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MTAA Pre-Budget Submission FY2021/22

Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA members provide all of Australia's healthcare professionals with essential product information, continuing education and training to ensure safety and to optimise the effective use of medical technology. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia.

Medical Technology

The medical technology (MedTech) industry is one of the most advanced and dynamic manufacturing sectors in Australia and has the potential to provide substantial health gains and highly skilled employment opportunities for Australians and add to Australia's export industry.

It is estimated that the total market for medical devices in Australia was valued at US$4.9 billion

There are 135 ASX-listed MedTech and pharmaceutical companies in Australia, with a market capitalisation of $179 billion.

The MedTech industry in Australia is a substantial employer. In 2014, it was estimated that the industry (including digital health) employs about 19,000 people.

It is also estimated that the total market for medical devices in Australia is valued at over US$4.9 billion, with a compound annual growth rate of 1.4% since 2014. Despite representing a small market, Australia ranks as a prominent developer of MedTech worldwide. From the smallest sutures and neurosurgical coils to the largest linear accelerators, MedTech provides the platform from which healthcare is delivered. Without MedTech, healthcare cannot be delivered.

Summary of Policy Priorities

The COVID19 Pandemic, created by a once-in-a-century pathogen, has presented Australia, and most other countries, with far-reaching social, environmental and economic challenges that have not been experienced since World War II. Developing a strategy for national resilience and preparedness means designing policies and programs that prioritise Australia's health and economic resilience, and will ensure Australia is prepared for the next century. The policy priorities outlined in this submission seek to provide overall savings, redirect existing funds, or foster growth in the Australian economy. MTAA's policies cover five (5) key areas of priority:

1. The future of Australia's Private Health System
2. Health Industry Policy
3. Health Regulatory Policy
4. Industry Policy
5. Economic and Tax Policy

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About MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of contemporary, innovative and reliable medical technology are delivered effectively and sustainably to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology (MedTech) used in the diagnosis, prevention, treatment and management of disease and disability. The MedTech industry is diverse, with medical products ranging from frequently used items such as syringes and wound dressings, through to high technology implantable devices such as pacemakers, defibrillators, bone and joint replacements, and other prostheses. MedTech includes hospital and diagnostic imaging equipment used in all settings, from the smallest rural clinic to the largest multi-site hospital, e.g., ultrasound and magnetic resonance imaging (MRI) equipment.

MTAA members develop and distribute the majority of all medical products used in the diagnosis and treatment of every disease and disability that Australians experience. Our member companies play a vital role in educating healthcare professionals with essential information, training and support to ensure safe, innovative and efficacious use of MedTech.

About MedTech In Australia

The MedTech industry is one of the most dynamic advanced manufacturing sectors in Australia and has sustained its potential to provide substantial health gains and high-level employment opportunities to Australians and grow Australia's export of technology. Through innovation, this industry will continue to expand and share its discoveries with the world.

By example, Prism Surgical, Cochlear Australia and ResMed are three Australian companies that have exported Australian innovation in medical devices to the world and continue to do so. The Australian Bureau of Statistics[1] (ABS) identified the industry as a growth industry, performing higher than average on indicators such as export, productivity and employment.

It is estimated that the total market for medical devices in Australia is valued at over US$4.9 billion[2]. Despite representing a small market, Australia compares favourably worldwide; according to the Worldwide Medical Device Factbook, Australia is ranked at 13th in terms of total market value.

Considering gross-value-added, which is a measure of the value of industry production, there have been steady increases for both the MedTech and the pharmaceutical sector. In 2019, it was calculated

[1] Australian Bureau of Statistics, Characteristics of Businesses in Selected Growth Sectors, Australia, 2013–2014. 2015, Australian Bureau of Statistics: Canberra.
[2] https://www.statista.com/statistics/716902/medical-equipment-market-size-in-australia/

that the gross value added for the entire industry was $5.2 billion, an increase from $4.9 billion in 2016.[3]

With continual growth and advancements in the industry, all surgical operations and clinical procedures performed in Australia involve some form of MedTech, whether it is patient consumables or diagnostic machinery. Over 2.5 million patient per year are served with assistive technology that provides A$3.6 to $4.5 billion annual value to the community. As a result, globally we have seen a 30% decline in annual mortality in the last 20 years, an 18.7% decline in disability rates in the last 15 years, and a 56% reduction in hospital bed days and an increase in life expectancy by 4.1 years. MedTech has been a key partner in these achievements. Currently, there are 135 ASX-listed MedTech and pharmaceutical companies in Australia, with a market capitalisation of $179 billion.

> More than 3,000,000 medical devices were used in 2019.

The MedTech industry in Australia is a substantial employer. In 2014, it was estimated the industry employs approximately 19,000 people, excluding those working in digital health. Overall, 78% of all MedTech employees have graduated with a university degree, demonstrating the highly educated nature of the workforce. Of these employees, 52% earned an undergraduate degree, and a further 25% completed a postgraduate degree.[4]

The MedTech Industry's COVID-19 response

Australia confirmed its first case of the Coronavirus (COVID-19) on 25 January 2020, it wasn't long before COVID-19, emerged as an international public health emergency and it was classified by the World Health Organization as a pandemic on 11 March 2020.

Within days of the WHO's designation, MTAA had provided a framework for a COVID-19 Industry Working Group. This Group included both MTAA members and non-member companies, who worked together to support the Federal Government's Taskforce and assist in securing essential supplies of ventilators, test kits, Personal Protective Equipment (PPE) and other ICU supplies required by the healthcare system to move swiftly to manage the Pandemic effectively.

The MedTech industry was quickly tasked by the Federal Government with supplying 7,500 ventilators. It was modelled that at the Pandemic's potential peak, Australia would require these to manage the 7,500 people needing mechanical ventilation at that time. MTAA member companies answered the call. This included a consortium of leading MedTech companies including Grey Innovation from Victoria who began the local manufacturing of ventilators.

MedTech's efforts extended well beyond ventilators with MTAA members such as Abbott providing six COVID-19 tests included in the ARTG and Hologic providing two. These companies are leading the charge in the development, manufacturing, and distribution of COVID-19 testing kits with Abbott's broad range of tests providing further opportunities for testing during the vaccination stage.

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[3] MTPConnect, MTPConnect 2020 Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan. 2020.

[4] [4] Deloitte, Medical technology industry workforce and skills review. 2015.

Further to this, local businesses who had previously never ventured into the health sector stepped up and became MedTech manufacturers. Distilleries such as Archie Rose Distilling Co in Sydney and Prohibition Liquor Co in South Australia switched from bottling gin to bottling hand sanitiser.

Existing local MedTech manufacturers had to increase production rates dramatically. Non-MTAA member Med-Con from rural Victoria used to produce 2 million facemasks each year. With the onset of the pandemic, the Australian Army stepped up to assist on the production line allowing Med-Con to produce 2 million face masks each week, 52 times their usual production rates.

MTAA member Stryker moved quickly to support Australia's need for additional ICU beds designing and producing rapid response ICU beds. Fortunately, the high numbers of hospitalisations that forced other jurisdictions to erect and use field hospitals and pop-up ICUs were mostly avoided in Australia.

Not all MedTech companies were able to ramp up production with many companies catastrophically affected by the national elective surgery suspension and subsequent state and regional suspensions. Companies who were exclusively focused on surgical procedures saw revenue drop to zero overnight.

All companies faced dramatic shifts to freight movements and costs. Overnight, airfreight services were cut, and companies had to adapt quickly. With 90% of Australia's exports usually shipped as additional cargo in passenger aircraft, our export capacity quickly fell, and prices rose by greater than 500%.

Throughout the Pandemic, the MedTech industry has adapted to change, absorbed additional costs, opened new production lines and shifted existing production capacity, joined forces with other companies, industries, and governments, and developed new procedures to keep Australians healthy. All of this occurred whilst the MedTech industry did its best to continue to support patients and the broader health sector. MedTech in theatre technicians spent countless cumulative days in quarantines, sometimes just to assist a single patient. Importers met demand and ensured Australia was supplied, even with immense costs that were not passed on.

