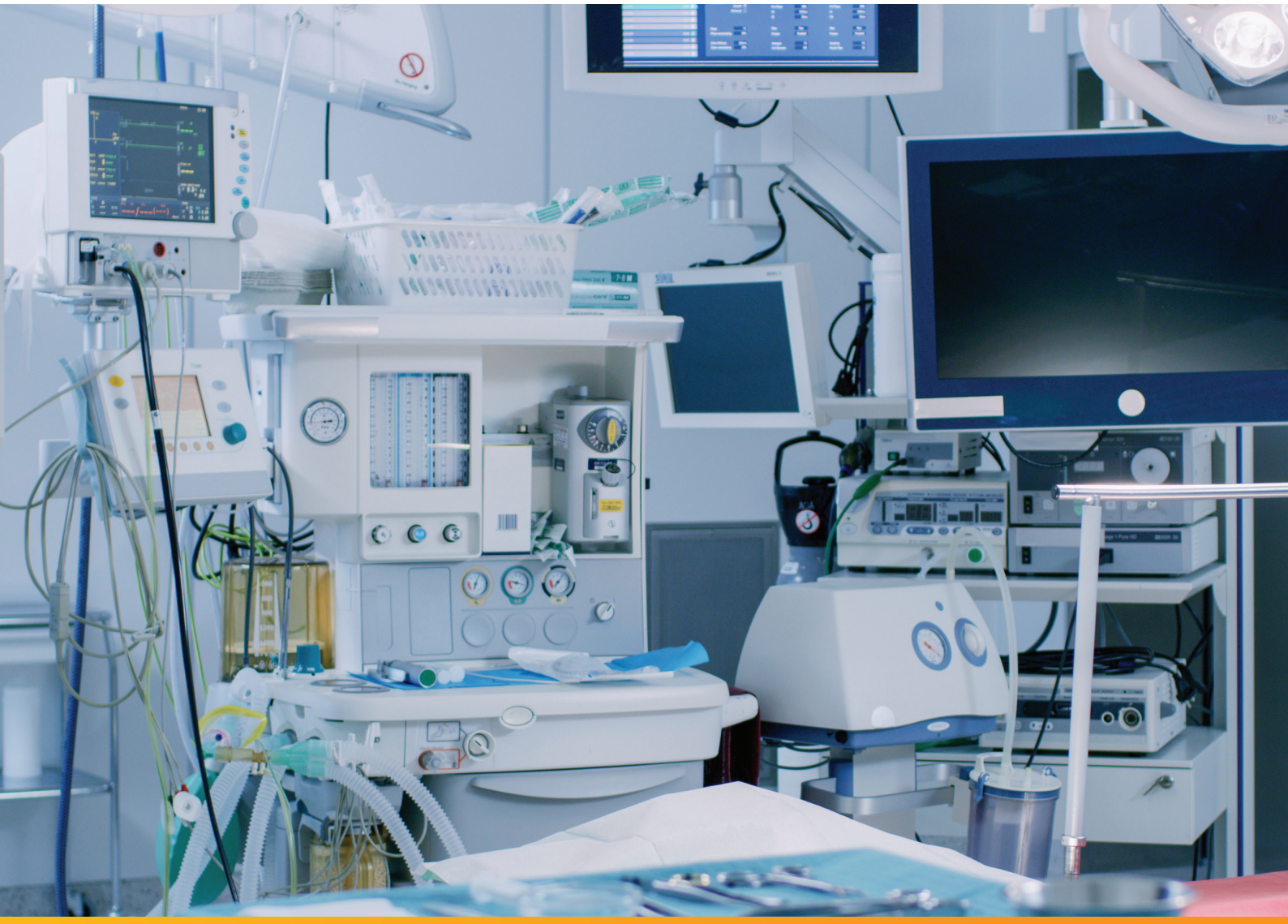
MTAA Medical Technology ASSOCIATION OF AUSTRALIA

MEDTECH ON THE HILL



The Value of Medical Technology

Securing the opportunities and overcoming the challenges of Australia's healthcare future

Based on key findings from Nous Group's report "The Value of Australian MedTech 2023" commissioned by the Medical Technology Association of Australia (MTAA)

From before we are born to our very last breath, Medical Technology (MedTech) enhances the lives of every Australian. These technologies prevent, detect, and diagnose illness, keep us connected to healthcare, and save lives.

Our world-leading healthcare system is changing at pace. It needs to. Our ageing population and increasing complex and chronic illness present a significant challenge to governments, healthcare professionals, and the community at large.

