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STRENGTHENING AUSTRALIA'S HEALTHCARE SYSTEM

PRE-BUDGET SUBMISSION

PREPARED BY THE MTAA

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MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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About MTAA

Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology (MedTech) 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 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 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 MedTech. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia.

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.

For example, Prism Surgical, Atomo Diagnostics and Grey Innovation 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 was valued at US$4.9 billion

The MedTech industry in Australia is a substantial employer. In 2014, it was estimated the industry employed 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.[2]

[1] Australian Bureau of Statistics, Characteristics of Businesses in Selected Growth Sectors, Australia, 2013–2014. 2015, Australian Bureau of Statistics: Canberra.

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

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 industry. In 2019, it was calculated 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 patients per year are served with technology that provides A$3.6 billion to $4.5 billion annual value to the community. As a result, globally this has resulted in 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.

Despite representing a small market, Australia ranks as a prominent developer of MedTech worldwide, and according to the Worldwide Medical Device Factbook, 13th in terms of total market value. 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.

The MedTech industry's COVID-19 response

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

Within days of the WHO's designation, MTAA provided the Australian Federal Government with 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 assisted 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.

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.

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

Existing local MedTech manufacturers had to increase production rates dramatically. 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 rate.

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, a situation that has re-emerged with the rapid onset of the Omicron variant in late 2021, placing yet more strain on already stretched MedTech companies.

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%. This continues to affect the industry, with no end in sight for excessive freight costs and shortages.

Throughout the pandemic, the MedTech industry has adapted to change, absorbed additional costs, opened new production lines, shifted existing production capacity, joined forces with other companies, industries, and governments, and developed new procedures to keep Australians healthy. All of this whilst continuing to support patients and the broader health sector. MedTech in-theatre technicians spent countless cumulative days in quarantine, 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 emergence of the Omicron strain, 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. As Australia starts to re-open, MedTech will continue to support Australia through the Pandemic and the transition to 'living with Covid'.

Summary of policy priorities

MTAA's pre-Budget submission outlines a series of policies that if introduced, would lead to improved patient outcomes and greater opportunities for Australia's MedTech industry to support patients both in Australia and around the world.

The COVID-19 pandemic has presented Australia and the world with far-reaching social, environmental and economic challenges not experienced since World War II. Developing a strategy for national resilience and preparedness means designing policies and programs that prioritise the nation's health and economic resilience, ensuring Australia is prepared for the years to come. MTAA's policies cover five (5) key areas of priority:

1. The future of Australia's private health system
2. Health policy
3. Health regulatory policy
4. Health industry policy
5. Economic and tax policy

The Future of Australia's Private Health System

Role of private health insurance

Private health care is an essential component of Australia's health system and provides choice, diversity and competition for consumers.

Without a viable private health sector, there would also be additional stress placed on an already over-burdened public system.

Private health insurance is an important mechanism through which consumers pay for private health care. Keeping private health insurance affordable will support Australians to access care in the private health sector and therefore take pressure off public health services.

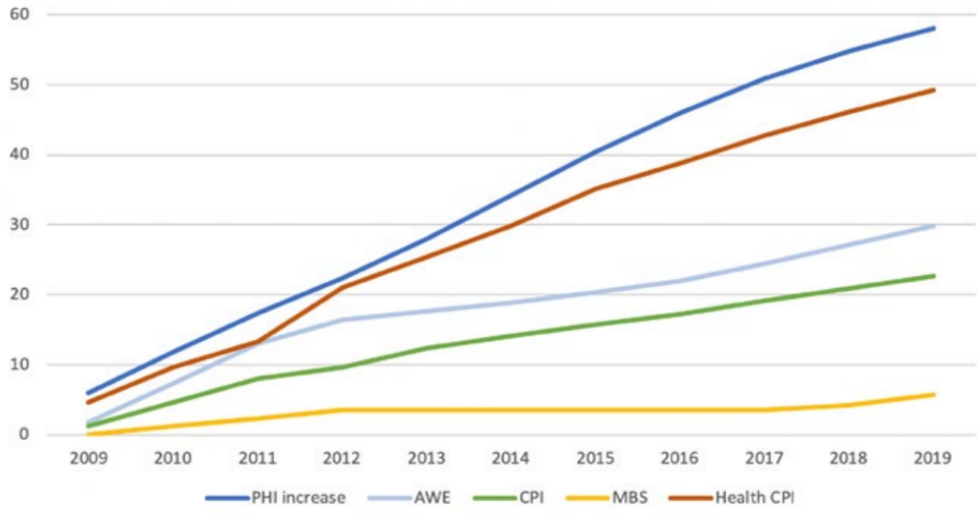
However, Australia's private health insurance industry is currently facing significant challenges.

This is due to a range of factors, including increased consumer demand from our ageing population and the consequent increasing prevalence of chronic disease.

Costs in the private health system are rising faster than overall healthcare costs. While Australia's overall healthcare expenditure rose 4.9% p.a from 2013-2018, costs in the private health system grew faster, with premium revenue up 5.9% per year.

The biggest driver of total premium growth has been higher average premiums paid by consumers for their private health coverage. Since 2013 private health insurance premiums have increased an average of 4.5% a year, while the number of people with coverage has only grown 1.3% a year.

Percentage growth of wages, MBS and private health insurance premiums



PHI increase – increase in premiums:
https://www1.health.gov.au/internet/main/publishing.nsf/Content/0B815BFEB8EDECA7CA257BF000195929/$File/Premium-Round-Individual-Insurer-Average-Premium-Increases%E2%80%931997-to-2020.pdf
AWE – Average Weekly Earnings: 6302.0 - Average Weekly Earnings, Australia 2009-2019
MBS – Medical Benefit Schedule: https://feeslist.ama.com.au/resources-ama-gaps-poster
CPI – Consumer Price Index and Health CPI – Health Consumer Price Index: ABS data 2009 - 2019 6401.0 - Consumer Price Index, Australia

AMA Prescription for Private Health Insurance - https://www.ama.com.au/media/ama-prescription-private-health

This means that private health insurance is becoming less affordable leading some consumers, often those at lower risk, to drop their insurance. This increases the risk pool of those retaining their insurance which in turn drives premiums higher and leads to another group of consumers leaving.

With only 44.5% of Australians covered by private health insurance hospital cover (June 2021 figures) and a faster decline in the participation by the young and healthy, the system is in need of reform. Unless private health insurance can address these rising costs, Australia risks overburdening its public healthcare system, putting the quality of patient care at risk.

Successive governments have tried to tinker around the edges with regulatory changes, government handouts, and cosmetic changes but these have not solved the fundamental problems with the private health insurance sector.

MTAA strongly supports the retention of private health insurance as a mechanism to support consumers to access private health care. However, we believe it is time for some major reforms which will support the long-term sustainability of the sector and ensure that private health insurance remains affordable.

These reforms need to focus on re-building public trust in private health insurance and restoring private health insurers to their original purpose of sharing the risk of health and medical expenses around their members.

The Seven Point Plan for Private Healthcare

MTAA has developed a seven point plan that will support the Government's objective of private health insurance retention as a mechanism to support consumers access, support long term sustainability of the private health system and ensure private health insurance remains affordable in Australia.

Each of the points outlined in the plan focuses on re-building trust in private health insurance and restoring private health insurers to their original purpose of sharing the risk of health and medical expenses around their members.

MTAA's proposed plan is outlined below:

1. ***Returning COVID-19 profits to consumers***

Corporate health insurers are enjoying record dividends this year, however, due the pandemic, many of their policy holders have not been able to use their insurance to access the health care they need.

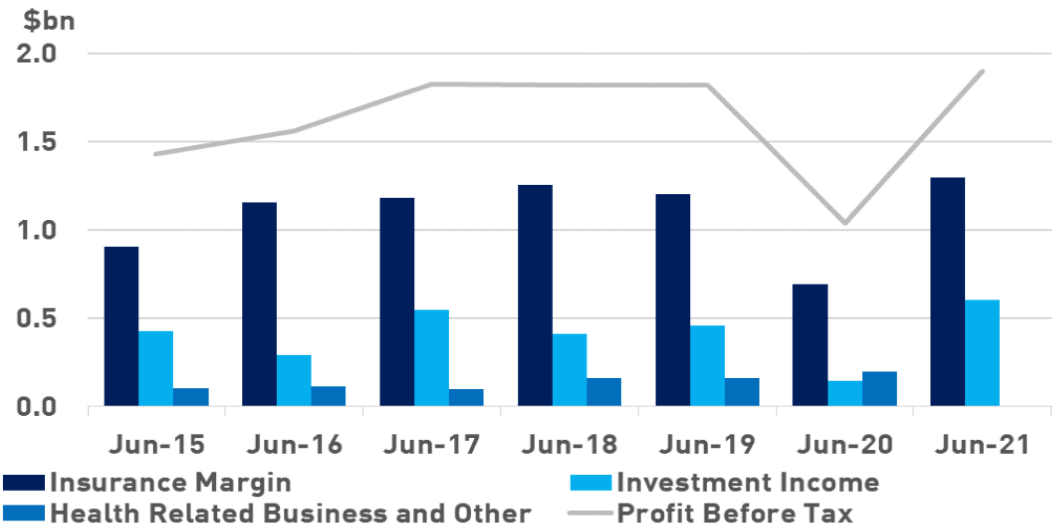
Last financial year companies like NIB and Medibank Private reported a drop in claims – due to COVID-19 pauses on elective surgery. This means they did not have to pay out as much, despite still collecting the same premiums from policy holders, leading to growth in revenue and record profits.

