Medtronic Engineering the extraordinary

Pre-Budget Submission 2022-2023

Submission by Medtronic Australasia Pty Ltd

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Introduction

Medtronic welcomes the opportunity to provide this pre-Budget submission for consideration as part of the 2022/23 Federal Budget.

The last two years have been challenging for all aspects of our healthcare system, and we should ensure that we harness the lessons of the ongoing COVID response across the healthcare sector to support the future sustainability of our health system. This includes building on the collaboration between industry and government in ensuring patients have access to the technology they need to save lives and maintain health.

Medical technologies are a vital part of our healthcare system that can improve preventive and primary care and greatly improve healthcare outcomes, while also reducing costs. The sector is constantly innovating to evolve healthcare and therapies and improve healthcare outcomes.

About Medtronic

As a global leader in medical technology, services, and solutions, Medtronic improves the health and lives of millions of people each year. Medtronic provides a wide range of products, therapies, and services with the emphasis on providing a complete continuum of care to diagnose, prevent, treat, and monitor chronic and acute conditions.

For over 40 years, Medtronic has been committed to Australian patients. We are headquartered in Macquarie Park, NSW, with almost 1000 employees across the country.

Medtronic has been conducting clinical trials in Australia for over a decade, including first-in-human studies covering conditions such as coronary artery disease, end stage renal disease and hypertension.

Medtronic are active members of the Medical technology Association of Australia (MTAA) and support the Industry's Code of Conduct.

Prostheses List

As part of last year's Budget, the Government confirmed that it would be proceeding with reforms to the Prostheses List as part of its package of measures aimed at the sustainability of Private Health Insurance (PHI).

We support a sustainable private health insurance system as part of Australia's unique dual healthcare system. As we have indicated in the past, we welcome sensible, sustainable reform of the Prostheses List and believe it is important that this reform process ensures patient access and clinician choice and supports innovation without undermining the value proposition for private health insurance.

According to research by Alpha Beta consulting, medical devices have not been a key driver of the growing costs of PHI premiums and will continue to play a minor role in the cost landscape.

Medical devices represent only one tenth of private health insurance benefits paid, with growth in device benefits driven entirely by clinician and patient demand.[1]

The medical technology sector has been the largest contributor to reduced premium increases in recent years through the delivery of over $1.4 billion in four rounds of PL benefit reductions to date.

As this latest round of reforms are implemented, the longer-term impact on patients, innovation and access to medical technology needs to be at the forefront of consideration.

We recommend the Government continue to work with the medical technology industry, hospitals, doctors and patient and consumer representatives to ensure PL reform encourages innovation and ensures patient access to lifesaving technologies.

Cardiac Technical Support Services

The reform process particularly has implications for patients, clinicians, hospitals and the industry in relation to Cardiac Technical Services that support cardiac implantable electronic devices (CIEDs).

CIEDs are life-changing and life-saving devices for patients with cardiac conditions. There are an estimated 220,172 Australian patients with CIEDs, increasing at a rate of approximately 18,000 a year (net) (KPMG, 2021)[2].

To support patients with CIEDs in the private system, it is estimated that more than 606,000 technical services will be performed annually by Industry Employed Allied Professionals (IEAPs) by the end of 2022. These services are an essential part of the clinical care provided to CIED patients in the private system and are required to ensure patient safety.

These services are provided at the time of implant, as part of device checks in accordance with CSANZ guidelines, as well as for a range of unscheduled reasons, such as if the patient is receiving other medical treatment or has a medical emergency. These technical services are particularly important in rural and regional areas.

The cost of providing these services has been estimated to be $103 million by the end of 2022[3]: It is important to note that the cost of providing these services and continuing to ensure coverage across the country, is increasing at a higher rate than the increase in the demand for CIEDs due to the components that make up these costs.

To ensure the universal access, high quality and on-demand services currently delivered without additional costs to patients, these services need appropriate consideration as part of the PL reform process.