As has been shown by the re-emergence of COVID-19 in Victoria, New South Wales, and South Australia, it is unclear how long this Pandemic will directly affect lives and the way people interact with the world. The MedTech industry is prepared to address the ongoing medical needs of the community as we continue our pandemic response.

Future of Australia's Private Health Industry

Australia's private health insurance system remains under strain. Despite government efforts to encourage more Australians to take up private health insurance, rising premiums and policy changes have driven the proportion of people with hospital coverage to 11-year lows. With only 43.8% of of Australians covered by private health insurance hospital cover policies as of September 2020, and a faster decline in the participation by the young and healthy, the system is in need of reform. Unless private health insurance improves, Australia risks overburdening its public healthcare system, putting the quality of patient care at risk.

Challenges with private health insurance are not new. The 1997 Industry Commission[5] (the precursor to the Productivity Commission) noted: "We observe that large numbers of people are relinquishing private insurance, that the shrinking pool of the insured tends to be older and higher users of health services". The question for young people investigating the value of private health insurance remains the same.

If private health insurers are able to make internal cost savings, either through efficiencies, or reducing high management expenses, that are reflected in a decrease in premiums, this may reverse the flow of people, particularly the young, leaving private health insurance and thus stop the so-called "death spiral[6]" currently facing the industry.

Some private health insurers have been quick to point the finger at medical devices and the Prostheses List (PL), calling for the PL to be scrapped and replaced with an a DRG model that would restrict patient access and surgeon choice. Whilst there are some issues with the PL that are currently being addressed, to say that reform of the PL would alleviate private health insurer's woes would be false. Devices, via the PL, make up less than 14% of Insurers Hospital costs and less than 10% of insurers total benefits. The MedTech industry, via our Strategic Agreement with the Hon. Greg Hunt MP, is already delivering $1.1 billion in savings. As such, the Government must look beyond changes to the Prostheses List to deliver sustainability for the private health system.

MTAA recommends the Federal Government work with all private health sector stakeholders, experts, and patient groups to reform the sector and restore the sustainability of private health in Australia.

Sustainability of the Private Health System

Australia's healthcare ecosystem relies upon a balance of public and private healthcare. Beyond this, Australia's private health insurance system also relies on a balance of case-mix and age. The young and healthy balance the cost of the old and sick through paying equal premiums. This is a simple notion that has ensured all privately insured Australians have access to our world-class health system.

Unfortunately, this system is out of balance; over the past two years, approximately 127,000 young people aged 20-34 have moved off private health insurance. Compounding this is the fact they have

[5] https://www.pc.gov.au/__data/assets/pdf_file/0006/156678/57privatehealth.pdf
[6] https://grattan.edu.au/confronting-the-private-health-insurance-death-spiral/

been replaced by 107,000 more people aged between 70 and 84. APRA estimates a further 345,000 young people will drop private health insurance by 2025.

Separation of fund management and healthcare delivery

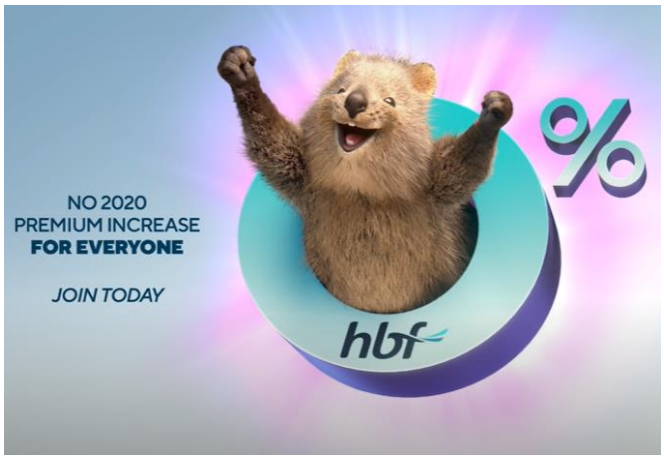
Private health funds have been too focused on serving as investment vehicles to turn a profit, provide perks to its executives such as bonuses and hospitality, and engage in expensive advertising campaigns, all the while young Australians have been abandoning private health insurance due to rising premiums.

Case Study: HBF 0% Increase

As a direct result of COVID-19 HBF cancelled their premium increase, proving the increases were a nice-to-have not a must-have.

David Greig, General Manager of HBF, said "We wanted to point out that, amongst health insurers, we really stand apart in the way we are supporting members during a challenging year," "While our main competitors have pushed ahead with increasing premiums or have postponed increases for just a select group of members, we have cancelled our 2020 premium increase for everyone."

HBF was so strong in their belief that the premium increase was not needed they rolled out a national advertising campaign pleading for Aussies to "hold out for a zero" because anything else is "a quokka sh!#".



The 21 December 2020 decision to increase insurance premiums (the second such increase in announced in 2020) was met with mixed views; some rightly were proud to point out that this was the lowest increase in over 20 years, others criticised insurers for again dipping into the pockets of struggling Australian families rather than looking to make their own savings. However, a notable portion of the media's attention generated by this announcement focused on what the premium increase meant for investors. For instance, the Australian Financial Review's James Fernyhough detailed the effect of the announcement on corporate health insurer stock prices rather than patients. The trend towards utilising private health insurance as an investment model is fundamentally at odds with its use as a the provider of finance for healthcare.

MTAA recommends such changes be made so that Private Health Insurers can prioritise their core business of providing funding for healthcare rather than their apparent current priority of prioritising maximising profit for investors.

Alternative levers for Private Health Insurance Sustainability

The 2019 report by AlphaBeta, *'Keeping Premiums Low: Towards a sustainable private healthcare system' outlines a number of options* that Government, policymakers, and insurers could activate in order to provide long term sustainability to private health insurance. These include:

- Saving $210 million* by improving the operational efficiency of private health funds,
- Saving $290 million* by optimising models of care and reducing admissions through prevention and promoting care in the community,
- Saving $250 million* by improving allied health offerings, and

- Saving $210 million* by constraining premium growth among Australia's top-performing funds.
  *savings figures are approximate and are based on the best available data.

These measures outlined within AlphaBeta's report could see a reduction in premium growth calculated at nearly $1 billion by FY22 (as of 2019), equating to approximately a 20% reduction in premiums.[7]

Beyond AlphaBeta's assessment of private health savings, in 2020, the Australian Medical Association outlined their prescription for private health insurers. This recommended:

- Restoring the private health insurance rebate for targeted groups to make private health hospital insurance affordable for younger Australians and those in the workplace on lower incomes,
- Reconsidering the Medicare surcharge levy levels and thresholds, in order to determine what settings are required to deliver on the policy intent, in a coordinated way with all future reforms,
- Standardising and increasing the minimum premium amount returned to the health consumer for every premium dollar paid,
- A review of the Lifetime Health Cover loading and penalties – especially the starting age to make it an easy choice for Australians to stay in private health insurance for life,
- Government youth discounts need to be enhanced and promoted,
- Introducing a higher standard of transparency to apply to health insurer policy documentation to clarify insurer policy benefit entitlements, and
- The establishment of an independent, well resourced, statutory body to regulate the legal conduct of the private health insurance industry.

MTAA endorses the solutions recently proposed by the AMA[8] and notes they closely align with proposals laid out by the 2019 report by AlphaBeta.

Further detail of the savings recommended by AlphaBeta can be found here.
Further detail on the AMA's prescription for private health insurance can be found here.

MTAA recommends Government utilise all measurers laid out in 'Keeping Premiums Low: Towards a sustainable private healthcare system' and the AMA's 'Prescription for Private Health Insurance to ensure Australian families are not over-paying for private health insurance and private health insurance can remain sustainable into the future.'