Between June 2020 and June 2021, insurers' net investment income rose a staggering 313.2% ($146.2 million to $603.9 million) and their net profits were up 93.7% ($754.0 million to $1.5 billion).

Table 1. Key performance data/metrics for the year to date

	Year to June 2020	Year to June 2021	Yearly Change
Premium revenue	$24.9 bn	$25.7 bn	3.2%
Fund benefits (claims)	$21.9 bn	$22.0 bn	0.3%
Gross Margin	12.0%	14.5%	2.4pp
Management expenses	$2.3 bn	$2.4 bn	5.2%
Net Margin	2.8%	5.0%	2.3pp
Net investment income	$146.2 m	$603.9 m	313.2%
Net profits after tax	$754.0 m	$1.5 bn	93.7%

Chart 1 – Breakdown of profit components (Year ending)



Source: *Quarterly Private Health Insurance Statistics (released August 2021) https://www.apra.gov.au/sites/default/files/2021-08/Quarterly%20private%20health%20insurance%20statistics%20highlights%20June%202021.pdf*

The large for-profit insurers benefitted significantly from this environment reporting dramatic increases in operating profits and investment incomes for the 2020/21 financial year. Medibank Private reported its operating profit soared 14.4 percent in 2020-21 to $538.6 million, underpinned by a 4.6 percent jump in membership while claims grew just 1.4 percent.

The pauses in elective surgeries during the pandemic were necessary but insurers should not have been able to profit from the difficult decision to delay access to needed surgery for thousands of their policy holders.

Rather than using this COVID-19 windfall to increase insurers' management bonuses and shareholder profits, these funds should be returned to policy holders in order to reduce the cost of their insurance over this difficult period.

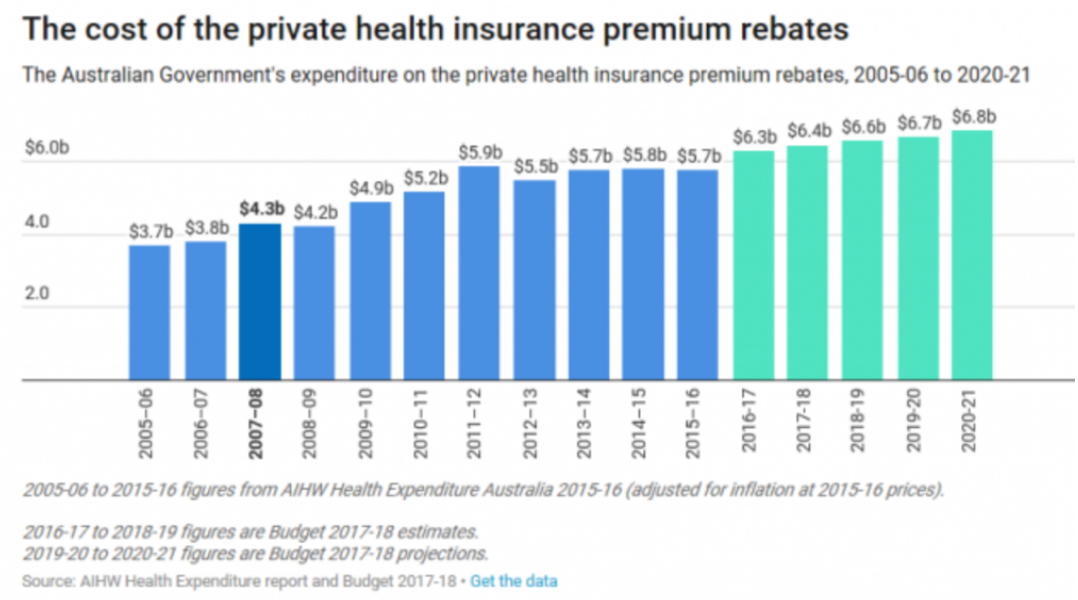
Recommendation: The Federal Government should explore all legislative and regulatory options to ensure the COVID-19 windfall insurers' have pocketed are returned to their policy holders.

2. Requiring insurers to pay out a minimum of 90 percent of their revenue to consumers

Private health insurance is heavily subsidised by the Federal Government via the private health insurance rebate and other tax incentives.

The aim of these subsidies is to provide a benefit to the Australian community – to assist people with insurance to afford private health care and to help those without by taking pressure of the public system.

The cost of this rebate is rising and is now close to $7 billion per year.



Source: *https://www.macrobusiness.com.au/2018/04/will-labor-take-axe-private-health-insurance/*

The rebate is designed to improve the affordability of insurance for consumers yet insurers benefit significantly from this subsidy, which adds to their profits and ability to pay management bonuses, executive salaries and shareholder dividends.

The corporate benefits from government subsidies should be secondary to policy holder benefits. It is not in the public interest for tax-payer subsidies to be used to deliver profits for health fund shareholders.

Insurers whose policy holders receive the benefit of the private health insurance rebate should be required to return 90 percent of their revenue to policy holders before they're able to use their profits to benefit corporate interests.

Recommendation: The Federal Government legislate that insurers be required to pay out a minimum of 90 percent of their revenue to their policy holders.

3. Establish a Private Health System regulator to develop a reform agenda to increase sustainability and protect patients

Major changes are needed to make private health affordable – in particular to address the ageing of the insurers' population and loss of younger policy holders.

Reforms need to have input from all key stakeholders – day hospitals, private hospitals, medical device manufacturers, doctors and consumers.

This process should start with a Private Healthcare Summit, as first suggested by the AMA.

The aim of this event is to create a solid platform for the medical profession, hospitals and insurers to work together more effectively to make private health insurance more affordable and improve its value proposition for consumers.

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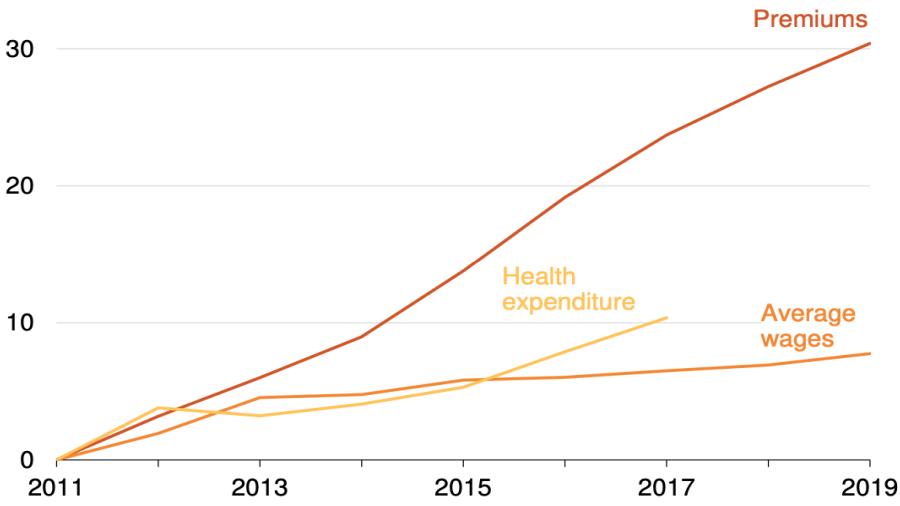
Figure 1.2: PHI premiums have consistently grown by more than wages over the past decade

Cumulative real growth in average PHI premiums, wages, and health expenditure per person, per cent



Notes: All series deflated using the Consumer Price Index. PHI increase is the industry weighted average per year. The effective premium payable by consumers would be even higher, because premiums are covering less today than a decade ago. Wages series is the average weekly ordinary time earnings of full-time adults in the year to the November quarter. Health expenditure is the average health expenditure per person.