To meet this challenge head on, the medical technology industry provides the innovations, infrastructure, workforce, and devices that can change the game.

The technology that can revolutionise care for many Australians, exists today. However, our current policies, systems and processes present barriers to the many Australians who could benefit. Long delays to access life-changing technologies and a system making it 'too hard' for certain technologies to be delivered, means some Australians do not have access to procedures, practices or devices that are standard practice in other countries.

To deliver on the promise of a reformed, enhanced, equitable health system for every Australian, MedTech is key. But we must work together to ensure:

- **Timely, equitable access** to the right medical technology, at the right time, wherever you live across Australia;
- **Valuing MedTech by the lives it improves**, rather than the cost in order to make it available to deliver access to the world's best advances in MedTech; and
- **Sustainable investment and processes** to deliver world-class technologies to Australians, whether the technologies are home-grown or from abroad.

Ultimately, advances in MedTech enables us to live longer, enjoy a better quality of life, remain productive, contribute to our communities and the economy.

JOHN'S STORY

John is in his 60's and lives in country Queensland with his wife and a campervan that allows him to travel Australia. After developing arthritis in both knees, and having additional trouble with his ACL, PCL and meniscus, John was quickly deprived of the ability to stand after sitting for extended periods. It reached a point where John could barely get out of a chair if he sat for longer than five minutes, and eventually his movement was so restricted, he could barely walk.

Earlier this year, John received a robotically-assisted bilateral knee replacement surgery, which was performed in less than a day. Through this operation, John's damaged knee tissue was replaced with an artificial joint with the assistance of a robotic device.

Since his surgery, John who hasn't been able to jog for five years, has regained the ability to walk properly, sit comfortably in his caravan, play with his grandchildren and soon, he is confident, the ability to run.

TIMELY, EQUITABLE ACCESS

An Australia where every patient has timely, equitable access to the medical technology they need to live longer, with a better quality of life – wherever they live.

MedTech improves care, efficiency, precision, and efficacy of the delivery of healthcare. Spanning a wide range of technologies – diagnostic machines, implantable devices, assistive technologies, surgical tools, consumables, and software – MedTech supports Australia's efforts to prevent and detect disease, provide medical support, and monitor health.

While hospital structures and hierarchies can take years to evolve[1], MedTech is continually advancing to ensure Australia is equipped to respond to the smallest and largest of public health issues. COVID-19 provided Australia valuable lessons on rapid MedTech development and spurred government investments into local MedTech manufacturing and sovereign capability.

Whilst the pandemic demonstrated that it is possible to streamline the development of, and access to, MedTech, it is more often the case that Australians do not have timely, equitable access to the latest advancements in clinical care.

For MedTech-related procedures to reach broad patient populations, the procedure must be listed on the Medical Benefits Scheme (MBS). When a procedure is listed on the MBS, healthcare providers can be reimbursed by the amount set by the government which helps to cover their costs. Procedures without MBS listings often see patients pay the full cost of procedures, even if the medical devices used in the procedure are approved by the TGA as safe and efficacious. For Australians with private health insurance, their insurance may cover medical technology listed on the Prescribed List. Therefore, delays have meant Australian patients do not have access to the medical technology, and clinical care, they need, when they need it.

FROM OUR VERY FIRST BREATH...

From the beginning to end of life, Australians have access to MedTech equipment and infrastructure that helps monitor health, diagnose, and treat disease. In 2020, there were 295,976 babies born in Australia; 96% of these births occurred in hospitals. The support of MedTech, from ultrasounds and foetal dopplers, to hearing tests in newborns, is essential during and after pregnancy.[2] It is through MedTech that we hear their first heartbeat, see their growing bodies, and learn about their health long before they enter the world.

The standardised use of these technologies gives babies the best chance at early intervention and a good start to life. Australian companies are developing new ways to improve detection and therapy in early life.

IN FOCUS: THE CHALLENGE OF TIMELY ACCESS

- Applying and receiving approvals for reimbursement can be a significant barrier to MedTech companies to get their technology into clinical use. **Regulatory environment (74%) and regulator pricing (55%) was an operational challenge** identified by survey respondents.[3]
- The process for **listing on the MBS** or Prescribed List/Prostheses List is lengthy and **can take several years** before MedTech becomes available to patients.
- Variation in state and territory procurement can also be a **barrier to access**, with each jurisdiction having **its own** health technology assessment, procurement and tendering processes.
- Overall, there is a long time between an idea and getting the product to patients, however, collaboration between industry, healthcare providers and the Australian government can help shorten this process.

