



## Special Commission of Inquiry into Healthcare Funding

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Edwards



# The Special Commission of Inquiry into Healthcare Funding

**Edwards Lifesciences**

## About Edwards Lifesciences

[Edwards Lifesciences](#), headquartered in Irvine, California, is the global leader in patient-focused, medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, enabling patients to live longer, healthier and more productive lives.

While many other companies in the medical technology industry are diversifying, Edwards Lifesciences has chosen to remain laser-focused on structural heart disease and critical care technologies. We have kept this focus because many patients remain under-served and there are ongoing opportunities to drive meaningful improvement in their care. This allows us to concentrate our resources and expertise, understand the patient's journey and challenges, and engineer potential solutions. We have maintained this focus because many patients remain under-served, and there are ongoing opportunities to drive meaningful improvement in their care.

At Edwards Lifesciences, we strive for big, bold advances set to fundamentally change the practice of medicine. We are dedicated to providing innovative solutions for people fighting cardiovascular disease.

## Executive summary

Edwards Lifesciences welcomes the opportunity to make a submission to the New South Wales (NSW) Special Commission of Inquiry into Healthcare Funding. In addition, as a member of the Medical Technology Association of Australia we support its contribution to this important Inquiry.

For the purposes of this submission, we plan to focus on elements of the below terms of reference:

- A. The funding of health services provided in NSW and how the funding can most effectively support the safe delivery of high quality, timely, equitable and accessible patient-centred care and health services to the people of NSW, now and into the future;
- C. The way NSW Health funds health services delivered in public hospitals and community settings, and the extent to which this allocation of resources supports or obstructs access to preventative and community health initiatives and overall optimal health outcomes for all people across NSW;
- F. The current capacity and capability of the NSW Health workforce to meet the current needs of patients and staff, and its sustainability to meet future demands and deliver efficient, equitable and effective health services including:
  - i. the role and scope of workforce accreditation and registration;

- ii. opportunities for an expanded scope of practice for paramedics, community and allied health workers, nurses and/or midwives;
  - iii. the role of multi-disciplinary community health services in meeting current and future demand and reducing pressure on the hospital system;
- H. New models of care and technical and clinical innovations to improve health outcomes for the people of NSW, including but not limited to technical and clinical innovation, changes to scope of practice, workforce innovation, and funding innovation.

The NSW Government Intergovernmental report<sup>1</sup> and Federal 2023 Intergenerational Report<sup>2</sup> all point to an ageing population, and that by 2061, one quarter of people living in NSW will be aged 65 or over, up from 17 per cent today. Critical to ensuring that NSW Health Budget growth is sustainable is keeping our ageing population active, whether through employment or other forms of community engagement. This will require healthcare delivery to proactively provide patient-centred interventions to mitigate complications that result in patients bouncing in and out of the emergency rooms (EDs).

Primary care is the remit of the Commonwealth; however, the next National Healthcare Reform Agreement provides a critical moment in time for States, like NSW to play a more active role in preventative and community health initiatives.

General Practitioners (GPs) are the first line of defence in delivering a sustainable healthcare system in NSW, but access and shortages are making this increasingly difficult for patients, which results in unnecessary ED presentations. Equally, for many of our patients suffering from heart valve disease (HVD) the symptoms can be subtle – shortness of breath, fatigue, or chest tightness. The humble stethoscope is the first and only primary care intervention that can help identify a heart murmur, yet it is underutilised.

Aortic valve disease is the most frequent cause of severe valvular heart disease. Its most common manifestation is aortic stenosis (AS) – a moderate-to-severe narrowing of the aortic valve. Today patients require treatment have access to two therapies for AS, open heart surgery, known as Surgical Aortic Valve Replacement (SAVR) or Transcatheter Aortic Valve Implantation (TAVI).

Unfortunately, NSW lags the rest of the country and comparable healthcare systems in adopting TAVI. This capacity enhancing technology is not being scaled, despite it demonstrating improved care processes at the clinical, organisational, and system levels. Evidence-based benefits, including lower per patient costs, better patient experience, and higher population health. Evidence that unambiguously shows how

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<sup>1</sup> [https://www.treasury.nsw.gov.au/sites/default/files/2021-06/2021-22\\_nsw\\_intergenerational\\_report.pdf](https://www.treasury.nsw.gov.au/sites/default/files/2021-06/2021-22_nsw_intergenerational_report.pdf)

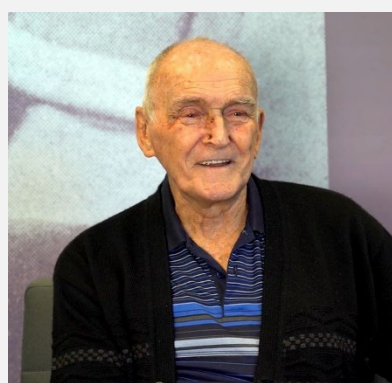
<sup>2</sup> <https://treasury.gov.au/sites/default/files/2023-08/p2023-435150.pdf>

products support integrated care are a central theme in contemporary health policy and industry collaboration will be crucial for accelerating progress towards a healthcare system that is fit for purpose.

The Baker Heart and Diabetes Institute report *Our hidden ageing: time to listen to the heart*<sup>3</sup>, highlights how wider access to therapies like TAVI provide an economic boost by enabling older Australians either being able to stay in employment longer or participate in productive non-market activities like volunteering and caregiving for a family member or grandchildren. Increased access to these types of innovations will allow us to better manage the sustainability of our ageing NSW population.

### Colin MacFarlane's story – Starr Edwards

Edwards Lifesciences is proud to have a long history of developing novel medical technologies to address the unmet clinical needs of patients suffering from HVD.



As a young boy, Colin suffered from rheumatic fever (just like our founder, Lowell Edwards). During a yearly school medical, he was told he had a heart murmur. He was just 14 years old.

By age 35, Colin needed surgery but had to wait 6 months for the life-saving valve to arrive from the US. In 1973, he received a new Starr-Edwards valve at Royal Prince Alfred Hospital. He was told it would last 10-15 years before it needed replacing.

As it turned out, that second surgery was never needed because the valve kept performing well.



‘I think once we got to 15 years, everyone threw their hands in the air and said, “pick a number, we don’t know!” remembers Colin.