Sources: Department of Health (2018b), ABS (2018), AIHW (2018), PHIAC (2013) and Grattan Institute analysis.

Source: *https://grattan.edu.au/wp-content/uploads/2019/07/918-The-history-and-purposes-of-private-health-insurance.pdf*

collaborative approach will be required to determine how to address the rising cost of private health insurance which is outstripping growth in wages and health expenditure.

A clear plan for reform would deliver certainty to consumers, rebuild trust in private health insurance and create a sustainable future for private health care.

Recommendation: The Federal Government convene a Private Health Summit that includes all stakeholders to develop a reform agenda for a sustainable private health sector.

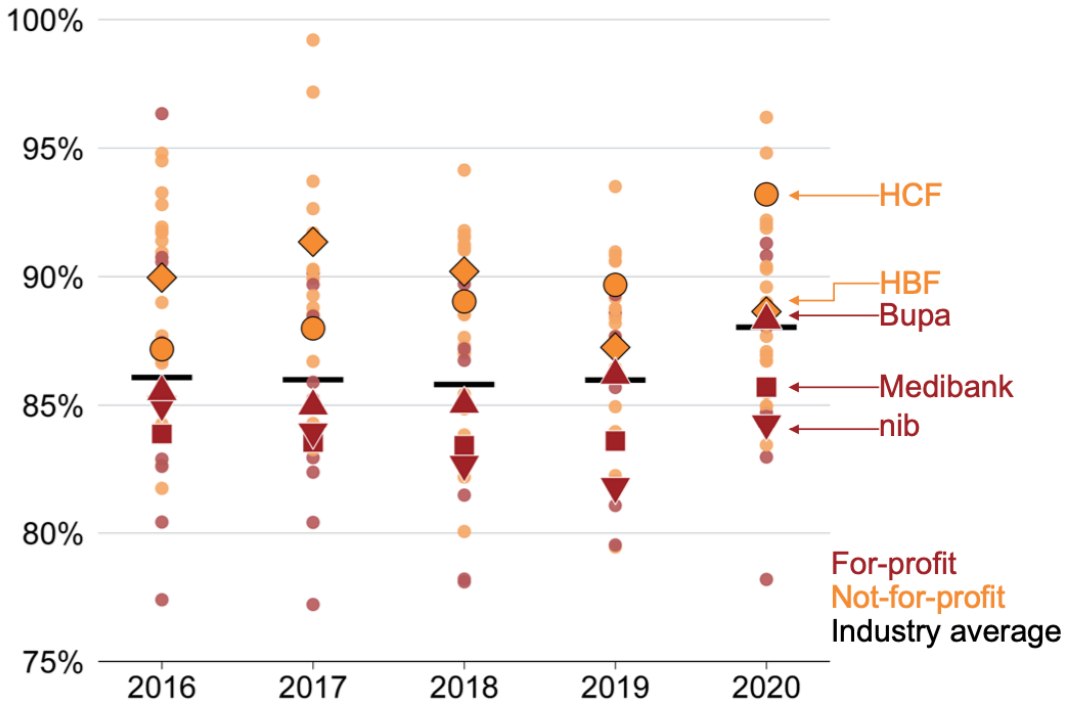
4. Refuse premium increases for insurers whose claims ratio is below the industry average

Premiums are corporate health insurers' largest source of revenue, and benefits paid are their largest expense.

The proportion of premium revenue returned to members in the form of benefits is known as the 'claims ratio'.

Figure 5.1: Many funds, both big and small, return less than 85 per cent of premiums to their contributors

Benefits paid as a proportion of premium revenue, by financial year



Notes: Fund benefits include benefits paid for hospital and general insurance (including state ambulance levies). Premium revenue includes all revenue from the health insurance business (excluding health-related business revenue and investment income). The datapoints for four small insurers are not shown because of missing and outlying data.

Source: *Grattan analysis of APRA (2020), https://grattan.edu.au/wp-content/uploads/2021/05/Stopping-the-Death-Spiral-Grattan-Report.pdf*

There is considerable variation in insurers' claims ratios – one factor contributing to this is variation in administrative costs, such as managing claims and differences in spending on advertising and promotions or management, board and executive salaries.

An analysis by the Grattan Institute of current claims ratios found that in 2019-20, nine insurers in Australia had claims ratios of less than 85 percent, including one with a ratio of less than 80 percent. If these insurers reduced premiums to achieve the 85 percent ratio, premiums in those funds would fall by an average of 2 percent.

Insurers should not be able to charge higher premiums unless they are operating efficiently.

As the Minister for Health is required to approve annual premium increases, the Minister should require insurers to provide additional justification for a proposed increase if the proportion of their premiums returned to policy holders are less than 80 or 85 percent.

This would force insurers to improve their own performance before asking for more money from members.

Recommendation: The Minister for Health should refuse premium increases for insurers who return less than 85% of premium revenue to policy holders without adequate justification.

5. Prevent insurers from providing rebates for unproven treatments

Private health insurers' payouts on alternative treatments like natural therapies, hypnotherapy and acupuncture are growing at a faster rate than spending on hospital services, medical care, and prostheses.

According to the Australian Prudential Regulation Authority (APRA), insurance payouts on natural therapies for the June 2021 quarter was 87 percent higher than for the same period in 2020. Benefits paid for acupuncture and hypnotherapy also increased significantly (49% and 34% respectively).

In contrast, payments for medical services, hospitals and prostheses grew by 34%, 21% and 32% respectively over this period.

The results highlight long-standing concerns that health insurance premiums are being driven higher by insurers extending cover to treatments with no proven medical benefit.

	June 20	June 21	Difference	% change
Acupuncture	$7 099 285	$10 600 671	$3 501 386	+49%
Natural Therapies	$28 749 569	$54 176 891	$25 427 322	+87%
Hypnotherapy	$24 896	$33 246	$8 350	+34%

Source: *https://www.apra.gov.au/operations-of-private-health-insurers-annual-report https://www.apra.gov.au/quarterly-private-health-insurance-statistics*

Two years ago, the Federal Government banned health insurers from covering 17 alternative therapies after a scientific review led by the Chief Medical Officer found they had no clinical efficacy.

The Government said the reform would cut expenditure and ease the pressure on premiums, but this clearly has not worked.

The Government should not be subsidising unproven treatments – insurers should not be able to receive the private health insurance rebate for products which cover non-evidence-based services.

Recommendation: The Federal Government should not allow insurers which continue to provide cover from unproven treatments to be able to offer the government-funded rebate to policy holders for these policies.

6. Standardisation of rebates for services across insurers to streamline administration and provide more certainty for consumers

Currently rebates for procedures vary dramatically across funds. Each insurer develops its own schedule of benefits for hospital services, and these can differ across the various policies offered by the same insurer. Insurers' arrangements with the treating doctor, and the treating hospital, also impact on the benefits offered.

This means that the same procedures conducted in the same setting by the same providers can attract different levels of rebate from insurers – resulting in different out-of-pocket costs.

These differences can be significant and result in wider variation in out-of-pocket costs experiences by consumers.

Benefits paid for select medical service by BUPA in 2020, by State/Territory

35657	Vaginal Hysterectomy	$695.80	$1112.80	$1129.45	$1139.60	$1048.90	$1106.50	$1273.95	$225.05 21%
37623	Vasectomy	$237.05	$364.55	$360.85	$384.00	$362.05	$356.60	$325.70	$58.30 18%
38306	Stent for coronary artery	$786.15	$1134.75	$1111.75	$1155.35	$1060.20	$1307.20	$1181.05	$247.00 23%
38500	Coronary Artery Bypass	$2268.75	$3395.35	$3432.00	$3531.30	$3187.10	$3929.50	$3733.95	$742.40 23%

Source: *AMA Private Health Insurance Report Card 2020*
https://ama.com.au/sites/default/files/documents/AMA_Private_Health_Insurance_Report_Card_2020.pdf

Even within the same health fund and policy, benefits for the same procedure can differ significantly depending upon the State or Territory where the consumer receives the service.

Benefits paid for select medical service by BUPA in 2020, by State/Territory *(Continued)*

MBS Item	MBS Description	MBS Fee	NSW/ ACT	VIC	WA	QLD	SA	TAS	NT	Variation
12203	Overnight Investigation for sleep apnoea	$606.35	$721.80	$851.75	$722.85	$720.60	$840.05	$720.60	$720.60	$131.15 18%
13918	Cytotoxic Chemotherapy	$101.00	$121.10	$141.80	$121.30	$107.55	$139.85	$107.50	$107.55	$34.30 32%
16519	Uncomplicated Delivery (of baby)	$715.65	$2068.15	$2194.20	$2104.30	$2064.20	$2271.05	$2057.55	$2101.55	$213.50 10%

Source: *AMA Private Health Insurance Report Card 2020*
https://ama.com.au/sites/default/files/documents/AMA_Private_Health_Insurance_Report_Card_2020.pdf

These differences cause confusion among consumers and make private healthcare less attractive overall. It also creates an administrative burden on providers who are required to keep track of the different rules for each fund and policy.