[1] KEEPING PREMIUMS LOW: Towards a sustainable private healthcare system, Alpha Beta, 2019
[2] KPMG Cardiac Implantable Electronic Device (CIED) service valuation, Appendix 1, MTAA Submission Options for Reforms and Improvements to the Prostheses List, February 2021
[3] KPMG Cardiac Implantable Electronic Device (CIED) service valuation, Appendix 1, MTAA Submission Options for Reforms and Improvements to the Prostheses List, February 2021

Transcatheter Aortic Valve Insertion

In 2021, the Medical Services Advisory Committee (MSAC) recommended Transcatheter Aortic Valve Implantation (TAVI) MBS items for both intermediate (April 2021) and low-risk (July 2021) populations with severe symptomatic aortic stenosis.

Aortic stenosis is a condition that 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, which makes it difficult for the valve to open and close.

TAVI is a procedure that repairs a damaged aortic valve. During a TAVI procedure, an artificial valve made of natural animal heart tissue is implanted into the heart. But 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 procedures can reduce pressure on hospital resources through less reliance on ICU resources, shorter hospital stay and shorter recovery time. TAVI penetration in Australian lags behind other countries.

Australian research indicates the overall costs for TAVI is $9,629 cheaper than open-heart surgery in the intermediate risk population.[4] Listing TAVI for both intermediate and low-risk as recommended by MSAC represents a cost *saving* over 5 years.

A recent study by the Baker Institute found that "offering transcatheter aortic valve implantation (TAVI) for people 65 years and above could potentially prevent the productivity loss of $117 million due to withdrawal from productive activities in a single year." It further noted that the avoidance of "cardiac symptoms (especially heart failure) is also economically beneficial in the elderly because of curtailment of losses in annual value of earnings from work, as well as childcare and volunteering activities."

In the MYEFO, funding was confirmed to implement the MSAC recommendation for patients at intermediate risk from surgical valve replacement. However, funding for patients at low-risk has not yet been confirmed. **This Budget needs to confirm that the MSAC recommendation will be implemented as soon as possible and no later than 1 July 2022.[5]**

Case Study – TAVI intermediate-risk and low-risk and the challenges in our end-to-end regulatory and reimbursement frameworks

[4] J Zhou, J., Liew, D., Duffy, S. J., Walton, A., Htun, N., & Stub, D. (2019). Cost-effectiveness of transcatheter aortic valve implantation compared to surgical aortic valve replacement in the intermediate surgical risk population. International Journal of Cardiology, 294, 17-22. https://doi.org/10.1016/j.ijcard.2019.06.057
[5] Our Hidden Ageing: Time to Listen to the Heart, Baker Heart and Diabetes Institute, 2021

Following a recommendation from MSAC in March 2016, Transcatheter Aortic Valve Implantation (TAVI) procedure for patients at high risk for surgery was included on the MBS in November 2017. In early 2020, MSAC applications were submitted by Medtronic for TAVI for patients at intermediate risk for surgery and TAVI for patients at low risk.

MSAC made positive recommendations about an MBS item for patients at intermediate and low-risk following its meetings in April 2021 and July 2021. This MSAC evaluation timeframe, although taking eighteen months, was one of the quickest evaluations we have experienced, and we thank the MSAC Secretariat for this. However, the end-to-end process for reimbursement means patients in the private system with intermediate and low risk indications are still waiting to access TAVI.

Even though this therapy was considered by the TGA with Priority Review Designation, and the MSAC pathway was quicker than the average assessment timeframe, most patients will still have to wait an additional twelve months after MSAC's recommendation for listing even if funding is confirmed through this Budget process. After developing symptomatic severe aortic stenosis, the average patient survival is two years without treatment.[6]

Whilst the Government is proposing changes to the MSAC pathway, it is unlikely such changes to implement a cost recovery framework will dramatically improve the timeframe for such assessment processes. The end-to-end pathway before patient access needs to be considered in totality, as addressing components of the regulatory and reimbursement process in isolation, will not address unnecessary delays that exist.