It’s almost 50 years since his valve replacement – and Colin’s still going strong. ‘Something turned out right,’ he said, noting that the valve ‘seems like it’s indestructible’.

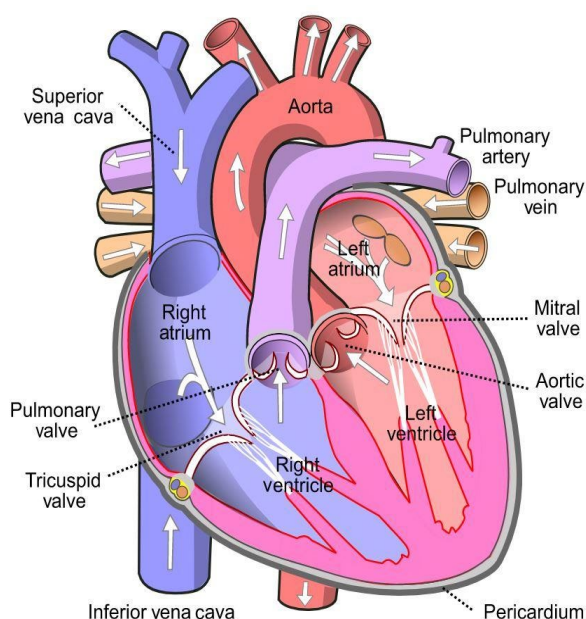
As his daughter, Cheryl says, ‘It’s given Dad a huge quality of life. He’s enjoyed the last 20 years of retirement, driving an F250 truck dragging a 22ft caravan around Australia’.

*Colin Macfarlane*

<sup>3</sup> <https://baker.edu.au/impact/advocacy/valve-disease>

## An overview of Heart Valve Disease

Heart valve disease is caused by the malfunctioning or abnormality of one or more of the heart's four valves. It affects the flow of blood through the organ. When working properly, the four valves – aortic, mitral, pulmonary, and tricuspid – ensure blood is flowing through these chambers in the right direction. If the heart valves become diseased or defective, they may not open or close properly, obstructing the flow of blood. If left untreated, this can lead to heart failure and ultimately death.<sup>4</sup>



## Burden of heart valve disease

The risk of developing HVD increases with age, noting older Australians (those aged 65+) are most affected. The ageing process causes the blood vessels to progressively lose their elasticity and become stiff, impacting the vascular structure and function. This arterial damage also increases mechanical stress on the valves. HVD is the most common cardiac condition affecting the progressively aging populations of high-income countries, such as Australia.<sup>5</sup> There are more than half a million Australians currently living with heart valve disease.<sup>6</sup>

Concerningly, an estimated 254,000 Australian cases of heart valve disease will go undetected this year alone, putting more than a quarter of a million Australians with faulty heart valves at risk of severe complications. The number of undiagnosed cases of heart valve disease is projected to spiral in the ensuing three decades, to 336,000 cases in 2031, and 435,000 in 2051,<sup>7</sup> placing a heavy burden on our nation's healthcare system, ageing population, and economy.

<sup>4</sup> Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin, Lee A. Fleisher, Hani Jneid, Michael J. Mack, Christopher J. McLeod, Patrick T. O'Gara, Vera H. Rigolin, Thoralf M. Sundt, Annemarie Thompson J Am Coll Cardiol. 2017 Jul, 70 (2) 252-289.

<sup>5</sup> Benjamin EJ, Virani SS, Callaway CW, Chamberlain AM, Chang AR, Cheng S, Chiuve SE, Cushman M, Delling FN, Deo R, et al. Heart disease and stroke statistics - 2018 update: a report from the American Heart Association. Circulation. 2018;137(12): e67-e492.

<sup>6</sup> Baker Heart and Diabetes Institute, *Our Hidden Ageing: Time to listen to the heart* 2021.

<https://baker.edu.au/impact/advocacy/valve-disease>

<sup>7</sup> Ibid

In an Australian, observational clinical cohort study examining echocardiograms on native aortic valves of 98,565 men and 99,357 women aged 65 years or older across 23 sites in Australia, from the National Echo Database of Australia (NEDA), the five year societal cost of premature mortality from AS was an estimated AUD 629 million in men, and \$735 million in women.<sup>8</sup> This clearly demonstrates the need for cost-effective strategies that promptly detect, and optimally treat this common condition within our ageing populations.

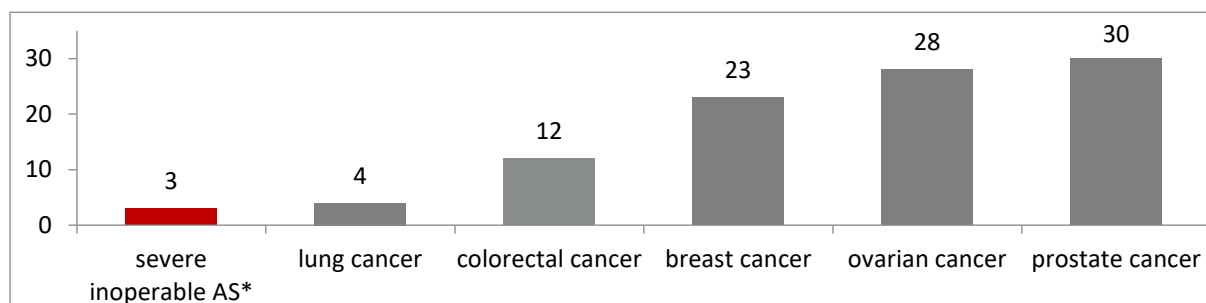
Alarming, the common symptoms of heart valve disease – shortness of breath, chest pain and palpitations, fatigue (low energy), cough, dizziness and/or fainting, difficulty when exercising, swollen ankles and feet, abdominal swelling, and a fast or irregular heartbeat – are often misattributed to ‘old age’.

If not identified, or treated, heart valve disease can compromise heart rhythm, and cause blood clots, stroke, heart failure, and death. Fortunately, a heart murmur, often the first symptom of heart valve disease, can usually be detected by a doctor listening to the heart sounds with a stethoscope.

Although serious, heart valve disease is increasingly treatable. With early detection and intervention, those affected can return to their everyday lives, and continue to contribute to their families, communities, and the economy.