Independent review of the Private Health Insurance Industry

In 2001 HIH was placed into provisional liquidation, making it, to date, the largest corporate collapse in Australia's history with liquidators estimating HIH's losses totalling up to A$5.3 billion. The subsequent Royal Commission observed that APRA had not recognised the trouble the large insurer was facing until too late. In comparison, APRA has begun calling for a major independent review of private health insurance, with nothing left off the table to ensure that the entire industry and all

[7] https://www.alphabeta.com/wp-content/uploads/2019/08/mtaa_keepingpremiumslow2-1.pdf
[8] https://ama.com.au/articles/ama-prescription-private-health

stakeholders can work towards a solution; a solution that would secure the ongoing role of private health insurance in the Australian healthcare system.

Worth noting are comments from APRA board member Geoff Summerhayes who stated that with the challenges faced by private health "only three private health insurers will still have a sustainable business model by 2022." The MedTech Industry stands resolutely with Government and is continuing to work with Minister Hunt to do our part. To date, we have agreed upon a deal that saves Australians $1.1 billion by reducing the cost of items on the PL. Unfortunately, despite claims from some pundits, reducing the cost of medical devices alone will not be nearly sufficient as prostheses represent a decreasing percentage of private health insurance benefits paid.

A review of the broader private health ecosystem is needed urgently to stop and reverse what commentators are calling a "death spiral."

MTAA recommends conducting an independent review into private health insurance.

Prosthesis List

The 2017 Strategic Agreement on Prostheses List reform signed between MTAA and the Commonwealth Government concludes on 31 January 2022. Incorporated into the Agreement is a commitment to implementing further PL reform following the expiry of the Agreement. The Government has advised MTAA that high-level PL reform will be announced in this upcoming May 2021 Budget. MTAA has engaged in working groups led by the Department of Health (the Department) since the Agreement began and welcomed the release of the Department's consultation paper on 18 December 2020. MTAA will be providing a detailed submission to this consultation, which closes on 15 February 2021.

However, there are some high-level points MTAA would like to make as part of its Budget submission.

The Agreement between MTAA and Government has been a success in contributing to lower PHI premiums. The Agreement alone has contributed $629.1 million (based on MTAA's modelling) in savings on prostheses to September 2020 and combined with the February 2017 cuts, savings exceed $1 billion. Further, additional savings are expected throughout the remaining 17 months of the Agreement, taking the $629.1 million to a total of $1.1 billion. Prostheses were 14.4% of total hospital benefits the year to date, September 2016, prior to the series of cuts beginning 2017. They are now 13.9%. Combined with the effect of the reduction in elective surgery due to COVID-19 in the year to September 2020, insurers have not paid one extra cent for prostheses.

Nonetheless, MTAA recognises that there is an opportunity for further reform of the PL. Any reform to the PL should be undertaken and guided by the following principles:

- Achieve good outcomes for patients by protecting access to devices they need,
- Maintain the unique components of the private system,
- Maintain surgeon choice of prostheses,
- Reduce the gap between public prices and private benefits,
- Maintain no out-of-pocket costs for prostheses,
- Promote improved utilisation of prostheses,
- Improve management of the Prostheses List,
- Maintain private sector viability, and

- Facilitate access to new innovation.

The Department has laid out two major options for reform. Option 1 abolishes the PL and replaces it with a set of average payments for prostheses based on diagnostic related groups (DRGs) used to fund the public sector, managed by the Independent Hospital Pricing Authority (IHPA). Option 2 retains the PL under the control of the Department and proposes a series of measures to restrict costs and access.

Both of these models, as presented by the Department, have significant drawbacks and will have consequences for patient access and likely make the private hospitals less viable and private insurance less attractive. However, MTAA is proposing a version of Option 2 which retains the best features of the current PL but provides reforms necessary to ensure its viability and sustainability into the future.

Option 1 using DRGs is a radical reform and will have a number of negative impacts as measured against the principles for reform outlined above.

These include:

- Paying by DRGs means abolishing the PL because it uses an average to cover multiple possible devices,
- Only a retained PL guarantees consumer protection for the surgeon's specific choice for the patient which is an important feature of private health insurance,
- Under DRGs hospitals are forced to undertake procurement and play a cost reduction role - they don't have infrastructure or funding to do,
- DRGs may incentivise patient shifting to the public setting or less optimal treatment pathways,
- Paying for specific technologies on a case payment basis using DRGs is completely untried,
- There is a lack of confidence in the granularity and accuracy of the National Hospital Cost Data Collection (NHCDC) for this purpose,
- There are large parts of the private hospital sector missing from the NHCDC,
- Most of the intended goals of DRGs can be achieved through reforms to the existing PL, and
- Potential for out-of-pocket costs which, for the most part, has not occurred under current PL arrangements.

Alternatively, Option 2, as currently proposed by the Department, risks:

- Few new technologies being funded,
- Narrowing of choice of prostheses, removing the benefits policyholders pay for,
- Market failure in some situations, and
- High costs for industry.

MTAA strongly supports retaining the current PL. Few parts of the private health insurance system have been as successful in retaining wide choice with no out-of-pocket costs. Reforms to improve value and administration are needed, but critical to these reforms is recognising that private health is not the same as public and important distinctions need to be maintained when private health is funded by individuals and families contributing their own money to gain access to healthcare. There are also important differences between the public and private sector due to patient mix, product mix, service mix and volume commitments.

MTAA recognises there are four main areas of reform needed:

1. Introduction of routine benefit reviews,
2. Refinement of criteria for listing,
3. Simplification and optimisation of the PL, and
4. Optimisation of access pathways.

The information provided below provides a high-level overview of MTAA's submission to the Department's consultation:

1. Benefit levels - Benefit levels on the PL have not been routinely adjusted, leading to the accusation that the benefit levels are inflated. This claim is greatly exaggerated. However, there is a need to create a mechanism that creates confidence that benefit levels on the PL reflect a competitive market. For this reason, MTAA proposes using domestic public prices as a reference point with appropriate adjustments for the private market to ensure choice is retained and other elements such as service levels are not undermined. This can be implemented in an incremental way to avoid negative consequences from precipitous change. This measure also requires treating separately the high and unique service costs of some implanted cardiac devices such as pacemakers.
2. PL Criteria – the vast majority of products on the PL must continue to have the guaranteed access that the PL affords. There are a small number of products that likely do not qualify under current criteria and should be removed following the expiry of the Strategic Agreement once suitable funding arrangements are in place. There are a wider group of products with a value up to $250 million which the General Miscellaneous Review report has recommended are also removed.
    a. Should this be considered necessary to the continued operation of the PL, and there is strong confidence from the health sector that no significant consumer impacts will arise, then items within the General Miscellaneous category should also only be removed following the expiry of the Agreement and with suitable funding arrangements in place, so that the removal is not simply cost-shifting from insurers to the hospitals.
3. Simplification and optimisation of the PL – there are a limited number of examples that have been shopped around suggesting that the PL is administratively broken. In fact, some additional resourcing and investment into IT infrastructure would solve many issues. However, there is also an opportunity for further simplification and improvement, for instance, by consolidating some groups on the PL, making product descriptions more transparent and improving feedback and education on utilisation. In addition, further cost recovery needs to be considered for all sectors that benefit from the PL, including the private health insurers. It should be noted that there is no way around the complexity of managing the vast array of devices used in surgery. It is a question of who undertakes this task. If not the Department, it will be the hospitals.
4. Access pathways – the benefit review proposal by MTAA offers a much simpler pathway to listing on the PL due to benefits being set using an adjusted reference mechanism. For the very limited examples of new technology, fit-for-purpose pathways need to be further refined. The Medical Services Advisory Committee (MSAC) pathway remains clunky for many new devices where there are not new procedures required, and the current proposal to further increase the role of MSAC would exacerbate this. New approaches must be agreed in order for private patients to access the best available technology.