An industry plan could include an initiative to standardise fund rebates, eliminating that excuse for variation in out-of-pocket payments. This would create certainty for policy holders, reduce the administrative burden on providers and increase the value of private health insurance overall.

Recommendation: The Federal Government work with insurers and other health stakeholders to develop an industry plan to standardise benefits across procedures, settings, doctors and funds.

7. Hold an inquiry into the corporate and tax structures of insurers to identify opportunities to reduce management expenses and prevent tax minimisation by shifting profits offshore

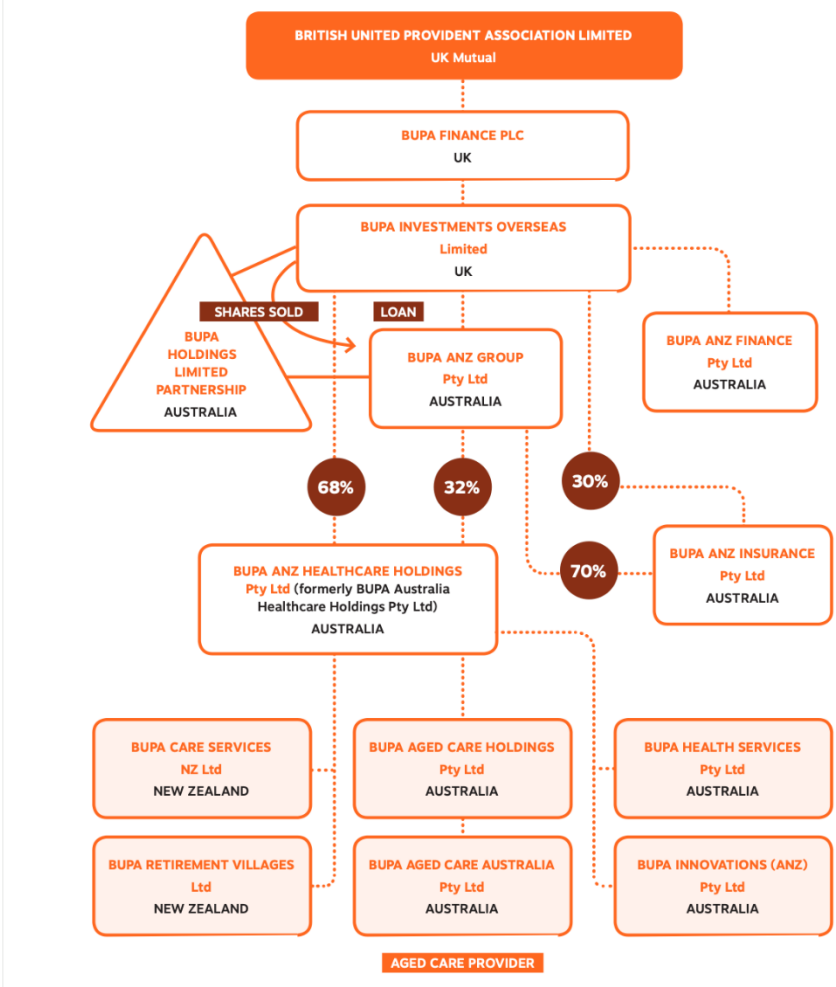
Tax reform advocates have called out insurers for receiving significant subsidies from the Federal Government while using “aggressive tax avoidance strategies”.

In 2019, Bupa Australia reached an agreement to pay $157 million to the Australian Taxation Office (ATO) after an investigation into the company involved claims of tax dodging.

This investigation found that Bupa used a number of “tax minimisation” practices including “thin capitalisation”, restructuring in order to shift profits between sectors and moving some functions offshore to avoid paying tax in Australia.

A report by Tax Justice Australia found that although Bupa is headquartered in the UK, it makes more profit in Australia and New Zealand than in the UK or any other region.

This report explained that as a mutual company, Bupa does not have shareholders and is required to reinvest profits back into its business. Bupa has issued bonds and therefore is required to making filings in the UK similar to a publicly listed company. It outlined how Bupa’s corporate structure is used to minimise the tax it pays in Australia.



Source: *Tax Avoidance by For-Profit Aged Care Companies: Profit Shifting On Public Funds Proposals For Transparency On Government Spending*
https://d3n8a8pro7vhmx.cloudfront.net/taxjusticeorgau/pages/59/attachments/original/1525175963/TJN_For-Profit_Aged_Care_Report.pdf?1525175963

Companies that receive high levels of government subsidies should be held to a high standard of tax transparency or a tax code of conduct which goes beyond the minimalist view of the tax rules.

An independent inquiry is needed to investigate how widespread these practices are within the private health insurance industry, and to make recommendations about how to increase transparency of their financial operations.

Recommendation: The Federal Government establish an independent inquiry to investigate the corporate and tax structures of insurers and make recommendations to prevent tax minimisation.

Other savings opportunities

The 2019 report "Keeping Premiums Low: Towards a sustainable private healthcare system" commissioned from AlphaBeta by the MTAA identified almost $1 billion of potential savings through improving insurer operating efficiency, reducing admissions, improving models of care, and increasing the focus on evidence-based medicine.

Some key findings of this report are as follows:

- The private health insurance sector has not extracted sufficient economies of scale in the wake of significant revenue growth and many funds are well above the industry average in operational expenditure.

- Significant savings can be achieved through optimising models of care, as well as reducing admissions through prevention and promoting care in the community. These levers could not only deliver short-term savings, they are also critical for the longer term sustainability of the health system. System reforms could underpin acceleration of change in this area.

- Reshaping the allied health offering can deliver better value for consumers while also generating savings worth nearly $250 million for the private health system.

- The 'Gold, Silver, Bronze, Basic' PHI coverage model may unintentionally restrict customers' access to the most appropriate treatment and technologies. The intent is to provide better clarity and consistency around policy inclusions and exclusions. However, it may also restrict access to appropriate treatments for customers without the means for greater coverage.

In 2020 the Australian Medical Association outlined their prescription for private health insurance. This report recommended a number of major changes to increase the sustainability of the private health sector including:

- 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.
- The establishment of an independent, well resourced, statutory body to regulate the legal conduct of the private health insurance industry.

Recommendation: The Federal Government seek stakeholder views on the recommendations of the AlphaBeta report.

Aortic valve disease and Transcatheter Aortic Valve Insertion (TAVI)

Severe aortic stenosis is the most common form of aortic valve disease, affecting about 3 per cent of people aged over 65. It stops blood from flowing easily throughout the body which can lead to heart failure because the aortic valve in the heart develops a severe build-up of calcium, making it difficult for the valve to open and close.

There are currently 150,000 people in Australia with moderate to severe aortic stenosis, and this is likely to climb to 200,000 over the next decade and reach 266,000 in 2051.

Severe aortic stenosis has traditionally been repaired with valve replacement via open heart surgery, a major procedure requiring use of a heart-lung bypass machine, intensive care unit admission, cardiac rehabilitation and a lengthy recovery. This traditional surgical approach remains appropriate in certain patient cohorts.

TAVI is a procedure that allows valve replacement to occur in a minimally invasive way, reducing recovery time, impact on hospital resources, cost and impact on the patient. During a TAVI procedure, an artificial valve is implanted into the heart. Instead of standard open-heart surgery where the chest cavity is opened during surgery, in TAVI a catheter is placed in the femoral artery in the groin and guided into the heart. TAVI has been used to treat patients with severe aortic stenosis at high risk of surgery in the private system since 2017.

A new report by the Baker Heart and Diabetes Institute ('Our Hidden Ageing – Time to Listen to the Heart') found that early intervention to treat aortic stenosis via TAVI for people aged 65 years and above could potentially prevent productivity losses of up to $117 million in a single year.

Recommendation: The Medical Services Advisory Committee (MSAC) has now recommended Transcatheter Aortic Valve Implantation (TAVI) for public funding for intermediate and low risk patients finding the "procedure to be safe, effective and good value for money". Given the value of this technology to health systems and patients, this recommendation should be implemented as soon as possible with this Budget confirming that patients at low-risk will have access to TAVI by no later than 1 July 2022.