Aortic valve disease is the most frequent heart valve disease. Its most common manifestation is aortic stenosis (AS) – a moderate-to-severe narrowing of the aortic valve. A patient living with severe AS is less likely to survive than a patient with metastatic cancer. Figure 1 shows, the five-year survival rate for severe AS is lower than all of the other major cancers. After symptom onset, patients with severe AS have a survival rate as 67% are likely to die within 5 years without aortic valve replacement (AVR).<sup>9</sup>

Figure 1:



<sup>8</sup> Ibid

<sup>9</sup> Strange, G., Scalia, G.M., Playford, D. et al. Uncovering the treatable burden of severe aortic stenosis in Australia: current and future projections within an ageing population. BMC Health Serv Res 21, 790 (2021). <https://doi.org/10.1186/s12913-021-06843-0>.

Cases of AS are predicted to climb to 200,000 in 2031, and 266,000 in 2051, respectively. Despite the increasing prevalence of AS, there has been little evidence on the societal cost of progressive AS, up until now.<sup>10</sup>

Current research suggests approximately 97,000 Australians are living with severe AS (which is treatable within current guidelines), of which 32,019 live in NSW, yet more than half of these individuals will die within 5 years without intervention.<sup>11</sup> The research estimates a further 3,019 (95% CI 9,000 to 9,500) more NSW residents aged  $\geq 60$  years will subsequently develop severe AS each year.<sup>12</sup>

### **GPs are the gateway to life-saving treatment for patients living with this quietly insidious disease.**

Cardiac auscultation — the process of listening to the heart and lungs through a stethoscope — is the first step in diagnosing HVD, without this crucial step, a person may go undiagnosed. Any abnormalities should be further examined via echocardiography – the test of choice. Many stakeholders incorrectly assume that this efficient, routine, and non-invasive test is included as standard as part of a heart health check. Without this crucial component potentially a patient over 65 years old will remain undiagnosed.

Professor Geoff Strange, and Professor David Playford of the School of Medicine at the University of Notre Dame Australia found that even within the mild-to-moderate AS cohort, who typically remain untreated based on current guidelines, the “*societal cost of premature mortality was estimated to be AUD 1.4m per 1000 men and AUD 2.4m per 1,000 women, over and above that observed in the no aortic stenosis group.*”<sup>13</sup> This analysis confirms patients with even non-severe forms of AS still experience a high societal burden, further reinforcing the importance of preventative measures, such as auscultation, which is listening to the heart with a stethoscope.

*“Australia currently lags with regards to the provision of primary care services and preventive health services, and these might be the most important investments to tackle an evolving burden of heart disease. Given the rising prevalence of aortic stenosis and its impact on mortality, it is time to revisit the*

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<sup>10</sup> Baker Heart and Diabetes Institute, *Our Hidden Ageing: Time to listen to the heart* 2021. <https://baker.edu.au/impact/advocacy/valve-disease>

<sup>11</sup> Strange, G., Scalia, G.M., Playford, D. et al. Uncovering the treatable burden of severe aortic stenosis in Australia: current and future projections within an ageing population. *BMC Health Serv Res* 21, 790 (2021). <https://doi.org/10.1186/s12913-021-06843-0>

<sup>12</sup> Ibid

<sup>13</sup> Ibid



*practice of watchful waiting and consider more proactive attempts to identify those at risk.”<sup>14</sup>*

Given the unavoidable burden of this treatable condition, it is common sense for policy makers to support the inclusion of auscultation in Heart Health Checks, given it is a high value, significantly cost-effective mechanism to help detect a heart murmur, and to ensure, if suspected, a timely referral for an echocardiogram.

We recognise the Medicare Benefits Scheme (MBS) is the Commonwealth responsibility, yet a Heart Health Check plays a critical role in GPs and our healthcare system better managing the burden from cardiovascular disease (CVD). A Heart Health Check is a 20-minute check-up with a GP to assess a patient’s risk of having a heart attack or stroke in the next five years. As part of the check, a doctor will ask patients about lifestyle, medical and family health history. They will also check blood pressure, cholesterol, and blood sugar levels, however, cardiac auscultation – listening to the heart with a stethoscope – is not a mandatory requirement.

Unfortunately, this requirement has not yet been adopted, despite over eight in ten (83%) Australians aged 60 years and over feeling that a stethoscope check of the heart should be done when they have a heart health check done by their GP that is covered by Medicare. Auscultation comes in second behind checking blood pressure (93%) and ahead of a cholesterol check (73%).<sup>15</sup>

Almost three in five (58% -down from 61% in 2020) Australians aged 60 years and over claim their GP’s check their heart with a stethoscope either every visit or occasionally. However less than one in four (23%-23% in 2020) say they do so at every visit and one in three (35%-down from 39% in 2020) say they only do so occasionally. Over two in five (42% - 39% in 2020) Australians 60 years and over claim their GP’s check their heart with a stethoscope either only rarely or never, with 28% (26% in 2020) saying it happens rarely and over one in ten (13% - 12% in 2020) saying it never happens. Despite the increased awareness of CVD as a result of the pandemic these figures shows a downward trend of listening to the heart by GPs.

On 29 March 2023 cardiovascular groups, Cardiac Society of Australia and New Zealand, Australian & New Zealand Society of Cardiac and Thoracic Surgeons, Victor Chang Cardiac Research Institute, Baker, Heart and Diabetes Institute, Heart Foundation, Hearts4Heart, Heart Support Australia and Australian Cardiovascular Alliance came together to emphasise *“calling for the inclusion of a stethoscope check as an efficient, routine, and non-invasive part of every Heart Health Check. Without this preventative*

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<sup>14</sup> Ibid

<sup>15</sup> Edwards Lifesciences sponsored YouGov Polling conducted online between 8th–14th September 2023, sample comprised of 1,041 Australians aged 60 years and older

*measure, individuals who are at high risk of heart disease may not be identified until they present with symptoms, which at that point would be too late.”*

A recent study<sup>16</sup> from a Heart Foundation recalled at-risk Australians via a text message from their GP clinic, for a Heart Health Check. It led to a 14-fold increase compared to control practices. Not only does this study show that an SMS recall system for Heart Health Checks can be effective and acceptable in general practice. Further, it demonstrates that disease specific MBS items are an effective way to manage patients with chronic diseases.