MTAA remains confident that its proposed solution will provide a viable PL into the future that continues to provide excellent access to necessary devices for private patients while maintaining the

value of health insurance. MTAA looks forward to furthering dialogue with the Government on these questions.

MTAA recommends any reform to the Prostheses List or implantable medical device reimbursement must be guided by the following principles:

- *Achieve good outcomes for patients by protecting access to devices they need*
- *Maintain the unique components of the private system*
- *Maintain surgeon choice of prostheses*
- *Narrow any gap between public prices and private benefits*
- *Maintain no out-of-pocket costs for prostheses*
- *Promote improved utilisation of prostheses*
- *Improve management of the Prostheses List*
- *Maintain private sector viability*
- *Facilitate access to new innovation*

Health Industry Policy

Remote Care opportunities

The 2020/21 Federal Budget began Australia's much-needed shift to remote care. Many across the health sector believed the shift to Telehealth[9] and Home and Community Care would take a decade, but in the case of Telehealth, the Government conducted these reforms within a week.

Industry commends the Government on these changes but notes it is essential the momentum gained is not lost, and further reforms continue to occur.

MTAA submits that while reforms are essential and will, beyond improving patient outcomes, improve the sustainability of private health insurance, it is vital that any policy focuses first on improving patient outcomes with any improvement to the sustainability of private health insurance being an additional positive outcome. To that end, doctors and medical professionals in consultation with their patient must be the sole deciders of where the patient is treated.

Home Health and Community Care

Home and community based care treatment options have been shown to improve patient health and other outcomes that matter to patients, such as the experience of receiving care. As service delivery options, they increase the effectiveness and efficiencies of medical treatment, reduce hospital re-admission rates and increase patient satisfaction. They enable Australians to access value-based care that focuses on managing conditions in the most relevant settings, rather than attend a hospital for care. Furthermore, integration of services is improved, because home health partners can provide a more complete picture, to inform medical professionals, which minimises the need for acute care.

[9] http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Factsheet-TempBB

Case Study: Remote Patient Management (RPM) with Baxter Sharesource

According to the 2019 ANZDATA report, there are 13,399 people receiving dialysis across Australia. 26% receive dialysis in their home, of which 18% receive peritoneal dialysis with the majority on automated peritoneal dialysis (APD). Adherence to treatment has traditionally been a concern for home dialysis patients and infrequent clinic visits means that treatment complications can go unrecognised for months at a time.

'Sharesource' is a revolutionary RPM software program that is integrated into Baxter's 'HomeChoice Claria' APD platform. It creates a constant, two-way connection that allows clinicians to access and interpret critical data and when necessary, remotely adjust prescriptions. This technology is increasing adherence, preventing complications, and improving patient outcomes.

A recent international study[1] also showed that treatment including Sharesource can lower hospitalisation rates when compared to traditional APD patients. When these effects were costed for the Australian environment, Sharesource has been estimated to save the health system between $855 -$3245 per patient, per year.

[1] Cost Consequence Analysis of Remote Monitoring with the HomeChoice Claria® with Sharesource® Platform for Automated Peritoneal Dialysis Patients in the Australian Setting. McElduff, PSarros &. s.l.: ISPOR Seoul, 2020, Vol. PUK3.

Home Care creates efficiencies and lowers long term costs, most notably with chronic conditions such as diabetes by empowering the patient to be a proactive participant in their care plan. With home infusions, reductions in hospital re-admissions, exposure to other risk factors, such nosocomial infections and the burden on hospital staff is greatly reduced.

A report by Alpha Beta found that by establishing home health services for as little as 10% of hospital admissions by determining those whose outcomes would be improved and private health insurers could save $8 million by FY2022. Early discharge to home health, for recovery, rehabilitation, medication monitoring not only delivers better health and patient outcomes but delivers savings as well. Transitioning 10% of hospital stays by FY2022 is forecast to save insurers $15 million. An example is with rehabilitation following total knee arthroplasty (uncomplicated) - instead of remaining in hospital for rest and rehabilitation, the patient can return home sooner, and receive rehabilitation services in the home, without the associated costs of hospital care (e.g., occupying a bed, medication management, service coordination for an otherwise well patient). The decision to transition a patient to home or community health care rests with the physician and the patient, so that the best outcome can be achieved. It is not for insurers or other stakeholders to predetermine the service delivery model.

MTAA recommends investigating the above budgetary measures as well as:

- Adequate and appropriate funding for medical services and support (i.e. MBS reform, expansion of MBS telehealth)
- Expansion of hospital substitution definitions in the private health setting
- Rebates and financial support for chronic haemodialysis and intestinal failure patients
- Investment in digital health technology and establish national standards for 'telehealth'
- Education and awareness for clinicians and patients and entrench home-based care in standardised undergraduate education.

Continuation of Telehealth Reforms

The Government's swift action to strengthen digital health during COVID-19 accelerated reforms in all areas of digital health, most notably in Telehealth. The efficiencies made possible by traditional (telephone) and new (internet) technologies ensured continuity in health care. The staged telehealth reforms ensured that patient safety, health, satisfaction, and wellbeing were not compromised from the biosecurity regulations of social distancing, isolation, quarantine and regulations and moratoriums on elective surgeries. Medicare-subsidised telehealth services were extended to include reimbursable primary care, generated new efficiencies in access and technology ultimately reduced the need for in-person care, reduced hospital re-admissions, emergency visits and ultimately improved patient outcomes.

Providing primary care via telephone has improved services to people in rural and remote areas as well as to disadvantaged persons. 30% of Australians do not have access to a computer or smartphone, and although the Government is investing in improving mobile coverage, large sections of the country have no cellular or internet signals at all.

The cost savings and improved patient outcomes during COVID-19 were so significant that telehealth reforms will continue to deliver value. Such reforms will have other benefits: strengthen control of personal and population health information, improve privacy and facilitate coordination of care. These benefits are aligned with contemporary practice in other countries, such as the US and the UK, and will result in high-quality, value-based health care.

MTAA recommends that the Government continue to explore how further utilisation of medical technology can improve the efficiencies of telehealth, and to include traditional and innovative telehealth solutions for a comprehensive and sustainable digital health platform in the future.

Further, MTAA recommends that the Federal Government continues the interim measures as new policies are formed.

Clinical Trials

Clinical trials are an integral part of the research and development of new treatments, interventions or tests, and the refinement of existing standards of care and clinical practices. As such, they are vital to the future of global healthcare.

The MedTech industry faces many obstacles in conducting clinical trials in Australia; including protracted start-up times, an excessive bureaucracy which provides no extra value and inconsistent requirements across state and territory health departments. MTAA wants to ensure the benefits of modern, innovative and reliable MedTech are delivered effectively to provide better health outcomes to the Australian community.

This can be achieved through the acceleration of the Government's Clinical Trials 'One-Stop-Shop' and 'Front Door' policy initiatives, that are currently being finalised. Not only will these policies contribute to economic growth in a COVID-19 recovery environment, including by attracting overseas investment, but more importantly, they will also lead to better health outcomes.

MTAA recommends the acceleration of the Government's Clinical Trials 'One-Stop-Shop' and 'Front Door' policy initiatives.

Cardiac Remote Monitoring

The COVID-19 Pandemic exemplified why an extension of remote monitoring (RM) for privately insured patients with implanted cardiac devices that are RM capable was needed. Private health insurers have been ordered to provide cover to patients with a high clinical need who were not provided with a remote monitoring system during hospital admission. Unfortunately, despite assurances from insurers, issuing of cardiac remote monitors is moving slowly if at all. Such a step would align cardiac remote monitoring with the widespread adoption of remote health services during the COVID-19 Pandemic and into the future.