Radiation Oncology Health Program Grants – Radiation Therapy Advisory Group

The Radiation Therapy Advisory Group (RTAG) is an authorised alliance within the Medical Technology Association (MTAA) for advocacy on issues of community interest in relation to Radiation Therapy (RT).

The Federal Government announced changes to the Radiation Oncology Health Program Grants Scheme (ROHPG) as part of its 2016-17 Mid-Year Economic and Fiscal Outlook (MYEFO). These changes reduced the scope of the capital funding available for radiation therapy providers. Capital funding was limited to linear accelerators (linacs) and the Government contribution was capped at $300,000 per year.

The Government reviewed the program again in 2020-21, including assessment of the impact these changes have had on the delivery of radiation therapy. But this did not remedy the issues caused by changes made in 2016.

By limiting funding to linacs, other technologies have been ignored which are not only critical but improve the treatment process by delivering it faster, imaging the cancer more efficiently and safely, and incorporating quality control processes into the treatment.

The 2016 changes to the ROHPG imposed significant limitations on investments into radiation therapy. This had knock-on implications for the wellbeing and mortality of many Australian cancer patients.

The core metric for radiation oncology is the percentage of optimum utilization rate. For radiotherapy across all cancers, this rate is currently recognised to be 48.3%.[4] However, Australia is still significantly below optimal utilisation of radiation oncology at somewhere between 35-40%[5]: we still have some distance to travel, and cuts to ROHPG now would quickly erode previous gains.

The Australian Institute of Health and Welfare (AIHW) latest report Radiotherapy in Australia 2018-19[6] already shows:

- Radiotherapy waiting times remain the shortest for those patients living in the highest socio-economic areas,
- Radiotherapy waiting times are 50% longer for those in the lowest socio-economic areas
- Median waiting time for radiotherapy differs by up to 300% between different states and territories
- Indigenous Australians receive 1.6% of all radiotherapy courses despite comprising 3.3% of the Australian population

RTAG believes that these disappointing figures fail to show the full picture of the increasing inequity of the distribution of investment in Radiation Therapy. Those areas with long wait times tend to also be those with significant access issues (be that distance or availability), which are also coupled with inadequate referral pathways.

Prior to the 2016 Government review of the ROHPG, RTAG provided analysis prepared contemporaneously by independent health economists, outlining significant concerns regarding the methodology underpinning the Government's reforms, not least that they had no supporting cost-benefit analysis. This report concluded that proposals to amend the ROHPG represented a significant change to the ecosystem of radiation oncology services and one that should not proceed without appropriate quantitative and qualitative assessment.[7]

With many of these deficiencies remaining in place with the conclusion of the Government's 2020-21 Review of the ROHPG, it is difficult to conceive that the sobering statistics outlined in AIHW's recent report can be addressed unless the mechanism for radiation therapy funding are reformed further.

In the context of COVID-19, this is all the more urgent. Cancer diagnoses and screenings were reduced by up to 40% 2020 owing to measures taken to mitigate transmission of the virus.[8] An influx of a large

[4] Barton, Michael et al, Review of Optimal Radiotherapy Utilisation Rates, Report to the Australian Government Department of Health & Ageing, Ingham Institute & CCORE, March 2013, p.575

[5] MP Consulting, "Review of the Radiation Oncology Health Program Grants Scheme", prepared for the Department of Health, August 2016, p.16 (ROTP use 38%)

[6] https://www.aihw.gov.au/reports/radiotherapy/radiotherapy-in-australia-2018-19/contents/introduction

[7] Evaluate, (2017, 21 February) Commentary: Proper Valuation of Proposed Changes to the ROHPG Scheme, prepared for the Radiation Therapy Advisory Group

[8] Cancer Australia (2020, September) Review of the impact of COVID-19 on medical services and procedures in Australia utilising MBS data: skin, breast and colorectal cancers, and telehealth services:

cohort of late-diagnosed cancer patients is projected as these delays and backlogs cascade through the health system. In order to manage this potential health crisis, adequate funding is required to bolster Australia's oncology sector, including access to the best forms of radiation therapy.

Recommendation: MTAA recommends the following changes in order for the ROHPG to successfully deliver on its stated objectives:

1) An urgent reassessment of the types of equipment that are eligible for ROHPG funding is needed, to ensure the funding is keeping up with best clinical practice as recommended by national and international guidelines.
2) Equipment types eligible for ROHPG funding be expanded to include adjunct devices that are necessary for the provision/accuracy/efficacy of radiation therapy, including but not limited to devices entered onto the Australian Register of Therapeutic Goods (ARTG) for the following:
    i. Brachytherapy devices
    ii. Stereotactic radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) technologies
    iii. Simulators such as computerized tomography (CT)/ Magnetic resonance imaging (MRI) / positron emission tomography (PET)
    iv. Surface guidance technology
    v. Treatment Planning Systems and associated software
    vi. Software to support image management and quality assurance
    vii. Oncology Information Systems
    viii. MRI Linacs
3) A top-up payment over the $3M threshold for advanced technologies:
    i. A number of these more advanced technologies are significantly more capital intensive than traditional linacs, but there are a number of cancer sites where they can deliver significantly better clinical outcomes.
    ii. Equity of access to the newest and most effective technologies is squarely in the remit of the scheme's core objectives, so top-up funding that will widen access to them is highly recommended.
4) Capital-intensive Therapeutic Goods Administration (TGA) approved treatment devices should be equally eligible for ROHPG funding.
5) Maintenance of the separation of ROHPG Capital Equipment Reimbursement and Medicare Benefit Schedule (MBS) Service Volume.
6) The re-inclusion of Network Information Systems (NIS) in the scheme so that radiation therapy providers can integrate the latest technology into their practice and improve patient outcomes Brachytherapy devices.

https://www.canceraustralia.gov.au/sites/default/files/publications/review-impact-covid-19-medical-services-and-procedures-australia-utilising-mbs-

Health Policy

Prostheses List

The Prostheses List (PL) is regulated by the Australian Government under the *Private Health Insurance Act* 2007 and sets out benefits that private health insurers must pay for specific medical devices used in hospital procedures when a consumer has relevant policy cover.

Few parts of the private health insurance system have been as successful in retaining wide clinical choice with no out-of-pocket costs. The PL impacts private health insurance expenditure and only indirectly impacts Federal Government expenditure through the rebate for private health insurance premiums.

MTAA welcomed the support from the Federal Government for reform of the PL in the 2021-22 Federal Budget. The Budget provided funding to support a number of reforms, including introducing a modified public-private referencing model, clarifying the scope of the PL and streamlining the listing process.

These reforms partly reflect proposals made to government by MTAA, in conjunction with medical, hospital and consumer groups, in order to support a sustainable and efficient pricing mechanism for medical devices in the private health system. Together they represent the most far-reaching reforms of the PL in its history.

These changes would follow benefit reductions outlined in the 2017 Agreement between the Federal Government and MTAA which, combined with reductions in February 2017, have seen average PL benefits reduce by 15% over the past five years, saving insurers $1.4b to Q3 2021.

Given that the PL is only 13.8% of total hospital benefits (YTD 2021) paid by insurers (compared to 14.5% 5 years ago), prostheses prices cannot be either the cause of membership decline or the solution to private health insurance affordability.

MTAA continues to work collaboratively with the government and other healthcare stakeholders, including the Australian Medical Association, the Australian Private Hospitals Association, Catholic Health Australia and Consumers Health Forum of Australia to develop solutions to improve the value of the PL to the Australian community.

Our goals in the negotiations over PL reforms have been to:

- Achieve good outcomes for patients by protecting access to the life-saving medical 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
- Facilitate access to innovation
- Reduce the pressure on the public hospital system

Achieving these goals requires taking into account the higher costs for the MedTech industry to supply products into the private health sector than the public sector, driven largely by wider choice in the private sector and volume arrangements in the public sector.

These issues are outlined in more details below in relation to the specific issues currently being negotiated with the Government.

Private adjustment to public benchmark

The public and private markets are not the same and this needs to be accounted for when benchmarking PL benefits to public prices. The public sector lowers prices in exchange for guaranteed volume by limiting surgeon choice, which can't happen in the private sector without reducing access for consumers or increasing out-of-pocket costs. On the other hand, the private sector is typically more costly to service than the public sector. The cost of greater choice in the private sector must be reflected in a remaining adjustment above the public price as the PL benefits are reduced.

Accounting for cardiac technical support services

Cardiac implantable electronic devices or CIEDs (pacemakers, defibrillators, implantable loop recorders) require significant servicing by skilled technicians over their lifetime. At present, the device industry provides the vast majority of these services in the private sector. This is funded through the current PL benefit for the devices. PL reform needs to account for these services both in the short and long term by providing ongoing funding before any new model is agreed and implemented as required.