The Victor Chang Cardiac Research Institute, Heart Health team travels around Australia offering free Heart Health Checks to help fight heart disease. Those checks are undertaken by trained professional staff, namely allied health, which helps to reduce the strain on GPs but offers an invaluable service to the community. As we look at funding of complex and chronic conditions, Governments need to explore alternative funding and expanding scope of practice where appropriate for other healthcare providers.

New models of care will be required to be scaled in the future to better manage chronic and complex conditions. The idea of blended payments to better manage patients with ongoing, chronic or complex needs will need to play a critical role in managing the sustainability of our healthcare system. As Dr Stephen Duckett, previously at the Grattan Institutes says: *“We must make it much easier for different types of skills to be available to patients, depending on what their problem is, and make sure it's all coordinated in general practice.”*<sup>17</sup> While we recognise inappropriate ‘scope creep’ needs to be managed for the purposes of trying to fill service gaps is a major threat to the health of the community. We need to see consistency across states and a commitment to the agreed-upon pathways.

The AMA supports all health practitioners working to their full scope of practice<sup>18</sup>. Given the workforce shortages in primary care the need for allied health, nurses, pharmacists and multidisciplinary specialist to expand the scope where it is safe and appropriate will benefit patients and the health system. The Pharmacy Guild – scope of practice of community pharmacists in Australia<sup>19</sup> - trained Queensland pharmacists have been successfully prescribing for uncomplicated UTIs since 2020. The NSW Government has expanded the scope of practice by giving patients greater access to vaccinations, contraception and medicines for minor ailments are examples that should be examined to see what else can be done to complement the critical role of GPs.

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<sup>16</sup> Raffoul N, Brims K, Zeng J, Knight J, Asham A, Mitchell JA, Jennings G, Bonner C. Feasibility of a text-mediated recall system to increase cardiovascular disease risk assessment in general practice: Mixed-methods pilot evaluation. Aust J Gen Pract. 2023 Jul;52(7):481-489. doi: 10.31128/AJGP-08-22-6541. PMID: 37423246

<sup>17</sup> <https://www.abc.net.au/news/2023-01-29/healthcare-system-funding-medicare-national-cabinet/101899664>

<sup>18</sup> <https://www.ama.com.au/articles/ama-submission-unleashing-potential-our-workforce>

<sup>19</sup> [https://www.guild.org.au/\\_data/assets/pdf\\_file/0023/106178/scope-of-practice-2023.pdf](https://www.guild.org.au/_data/assets/pdf_file/0023/106178/scope-of-practice-2023.pdf)

### Recommendations:

- **NSW Government should partner with the Commonwealth and other healthcare stakeholders to increase funding toward preventative primary-care and blended funding for chronic and complex conditions.**
- **Heart Health Checks are an effective tool to better manage patients with cardiovascular disease. NSW Government should partner with healthcare providers to increase uptake of Heart Health Checks. We urge the NSW Government to recommend cardiac auscultation to be made part of the physical examination alongside blood pressure and cholesterol.**

#### Case Study:

**Presentation:** A lady presents in Jan 2022 with 1 week of cough, chest pain and shortness of breath. She was seen by the relieving GP, Prof Kidd, out of hours.

**Observations:** A heart murmur was detected by auscultation. Patient was unaware she had a murmur. Echo and bloods ordered. A letter was sent to her regular GP.

**Results:** Echo showed severe mitral valve prolapse. She was seen urgently at the Prince Charles Hospital, where her valve was replaced, and her coronary artery stented. The patient returned to Prof Kidd crying and thanking him for saving her life.

Prof Kidd said:

*“It was a very powerful experience. I will probably remember it for the rest of my life.”*

### Treatment: Aortic Valve Replacement

Aortic stenosis is the most common type of heart valve disease for people 65 and older and affects 1 in 8 people over 75. This type of valve disease means the aortic valve cannot fully open or close properly. Over time, the leaflets become stiff, which reduces their ability to fully open and close. When the leaflets don't fully open, the heart must work harder to push blood through the aortic valve to the body. As a result, less oxygen-rich blood flows from the lungs to the brain and the rest of the body, which may cause symptoms. Severe aortic stenosis with symptoms, commonly known as heart valve failure, can be life-threatening if left untreated.

Many patients mistakenly think the symptoms are normal signs of aging. Studies have shown that while many aortic stenosis patients initially report no symptoms, after closer examination, 32% do have symptoms.<sup>20</sup>

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<sup>20</sup> Das P, Rimington H, Chambers J. Exercise testing to stratify risk in aortic stenosis. Eur Heart J. 2005;26(13):1309-1313.

Depending on how far the aortic stenosis has progressed, a doctor may prescribe medication at first to help control the symptoms. However, once heart valve disease advances to the severe stage, medication alone will not treat it and it will continue to get worse until the aortic valve must be replaced.

Severe aortic stenosis has traditionally been treated with aortic valve replacement (AVR) via open heart surgery (SAVR), 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 was initially offered as an alternative to SAVR in patients with high surgical risk. However, the high level of safety and effectiveness of the procedure has led to its use in a wider range of patients who are younger, with low surgical risk.<sup>21</sup>

While the US, and Europe approved all patients with severe symptomatic AS being eligible to TAVI in 2019 meanwhile the Medical Services Advisory Committee only recommended TAVI for all surgical risk AS patients in July 2022. Australia has been much slower to adopt TAVI and the benefits that it provides patients. TAVI has demonstrated cost-effectiveness or cost-savings versus SAVR for high-, intermediate-, and low-risk patients in Australia.<sup>22</sup>

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. TAVI has been placed under more scrutiny than most procedures in Australian medical history. It represents a once-in-a-generation paradigm shift in the care of heart valve disease patients.

Over the last few years, treatment of severe symptomatic aortic stenosis patients across all surgical risk categories has drastically changed to adopt a less-invasive approach. TAVI has been developed as a very reproducible and safe procedure. Australian and overseas evidence shows that TAVI is significantly cheaper than surgery.<sup>23</sup>

During a TAVI procedure, the patient's damaged heart valve is replaced using a heart valve made of natural tissue obtained from the heart of a cow. The new valve is delivered via catheter, thereby avoiding open heart-valve surgery.

Special imaging equipment is used to guide position and placement of the new valve. In the case of TAVI, the replacement valve collapses to a very small diameter and is

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<sup>21</sup> Sa, M., et al., *Asymptomatic severe aortic stenosis, bicuspid aortic valves and moderate aortic stenosis in heart failure: New indications for transcatheter aortic valve implantation*. Trends Cardiovasc Med, 2020.