In 2020 it was identified that there is a gap in coverage of privately insured patients with cardiac implantable electronic devices. Those who did not receive a monitor at the time of device implantation do not qualify to receive the system through the Prostheses List since it is not provided in a hospital. This restriction is arbitrary and exposes vulnerable patients with significant cardiac conditions to external factors and infection by requiring them to attend clinics more often. Extending insurance coverage to out-of-hospital provision of remote monitoring systems for those with a high clinical need is a simple, effective solution with a minimal cost impact.

Medical Services Advisory Committee and Prostheses List Advisory Committee have endorsed Remote Monitoring as a cost-effective and clinically effective solution for patients. Uptake of RM in the private sector is now approximately 90%. Patients with older devices are likely to benefit from extending the RM system provision. MSAC determined the service cost-effectiveness with the cost of the remote monitoring device to be $3,000. The Government then decided to list the RM system on the prostheses list (PL) at $1960 and the benefit has since been reduced to $1450 further improving its cost-effectiveness.

MTAA recommends government ensure private health insurers to fund cardiac remote monitoring and monitor the issuing of these devices.

Health Regulatory Policy

Therapeutic Goods Administrations Systems

The 2020/21 Federal Budget included $12M for the TGA's Digital Transformation project. These funds will modernise a system that has only undergone patchwork improvements since it was first launched in 1998. This transformation will hopefully shift TGA's IT system, based on an IBM Lotus Notes platform, to a modern platform allowing interoperability, cross-platform communications, and advanced search options. It is therefore critical that the transformed platform ensures TGA, and its IT system can ensure patient safety as well as performing activities such as:

- Applications tracking, status transparency (important for streamlining resource usage and efficiency);
- Ability to provide information in a usable format (e.g., TGA KPIs, post-market product recalls);
- Better ability to search and link various TGA databases (ARTG, IRIS, DEAN); and
- Implement a Unique Device Identification (UDI) system in Australia, which also includes the setting up of an Australian UDI database or AusUDID.

The TGA and the MedTech industry frequently interact via the TGA IT systems. Historically poor IT systems hamper these interactions, creating additional regulatory burdens, increasing cost and time, and disrupting business focus - all of which the Government is committed to alleviating. TGA also

works with other agencies and stakeholders who need to be able to access TGA systems in a timely and efficient way.

The ability to search databases with reporting capabilities is critical for enabling timely intervention in the interest of patient safety. Additionally, old IT systems are more vulnerable to cyber threats. TGA manages information about therapeutic goods that is essential for the reliable functioning of the healthcare system. This information must be accurate, reliable, and secure at all times.

With the European Union Medical Device Regulation (EU-MDR) changes arriving, this has never been a more critical requirement.

MTAA anticipates that through industry collaboration, the upgraded system will:

1. Increase patient safety with earlier and wider detection of safety signals, including links with patient implant cards and patient information leaflets.
2. Speed up robust scrutiny of innovative products, decreasing the regulatory burden and improving timely patient access to assessed technologies; and
3. Avoid cybersecurity issues exposing commercial and patient privacy information.

MTAA recommends the $12 million over four years allocated to the TGA's Digital Transformation be brought forward where practicable to accelerate this vital work and stimulate the post COVID-19 economy.

Removal of red tape and inter-jurisdictional regulatory duplication

With patient safety the number one priority of any health regulatory body it is only fitting that regulators put in place safeguards to ensure regulations are followed, and patients are safe. Unfortunately, this can sometimes result in overlaps and duplication of existing regulatory measures across different jurisdictions. If the Federal Government worked with State and Territory Governments and health departments to eliminate red tape that duplicates federal regulatory requirements patient safety would remain at its existing high level and industry could focus on improving patient outcomes rather than regulatory red tape.

Case Study: Health Share Victoria

Health Share Victoria (formerly Health Purchasing Victoria) require companies hold registration with GS1 Australia's platforms Recall Health and National Product Register (NPC)

This results in the payment of multiple fees including ongoing annual fees to GS1 as a condition for participation in public hospitals tenders. This is a duplication as the TGA already has requirements and databases for product recall and product information.

The cost, time and effort that sponsors spend to meet the duplicative requirements at State level erode the financial profitability and competitiveness of Australian medical device companies.

MTAA does, however, recognise the importance of a robust system and as such, any reasonable regulatory process that does not have a federal equivalent should be standardised nationally to ensure patient safety and access is equal across the Federation.

MTAA recommends the Federal Government work collaboratively with State Governments to reduce regulatory duplication and unnecessary red tape.

Industry Policy

Research and Development

For the past decade, gross R&D investment in Australia has declined, now currently at 1.88%, below the OECD average of 2.38%.

Australia could be positioned as a global hub for Research and Development (R&D) as it has been in the past. The comparatively low impact of COVID-19, combined with a highly skilled and well-educated workforce means Australia has a strong foundation for the growth of R&D. Investment in R&D has a dual influence on the Australian economy. Not only does it generate future research, it leads to better health outcomes, and provides more skilled employment pathways. Therefore, expanding R&D must always be a key consideration for the Government's COVID-19 recovery strategy, in the short and long term

Australia has a history of strongly supporting early-stage R&D, but this is not continued in translating this research to commercialisation and ultimately export. Ensuring support for R&D throughout the entire pathways, from conception to commercialisation will ensure growth and sustainability of our supported efforts, and restore Australia's reputation as an attractive location for R&D. All Australians benefit from these investments.

A significant number of member companies at the commercialisation stage already, have indicated that investment in R&D through incentives and grants does not meet the needs of MedTech. It is preferred that early-stage R&D support is shifted towards commercialisation, I.e., through purchase orders, by government procurement agencies for specific high-need equipment. Our companies have typically already invested in early-stage R&D, assumed all the associated risks, but cannot forecast uptake of products at the commercialisation state in advance. Support via pre-delivery purchase orders would ensure the entire R&D process and outcomes can be realised, thereby reducing some of the risk associated with innovation. Such support would ensure research can be translated into production and deliverables. Since states and territories are the largest procurers of all medical equipment, services, and devices this could be considered in relation to national health reform, in addition to industry policy.

MTAA recommends investing in R&D as a key part of the Government's COVID-19 recovery strategy. In particular, MTAA recommends:

- *Strengthening support through the full R&D pathway from preliminary research up to and throughout the commercialisation phase; and*
- *Investing in final stage R&D through purchase orders rather than grants of equal value;*

Advanced Manufacturing

Australia is viewed as a country that produces high-quality, reliable advanced manufacturing (AM). The COVID19 pandemic has solidified this reputation and demonstrated it can accomplish this with safety in mind. AM is expected to grow rapidly in MedTech, particularly in artificial intelligence, digital health and consumables, e.g., diabetes supplies.

Australian Advanced Manufacturing

With the support of Government MedTech companies responded to the sudden demand for supplies with flexibility and agility. The National Medical Stockpile (NMS was fortified and global supply chains expanded.

The Prime Minister announced the Modern Manufacturing Strategy (MMS) in his speech to the National Press Club, prior to the 2020/21 Budget. The MMS envisions Australia as a place where manufacturing is of such high quality, safety, efficiency, and therefore, desirable for foreign investment. This will contribute to a resilient economy and create jobs now and for future generations. Medical Products are included in the six priority areas targeted for co-development over the next ten years.

As the Pandemic progressed, Australia's access to the global supply chain became strained but did not ever fail. The Government requested the supply of 7,500 ventilators, tens of millions of COVID-19 testing kits and essential emergency supplies, within a matter of weeks. The MedTech global supply chain and local manufacturers responded, and the items were supplied without disruption, with the exception of a sole outlier – supply of personal protective equipment, (PPE). PPE was in such demand world-wide, that the unprecedented pressure in the entire global supply chain came close to breaking point. MedTech was able to identify reliable sources globally, along with rapid increases in production by Australian domestic suppliers. Despite the gruelling response, the expectation that Australia can continue to manufacture PPE and other low-cost items is not realistic, because when once global manufacturing returns to stable levels, Australian-made PPE cannot compete on price.