Ensuring products removed from the PL are properly funded

The Government has announced an intention to remove significant numbers of products from the PL, with a first tranche from 1 March 2022. This requires alternative funding arrangements to be in place between insurers and hospitals but there is no plan to ensure this occurs. MTAA understands this has been delayed for 1 year to allow funding arrangements to be established but in the meantime these products are to take an immediate reduction down to the public price which penalises the MedTech industry for lack of progress in these funding arrangements, as well as the flow on of potential negative impacts on patients. Furthermore, products that belong in these groups are consistently being denied interim listing, creating a competitive inequity that undermines competitive fairness and is inconsistent with Australia's trade obligations.

Efficient PL listing processes that recognise innovation

The continued lifeblood of industry and the opportunity for patients is access to new medical technology. At present the PL listing process rarely recognises new innovation with higher benefits. Furthermore, there is often excessive process and insufficient communication with sponsors. The Department has declared an intent to re-evaluate cost recovery including imposing cost-recovery on the Medical Services Advisory Committee (MSAC) process with no obvious benefit in speed or simplicity. If costs are to increase then better, more efficient processes that recognise innovation are needed.

Clinician-led utilisation measures

Insurers have frequently complained that clinicians overutilise some devices, and so the Department of Health plans to implement reform encouraging improved utilisation. It is important this process is led by clinicians or else it could lead to unreasonable restrictions on choice that simultaneously create administrative burdens for clinicians and hospitals.

MTAA welcomes further reform to enhance the value that the PL already delivers to consumers. However, reforms should reflect the objective of the PL to deliver patient access and choice without out-of-pocket costs. Likewise, industry needs certainty and fair reward for innovation so that it can continue to service and bring medical advances to private patients. MTAA looks forward to further dialogue with the government on these key points.

Recommendations:

- PL benefits to be benchmarked against the weighted average public price at product and group level
- The public benchmark for benefit reductions includes an adjustment for higher costs in the private sector
- The regrouping process recognises product differences and does not drive further savings
- Cardiac technical support services are properly funded to ensure patient care
- Products identified for removal from the PL do not take immediate full benefit cuts and new products in these groups can still list on the PL in the interim until removals occur
- Listing processes are made more efficient and reasonable for new innovation without excessive industry cost
- Utilisation measures are clinician-led

Patient and healthcare worker safety

MTAA recommends the introduction of a new 'Patient and Healthcare Worker Safety Policy' to direct all healthcare organisations to meet mandatory timelines for the adoption of TGA approved products that are classified as Safety Engineered Devices and will reduce the risk of harm to either Patients or Healthcare workers due to either design or the materials that are used within their design.

This policy should align with the EU Sharps Directive where the use of safety-engineered devices was specified into EU Law in June 2012 and required to be implemented in all EU countries by May 2013 at the latest. The specific clause in the Directive refers to "providing medical devices incorporating safety-engineered protection mechanisms".

This Policy should be designed to affect both Public and Private healthcare organisations and would need to be designed to create the safest possible work environment in the hospital and health care sector.

This policy would reduce the risk of harm, and the associated downstream cost of this harm, that mandatory adoption of SEDs could prevent. A key element of this policy would be the setting of mandatory adoption requirements and timelines

Already, peak bodies such as SafeWork, The Australian Commission on Safety and Quality in Healthcare and the Australian & NZ College of Anaesthetists have made clear recommendations for the adoption of SEDs, however they all lack the ability for these recommendations to be made mandatory. As a result, these recommendations are, at best, significantly delayed compared to other comparable countries around the world or, at worst, not implemented at all.

Recommendation: MTAA recommends the Government introduce a 'Patient and Healthcare Worker Safety Policy' to ensure all healthcare organisations meet mandatory timelines for the adoption of TGA approved products that are classified as Safety Engineered Devices.

Case Study: Prevention of needle stick injury by using passive Safety Engineered Cannula's in healthcare organisations

In Australia, more than 18,000 healthcare professionals receive a needlestick injury each year. [1] This costs our healthcare system approximately $18.6 million each year. It also has a psychological and physical impact on a clinician, such as anxiety around the risk of transmission of bloodborne pathogens. Other costs can include vaccinations, post-exposure prophylaxis, counselling for affected staff members and leave a staff member may need to take from work. Needlestick injuries can happen during the cannulation process, after the cannula has been used but before it has been disposed and during its disposal. [2]

In a large multicentre study, the risk of needlestick injuries due to conventional non-safety devices was clinically proven to be 25-fold higher than that observed for safety devices.[3] This study included five healthcare institutions in Italy and evaluated the incidence of needlestick injuries among safety and conventional devices from 2006 to 2010.

In this study 122,464 patients were observed and 286 needlestick injuries were reported. The risk of needlestick injuries due to conventional catheters was 44.9% whereas the risk for safety catheters was 1.9%. The rate of needlestick injuries declined by 47% between 2006 and 2010 while 24% of conventional catheters were replaced by safety catheters at the start of the study. Towards the end of the study, safety devices had almost completely replaced conventional devices.

B. Braun's Introcan Safety® IV Catheter is one example of a Safety Engineered Device that incorporates Passive Safety Technology via an integrated fully automatic Safety Shield that protects the needle tip and prevents needle-stick injuries to patients and healthcare workers.

[1] https://www.mtaa.org.au/sites/default/files/uploaded-content/website-content/Sharpsv5.pdf Use of safety-engineered medical devices (SEMDs) to improve prevention of needlestick and sharps injuries in the healthcare setting August 2021.
[2] Jagger, J. & Bentley, M. B. (1997), Injuries from Vascular Access Devices: High Risk and Preventable, Journal of Intravenous Nursing, Vol 20 (65), p.S33-S39.
[3] Sossai, Dimitri, et al. "Efficacy of safety catheter devices in the prevention of occupational needlestick injuries: applied research in the Liguria Region (Italy)." Journal of preventive medicine and hygiene 57.2 (2016): E110.

Reimbursement of innovative medical devices that do not meet Prostheses List criteria

There is no routine funding mechanism for effective therapeutic medical devices that are used at home. The Prostheses List and State and Territory hospital funding generally covers only hospital-use therapeutic devices. The MBS only funds diagnostic devices.

This gap needs to be closed especially as technologies diversify and become more centred on home-based care. This gap prejudices funding in favour of expensive hospital admissions. A new scheme for funding community-based medical device use needs to be established.

Principles for reimbursement can be similar to that of the Prostheses List or MBS funding.

Example of Working Model: UK MedTech Funding Mandate[9]

In the United Kingdom, NHS England and NHS Improvement have outlined how research and innovation should drive better outcomes and experience for patients[10]. The *MedTech Funding Mandate* (MTFM) came into effect in April 2020 with the aim of accelerating the uptake of selected National Institute for Health and Care Excellence (NICE)-approved, cost-saving medical devices, diagnostics, and digital products in the NHS, meaning patients will get access to these technologies faster. This policy helps to address financial and procurement barriers to the adoption of devices, diagnostics, and digital products. The aims of the policy are to: i) direct the NHS on which MedTech innovations are effective and likely to give savings on investment; ii) ensure the NHS has a sustainable approach to overcoming the financial barriers to adopting medical devices, diagnostics, and digital products.

The following criteria were used to select technologies appropriate for the 2020/21 policy. The technologies had to have had a positive NICE medical technologies guidance (MTGs) or NICE diagnostics guidance (DGs) published by 30 June 2020 identifying technologies that:

i) are effective
ii) deliver material savings to the NHS: the benefits of the innovation are over £1 million over five years for the population of England
iii) are cost-saving in-year with NICE modelling demonstrating a net saving in the first 12 months of implementing the technology
iv) are affordable to the NHS: the budget impact

The policy mandates that the clinically appropriate use of these medical devices by providers should be funded by local commissioners. Compliance with the MTFM is a condition of the NHS Standard Contract for 2021/22, with the guidance stating '*The NHS Standard Contract will require both commissioners and providers of NHS-funded services to comply, as relevant, with their obligations under, and any recommendations contained in, the MedTech Funding Mandate.*

[9] https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2021/01/mtfm-policy-guidance-jan-2021.pdf
[10] https://www.england.nhs.uk/aac/about-us/

Case Study: gammaCore for Cluster Headache

gammaCore Sapphire™ (non-invasive vagus nerve stimulator) is a therapeutic medical device used in the treatment of Cluster Headache. In 2019 NICE published Medical Technologies Guidance recommending the use of gammaCore to treat CH in the National Health Service[11].