<sup>22</sup> Ibid

<sup>23</sup> Zhou J, Liew D, Duffy SJ, Walton A, Htun N, Stub D. Cost-effectiveness of transcatheter aortic valve implantation compared to surgical aortic valve replacement in the intermediate surgical risk population. *Int J Cardiol*. 2019;294:17-22. doi:10.1016/j.ijcard.2019.06.057

crimped onto the balloon device. The surgeon positions the replacement valve inside the patient's natural aortic valve and inflates the balloon. This causes the replacement valve to expand, pushing the faulty valve aside. The replacement valve begins to function as soon as the balloon catheter deflates to permit the flow of blood.

Since the replacement valve is placed using minimally invasive techniques, patients usually experience a much more rapid recovery than they would from a traditional, open-heart valve replacement. The catheterisation procedure typically takes one hour, and patients are up and walking within 24-48 hours of the procedure. In fact, patients are often up and walking even earlier – within 4 hours of the procedure and the typical hospital stay is no more than 3 days. Hospital continues to see efficiencies with many public hospitals doing next day discharge or discharged within 48 hours of the procedure, compared to an average length of stay (LOS) in hospital for SAVR at or around 7-11 days, including time in ICU.

When compared to surgery, TAVI has produced superior, or at least comparable, results. Our SAPIEN valves are the most widely studied transcatheter valves, with more than 30,000 patients treated in clinical trials and registries in over 65 countries around the world. Since the first commercial approval in Europe in 2007, Edwards Lifesciences' SAPIEN valves have treated hundreds of thousands of patients worldwide.<sup>24</sup>

New data from the PARTNER 3 trial demonstrate continued low rates of all-cause mortality, disabling stroke and rehospitalization at five years.<sup>25</sup> These data, which represent the longest clinical follow-up for a low surgical risk cohort of TAVI patients, were presented during a late-breaking clinical trials session at the 35th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, and published simultaneously in *The New England Journal of Medicine*.<sup>26</sup>

The five-year follow-up findings from the PARTNER 3 trial reaffirm the clinical outcome benefits of TAVI as a meaningful alternative to surgical therapy for low-risk severe, symptomatic AS patients. In the TAVI arm, rehospitalization for this elderly patient population was less than 3% per year over five years. Valve durability indicators were also stable over time with no difference in the incidence of bioprosthetic valve failure related to structural valve deterioration (1.4% vs. 2.0%) or reintervention rates (2.6% vs. 3.0%) between TAVR and SAVR.

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<sup>24</sup> <https://www.edwards.com/ns20191106>

<sup>25</sup> <https://www.edwards.com/newsroom/news/2023-10-24-five-year-data-from-partner-3-trial-demonstrate-ex>

<sup>26</sup> Mack MJ, Leon MB, Thourani VH, Pibarot P, Hahn RT, Genereux P, Kodali SK, Kapadia SR, Cohen DJ, Pocock SJ, Lu M, White R, Szerlip M, Ternacle J, Malaisrie SC, Herrmann HC, Szeto WY, Russo MJ, Babaliaros V, Smith CR, Blanke P, Webb JG, Makkar R; PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. *N Engl J Med*. 2023 Oct 24. doi: 10.1056/NEJMoa2307447

TAVI is associated with numerous procedural efficiencies and continued technological advancements that provide opportunities for cost savings. Average hospital length of stay for TAVI has continued to decrease by 7 days from 2012 to 2017, with TAVI index hospitalisation plus follow-up costs declining more than 22% during that period.<sup>27</sup> The overall costs for TAVI are \$9,629 less expensive than open-heart surgery and delivering greater improvements in quality of life and longevity.<sup>28</sup>

Switching patients from open-heart surgery to TAVI there will result in:

- reduced demand for ICU beds;
- lower incidence of heart failure, atrial fibrillation and life threatening or disabling bleeds;
- less demand on staff; and
- shorter lengths of hospital stay for patients.<sup>29</sup>

TAVI enables physicians to treat more patients with equivalent/superior outcomes all at a lower cost compared to open heart surgery. Increasing access to TAVI for all patients will enable NSW Health to save more lives, save money, reduce hospital resource utilisation and free up capacity/resources for other service lines – thereby reducing waiting lists.

Edwards Lifesciences in partnership with internationally renowned clinicians have developed a program called “Benchmark”. The program has developed a set of best practices that can be easily implemented across different hospitals, including those in different healthcare systems. Taking a minimalist approach to TAVI with a focus on conscious sedation, recovery outside the ICU, and a goal of next-day discharge that unlocks the inherent benefits of TAVI’s less invasive nature while preserving patient outcomes.

An Australian single centre study reviewed 135 consecutive patients who underwent minimalist TAVI found next day discharge was safe and feasible in almost three quarters of patients undergoing minimalist TAVI, with a very low rate of 30-day readmission.<sup>30</sup>

At EuroPCR in 2023, new data from the Benchmark Registry<sup>31</sup> in Europe demonstrated the safety and effectiveness of this streamlined treatment pathway for patients receiving TAVI. The study observed 2,405 patients across 28 sites in seven European countries to determine if implementing a set of tailored Benchmark practices could

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<sup>27</sup> Shah KK, Elder D, Nguyen MT, Turner L, Doyle M et al. (2021) Transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement for aortic stenosis (SAVR): a cost-comparison study. *Heart Lung Circ* 30 (12): 1918-1928.

<sup>28</sup> J. Zhou, D. Liew, S.J. Duffy, et al., Cost-effectiveness of transcatheter aortic valve implantation compared to surgical aortic valve repl..., *International Journal of Cardiology*, <https://doi.org/10.1016/j.ijcard.2019.06.057>

<sup>29</sup> [https://www.onlinecjc.ca/article/S0828-282X\(19\)31158-4/fulltext](https://www.onlinecjc.ca/article/S0828-282X(19)31158-4/fulltext)

<sup>30</sup> Eaves S, Lees C, Jin D, Rayner C, Paleri S, Rowe S, Lee J, Hayat U, Adams H. Dedicated Next Day Discharge Post Minimalist TAVI: The Tasmanian Experience. *Heart Lung Circ*. 2023 Feb;32(2):232-239. doi: 10.1016/j.hlc.2022.09.011. Epub 2022 Oct 20. PMID: 36272953.