Australia must look to AM, in innovation, automation, artificial intelligence, robotics and the like, to become competitive in the MedTech sector. To that end, the Advanced Manufacturing Fund that provides co-investment to companies that increase manufacturing will contribute to the transformation of Australia's manufacturing sector. However, investment in research and development alone is not enough.

The Government must provide broad opportunities for Australian manufacturers, particularly for those who are already manufacturing here, but face numerous market restrictions for expansions. By example, the highly regulated and siloed way in which local governments conduct procurement processes - although espoused to support locally made products, procurement in practice supports only the lowest price. MedTech companies are aware of how to grow manufacturing, but there are insufficient indicators that their products would be successful in procurement tenders. Other barriers make expansion a high risk proposition. Factors that are entrenched in the health sector include corporate tax rates, high employment and high energy costs. Government facilitation of AM needs to be a whole-of-government approach, that reduces red tape, and provides other supports to ensure sustainability and growth.

MTAA recommends continuing the Modern Manufacturing Strategy and simultaneously investing in expanding the opportunities for Australian manufactures to expand into markets where supply does not meet current demand.

Cost of Energy

MTAA recognises the Federal Government's 2020 announcement on gas and energy pricing. This is a strong step in the right direction, however, the material effect of the policy is yet to be realised. Further, energy prices are expected to rise in the near future, due to the increased global demand for gas, forcing manufacturers to reconsider their use of off-grid electricity. To this end, MTAA endorses the recommendation on "Energy" in the Australian Chamber of Commerce and Industry's Pre-Budget Submission.

MTAA recommends that Government consider and act upon the recommendations on "Energy" in the Australian Chamber of Commerce and Industry's Pre-Budget Submission. *In particular MTAA recommends Government:*

- *Work through the Energy NCRC to achieve a national agreement that integrates energy and carbon emissions policies to provide the long-term certainty necessary for private investment in major energy projects.*
- *Work more cooperatively with state and territory governments through the Energy NCRC to better coordinate the development of renewable energy generation, transmission and distribution infrastructure.*
- *Remove embedded networks to give all electricity customers access to competitive retail networks.*

Economic and Tax Policy

Tax Reform

Tax reform is needed if MedTech is to reach its potential in Australia. Australia's corporate tax rate, especially for large employers is disincentivising businesses to operate in Australia. Lowering Australia's corporate tax rate to closer to the OECD average of 23.59% would be a major incentive that would attract substantially attracting more investment into Australia.

MTAA recommends the Government lower the corporate tax rate of all companies to closer to or lower than the OCED average of 23.59%

Taxation of Intellectual Property

Australia's investment in R&D continues to lose traction. Although Australia is ranked 13th in terms of government tax and direct funding support for R&D, its ranking for the outputs of this investment continues to fall further behind, dropping from 18th in 2011, 20th in 2018, to 22nd in 2019. The

commercialisation of our IP is losing ground, with economic activity being lost to peer nations, missed opportunities for well-paid jobs in advanced manufacturing, and a losses in licensing and royalty benefits.

Currently, the Commonwealth, via the R&DTI, the MRRF, and NHMRC, spend more than $3B p.a to support medical breakthroughs. However, commercial growth is stalled as the process to translate research into commercialisation is not incentivised. Currently, there are no incentives for onshore commercialisation of IP, and results, in effect, to the exportation of government-funded IP at the precise time where there is opportunity for profitability, which would deliver further value to the Australian economy. The level of support required for the Government to achieve this, can only be calculated once the specific parameters of this policy are defined. MTAA welcomes further discussion with the Government on this point.

MTAA recommends the Government to investigate international solutions such as the UK's Patent Box, Ireland's Knowledge Development Box, or section 238 of the French General Tax Code. By significantly reducing the marginal tax rate for income earned on locally developed and owned IP, these policies incentivise companies to:

- *Keep IP onshore;*
- *Expand local manufacturing of the IP; and*
- *Pay the taxable portion of the related review back to the country that invested in their initial R&D.*

Policy Horizon Scanning

MedTech is a rapidly innovating industry, although unlike many other industries, MedTech moves through many small, fast, iterative steps. As such, emerging policy needs can be difficult to see until needs become exceptionally pressing. To this end MTAA compiled a list of emerging technologies and policy issues Government should be aware of, available in Appendix B.

Emerging medical technologies in Australia

While many new and expanding fields are attention-grabbing, it is vital to realise that many important strides in MedTech innovations will be through incremental iterations in more traditional spaces. This includes utilising new materials and creating greater interconnectivity for existing systems and devices as well as utilising the technologies described in Appendix B.

Many new technologies could come to Australia in the next few years. The Food and Drug Administration (FDA) Breakthrough Device Designation is for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Designation speeds up the review process for regulatory approval. It is worth noting that to May 2020 [10] This highlights the enormous rapidity and importance of developments in MedTech to address a range of unmet clinical needs. The FDA's Breakthrough Device Designations provide global regulators, innovators, and policymakers, with a repository of the latest in MedTech and can be used as a tool for these bodies to conduct horizon scanning exercises.

MTAA recommends the Government acknowledge the future policy realities of the MedTech industry and make such provisions so that Australian patients can continue to access the latest advancements in medical technology and health care.

If this submission has raised any questions for you or you would like to organise a briefing, please contact MTAA's Public Affairs and Communications - Edward Strong at estrong@mtaa.org.au or Director of Policy - Paul Dale at pdale@mtaa.org.au

[10] Kelly, S. FDA Breakthrough Devices Program nears 300 designations, MedTech Dive. 2020, May 27. https://www.medtechdive.com/news/fda-breakthrough-devices-orteq-archerdx-terumo-thermedical-helius-photopharmics/578562/

Appendix A – MTAA Members

MTAA Members

- 61medical Pty Ltd
- 3D-Matrix Medical Technology Pty Ltd
- 3DMEDiTech
- 3DMorphic Pty Ltd
- 3M Australia Pty Ltd
- Abbott [Vascular] Australasia
- Abbott Medical Australia Pty Ltd
- Alcon Laboratories (Australia) Pty Ltd
- Allergan Australia Pty Ltd
- AlphaXRT
- Amplifon Australia
- Analytica Ltd
- APNE Surgical Pty Ltd
- Atomo Diagnostics Ltd
- Australasian Medical & Scientific Ltd
- Australian Dermatology Equipment
- Avanos Medical Australia Pty Ltd
- B Braun Australia Pty Ltd
- Bard Australia Pty Ltd
- Bausch & Lomb (Australia) Pty Limited
- Baxter Healthcare Pty Ltd
- Biocelect Pty Ltd
- Biotronik Australia Pty Ltd
- Boston Scientific Pty Ltd
- Brainlab Australia Pty Ltd
- BTC Health (BTC Specialty Health Pty Ltd)
- Cardinal Health Australia 503 Pty Ltd
- ConMed Australia
- Cook Australia Pty Ltd
- Corin (Australia) Pty Ltd
- Cortical Dynamics Limited
- Culpan Medical Australia Pty Ltd
- Device Technologies Australia Pty Ltd
- Edwards Lifesciences Pty Ltd
- Elekta Pty Ltd
- Exactech Australia
- Fresenius Kabi Australia Pty Ltd
- Fresenius Medical Care Australia Pty Ltd
- Gamma Gurus
- Gel Works Pty Ltd
- Getz Healthcare Pty Ltd
- Grey Innovation
- Hemideina
- Hologic (Australia) Pty Ltd
- Horten Medical
- Johnson & Johnson Medical Pty Ltd
- KLS Martin Australia Pty Ltd
- Laminar Air Flow Pty Ltd
- LifeHealthcare Pty Ltd
- LivaNova Australia Pty Ltd
- Materialise Australia Pty Ltd
- Medacta Australia Pty Ltd
- MED-EL Implant Systems Australasia Pty Ltd
- Medical Specialties Australia Pty Ltd
- Medigroup Australia Pty Ltd
- Medi Press
- Medtronic Australasia Pty Ltd
- MicroPort CRM Pty Ltd
- Molnlycke Healthcare
- NeedleCalm Pty Ltd
- Nevro Medical Pty Ltd
- NL-Tec Pty Ltd
- Olympus Australia Pty Ltd
- Palette Life Sciences Australia
- Paragon Therapeutic Technologies
- Prism Surgical Designs Pty Ltd
- Roche Diabetes Care Australia Pty Ltd
- Singular Health PTY LTD
- Smith & Nephew Pty Ltd
- Smiths Medical Australasia Pty Ltd
- Spectrum Surgical Pty Ltd
- Stryker Australia Pty Ltd
- Teleflex Medical Australia Pty Ltd
- Terumo Australia Pty Ltd
- Tunstall Australasia Pty Ltd
- Varian Medical Systems Australasia Pty Ltd
- Vitalcare Pty Limited
- W. L. Gore and Associates (Aust) Pty Ltd
- Wright Medical Australia
- Zimmer Biomet