Stroke

We were pleased to see the release of the National Strategic Action Plan for Heart Disease and Stroke and commend the Government for working with the Stroke Foundation and Heart Foundation on this Plan and the four priorities areas as part of the roadmap for more effective prevention, treatment and management of heart disease and stroke.

Stroke is a major cause of prolonged neurologic disability in adults and has significant clinical and cost burdens. Improved management of patients during the acute phase of stroke treatment can save patients' lives and help to reduce both the clinical and cost burden of stroke.

A recent report, **'**The economic impact of Stroke in Australia, 2020,' published by the Stroke Foundation and Deloitte Access Economics, highlights the burden of stroke in Australia – on patients, the health system and productivity.

[6] (Lester SJ, Heilbron B, Gin K, Dodek A, Jue J. The natural history and rate of progression of aortic stenosis. Chest. April 1998;113(4):1109-1114.)

This report estimates that in 2020, the economic cost of stroke was $6.2 billion, with an additional $26 billion in lost wellbeing as a result of long-term disability and premature death. It found that the financial and economic burden of stroke in 2020 to the Australian Government was $2.5 billion.[7]

The report also notes that regional and rural Australians are as much as 17% more likely to experience stroke and have poorer health outcomes as a result of limited access to "well-established" standard stroke treatments, and that more than 80% of strokes in Australia are preventable by managing modifiable risk factors.

Mechanical (or endovascular) thrombectomy (MT), also known as endovascular clot retrieval, is a highly specialised and time-critical treatment for ischaemic stroke. It is a minimally invasive and highly effective treatment that reduces the occurrence of disability and death. A number of randomised controlled trials (RCTs)[8] have demonstrated a significant clinical benefit and improvement in functional outcomes in patients treated with MT in comparison to those treated with usual care (thrombolytic or anti-thrombotic therapy). MT as a treatment for large vessel occlusion can even be suitable for selected patients up to 24 hours after symptom onset. (Point out if this is longer than the period within thrombolysis can be started).

This technology is revolutionising stroke treatment around the world, but more needs to be done to ensure eligible patients are diagnosed and treated in a timely way in Australia.

As the report notes, Australia has led the way in proving the benefits and safety of endovascular clot retrieval, but currently only 3% of strokes in Australia are treated via endovascular thrombectomy[9], despite a 2013 Australian based population study suggesting that 7-13% of ischaemic strokes are eligible to receive MT.[10]

Deloitte Access Economics also modelled in the stroke report the impact of an increase in the number of stroke patients receiving endovascular thrombectomy from 3% to 10% of patients nationally, finding that:

- Increased rates of endovascular thrombectomy is likely to lead to almost 70 fewer deaths at 3-months, extending to 135 deaths over 5 years due to improved stroke outcomes.

[7] Stroke Foundation and Deloitte Access Economics, *The economic impact of stroke in Australia, 2020*
[8] Berkhemer O a., Fransen PSS, Beumer D, et al. A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke. N Engl J Med. 2014:141217070022009. doi:10.1056/NEJMoa1411587
Goyal M, Demchuk AM, Menon BK, et al. Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke. N Engl J Med. 2015:1–12. doi:10.1056/NEJMoa1414905.
[8] Campbell B, Mitchell P, Kleinig H, et al. Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection. 2015:1–10. doi:10.1056/NEJMoa1414792.
[8] Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 Hours after Symptom Onset in Ischemic Stroke. N Engl J Med. 2015:150417035025009. doi:10.1056/NEJMoa1503780.
[8] Saver J, Goyal M, Bonafe A, et al. Stent-Retriever Thrombectomy after Intravenous t-PA vs. t-PA Alone in Stroke. 2015:1–11. doi:10.1056/NEJMoa1415061
[9] Stroke Foundation and Deloitte Access Economics, *The economic impact of stroke in Australia, 2020*
[10] Chia, N. (et al), Determining the Number of Ischemic Strokes Potentially Eligible for Endovascular Thrombectomy, Stroke. 2016;47:1377–1380

- The potential savings from meeting this benchmark in 2020 were estimated to be $454.2 million over 5 years (in Net Present Value terms).