<sup>31</sup> <https://cardiovascularnews.com/euroPCR-2023-benchmark-registry-data-demonstrate-improved-tavi-efficiency/>

improve hospital LOS, intensive care unit (ICU) bed occupancy, and patient and staff satisfaction while preserving patient safety. Patients undergoing TAVI experienced a 25% reduction in ICU stay and a 33% reduction in the median hospital LoS while maintaining 30-day clinical outcomes similar to patients treated before the implementation of the Benchmark pathway.

**Recommendations:**

- **NSW Government should increase funding priority towards TAVI to scale the benefits to the healthcare system and to patients.**
- **NSW Government should pilot quality improvement programs by partnering with medical technology companies on minimal TAVI that seeks to increase the efficiencies in the healthcare system while maintaining patient outcomes.**



Phil Holmes, 73, leads a busy lifestyle, until 2021 he was Head of Insurance for a leading glass supplier, father-to-three, and grandfather-to-five. He steals any free time he can find at his local gym.

In November 2018 however, Phil experienced a health scare. After visiting his GP for an annual check-up, he was informed of a slight “swishing” sound in his heart.

However, it wasn’t until Phil was participating in a work-related fundraiser where he was required to perform 1,000 pushups in a month, that he experienced unusual shortness of breath and extreme fatigue.

After visiting his heart specialist, Phil was subsequently diagnosed with heart valve disease.

Following discussions with his heart specialist about potential treatment options, Phil decided to undergo a TAVI procedure in September 2019.



I had the procedure on the Friday and returned to work from home the following Monday. I was back at the gym a couple of weeks later.

I believe all Australians aged 65 and over should be well-informed about heart valve disease and the various treatment options available.

Heart valve disease is real. It must be treated with both the urgency and due attention it deserves.”

Phil Holmes

## Capacity Enhancing Innovation

Capacity-enhancing innovations refer to technologies that enable the use of existing resources in a more optimal way. TAVI is a perfect example of capacity-enhancing innovations, which can bring efficiencies across the continuum of care, even across sectors. Such innovations have the potential to release material and human resources that can be reallocated to improve the care of e.g., complex patient cases. However, we see in NSW the incentives for capacity-enhancing technologies are currently limited.

During the COVID-19 pandemic, a significant amount of routine and even urgent care was deferred. We are seeing the consequences of this problem play out even for cardiac patients with severe AS. This is made worse by patients staying away from visiting their healthcare professional or seeking treatment.<sup>32</sup>

One in three patients waits longer than the recommended 90 days for category two elective surgery, such as AVR.<sup>33</sup> Based on our market analysis, the average TAVI patients are waiting approximately 6 months for treatment. The problem is exacerbated by workforce shortages, cases being cancelled, and bed block. Delayed access to treatment plays out, the increases probability of death on the waitlist goes from 3.7% mortality while waiting for valve replacement for 1 month to 11.6% mortality while waiting for 6 months.<sup>34</sup>

The average number of days patients are waiting for a cardiology specialist clinic appointment remains well above pre-COVID-19 historical trends. Addressing this is crucial to ensuring patient safety and minimise the impact of deferred care.

In NSW, the waitlist for TAVI varies from 3-4 weeks in the private sector to upwards of 6-12 months in the public sector. Based on the average waiting time per hospital, we estimate that up to 28% of patients die while waiting for a TAVI at Australian public hospitals, in 2022 in NSW, this translates to between 9 and 59 deaths.<sup>35</sup>

The triple effect of COVID delays, limited structural therapy days, and limited TAVI funding has resulted in NSW public health adoption of TAVI being the second lowest per

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<sup>32</sup> <https://www.monash.edu/turner-institute/news-and-events/latest-news/2021-articles/one-third-of-adults-in-victoria-avoid-routine-urgent-or-emergency-medical-care-because-of-covid-19-concerns>

<sup>33</sup> <https://www.ama.com.au/health-is-the-best-investment> which cites <https://www.aihw.gov.au/reports/hospitals/australias-hospitals-at-a-glance/contents/about> and <https://ranzcog.edu.au/wp-content/uploads/2022/05/National-Elective-Surgery-Categorisation.pdf>

<sup>34</sup> Malaisrie SC, McDonald E, Kruse J, Li Z, McGee EC Jr, Abicht TO, Russell H, McCarthy PM, Andrei AC. Mortality while waiting for aortic valve replacement. *Ann Thorac Surg.* 2014 Nov;98(5):1564-70; discussion 1570-1. doi: 10.1016/j.athoracsur.2014.06.040. Epub 2014 Sep 18. PMID: 25240781

<sup>35</sup> These estimates were derived from the number of TAVIs performed in public hospitals and the waitlist mortality rates estimated from referral to treatment (Malaisrie et al. 2014; Elbaz-Greener et al. 2018). Since published waitlist mortality rates are based on time from *referral* to treatment, they may overestimate mortality rates from *diagnosis* to treatment. As such, we included the lowest waitlist mortality rate that we found (Elbaz-Greener et al. 2018) as a lower bound. Additionally, published TAVI waitlist mortality rates are limited to high risk or inoperable patients, so we used AVR waitlist mortality rates to include lower risk patient populations.



capita in Australia. Last year NSW public hospitals performed ~440 TAVIs compared with ~640 in Victoria. TAVI has become the standard of care in many countries around the world, including the USA, UK, Canada, and in Europe.<sup>36</sup>

Based on market data between 2019 and 2022 of all AVR procedures, NSW public hospitals performed 39% of all TAVI procedures, whereas over the same period Victoria performed 51%. Unfortunately, what this means for public patients in NSW is we have inequity of access within NSW but also between different public health systems within Australia.

Further, it means public patients in NSW who are otherwise in good health and at a low surgical risk are more likely to be referred to surgery. These are most likely the stronger, healthier patients who have most to gain from a less-invasive procedure that allows them to return to normal activities (like paid or voluntary work) more quickly. We know based on recent YouGov survey results that 40% of those aged 60-64 and 31% of those 65-69 years olds nominated paid full-time or part-time work as something they do on a regular basis.<sup>37</sup> Reinforcing the importance of being able to return to daily activities as critical in the treatment choices.