Appendix B – Future and Emerging Medical Technologies

Whilst not needing immediate action by the Government, there are a number of future and emerging medical technologies that need to be brought to the attention of the Government. To ensure the Government is best able to prepare for the future Appendix B is a copy of part of MTAA's submission to the Inquiry into approval processes for new drugs and novel medical technologies in Australia.

Each of the below emerging medical technologies will require some shift in Government policy to enable them to best help Australian patients. MTAA does not expect, nor request any immediate policy shift in relation to these technologies but rather wants to inform the Government that a shift, at some time in the future, will be necessary.

3D printing and bioprinting

3D printing of medical devices is already a reality in the Australian health system. 3D printing allows customised bone and joint replacement implants to be created by orthopaedic and craniomaxillofacial (skull and jaw) surgeons that reflect the patient's body and the nature of the damage. Typically, they are combined with customised surgical guides, which are 3D models of the patient's relevant anatomy, and used to plan the surgery and the implant placement.[11] Continued growth in utilisation and sophistication of these techniques is expected to continue.

3D Bioprinting is an additive manufacturing process where biomaterials, such as cells and growth factors, combine to create tissue-like structures that imitate neural tissue. The process that occurs is like 3D printing and uses the technology bioink to produce the composite layers always in a sterile environment[12].

Potential applications of 3D bioprinting into the future include:

- Artificial organ creation to treat vital organ failure at a much speedier pace than traditional methods. This is still largely experimental but would make a profound difference to the thousands of patients waiting for organ donors
- Medical Device and pharmaceutical testing reduce ethical issues (speeding up the research process) and are more cost-effective than traditional methods of testing.
- Cosmetic Surgery: for plastic surgery & skin grafting – clinically necessary in Australia, granted our high incidence and prevalence of skin cancer, particularly in older age[13] and specific cultural cohorts[14]. 3D bioprinting can also be used for burns victims and patients with traumatic skin injuries.

[11] Daniel, D. 3D printing implants and organs is the new reality, Healthcare IT News. 2018, December 17. https://www.healthcareit.com.au/article/3d-printing-implants-and-organs-new-reality

[12] Mashambanhaka F. What Is 3D Bioprinting? – Simply Explained. 2018 Nov. https://all3dp.com/2/what-is-3d-bioprinting-simply-explained/#:~:text=Bioprinting%20is%20an%20additive%20manufacturing,structures%20that%20imitate%20natural%20tissues.&text=In%20essence%2C%20bioprinting%20works%20in,object%20layer%2Dby%2Dlayer.

[13] Curchin DJ, Harris VR, McCormack CJ, Smith SD. Changing trends in the incidence of invasive melanoma in Victoria, 1985–2015. Medical Journal of Australia. 2018 Apr;208(6):265-9. https://onlinelibrary.wiley.com/doi/abs/10.5694/mja17.00725

[14] Watts CG, Madronio C, Morton RL, Goumas C, Armstrong BK, Curtin A, Menzies SW, Mann GJ, Thompson JF, Cust AE. Clinical features associated with individuals at higher risk of melanoma: a population-based study. JAMA dermatology. 2017 Jan 1;153(1):23-9. file:///C:/Users/KatrinaBirrell/Downloads/jamadermatology_watts_2016_oi_160047.pdf

MTAA recommends the Government investigate reviewing the approvals process for medical devices in relation to personalised devices (such as 3D printed medical devices) to ensure the process and core similarities amongst devices require approvals but each individual, personalised device does not.

Artificial intelligence

The European Commission states that 'Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals'.[15] It is more than just the use of algorithms.

The use of (AI) is growing rapidly in healthcare for its ability to improve population and individual health. AI takes advantage of the significantly increased data available in healthcare, combined with massive increases in computational power to detect what might take many years to detect with other methods. This includes earlier disease detection, more accurate diagnosis, identification of new observations or patterns on human physiology, and development of personalised diagnostics and therapeutics.[16]

Case study: Ai To Detect Colorectal Cancer

Medtronic is using artificial intelligence to improve patient outcomes, including recently launching the first system worldwide using artificial intelligence to detect colorectal polyps.

The TGA has approved the use of Medtronic's GI Genius™ intelligent endoscopy module for use in Australia. This device uses artificial intelligence to provide real-time automatic detection of colorectal polyps of all shapes, sizes, and morphology. The module uses advanced artificial intelligence to highlight the presence of pre-cancerous lesions with a visual marker in real-time – serving as a vigilant second observer.

Studies have shown that every 1 percent increase in adenoma detection rate reduces the risk of colorectal cancer by 3 percent.

(Corley et al 2014. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. NEJM 2014; 370(14): 1298-1306)

Uses of AI in health include:

- Computer-aided detection (CAD) systems to help doctors interpret medical images
- Prediction of certain negative events, such as falls in the elderly, based on past patterns
- Autonomous diagnostic decision-making systems help detect signs of diabetic eye disease (retinopathy)
- Machine learning algorithms to help assess the risk of sudden cardiac death or other heart diseases based on electrocardiograms and cardiac MRI images

[15] Mashambanhaka F. What Is 3D Bioprinting? – Simply Explained. 2018, November. https://ec.europa.eu/digital-single-market/en/news/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines

[16] Artificial Intelligence in MedTech: Delivering on the Promise of Better Healthcare in Europe, MedTech Europe. 2019, November. https://www.medtecheurope.org/wp-content/uploads/2019/11/MTE_Nov19_AI-in-MedTech-Delivering-on-the-Promise-of-Better-Healthcare-in-Europe.pdf

- AI in endoscopy to automatically detect colorectal polyps of many different types (Medtronic GI Genius™ intelligent endoscopy)
- Personalised health guidance based on patient data captured by apps added to genetics and blood markers
- Support clinicians in telehealth consultations by combining patient-reported and sensing data

MTAA recommends the Government investigate reviewing how artificial intelligence can be best regulated and how approval processed may need to be refined or tailored to suit this emerging technology.

Digital therapeutics

Digital therapeutics have been on the market for about ten years but have only recently come into their own. In order to be called digital therapeutic, a product has to be software-driven, evidence-based, and make a claim to prevent, manage, or treat a medical disease or disorder.[17] Digital therapeutics include leading and emerging technologies such as virtual reality online therapies to help people to adopt healthy behaviours and social robots[18]. Potentially, their greatest use is to stimulate behaviour change, which is important for the management of chronic disease and the treatment of substance abuse. Virtual reality online therapies can also be used to treat mental health conditions.

MTAA recommends the Government, in due course, investigate the expansion of digital therapies to treat chronic disease, substance abuse, and mental health challenges.