We therefore call on the Government to ensure adequate support for the implementation of the recommendations of the National Strategic Action Plan for Heart Disease and Stroke and for a commitment to provide regular reporting on progress made against the recommendations.

In addition, we support the calls from the Stroke Foundation for additional investment in the FAST campaign and funding for the StrokeConnect Navigator Project.

Diabetes technology for people over the age of 18

Diabetes mellitus is a complex, chronic, progressive disease that has an extensive impact on individual and family life. For the estimated 127,000 people with Type 1 Diabetes (T1D) in Australia and the 3,800 people diagnosed each year there is no prevention or cure.[11] Life expectancy at birth for people with T1D in Australia has been estimated to be about 12 years less than the general population, with death rates for people with T1D nearly twice as high compared to people without diabetes, and the disparity higher among those under the age of 45.[12]

Access to diabetes technology, such as insulin pumps and continuous glucose monitors, can significantly improve the quality of life for a patient with diabetes. Diabetes technology enables both patients and their health care professionals to make informed decisions based on real time patient data.

There remains limited access to diabetes technology in Australia, only 10 per cent of Australians with T1D use an insulin pump, lower than in many other developed countries with a similar disease burden.[13] Factors that may affect the use of diabetes technology include the lack of subsidised access for people over the age of 18 for insulin pumps, and over the age of 21 for CGM, the lower proportion of young Australian adults with private health insurance and socioeconomic status (insulin pump use in areas of high socioeconomic status (14%) compared to use in low socioeconomic areas (6%)).[13]

In order to provide fairer access to life-saving diabetes technology, a review and expansion of eligibility criteria for funding is necessary, in particular:

- **To expand access to insulin pumps and CGMs for adults and children who need it and who are otherwise unable to access the technology.**
- **Allowing people who are currently accessing CGMs through the NDSS to continue to have access after they turn 21 years of age and not have to revert to fingerpicking to monitor their blood glucose during their young adulthood.**

[11] NDSS Statistical Snapshot for June 2021
[12] Australian Institute of Health and Welfare 2017. Deaths among people with diabetes in Australia, 2009–2014. Cat. no. CVD 79. Canberra: AIHW.
[13] Australian Institute of Health and Welfare, Insulin pump use in Australia. Diabetes series number 18. Cat. no. CVD 58, 2012, AIHW: Canberra and Australian Type 1 Diabetes Research Agenda, Juvenile Diabetes Research Foundation, Sydney, 2010

- **People beyond 18 years of age should continue to have access to insulin pumps through the Insulin Pump Program and not have their technology taken away from them once they reach the age of 18 and thus reverting to multiple daily injections.**

A New Frontier – Delivering better health for all Australians, Report of the House of Representatives Committee on Health, Aged Care and Sport

Medtronic was pleased to participate in the recent Parliamentary Inquiry into ways to improve access to novel medicines and medical devices. We congratulate the members of the Committee on the completed report A New Frontier – Delivering better health for all Australians. This is a comprehensive overview of some of the challenges in our regulatory and reimbursement frameworks. We appreciate that Government is already moving to implement some of these recommendations, starting with a cost-recovery framework for MSAC. While we consider that there are other recommendations that can be implemented quickly, and which are long overdue including the use of real-world evidence in Health Technology Assessments, we consider that the focus needs to be on an end-to-end approach to ensure our system works for patients and has access to new, innovative modern technology at its centre. Current reform processes, such as Prostheses List reform, will erode this objective if not implemented transparently and with stakeholder support.

Conclusion

We again thank the Government for the opportunity to provide our comments through this pre-budget submission. For more information on the content of this submission, please contact Kate King (kate.king@medtronic.com)