When we look at the AVR patients per million across Australia we see that NSW is the second lowest in Australia with 293 patients per million in 2022 compared with 390 patients per million in Queensland. When you compare Australia overall with international markets like Germany and France where the AVR per million is 494 and 391 respectively. If we look at the treatment rates in the US the figure is ~12% meanwhile in NSW it is 8% compared with 10.2% in Queensland.

Figure 2:

| Year | Total Public NSW treatment rates (TAVIs per million of population) | Total Public VIC treatment rates (TAVIs per million of population) |
|------|--|--|
| 2023 | 82   | 131  |
| 2024 | 78   | 122  |
| 2025 | 79   | 122  |
| 2026 | 79   | 122  |
| 2027 | 80   | 123  |

Figure 2 highlights that Victorian treatment rates looking out to 2027 shows 1.5 times as many patients per million of population than NSW. We estimate the number of TAVIs

<sup>36</sup> Cribier, A., *The development of transcatheter aortic valve replacement (TAVR)*. *Glob Cardiol Sci Pract*, 2016. 2016(4): p. e201632; Asgar, A.W., et al., *2019 Canadian Cardiovascular Society Position Statement for Transcatheter Aortic Valve Implantation*. *Can J Cardiol*, 2019. 35(11): p. 1437-1448. Overview of the Baker Heart and Diabetes Institute whitepaper Page 5 of 5; and MacCarthy, P., et al., *Extended Statement by the British Cardiovascular Intervention Society President Regarding Transcatheter Aortic Valve Implantation*. *Interventional cardiology* (London, England), 2021. 16: p. e03-e03.

<sup>37</sup> Edwards Lifesciences sponsored YouGov Polling conducted online between 8th–14th September 2023, sample comprised of 1,041 Australians aged 60 years and older

to be performed in the public system over the next five years ('23-'27) will generate a \$136M in savings to the healthcare system, with NSW netting ~\$39M, yet that share could be larger if the adoption rate in NSW increased closer to that of Victoria.

Reimbursement and procurement decisions in medical technology are primarily made by comparing the short-term clinical value with the monetary costs of new technologies. By better forecasting the benefits from innovations like TAVI NSW could increase its share of the savings over the forward estimates. Unfortunately, capacity-enhancing qualities are rarely taken into account—neither as a value component nor as an opportunity for long-term cost savings (considering the overall system).

As a result, hospitals typically do not show additional willingness to pay for technologies with capacity-enhancing qualities. Furthermore, there is no systematic incentivisation of such solutions by policymakers and payers. It is therefore necessary to systematically promote capacity-enhancing innovations by politicians and payers to integrate them more strongly into care for the benefit of the overall system.

#### **Recommendations:**

- **NSW Government to prioritise funding toward TAVI to bring it closer to other comparable states like Victoria so that we can reduce the inequity of care we are seeing due to an underinvestment in this therapy for patients with severe symptomatic aortic stenosis.**
- **Possible approaches include consideration of capacity-enhancing qualities in purchasing decisions.**

### **Cost of heart valve disease to the community and economy**

The Baker Institute “*Our Hidden Ageing: Time to Listen to the Heart*” whitepaper found early intervention in the form of non-surgical valve replacement could prevent productivity losses of up to AUD \$117 million in a single year, while patients gain more than 384,000 QALY.<sup>38</sup>

TAVI may also reduce the risk of individuals developing serious cardiovascular-related complications — one of the largest financial burdens on our nation’s health system. Offering wider access to TAVI has been shown to lower economic costs, due to the reduced risk of developing heart failure, which is associated with high unemployment.

The Australian Government’s 2021 Intergenerational Report projects that in 2060–2061, 23 per cent of our population will be aged over 65 years, a rise of around 7 per cent from

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<sup>38</sup> Baker Heart and Diabetes Institute, *Our Hidden Ageing: Time to listen to the heart* 2021.

2020–2021.<sup>39</sup> The 2023 Intergenerational Report highlights over the next 40 years that ageing of our population will mean real total health spending on those aged over 65 years is expected to increase around six-fold.<sup>40</sup> The NSW Government will need to find a way to be more efficient with every health dollar they allocate given this demographic reality:

*“Considering escalating health pressures, it will be important to ensure that the health system provides value for money. This requires a health system that innovates and prioritises funding a patient-centred and sustainable Australian healthcare system that delivers the best outcomes for communities. This will require funding arrangements that continue to effectively invest in preventive health and evidence-based health care spending.”<sup>41</sup>*

As NSW Intergovernmental report<sup>42</sup> highlights advances in health care and medicine will see people living longer with life expectancy projected to reach 91.7 years of age for women and 89.4 for men by 2061, compared to 85.9 for women and 82.2 for men in 2020. The challenge for Governments around the world is to use public policy to slow the growth of healthcare costs associated with longer life expectancy.

However, this view disregards the value of older people’s contribution to society through non-market activities, including volunteering, childcare, and caregiver support, which in turn, helps to support the nation’s economy. The value of unpaid services provided by older Australians should be recognised when developing policies for them.<sup>43</sup>

Evaluating the impact of cardiovascular disease (CVD), such as heart valve disease, and interventions such as TAVI, on those under 65 years of age, could influence their perceived value about work-related (market) activities and productive non-market activities (PNMA).

To determine the link between CVD and the value of the contribution made by older Australians to our economy, data from two major Australian household surveys — Household, Income and Labour Dynamics in Australia (HILDA), and the Australian Longitudinal Study on Women’s Health (ALSWH) was analysed.<sup>44</sup>

CVD was found to compromise a person’s participation in work-related activities, with the volume of hours spent on market and non-market activities decreasing as the

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<sup>39</sup> Australian Government - The Treasury. *2021 Intergenerational Report*. 2021 [July 2021]; Available from: <https://treasury.gov.au/publication/2021-intergenerational-report>.

<sup>40</sup> <https://treasury.gov.au/publication/2023-intergenerational-report>

<sup>41</sup> Ibid

<sup>42</sup> <https://www.treasury.nsw.gov.au/nsw-economy/2021-22-nsw-intergenerational-report>

<sup>43</sup> Baker Heart and Diabetes Institute, *Our Hidden Ageing: Time to listen to the heart* 2021.