NICE and NHS England and Improvement evaluation of gammaCore
As part of the Medical Technology Guidance, NICE created an economic resource impact model which estimates the potential financial savings generated through the adoption of gammaCore through the MedTech Funding Mandate policy[12].

The outcome of the model is summarised in the table below. The numbers provided are per 1 million of the population and show in year financial savings based on gradual adoption of gammaCore throughout the NHS.

	Year 1	Year 2	Year 3	Year 4	Year 5
Total Current cost of treating CH	£ 3,931,305	£ 3,931,305	£ 3,931,305	£ 3,931,305	£ 3,931,305
Total Future cost of treating CH	£ 3,915,569	£ 3,899,669	£ 3,884,657	£ 3,876,576	£ 3,849,295
Resource Impact	-£ 15,735	-£ 31,636	-£ 46,647	-£ 54,728	-£ 82,010

The total 5-year financial impact in the UK for all Cluster Headache patients is estimated to be in the region of £4.5 million[13]

Recommendation: The Federal Government establish a new funding pathway for therapeutic medical devices used in the community, incorporating HTA evaluation.

[11] https://www.nice.org.uk/guidance/mtg46
[12] https://www.nice.org.uk/guidance/mtg46/resources
[13] https://www.nice.org.uk/guidance/mtg46/resources/resource-impact-template-excel-7078045645

Regulatory Policy

Regulatory resource requirements

The introduction of Medical Device Reporting (MDR) in Europe will have a major impact on the regulatory requirements in Australia, specifically due to TGA's platform harmonisation with the EU. Changes involve increased clinical evidence, updating of medical device registrations, the additional regulatory inclusion of software and personalised medical devices, as well as the introduction of patient information and device tracking for all implants.

These changes will further improve the safety and effectiveness of medical devices but will require the release of additional TGA funds accumulated from Industry fees to support these substantial flow-on requirements.

Additional Health resources will also be required to assist in the streamlining of patient access to safe and efficient emerging technologies and reviewing the regulatory framework and processes that support them.

The use of Real World Evidence (RWE) for regulatory purposes has been cited by many submissions to the recent House of Representatives *inquiry into approval processes for new drugs and novel medical technologies in Australia*, as an ideal way to provide such increased access. As well as TGA needing to introduce changes to its regulations and data networks, this will require the implementation of health data collection, collation and analysis via clinical quality registries and other data networks and require setup funding.

A recent framework and strategy from the Australian Commission on Safety and Quality in Health Care, endorsed by the Health Minister as a critical component of a continuously improving health system, has demonstrated the importance of registries and data-sharing and also the significant return on investment when such data networks are utilised. A dual achievement would then be realised by way of expediated access to new drugs and novel technologies in Australia which would further provide significant returns on investment for the country.

Taking this into account, the current industry funding/cost recovery model needs to be reviewed. There will be benefit to the Australian public with better and faster access to new drugs and novel technologies with funding to TGA. In turn, this would further provide significant returns on investment for the country.

Recommendation: MTAA recommends increased TGA resources for the following in 2022:

- MDR changes that will impact ARTG listings
- UDI implementation
- Digital transformation
- Changes resulting from the review of real world evidence and patient reported outcomes
- Ongoing cost of fee free services such as the Special Access and Authorised Prescriber Schemes
- Continued regulation of COVID-19 treatments and vaccines – education, communication, post market efforts, support for sponsors

Additionally, MTAA recommend a review of the current industry funding/cost recovery model.

Recommendation: The Federal Government review 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.

Industry Policy

Expansion of the Patent Box

MTAA supports the Federal Government's patent box policy that provides a tax concession for companies with MedTech products that were invented, commercialised and manufactured in Australia (provided originating patents were filed with IP Australia after 11 May 2021). This is a welcomed step forward to support Australian innovations by ensuring Australia and its people can benefit from its own technologies and bolster its sovereign capabilities.

The global COVID-19 pandemic has cast a spotlight on the importance of Australia supporting local innovations and their pathway to global commercialisation. Prior to COVID-19, Australia had experienced erosion in medical manufacturing because it was not an internationally competitive location to commercialise medical products / pharmaceuticals. For example, Pfizer's closure of its Bentley, WA facility, to be completed by 2024, will result in the loss of 470 facility jobs and those in its supply chain, including the loss of exports to North America, Europe, China and Latin America. This situation is occurring in an overall environment in which Australia would benefit significantly from the creation of a skilled workforce, export opportunities and increasing medical supply sovereignty, which are now government priorities, outlined in the Modern Manufacturing Strategy.

MTAA supports the patent box policy providing that its design will provide an incentive for the commercialisation and manufacturing of MedTech in Australia. That is, the policy will augment and harmonise support beyond research and development by incentivising the retention in Australia of the whole-of-life cycle processes of commercialisation, manufacture, growth and export. However, the current concessional tax rate of 17% is too high compared to other eligible jurisdictions.

In addition, MTAA views the current policy design of the patent box as proposed by Treasury as too restrictive for medical technology companies to access for several reasons:

- The focus is on holding patents in Australia when it is patents in the major income-earning markets like the US, EU and Japan that really matter
- The eligibility being for patents only applied for from 11 May 2021 means that products which have patents but are still undergoing major R&D – as is typical - will miss out
- The ability to claim only on R&D conducted in Australia when it is frequently the case that some R&D for an Australian project needs to occur overseas
- The Australian IP patent status is unlikely to clearly define whether a product can be used or classified as medical device

In light of this, MTAA proposes the formation of a permanent working group (PWG) to support Treasury's objectives and processes to implement the patent box. The PWG, consisting of medical technology and biotechnology experts, local manufacturers (including SMEs) and supply chain experts, and tax experts in the life-sciences field, will engage with Treasury and other groups, as the process

progresses and provide insights to ensure that the intended beneficiaries of the policy will find the policy instrumental to stimulating innovation.

MTAA understands that Treasury has planned future consultations, however, we believe that the MedTech industry's position is most effectively served via a permanent working group – considering that this is the first time that government has offered a corporate tax incentive to specific sectors to facilitate growth. Examples of member organisations to include in the PWG are: MTAA, Research Australia, Medicines Australia, AusBiotech, Department of Industry, Science, Energy and Resources, Export Council of Australia, representatives from the Supply Chain Initiative and the Modern Manufacturing Initiative.

Recommendation: MTAA recommends the formation of a permanent working group to support Treasury's objectives and processes to implement the patent box.

Putting patients at the centre of public health procurement

An efficient, value-based public procurement of devices by states and territories is critical to ensure all Australians receiving care in our public hospitals have access to world-class medical devices.

Improved public procurement can help to reduce the pressure on health budgets, deliver increased value, and foster the development of high-quality products and innovations in local public hospital markets. Redesigning current tender processes can unlock substantial shared benefits, and the Federal Government has an important role to play to reform procurement policy and processes consistent with the strategic long-term health reform principles outlined in the National Health Reform Agreement Addendum 2020-2025.

Guiding principles have been developed by MTAA to help direct all State and Territory health procurement agencies towards procurement policy and process reform that puts patient outcomes at the centre of public health procurement. The principles include:

1. Professionalise procurement to ensure the highest standards of procurement practice
2. Focus on value and outcomes for patients, healthcare professionals and the health system
3. Pursue genuine partnership between industry and government
4. Support an environment for healthcare innovation to thrive

Recommendation: MTAA recommends State and Territory governments be required, under their reporting responsibilities for the National Health Reform Agreement, to transparently outline their processes for adopting efficient value-based procurement.

Local manufacturing

MTAA supports the Modern Manufacturing Strategy currently being implemented by the Federal Government to help Australian manufacturing scale up and become more competitive and resilient.

MTAA agrees that the medical products industry is an area where Australia has the potential to build a sustainable competitive advantage, and accordingly, welcomes the investments made via the Modern Manufacturing Initiative, the Supply Chain Resilience Initiative and the Manufacturing Modernisation Fund.

However, while these programs supporting the Australian MedTech industry invest in research and development and manufacturing capability, they do not assist in creating a sustainable market for medical technologies in Australia. R&D grants and investment incentives by themselves are not enough to get the result that Government is seeking – growth of a sustainable MedTech manufacturing industry in Australia.