OUR OPPORTUNITY

The pathway for MedTech to reach patients in Australia is complex. The process can be lengthy due to the challenges of listing procedures on the MBS and devices on the Prescribed List. It is often only after MedTech is listed that it is made widely available to patients, including those in critical need, such as Eden.

WHAT AUSTRALIAN PATIENTS NEED:

The House of Representatives inquiry into approval processes for new drugs and novel medical technologies in Australia – *The New Frontier - Delivering better health for all Australians* was a landmark inquiry that recognised the new frontier of medicine and MedTech that is giving hope to Australians living with a wide range of conditions. It made strong recommendations that will ensure Australians continue to have timely access to medicines and MedTech, and that our health systems deliver, rather than hinder, that outcome. This would include streamlining complex approval processes.

The MedTech Industry support the recommendations outlined in The New Frontier and call on the Australian Government to commit to the recommendations.

When it comes to ensuring Australians enjoy the full benefits of medical technology, collaboration and consultation is required with Industry, clinicians, and patients themselves to ensure policies are effective, equitable and sustainable for all.

EDEN'S STORY

For as long as anyone had known him Eden was an active kid. Having been accepted into a development squad for mountain biking, Eden was skilled and beginning to show a lot of sporting promise. However, Eden experienced significant leg and back pain throughout his primary school years that prevented him from doing simple things like sitting cross-legged on the floor of his classroom. His pain continued to intensify until just after primary school, when the feeling was so unbearable even a sneeze would bring him to tears.

At age 14, Eden was diagnosed with Stage 4 Spondylolisthesis where one of his vertebrae slipped entirely off the one below and, due to the additional pressure caused, his vertebrae had started to fracture. In addition to chronic pain, Eden dealt with significantly reduced mobility for two years, barely being able to walk, before being able to access surgery. This is when doctors fitted a TLIF cage, also known as a banana cage, using pedicle screws and rods to realign Eden's spine and, carefully, his nerves. This complex surgery lasted more than 12 hours, but for Eden it has been life changing.

Though there was a limit to how much surgeons could manipulate his spine, Eden's life since has been incomparable to before. He has not only resumed his sporting hobbies, but has competed professionally, including in the World Cross Country Championships in Orange, NSW.

Eden still remembers when doing a bunny hop was unachievable and now prepares to sit the HSC later this year.

[1] Thimbleby H. Technology and the future of healthcare. J Public Health Res. 2013;2(3):e28. Published 2013 Dec 1. doi:10.4081/jphr.2013.e28
[2] Australian Institute of Health and Welfare, 2022. Mothers & babies. Available at: Mothers & babies Overview - Australian Institute of Health and Welfare (aihw.gov.au). Accessed: May 2023
[3] Data collected between July 1 2020 - June 30 2021

SUSTAINABILITY & VALUE

An Australia where people have a health system that provides what they need to maintain health today, whilst pre-empting the advances needed for tomorrow.

The responsibility of the Australian Government, and healthcare providers across the country, to sustainably provide the best outcomes for patients is no small feat. Sustainable access to MedTech – from as small as a syringe to as complex as a kidney stone-smashing lithotripsy laser – is critical to patients receiving the best health outcome. However, the ability for patients and clinicians to have *access* to technology is only the beginning.

They need to know that the technology they have access to is the *best available* – valued for the superior health outcome it provides. They need certainty that the technology will be reliably available, and that innovation will keep pace with increasingly complex health needs.

Many complex devices used for chronic diseases have seen growth in use in the past 10 years.[4] While data does not show the total number of devices being used in Australia, it illustrates a trend of steady growth in the use of complex implantable devices which provide sustained benefits. Each has seen >30% increase in MBS claims (private sector claims) since 2012.

To ensure our health system is sustainable, in an environment of increasing complexity of health care needs and rising costs, the value of medical technology must be determined by the outcomes they achieve, rather than cost alone. Australia's current regulatory and reimbursement process, as well as procurement practices, are not fit-for-purpose to prioritise best outcomes.

Ultimately, both the Australian Government and patients are paying the price.

AT THE HEART OF THE MATTER

Cardiovascular disease (CVD) continues to be one of Australia's greatest disease burdens, affecting 1.2 million people across the country.[5] This is despite the fatal burden from CVD falling over the last 20 years, from 17.2 years lost per 1000 population in 2003 to 7.0 years lost in 2022. This is due to a number of advancements in prevention, detection and treatments - including radical advances in medical technology and how it is used.