<sup>44</sup> Melbourne Institute. *HILDA Statistical Reports*. 2020 [July 2021]; Available from:

<https://melbourneinstitute.unimelb.edu.au/hilda/publications/hilda-statistical-reports>; Women's Health Australia. *Australian Longitudinal Study on Women's Health (ALSWH)* [July 2021]; Available from: <https://alswh.org.au/about/the-study/>.

severity of the disease grew. CVD was linked to a 3% to 27% reduction in the likelihood of a person participating in work.

Similarly, a person's ability to participate in PNMA was shown to reduce with CVD, particularly with increasing severity of disease. Informal care was most affected, with a decline of up to 82% in the hours contributed by older people, followed by volunteering activities (14–32%), and childcare (14–57%). The data also showed loss of earnings (from work) due to CVD ranged from around AUD \$2,500 to a decline of AUD \$19,440.

Just as the NSW Intergovernmental report shows, the overall participation rate is projected to decline over the next 40 years. This will occur despite increasing participation amongst working age women and those over the traditional retirement age of 65 years.<sup>45</sup> Further, while the aged dependency ratio will significantly increase by 2061, this underscores the importance of both migration to NSW while also keeping older Australians active and in the workforce whether in paid employment or PNMA.

We know that unhealthy adults are less likely to participate in the workforce, therefore, don't pay taxes resulting in productivity declines and burdens increase on care providers. As a result of COVID, we now understand the implications of health issues on work, social, and economic conditions. No single answer will solve all the issues related to aging in NSW, but a broad multidisciplinary approach is needed.

As Professor David Bloom from Harvard University explains *“the biggest source of uncertainty regarding population ageing is the quality of the additional years that more and more people will live. Will increased longevity translate into more years of morbidity, dependency, and loneliness? Or will our additional years be meaningful and engaged, supported by physical and mental robustness?”*<sup>46</sup>

Technological innovation, in particular medical technology will play an important role in achieving healthy ageing. Prof David Bloom and a research team led by JP Sevilla from Harvard University School of Public Health recently evaluated the use of TAVI among elderly US patients with severe symptomatic AS: its payer perspective cost-utility analysis netted \$212,199 in monetary benefits per patient, while its societal perspective cost-benefit analysis indicated \$50,530 per patient.<sup>47</sup> Notwithstanding the study's US focus, this reinforces the findings from an Australian perspective in the Baker Institute report “Time to Listen to Heart” that there would appear to be very high and attractive secondary benefit associated with transformative innovations like TAVI.

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<sup>45</sup> [https://www.treasury.nsw.gov.au/sites/default/files/2021-06/2021-22\\_nsw\\_intergenerational\\_report.pdf](https://www.treasury.nsw.gov.au/sites/default/files/2021-06/2021-22_nsw_intergenerational_report.pdf)

<sup>46</sup> <https://cepr.org/voxeu/columns/healthy-ageing-healthy-economy>

<sup>47</sup> Sevilla JP, Klusty JM, Song Y, Russo MJ, Thompson CA, Jiao X, Clancy SJ, Bloom DE. Cost-utility and cost-benefit analysis of TAVR availability in the US severe symptomatic aortic stenosis patient population. *J Med Econ.* 2022 Jan-Dec;25(1):1051-1060. doi: 10.1080/13696998.2022.2112442. PMID: 35983718.

This highlights the need for public policy to change its attitude to older workers as our ageing population increases. We will need to find ways to keep older workers who want to work in the workforce and new way to invest in the upskilling of an ageing workforce.

### Recommendations:

- **By prioritising funding of medical technology that plays an important role in achieving healthy ageing will drive funding that is patient-centred and sustainable for NSW.**



Valma Schaefer is an active 76 years old who lives in the Hunter Region of New South Wales.

Last year she found that she couldn't do the things that she normally did like being involved with her two grandchildren. She was diagnosed with aortic stenosis after going in for something else.

TAVI has brought her back to life again and she wants to remind people don't take it for granted that it's just because of your age it's important to have it checked by your doctor.



I wasn't really nervous about going into it at all, because having read as much as I could, it seemed such a perfect solution to my problem,

To be able to instantly recover, that's the amazing part. One day I'm having trouble walking down to the loo and the next day, I'm up and I'm off."

Valma Schaefer

## Conclusion

Edwards Lifesciences appreciates the opportunity to contribute to this Special Inquiry into NSW health funding.

With an ageing population in NSW, the burden of AS will continue to increase at a rate of 3,019 patients each year, however, current research suggests NSW public hospitals are treating less ~1k per year despite approximately 32,000 NSW residents currently living with severe AS. Unfortunately more than half of these individuals will die within 5 years without intervention.<sup>48</sup>

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<sup>48</sup> Strange, G., Scalia, G.M., Playford, D. et al. Uncovering the treatable burden of severe aortic stenosis in Australia: current and future projections within an ageing population. BMC Health Serv Res 21, 790 (2021). <https://doi.org/10.1186/s12913-021-06843-0>

Primary care plays a central role in the sustainability of our healthcare system, yet the current models will not deliver in the decades to come. Investment in preventative care and blended funding, leveraging multidisciplinary teams to manage chronic and complex conditions will be needed. For example, Heart Health Checks are an effective tool to better manage patients with cardiovascular disease, however, cardiac auscultation should be part of the physical examination alongside blood pressure and cholesterol.

We are advocating for NSW Government to provide additional funding towards TAVI so more patients with severe symptomatic aortic stenosis can benefit from timely diagnosis and equitable access to effective treatment. This would address the inequity of access in NSW to TAVI despite it being a:

- clinically effective treatment that rivals or surpasses open-heart surgery;
- cost-effective procedure that is almost \$10,000 less costly than surgery; and
- patient-friendly treatment that is less invasive, requires less time in hospital and enables a faster return to normal activities of both market and non-market value.

Capacity-enhancing innovations like TAVI offer a significant opportunity to relieve the burden on the healthcare system, both financially and in terms of personnel retention, to improve medical care and to increase patient well-being. However, the current narrow assessment of the added value of innovative medical technologies, as well as the lack of structural incentives on the part of policymakers and payers, represent major hurdle.

Given the challenges to our public health system faced from COVID, it makes sense from the standpoint of both patient and economic outcomes to increase the utilisation of TAVI to better manage our ageing population and empower older Australians to have a powerful ageing experience.

Edwards Lifesciences welcomes the opportunity to participate in this Inquiry and would happily provide further evidence as necessary.