The local industry also needs a market to sell into to justify manufacturing devices here. This can be achieved in a couple of key ways:

1. **Targeted tender program to build sovereign capability for essential devices**

MTAA recommends a targeted tender program aimed at specific, defined areas of sovereign priority to be filled by Australian manufacturers working from the model initially used to resolve supply chain challenges around ventilators and PPE at the height of the pandemic. This would require development of a priority list based on required capabilities in the event of future supply chain stress. While serving a critical health need, these targeted tender programs would also provide an opportunity for government and private industry to co-invest in sovereign capability, whilst simultaneously building a sustainable value proposition for that capability in Australia with a local customer, in the form of government health procurement. The program would also contain criteria requiring the tender applicants to show how the capability could become competitive over time against overseas competition, both in local and export markets.

2. **Introduction of measures to ensure local manufacturers are accurately assessed for total economic benefit in government purchasing decisions**

Existing mechanisms to preference local manufacturers in state government tender processes are frequently overridden by 'direct cost considerations when final decisions purchasing decisions are made. MTAA recommends that it be made a condition of the Commonwealth funding of the state government health systems, that genuine consideration be given to the economic benefits of sourcing products from local manufacturers, and the multipliers that the job creation and the return of tax revenue to both state and federal governments are taken into account.

Recommendation: MTAA recommends the Government support local manufacturing through the introduction of programs specifically designed to growth of a sustainable MedTech manufacturing industry in Australia

1. A targeted tender program aimed at specific areas of sovereign priority to be filled by Australian manufacturers
2. Measures to ensure local manufacturers are accurately assessed for total economic benefit in government purchasing decisions

Sustainable Digital Healthcare Reforms

One in every two Australians suffer with chronic disease[14]. In 2019, spending on health increased by about 50% since 2008[15] and this trend is expected to continue which will further strain the healthcare system.

Virtual care services have the potential to tackle many of the challenges faced by the system but are grossly underutilised, accounting for only 0.1 percent of all federally funded pre-COVID-19 attendances. The COVID-19 crisis has seen general practice, mental health, specialist, and allied health consultations delivered via technology, resulting in continued access to healthcare for many patients in a safe, efficient, and equitable manner, at scale[16].

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. This generated new efficiencies in access and technology, leading to reduced need for in-person care, hospital re-admissions and emergency visits and ultimately improving 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 United States https://telehealth.va.gov and the United Kingdom https://www.england.nhs.uk/tecs, and will result in high-quality, value-based health care.

[14] DoH, Chronic Conditions in Australia, March 2020, https://www.health.gov.au/health-topics/chronic-conditions/chronic-conditions-in-australia

[15] AIHW, Australia's health, 2018 https://www.aihw.gov.au/getmedia/7c42913d-295f-4bc9-9c24-4e44eff4a04a/aihw-aus-221.pdf

[16] PWC, Reimagining healthcare: telemedicine initiatives for COVID-19 April, 2020 pwc.com.au/digitalpulse/healthcare-telehealth-coronavirus.html

Recommendation: The Federal Government works with industry to develop a technology enabled healthcare system that:

- Facilitates equitable patient access to connected healthcare services via remote patient monitoring
- Funds remote patient monitoring and hospital transition programs shown to reduce hospital stays
- Encourages private health investment in programs that reduce hospital admissions
- Supports the delivery and measurement of value-based health initiatives
- Supports innovative telehealth funding models for Community care.
- Incentivizes care providers to treat illness rather than manage it
- Delivers safe and secure, essential data, for effective population health management.
- Invests in infrastructure and regulatory frameworks that support an ICT enabled health care system

Remote Patient Monitoring

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. These service delivery options 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.

Home and community care creates efficiencies and lowers long term costs, most notably for 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 as nosocomial infections, and the burden on hospital staff is greatly reduced.

A report by AlphaBeta found that by establishing home and community care for as little as 10% of hospital admissions by determining those whose outcomes would be improved, private health insurers could save $8 million by FY2022.[17] Early discharge to home and community care for recovery, rehabilitation and medication monitoring not only delivers better health and patient outcomes but delivers savings as well. AlphaBeta forecast that transitioning 10% of hospital stays would save insurers $15 million. An example is 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 and community 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.

[17] AlphaBeta Report, Keeping Premiums Low: Towards a sustainable private healthcare system 2019 https://alphabeta.com/wp-content/uploads/2019/08/mtaa_keepingpremiumslow2-1.pdf

Case Study: Remote Patient Monitoring 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.

Case Study: Remote Patient Monitoring with Connected Health – Staying Strong Program – Integrated Living Australia

Integrated Living is a not-for-profit community care business, breaking new ground with its Australian Government funded telehealth monitoring pilot project, Staying Strong. Targeting older Aboriginal and Torres Strait Islanders in regional and rural communities.

The project findings highlighted the utility of the Staying Strong telehealth model in the clinically efficient and cost-effective delivery of health care. The model is now an integral part of Integrated Living's broader strategy to deliver enhanced health outcomes for older people in rural and regional Australia.

The initial NBN funded pilot trial, involved two models of telehealth monitoring of vital health signs: in-home model and a hub model, and supporting indigenous communities. High blood pressure, Type 2 diabetes and high blood cholesterol were the top three chronic health conditions suffered by the project participants. The project was also developed to determine the acceptance and usability of telehealth systems by indigenous communities.

Outcomes:

The Integrated Living Staying Strong pilot project demonstrated that remote telehealth monitoring with broadband technology is cost effective saving an estimated 40% of the cost of a face-to-face model. There was a very high acceptance and compliance by the participants

The broadband technology enabled greater nurse caseload, flexible and responsive remote triaging, reduced need for routine GP visits, facilitated accurate and timely medical diagnosis, and reduced unplanned hospitalisation. These outcomes contribute to cost savings in health expenditure.

Case Study: CSIRO Home Monitoring of Chronic Disease for Aged Care

Funded by the Australian Government Telehealth Pilots Program, CSIRO partnered with NGOs, local health districts, hospitals and industry partners and technology providers to deliver a national telehealth trial of home monitoring of chronic disease for aged care. Trial partners across the country including ACT, Townsville, Bacchus Marsh and Melton, Launceston and Greater Western Sydney meant this was Australia's first large scale telehealth clinical trial.

In total 287 patients participated in the trial across the six sites. Test patients were provided with a telehealth device that included participant/clinician video conferencing capabilities, messaging features and the delivery of clinical and study specific questionnaires, as well as vital signs devices to monitor their ECG, heart rate, spirometry, blood pressure, oxygen saturation, body weight and body temperature, with glucometry an optional add-on.

The 12-month trial enabled chronic disease patients to self-manage their conditions at home through the provision of telehealth services. Health workers could assess changes in their patient's conditions remotely and provide appropriate care interventions earlier to help them stay out of hospital and improve their quality of life.

Outcomes:

Home monitoring saves healthcare dollars and patient lives. The research showed savings of 24% over the year to the healthcare system made through falls in the number and cost of GP visits, specialist visits and procedures carried out. Patients in the trial also reported improvements in anxiety, depression and quality of life, with many finding that home monitoring gave them a better understanding of their chronic conditions.

- 46.35% reductions in rate of MBS expenditure
- 25.5% reduction in rate of PBS expenditure
- 53.2% reduction in the rate of admission to hospital
- 75.7% reduction in the rate of length of stay
- >40% reduction in patient
- >83% user acceptance and use of the telemonitoring technology
- >89% of clinicians would recommend telemonitoring services to other patients

The research showed the return on investment of a telemonitoring initiative on a national scale would be in the order of five to one by reducing demand on hospital inpatient and outpatient services, reduced visits to GPs, reduced visits from community nurses and an overall reduced demand on increasingly scarce clinical resources.

Analysis of this model suggests that for chronically ill patients, an annual expenditure of $2,760 could generate a saving of between $16,383 and $19,263 pa, representing an ROI of between 4.9 and 6.0. https://www.csiro.au/en/research/health-medical/diagnostics/home-monitoring

Recommendation: The Federal Government implement the following measures be taken to enable the benefits digital health and remote care:

- Adequate and appropriate funding for medical services and support (i.e., MBS reform, expansion of MBS telehealth e.g., chronic disease management).
- Expansion of hospital substitution definitions in the private health setting.
- Rebates and financial support for chronic disease patients requiring long term care in a community setting.
- 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.
- increasing funding and support for home care packages to include telehealth packages for home care nursing and chronic disease management.
- Adequate funding to enable the assessment and value of digital healthcare service models in consideration of:
    - Safety and clinical effectiveness
    - Patient and social benefits
    - Economic impact; and
    - Organisational benefits.

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'.[18] 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.[19]

[18] 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

[19] 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

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
- 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

Recommendation: The Federal Government should investigate reviewing how artificial intelligence can best be regulated and how approval processed may need to be refined or tailored to suit this emerging technology.

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 closer to the OECD average of 23.59% would be a major incentive that would attract substantially more investment into Australia.

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

Further Information Contact

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