One example is a therapy called transcatheter aortic valve implantation (TAVI), where a doctor threads a catheter through an artery in the groin up into the heart. TAVI has emerged as a low-risk alternative to open-heart surgery for the 97,000 Australians living with heart valve disease, severe aortic stenosis. The therapy can offer immediate benefits to the patient, such as increased energy levels, breathing ability and less pain. It is estimated to reduce lifetime costs by US$10,000.

Economic modelling by the Baker Institute showed that offering a TAVI for people aged 65 years and over could potentially prevent $117 million in productivity loss in a single year due to withdrawal from productive activities like volunteering, or looking after grandchildren.

OUR OPPORTUNITY

As Australia enters into a period of healthcare reform – from primary care to the HTA review – medical technologies are the cornerstone of enabling value at every point across the system.

Making sure *health outcomes, rather than cost,* are central to how medical technologies are assessed, reimbursed, and procured will further ensure sustainability of our whole health system well into the future. This will ultimately drive better health outcomes, enhance cost saving and reduce waste.

WHAT AUSTRALIAN PATIENTS NEED

Australians need access to medical technologies, devices and procedures that offer the best possible health outcome. Whether, like Matt, that includes peace of mind and ability to function in a workplace, or beyond, other interventions rarely suffice.

The MedTech industry welcomes the opportunity to collaborate with government and stakeholders on health reform, including the HTA review and the modernisation of reimbursement processes for medical technologies.

MATT'S STORY

Matt is a former paramedic from Yass, where he lives on a small acreage. After twenty-five years in the field, Matt enjoys spending his days as relaxed as possible, looking after his cats, dogs, sheep and chickens.

Matt went to scratch his back one day and felt a lump. He went straight to his GP and then to a surgeon, who even upon removing the lump was not sure what it was. It wasn't until Matt's pathology results returned that he was diagnosed with an incredibly aggressive form of cancer, Merkel Cell Carcinoma.

Merkel Cell Carcinoma is equally as aggressive and fast acting as melanoma, however it happens to respond very well to radiation. Radiation can in fact cure this type of cancer.

Chemotherapy, in comparison, was the palliation route.

Despite being told, "we need to treat this with radiation asap," Matt had to wait 3.5 weeks for a radiation machine to become available. Only three machines were available at the closest regional cancer centre to Matt, and the waiting list was long.

Over the course of 7 weeks Matt had 30 radiation sessions. For the majority of this course, Matt joked that the nurses were sprinkling fairy dust on him, due to the lack of side effects or visible treatment. "It was like magic."

If it were a few more months before Matt found his lump, it would have metastasised, and killed Matt quickly.

Instead, when asked how he is now doing, Matt says with warmth, "I'm back to 98% function, as far as I'm considered, I'm a lucky man."

[4] Medicare Benefits Schedule Data, item claims from 1st January 2012 to 31st December 2022
[5] The Australian Government Department of Health and Aged Care, 2021. What we're doing abut cardiovascular conditions. Available at: https://www.health.gov.au/topics/chronic-conditions/what-were-doing-about-chronic-conditions/what-were-doing-about-cardiovascular-conditions. Accessed: May 2023
[6] Australian Commission on Safety and Quality in Health Care, 2017. Women to benefit from first national treatment standard for heavy periods. Available at: https://www.safetyandquality.gov.au/about-us/latest-news/media-releases/women-benefit-first-national-treatment-standard-heavy-periods. Accessed: June, 2023

A SUSTAINABLE MEDTECH FUTURE FOR AUSTRALIA

Australians deserve access to medical technology that reimagines and transforms their healthcare experience, enhances and ultimately saves their lives – whether it is bringing the world's greatest technology to our shores, or developing home-grown innovations.

Australia has a long a strong history of investing in innovation, which has been to the advantage of both the healthcare system and the broader economy. Importantly, this investment directly benefits Australians, ensuring they have access to up-to-date, world-class treatments.

Australia is a nation that has punched above its weight in MedTech – the electronic pacemaker, the ultrasound, sleep therapy and multi-channel cochlear implants were all medical advances created right here, in Australia.

Federal and State governments are investing to accelerate the growth of the MedTech industry. Individual investment in MedTech innovations come from a variety of sources including universities, start-ups and MedTech organisations of all sizes, some with origins as spin-offs, start-ups, universities and as subsidiaries of global organisations, with the industry's total contribution to gross domestic product (GDP) in 2021/22 being $5.4 billion.