Robotic surgery

Robotic surgery is increasingly widespread globally and in Australia. It commonly involves the use of a camera arm and mechanical arms which are controlled by the surgeon while viewing the surgical site in high-definition, magnified 3D images on a computer. It is typically used in minimally invasive surgery that involves only very small incisions. Surgeons have continually searched for less invasive approaches to surgery, and the focus is increasingly on miniaturisation.[19]

While these systems seek to improve on existing approaches, there is a further area of development for microbots which are constructs at the sub-millimetre level with surgical functionality. Theoretically, these constructs could be deployed into a patient's bloodstream through conventional access, and then maneuvered to a specific destination to carry out a designated task without a surgeon even touching the patient's skin. These systems are still very early in their development, but individual areas of research are beginning to integrate into a more cohesive image of what microbots of the future may be. Microbots represent a potentially revolutionary concept in surgery.

[17] Makin, S. The emerging world of digital therapeutics, Nature. 2019, September. https://www.nature.com/articles/d41586-019-02873-1
[18] NATURE, S106, Vol 573, A smarter way to treat, Makin S, 2019
[19] Annals of Laparoscopic and Endoscopic Surgery, Emerging surgical robotic technology: a progression toward microbots, Khandalavala K, et al, 2020 http://ales.amegroups.com/article/view/5499/html

MTAA recommends the Government, in due course, investigate amending regulatory and reimbursement policy so that advanced robotic surgeries, such as microbots, are available to Australian patients.

Neurological stimulation

Neuromodulation is the treatment of neurological challenges through the stimulation of the brain or nervous system via targeted electrical pulses. Advances in both bioengineering and neurology have resulted in a fast-developing way to treat chronic diseases, sometimes known as bioelectronic medicine. Scientists are able to identify specific nerves and implant devices that can be activated when needed to change their activity and so control cells in organs targeted by those nerves that regulate the body's many immune and metabolic responses.[20]

Neuromodulation is already a safe and effective treatment, largely deployed for movement disorders including Parkinson's disease tremor and dystonia, as well as epilepsy, psychiatric disorders such as depression/obsessive-compulsive disorder/Tourette's, and a variety of previously intractable chronic pain syndromes as well as the loss of bladder control.[21]

Conditions that have been treated or symptom-managed experimentally, and might be treated in the future using neuromodulation, including Alzheimer's disease, rheumatoid arthritis, Crohn's disease, additional types of untreated pain, cluster headaches and even cardiovascular disease. Particularly while pharmaceutical approaches to treating psychiatric and neurological disorders have been meeting with limited success[22] , non-pharmacological ways of treating brain-related pathologies may be of crucial importance if progress is to be made.

Among patients with anorexia nervosa, implanted deep brain stimulation has been able to successfully stimulate the regions of the brain controlling dysfunctional behaviour leading to reduced anxiety, improved wellbeing and mood, and increased Body Mass Index (BMI) score[23].

MTAA recommends the Government, in due course, investigate how neurological stimulation, a treatment already returning positive results for private patients, could be better accessed by all Australian Patients.

Physiological and neurological monitoring and control

Neurological monitoring and control devices are devices that are controlled via connection to the brain. Whilst still well beyond the horizon, neurological monitoring and control devices represent

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[20] Park, A. Why it's time to take electrified medicine seriously, TIME. 2019, October. https://time.com/5709245/bioelectronic-medicine-treatments/

[21] Farrell, S, M., Green, A., and Aziz, T. The use of Neuromodulation for symptom management, US National Library of Medicine National Institutes of Health. 2012, September 19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6769574/#:~:text=Neuromodulation%20(deep%20brain%20stimulation%2C%20motor,4%5D%2C%20psychiatric%20disorders%20such%20as

[22] Gribkoff VK & Kaczmarek LK (2017) The need for new approaches in CNS drug discovery: Why drugs have failed, and what can be done to improve outcomes. Neuropharmacology 120:11-19.

[23] Lipsman N, Lam E, Volpini M, Sutandar K, Twose R, Giacobbe P, Sodums DJ, Smith GS, Woodside DB, Lozano AM. Deep brain stimulation of the subcallosal cingulate for treatment-refractory anorexia nervosa: 1 year follow-up of an open-label trial. The Lancet Psychiatry. 2017 Apr 1;4(4):285-94.

leaps in health outcomes that until recently was the basis of science fiction. Emerging research into brain-computer interface (BCI) technologies centre around the creation of a direct communication pathway between an enhanced or wired brain and an external device usually through the detection of electronic pulses within the brain. BCIs are often directed at researching, mapping, assisting, augmenting, or repairing human cognitive or sensory-motor functions.[24]

Case study: Neuralink Corporation

Neuralink Corporation is an American neurotechnology company founded by Elon Musk and others, developing implantable brain–machine interfaces (BMIs). Whilst Neuralink is reported to be still conducting pre-trial research they have demonstrated a concept that implanted very thin (4 to 6 µm in width) threads into the brain, the demonstration proved it could read information from a lab rat via 1,500 electrodes in the brain.

The initial goal of Neuralink's technology will be to help people with paralysis to regain independence through the control of computers and mobile devices. In July 2020, Neuralink obtained an FDA breakthrough device designation which allows limited human testing under the FDA guidelines for medical devices

Wikipedia. 2020 October. https://en.wikipedia.org/wiki/Neuralink

1Lopatto, E. Elon Musk unveils Neuralink's plans for brain-reading 'threads' and a robot to insert them https://www.theverge.com/2019/7/16/20697123/elon-musk-neuralink-brain-reading-thread-robot

Whilst Neurological monitoring and control devices are still in the early stages of R&D with some animal testing taking place, MTAA recommends the Government, in due course, make such changes to regulation and policy that these devices, once a topic of science fiction, be made accessible to Australian Patients.

Telehealth

It is well discussed that COVID-19 accelerated the introduction of telehealth into Australia and shows what can be achieved through political will and stakeholder collaboration. Through COVID-19, 32.8 million telehealth services were delivered (to 30 September 2020) at a cost of over $2.4 billion[25]. MTAA welcomes the Federal Government's extension of its COVID telehealth arrangements for an additional six months as the long-term plan is developed and implemented. Security is critical to the

[24] Krucoff, Max O.; Rahimpour, Shervin; Slutzky, Marc W.; Edgerton, V. Reggie; Turner, Dennis A. (1 January 2016). "Enhancing Nervous System Recovery through Neurobiologics, Neural Interface Training, and Neurorehabilitation". *Frontiers in Neuroscience*. **10**: 584. doi:10.3389/fnins.2016.00584. PMC 5186786. PMID 28082858.

[25] Department of Health. Budget 2020-21: Record health and aged care investment under Australia's COVID-19 pandemic plan. 2020 October. https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/budget-2020-21-record-health-and-aged-care-investment-under-australias-covid-19-pandemic-plan

success of telehealth.

Case study: Apple Watch Series 4

Apple Watch included an ECG feature in 2018 as part of its Series 4. It's sparked a number of headlines for its role in saving people's lives due to falls or irregular heartbeats. However, because the feature acts like a medical device, monitoring your heart rate and providing health advice, it would require listing via the TGA on the Australian Register of Therapeutic Goods (ARTG). As of September 2020, Apple were yet to lodge an application to the TGA in regard to the listing of any of their products.

Telehealth goes beyond merely a video link when it begins to incorporate sensing and diagnostic technology that can be used in real-time, including smart technology. This can also involve the use of artificial intelligence to process and report on significant patient information, as noted earlier in this submission.

Some notable examples of where medical technologies that could support telehealth are bio-sensing wearables such as digital blood pressure monitors, glucose sensors and even the latest Apple Watch.[26]

Telehealth is hardly a new concept; however the full capabilities of telehealth and remote healthcare have not yet been realised. MTAA recommends the Government act soon to ensure the next wave of telehealth and internet-of-things enabled medical devices are not delayed due to a burdensome regulatory landscape.

[26] https://www.gizmodo.com.au/2020/09/australians-are-still-no-closer-to-getting-apple-watchs-ecg-feature/