Importantly, an estimated 17,000 people were employed directly in Australia in 2021/22 in MedTech-related work and a further 34,000 people worked in jobs that support and supply the industry. Over half of the total MedTech workforce are women, and senior representation of women in the industry is above the Australian average.

At the core of investment in MedTech is ensuring Australians benefit – and clinical trials provide Australians with timely access to break-through innovations. In 2019, more than 1800 clinical trials started, involving over 95,000 participants and $1.4 billion of investment into the economy. For Australian clinical trials starting in 2022, 9.2% were for MedTech.[8]

BEWARE THE VALLEY OF DEATH

MedTech, unlike many other industries, requires significant investment before there are any potential financial returns. A common struggle for Australian researchers is to overcome the funding 'valley of death' before research can progress into clinical trials and beyond. Therefore, many small MedTech companies operate at a significant loss. This contributes to an exodus of home-grown innovators in pursuit of investment opportunities.

Bringing world-class innovation to our shores can be a long process for manufacturers, riddled with bottlenecks. The top two barriers to growth are reimbursement and regulatory approval processes, which are critical components of access to the Australian market.[9] This ultimately means Australian patients are at risk of missing out on new medical technologies that their international counterparts can readily access, because the process is too costly and complex. This also contributes to local companies taking manufacturing off-shore. As a result, Australia misses out on the associated value-adds of employment, expertise and supply chain uplift.

OUR OPPORTUNITY

The opportunity exists for the Australian Government and stakeholders to simplify the current complex pathways for MedTech to reach patients in Australia. This includes reforms to MedTech regulation, review processes and reimbursement approvals.

Australia has the opportunity to become a destination of choice for innovators and manufacturers – locally and abroad. Ongoing support for clinical trials is vital to overcome the 'valley of death', and sure up Australia's sovereign capability in MedTech.

WHAT AUSTRALIAN PATIENTS NEED

Australians need access to MedTech that will deliver the best health outcome possible, regardless of where the technology is from. Living in Australia should not be a barrier to accessing the best technologies for patients, and their clinicians.

INNOVATION AND INVESTMENT

- Australian MedTech patents have grown at an average rate of 7% a year since 2010 and have risen from 4.5% to 6% of all MedTech patents filed in Australia from around the world.
- Seventy-one per cent of surveyed MedTech companies indicated their products had some level of local development.
- Since 2002 Australia has hosted over 2,300 MedTech clinical trials. More than 60% of surveyed companies indicated they have trials starting in the next 12 months.
- Over 80% of small MedTech companies (revenue < $10 mil/year) operated at a loss.[10]

MARINA'S STORY

In 2018, Marina, a corporate senior executive, woke up with what she thought was a headache and lethargy. After suddenly dropping her coffee on the floor during a work meeting, she decided to go home. On her way home from work, Marina went to her GP, who immediately called an ambulance. The stroke team at RPA Hospital was alerted and ready to take her for a CT scan on arrival. Marina was diagnosed with an ischaemic stroke. She was just 41 years of age.

The stroke Marina suffered meant that a large portion of her brain was denied blood and, without intervention, she would have died.

Luckily, the hospital stroke team determined she met specific criteria to undergo an innovative, complex and delicate procedure called endovascular clot retrieval (ECR). ECR, needs to be performed within a certain period of time, and when it is, the procedure can significantly reduce the potential for the disabling consequences of stroke.

ECR restores blood flow to the brain in patients with larger clots that cause the most devastating strokes. The clot blocking the brain vessel is removed by a special team that access the problematic spot through an artery, restarting essential blood flow. This team includes an anaesthetist, neurointerventional radiologist, neurologist, intensivist and specialist nursing staff in an angiography suite.

The procedure enables one in three patients on average to recover almost completely, and regain independence three months after the stroke.

"Had it not been for the surgery I was able to receive through MedTech, I would not be here sharing my story. I was told other patients would have had other parts of their body shut down and never recover."

Today, Marina maintains her senior position managing a team of 60 staff. She is mother to two children, thriving in her personal and professional life.

[7] Australian Government Department of Industry, Energy, Science and Resources, 2021. Australia's Clinical Trials Sector. Available at: https://www.mtpconnect.org.au/images/MTPConnect_Australia's%20Clinical%20Trials%20Sector%20report%202021.pdf. Accessed: May 2023

[8] Nous analysis of Australian and New Zealand Clinical Trials Registry (ANZCTR) and Clinicaltrials.gov data

[9] Data collected between July 1 2020 - June 30 2021

[10] Loss as defined by a deficit in operating surplus. Data on file.